EU-LIFE's 4 elements to strengthen Europe's competitiveness through the EU Life Sciences Strategy

EU-LIFE's input to the EC "Call for evidence" - A strategy for European life sciences

EU-LIFE, the alliance of leading research institutes in the life sciences across Europe, welcomes the European Commission's initiative to develop a strategy for European life sciences and consult the expert community. The life sciences' strategic importance for Europe's health, environmental sustainability, and economic prosperity requires a commensurate, solid strategy designed to leverage Europe's full potential as a global leader in high-value technologies.

How to build a strong strategy? EU-LIFE proposes to leverage Europe's strengths to become a global leader by focusing on **four elements**: (1) leverage Europe's strengths in discovery-driven research (2) systemic strategy for research infrastructures, (3) harmonised collection and use of research data, and (4) enable a coherent innovation ecosystem in the life sciences.

Table of contents

Element 1: Leverage Europe's strengths in discovery-driven research to become a global leader in the life sciences

Europe must build up on its strengths to overcome its weaknesses. As stated by Draghi, *Europe has a strong position on fundamental research and patenting*. However, Europe is no longer leading worldwide in fundamental research at least in many life sciences areas such as biomedical research.

Current investments in fundamental research are simply not sufficient. To become a global leader at the forefront of transformative innovation and develop a sustainable life sciences-based industrial robustness, the EU must **increase investment in discovery-driven research** that enables the breakthroughs and mechanistic understanding necessary to develop new planetary solutions. These investments must be **robust and long-term** for a leading role of the EU in scientific research worldwide.

In the Life Sciences Strategy, the EU must **prioritise areas where it can be a true game-changer** for the people and the planet, by taking a worldwide lead, while strategically **filling the gaps** less addressed by other regions of the world. At this very particular moment in History, Europe must prioritise scientific and technological areas that help **prevent, detect, and treat disease earlier and more effectively**. Equally, it must invest in **climate science and biodiversity** to ensure a safer and healthier environment. These fields are deeply connected—there is no human health without planetary health.

A key development that Europe should foster is the **integration of complex biological systems** to understand better health and disease, including research on **multi-system biology** (e.g. brain–immune system, cancer–microbiome interactions) and **new approach methodologies** (e.g. 3D cell cultures, spheroids, tumoroids) that simulate physiological conditions more accurately. Investment in **interdisciplinary research** (e.g. cancer immunology, neuroinflammation) that applies insights and methods from one field to solve critical challenges in another, must be prioritised. Likewise, **technologies such as "omics"** (e.g. genomics, metabolomics) and **AI for life sciences** are assets that must be further developed to ensure European sovereignty and industrial robustness.

Areas of strategic importance for Europe in the life sciences include:

- **Discovery-driven research** that advances mechanistic understanding in areas such as early disease detection and prevention and drives predictive modelling and design, protein- and cell engineering, and integrative science spanning from molecules to ecosystems—with applications ranging from sustainable biomaterials & agriculture to healthy aging.
- **Digital Transformation**: Artificial Intelligence (AI) offers unprecedented opportunities to increase research efficiency, new approach methodologies, accelerate drug discovery, and enable new levels of analysis and prediction/diagnostics in the life sciences. Technologies such as AI, machine learning, digital twins, quantum computing in discovery-driven research can lead to groundbreaking innovations in healthcare and biotech. Cybersecurity is another relevant area.
- **Synthetic biology**, enabling sustainable innovation across health, agriculture, and the bioeconomy.
- **Integrated "omics"** basic research, including spatial transcriptomics.
- **Personalised medicine**, including gene editing therapies, mRNA therapeutics, immunotherapies, 3D cell culture models (e.g. spheroids and tumoroids), organ-on-chip, lab-on-chip, novel sequencing technologies and multi-omics, offering tailored therapies and early intervention.
- **Microbiome research**, potentially leading to novel anti-microbial therapies.
- **Healthcare Innovations**: Focusing on pre-diagnostics, biomarkers, and preventive medicine (wearables and telemedicine). This can reduce the burden of chronic diseases and improve overall public health.
- **Cutting-edge drug development techniques**, such as targeted protein degradation, cancer vaccinations and advancements in medical devices and diagnostics can significantly improve healthcare outcome.

- **Biotechnology and biomanufacturing**, can drive innovations in healthcare, agriculture, and environmental sustainability. Technologies like synthetic biology and CRISPR are essential.
- **Climate-Resilient Crops and Food Systems:** Developing and implementing climate-resilient agricultural practices is crucial, including breeding drought-resistant crop varieties (precision agriculture, genetic modification) and adopting agroforestry practices (e.g. vertical farming). These innovations can help ensure food security and sustainable agriculture in the face of changing climate conditions.

Element 2: Systemic strategy for Research infrastructures must include the small and medium scale

To contribute for a successful European life sciences strategy, **researchers need to access a state-of-the-art toolbox** (e.g. advanced imaging systems, sequencing, multi-omics and computational tools, shared biobanks) **for innovative research** (i.e. lead generation in new emerging fields). In areas such as synthetic biology, we need places where scientists can design and test useful biological materials—for example, for new medicines or sustainable products—, and perform essential validation studies. Across all areas, including AI and clean energy, it's important **that infrastructures work well together** and are open to **researchers from all regions of Europe**. Another critical aspect is to **reduce dependency on non-European platforms** by investing in cutting-edge, sovereign infrastructures.

Accessibility must be inclusive across all European regions to strengthen the European Research Area – **small and medium scale research infrastructure play a pivotal role** in this universal, generalised accessibility.

What is currently lacking at EU level is **clear support to small and medium-sized research infrastructures**, which are often hubs of specialized expertise and innovation designed and developed within the scientific community, hosted at research centres and universities across all regions of the continent. Whereas it is important to maintain a coherent strategy for large-scale research infrastructures, small and medium scale infrastructures must be part of that strategy - **as they are the backbone of the competitiveness of scientific research in Europe**. This is particularly relevant in the life sciences. Therefore, the European Life Sciences Strategy should contemplate **strategies for the long-term sustainability of small and medium scale research infrastructures**, including securing funding, maintaining technological relevance, ensuring continuous training and development for staff and maintaining these infrastructures connected and networked across Europe.

Likewise, **coherence between investments in Research and Technology Infrastructures** must be ensure. One cannot shadow the other, nor tap into the same previous basket of investments. Technology infrastructures based at European industries should leverage private investment from the industry whereas research infrastructures based at research performing organisations require mainly public investment at both European and national level.

Element 3: Harmonised collection and use of research data

Challenges in research data sharing and storage have a critical impact in European competitiveness and are a key element to be addressed by the European Life Sciences Strategy. The barriers to share, merge or reuse research data sets from different countries prevent researchers from scaling their scientific studies and reach the global, leading impact of their research. There are three main sets of barriers: legal and regulatory; contractual and bureaucratic; and practical and technological. Addressing these issues through harmonized regulations, streamlined agreements, dedicated funding, and scalable EU-based technological solutions is crucial for strengthening European life sciences.

Legal and Regulatory Barriers

Data sharing within the EU faces significant challenges due to a **lack of harmonization** and **restrictive interpretations** of regulations. Lack of alignment of national legislation across the 27 Member States and third countries lead to fragmented and inconsistent data-sharing policies. In addition, differing interpretations of the General Data Protection Regulation (GDPR) and related laws pose obstacles to cross-border data exchange. Because of this, many research projects are significantly delayed or simply cannot take place. Moreover, the GDPR is often applied in an overly cautious manner at national level, obstructing effective data sharing. This can occur as well with the AI Act, and the European Health Data Space (EHDS).

Potential solutions to these barriers are:

- **Harmonized Data Transfer Agreements (DTAs)** across the EU to facilitate seamless sharing.
- **Standardized GDPR Interpretations** for research data use, ensuring clarity and reducing inconsistencies. More guidance at the European level how to interpret and implement these legal frameworks is urgently needed, also vis-à-vis the AI Act and EHDS.
- **Align national laws with GDPR, EHDS, etc.**
- Promote a **less restrictive interpretation of GDPR** and other legal frameworks that does not compromise privacy and has the same interpretation across Europe. Recently, the European Data Protection Board has published an opinion that argues in favour of a strict interpretation of the GDPR; this opinion has caused countries to be stricter.
- Implement a **tiered consent model** (e.g., opt-out for general health data, opt-in for sensitive data).
- **Regulatory clarity on data sharing with non-EU partners** to address challenges of collaboration with the UK, US and others. Establish common "trusted research and innovation principles".

Contractual and Bureaucratic Challenges

Data-sharing agreements often require extensive negotiations, overburdening legal departments, with differing interpretations of GDPR leading to repeated revisions—especially when there is turnover among the legal staff. Cross-border data sharing is further complicated by varying regulations across

EU and third countries. In large research consortia, establishing multi-institutional agreements can take years, severely delaying research progress

Potential solutions to overcome these challenges are:

- **Pan-European DTAs** to standardize and simplify legal procedures.
- **Training and networking** for researchers producing and using data and Data Protection Officers (DPOs). Expand knowledge-sharing efforts through workshops, conferences, and working groups to align best practices.
- **Standardization and clear guidance** on how to interpret the legal frameworks governing data exchange would be very helpful.
- A **European Oversight Body** to facilitate smoother legal and institutional processes.
- **Involvement of patient representatives** to increase trust in responsible data-sharing practices.

Practical and Technological Issues

Data sharing in the EU also faces major practical and technological challenges. Concerns over data security, sovereignty, and reliance on US-based platforms limit the adoption of cloud-based solutions, while European-led large-scale data storage solutions (e.g., EMBL-EBI) are limited. Europe needs scalable solutions combining storage for sensitive research and health data with highly scalable computational capabilities.

Accessibility of research data of all types is a persistent issue due to lack of federated and/or peer-to-peer solutions and the supporting infrastructures that can handle the growing volume of research data produced. Poor data structuring, lack of standardized research data management, and insufficient institutional resources make integration, storage and sharing difficult. Additionally, the high costs of cloud services pose a real challenge for research organisations. The lack of funding for long-term data storage jeopardizes the storage, availability, re-use and accountability of data and results.

The divide between healthcare and research data further exacerbates the problem, as health data infrastructure is fragmented and often does not consider the needs of research usage, leading to inconsistent data quality for research.

Potential solutions for these issues are:

- **Scalable European data solutions**: Establishing and increasing funding for secure EU-based cloud and computational resources to reduce reliance on non-European platforms.
- **Investment in federated data networks**: Encourage institutions to adopt federated models to reduce the need for direct data transfer. Expanding models such as the European Genome Archive - EGA's federated network ensures secure and compliant data access while reducing legal fragmentation. Federated data accessibility is complex and requires significant administrative effort. EHDS is creating a framework but progress remains to be monitored.
- **Standardized metadata and repositories**: Encouraging the adoption of FAIR data principles and federated repositories ensures long-term data accessibility and interoperability.
- **Infrastructure and interoperability enhancements**: Encourage the integration of different federated networks. For example, integrating genomic and life science data platforms (e.g., EGA

& ELIXIR) fosters cross-domain research. Also, secure that EHDS does not hinder federated data network's role.

- **Keep developing and streamlining collaborative platforms** that facilitate cross-discipline and cross-technology research and data sharing, i.e., European Cloud services, storage space and computational capacity including ecological aspects, such as (but not limited to) EOSC. EOSC is expected to become a common research data framework that is widely adopted by the research community and innovators, but it must address researchers' needs comprehensively (e.g. interoperability, intellectual property, security, domain specific needs) and must become more visible to - and adopted by - researchers and institutions. This is not the case yet.
- **Dedicated funding streams for data management** separated from – and not tapping into – research budgets.
- **Digital transformation in healthcare**: Aligning digital health initiatives with research needs to ensure clinical data is securely and efficiently shared for scientific advancements.

Element 4: Enable a coherent innovation ecosystem in the life sciences

A robust innovation ecosystem must bridge the gap between discovery-driven research and real market implementation. To achieve this, structural, financial, investment, regulatory and administrative barriers need to be addressed.

Structural measures: Enable inter-sectoral collaboration

The European Life Sciences Strategy should promote **partnerships**, establish **collaborative platforms** and **international collaboration**, strengthening ties between **startups,** established **tech companies**, and **research institutes** to accelerate development and deployment of innovations. For a successful European Life Sciences Strategy, collaboration needs to be supported in a way to truly enable them to test ideas, build trust and understand each other's needs, while developing jointly solutions for global challenges.

It is particularly relevant to incentivise **academia-industry-clinic collaboration** with modular, flexible funding in the health space. For example, by establishing a Grand Challenges programme, promote sabbaticals across sectors, etc.

In funding programmes, the European Life Sciences strategy must **nurture directionality without prescriptiveness**. Currently, the modus operandi of EU funding in global challenges (e.g. Pillar 2 of Horizon Europe) is too prescriptive by imposing artificial constraints to researchers, innovators and experts to deliver on the intended outcomes - as a result, the maximum impact is not achieved. They are also **too complex for researchers to embark on** – many researchers simply do not find scope or significance in the Pillar 2 Horizon Europe calls. Therefore, **stop the top-down prescription in the calls, while keeping directionality**.

The EU Life Sciences Strategy is a concrete opportunity to provide a **simple, flexible and bottom-up framework** where researchers and innovators will embark on solving the problems that need to be

addressed. It is also a once-in-a-life-time opportunity to tailor the EU instruments to the needs of the sector including **address unrealistic expectations** from funding agencies regarding **timelines for translational success in the life sciences**. Funding needs to be more **flexible** for projects that need time to grow into real-world solutions.

A **stronger risk-taking culture** is needed in Europe in the life sciences, to allow for wider spectrum of solutions to appear. For example, introduce a quota for risky projects within life sciences programmes and act on promoting this risk quota not only at the scientific community level but also in project managers and evaluation procedures in funding agencies.

Finaly, the success of the European Life Sciences Strategy largely depends on **public trust** and ultimate uptake of innovation and breakthroughs by relevant stakeholders beyond research and industry. An important part of the strategy should focus on enhancing patients, users and public engagement in health and environmental innovation pathways.

Financial measures

While a priority for the European Life Sciences Strategy is welcomed and deemed crucial for the competitiveness of Europe, **words must come with action**. At the financial level, this means that the EU has, in the Life Sciences Strategy, forged an obligation to avoid budgetary trade-offs between life sciences and other priorities, ensuring predictable support to the life sciences.

The funding instruments that will ensure the implementation for the EU Life Sciences Strategy must therefore provide **sustainable funding to bridge discovery and application**, with specific funding streams for **de-risking assets** that are not yet market ready.

As **general rule**, sufficient public funding for the early steps of research (low TRLs, high-risk) must be envisioned, while encouraging private investment in the translational and commercial phases (high TRLs) where the private sector can accommodate better the lower inherent risk investment associated.

Investment gap

There is a **major funding gap** in European biotech. For example, up to 5x less late-stage clinical development capital and up to 7x less capital from public markets compared to the US, pushing companies to seek funding abroad. European venture capital is heavily focused on early-stage assets, lacking the resources to support companies through later clinical phases.

To strengthen Europe's biotech ecosystem, a range of targeted measures include **boosting (pre-)seed investment** and **improving the European venture capital landscape** by fostering a stable fiscal environment and harmonizing financial oversight. There is a push to diversify the investor base and support funds tailored to Europe's biotech needs. A unified, specialized public market for biotech, such as a Eurotech Stock Exchange, would improve capital access, alongside the development of biotech-

specific regulatory expertise across Member States, including a dedicated rulebook, tailored prospectus rules, and trained financial regulators.

Regulatory and administrative measures

The life sciences field is especially hindered by **heavy administrative and regulatory burdens** that must be strategically alleviated without compromising the safety and standards of the European values. It is not about lowering ethical standards; it is about streamlining processes and regulations.

The complexity and fragmentation of the regulations across the different countries must be reduced significantly. Key aspects for the European Life Sciences Strategy include **harmonising ethics and regulatory reviews for multi-country trials** and simplifying compliance across the ever-growing landscape of **EU legislations in the life sciences** (e.g., GDPR, EHDS, NIS2, Nagoya, DSI). Regulatory delays of up to 2–3 years versus the US, fragmented market access across 27 Member States, and an 8-year registration process in ag-biotech further hinder progress. Additionally, Europe's declining role in clinical trials and limited openness to innovations like NGTs risk ceding leadership to other regions of the world in both healthcare and agricultural innovation.

To increase the chances of success of life sciences companies, the **European product legislations should be proportionate, and science-based**. In some areas, Europe has very strict requirements that in addition have seen increasingly data requirements without any change in the regulation. The typical example is GMOs: data that were sufficient 5 years ago, are no longer sufficient today, while the regulatory requirements have not changed. A Coalition of the Willing could define EU-level marketing authorization pathways, supported by specialized national authorities. Streamlined ethical approvals through single, specialized committees per country would reduce delays.

Conclusions

EU-LIFE envisions **scientific research —particularly in the life sciences— as a strategic cornerstone of Europe's resilience, prosperity, and global leadership**[1]. As recent high-level reports have emphasized, strengthening the EU's single market and competitiveness requires a robust foundation in innovation, with life sciences offering transformative potential across key sectors including health, agriculture, energy, and food. By **embedding scientific research at the heart of** its new **strategy** through the 4 elements elaborated above, the EU will not only address pressing industrial and societal needs but also ensure preparedness for future crises, reinforce economic security, and support the twin digital and green transitions. **Investing in life sciences scientific research** is therefore not only an opportunity but a **necessity** for safeguarding Europe's **strategic autonomy** and sustaining the well-being of its people and the planet.

Barcelona, 16 April 2025

[1] Scientific research is a strategic necessity for resilience and competitiveness in Europe EU-LIFE reply to the EC strategic foresight "call for evidence", 19 March 2025

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