



Unravelling Sustainable Business Transformation in Life Sciences

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Introduction

Covid-19 was a litmus test that gave Life Sciences companies an opportunity to shine at their best – helping to tackle the big challenges of humanity through innovation and expediency. In response, the Life Sciences sector rose to the occasion: rolling years of research, investment, and experience out of the lab and onto production lines at unprecedented speed to mitigate the effects of the crisis.¹

As a society, we've been reminded that Life Sciences companies are uniquely placed to impact society and the environment through their resources and expertise. The sector can now seize the opportunity to carry that momentum forward by demonstrating commitment to evidence-backed action that generates positive impact and sustains business growth and stakeholder trust in the long term.

Indeed, one of the most notable developments is the integration of sustainability² into the business, leveraging it as a springboard to achieve improved reputation, more impact, and future growth. In the Life Sciences sector, there is significant room to make bigger strides with these advantages and act on clear opportunities for investment and transformation. Many Life Sciences companies in Europe, the Middle East, India, and Africa (EMEIA) are already applying ESG considerations for better decision-making, according to 2023 research by Source.³

Strategically, this includes exploring exciting possibilities for growth and renewal across the sustainability opportunity space and the value chain, as well as leaning into new partnerships and alliances.

In the coming pages, we'll share sector-specific views on how sustainability and ESG-related trends and evolutions across the Life Sciences ecosystem affect individual organizations and the sector.

We see a notable trend of Life Sciences companies moving ESG & sustainability to the center of their decision-making agendas.

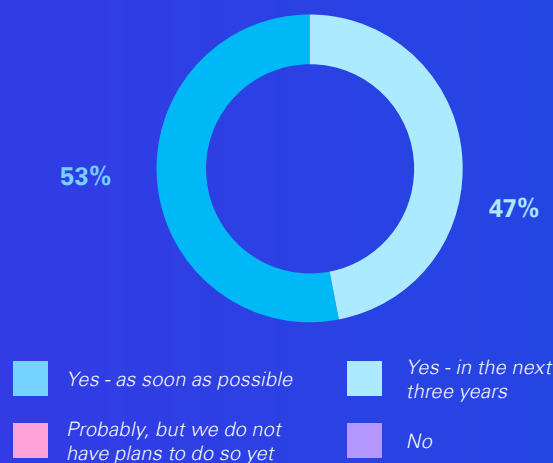
It is our conviction that this is not only because authorities are pushing them to engage with CSRD or ESG reporting requirements. Rather, it is because executives see a strategic advantage and under-explored economic and impact potential for their business.

This stronger connection between ESG & sustainability, on the one hand, and the top- and bottom-line of Life Sciences companies on the other, is (in our view) also the way forward.



Michael Wagemans
Partner, ESG & Sustainability,
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In your opinion, does your organization need to change its approach to ESG within the next three years to survive ?



Based on 100 respondents from companies in the EMEIA Life Sciences sector. Research by Source (2023). Figure reproduced with permission.

1 KPMG. (2022). *Life Sciences for a better world*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2022/SPT-brochure-LifeSciencesForBetterWorld-eng-LR.pdf>
 2 For the purposes of this publication, we use 'sustainability' as a general term, and refer to Environmental, Social, and Governance ('ESG') more specifically in the context of sustainability reporting.
 3 Price, B. (2023). *Life Sciences: KPMG EMEIA Sector Growth Opportunities*. Source. [Presentation].

01

Be bold about sustainable business transformation



What's at stake?

There is a radical shift underway in how businesses operate and their relationship with society. Across economies, sustainability has grown in importance, climbing from the periphery to the core of business strategy. As a critical sector for society, the Life Sciences sector faces the simultaneous challenges of being significantly affected by changes in our natural environment, social demographics, and geopolitics; facing intensifying scrutiny from the public and regulators; and competing with upstart companies that are disrupting healthcare with increasingly personalized solutions.

When it comes to sustainability, executives are being asked to step up, lead on key issues, and come up with solutions to help society address present and future challenges by contributing expertise and resources from their respective sectors. Companies are expected to demonstrate purpose and measurable value to both the economy and society. There is increased emphasis on the non-financial elements of annual reporting processes, and 'time and resources must be invested into ensuring that non-financial data is as robust as financial data.'⁴

These shifts are catalyzing business transformation in the Life Sciences industry. Pharmaceutical, medical devices and technology, and biotechnology companies are at varying stages of pursuing more purpose-driven models, providing affordable therapies and products, improving ecological and environmental performance, and operating in a transparent and responsible manner.

The stakes are high, but now is not the time to hold back. Hesitancy risks a discordant response to sustainability challenges, exposure to more motivated competitors, reputational damage, and increased regulatory oversight. We are in a decade of not only hyper-connectivity, but hyper-interdependency, and the strategies and approaches that got us to this point need to be updated simultaneously to account for the greater sophistication of these systems. A confident, coordinated approach that involves all aspects of the business is the clear way forward for companies that are serious about the future.

Combining sustainable and digital transformations

Sustainable and digital transformations naturally complement one another and should be engaged together to maximize their value and impact. This dual transformation is especially important as incoming environmental, social, and governance (ESG) reporting

requirements necessitate new and improved data solutions and architecture for collecting and analyzing information about Life Sciences companies' activities.

While the Life Sciences industry is in transition, there is significant variance in the maturity level of different areas of data collection and measurement. Non-financial data architecture is nowhere near as sophisticated and robust as its equivalent in financial and accounting frameworks.⁵ For example, while there are clear metrics to assess carbon emissions, other social and environmental data can be more challenging to collect and assess, such as the company's direct and indirect impact on biodiversity or contributions to improving the health outcomes of an un(der)served community.

That's why it's imperative for strategic investment in digital systems and technologies to include built-in processes to support non-financial reporting from the outset. Not only is this important from a compliance perspective, but insights gained from these processes also serve a critical strategic business function: helping companies to invest in ways that improve resource-use efficiency, increase profitability, and identify risks and opportunities. This can further bolster credibility when it comes to contributing solutions to global challenges faced by society and the environment.

With improved non-financial data architecture, companies can gain valuable insights into how their business is performing so that they can more precisely target areas of improvement and invest more effectively. This will also satisfy the expectations and needs of various stakeholder groups, such as regulators, investors, creditors, and top-level talent.

When it comes to sustainability, digital transformation also offers distinct benefits that go beyond meeting regulatory criteria. Having access to real-time data insights and leveraging new technologies can enhance Life Sciences companies' capabilities to act as a force for good. Among others, the applications for such information include finding new ways to improve medication adherence or efficacy, as well as being able to deliver more precise information to demonstrate transparency and build trust when engaging with patients and other stakeholders.

What's more, the competitive landscape for digital transformation in Life Sciences is being enlivened by the increasing use of artificial intelligence (AI), with multiple potential benefits for society and the environment.

⁴ KPMG. (2023). *Navigating CSRD Reporting in Life Sciences*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2023/Navigating-CSRD-Reporting-in-Life-Sciences-July-2023.pdf>

⁵ KPMG. (2023). *Navigating CSRD Reporting in Life Sciences*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2023/Navigating-CSRD-Reporting-in-Life-Sciences-July-2023.pdf>



AI as an accelerator

AI applications for Life Sciences are a direct response to market pressures and demand for faster innovation. AI and modelling-based clinical trials, for example, can lead to lower impact on the health of patients – such as by reducing adverse negative effects of a trial going wrong - and can reduce the environmental footprint of the entire trial taking place, while accelerating the development-to-launch solution life cycle.

The list of use cases for AI in the Life Sciences sector is already long, ranging from drug discovery and design, to clinical trials, medical device development, personalized medicine, biomarker identification, medical imaging and electronic healthcare record (EHR) analysis, among others.⁶

This list will only grow as AI technology becomes more sophisticated and scientific innovation develops alongside it. For example, using AI to trace and combat counterfeit drugs, or AI-enhanced data analysis to identify the right patient populations – or different patient populations with unmet needs – so that drugs and other medical interventions can be more efficiently developed than using the traditional ‘trial-and-error’ method, so they can be made available to patients faster.⁷

AI can also improve efficiency in discovering therapeutic targets for small molecules, biologics (primarily antibodies), and gene therapy. It accelerates small molecule discovery by aiding in faster compound

development, efficient compound selection, and reducing the overall number of compounds synthesized, potentially uncovering molecules overlooked by traditional high-throughput screening methods.⁸

Just as AI-enhanced data processes can lead to better product and service outcomes, it can help companies to design, measure, manage, and report on their sustainability activities, while helping to spot unexplored data patterns that can reveal opportunities for future investment in high-impact actions that contribute to the environment and society.

All of this also has implications for recruitment and retention, amid fierce competition for highly skilled talent. There is already a shortage of technical expertise, not just in the Life Sciences sector, but across the global labor market. To get the most value, it’s important for companies to be laser-focused on developing a workforce strategy that envisages the twin development of AI-driven innovation and sustainability capabilities from the outset, to avoid costly and time-consuming restructuring later.

When it comes to workforce planning, this means not just looking at recruitment and retention, but also how to responsibly leverage AI in a way that can support existing workforce output optimization amid this talent shortage, with due attention paid to regulatory, ethical, and HR-related concerns.⁹ Given this complexity, it makes sense for the incorporation of AI and the wider digital transformation to be considered in the context of a larger, systemic approach.

6 Burke, H. (2023). Top 20 ways Artificial Intelligence is advancing life sciences | Proclinical Recruitment Blogs. Proclinical. Retrieved from: <https://www.proclinical.com/blogs/2023-4/top-20-artificial-intelligence-life-sciences>

7 Whelan, S. (2024). Using AI to get medicines to patients faster. Drug Discovery from Technology Networks. Retrieved from: <https://www.technologynetworks.com/drug-discovery/blog/using-ai-to-get-medicines-to-patients-faster-383814>

8 Whelan, S. (2024). Using AI to get medicines to patients faster. Drug Discovery from Technology Networks. Retrieved from: <https://www.technologynetworks.com/drug-discovery/blog/using-ai-to-get-medicines-to-patients-faster-383814>

9 Price, B. (2023). Life Sciences: KPMG EMEA Sector Growth Opportunities. Source. [Presentation].

Leveraging a systems-change approach

Successful transformation requires an understanding of the complexity and interconnectedness of the regulatory, economic, social, and natural systems in which we work and live. This holistic ‘systems thinking’ is rooted in ‘thinking in terms of connectedness, relationships, patterns, and context.’¹⁰

Applying systems thinking to the challenge of sustainable business transformation, successful change management relies on coordinated communication and transparency between stakeholders in the organization (connectedness and relationships), while implementing a strategic combination of key initiatives throughout the portfolio of business units, product portfolio, operations, and people management (patterns and context). It’s a highly dynamic process that requires focused and consistent leadership to choreograph and deliver, but – when coordinated as a whole system change – is key to shaping a leading position with stronger financial and impact returns.

For the Life Sciences industry, this includes implementing initiatives to:

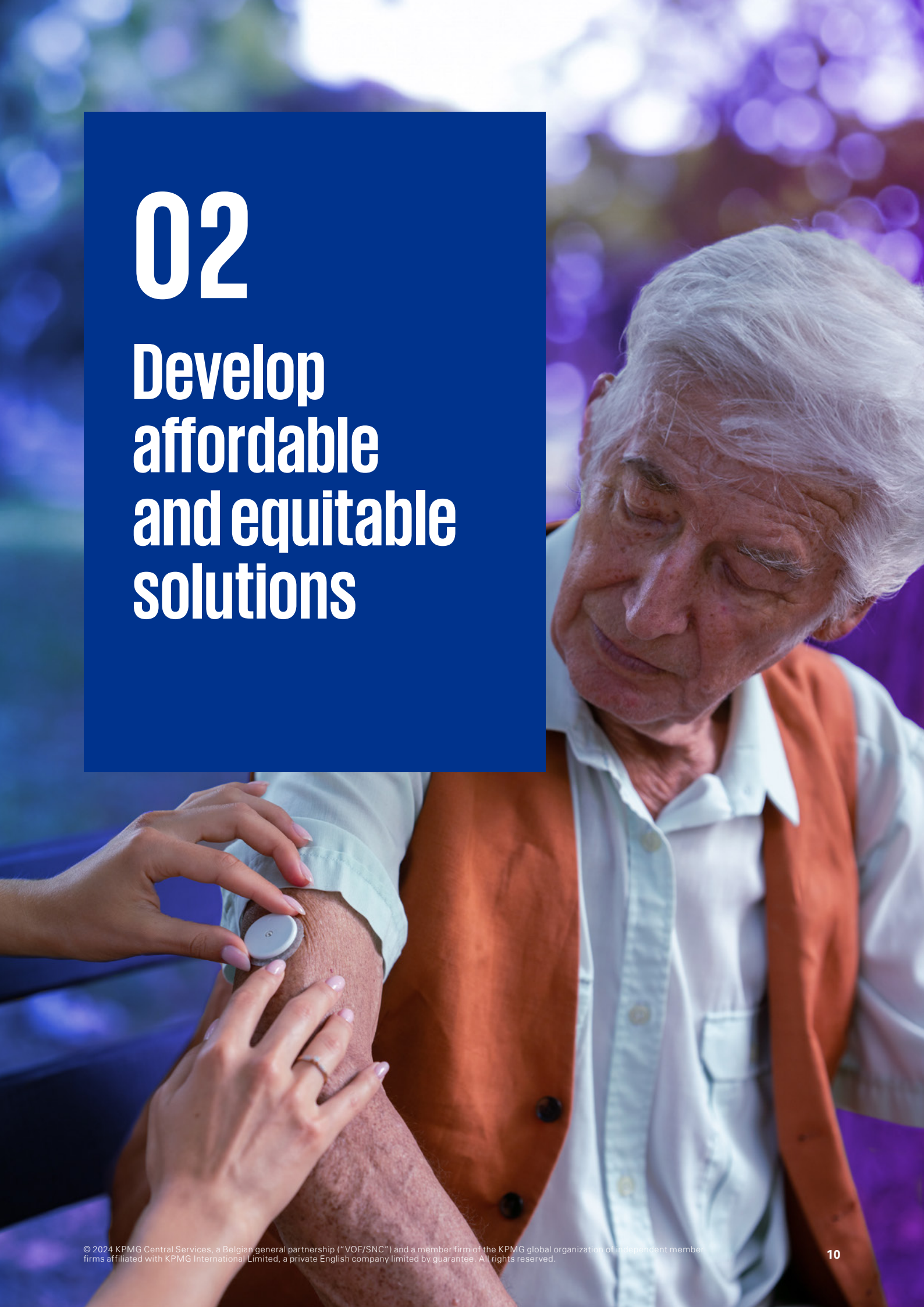
- ▶ Develop and distribute **affordable therapies and products** to both support business objectives and have a more positive impact on society;
- ▶ Improve **ecology and environmental performance** through better waste management and increased circular practices, shorter supply chains (e.g., positioning manufacturing and distribution centers closer to key customers and communities);
- ▶ Implement **robust and transparent sustainability governance** to ensure that the organization’s activities are aligned with its sustainability objectives, including due diligence and monitoring of value chains to reduce risks related to Human Rights, animal welfare, and product stewardship; and
- ▶ Ensure that **relevant, coherent data** can be collected and processed on these activities to comply with **non-financial reporting and assurance requirements** and help stakeholders understand how the company is performing.



¹⁰ Definition of systems thinking by Fritjof Capra, as quoted by Wayne Visser in *Thriving*. Source: Visser, W. (2022). *Thriving: The Breakthrough Movement to Regenerate Nature, Society, and the Economy*. Fast Company Press. ISBN-13: 978-1-63908-007-6

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Develop affordable and equitable solutions



Access to Medicines and Treatments

Affordable, fair, and timely access to effective medical and healthcare solutions is a critical pillar for the Life Sciences sector, with significant societal impact potential. The question of how to strategically improve access to these solutions includes considering the full range of end-users in the design of products, ensuring diverse and inclusive clinical trial data sets¹¹ during the development phase, and facilitating fair and equal distribution in traditionally un(der)served communities, as well as higher socio-economic segments of society. While the scope of access was once narrowed to availability and price, the scope of what it means in current society is widening. Access includes literacy (access to information, including scientific articles), access to the diagnosis (not only the solution), and access to solutions that are made for specific demographics, to name a few considerations. The broadening scope of access represents a key business opportunity for Life Sciences and the expectations of stakeholders are rapidly changing.

Access to quality healthcare and life-saving treatments is a fundamental Human Right. Yet, according to the latest monitoring report by the World Health Organization and World Bank Group,¹² approximately 4.5bn people (>55% of the global population in 2021) have limited or no access to healthcare or medication, and one in 10 drugs sold in developing countries is fake or substandard,¹³ leading to hundreds of thousands of deaths every year.

With the global population projected to increase to around 8.5bn people by 2030,¹⁴ and the greatest increases in low- and middle-income countries (LMICs), there is huge opportunity for Life Sciences companies to ensure access to health services and medical treatments through the development of partnerships that contribute to more integrated business and service ecosystems. This would also provide clear social benefits by improving healthcare outcomes for LMIC communities.

Within these ecosystems, companies can reap significant gains from developing strategic partnerships and collaborating more closely on projects of mutual interest. Doing so enables

companies from these segments to be better aligned with healthcare providers and end-users, supplying them with the complementary products and services they need. At the same time, this also helps companies to spread their risk and improve their efficiency by avoiding duplication of work and resources, which can improve profit margins.

Areas that offer potential for new partnership development include patent licensing; equity acquisition; non-equity alliances; joint ventures; R&D collaboration; and commercialization. For example, developing partnerships around non-exclusive voluntary licensing (NEVL) to allow generic manufacturers to supply patented products to communities that struggle to access the medicines and medical devices they need is a highly effective way for pharmaceutical and medical device companies to better serve LMIC communities.¹⁵

Successful partnerships have several features in common:

- Risk consideration;
- Clearly defined partnership scope;
- Detailed partnership agreements;
- Auditing technologies and competencies;
- Exit strategy;
- Conducting regular and purposeful business assessments by defining milestones that can be measured reliably as stop-and-go decision points; and
- Demonstrable evidence of impact.



11 KPMG. (2022). *Diversity, Equity, and Inclusion in Clinical Research*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2022/LifeSciences-DiversityEquityInclusion-ClinicalResearch.pdf>

12 World Health Organization & International Bank for Reconstruction and Development / The World Bank. (2023). *Tracking universal health coverage: 2023 global monitoring report [Report]*. Retrieved from: <https://iris.who.int/bitstream/handle/10665/374059/9789240080379-eng.pdf>

13 World Health Organization: WHO. (2017, November 28). *1 in 10 medical products in developing countries is substandard or falsified*. World Health Organization. Retrieved from: <https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>

14 United Nations. (n.d.). *Population | United Nations*. Retrieved from: <https://www.un.org/en/global-issues/population#:~:text=The%20world%20population%20is%20projected,and%2010.4%20billion%20by%202100.>

15 Access to Medicine Foundation. (2022). *Access to Medicine Index 2022*. Retrieved from: https://accesstomedicinefoundation.org/medialibrary/2022_access-to-medicine-index-1669982501.pdf

Developing partnerships to build a business with social impact

“At Bayer, we have a clear expectation that our social impact approach to access to medicine will generate sales and turnover, while also serving society. Maybe at a different speed with a slightly diluted margin, but we expect to generate business, so we are investing both financially and in developing effective relationships with our partners across the globe accordingly.

Wherever you try to develop new business approaches to provide better access to medicine, I haven't seen one where it works without partnerships. Shifting from traditional core businesses to enter new spaces is a complex process, so finding the right partners with local understanding is vital to ensuring a successful outcome. This is especially the case in low- and middle-income countries, where you may need to re-design your business to adapt it to the local operating environment.

For example, one of Bayer's key social impact targets is to help 100 million women around the world access contraception by 2030. Women in different countries face different challenges in this regard, so the way we organize our access to contraception program is always in local partnerships. We run our access to contraception program as a social business model, and while we do not yet always achieve the same margins that we used to with a traditional approach, we re-invest the money that we do make into that same business to help it thrive so that we can achieve our 2030 goal.

We have also recently opened a Global Health Unit, where we try to access countries where we don't currently have representation - typically developing countries, including many in Africa. Again, if we don't have direct business representation, we can only work through partnerships, which further underlines just how important good partners are to delivering results for both our businesses and society.”



Klaus Kunz
Vice-President, Head
of ESG/External Engagement
and Performance Reporting¹⁶
Bayer

Sharing scientific innovation to serve a broader patient base

Innovation in Life Sciences lies at the intersection of social and environmental sustainability. Not only can it support socio-economic improvements, but it is also key to finding solutions to emerging diseases caused by climate change and keeping up with demographic changes that need new solutions for new problems. However, the impact is highly dependent on the extent to which scientific innovation is actively dispersed through the economy, whether through new business lines, partnerships, public procurement, or philanthropy.

Many Life Sciences companies cite contributing to the third UN Sustainable Development Goal¹⁷ - which aims to achieve universal health coverage and the provision of safe and affordable medicines and vaccines for all - as relevant to their businesses in their corporate sustainability messaging. This should naturally extend to striving to ensure equitable access to their innovations, particularly for vulnerable populations and un(der)served regions. However, it doesn't mean that Life Sciences companies need to be alone in working on this. Balancing intellectual property rights with broader Human Rights to benefit from scientific progress is a nuanced challenge.

Life Sciences entities should explore mechanisms that promote open access to knowledge and innovation while maintaining incentives for research and development. Collaborative initiatives and licensing arrangements may help in striking this balance, as well as exploring possibilities to leverage patent expirations, reorienting them from a business risk to an opportunity by providing a service that educates partners or patients on these products. This could take the form of a business line (training and education) and/or be part of a wider philanthropic program, which supports the company's reputation as a leader and a force for social good.

Meanwhile, joint efforts between governments, industry, and civil society are also needed to promote the realization of the universal right to healthcare, and discriminatory practices that hinder access based on socio-economic factors must be eliminated.

Scientific innovation makes it possible to serve a broader patient base with ever-more diverse needs, which is not only good for society, but presents clear economic opportunities for business expansion. For example, in many countries the population demographics are shifting such that the percentage of the population that is elderly is growing. This implies a higher burden of non-communicable diseases, with a corresponding opportunity for business expansion in non-communicable

¹⁶ Dr. Kunz kindly provided input to this publication in 2023, during his tenure at Bayer (July 2001 – March 2024).

¹⁷ United Nations Development Program: UNDP. (n.d.). Sustainable development goals. United Nations. Retrieved from: <https://www.undp.org/sustainable-development-goals>

therapies and contributions in consortia to fight new age-related diseases.

Innovative technologies also enable Life Sciences companies to react more quickly to new opportunities and better serve evolving patient needs, some of which may only affect small numbers of the population but may nonetheless be vital to those patients' care and recovery. This includes examples such as 'technology that makes it possible to manufacture cell and gene therapy for an individual patient'¹⁸ or working with specific demographics, using a patient engagement approach to help design, develop, and distribute appropriate products and therapies that account for the patients' experiences, needs, and preferences.

Ethical Research and Clinical Trials

Human Rights considerations are central to ethical research and clinical trials. Informed consent, privacy, and the protection of vulnerable groups are paramount. The World Medical Association's (WMA) Declaration of Helsinki¹⁹ and the Good Clinical Practice (GCP) guidelines²⁰ underscore the importance of respecting participants' autonomy and rights. Life Sciences entities must conduct rigorous ethical assessments to prevent exploitation and uphold the dignity of research subjects.

Ensuring treatment-patient fit is critical to successful patient outcomes for the Life Sciences and healthcare sectors alike. This starts from the development phase of a new drug or medical device, ensuring that the test subject populations in clinical trials are representative of the diversity of society, especially in terms of sex, ethnicity, and age. Historically, clinical trial subjects have been disproportionately male and in the 18-35 age group. There may be risks and benefits associated with medical solutions that do not apply to this demographic, and therefore may make the treatment either less suitable for other patients or result in missed opportunities to provide more effective treatment – especially where one demographic may respond better than another to a particular treatment.²¹

Getting the right diagnosis and treatment is intrinsically linked with how clinical trials are set up and conducted. Not only that, but vulnerable patients need to be confident that the diagnosis and treatment that they receive is the right fit for them. Building trust with these patient communities and developing treatments that are more effective for them will be the foundation for significant business expansion in the future.

Improving scientific innovation through patient engagement

"Patient engagement is meaningfully and systematically partnering for the long term with patients, their caregivers, patient advocates, and patient organization representatives to deliver better outcomes. Throughout the innovation life cycle, we implement a framework that ensures continuous dialogue with the patient community to understand their needs, preferences, and priorities to inform our decision-making, co-create solutions, and empower their voices.

Patient engagement is a key driver of our Patient Value Strategy - UCB's corporate strategy. Among our flagship projects is direct patient input at our Benefit-Risk Board (BRB), UCB's highest governance body addressing benefit and risk topics. Selected patient-experts with benefit-risk assessment experience are on the BRB as non-voting members; they provide input to inform our decision-making but are not responsible for the BRB's decisions.

We also co-established a strategic council - a best practice for partnership with patient communities - with the major patient organizations for a particular disease to resolve key research problems, from diversity in clinical trials to interactions with regulatory bodies. For example, during an early-stage clinical study for a medicine under investigation, we discovered an unexpected adverse reaction. Through the council's patient groups, UCB was able to quickly gain feedback from patients with the same profile as those in the study, to understand whether the medicine's benefits outweighed the reaction risk. Instead of a resource-intensive patient preference study, the patients' direct and timely input helped our team to confidently continue the research.

Patient engagement delivers better outcomes by addressing what matters most to patients. Alongside social benefits, this improves resource efficiency and sustainability in the product life cycle. By involving patients, we can focus our efforts on developing products and solutions that closely meet patients' priorities and bring effective treatment to market as quickly as possible."



Alexandra Moutet
Global Head of Patient Engagement
UCB

18 SAP. (2022). *The Transformation Mindset: How Growing Life Sciences Companies Scale Profitably and Sustainably*. Retrieved from: <https://www.sap.com/cmp/dg/transformation-mindset-life-sciences/typ.html?pdf-asset=a24ce33c-317e-0010-bca6-c68f7e60039b&page=1>

19 The World Medical Association: WMA. (n.d.). *WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects*. Retrieved from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

20 European Medicines Agency. (2022). *Good clinical practice | European Medicines Agency*. Retrieved from: <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-clinical-practice>

21 KPMG. (2022). *Diversity, Equity, and Inclusion in Clinical Research*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2022/LifeSciences-DiversityEquityInclusion-ClinicalResearch.pdf>

03

Improve environmental performance



Decarbonization

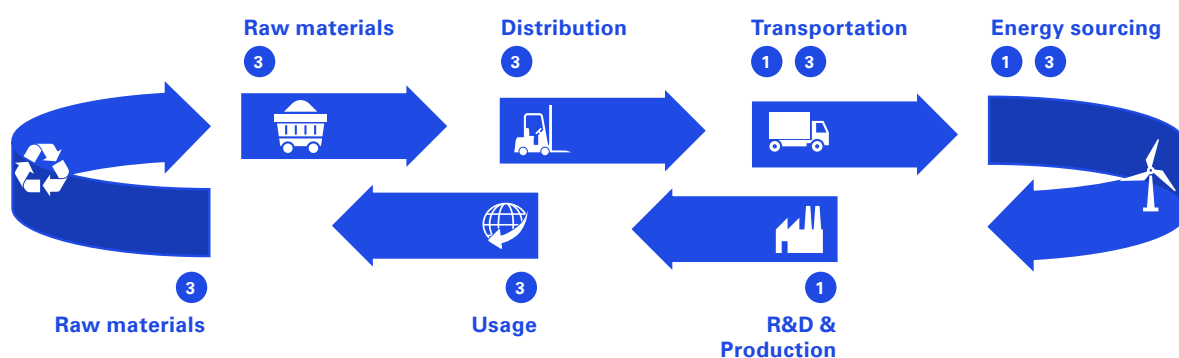
As part of the wider healthcare system - which accounts for 4.4% of global emissions²² - Life Sciences companies have a key role to play in the transition to net zero. Positioned in the middle of the value chain, Life Sciences companies' emissions are indirectly affected by the activities of their upstream suppliers, such as raw materials and ingredients manufacturers, as well as the direct emissions produced by their own operations.

From a double materiality perspective, Life Sciences are also impacted by climate change. The impacts of climate change increasingly affect human health and the vulnerability of global populations to concurrent health threats. Climate change already impacts the spread of infectious diseases and exposure of populations to a higher risk of emerging diseases.²³ Extreme climate events, such as drought and flooding, can lead to a higher demand for life-saving drugs and treatments, but may also add significant risk to business continuity due to supply chain disruption.

Decarbonize your value chain!

Companies face increased Scope 3 emissions reduction pressure and are increasingly looking at circular models for solutions

- 1 Scope 1: direct emissions from owned/ controlled sources
- 2 Scope 2: indirect emissions from generation of purchased energy
- 3 Scope 3: indirect emissions that occur in a company's value chain



Most Life Sciences emissions sit across the supply chain, so-called Scope 3 emissions. It is estimated that the supply chain accounts for more than 70% of emissions – arising largely from the manufacture, transport, and disposal of goods and services such as medical devices and pharmaceuticals.²⁴ The remaining emissions are direct emissions (Scope 1) and purchased energy emissions (Scope 2). When focusing on decarbonization, Life Sciences companies should align with the decarbonization hierarchy – aiming to avoid and subsequently reduce emissions. Companies should consider neutralizing unavoidable emissions and investing in Beyond the Value Chain Mitigation (BVCM)²⁵ to support the societal transition to net zero. A range of decarbonization solutions are available to the sector with some examples provided below.²⁶



22 Health Care Without Harm & ARUP. (2019). Health care's climate footprint: How the health care sector contributes to the global climate crisis and opportunities for action. Retrieved from: https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf

23 Romanello, M. et al. (2022). The 2022 report of the Lancet Countdown on health and climate change: health at the mercy of fossil fuels. The Lancet, 400(10363), 1619–1654. DOI: [https://doi.org/10.1016/s0140-6736\(22\)01540-9](https://doi.org/10.1016/s0140-6736(22)01540-9)

24 Health Care Without Harm & ARUP. (2019). Health care's climate footprint: How the health care sector contributes to the global climate crisis and opportunities for action. Retrieved from: https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf

25 Science Based Targets initiative: SBTi. (n.d.). Beyond value chain mitigation - science based targets. Retrieved from: <https://sciencebasedtargets.org/beyond-value-chain-mitigation>

26 Based on research by KPMG's Global Decarbonization Hub and KPMG in Ireland.

Target Area	Strategy	Example Solutions
Energy	Avoid/Reduce emissions	<ul style="list-style-type: none"> Improve building energy use efficiency through the completion of an energy audit to target efficiency measures such as insulation and HVAC optimization Renewable heat and power – sourced for example through Corporate Power Purchase Agreements or via on-site generation Low/zero carbon transport e.g., electrification, hydrogen- or bio-based
Equipment	Avoid/Reduce emissions	<ul style="list-style-type: none"> Artificial Intelligence can improve the energy and resource use efficiency of Life Sciences product development 3D Printing can improve material use efficiency of R&D processes
Product	Avoid/Reduce emissions	<ul style="list-style-type: none"> Integrate the 12 principles of green chemistry into product synthesis Product and packaging redesign to embed circular principles
Unavoidable emissions	Neutralize emissions	<ul style="list-style-type: none"> Investment in carbon removal projects within (insetting) or outside the value chain. Example projects include BECCS, improved soil management and improved forest management
Societal transition to net zero	BVCM	<ul style="list-style-type: none"> Investment in carbon removal or avoidance/reduction projects within (insetting) or outside the value chain. Example projects include forestry, peatland conservation and cookstoves

Source: KPMG Research and Analysis

Life Sciences companies can drive the uptake of technical solutions through supply chain engagement and net-zero aligned procurement policies; investment in low carbon R&D; upskilling; and the development of sectoral decarbonization pathways to identify emission hotspots. Life Sciences companies should ensure they have a comprehensive understanding of their impact on and exposure to climate change – through the completion of a carbon footprint assessment and climate change risk assessment (including scenario analysis).

While decarbonization options are readily available for the sector, challenges remain, with cost being a critical barrier to achieving meaningful decarbonization.

Outside of cost, Life Sciences companies are challenged with complex, global supply chains making it difficult to influence decarbonization. Improved data tracking and traceability, and sectoral collaboration for value chain decarbonization, can help overcome this barrier. Life Sciences companies are highly regulated and often require approvals to implement changes to products and processes – this can act as a hurdle for scaling new low-carbon solutions.

The sector is already mobilizing on decarbonization. Sectoral initiatives have been established to drive action, such as the Sustainable Markets Initiative's Health System Task Force members,²⁷ which require their suppliers to set science-based targets by 2025. This progress by sector leaders is a critical step toward transitioning the Life Sciences to net-zero.

Circular Economy

"Circularity has the capacity to shift the business model of Life Sciences companies and open new potential revenue streams, such as creating new service lines for reprocessing, repairing, and/or recycling medical instruments and devices.

By applying regenerative and circular design principles to the use of resources and how Life Sciences businesses are run, companies can help secure the long-term future of their value chains, while reducing costs related to logistics and raw materials."



Suzanne Kuiper

Director of Circular Economy and Product Decarbonization

KPMG's Global Decarbonization Center

We see an accelerated market trend and regulatory push – such as the UN's Plastics Treaty Initiative²⁸ - to reduce waste and shift to circular production and operation processes. Circularity has the capacity to shift the business model of Life Sciences companies and open new potential revenue streams, such as self-administered care and waste management.

It's important to first acknowledge that there are some products or components that, for legal and hygienic reasons, will always require incineration at the end of

²⁷ Sustainable Markets Initiative. (n.d.). Health Systems taskforce. Retrieved from: <https://www.sustainable-markets.org/taskforces/health-systems-taskforce/>

²⁸ United Nations Environment Programme: UNEP. (2022). Historic day in the campaign to beat plastic pollution: Nations commit to develop a legally binding agreement [Press release]. United Nations. Retrieved from: <https://www.unep.org/news-and-stories/press-release/historic-day-campaign-beat-plastic-pollution-nations-commit-develop>

their life cycle, with unavoidable emissions. This is mandated by law and not something Life Sciences companies can mitigate in a sustainability strategy. However, it's not uncommon for clean waste materials (which could be recuperated/recycled) from the Life Sciences and healthcare sectors to still be incinerated alongside contaminated materials. Whether this is due to a lack of separation of materials from the collection point (healthcare providers or the Life Sciences companies themselves) or a 'better safe than sorry' approach from waste management companies, the result is that emissions from incineration may be higher than necessary.

There is an opportunity for Life Sciences companies to work in partnership with healthcare providers and waste disposal companies to better inform and educate one another on what happens to waste products and end-of-life disposal and investigate ways to reduce waste and limit emissions – either at the source, or at disposal.

Where there are new technologies available for greater accuracy in waste sorting, there are also opportunities to transform this process to contribute to the overall sustainability of the value chain.

Meanwhile, when it comes to choosing materials for products and designing packaging, for example casings for certain types of medical devices, there is significant potential for the industry to seize the possibilities offered by alternatives. Companies that are not already doing so could expand their offering to patients and healthcare customers by creating new service lines for reusing, reprocessing, repairing, and/or recycling parts of medical instruments and devices. This would help the Life Sciences sector to shift from a linear industry, to one which is instead a regenerative partner²⁹ to the communities and markets in which it operates.

As the healthcare industry shifts from centralized to more self-administered care, we fully expect the demand for single-use products to increase.

Single-use items and other disposables can have a waste impact on the environment – especially the marine environment, where most plastics and microplastics are found. This was particularly noticeable during the COVID-19 pandemic, when single-use products such as commercially sold surgical masks and PCR self-test casings were increasingly found amongst waste in rivers and the



marine environment. These can then become choking hazards for animals that mistake them for food or break down into microplastics which enter the food chain, with negative health consequences for plant, animal, and human life at every trophic level; the long-term health effects of which are only just beginning to be understood.

Circularity is not limited to plastics, of course. Especially for medical devices, there are also the electronic components, gases (e.g., helium for MRI machines), rare earth minerals and metals, and batteries to consider, which have associated challenges when it comes to resource scarcity and end-use recyclability. In the EU, there are regulatory imperatives for medical device producers to be able track a device throughout its complete life cycle - right up to the point of disposal.³⁰ Companies are expected to maximize opportunities for circularity throughout the life cycle of medical devices, reprocessing and collecting for re-use where possible, and facilitating safe and responsible waste disposal for components that cannot be re-used or recycled.³¹

All-in-all, we expect that there will be increased scrutiny of companies contributing to plastic, waste, and biochemical pollution of land, air, and water systems, implying significant reputational and regulatory risk for companies that have not taken steps to reduce these impacts.

29 Silverthorne, K. (2021). *Doughnut Economics and the Circular Economy: Implications for the healthcare industry and the role of medical writers and communicators*. In *Medical Writing* (Vol. 30, Issue 3). Retrieved from: https://journal.emwa.org/medical-decision-making-and-health-technology-assessment/why-would-the-healthcare-industry-need-a-doughnut/article/10015/why-would-the-healthcare-industry-need-a-doughnut_.pdf

30 KPMG. (2023). *From Linear to Circular - Sustainability in the Medical Device Industry*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2023/From-Linear-to-Circular-Sustainability-in-the-Medical-Device-Industry.pdf>

31 KPMG. (2023). *From Linear to Circular - Sustainability in the Medical Device Industry*. Retrieved from: <https://assets.kpmg.com/content/dam/kpmg/be/pdf/2023/From-Linear-to-Circular-Sustainability-in-the-Medical-Device-Industry.pdf>

Collaborating with competitors to develop circular medical device systems

“Novo Nordisk is embracing a circular approach to achieve net zero environmental impact. We’re designing and producing products that can be recycled, while reshaping business practices to minimise consumption and turn waste into new resources.

As part of this, we’re spearheading a take-back industry solution to recycle plastic from injection pens. Plastic and the injection pens are very tangible - the patient has it in their hands, and everybody can relate to it – so it’s both easy to communicate and understand.

Our returpen™ pilot started with three cities in Denmark, then scaled to a national project. In May 2023, we teamed up with peers and competitors to launch an industry pilot. Hence, we are now four leading pharmaceutical companies (including us), a pharmaceutical association, two patient organizations, a medical industry association, hundreds of pharmacies, clinics, competing distributors, and a recycling partner collaborating on solving the end-of-life product challenge. Furthermore, we are running Novo Nordisk pilots in the UK, France, and Brazil, and are expanding.

At management level, we’ve experienced the impact of thinking differently about sustainability - joining forces with peers and competitors to share capabilities, benefits, and risks. It’s groundbreaking to work this way. We compete head-to-head in commercial markets but believe it’s better to collaborate on sustainability.

We’ve also seen that employees, regulators, and other stakeholders respond well to such explicit examples of action. For instance, the UK’s National Health Service is highly committed to net zero and only wants to collaborate with manufacturers that share this vision. It’s increasingly critical to demonstrate a circular approach, communicating data with granularity and evidence of impact. The take-back program resonates well because it’s action-oriented, with tangible results, while helping to build a circular system across the whole value chain for the future.”



Niels Otterstrøm Jensen
Head of ReMed Programme
Corporate Environmental Strategy
 Novo Nordisk



Biodiversity and Nature

The Life Sciences sector plays a pivotal role in human health and wellbeing, constantly striving to develop new ways to combat illness and disease. However, amid the pursuit of medical advancements, it is essential for Life Sciences companies to recognize the profound impact and dependencies they have on biodiversity and the environment. As stakeholders increasingly demand sustainability and responsibility, Life Sciences companies have an opportunity to embrace their unique position in the value chain and take proactive measures to become champions of biodiversity conservation.

Life Sciences companies also need to consider the impact of their products' active ingredients on water, soil, and air after use. Improper disposal of expired pills and medical waste is unfortunately common, leading to biochemical pollution and the release of resistant active ingredients³² into the environment. Together with microplastics, active pharmaceutical ingredients (APIs) can disrupt the endocrine functions of many species, which can impact fertility and

³² Kumar, V., Bansal, V., Madhavan, A., Kumar, M., Sindhu, R., Awasthi, M. K., Binod, P., & Saran, S. (2022). Active pharmaceutical ingredient (API) chemicals: a critical review of current biotechnological approaches. *Bioengineered*, 13(2), 4309–4327. DOI: <https://doi.org/10.1080/21655979.2022.2031412>

hormonal functions necessary for healthy populations. Lower fertility rates amongst wild species can reduce genetic diversity in natural species populations over time – both flora and fauna – which could have significant consequences for the future potential of these ecosystems as resources to support innovation in the Life Sciences sector.

As climate change intensifies, migration and ecosystem patterns of wildlife are also changing, bringing them ever closer to human and livestock populations in search of food and shelter. If these species are carrying communicable diseases caused by bacteria, due to biochemical waste in the natural environment, this will have severe consequences for livestock and human health.

There is already a rising number of zoonotic diseases being transmitted between animals and humans through closer proximity of wildlife, livestock, and human populations. Addressing the issue of communicable diseases related to biochemical waste is therefore crucial to mitigate the Life Sciences sector's impact on biodiversity and the effects that unhealthy ecosystems' wildlife populations can impose on human health.

There is an opportunity for biotech and pharmaceutical companies to take the lead on improving end-user education around the dangers of overuse of antibiotics and anti-viral medications (e.g., by livestock producers and fisheries). There is also an ecosystem development opportunity for Life Sciences companies to work more closely in partnership with retailers, healthcare providers, and waste management services to develop improved waste management pipelines through sharing expertise and resources.

The growing understanding and severity of the material impacts of APIs on society and the environment requires the targeted attention of executives and board members. Biochemical waste must be urgently prioritized as the most critical effect on biodiversity that biotech and pharmaceutical companies need to address in their corporate strategy.

Water Management

By 2050, it is expected that the world will experience a 20-30% increase in global water demand,³³ with 75% of the global population facing issues with

drought, potable water shortages, and water pollution.³⁴ We will face challenges with both the quantity and quality of available fresh water. Europe is no exception to this, with approximately 30% of European territories already experiencing water scarcity for a significant part of the year, and the situation is worsening.³⁵

This will not only affect individual households but place significant strain on companies that rely on water for their operations. As a highly water-intensive sector, there are major risks and dependencies related to water that Life Sciences companies need to address by investing in long-term resilience and adaptation. This is especially the case for Life Sciences operations that require highly purified water (e.g., pharmaceutical R&D and production) and need additional measures to avoid contamination with pathogens, bacteria, and viruses.

We foresee that there will be fiercer competition for quality water resources in the coming years, with demand outstripping supply in many countries.³⁶ In extreme cases, this could also lead to governments rationing national water supplies among critical industries. To mitigate these possibilities, it's important for biotech and pharmaceutical companies to find solutions to reduce the water intensity of their product development, production processes, and facilities. This includes investing in water circularity infrastructure and solutions for greater water independence, so that companies are less reliant on freshwater withdrawals from reservoirs and underground water supplies. For forward-thinking companies that are especially skilled at this, there is an **opportunity to both become net water positive and develop water-efficient technologies that can then be patented and sold to generate additional revenue.**

Of course, water management is not just about water intake, but also how wastewater is processed to prevent active ingredients, chemicals, and other biological materials from contaminating the natural environment.

Systems thinking is useful to identify co-benefits from wastewater management. For example, innovative solutions in wastewater treatment and circular solutions will help reduce greenhouse gas emissions, and nature-based solutions at the watershed level can increase availability and quality of water.

33 UNESCO World Water Assessment Programme & UN-Water. (2023). *The United Nations World Water Development Report: Partnerships and Cooperation for Water*. UNESCO Publishing. Retrieved from: <https://www.unwater.org/publications/un-world-water-development-report-2023>

34 United Nations Convention to Combat Desertification: UNCCD. (n.d.). *Drought*. United Nations. Retrieved from: <https://www.unccd.int/land-and-life/drought/overview>

35 European Environment Agency. (2023). *Water scarcity conditions in Europe (Water exploitation index plus)*. European Union. Retrieved from: <https://www.eea.europa.eu/en/analysis/indicators/use-of-freshwater-resources-in-europe-1>

36 Kuzma, S. (2023). *25 countries, housing one-quarter of the population, face extremely high water stress*. World Resources Institute. Retrieved from: <https://www.wri.org/insights/highest-water-stressed-countries#:~:text=According%20to%20data%20from%20Aqueduct%2C%2031%25%20of%20global,%2415%20trillion%20%2824%25%20of%20global%20GDP%29%20in%202010.>

04

Implement better governance



Aligning incentives: Remuneration based on sustainability performance

With the best of intentions, none of the above approaches to sustainable transformation are likely to be successful without seriously considering the intrinsic and extrinsic incentives of managers to bring their teams into alignment with the overall strategic objectives of the organization.

Change management requires buy-in, typically through a combination of good two-way communication to build trust, investment in the resources necessary for the desired change to be successful, and incentives to motivate people within the organization to direct their efforts towards the desired change.

Linking board, executive, and management compensation (and budgets) to sustainability and ESG targets is a highly effective way to ensure alignment with the company's sustainability goals. This is useful for corporate strategists to remember and factor into their planning: managers are inclined to direct their resources according to the incentivized outcome. This does not necessarily mean that the outcomes will align with the corporate strategy, as the company's stated objectives may be at odds with how performance is rewarded in practice.

We are already hearing that Life Sciences investors increasingly expect that ESG performance-based remuneration will be linked to topics where Life Sciences have the greatest impact (e.g., social impact related to access to medicine) rather than more general targets (e.g., decarbonization). This empowers Life Sciences companies to be more targeted in their activities and investment towards a net positive impact on society and the environment, using their expertise and resources in places where other sectors have fewer levers to make a difference.

Sustainable Finance

New financial instruments

ESG financial instruments are rapidly gaining momentum as companies across various sectors recognize the value of sustainable and responsible practices. In the Life Sciences industry, this trend

presents a promising opportunity to access the growing global market for green and social debt. These financial instruments include green bonds and loans, ESG-linked bonds and loans, sustainability bonds, and social bonds, all designed to finance projects with positive environmental and social impacts.

Life Sciences companies that can demonstrate tangible evidence of their ESG activities stand to benefit from lower financing costs. By showcasing commitment to environmental, social, and governance initiatives, companies can attract investors seeking to support sustainable businesses. As a result, they can enjoy significant financial advantages, as studies have shown that companies leading on ESG can achieve up to 2.5 times higher earnings before interest, taxes, depreciation, and amortization (EBIDTA) compared to ESG laggards.³⁷

To capitalize on this growing trend, Life Sciences companies should proactively align their portfolios and research and development (R&D) activities with sustainability objectives. By integrating ESG principles into their strategies, these companies can position themselves to benefit from the capital flowing into sustainable assets. Embracing sustainability and responsible practices not only enhances their reputation and appeal to socially conscious investors but also unlocks potential financial gains and competitive advantages in the market.

Public grants and incentives

However, it's not only the private sector that has stepped up its game when it comes to allocating capital to innovation and incentivizing the transition towards increased sustainability. In addition to the green financial instruments offered by banks and other creditors, there is also an increasing number of grants, subsidies and other financial incentives available at municipal, regional, national, and European levels.

Among the current grants and incentives available to the Life Sciences industry to boost sustainability activities, the most significant in Europe include the EU Green Deal Industrial Plan,³⁸ the Horizon EU Innovation Health Initiative,³⁹ and the EU4Health 2024 Work Programme.⁴⁰

Under the EU Green Deal Industrial Plan in particular, Life Sciences companies can access funding to help scale net-zero technologies through several multi-billion euro funds and grants. The most substantial of these is the Invest EU fund (totaling EUR 372bn),⁴¹ closely

³⁷ Based on KPMG desk research, drawing on different sources.

³⁸ European Commission. (n.d.) The Green Deal Industrial Plan. European Union. Retrieved from: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/green-deal-industrial-plan_en

³⁹ European Commission. (n.d.). Innovative Health Initiative. European Union. Retrieved from: <https://www.ihl.europa.eu/>

⁴⁰ European Commission. (2023). Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2024. European Union. Retrieved from: https://hadea.ec.europa.eu/system/files/2023-12/EU4Health%20programme%202024_0.pdf

⁴¹ InvestEU (n.d.) European Union. Retrieved from: https://investeu.europa.eu/investeu-programme/investeu-fund_en

followed by the REPowerEU RRF funds (totaling EUR 250bn), as well as the smaller, but still significant, Innovation fund (EUR 40bn).

There are also possibilities to participate in funding offered under the Horizon EU Innovative Health Initiative (IHI), a public-private partnership which has a total available funding budget of EUR 2.4bn under the Single Basic Act (SBA) and aims to support the creation of an EU-wide health research and innovation ecosystem for diseases management and healthcare.⁴²

Another example is the EU4Health 2024 Work Programme, which targets COVID-19 and Ukraine-related health issues, alongside the ambition to support mental health, global health, digital health, and cancer screening, while boosting medicine production in Europe. Its total available budget is EUR 752.4m.

These are only a few of the many funding possibilities at EU level of relevance to innovation, research, health, sustainability, and other Life Sciences areas of interest. A more comprehensive overview of currently active EU funding initiatives and platforms can be found on the website: <https://eufundingoverview.be>

Taxation

The growing importance of green taxation as a tool to limit the impact of a company's activities on the environment requires companies to assess the environmental impact of their processes and supply chain. Good management of a group's environmental footprint assumes a clear understanding of the existing environmental tax contribution of a company, as well as assessing the impact of these changes to the group (e.g., the changes to the EU Energy Taxation Directive, plastics packaging tax, water tax, tax on renewable energy) and tax risk is emerging as a key operational and reputational issue for boardroom agendas.

The impact of these regulations on the Life Sciences sector is wide ranging – from packaging and waste taxation to the impact of the EU Carbon Border Adjustment Mechanism (e.g., on imports of chemicals such as ammonia). Many companies in the Life Sciences sector are combining their efforts into one broader project – a review of their value chain through a sustainability lens. As Life Sciences organizations get better at mitigating the environmental impact of their activities, this may open the door to some of the advantages offered by governments as incentives for change.

Customers increasingly look to do business with companies that approach tax openly and responsibly. Building that trust starts when companies demonstrate

that they are paying the right amount of taxes – when and where they should. Multinational groups with a consolidated turnover of EUR 750 million or more and operating in the EU will soon be faced with a tax transparency requirement through the introduction of the EU Public Country-by-Country Report ("CbCR") – generally applicable after June 2024.

The Public CbCR will require disclosure of tax relevant information by jurisdiction, such as revenues, amount of taxes accrued and paid, and number of employees. While groups likely already have the required data to populate the EU Public CbCR, the more pressing concern is how such information will be perceived or interpreted by the public. Tax teams will have to work with their Public Relations and Corporate Communications teams to ensure the narrative accompanying this public disclosure is consistent – which business leaders within the group will also need to be informed of and prepared for.

As the legislative landscape continues to evolve, such as with the OECD's implementation of the global minimum corporate tax rules, it is important for companies to stay abreast of such developments, especially as these may impact local tax incentives and credit opportunities. While many Life Sciences companies benefit from specific incentive regimes foreseen to attract investments or to support R&D activities, the continued application of these incentives will need to be evaluated against the ongoing implementation of the global minimum tax rules.

Due Diligence: Human Rights and Sustainability in the Value Chain

In the EU, there is an ongoing trend towards the legal enforcement of human rights due diligence. The EU Taxonomy Regulation requires that companies in scope fulfil minimum safeguards for human rights, requiring targeted due diligence, and according to the Corporate Sustainability Reporting Directive (CSRD), human rights due diligence should feed into double materiality assessments.

European Sustainability Reporting Standards (ESRS) also require reporting companies to disclose information on their human rights due diligence and additional rules on how companies must conduct human rights and environmental due diligence will be further enforced through the forthcoming EU Corporate Sustainability Due Diligence Directive (CSDDD), which is projected to be ratified in 2024. The scope of the Directive extends to both large EU and Non-EU companies, although smaller entities might also experience indirect ramifications.

⁴² European Commission: Directorate General for Research and Innovation. (2022). Innovative Health Initiative. European Union. Retrieved from: https://research-and-innovation.ec.europa.eu/research-area/health/innovative-health-initiative_en

Proactive social compliance: Human rights due diligence in complex global supply chains

“At Fresenius, our comprehensive human rights due diligence program closely connects with our core responsibilities as a healthcare company: Respecting human rights in all our activities. Building on the UN Guiding Principles on Business and Human Rights (UNGP), our program extends group-wide to prevent, end, or minimize adverse impacts on human rights and the environment in our own operations and supply chains.

The support of our Management Board is crucial for implementing human rights due diligence on a global scale. Overseeing the program, the Management Board has also anchored this commitment in a human rights statement applying across all operations and to our suppliers. As part of the five pillars of our program, our risk assessments evaluate human rights impacts, define and implement risk-minimization measures, and facilitate internal and external reporting on our progress. A dedicated grievance system also enables employees and all external stakeholders to anonymously report possible human rights or other compliance violations. Collaborating and promoting information exchange across our companies is a fundamental aspect of our human rights program, so we’ve established an interdisciplinary Human Rights Council consisting of representatives of various departments.

While we’ve made good progress, upholding human rights and environmental compliance across multinational operations and supply chains requires constant development and improvement. We use platforms and automated processes to improve supply chain transparency. This is a challenging task, working with thousands of Tier-1 suppliers in complex supply chains and depending on more than 190,000 colleagues in production sites, clinics, and offices around the globe.

We care deeply about upholding our human rights commitment because we see it as our responsibility to not only comply with regulations and societal expectations, but to extend this commitment to our partners. We plan to expand exchange with stakeholders based on risk analysis results, as accelerating progress with our human rights program depends on collaboration and continuous improvement.”



Lasse Kowalewski
Head of Group Human Rights Office
Fresenius

In addition to the EU legislation, several countries (e.g., France, Norway, Germany) have adopted legislation requiring human rights due diligence to at least some level. For example, the German Supply Chain Act already imposes penalties of up to 2% of global revenues for infractions. CSDDD is envisaged to be enforced through administrative supervision and civil liability. Member States will designate an authority to supervise and impose effective, proportionate and dissuasive sanctions, including fines and compliance orders. Additionally, Member States will ensure that victims receive compensation for damages resulting from the failure to comply with the obligations of the new proposals.

Especially given the critical role of human rights in clinical and product trials in the Life Sciences industry, **we recommend that large Life Sciences companies incorporate and ensure adequate CSDDD compliance in their core business strategy, including dedicated oversight by directors at the management and board levels.**

Governance Bodies

New ESG regulations are introducing additional obligations for supervisory and management bodies. What’s more, ESG governance is increasingly operating in an environment of pressure from social activism and climate litigation.

For example, company directors face direct liability with respect to Articles 25 and 26 of the proposed Corporate Sustainability Due Diligence Directive (CSDDD), which outline the requirements that company directors must fulfil regarding duty of care and the duty to set up and oversee due diligence. More specifically, Article 25 stipulates that directors are expected to ‘take into account the consequences of their decisions for sustainability matters, including, where applicable, human rights, climate change and environmental consequences, including in the short, medium and long term.’⁴³ Directors also face indirect liability under Article 22 of the CSDDD, which outlines rules on civil liability for companies, as well as potential interaction with corporate legislation at national level.

As a general standard, companies need to make sure that they put the right governance bodies in place to manage and steer/oversee ESG and equip those bodies with the skills and resources to do the job correctly. It can also be valuable to add an ‘outside-in’ dimension to the governance structure, by appointing an external ESG advisory board that acts as a sounding board and has an accountability role in ensuring that the supervisory board and management are kept updated as to what’s expected of them.

⁴³ European Commission. (2022). Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937. COM/2022/71 final. European Union. Retrieved from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0071>

05

Prepare for ESG reporting & assurance



"International regulators are pushing the Life Sciences sector to increase investments and actions on ESG. In Europe, the Green Deal pushes regulation in frameworks that companies need to align with, mainly the CSRD, the EU Taxonomy, and the ESRS.

While regulators are currently allowing some flexibility to give companies the opportunity to transform their business models, we expect oversight to become stricter in the coming years as we approach the end of the phase-in periods, with significant financial penalties for non-compliance.

Companies need to prepare for this transition and ensure they have the necessary processes in place for rigorous data collection and reporting."



Andrea Sternisko
Head of ESG Life Sciences & Chemicals / Partner of the ESG Service Group
 KPMG in Germany

EU ESG Regulation

The international policy and regulatory landscape is pushing the Life Sciences sector to increase investment and action on ESG. In Europe, the main regulatory frameworks that Life Sciences companies need to align with are the Corporate Sustainability Reporting Directive (CSRD) and the EU Taxonomy (EUT). These frameworks stem from the EU's flagship climate project, the European Green Deal, which contains a comprehensive range of policy and sustainable financing initiatives designed to ensure that the EU will become the first climate-neutral bloc by 2050.⁴⁴

It's also important to note that the EU's ESG regulation is not limited to reporting requirements. There are many other standards and criteria that are relevant – or may become relevant – to Life Sciences companies, such as eco-design or extended producer responsibility, which impact product development, supply chains, and product life cycle planning.

Aligning European reporting requirements with group reporting requirements in other jurisdictions

"As a leading MedTech company, Olympus is committed to sustainability as we understand the impact of our business activities on the environment and society, but also the opportunities of a sustainable business model and transparent communication with our stakeholders. Therefore, we consider the implementation of the CSRD not only as a challenge but also as a driver for transformation.

Collecting necessary data from operations and our supply chain requires clear processes for data collection, ensuring data accuracy, reliability, and consistency, and meeting the requirements of the CSRD. Establishing appropriate internal controls requires clear processes for data validation and verification, identifying and addressing potential errors or inaccuracies in ESG reporting. Aligning ESG reporting processes with overall business strategy and objectives requires clear goals and targets for ESG performance, integrating ESG reporting into decision-making processes, and meeting the reporting deadlines and requirements set out in the regulation.

On the Olympus sub-holding level, based in Europe with headquarters based in Japan, we face additional challenges in aligning the European regulatory requirements with reporting requirements for the whole Olympus Group, ensuring ESG data points and reporting processes are consistent with the requirements of the relevant jurisdictions.

To meet these needs, we defined an effective ESG Target Operating Model and an appropriate ESG Governance structure, incorporating ESG factors into our overall business strategy and objectives, with clear goals and targets for ESG performance, integrating ESG reporting into decision-making processes, and defining reporting processes and responsibilities.

As a MedTech company, we are committed to upholding the highest standards of sustainability and ethical business practices, and we will continue to invest in our ESG-Governance structure and ESG Target Operating Model to ensure that we are meeting the evolving needs of our stakeholders."



Cornelia Peško
Environment & Safety Manager
Corporate Quality Management
 OLYMPUS EUROPA SE & CO. KG

⁴⁴ European Commission. (2021). *The European Green Deal*. European Union. Retrieved from: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en#:~:text=The%20European%20Green%20Deal%20%E2%80%93%20A%20commitment%20to%20future%20generations&text=To%20overcome%20these%20challenges%2C%20the%20growth%20decoupled%20from%20resource%20use

EU Taxonomy & Life Sciences

The EU Taxonomy Regulation⁴⁵ underpins sustainability frameworks on financial and non-financial reporting by providing an EU-wide classification system for sustainable economic activities. It provides standardized definitions of what is and isn't considered sustainable from a European regulatory perspective and is mandatory for all companies in scope of the CSRD.

When the CSRD comes into effect, the EUT reporting scope will widen to include European entities that fulfil two of the following three criteria: i) 250+ employees; ii) exceeding EUR 25 million net turnover; iii) exceeding EUR 50 million balance sheet total, as well as listed small and medium-sized entities.⁴⁶ For companies headquartered in third countries with subsidiary operations in the EU, the threshold for inclusion under the EUT reporting scope is a net turnover of EUR 150 million generated in the EU.

In April 2023, the European Commission published the EUT Technical Screening Criteria for the environmental objectives focused on water and marine resources; circular economy; pollution prevention and control; and biodiversity and ecosystems – all of which are relevant for Life Sciences companies as outlined in previous chapters - and for the first time included two specific economic activities for pharmaceutical companies under the pollution prevention and control environmental objectives: **1.1 “Manufacture of active pharmaceutical ingredients (API) or drug substances”** and **1.2 “Manufacture of pharmaceutical products.”**

This widens the activities that are now considered material for Life Sciences companies to disclosure in their annual sustainability statement.

New economic activities for pharmaceutical companies to be reported in EUT Disclosures:

1.1 “Manufacture of active pharmaceutical ingredients (API)” or drug substances is described as the manufacture of any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical product including receipt of materials, processing or packaging of the API and related controls. The economic activities in this category could be associated with NACE code C21.1 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

1.2 “Manufacture of pharmaceutical products” (or drug products) includes operations of receipt of materials, production, packaging, repackaging, labelling, re-labelling, quality control, release, storage, and distribution of APIs and related controls. The economic activities in this category could be associated with NACE code C21.2 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Assurance Expectations

As companies shift from the Non-Financial Reporting Directive (NFRD) to CSRD, a new auditing requirement emerges. Under the CSRD, companies are now mandated to obtain limited assurance for their non-financial information. This process necessitates auditors to provide a conclusion that, based on their procedures, they are not aware of any material misstatements in the reported data. However, unlike typical limited assurance, this initial phase under the CSRD will involve a more comprehensive audit process due to the newness of the requirement and the associated risks, particularly in the first year of its application.

After three years, it is anticipated - though not yet confirmed - that the European Commission may advance the requirement to reasonable assurance, further aligning it with the standards applied to financial reporting. This transition is integral to enhancing the connection between financial and non-financial information, necessitating more rigorous data collection and reporting processes.

⁴⁵ Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (Text with EEA relevance). (2020). Official Journal of the European Union, L 198, p 13–43. ELI: <http://data.europa.eu/eli/reg/2020/852/oj>

⁴⁶ KPMG. (2023). De-tangling the EU Taxonomy. Retrieved from: <https://kpmg.com/be/en/home/insights/2023/06/sus-de-tangling-the-eu-taxonomy.html>

Sector-specific Regulation

In addition to the European Green Deal frameworks that impact all companies operating in Europe, there are five key regulatory changes that Life Sciences companies need to keep up with:

Regulation	Description
Clinical Trials Regulation - CTR	Single set of rules for clinical trials conducted in the EU, replacing the Clinical Trials Directive CTD of 2014 and introducing a Clinical Trials Information System (CTIS) to harmonize the processes for assessment and supervision of clinical trials in the EU.
General Pharmaceutical legislation	Future-proof and crisis-resistant medicines regulatory system ensuring access to affordable medicines, foster innovation, improve supply security.
Medical Device Regulation - MDR	Requirements for manufacturers placing medical devices on the EU market, including documentation, clinical evaluation, post-market clinical surveillance and product traceability, replacing the Medical Device Directive (MDD).
Representative Actions Directive - RAD	EU-wide legal framework on representative actions for the protection of the collective interests of consumers, including injunctive measures, redress measures, or both.
Artificial Intelligence (AI) Liability Directive - AILD	Protects individuals harmed by AI systems at the same level as for other technologies, considering a rebuttable presumption of causality to ease the burden of proof for victims.

At every level, there are significant regulatory changes underway that require Life Sciences companies to invest in their data architecture to be fully compliant with mandatory disclosure requirements. By preparing today, companies can avoid costly penalties later on.



06

Conclusions and outlook for Life Sciences companies



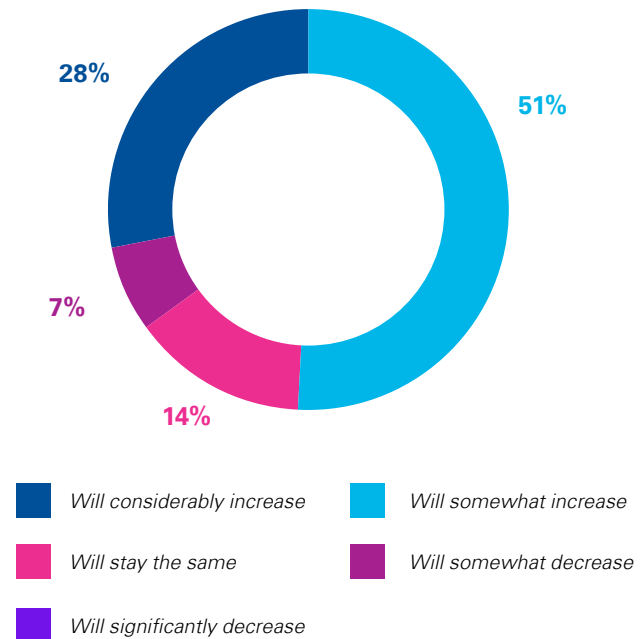
While regulators are currently allowing some flexibility to give companies the opportunity to transform their business models, we expect oversight to become stricter in the coming years as we approach the end of the phase-in periods for frameworks such as the EU Taxonomy and CSRD, with significant penalties for non-compliance.

Meanwhile, Life Sciences companies may also discover that companies that are sustainability leaders will have the widest choice of financial instruments to access to increase their profitability (EBITDA) and the competition for these instruments is still low, which increases strategic opportunities. However, we do not expect that this will continue indefinitely. While early-moving companies and consumers have received significant subsidies and tax advantages for switching to more sustainable technologies, as these markets mature and become more independently sustainable, the levels of subsidies are gradually decreasing, so latecomers to the market have significantly fewer options to avail of incentives to ease their investment.

We expect to see a similar pattern when it comes to ESG subsidies and incentives – early companies and leaders will have many more opportunities to increase their upside from their investments, whereas laggards who invest only to the level of minimum compliance will see much lower returns and fewer opportunities.

However, Life Sciences companies' investment in ESG and sustainability is not just driven by the sticks and carrots of regulatory considerations and extrinsic financial incentives. There is real recognition in the sector that investing in sustainability and ESG is part of an overall business opportunity to gain competitive advantage, as customer and partner behavior shifts to prioritize more responsible suppliers who can demonstrate that their sustainability and ESG values run deep and are widespread throughout their organizations. This is supported by 2023 research by Source, which revealed that 79% of companies surveyed in the EMEIA Life Sciences sector expect their investment in sustainability and ESG to increase in the next three years.⁴⁷

To what extent do you expect your organization's overall investment in sustainability and ESG issues to change in the next three years ?



Based on 100 respondents from companies in the EMEIA Life Sciences sector. Research by Source (2023). Figure reproduced with permission.

There are many reasons to be motivated and optimistic about the Life Sciences sector's evolution into a leading force for good when it comes to sustainability and ESG. We are no longer in a market populated solely by tentative sustainability pioneers. Enhanced by a rapidly expanding range of technological advances, the ESG realm is now settling into a phase of greater cohesion and maturity, in which those purpose-driven Life Sciences companies that have their sustainability, ESG, and digital infrastructure in place will reap the greatest benefits and cement their position as market leaders for the coming years.



47 Price, B. (2023). *Life Sciences: KPMG EMEIA Sector Growth Opportunities*. Source. [Presentation]

To make the most of this opportunity, we recommend that Life Sciences companies:

- ▶ **Invest in coordinated change management throughout the entire organization and value chain.** As tempting as it may be to make small tweaks here and there, what we've seen time and again is that a hesitant approach leads to hesitant results. We encourage business leaders to be bold, leverage systems-thinking and take a coordinated approach to change management that successfully transforms their businesses. Strategic communication to ensure buy-in across all levels of the organization and value chain is critical here as well.
- ▶ **Develop affordable therapies and products.** Life Sciences companies are in the unique position of being able to have a positive social impact at every stage of the patient's journey: from prevention, to treatment, to management and/or cure. As a critical sector, the products and services developed by Life Sciences companies are needed in every country and community. This places Life Sciences companies in an influential position in healthcare ecosystems that they can leverage for social good to ensure fair, equitable, and affordable access to their products and therapies, and is a key pillar upon which the reputation of Life Sciences companies is upheld or weakened.
- ▶ **Improve ecology and environmental performance.** Given the close relationship between Life Sciences companies and the environment, this is a no-brainer. It's in the existential interest of Life Sciences companies to invest in and support initiatives that reduce environmental harm, regenerate biodiversity, and increase circularity of products and materials.
- ▶ **Implement better governance.** Increased regulation brings increased scrutiny by stakeholders and risk of liability for directors. Life Sciences companies should reduce risks by investing in the appropriate technology for data collection and ensure that due diligence and monitoring activities are taken seriously – especially in areas of the value chain where there is higher third-party risk.
- ▶ **Prepare for ESG reporting and assurance.** Love it or hate it, ESG is here to stay for the foreseeable future. While regulators are currently allowing some flexibility to give companies to adapt to the new requirements, investing in improving your company's ESG performance now can reduce your exposure to regulatory risk and help you avoid costly surprises in the future.
- ▶ **Prioritize responsible and transparent stakeholder communication.** This is critical to build and maintain trust in the intentions and activities of Life Sciences companies. Being proactive in communicating and collaborating with regulators, partners, investors, communities, customers, and others in the value chain is essential to demonstrate leadership and deliver on sustainability and ESG objectives.

07

How we can help



"KPMG has invested deeply in our expertise and established a community of specialist talent at the nexus of Life Sciences, sustainability, and ESG.

We're also able to draw on wider multidisciplinary expertise from across our entire international network of firms. This structure means we can offer precisely tailored team configurations to support the specific needs of our pharmaceutical, medical devices, and biotechnology clients."



Jon Haynes
Head of Life Sciences, KPMG EMA
 KPMG

From biotechnology startups and medical device companies to pharmaceutical multinationals, KPMG is in the unique position of being able to offer our clients full access to our tightly knit network of experienced Life Sciences and Sustainability/ESG experts, so you

can draw on local knowledge and sector specific expertise, available onsite wherever your operations are located across the European, Middle-Eastern, and African regions.

Not only that, but our services in these areas are also well-connected with our other professional services and sectoral expertise, offering you a flexible range of multidisciplinary options that can be tailored to the specific needs of your company and adapted to different situations or to support your evolving strategy along every step of the journey.

There's good news ahead for the Life Sciences sector, with many opportunities for companies to not only increase revenues and demonstrate regulatory compliance, but also gain strategic advantage with an integrated ESG approach. To go deeper into some of the perspectives we've shared and better understand how you can use them to your company's advantage, please don't hesitate to reach out to us. We're passionate about these topics and welcome the opportunity to discuss any aspect with you in more detail.



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