EUROPEAN
COMMISSION

Brussels, 2.7.2025
COM(2025) 525 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Choose Europe for life sciences
A strategy to position the EU as the world's most attractive place for life sciences by 2030

Choose Europe for life sciences
A strategy to position the EU as the world's most attractive place for life sciences by 2030

1. EUROPE'S LIFE SCIENCES OPPORTUNITY: A STRATEGIC VISION FOR GLOBAL LEADERSHIP

Introduction

The European Union has the ambition to become the global beacon for life sciences by 2030, offering an ecosystem where innovation thrives and breakthroughs in health, food, and sustainability improve lives.

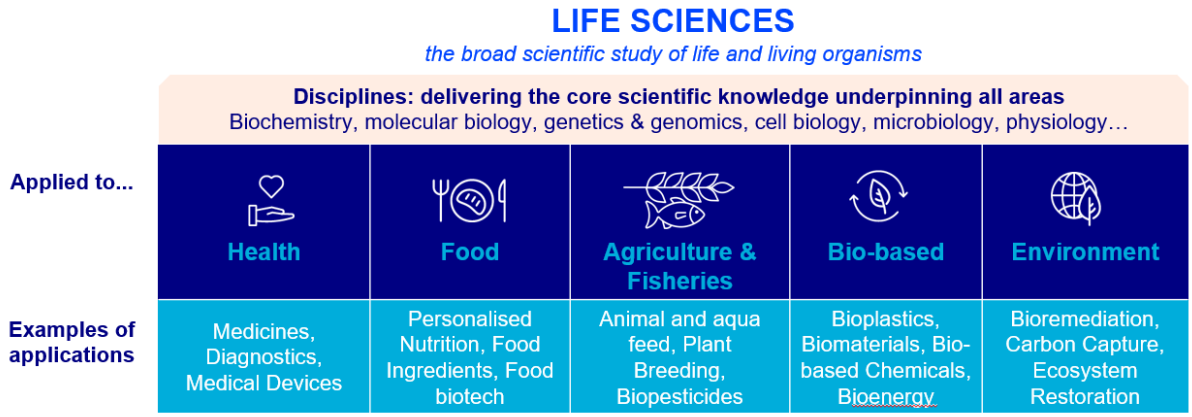
Life sciences are at the heart of Europe's ability to improve lives, grow a competitive economy, and protect the planet. From breakthrough medical treatments to sustainable agriculture and climate-smart solutions, they are driving the innovations that will shape a healthier, safer, and more prosperous future for all Europeans. This strategy puts forward a bold yet practical ambition: to make the EU a global leader in life sciences, translating cutting-edge research into real-world solutions that strengthen public health, encourage the deployment of clean technologies, and support and scale new industries and high-quality jobs in Europe.

Europe's excellence in health, biotech, agriculture, food and environmental science must be further supported by targeted investments and better coordination across sectors, regions, and scientific disciplines. The tangible advantages can be multiple: from accelerating medical innovations to preventing and treating disease, personalising care, and strengthening health systems; from supporting competitive, sustainable and resilient food systems and bio-based industries that protect nature and reduce environmental impact, to new biotechnologies that fuel growth in areas like biomanufacturing and advanced materials. All these will directly contribute to strategic resilience by securing access to critical knowledge, tools, and technologies made in Europe.

For citizens, this means better health at all ages, wider choice of safe food, cleaner and more resilient environments, and strong, future-ready economies. For businesses, it offers dynamic innovation ecosystems and predictable paths to scaling up solutions. In addition to staying competitive, this is also a strategic investment in intergenerational fairness, as the aim is for Europe to lead with purpose, so that innovation serves people and the planet, both now, and for generations to come.

What are life sciences?

Life sciences study living systems, from human beings, animals, plants, microorganisms to ecosystems and their interconnectedness, via a number of often interrelated disciplines. Progress in understanding the mechanisms of life has opened new horizons and opportunities to use life science applications in several sectors (such as health, food or agriculture – see below). The innovative power of life sciences lies in harnessing breakthrough technologies including biotechnologies[1], digitisation and artificial intelligence (AI). Biotechnology, an essential tool to progress knowledge in life sciences, is also seen as a sector in itself, covering many application areas from food and health to industrial processes and cosmetics.



Recent high-level reports (Letta[2], Draghi[3], Heitor[4], Niinistö[5]) provided recommendations for the EU to strengthen its single market, competitiveness and crisis preparedness. Life sciences and their applications hold great potential to put these recommendations into practice and to shape the future of Europe.

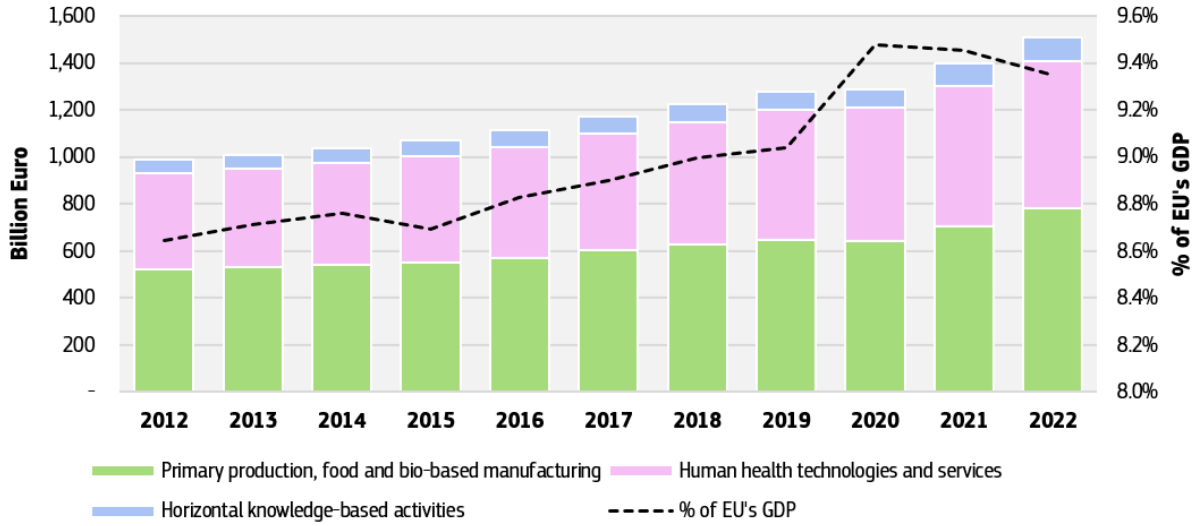
President Ursula von der Leyen's Political Guidelines[6] highlighted the strategy for European life sciences as a priority for the 2024-2029 Commission. The Commission has since published the Competitiveness Compass[7], underlining the potential of life sciences to boost competitiveness across multiple sectors, and their role in driving innovation in biotechnology.

[1] Biotechnology is the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services (OECD; https://dx.doi.org/10.1787/085e0151-en). Biotechnology is a subset of life sciences (see Haaf, A., Sale, V., '*Measuring the Economic Footprint of the Biotechnology Industry in the European Union, prepared for EuropaBio'*, WifOR Darmstadt, 2025 https://www.europabio.org/wp-content/uploads/2025/03/WifOR_EuropaBio2025.pdf; or UK Bioindustry Association https://www.bioindustry.org/about/what-is-biotech.html).
[2] https://single-market-economy.ec.europa.eu/news/enrico-lettas-report-future-single-market-2024-04-10_en.
[3] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en.
[4] https://ec.europa.eu/commission/presscorner/detail/en/ip_24_5305.
[5] https://commission.europa.eu/topics/defence/safer-together-path-towards-fully-prepared-union_en.
[6] https://commission.europa.eu/document/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en.
[7] COM(2025) 30 final (https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34_en).

Context

The European life science sectors[8] employed around 29 million people in 2022 altogether. They generated EUR 1.5 trillion in value added, corresponding to 13.6% of overall employment in the EU and 9.4% of the EU's GDP (see Figure 1)[9]. Over the past decade, the EU's life science sectors generated steady annual growth of 4-7% of their value added.

Figure 1: Value added generated by the life science sectors (in EUR million and as a percentage of the EU's GDP; from Lasarte-López, J., González-Hermoso, H., M'barek, R., 2025)



Key demographic indicators such as Europe's ageing population, and rising health care costs call for smarter, more cost-effective ways to prevent, diagnose, and treat disease. As we look to the future, more attention can be devoted to the care of all generations, especially the elderly. The dynamics of the so-called 'silver economy' and the longevity economy can be harnessed to drive innovation, research and economic growth. Maintaining a healthy population, including via healthy and nutritious diets, is crucial for prosperity and societal well-being. Furthermore, in an era of great geopolitical challenges, health innovation is critical to ensure the EU's health security and autonomy. The European agriculture and food sectors are a hub for innovation, with new products and value chains that combine safety, sustainability, and social responsibility. Vibrant rural areas and innovative food industries rely on advancements delivered by life sciences, while sustainable advanced biofuels and fuels derived from waste-based processes contribute to climate objectives and energy security. Life sciences technologies also play a vital role in protecting and restoring the environment, improve practices such as agro-ecology, agro-forestry or organic farming in developing products to reduce greenhouse gas emission or new

[8] The life sciences sectors comprise the activities that rely on life sciences knowledge and innovation, including healthcare, pharmaceuticals, biotechnology, medical devices, and agrifood technologies (see Lasarte-López, J., González-Hermoso, H., M'barek, R., *The Life Sciences sectors in the EU: drivers of economic growth and innovation*. European Commission, Seville, 2025, JRC142396, https://publications.jrc.ec.europa.eu/repository/handle/JRC142396).

[9] Lasarte-López, J., González-Hermoso, H., M'barek, R., *The Life Sciences sectors in the EU: drivers of economic growth and innovation.* European Commission, Seville, 2025, JRC142396, https://publications.jrc.ec.europa.eu/repository/handle/JRC142396.

crop varieties resilient to climate change, and in reducing the environmental footprint of industry, helping to safeguard Europe's natural resources for future generations.

Europe's strong points

Europe has the potential to be a global leader in life sciences. It offers top-tier research and education opportunities, and a steadfast commitment to academic freedom, diversity and inclusion, as emphasised in the *Choose Europe* initiative[10]. Europe is home to a dynamic life science landscape[11], with **world-class research institutions** and infrastructures producing pioneering work and **biotech clusters**[12] that stimulate innovation.

The EU consistently ranks among the top regions globally for **life science publications**[13]. It is also dynamic in terms of **global high-value patenting** in the sector of biotechnologies, ranking second (with a 18% share), behind the US (with 39%). However, its position will soon be challenged by China, which is catching up quickly (with a 10% share)[14, 15].

In terms of **industry dynamism**, biotechnologies are strong drivers for innovation in the life science sectors and are critical to the EU economy and the competitiveness of its industry. Productivity in this sector is significantly higher than the EU average and its employment is growing six times faster than the overall EU economy[16]. This underlines the enormous potential of European biotechnology for industrial applications. In 2024, the EU was home to 15% of the world's top firms in terms of research and innovation (R&I) investment in the health-related life science sector (64 companies headquartered in the EU)[17]. Products developed in the EU are associated with quality, safety and efficacy. At the same time, business expenditure on R&D in the life science sectors almost doubled between 2012 and 2022 (see Figure 2)[18].

[10] 'Choose Europe' positions Europe as the destination of choice for research, innovation, and entrepreneurship (https://commission.europa.eu/topics/research-and-innovation/choose-europe_en).

[11] Lasarte-López, J., González-Hermoso, H., M'barek, R., *The Life Sciences sectors in the EU: drivers of economic growth and innovation.* European Commission, Seville, 2025, JRC142396, https://publications.jrc.ec.europa.eu/repository/handle/JRC142396.

[12] A biocluster, is a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation.

[13] Total number of publications in journals categorised as 'Life Sciences' and 'Health Sciences' under the ASJC Subject Areas, normalised on the countries' respective populations; data retrieved in April 2025.

[14] Grassano, N. et al., *Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis*, Publications Office of the European Union, Luxembourg, 2024, doi:10.2760/567451, JRC137266.

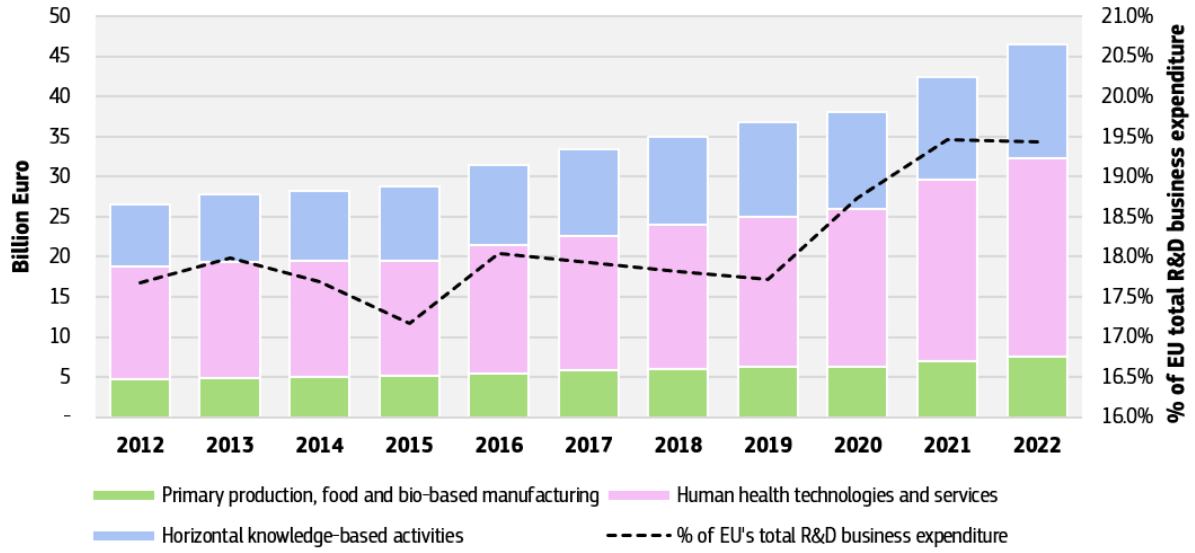
[15] Grassano, N., M'barek, R., *Trends in Patents in Life Science: focus on Pharmaceuticals and Medical Technologies*. European Commission, Seville, 2025, JRC142609, https://publications.jrc.ec.europa.eu/repository/handle/JRC142609.

[16] Haaf, A., Sale, V., *Measuring the Economic Footprint of the Biotechnology Industry in the European Union, prepared for EuropaBio*, WifOR Darmstadt, 2025 (https://www.europabio.org/wp-content/uploads/2025/03/WifOR_EuropaBio2025.pdf).

[17] https://iri.jrc.ec.europa.eu/data.

[18] Lasarte-López, J., González-Hermoso, H., M'barek, R., *The Life Sciences sectors in the EU: drivers of economic growth and innovation.* European Commission, Seville, 2025, JRC142396, https://publications.jrc.ec.europa.eu/repository/handle/JRC142396.

Figure 2: Business expenditure on R&D in the life science sectors (from Lasarte-López, J., González-Hermoso, H., M'barek, R., 2025)



Challenges ahead

The EU faces **fierce competition at global level** from other economies such as the US and China, with a growing innovation gap and an alarming failure to translate innovation into products or services. Innovative companies **struggle to scale up in Europe**[19]. The gap in venture capital investments is also widening. These negative trends signal structural barriers affecting Europe's life science value chains. **Fragmented R&I ecosystems**, **limited** and **often delayed valorisation** of technology breakthroughs and **underuse of data and artificial intelligence** (AI) are limiting our potential.

Moreover, some trends in the life sciences sector point to worrying developments: for example in terms of the number of clinical trials performed[20] or the market share for high-value products such as advanced therapy medicinal products (ATMPs).

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

It is essential to overcome these barriers to unlock the full potential of life sciences. Regarding biotechnologies, the Commission is already assessing how to streamline EU legislation and its implementation to reduce fragmentation, tap the potential for simplification and shorten the

[19] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en.
[20] Key performance indicators (KPIs) to monitor the European clinical trials environment. Documents - European Union (https://accelerating-clinical-trials.europa.eu/documents_en?f%5B0%5D=document_title%3AKPI&f%5B1%5D=priority_actions_priority_actions%3A2).

time to market for biotech innovations. The forthcoming **Biotech Act** will aim to accelerate the translation of biotech innovation into improved industrial processes and products that can be brought to market.

Unlocking the potential of vibrant life sciences in the EU – a strategy for European life sciences

The overall objective of this strategy is **to position the EU as the world's most attractive place for life sciences by 2030**[21]. The strategy announces a series of actions to develop and implement over the coming years to foster a dynamic and competitive life sciences ecosystem. Realising this vision necessitates coordinated action across **the entire life sciences value chain** – from R&I to market deployment and user uptake of safe and sustainable products and services. It also requires working together with Member States and life science stakeholders to make the most effective use of investments, expertise and resources.

To achieve these goals, the strategy proposes action in three interconnected phases, which all underpin the 'life science innovation journey':

- optimising the R&I ecosystem to achieve a globally competitive life science sector: through strengthened cooperation and optimised use of resources, promoting a holistic approach, using the power of data and AI, ensuring adequate skills and supporting a sustainable industry;
- ensuring smooth and rapid market access for life science innovations: through more innovation friendly regulation, use of the innovation principle as well as regulatory sandboxes, and better mobilisation of private and public investments;
- boosting the uptake and use of life science innovation: through better means to engage with citizens to beat disinformation and build trust, and to work closer with end-users to ensure adequate solutions for their specific needs.

Several EU initiatives, including the EU startup and scaleup strategy[22], the savings and investments union strategy[23], the Union of Skills[24], and the upcoming EU Biotech Act, medical countermeasures strategy, stockpiling strategy and bioeconomy strategy, will contribute to reaching the aims set out in the strategy for European life sciences.

The Commission proposes a reinforced coordination of its services to implement and monitor the actions in the strategy.

Over EUR 10 billion from EU funding programmes (Horizon Europe, EU4Health, Digital Europe, LIFE, Innovation Fund, Erasmus+) annually support action to implement this strategy in the current multiannual financial framework.

[21] Progress will be measured against indicators tracking growth in the sector such as employment, value added, business expenditure in R&D and the number of multi-country clinical trials.
[22] COM(2025) 270 final (https://research-and-innovation.ec.europa.eu/document/download/2f76a0df-b09b-47c2-949c-800c30e4c530_en).
[23] COM(2025) 124 final (https://finance.ec.europa.eu/document/download/13085856-09c8-4040-918e-890a1ed7dbf2_en?filename=250319-communication-savings-investmlents-union_en.pdf).
[24] COM(2025) 90 final (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52025DC0090).

2. OPTIMISING THE R&I ECOSYSTEM TO PROMOTE A GLOBALLY COMPETITIVE LIFE SCIENCE SECTOR

Reinforcing European R&I

The creation of new knowledge is an essential basis for a vibrant life sciences ecosystem and for the development of technologies and innovations. Horizon Europe, the EU framework programme for R&I, supports fundamental and frontier research[25] and works to translate emerging discoveries into practical applications and products[26], including through collaborative interdisciplinary projects[27]. This is complemented by the EU cohesion policy which focuses on strengthening regional R&I capacities. The Commission will continue to support robust life science research. The Commission will also support pan-European research and technology infrastructures[28] and optimise production processes, e.g. for bioeconomy technologies. The forthcoming **EU strategy on research and technology infrastructures** will aim to strengthen their sustainability, coordination and accessibility.

Although the EU has a strong R&I foundation, it faces barriers in turning scientific breakthroughs into real-world applications. Despite a range of funding instruments, the EU has yet to excel in providing support for technologies across development stages and it lacks sufficient follow-on funding for promising results.

The challenge of fragmentation and silos can be overcome by **bringing together life science disciplines, stakeholders and funding** into dynamic and connected **R&I ecosystems** as cooperation between researchers, innovators, industry, users and policymakers are better at matching specific needs for solutions with promising innovation. They also improve the efficiency of the process of translating knowledge into real-world applications.

Successful models for R&I ecosystems include partnerships, missions and bioclusters. European Partnerships[29] and EU Missions[30] under Horizon Europe foster long-term collaboration, reduce fragmentation and bring critical scale.

The co-funded partnership European Rare Diseases Research Alliance (ERDERA[31]) aims to make Europe the global leader in rare diseases research and innovation by bringing together EU and national research funders. It also includes the European life sciences research infrastructures, the JRC-managed European Platform on Rare Disease Registration[32], patient

[25] See for example European Research Council (https://erc.europa.eu/projects-statistics/mapping-erc-frontier-research) and EIC Pathfinder (https://eic.ec.europa.eu/eic-funding-opportunities/eic-pathfinder_en).
[26] See the 2024 biannual monitoring report on partnerships in Horizon Europe (https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/8f71dfd0-76fe-11ef-bbbe-01aa75ed71a1) and EIC Accelerator (https://eic.ec.europa.eu/eic-funding-opportunities/eic-accelerator_en).
[27] Horizon Europe, pillar II - Global challenges and European industrial competitiveness.
[28] There are already three technology infrastructures for safety testing of medical technologies and four for nano-enabled bio-based materials: Open Innovation Testbeds for Advanced Materials – European Commission (https://op.europa.eu/en/publication-detail/-/publication/0aaf1e05-2082-11ee-94cb-01aa75ed71a1/language-en).
[29] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe_en.
[30] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe_en.
[31] https://erdera.org/.
[32] https://eu-rd-platform.jrc.ec.europa.eu/_en.

organisations, the EU4Health-funded European Reference Networks[33] and research-performing public organisations, foundations and industry. Other EU co-funded partnerships include Biodiversa+ offers opportunities for the restoration and protection of ecosystems and to support One Health and the European Partnership on Animal Health and Welfare[34] which offers opportunities to foster life sciences research to bolster animal health. Within the Common Agricultural Policy, the European Innovation Partnership for Agricultural Productivity and Sustainability supports local bottom-up innovative projects, to ensure that advances in life sciences become practical innovations that address the real needs of farmers, foresters, and rural communities.

The goal of the EU Mission 'A Soil Deal for Europe' (Mission Soil)[35] is to create 100 Living Labs and Lighthouses by 2030 to promote sustainable land and soil management in urban and rural areas.

To further support the uptake of life sciences innovations across all R&I ecosystems, the EU will, through its Cohesion Policy, foster stronger interconnectivity and territorial cohesion among local, regional, and national actors. By capitalising on the new flexibilities introduced through the Cohesion Policy mid-term review, notably the option to reallocate European Regional Development Fund resources to the Interregional Innovation Investment (I3) instrument, this can help scale life sciences solutions and better integrate R&I value chains across countries and regions.

The European Institute of Innovation and Technology **(EIT)** Community, in particular the EIT Health, EIT Food, EIT Climate and the upcoming EIT Water Knowledge and Innovation Communities (KICs), play a central role in advancing life sciences across Europe. It spans education, entrepreneurship, investment, and cross-sector collaboration, all aimed at fostering innovation and addressing major healthcare, agriculture, food systems or climate-related challenges.

Bioclusters, also supported by the activities of the European Cluster Collaboration Platform, represent yet another type of ecosystem at local, regional or national level. They bring together different stakeholders in view to speed up innovation by concentrating knowledge in specific life science fields, especially in biotechnology. Such models should be leveraged for multi-country clinical trials and ATMPs.

Leveraging the capacities of European bioclusters will also generate major benefits. Europe already hosts several bioclusters. There is scope to improve their global standing[36] to attract

[33] https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/european-reference-networks_en.
[34] https://www.eupahw.eu/.
[35] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/soil-deal-europe_en.
[36] Van Looy, Bart, et al. 'Growth of biotech clusters over several decades through pioneering, variety and entrepreneurial science.' *Nature biotechnology* 42.1 (2024): 20-25.

private capital, spur entrepreneurship and ensure the EU remains competitive. By identifying more centres of excellence[37], the EU can boost its capacity in life science innovation.

Such R&I ecosystems lend themselves well, e.g. for ensuring sustainable management of biomass, or the development of medical countermeasures or for critical medicines, which will respectively be covered through the upcoming **bioeconomy strategy, medical countermeasures strategy** and **Critical Medicines Act** [38]. The Draghi and Letta reports point to the need for actions particularly for multi-country clinical trials and ATMPs.

Investing in ATMP research and development is critical not only to improve patient outcomes but also to strengthen Europe's position as a global leader in biomedical innovation. ATMPs represent a cutting-edge category of treatments designed to treat a wide range of human diseases, including severe, chronic or rare diseases where standard treatments often fall short.

For example, children with the rare genetic disease ADA-SCID (known as 'bubble children') had to live in sterile and isolated conditions due to their compromised immune system. European researchers pioneered the first ATMP to treat ADA-SCID, partly funded by the framework programmes for research and innovation[39]. The therapy, which only needs to be administered once, corrects the defective gene in the immune cells allowing these children to go back to school and lead fulfilling lives. Another example is the Arrest Blindness project[40], which developed a bio-cornea restoring vision to patients who otherwise would have remained visually impaired or blind[41].

Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human or animal health outcome[42]. These research studies are essential to turn scientific discoveries into real-world healthcare solutions[43]. Europe has unique advantages in human clinical research, thanks to its large population and rich genetic diversity, as well as scientific excellence, research infrastructures, and high ethics, quality and safety standards. An inclusive approach to clinical trials is essential to harness these advantages[44].

[37] Centres of Excellence are specific entities within bioclusters focused on a particular area of expertise, providing key innovation infrastructures for the advancements of research in specific high value technologies, knowledge transfer and product development.

[38] https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en.

[39] Advanced Cell-based Therapies for the treatment of Primary ImmunoDeficiency (CELL-PID; FP7) (https://cordis.europa.eu/project/id/261387); DevelopIng Genetic medicines for Severe Combined Immunodeficiency (SCIDNET; Horizon 2020) (https://cordis.europa.eu/project/id/666908).

[40] Advanced Regenerative and REStorative Therapies to combat corneal BLINDNESS (ARREST BLINDNESS) (https://cordis.europa.eu/project/id/667400).

[41] The Swedish company LinkoCare (https://www.linkocare.com/) further developed the bioengineered cornea: LinkCor® is a biocompatible corneal implant for managing corneal blindness and impairment.

[42] See World Health Organization definition (https://www.who.int/health-topics/clinical-trials#tab=tab_1); in the Clinical Trials Regulation 536/2014 clinical trials are defined more narrowly as testing investigational medicinal products on humans in specific conditions.

[43] This includes treatments based on nuclear medicine techniques, such as innovative targeted cancer therapy, promoting access to European patients. In this domain, thanks to the available nuclear infrastructure and assets, the Commission's Joint Research Centre, developed the breakthrough Actinium-225-PSMA. This innovative compound has demonstrated the high potential of targeted alpha therapy for cancer treatment and has stimulated significant interest worldwide in development of further radiopharmaceuticals labelled with Actinium-225.

[44] See WHO Guidance for best practices for clinical trials (2024).

To improve the framework for clinical research in Europe we need to address regulatory challenges (see section 3) and improve the clinical research ecosystem such as through supporting infrastructures and clinical trial centres and networks. In addition, more funding for multi-country clinical trials in Europe needs to be mobilised and the model of regionally integrated clinical research centres promoted, especially to support SMEs and for public health-promoting clinical research.

The Commission will continue to contribute facilitating multi-country clinical trials through European partnerships, including the Innovative Health Initiative Joint Undertaking (IHI JU)[45], capitalising notably on existing European research infrastructures[46], clinical trial networks or mechanisms for coordination of clinical trials related to preparedness[47]. The Commission will also pilot a new approach to funding multi-country clinical trials and propose further actions to improve the funding landscape.

The Commission is also working through the Accelerating Clinical Trials in the European Union (ACT EU[48]) initiative to support clinical trials through regulatory, technological and process innovation.

The Commission will continue to work together with the Member States medical research ethics committees in the **MedEthicsEU**[49] initiative, to step up efforts to align their operational procedures. In this context, the development of model templates that can contribute to harmonising national requirements will continue and their use incentivised.

As regards the increasing number of innovative and personalised treatments that combine medicines and medical devices, the **COMBINE programme**[50] supports sponsors when they apply both the regulatory framework for clinical trials of medicines and for medical devices. The programme aims to streamline the interface between these regulatory frameworks. An **'all-in-one' coordinated assessment procedure**, combining approval from medicine and device authorities and ethics committees across several Member States in a single process, reducing administrative burden on sponsors is being piloted.

Given the potential of partnerships and bioclusters, the Commission urges Member States and other partners to boost their support for European partnerships and to scale up targeted R&I investment at local, regional and national levels.

[45] https://www.ihi.europa.eu/projects-results/health-spotlights/impact-clinical-trials.
[46] Such as ECRIN, the European Clinical Research Infrastructure Network (https://ecrin.org/ecrin.org); BBMRI, the European Research Infrastructure for biobanking and biomolecular resources (https://www.bbmri-eric.eu); or EATRIS, the European infrastructure for translational medicine (https://eatris.eu).
[47] Sub-Group of the HERA Board to advise on the prioritisation of clinical trials and their funding for public health emergencies (E03860/1; https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&fromMainGroup=true&groupID=104872); Horizon Europe CoMECT project (https://cordis.europa.eu/project/id/101136531).
[48] ACT EU is a joint initiative of the Commission, the European Medicines Agency and the Heads of national Medicines Agencies (https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/accelerating-clinical-trials-eu-act-eu).
[49] https://health.ec.europa.eu/medicinal-products/clinical-trials/medethicseu_en.
[50] https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en.

Lastly, to stay ahead globally, the EU must identify emerging scientific breakthroughs at an early stage through **'horizon scanning'**[51] and then support their rapid translation into innovation. This will help to inform public investments[52] and their prioritisation. The **Life Sciences Coordination Group** (see Section 5) will play a central role in mapping opportunities, aligning funding priorities and integrating existing activities[53].

Proposed actions:

- ***(Flagship)*** *The Commission will propose an investment plan for clinical research to facilitate funding for multi-country clinical trials, in compliance with competition rules, and to further develop and streamline European research infrastructures in the field of clinical research.*
- ***(Flagship)*** *The Commission will create a network of European Centres of Excellence in advanced therapy medicinal products (ATMPs) to coordinate their further development, together with the Member States, taking into account existing centres, with EUR 4 million financial support from the Horizon Europe work programme 2026-2027*[54]*.*
- *The Commission will continue to support, monitor and evaluate the implementation of the Clinical Trials Regulation with the overall aim to make Europe more competitive for clinical trials and medical research investments.*
- *The Commission will launch a pilot for phased, stepwise funding of collaborative research under the Horizon Europe work programme 2026-2027*[55]*, leveraging results from past EU projects, to accelerate the development of promising health technologies.*
- *The Commission will explore a pilot to identify and exploit collaboration opportunities between EU Biotech clusters across the EU, with a focus on supporting the scaling-up of their startups as well as on enhancing their global industrial innovation standing. The action should build upon existing actions, such as the European Cluster Collaboration Platform.*

Promoting a holistic approach to the life sciences

The EU currently lacks a coherent and integrated framework for the life sciences, which limits the scope for policy alignment, cross-sector collaboration and sustainable solutions. Areas which would greatly benefit from a more integrated framework are those requiring One Health approaches, as well as the area studying the links between climate change and health.

The **One Health**[56] approach recognises the interconnectedness of human, animal and environmental health and seeks to tackle global challenges in a sustainable manner. The EU can

[51] Detecting emerging evidence and early signals of change in the present to help anticipate their potential future impacts (https://www.oecd.org/en/about/programmes/strategic-foresight.html), including regarding scientific and technological developments with potential for application.
[52] See for example EIC Tech Report 2024.
[53] For instance through the use of the Innovation Radar (https://innovation-radar.ec.europa.eu/); or studies like 'Weak signals in Science and Technologies' (2024; (https://publications.jrc.ec.europa.eu/repository/handle/JRC140959).
[54] Within the existing envelopes of the programme.
[55] Within the existing envelopes of the programme.
[56] https://health.ec.europa.eu/one-health/overview_en.

embrace the One Health approach to better protect people's health, empower the green transition and boost competitiveness. Ensuring environmental health and halting the extinction of species are of outmost importance. The scientific opinion, '**One Health Governance in the EU**'[57], recommends action to tackle the fragmentation of policies, the lack of trans- and interdisciplinarity, and insufficient coordination among related sectors. A prime example of added value by adopting a One Health approach is combatting antimicrobial resistance, which can only be defeated if interlinkages between humans, animals and the environment are considered. The EU can build its work in this area on the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach[58] and EU-Member State collaborations[59]. Another example is better preparedness and response to infectious diseases, where collaborations such as DURABLE[60], a network of public and animal health laboratories and academic research institutes, reinforce the EU's capacity to rapidly respond to emerging, serious cross-border threats to health.

Adopting a One Health approach would also create significant opportunities in the field of **microbiomes,** which are communities of microorganisms such as bacteria or fungi living together in a specific environment, with deep interconnections. A thorough understanding of microbiomes and their interactions will create opportunities to improve and create new products for health, food, sustainable agriculture and forestry, aquaculture and ecological restoration.

In parallel, we need to deepen understanding of the links between climate change and health, with attention to different age groups, including older persons and persons with disabilities[61]. The new **strategic research and innovation agenda on health and climate change**[62] will support the development and deployment of high-impact solutions, including health-risk surveillance tools, prevention-enhancing interventions and low-carbon medical technologies. The upcoming **European climate adaptation plan** will assist Member States in strengthening resilience planning, updating climate risk assessments and developing more robust climate-resilient infrastructure taking into account the experience gathered by the EU Mission on Adaptation to Climate Change[63] as well as the concepts and principles of the New European Bauhaus.

Proposed actions:

- ***(Flagship)*** *The Commission will promote One Health approaches in research and innovation by collaborating with Member States and other stakeholders to:*

[57] Scientific opinion by its Scientific Advice Mechanism 'One Health Governance in the European Union' (https://op.europa.eu/en/publication-detail/-/publication/56b65e58-a309-11ef-85f0-01aa75ed71a1/language-en).
[58] https://health.ec.europa.eu/publications/council-recommendation-stepping-eu-actions-combat-antimicrobial-resistance-one-health-approach_en.
[59] E.g. the Joint Programming Initiative on Antimicrobial Resistance (https://www.jpiamr.eu/), the upcoming European partnership on One Health Antimicrobial Resistance (EUP OHAMR; https://www.jpiamr.eu/activities/one-health-amr/), or the European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EUJAMRAI2; https://eu-jamrai.eu/).
[60] https://durableproject.org/.
[61] See for example https://www.ohchr.org/en/climate-change/impact-climate-change-rights-older-persons.
[62] https://op.europa.eu/en/publication-detail/-/publication/616cce9c-39e5-11f0-8a44-01aa75ed71a1.
[63] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/adaptation-climate-change_en.

i) identify further priority areas that would benefit from One Health approaches for consideration for financial support, leveraging existing data and repositories, and
ii) develop guidance to support inter- and transdisciplinary R&I in One Health.

- ***(Flagship)** The Commission ambitions to make the EU a world-class innovator in One Health microbiome-based solutions, including by mobilising close to EUR 100 million under the Horizon Europe work programmes for 2026-2027 to support development and deployment of such solutions.*
- ***(Flagship)** The Commission will implement the new strategic research and innovation agenda on **health and climate change**, including through mobilising EUR 170 million Horizon Europe funding and invites Member States and industry to contribute. The Commission will also propose a global research collaboration to foster alignment between global funders and to support the development of solutions to increase our resilience and to support climate adaptation and mitigation.*
- *The Commission will develop a strategic R&I agenda on food systems to foster development of competitive, sustainable and resilient food systems solutions, complementing the forthcoming strategic approach to R&I in agriculture, forestry and rural areas announced in the Vision for agriculture and food*[64].

Unlocking the power of data and AI for breakthrough innovation

Access to large-scale, high-quality datasets and the ability to analyse them are essential to advance life science discoveries. The explosion of data generated worldwide[65], combined with rapid advances in artificial intelligence (AI) offer significant opportunities for different areas such as environment or health. These include the analysis of complex biological systems, the development of personalised healthcare, including tailored solutions for specific populations such as women and older people and many more.

Europe has been a frontrunner in adopting AI for scientific research and several EU initiatives have been launched to tap in the European AI and data capabilities[66].

The AI Continent Action Plan[67], the forthcoming Apply AI strategy, along with a dedicated strategy for AI in science and the AI Factories[68], will further accelerate the uneven uptake of AI and facilitate life science AI powered breakthroughs[69]. At least 10 out of 13 AI Factories, which bring together the necessary resources and stakeholders to build cutting-edge AI models and applications, will cater for ecosystems relevant for life sciences, among others supporting drug discovery and genome analysis. Furthermore, EUR 20 billion will be invested to create up to five AI Gigafactories dedicated to development and training of next-generation AI models containing trillions of parameters.

[64] COM(2025) 75 final (eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0075).
[65] In less than a decade, the volume of global data has increased five-fold (European strategy for data, COM(2020) 66 final). According to Forbes, healthcare data is expected to comprise around 36% of all the data in the world by the end of 2025 (https://www.forbes.com/councils/forbestechcouncil/2023/12/12/what-to-do-about-healthcares-messy-desk-data-dilemma/).
[66] For example: the 'GenAI4EU', the European '1+ Million Genomes' Initiative, European Initiative to UNderstand CANcer, European Reference Networks & their registries.
[67] https://commission.europa.eu/topics/eu-competitiveness/ai-continent_en.
[68] https://digital-strategy.ec.europa.eu/en/policies/ai-factories.
[69] As exemplified in https://cordis.europa.eu/article/id/459569.

In the health sector, the European Health Data Space (EHDS) Regulation[70] establishes a clear framework for accessing electronic health data in a secured and streamlined way.

The rules and principles of the General Data Protection Regulation are embedded in legal frameworks such as the EHDS, the Data Governance Act and the AI Act to enable research and innovation that relies on personal data. Moreover, the forthcoming Data Union Strategy will adopt a cross-sectoral approach for increasing data availability and use for AI and addressing legal fragmentation, ensuring a more cohesive and efficient data environment across the EU.

However, challenges persist. Fragmentation in national application of EU legislation and diverging national interpretations create legal uncertainty and continue to limit the full use of personal data[71]. The coexistence of personal and non-personal data, the various data formats, combined with diverse data access regimes and the fact that data remains often siloed adds to the complexity. These challenges are exacerbated by ethical concerns around AI and data use and reuse.

To address these challenges, **a closer cooperation** needs to be established between **Member State authorities,** responsible for life science R&I, AI and data related domains, and EU institutional stakeholders to tackle data-related challenges in a consistent manner. Such collaboration will enhance the mutual understanding on the increasingly complex, cross-cutting and horizontal challenges in data sharing for life sciences, will facilitate exchange of good practices and harmonisation of approaches in areas that go beyond sector-specific regulatory domains. Building on this cross-regulatory cooperation, the Commission will consider the most appropriate way forward to address the unresolved recurring challenges faced by R&I stakeholders.

Research and innovation in life sciences also relies heavily on the understanding and exploration of both human and **non-human genomic and biological data** (biodata)[72] **including taxonomic data**. The linkage of non-human and human data would be particularly important to advance the One Health approaches, as previously mentioned. The Commission is already supporting the establishment of a comprehensive European genomic reference database to support advancements in personalised medicine.

The acceleration of scientific discoveries, preservation of biodiversity, and contribution to nature restoration[73] is also critically dependent on improving the quality, accessibility, interoperability and sustainability of biodata resources. Stronger multilateral international collaboration is needed with like-minded partners to secure long-term access to and stewardship of global biodata resources.

Finally, to fast-track life science discoveries from idea to market, researchers and innovators should be equipped with an AI-powered **interactive tool** to navigate through the EU's

[70] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en.
[71] Second Report on the application of the General Data Protection Regulation, COM(2024) 357 final.
[72] Such as the 'Catalogue of Life', which provides an index of known species of animals, plants, fungi, and microorganisms, as the basis for collaboration with like-minded partners in international fora such as the G20 and contribute to achieving the objectives set in relevant international agreements such as the Kunming Montreal Global Biodiversity Framework.
[73] Regulation (EU) 2024/1991 on nature restoration (https://eur-lex.europa.eu/eli/reg/2024/1991/oj/eng).

regulatory landscape and fully leverage the data repositories and available services. Such a tool will address the cross-disciplinary and cross-sectorial needs of modern life scientists, supporting researchers and innovators in i) embedding regulatory compliance at the very early design stage, ii) overcoming data findability barriers and iii) fully utilising the data services provided by EU-funded infrastructure and instruments (see Section 3).

Proposed actions:

- ***(Flagship)*** *The Commission will establish a European Life Sciences R&I Data Assembly bringing together a range of EU and Member State authorities working in data-related domains and key EU R&I bodies to support consistent interpretation and harmonisation of relevant legal data frameworks and to strengthen cross-regulatory coordination and collaboration.*
- *The Commission will support activities to develop and populate strategic biodata resources, including non-human biodata, and enable access for European and global users in complement to the European Data Union strategy.*
- *The Commission will invest EUR 50 million in integration of multi-modal generative AI technologies into multidisciplinary biomedical research via the Horizon Europe Work Programme 2025.*
- *The Commission will invest EUR 25 million from the Digital Europe work programme 2026 to boost the European genomic data infrastructure, in alignment with the EHDS.*

Life sciences as a driver for industrial sustainability

Accelerating the development and adoption of innovative, circular, resource-efficient, and low-emission biotechnologies is crucial to tackling climate change, biodiversity loss and pollution, reduce soil degradation and ensure the sustainable provision of ecosystem services. To unlock the full potential of biotechnology to improve industrial processes and to green European industry, targeted investments are needed across the entire innovation pipeline and across all Member States and Regions, particularly in territories facing innovation challenges. This includes reducing the use of resources, water and energy, in line with the Clean Industrial Deal.

Life science innovation can help reduce Europe's dependence on limited sustainable biomass[74] by deploying regenerative and nature-based solutions and using biomass more efficiently, turning waste into valuable products and supporting the use of carbon from carbon capture and utilisation. Supporting the advancement of novel methodological approaches in biomanufacturing is essential, as it enhances attractiveness for industrial adoption of biotechnology. New technologies for **bioremediation** also play an important role in restoring the environment. The **European water resilience strategy** indicates that research and innovation can have the potential to significantly reduce the costs of remediation of highly persistent pollutants, such as per- and polyfluoroalkyl substances (PFAS), through novel, including bio-based, technologies. Biorefineries are a key example of how life science technologies can support and enable a circular bioeconomy[75]. Several EU initiatives have

[74] https://knowledge4policy.ec.europa.eu/visualisation/eu-bioeconomy-monitoring-system-dashboards_en.
[75] https://www.fao.org/food-safety/news/news-details/en/c/1735814/.

successfully transformed waste and residue streams from agricultural, fisheries and aquaculture[76] into higher-value products such as food, feed, fertilisers, textiles and plastics[77].

As an example, the project **Circular Biocarbon**, funded by the Circular Bio-based Europe Joint Undertaking, is working with local authorities to use municipal waste to produce bio-polymers that have a range of applications from agriculture to advanced materials. There is an expectation that the project's results can be replicated by over 20 000 European waste recovery facilities, offering a pathway to valorise close to 50% of the ~220 million tons of municipal waste generated annually in the EU[78].

Advanced fermentation technologies such as precision and biomass fermentation offer significant potential, as they can produce a wide spectrum of high-end products[79, 80] from renewable raw materials with low environmental impact. Products include a wide variety of sustainable food ingredients (e.g. natural colorants, low caloric sweeteners), biopolymers (e.g. spider silk), cosmetics or biosurfactants, biopesticides, or chemicals. Startups and other SMEs are playing a leading role in driving innovation in advanced fermentation technologies[81]. Upscaling is a capital-intensive and challenging process and requires for example development of biomass pre-treatment and downstream processing.

The upcoming new **bioeconomy strategy (2025)** will drive the deployment and uptake of such innovations across value chains while ensuring sustainable supply of biomass. Complementary initiatives (including the **Circular Economy Act,** the **Communication on Advanced Materials for Industrial Leadership**[82] and the **revised Commission recommendation on Safe and Sustainable by Design (SSbD) Chemicals and Advanced Materials**[83]) pursue the EU's sustainability and competitiveness objectives. The SSbD framework aims to become a global benchmark for innovation in the clean industrial transition, encouraging industry to replace substances of concern with safer, more sustainable alternatives. In preparation for the **Advanced Materials Act**, the Commission will also explore with stakeholders how material sciences and life sciences can mutually reinforce the competitiveness of their related sectors.

Novel tools such as **new approach methodologies** (NAMs) – innovative experimental methods that do not involve live animals – can accelerate innovation, reduce costs and increase efficiency in industrial R&I. These methodologies use a range of modern technologies such as advanced computer models and virtual twins[84] (digital representation of for example cells,

[76] Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52021DC0236).
[77] See for example demonstration and flagship biorefineries under the Circular Bio-based Europe Joint Undertaking, https://www.cbe.europa.eu/.
[78] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Municipal_waste_statistics.
[79] The transition pathway for the agri-food industrial ecosystem identified precision fermentation as an innovative agri-food technology that should be explored to boost EU competitiveness: https://single-market-economy.ec.europa.eu/sectors/agri-food-industrial-ecosystem/transition-pathway-agri-food-industrial-ecosystem_en.
[80] https://www.fao.org/food-safety/news/news-details/en/c/1735814/.
[81] https://gfi.org/resource/fermentation-meat-seafood-eggs-dairy-and-ingredients-state-of-the-industry/.
[82] COM(2024) 98 final (https://research-and-innovation.ec.europa.eu/document/download/0fcf06ea-c242-44a6-b2cb-daed39584996_en?filename=com_2024_98_1_en_act_part1.pdf).
[83] https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en.
[84] See for example the European Virtual Human Twins Initiative (https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins).

tissues, organs or living systems). NAMs can complement or replace certain animal studies, speeding up the development of safe and effective medicines and improving safety assessments of chemicals and other products. By adopting and investing in these new tools, industry can innovate faster, reduce costs and make research and development more sustainable.

Proposed actions:

- *The Commission will support research and innovation in cross-sectoral life science technologies to develop new products that can drive industrial innovation and sustainability (including novel molecules and advanced materials), improve the efficiency of biomanufacturing and other industrial biotechnology processes, and support bioremediation. This includes mobilising EUR 200 million under the Horizon Europe work programme 2026-2027.*
- *The Commission will support the scale-up and uptake of sustainable advanced fermentation by promoting innovation through public-private partnerships and supporting the scaling-up of startups and other SMEs operating in this area and by organising an annual conference on advanced fermentation to connect stakeholders, foster collaboration and promote knowledge exchange.*
- *The Commission will support life sciences research and innovation to promote the leadership position of the European Union for bioeconomy solutions and sustainable management of biomass. This includes mobilising more than EUR 150 million under the Horizon Europe work programme 2026-2027.*
- *The Commission will collaborate with Member States, industry, academia and regulators to support development, validation and uptake of new approach methodologies to de-risk the development of new medicinal products and medical devices through a new European Research Area (ERA) policy action[85]. In addition, the Horizon Europe programme will allocate EUR 50 million to these methodologies through its work programme 2026-2027.*
- *The Commission will continue to support the emergence and adoption of the next generation of virtual human twins solutions in the context of the European Virtual Human Twins Initiative. The Commission will dedicate EUR 8 million for a Virtual Human Twins Incubator to support uptake of virtual human twin solutions in the European market and their use in clinical research (e.g. clinical trials, clinical investigations) through the Digital Europe Work Programme 2025-2027.*

Strengthening skills and careers for competitive European life sciences

Life sciences are evolving rapidly. Constantly emerging new knowledge, techniques and technologies make it challenging for academics, researchers and practitioners to keep up with advances. At the same time, researchers face career challenges, including limited career

[85] See ERA Policy Agenda 2025-2027 (https://european-research-area.ec.europa.eu/era-policy-agenda-2025-2027).

prospects, restricted mobility and persistent gender imbalances in science, technology, engineering and mathematics (STEM) fields[86].

Given the current geopolitical context, the EU reiterates its commitment to academic freedom and to open international research collaboration, positioning Europe as a hub for global innovation and fostering progress in critical life science fields such as health and climate. The EU has a range of instruments to support the development of skills and foster links between academia and industry, including the **Marie Skłodowska-Curie Actions,** the **EIT**[87], **Erasmus+** supported programmes and training schemes provided by European research infrastructures. The Commission encourages Member States to strengthen national programmes that promote innovation and entrepreneurship in key life science sectors, as well as lifelong learning, upskilling and reskilling for professionals in these sectors.

The recently launched Union of Skills[88] proposes targeted actions to promote future-oriented skills for Europe's competitiveness. The accompanying STEM education strategic plan[89] aims to enhance the quality of STEM education and training and foster talent in critical, fast-growing fields such as life sciences, including through a **STEM specialist fellowships** to attract top scientists and experts to the EU, and by strengthening cooperation between education, research, and business to create synergies and facilitate knowledge transfer. Also, the strategic plan will promote future-oriented STEM curricula in schools, vocational education and training and tertiary education. In line with these efforts, the ecosystems around AI Factories will contribute to developing the cutting-edge skills and expertise of a new generation of scientists and professionals across various fields, including life sciences.

To make research careers more attractive, the EU will implement the new **European framework for research careers,** the **Council Recommendation** on attractive and sustainable careers in higher education[90] and the European Charter for Researchers[91], supported by tailored instruments[92]. Building on these, the Commission will work to attract global research talent and overcome any remaining legal barriers by action under the forthcoming **European Research Area (ERA) Act** (2026).

Furthermore, an enhanced use of the European digital skills certificate and the digitalisation of academic qualifications and other certificates, including micro-credentials, as well as digitally accessible individual learning accounts, will increase transparency on available training and support opportunities, and facilitate automatic recognition of academic qualifications to unlock training and work opportunities for scientists across the EU. The EU Digital Identity Wallets

[86] E.g. women file only 10% of patent applications (https://projects.research-and-innovation.ec.europa.eu/en/knowledge-publications-tools-and-data/interactive-reports/she-figures-2024).
[87] The EIT Community, in particular through relevant KICs, leads efforts to attract new talent and upskill the existing workforce through reskilling initiatives, on-the-job training, personalized learning journeys that integrate entrepreneurship and industry trends, coordinating skills partnerships with industry and other learning opportunities.
[88] https://commission.europa.eu/topics/eu-competitiveness/union-skills_en.
[89] A STEM Education Strategic Plan: skills for competitiveness and innovation (COM(2025) 89 final; https://education.ec.europa.eu/document/stem-education-strategic-plan-legal-document).
[90] Council Recommendation of 25 November 2024 on attractive and sustainable careers in higher education
[91] Council Recommendation of 18 December 2023 on a European framework to attract and retain research, innovation and entrepreneurial talents in Europe.
[92] https://european-research-area.ec.europa.eu/horizon-europe-support-research-careers.

that will be launched by end of 2026 by all Member States will offer an EU-wide platform for handling digital qualification certificates and putting them in the hands of scientists.

Proposed actions:

- ***(Flagship)*** *The Commission will take action to support the career development of life science researchers and to help researchers from non-EU countries set up in the EU, including through the* ***'Choose Europe' initiative,*** *and work in synergy with similar activities run by the Member States*[93].
- *The Commission will launch a foresight study to identify the competences, skills and training needs for the life sciences, including for optimising the uptake of artificial intelligence. With EUR 1 million financial support from the Horizon Europe work programme 2026-2027, the study will complement relevant data and analysis by the European Skills Intelligence Observatory.*

3. PROVIDING SMOOTH AND RAPID MARKET ACCESS FOR LIFE SCIENCE INNOVATIONS

Promoting innovation-responsive regulation

Europe's high standards for quality, safety, and efficacy in life sciences underpin public trust and ensure that innovations deliver real value to people. However, regulatory and administrative hurdles can significantly slow down the journey from idea to market, driving up costs and creating uncertainty – particularly for startups and innovators. In the area of bioeconomy solutions, the upcoming new **Bioeconomy Strategy** (2025) will propose actions on accelerating the market uptake and scale-up of bioeconomy solutions, maximising resource efficiency and securing sustainably sourced biomass supply, looking at regulatory barriers and investments needs.

Fragmentation and complexity in regulatory pathways are a challenge, especially for novel products, or combined products that fall under multiple legal frameworks or need to progress through different regulatory stages. This leads to slow timelines and the risk of conflicting decisions. Even with centralised approaches, long authorisation procedures under regulatory frameworks that require pre-market authorisation to ensure safety for human health and the environment can delay market entry of innovative products. For multi-country clinical studies, the need for trials to go through parallel national ethics approval can result in delays.

In order to fully unlock the potential of biotech innovation in Europe, it is important to assess current regulatory procedures, particularly for health, medical devices and food applications, in order to make them more agile and proportionate, without compromising safety or scientific rigour. Efforts should also be made to increase efficiency and to significantly reduce the length

[93] Such as life sciences-relevant national and regional initiatives under Choose Europe for Science (https://euraxess.ec.europa.eu/jobs#choose-europe-for-science-new), including e.g. the French Safe Place for Science initiative, or the Danish Science Hub Denmark.

of authorisation procedures in the health, medical devices and food areas, to make the EU more attractive in comparison to other regions in the world.

Regulatory systems need to be responsive to emerging technologies and keep pace with scientific progress. Future legislation should integrate experimentation clauses, derogations and the use of test environments such as regulatory sandboxes[94] as was done for example in the proposed reform of the EU pharmaceutical legislation. This provides the flexibility to test new solutions, gather evidence and ensure that regulatory frameworks remain responsive and supportive of innovation.

The EU is committed to advancing the **innovation principle**[95], which is a policymaking tool designed to ensure that policy and regulation actively support innovation as a driver for achieving the EU's strategic objectives, including health security, environmental safety, sustainability and economic resilience. The EU is also obliged by its founding treaties to strive for a high level of protection of human health and the environment. This means shaping a regulatory environment that both upholds Europe's rigorous standards and creates the best possible conditions for life science innovation to thrive and to meet societal needs. European Partnerships under Horizon Europe, especially Joint Undertakings such as the Innovative Health Initiative Joint Undertaking (IHI JU), are well placed to support regulatory changes in scientific domains and to strengthen the EU's capacity to adapt regulation to emerging technologies in full commitment with the precautionary principle.

Standards have an important role in facilitating innovation and market access by influencing industry practices, guiding policies and ensuring that products and processes meet recognised benchmarks for quality, safety, and sustainability. The Commission will continue to encourage the elaboration and updating of European standards in the field of life sciences and in particular for biotechnology and biomanufacturing, with support of the European standardisation organisations and in compliance with EU competition rules.

For example, efforts are underway through the IHI JU[96] to develop a comprehensive framework for robust regulatory sandboxes in the human health area, notably in relation to the reform of the EU pharmaceutical legislation.

Cooperation between national and EU Agencies in the co-funded Partnership for the Assessment of Risks from Chemicals[97] facilitates the timely uptake of innovation into regulatory practice.

Early regulatory guidance for researchers and innovators plays a critical role in the life science innovation journey. The Commission plans to create **an AI-powered interactive tool to help researchers and innovators navigate the EU regulatory landscape,** complementing the information available to companies through the Biotech and Biomanufacturing Hub,

[94] Commission Staff Working Document: Regulatory learning in the EU Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy (SWD(2023) 277/2 final).
[95] https://research-and-innovation.ec.europa.eu/law-and-regulations/ensuring-eu-legislation-supports-innovation_en.
[96] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ihi-2024-08-03-two-stage.
[97] https://www.eu-parc.eu/.

particularly for the early stages of research and development. This personalised assistance tool will help innovators navigate cross-sectoral and cross-technology regulatory frameworks from the early stage of innovation design. The tool will be interactive to help users identify and access key information, datasets and tools, tailored to their specific innovative needs.

A predictable and balanced intellectual property (IP) framework is crucial for a vibrant life science innovation ecosystem. IP is frequently a critical asset that startups leverage to secure financing for their R&I activities. The Commission promotes the Unitary Patent system and encourages all EU Member States to join this system. To enhance the EU regime for supplementary protection certificates (SPCs), the Commission actively supports the ongoing co-decision process for a reform of that regime and aims for the rapid creation of a unitary SPC, which will promote the uptake of the unitary patent. The Commission also monitors the application of the Directive 98/44/EC on the legal protection of biotechnological inventions to ensure it remains fit for purpose. Finally, the Commission supports filing and management of IP rights, including action under the SME Fund.

Further, multiple reforms of existing regulations and already adopted regulations as well as regulations yet to be proposed aim support the advancement of the 'innovation principle', whilst safeguarding a high level of protection of human health and the environment.

The proposed **reform of the EU pharmaceutical legislation**[98] includes measures to streamline the regulatory framework for the development and timely authorisation of innovative medicines. This reform provides for early interaction between regulators and companies, especially start-ups and SMEs. It also includes future-proofing measures to ensure that the regulatory system keeps pace with scientific and technological progress, such as regulatory sandboxes and adapted frameworks to foster cutting-edge innovation.

The EU **Health Technology Assessment Regulation** introduces the possibility for health technology developers of medical products to ask for advice on their clinical development plan in parallel to the scientific advice given in the context of the medicines' regulatory process. This is expected to facilitate the production of clinical evidence able to simultaneously meet regulatory and HTA requirements and speed up market access to innovative products.

The Clinical Trials Regulation[99], and associated actions represent efforts to ensure Europe's attractiveness and competitiveness for clinical research investments and provide patients in Europe with early access to innovative medicines. The Commission will continue, in close cooperation with Member States and relevant stakeholders, to ensure appropriate implementation of the Clinical Trials Regulation, in particular with regard to **multi-country clinical trials.** Progress is monitored by collecting key performance indicators which are regularly published[100].

[98] https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en.
[99] https://health.ec.europa.eu/medicinal-products/clinical-trials/clinical-trials-regulation-eu-no-5362014_en.
[100] https://accelerating-clinical-trials.europa.eu/documents_en?f%5B0%5D=document_title%3AKPI&f%5B1%5D=priority_actions_priority_actions%3A2.

Medical devices and diagnostics are essential to healthcare systems because they enable accurate disease detection, effective treatment, and continuous patient monitoring, ultimately improving health outcomes and saving lives. They have a short innovation cycle and need to reach the market efficiently. The Commission is working to **address challenges identified regarding the regulatory framework for medical devices and in vitro diagnostic devices**. It is conducting a targeted evaluation of the concerned regulations. Based on this evaluation, the Commission will be ready to **propose a legislative intervention** that strikes the balance between simplifying EU regulations related to medical devices and in vitro diagnostics, and effectively protecting patient safety and public health, also considering health emergencies.

In addition, the upcoming **European Business Wallet**[101], which will be a tool for simplification and decreasing administrative barriers, will support researchers to manage regulatory requirements, such as securely managing and sharing their verified data and credentials with public administrations and/or investors.

Finally, the Commission will propose the **European Biotech Act** to make the EU regulatory environment more conducive to innovation, attract innovators and investors, and make it easier for spin-offs, start-ups and scale-ups to bring biotechnologies from the laboratory to the factory and onto the market. Furthermore, the Act will also include measures complementary to regulatory aspects.

Proposed actions:

- ***(Flagship)*** *The Commission will propose* ***an EU Biotech Act*** *to make the EU regulatory system more conducive to biotech innovation in various biotech sectors, alongside supportive measures.*
- ***(Flagship)*** *The Commission will be ready to* ***propose legislation*** *that strikes a balance between simplifying EU regulations related to medical devices and in vitro diagnostics, with a view to facilitate businesses' operations across the EU single market, and effectively protecting patient safety and public health.*
- *The Commission will create an AI-powered* ***interactive tool*** *to help researchers and innovators navigate the EU regulatory landscape, particularly in the early stages of research and development.*

Unlocking public and private investment

The life science industry in Europe still faces significant financing and investment challenges. The challenges include fragmented capital markets, an over-reliance on bank financing and a lack of coordination in public funding. Europe's relatively underdeveloped initial public offering (IPO) market, limited venture capital (VC) availability, and low level of involvement with institutional and foreign investors further constrain the sector's ability to grow and scale[102].

[101] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14663-European-Business-Wallet-digital-identity-secure-data-exchange-and-legal-notifications-for-simple-digital-business_en.

[102] Attracting Life Science Investments in Europe, Oct 2023; https://www.biomedeurope.org/wp-content/uploads/2024/09/Life_Science_Attractiveness_-_2023_November_22_Final_Final_LR2.pdf.

While VC investment in the EU has improved over the past decade, it remains below the levels seen in other global regions.

In 2024, health, life sciences and deep tech attracted significantly more investment than other sectors. However, much more is needed to fully tap Europe's potential and to build competitive leadership in these fields[103].

Long development and authorisation timelines, notably for health-related products, combined with the specialised expertise needed to evaluate investments in this area, make it more difficult for investors to identify and invest in promising opportunities. This limits innovators' ability to scale up and bring life sciences solutions to market in the EU.

Public support mechanisms play a key role in de-risking investments and in helping startups reach critical development milestones that can attract follow-on private capital. The Commission has already taken targeted steps to improve access to finance for life science technologies and innovations. These include the European Circular Bioeconomy Fund, the HERA Invest scheme and dedicated support for life science startups and scale-ups through InvestEU and the European Innovation Council (EIC)[104]. In addition, broader EU financing initiatives such as the Strategic Technologies for Europe Platform (STEP) and the InvestEU programme are improving access to capital by supporting innovation-driven companies and providing anchor investments in VC funds[105]. Shared management funds, notably the European Regional Development Fund, also play an important role in supporting innovative companies to access financing through grant and financial instruments, as well as by attracting additional private investments.

To address key challenges in the functioning of EU capital markets, the Commission is implementing the Savings and Investment Union (SIU) strategy[106]. The SIU will reduce market fragmentation, create better investment opportunities for citizens and help to expand funding options for businesses. In particular, it will seek to improve access to equity and debt financing for all companies, including startups and scaleups, strengthen the role of venture capital and institutional investors and better align EU public funding instruments with SIU objectives.

In addition, the recently adopted **EU startup and scaleup strategy** (2025) proposes how to facilitate the growth of innovative companies in Europe and accelerate their access to financing and the market. It specifically acknowledges the critical strategic importance of life sciences and biotech. The Scaleup Europe Fund, announced in the European startups and scaleups strategy, will bridge the funding gap and unlock private investments for startups working in areas that are strategic for Europe's technological sovereignty and economic security, including in the life sciences. The work of the Fund will be supplemented by measures for unlocking the

[103] The 2025 European Deep Tech Report.
[104] According to the EIC Impact report 2025, between 2020-2024 up to EUR 625 million worth of investments were made in life science startups (industrial biotechnology, agri-food biotech and healthcare biotech).
[105] The EIB is the largest venture debt provider to the life sciences sector in Europe with a portfolio of over EUR 2.7 billion at the end of 2023 supporting more than 100 innovative companies, almost half of which are in the biotechnology field (Draghi Report 2024).
[106] Savings and Investments Union A Strategy to Foster Citizens' Wealth and Economic Competitiveness in the EU (COM(2025) 124, final).

participation of institutional investors and pension funds, which are also crucial as they are underrepresented in the European life sciences funding landscape.

The upcoming **European Innovation Act** (2026) will further promote access to assets generated by publicly funded R&I.

Joint investments by public funders, foundations and industry have also proven to be an efficient means to tackle high-risk research and novel application areas with potentially high benefits in the life sciences. European partnerships – such as the IHI Joint Undertaking, the Global Health EDCTP3 Joint Undertaking or the Circular Bio-Based Europe Joint Undertaking – bring together private and/or public-sector partners. They have enabled long-term research collaboration and financing to tackle challenges in those for their respective sectors and they have demonstrated their usefulness in strengthening European competitiveness.

Structured interaction is needed between industrial partners and investors to further accelerate the growth and scale-up of breakthrough life science startups. European partnerships under Horizon Europe and the Enterprise Europe Network will be leveraged, together with the EIC portfolio of cutting-edge life science companies, the EIC Trusted Investors Network (TIN) comprising experienced investors managing over EUR 300 billion in assets. These interactions will be demand-driven and flexible, geared around common interests, such as co-investment opportunities, acquisition pathways, and early engagement on unmet technological needs, and will be undertaken in compliance with competition rules.

Proposed action:

- ***(Flagship)*** *To fast-track life science startups in their journey to the market, the Commission will launch a matchmaking strategic interface connecting life science startups, industry and investors, leveraging the EIC's portfolios, the EIC's Trusted Investors Network (TIN) and other key European stakeholders.*

4. BOOSTING THE UPTAKE AND USE OF LIFE SCIENCE INNOVATION

Using public procurement to foster the uptake of innovation

The public sector needs innovative, sustainable solutions and has the power to shape solutions and create markets. As suggested in the Letta's report, EU and national budgets should prioritise investment in and deployment of advanced health technologies through public procurement. Public institutions are also an important policy lever for incentivising green procurement, for example in promoting healthy and sustainable diets. In sectors with high public spending such as the healthcare sector, public procurement of innovative solutions is a strategic tool to foster the uptake of innovations and to create opportunities for European companies to access markets and grow. Anchoring calls for the procurement of innovation in previously supported research or in emerging areas not only reinforces support along the full R&D pipeline but also allows the public sector to respond rapidly to evolving needs.

At present, public procurement rules are complex and the potential of innovation procurement is not fully exploited. There is also underinvestment in the procurement of innovative products and services. This makes it difficult for innovative companies in the life sciences to enter the

EU public procurement market. The revision of **EU public procurement rules** and the upcoming **European Innovation Act** will promote measures to help innovative companies find first customers and apply for public and private-sector procurement. The Commission will launch actions to foster the broader use of innovation procurement across the EU.

Proposed action:

- *The Commission will, through Horizon Europe and EU4Health, stimulate the procurement of life science innovation through dedicated calls in areas such as adaptation to climate change, next-generation vaccines or affordable solutions for cancer, backed by funding of approximately EUR 300 million*[107].

Building public trust and outreach

Life science innovations significantly contribute to peoples' daily life and to individual and social well-being. To foster public trust and the acceptance of technologies, people must understand how life sciences work and how technologies may improve people's well-being[108].

This trust is not guaranteed. It is increasingly threatened by the rapid spread of mis- and disinformation and by insufficient outreach to people to address their concerns and expectations. To maintain and deepen trust, especially among young people, R&I policymakers and industry players must be better equipped to engage with the public and to pursue responsible research.

Public understanding is particularly critical in areas like agriculture and food technology, where innovation intersects with health and sustainability considerations. These issues will be brought to the agenda of the annual Food Dialogue announced in the Vision for Agriculture and Food. A lack of clear information about the risks and benefits of the so-called 'ultra-processed foods' can create uncertainty for consumers. The Commission will seek scientific and ethical advice on so-called 'ultra-processed foods' from the Scientific Advice Mechanism and the European Group on Ethics in Science and New Technologies.

Inclusive dialogue helps improve awareness, build acceptance, support the responsible deployment of innovation and promote accurate information. EU-funded research projects have a key role in enabling dialogue with people, civil society, authorities and industrial players. The Commission calls on Member States to also strengthen science communication and outreach to members of the public.

Proposed actions:

- *The Commission will mobilise EUR 2 million financial support from the Horizon Europe work programme 2026-2027 to support life science stakeholders and policy makers in*

[107] Within the existing envelopes of the programmes.
[108] See WHO 2021, Health Promotion Glossary of Terms 2021 (https://iris.who.int/bitstream/handle/10665/350161/9789240038349-eng.pdf?sequence=1%209789240038349-eng.pdf).

public outreach by setting up a repository of tools and best practices in responsible R&I, risk and science communication, and pilot public outreach measures.

5. GOVERNANCE – A LIFE SCIENCE COORDINATION GROUP

Life science policy in the EU needs to be coordinated to help overcome the barriers and challenges that hinder the process of translating innovative ideas into products and services that respond to the needs of the end-users. It is key to bring together European and global stakeholders including industry, academia and civil society to ensure that EU action is aligned with stakeholder priorities, resources and international developments, and to leverage support for the development and uptake of innovative life sciences. It will ensure that various initiatives relevant to life sciences and their sectors, especially the EU startup and scaleup strategy, complement and synergise each other.

Proposed action:

- ***(Flagship)*** *The Commission will reinforce the coordination of its services and set up a* ***'Life Science Coordination Group'*** *within the Commission to ensure innovation-friendly coherent policies, funding and activities. The Coordination Group will also:*
    - *organise high-level topical discussions between policy makers and stakeholders;*
    - *monitor progress in implementing this strategy;*
    - *manage the European Life Science R&I Data Assembly;*
    - *support the development of an interactive tool to help European researchers and innovators navigate the life science regulatory landscape and provide information on data services and tools;*
    - *organise and manage other activities, such as:*
        - *creating a stakeholder forum for life sciences to encourage broad dialogue and engagement;*
        - *developing and coordinating horizon-scanning capabilities to identify promising emerging technologies with high potential for life sciences.*

6. CONCLUSIONS

The European life science sector is at a critical juncture. With its capacity to drive innovation, boost competitiveness, provide quality jobs and enhance societal well-being, life sciences are a strategic pillar that underpins Europe's future prosperity.

To unlock the sector's full potential, it is vital to strengthen the entire value chain, from R&I to the deployment and uptake of new applications. This requires a regulatory environment that not only keeps pace with innovation but also fosters responsible experimentation, so that emerging solutions can be tested, refined and brought to market both swiftly and responsibly.

The strategy will not be implemented by the EU alone; it takes a multi-stakeholder approach. This includes active involvement from Member States, researchers, innovators, companies, investors, legislators, members of the public and civil society. Success depends on achieving a shared commitment across all levels – European, national and regional. Lastly, it is also

essential to cooperate on a global scale to overcome complex challenges, drive scientific progress and ensure that the benefits of life science innovation are equitably shared.

With coordinated action, strategic investment and inclusive governance, Europe can lead the next wave of life science innovations – improving lives, boosting resilience and shaping a healthier, more sustainable future for generations to come. The Commission will monitor the action taken to this end and will report by 2028 on implementation of the strategy.

In sum, this strategy sets out how to generate the tangible and lasting benefits described above and the funding available. It is now time for action. Choose Europe for life sciences!

THE STRATEGY FOR EUROPEAN LIFE SCIENCES

ACTIONS SUMMARY

Reinforcing European R&I
• **Clinical Research Investment Plan (2026)** • **Establish a European Network of ATMP Centres of Excellence (2026)** • **Monitor the implementation of the Clinical Trials Regulation (from 2025)** • **Pilot on stepwise collaborative research funding for health innovations (2026)** • **Pilot on exploiting collaboration among EU Biotech clusters (from 2026)**
Promoting a holistic approach to the life sciences
• **One Health approach to R&I (from 2026)** • **One Health Microbiome Initiative (2026)** • **Implement the Climate Change and Health R&I Agenda and set up global collaboration (from 2026)** • **Strategic R&I agenda on food systems (2026)**
Unlocking the power of data and AI for breakthrough innovation
• **Establish a European Life Sciences R&I Data Assembly (2026)** • **Support for strategic biodata resources (2025)** • **Invest in multi-modal generative AI technologies in biomedical research (2025)** • **Boost the European genomic data infrastructure (2026)**
Life sciences as a driver for industrial sustainability
• **R&I to drive industrial innovation and sustainability (from 2026)** • **Scale-up and uptake of sustainable advanced fermentation innovations (from 2026)** • **R&I for the sustainable management of biomass (from 2025)** • **Development and uptake of New Approach Methodologies (NAMs) (from 2025)** • **Virtual Human Twins Incubator (2025-2027)**
Strengthening skills and careers for competitive European life sciences
• **Life Sciences career development through Choose Europe (from 2025)** • **Foresight study to identify the competences, skills and training needs for the life sciences (2025)**
Promoting innovation-responsive regulation
• **EU Biotech Act (at the latest 2026)** • **Regulatory simplification for medical devices and in vitro diagnostics (from 2025)** • **AI-powered interactive tool on the EU regulatory landscape (2026)**

Unlocking public and private investment
• **Life Sciences Investors & Corporates Interface (2026)**
Using public procurement to foster the uptake of innovation
• **Support for procurement of life science innovation (2025)**
Building public trust and outreach
• **Repository of tools in responsible R&I, risk and science communication, and pilot community engagement actions (2026)**
Governance – A Life Science Coordination Group
• **Life Science Coordination Group (2025)**