Sustainable competitiveness:

Bayer's vision for the next **European Commission 2024-2029**

Setting the ***scene***

Following successive recent crises, it's time to reset the agenda for the direction of the European Union. Bayer is at its heart a European company, with our destiny shaped right here in the EU. Our more than 160-year history has shown that an enabling regulatory and business ecosystem that supports the life science industry can lead to remarkable innovations that benefit all in society. We are committed to developing and marketing innovation in Europe: in 2022, nearly half of our total research and development (R&D) expenditure took place in the EU (€2.9bn) and we have more than 36,000 employees in EU countries representing over a third of our global workforce.[1]

We want to see a strong European economy, based on sustainable competitiveness and productivity. At its core, this also means a strong social market economy providing the stability and cohesion required for robust democracies. Climate change is already having an impact on our way of life – and it is fundamental that we take action to limit global warming to just +1.5C under the Paris agreement. This also presents an opportunity to rethink and innovate to develop new solutions that will lead Europe and the world into a more sustainable future. Harnessing this economic potential for Europe will ensure the social balance that delivers citizens' support for democracy. To reach these goals, research and development into the life sciences must be allowed to succeed so that Europe can be competitive on the world stage with thriving industries at home.

As European Commission President Ursula von der Leyen outlined at the beginning of her mandate in 2019, **fighting climate change and strengthening Europe's competitiveness must go hand in hand.** Europe has advanced its Green Deal agenda significantly over the past years and is delivering on climate protection. However, it has not done the same for industrial competitiveness and the EU is at risk of losing the global economic race. The Commission now needs to put the same emphasis on fostering conditions which can help European companies gain competitive advantage on the world market, through driving sustainable business models and products.

The following pages outline Bayer's top priorities that the next European Commission should focus on: embracing technological innovation, simplifying the regulatory environment, supporting sustainable growth in agriculture, increasing the uptake of digital solutions across the economy, and championing a strong trade agenda.

The programme for 2024-2029 should focus on a growth-enhancing regulatory environment to incentivise innovation, reduce administrative burden, and ensure long-term competitiveness for European industry.

[1] 2022 is most recent data year available. In 2022, Bayer's global R&D expenditure was €6.2bn, of which €2.9bn was in EU27, representing around 47%. As of 31st December 2022, there were 36,266 employees in the EU27 and 101,359 globally (FTE).

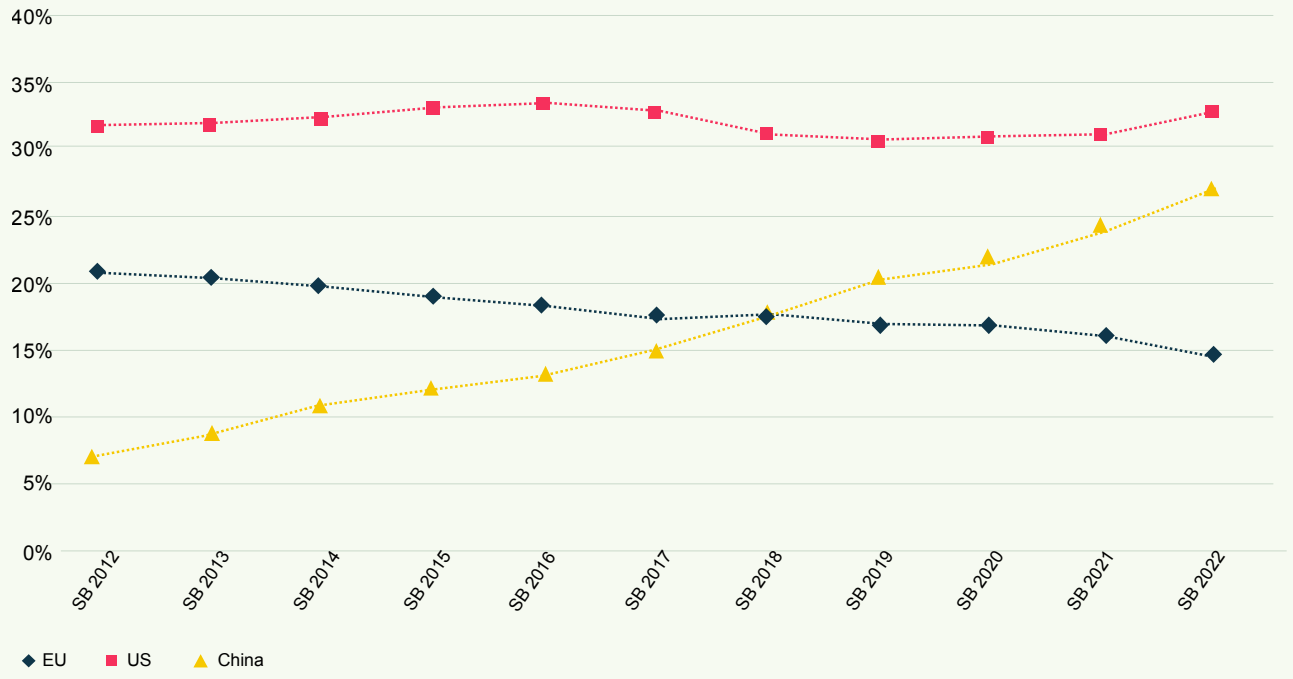
Science **first and foremost**

For the EU to be globally attractive for investment and research, there needs to be a holistic approach that incentivises innovation, particularly on areas with a high growth potential. The paradox is that while the EU continues to be at the forefront of knowledge and science globally with world-class universities, ahead of both the United States and China,[2] when it comes to translating science into a pipeline of products, growth has been far too slow. The gap between the EU, the US, and China is now widening to a highly concerning extent. According to recent projections, by 2030, Europe's share of global pharmaceutical expenditure will fall to just 25% down from 37% in 2010.[3]

This worrying development is also illustrated by the findings of the 2022 EU Industrial R&D Investment Scoreboard showing that the US has the greatest number of top R&D investors globally, and while China is second only to the US, it is continuing to consolidate its advantage over the EU.[4] In particular, China has now overtaken the EU in terms of R&D investment ahead of predictions and this trend is unlikely to be reversed without concerted action. The total volume of R&D invested by these two regions (EUR439.7bn and EUR195.9bn respectively) is now far outpacing EU investment (EUR192.8bn).[5]

There is no doubt that the EU is a strong scientific and academic powerhouse, but the development of the application of science is equally important. Where the critical technologies of tomorrow are produced will inevitably influence how successful a given region is. It is not enough to legislate to keep industry in the EU, but rather companies should choose to invest in R&D and production in Europe because it is the best place to do business. For this, the EU needs to develop collaborative ecosystems to increase access to capital for scaling up, encourage the entrepreneurial spirit and risk-taking (including for both scientists and funding sources), and ensure regulatory certainty to support new technologies and inventions.

Share of global R&D investment by region, 2012 to 2022



Note: Data from Scoreboard (SB) editions 2012 to 2022. | Source: The 2022 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG R&I.

The EU must **maintain trust in science-based policymaking** to ensure decisions continue to be predictable for market participants, are driven by progress, and supported by robust data.

// Vast amounts of scientific and real-world data are provided to regulators during the existing processes for the authorisation and placing on the market for chemicals, including for plant protection products, and medicines, including both prescription and non-prescription drugs. Marketing authorisations need to continue to be based on risk assessment. Chemistry is key in many ways to reaching the Green Deal targets and should not be restricted where risk assessments prove their safe use or where alternatives do not exist.

Europe should embrace the **opportunities that biotechnology provides**, particularly the combination of biology, chemistry, and AI as drivers of paradigm shifting innovation. Increasingly this innovation space has been left to other regions in the world. For example, with green biotechnology, North America has become the hub for the agricultural gene-editing industry with 78% of global market share, while Europe accounts for just 4%.[6]

// Biotechnology is one of the key trends for the future: cell and gene therapies in pharmaceutical research as well as new genomic techniques in plants. A clear EU **Biotechnology Strategy**, setting out how biotechnology can contribute to several EU objectives would reinforce Europe's commitment to treat this area as a priority. The Strategy should tackle areas including capital and financing, skills and labour, R&D and innovation, and strengthening manufacturing and supply chains. The European Commission should avoid a siloed approach to regulation of key sectors and technologies.

[2] Brinckmann, S., et al "Can European biotechs achieve greater scale in a fragmented landscape?" McKinsey & Company, 29 June 2021, https://www.mckinsey.com/industries/life-sciences/our-insights/can-european-biotechs-achieve-greater-scale-in-a-fragmented-landscape#

[3] Dolon, "Revision of the General Pharmaceutical Legislatoin: Impact Assessment of European Commission and EFPIA proposals," EFPIA, November 2023, https://www.efpia.eu/media/msadqxbf/revision-of-the-general-pharmaceutical-legislation-gpl-impact-assessment.pdf

[4] Grassano, N., et al, "The 2022 EU Industrial R&D Investment Scoreboard", Publications Office of the European Union, 2022 doi:10.2760/485748, JRC132035

[5] Grassano, N., et al, "The 2022 EU Industrial R&D Investment Scoreboard", Publications Office of the European Union, 2022 doi:10.2760/485748, JRC132035

[6] Malhotra, B., "Special reports: Agrow Game Changers Gene-Editing Technologies and Their Applications 2020", IHS Markit, 2019

Keeping pharmaceutical research in Europe gives European patients fast access to cutting edge technology that has the potential to combat disease.

// Advanced Therapy Medicinal Products, including cell and gene therapy, are at the forefront of global innovation in healthcare, and it is vital that Europe is competitive in this technology. However, clinical trial activity on Advanced Therapy Medicinal Products (ATMPs) is almost twice as high in the US and nearly three times as high in the Asia-Pacific region, demonstrating a widening gap with Europe.[7] **Incentivising pharmaceutical research** requires regulatory frameworks that are innovation-focused and flexible to suit the demands of new diagnostics, treatments, and biotechnology.

Cell and gene therapy

Cell therapy

We are testing new cell therapies aiming to compensate for the progressive loss of nerve cells in Parkinson's disease.

Gene therapy

We are testing a new gene therapy which boosts survival and functionality of the patient's own cells which are usually lost in Parkinson's disease.

// More than 10 million people worldwide are suffering from Parkinson's disease. Cell and gene therapies offer the opportunity to revolutionise the way Parkinson's is treated by focusing on the source of the disease instead of the symptoms. **BlueRock Therapeutics** and **AskBio** are currently working on cell and gene therapies which could potentially stop or even reverse the disease.

// A predictable intellectual property and research incentives system, combined with a broad understanding on Unmet Medical Needs to encourage R&D efforts, as well as digital and health data sharing frameworks that support robust e-health and research systems, will give the means to facilitate public health innovation and economic growth in the EU.

[7] Wilsdon, T., et al, Charles Rivers Associates, "Factors affecting the location of biopharmaceutical investments and implications for European policy priorities: Final Report," EFPIA, 3 October 2022 https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf

A new deal ***for industry***

The EU's future competitiveness will depend on how keenly it pursues the Better Regulation agenda. Regulatory compliance costs for businesses continue to increase, creating a less favourable ecosystem compared with other global actors. Advancing work towards a growth-enhancing regulatory environment must be a priority for the next term.

Renewed attention on industrial competitiveness should **focus on the simplification of the regulatory environment and reducing administrative burden** for businesses.

// The cumulative impact of policies that have been proposed during the past few years must be reviewed. As an example, the combined impact that the Farm to Fork strategy and the Chemical Strategy for Sustainability could have on food affordability must be considered when new policies are proposed.

Key figures of the European Commission Work Programme 2023

43 ***New policy initiatives***

116 ***Pending priority proposals***

// **Competitiveness checks for new legislative proposals** should be implemented. This should consider the current regulatory landscape and cumulative impact, whether there are conflicting goals in other proposals, how proposals will be implemented in the real-world, and the international context to not negatively impact businesses in the EU.

// While environmental safety is now an essential element in sustainable industry policy, decisions on the **environmental impacts of pharmaceutical products** should, in principle, lead to **risk mitigation** to not further reduce availability of important medications and ensure access for patients across the EU.

Global alignment of sustainability reporting standards will be necessary to ensure clarity for investors as the EU moves towards a zero emissions economy by 2050.

// Reporting requirements should be rationalised across green, digital, and economic legislation. Harmonised standards on an international level will support this ambition and will avoid uncertainty for businesses that operate across different reporting regimes. The target of a 25% reduction of reporting requirements as outlined by the Commission should be further elaborated upon in the next term.

Industry needs **predictability about the protection of intellectual property and its enforcement** due to the duration and complexity of innovation processes as well as rising research and development costs.

// Intellectual property rights, including patents, trade secrets, trademarks, designs, plant variety rights as well as patent term restoration measures like supplementary protection certificates, are a crucial part of the innovation process, especially when it is driven by significant investments, specialised research, and a significant risk of failure. This is the case in plant breeding, pharmaceutical research, or crop protection development. Without effective patent protection, product development and investment in R&D are not viable in the life sciences sector.research, and a significant risk of failure. This is the case in plant breeding, pharmaceutical research, or crop protection development. Without effective patent protection, product development and investment in R&D are not viable in the life sciences sector.

[8] European Commission, "Commission Work Programme 2023," 18 October 2022, https://commission.europa.eu/strategy-documents/commission-work-programme/commission-work-programme-2023_en

*Sustainable **growth***

Climate change is one of the world's most pressing challenges and, as a life science company, Bayer recognises the risks posed to our planet's ecosystems and the health of our populations. Global food systems are under immense pressure around the world from challenges including climate change, leading to an increase in global hunger. More food will be needed to feed a growing population, as already today access to food and nutrition remains uneven around the world. Collectively, the world faces the urgent challenge of creating agricultural systems that help farmers adapt to climate change impacts and run a commercially viable business, while also protecting our planet, limiting the further expansion of farmland, and renewing Earth's natural ecosystems. **Regenerative agricultural practices that "produce more with less, while restoring more" are fundamental** to addressing this challenge and Europe must embrace this opportunity.

Regenerative agriculture is about adopting a **system-wide approach** to farming that aims to **deliver measurable outcomes** in terms of both productive capacity and sustainability. This approach must be given priority in policymaking.[9]

// Outcome-based approaches to farming have the potential to unlock benefits for farmers, environment, and society.

// By focusing on what objectives should be achieved, be that water conservation, carbon emissions reductions or sequestration, yield and output increases, or limiting land-use change, there will be more efficient use of existing and new technologies that can create the most impact, ensuring emphasis on the solutions that work best. It is critical to define the major areas of contribution for agriculture and which indicators could be used to determine progress, while being inclusive towards different agricultural systems. For future legislation, including the next Common Agriculture Policy, this outcome-based approach should be implemented.

Rapid access to farming innovation, including chemistry, biology, and data science, will not only help drive the transition in agriculture but it can support the goal of more resilient food systems in light of climate change.

// High quality seeds with adapted characteristics, digital and precision agriculture technologies, and crop protection products are vital solutions for farmers.

// Innovations like CoverCress™, a harvestable low-input winter oilseed crop that has been developed through breeding and gene editing tools, have the potential to help farmers store carbon in the soil, while improving soil health by increasing organic matter content and contributing to healthy field microbiomes. When used as a cover crop between rotations, it can also generate an additional revenue stream for farmers through the oil produced from the crop.

The CoverCress™ seed technology delivers value across the entire supply chain. The cover crop itself sequesters carbon, improves soil health, and reduces water and nutrient movement. The oil produced from the crop can be transformed into renewable bio-diesel, sustainable aviation fuel, or into high protein meal for animal feed.

Farmers are central to this transition and ensuring that farming in Europe is a viable economic activity for current and future generations is necessary to guarantee the long-term success of EU agriculture.

// Regenerative agricultural systems also have the potential to drive production gains and income growth for farmers while also providing net benefits to nature. For example, it enables farmers tap into new sources of revenue, such as receiving payments for carbon sequestered, and grow their business in line with policies under the EU Green Deal. This would make the future of farming more sustainable and create a win-win-win for farmers, society, and our planet.

[9] Bayer, "Farmer Voice Survey: Farmers Share Their View of a Sustainable Future," 12 October 2023, https://www.bayer.com/en/agriculture/farmer-voice

*AI for **the future***

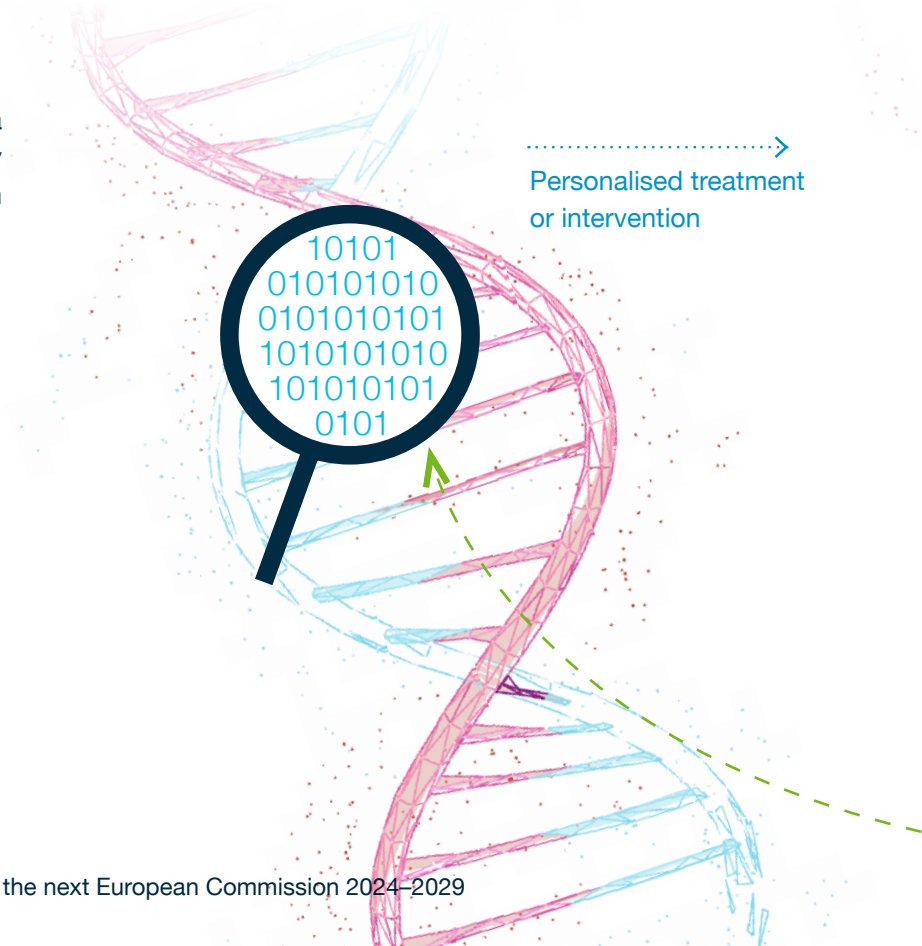
Artificial intelligence has already revolutionised the life science sector at all stages, enabling scientists to leverage vast amounts of data to solve complex medical and agricultural challenges, and yet its full potential is far from realised. The **regulatory environment often does not keep pace** with the changes that have the potential to transform our economy. The European Commission must ensure the uptake of digital solutions through tools that support innovation and research using data and AI, such as fit-for-purpose legislative frameworks, in tandem with sufficient resources for robust digital infrastructure and adequate digital literacy.

AI is now fundamental to the future of life science sector and the EU should be ahead of technological developments offered by AI to stay competitive in life sciences. This requires increased investment to strengthen fundamental research and scientific breakthroughs, upgrade infrastructure, facilitate the uptake of AI, and improve access to data.

// Digital twin technology in clinical trials can help accelerate the process of finding treatment options across multiple disease areas. The in-silico trial or digital twin can be used to model the safety or efficacy of a particular treatment or refine dosage. In crop protection development, machine learning, virtual protein screening, and computational predictive modelling can help design new modes of action to precisely target the pest and minimise impact to other organisms in the environment. These are just two examples of where AI can enable faster and more accurate discoveries, with potential benefits for patients, farmers, researchers, and society as a whole.

What is a digital twin?

Digital twins are virtual recreations of a person, organ or tissue. Boosted by AI, they can simulate biological processes to obtain information or efficacy of a treatment, investigate potential drug-drug interaction, or refine dosing.



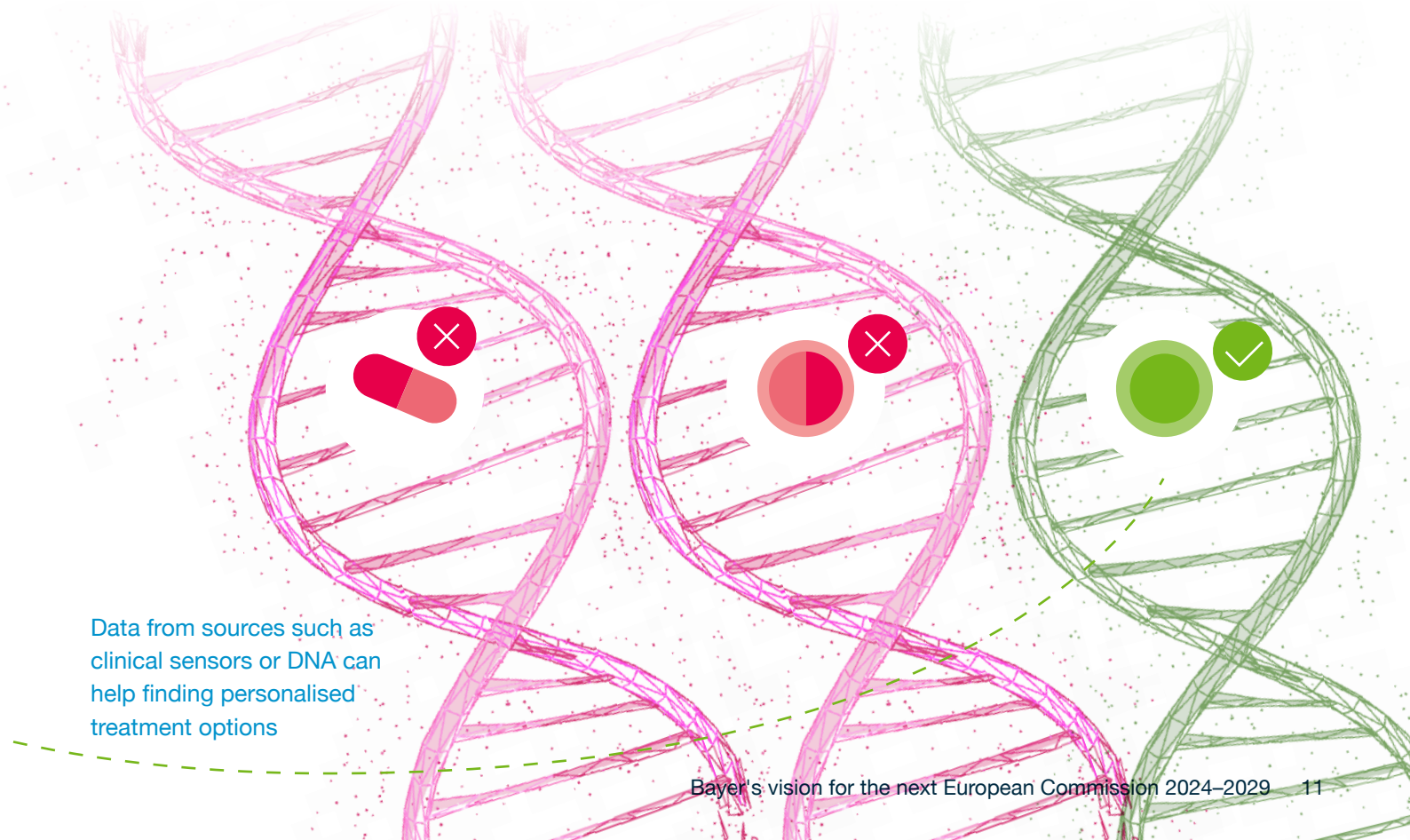
The Commission should **build trust and facilitate access to health data for scientific research**. This requires constant improvement to digital frameworks that enable innovation in healthcare, whether by ensuring access to quality data while respecting (patient) privacy or creating fit-for-purpose frameworks for ethical and safe AI models. Technologies like artificial intelligence, machine learning, and digital twins are already bringing new research and development capabilities, thereby helping to get medicines to patients faster.

// The **appropriate ecosystem for digital technologies to thrive** should be created and maintained. The lack of digital infrastructure and poor digital literacy prevents innovators, manufacturers, and patients from capitalising on digital technologies. It is essential that sufficient resources are earmarked to maintain this infrastructure and ensure that European citizens and healthcare professionals know how to leverage it.

It is necessary to develop a comprehensive **EU strategy on the digitalisation of agriculture**. Precision agriculture is expected to become the most influential trend in farming globally, with North America now leading in adoption of these technologies, while Europe is far behind.[10] Addressing this imbalance in the digital transformation is crucial for EU agriculture to remain competitive globally.

// The potential of digital and precision agriculture to help farmers optimise the use of agricultural inputs, meet climate goals, and maximise their yields is recognised. However, concrete initiatives to untap this potential and mainstream digital agriculture across the EU have been lacking, and policy coordination remains a challenge. The EU should adopt an overarching digital farming strategy, looking at barriers and opportunities to strengthen digital in agriculture from skills, rural broadband, data frameworks, and financing.

[10] Shahbandeh, M., "Global Digital Agriculture Market 2020, by region," Statista, 13 April 2022, https://www.statista.com/statistics/1302323/global-digital-agriculture-market/



Data from sources such as clinical sensors or DNA can help finding personalised treatment options

Europe ***as a global partner***

A strong and open trade agenda must be championed by the EU Institutions. Continuing to open markets for EU companies through deepening ties with allies and trading partners, preserving fair trade principles, and addressing risks in a targeted way are essential for long-term growth. As a global life science company operating in more than 80 countries worldwide, Bayer supports free trade, a rules-based international order, and multilateral approaches in legislative measures.

In times of geopolitical upheaval, the EU must recalibrate its strategic compass, using political and economic instruments more coherently and identifying not only risks but also opportunities more effectively. The **EU needs to continue prioritising market access, including the ratification of pending bilateral trade agreements.** If EU is not seen as a reliable ally for key regions in the world, other global actors will take advantage and replace the EU as partner of choice.

// A landmark trade agreement such as the ones with Mercosur, India, and Indonesia would demonstrate the EU's commitment to global cooperation and to a multilateral rules-based trading system. These agreements could permanently shape the rules for close trade relations, promote the multilateral principles of transparency, equal treatment and non-discrimination, and strengthen international agreements to promote social and environmental standards.

// Economic growth and sustainable development go hand in hand so the EU must continue work on the **Global Gateway Initiative.** People in all regions of the world should be able to live a better life in harmony with the ecosystem. The initiative should focus on how the EU can unlock private sector investments in Africa, Latin America, and Asia. Amongst others this should include trade agreements, investment and financing plans and capacity building. This should be inclusive to all healthcare sectors, including biopharmaceuticals and women's health, as well as other sectors such as agriculture and nutrition.

The EU should reflect upon the global impact of the Green Deal and how agricultural conditions and challenges faced by farmers vary across the globe, necessitating different solutions.

// The EU has a reference role for agriculture and agricultural trade, and any policy changes do have an impact on the sustainability of global food systems. **Policies need to be data-driven, predictable, transparent, based on sound science and risk assessment, consistent with international obligations and aligned with international standards.** The EU should consider dialogue with third countries impacted by new proposals that have global implications.

Conclusion

It is true that the EU is not the only global region developing sustainable businesses and technologies, but if Europe's goal is long-term prosperity for its citizens, stability for its democracies, then industry must be welcome in Europe. Bayer believes that the future of a strong European economy is rooted in **incentivising innovation, reducing administrative burden, and ensuring long-term competitiveness for European industry.**

The next term for the European Commission should focus on the following areas: embracing science and research to become a world leader in technological innovation, simplifying the regulatory environment and incorporating outcome-based regulation in areas such as regenerative agriculture, leveraging AI solutions across the economy, and championing a strong open trade agenda as a reliable global ally.

With these priorities, Bayer looks forward to contributing to future policy-making discussions as a constructive partner invested in Europe's long-term success.

About *Bayer*

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com

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