Non-Financial Statement**

The combined management report of Merck KGaA, Darmstadt, Germany, and the Group for the fiscal year 2021 includes for the first time a combined non-financial statement in accordance with sections 315b and 315c in conjunction with 289b to 289e of the German Commercial Code (HGB) in the form of a separate chapter. Our non-financial statement orients towards the requirements of the Global Reporting Initiative (GRI) standards. It also includes our reporting in accordance with the EU taxonomy regulation.

KPMG AG Wirtschaftsprüfungsgesellschaft conducted a **limited assurance engagement** of the combined non-financial statement. References to information not included in the management report are not part of the non-financial statement. The additional content provided on both the company's websites as well as external websites that are linked in this report are not part of the information assured by KPMG – excluding references to our Sustainability Report. Our Sustainability Report meets the requirements of the Global Reporting Initiative (GRI) standards – Comprehensive option. It will be available **online** as of April 12, 2022. With this, we disclose topics set forth by Sustainability Accounting Standards Board (SASB) and Task Force on Climate-related Financial Disclosures (TCFD).

Description of our business model

Our business model as well as our Group structure, governance and strategy are described under "**Fundamental Information about the Group**".

Governance

The requirements we place on responsible corporate governance are derived from our **company values** on the one hand and from the regulations, external initiatives, and international guidelines to which we are committed on the other hand. We have integrated these requirements into our **sustainability strategy** and our **Group-wide guidelines**. These guidelines comprise charters and principles that are valid for the entire company as well as specific standards and procedures for individual business sectors and sites.

Some examples: Our **Human Rights Charter** aligns with the **UN Guiding Principles** for Business and Human Rights. Our Group-wide **Social and Labor Standards Policy** reflects the labor standards of the International Labour Organization (**ILO**). Our **EHS Policy** (Corporate Environment, Health and Safety Policy) for environmental impact mitigation and health and safety forms the basis for implementing the chemical industry's **Responsible Care® Global Charter** within our company. Our Regulatory Affairs Governance Policy for chemical products sets out the processes and management structures for product safety.

We comply with all applicable laws as a matter of principle. Where necessary, we review our internal guidelines, standards and instruction manuals on compliant behavior and adapt them to reflect changes in the regulatory landscape.

Roles and responsibilities

Based on the requirements set forth in charters, principles and policies, our internal standards give specific guidance for operational processes. They are constantly updated by the relevant departments and are available on our intranet. Our managers implement these standards in their respective areas of responsibility and ensure that they are adhered to. In addition, we educate and train our employees on all guidelines that apply to them.

** The summarized non-financial statement was not part of the audit of the financial statements but was subject to a separate limited assurance audit by KPMG.

We employ management systems to steer processes and define goals, actions, and responsibilities. These systems are based on standards such as the internationally recognized quality management standard ISO 9001, good working practices (GxP) in the pharmaceutical industry and ISO 14001 for environmental management. Our company regularly undergoes **ISO 14001** and **ISO 9001** certification, which are conducted by an independent auditing firm. We hold group certificates for both standards.

We support the following responsible governance initiatives:

- United Nations **Global Compact**
- Chemical industry's **Responsible Care® Global Charter**
- Company network Together for Sustainability (**TfS**)
- Pharmaceutical Supply Chain Initiative (**PSCI**)
- Initiative Chemie[3], a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE).

Strategic and organizational approach to sustainability

Numerous global challenges, such as climate change, resource scarcity and unequal access to health in various countries, are also crucial to our company. In order to address them, we continuously seek solutions made possible by science and technology. At the same time, we are working to make our business models more resilient.

We describe our sustainability strategy in the "**Strategy**" section of the management report within the Annual Report for 2021 and, in more detail, in the Sustainability Report for 2021 in the chapter entitled "**Sustainability Strategy**".

Roles and responsibilities

Our Executive Board has Group-wide responsibility for our sustainability strategy. It has adopted our three strategic goals: In 2030, we will achieve human progress for more than one billion people through sustainable science and technology. By 2030, we will integrate sustainability into all our value chains. And by 2040, we will achieve climate neutrality and reduce our resource consumption (details can be found under "**Strategy**").

The Group Corporate Sustainability unit is responsible for developing and shaping the sustainability strategy and it regularly informs the Executive Board about the progress made and the need for action. It is part of the **newly created Group function** Corporate Sustainability, Quality and Trade Compliance, which reports to the Chair of the Executive Board. Consequently, overarching Executive Board responsibility for Environment, Social, Governance (ESG) also lies with the Chair of the Executive Board.

Group Corporate Sustainability is also responsible for the Corporate Sustainability Council. The committee consists of representatives from our business sectors and from key Group functions, such as Procurement, HR and Strategy. Council members from various countries provide input on regional sustainability aspects. The Corporate Sustainability Council steers and monitors the Group-wide implementation of the sustainability strategy. It aligns the strategy with the individual business strategies, defines priorities, specifies globally applicable sustainable guidelines, and recommends corresponding initiatives to the Executive Board. With their respective area of responsibility, each Executive Board member is also responsible for sustainability.

In November 2021, we established an external expert committee for sustainability issues. The Sustainability Advisory Panel of Merck KGaA, Darmstadt, Germany (**MSAP**) consists of six independent international experts

on sustainability-related topics. They advise the company on selected issues and assess their sustainability aspects as well as the company's planned activities.

Topics for the non-financial statement

Pursuant to section 289c para 3 of the German Commercial Code, we are obligated to review topics for their "double materiality". The principle of double materiality requires companies to disclose non-financial information as soon as the following two criteria are met: Firstly, the information makes it possible to understand how the company's business activities affect non-financial aspects. And secondly, the information is necessary to understand the company's course of business, results of operations and economic position. In 2021, we examined the topics identified within the scope of a **materiality analysis** in accordance with the Global Reporting Initiative standards (GRI) for their double materiality.

The following topics achieved the relevance threshold for double materiality in 2021. They cover fiscal 2021 and pertain to our entire Group, including its 227 companies in 66 countries. Any deviations from the reporting framework are indicated on a case-by-case basis.

Aspect	Topic
Environmental matters	• Environmental management • Climate action • Plant, process and transport safety • Chemical product safety
Employee-related matters	• Recruiting and retaining talent • Diversity and inclusion • Health and safety
Social matters	• Sustainable supply chains (including the mica supply chain) • Patient safety • Product-related crime • Prices of medicines • Clinical studies • Bioethics • Digital ethics • Data protection and security
Respect for human rights	• Human rights
Anti-corruption and anti-bribery	• Governance and compliance (including anti-corruption anti-competitive behavior) • Responsible marketing • Interactions with health systems
Other topics	• Sustainable innovation and research & development

As part of our approach to comprehensive risk and opportunity management, we also identify current and potential risks and opportunities resulting from environmental, social and governance aspects. This includes tracking information on the gross risks in terms of potential damage and probability, as well as the residual net risks remaining after mitigation measures have been executed. We did not identify any net risks that fulfill the materiality criteria as set forth by section 289c (3) no. 3 and 4 of the German Commercial Code. Additional risks are described in the **Report on Risks and Opportunities** in the combined management report.

Environmental matters

Environmental stewardship

Minimizing negative environmental impacts and taking meaningful climate action requires a holistic approach while also constantly monitoring practices and performance. Our goal is to avoid harmful emissions into the air, water, and soil as far as possible. Our production sites are located in established industrial and commercial zones. Before acquiring a company – and thus its facilities – we first conduct an environmental risk assessment, taking into consideration information from publicly accessible sources such as local residents and non-governmental organizations (NGOs).

Roles and responsibilities

The Chair of the Executive Board and CEO of our company responsible for environmental stewardship, which also covers climate action, water management, waste and recycling, biodiversity, and plant and process safety. Her duties include the approval of overarching Group-wide guidelines, such as our EHS Policy.

The Group function Corporate Sustainability, Quality, and Trade Compliance is responsible for steering all the related measures globally. SQ senior leadership approves operational standards and regularly reports on environmental stewardship to the Executive Board. Every year, SQ prepares an environment, health and safety report that covers topics such as climate action, water management, waste and recycling, and plant and process safety. The Executive Board uses this report to steer the strategic direction and as verification for our ISO 14001 certifications.

Within our business sectors, the Operations Leadership Committee (OLC) makes strategic decisions on issues pertaining to emissions, energy, water and waste topics. This body consists of representatives from Life Science, Healthcare, and Electronics, as well as from SQ. Decisions made by the OLC and any resulting actions are implemented by the respective business sector. Once per quarter, the OLC members update their leaders on matters relating to environmental stewardship.

Our commitment: Standards and standard operating procedures

Our approach to environmental management is founded on our Group **EHS (Environment, Health and Safety) Policy**, which has been approved by our Executive Board. Aligned with the requirements of the chemical industry's **Responsible Care® Global Charter** and the ISO 14001 environmental management standard, this policy underscores our leaders' responsibility for environmental stewardship and health and safety. It is also aimed at our suppliers, calling on them to likewise adopt higher standards of environmental sustainability and safety. Our EHS policy thus complements the **Responsible Sourcing Principles** of our Group Procurement function. In addition, through our Contractor EHS Management Standard, we ensure that our contract partners also take environment, health and safety aspects into account.

Potential EHS risks posed by acquisitions, divestments or site closures are assessed within the scope of due diligence, a process defined in our EHS Due Diligence and Post Merger Transaction Standard. We prioritize new sites when performing audits.

Material investments in environmental impact mitigation

Efforts to prevent and monitor air, water and soil emissions entail significant expense on our part, as does proper waste disposal. Moreover, we set up provisions for groundwater and soil remediation to ensure that we can execute all the necessary measures. As of December 31, 2021, our **provisions for environmental protection** totaled € 153 million, 94% of which was attributable to Merck KGaA, Darmstadt, Germany.

Assessing environmental impacts

As a matter of principle, we conduct risk-based assessments along with audits on all our production facilities every three years with the goal of analyzing and minimizing our environmental footprint. Conducted by Corporate Sustainability, Quality, and Trade Compliance (SQ), these assessments serve to ensure that our requirements are being met, with appropriate corrective measures being implemented as needed. In our Group EHS audits, we assess our sites' performance on a five-tier scale ("excellent", "good", "satisfactory", "poor", and "critical"), which in turn determines how frequently audits are conducted. If the findings are deemed to be good, we audit the facility less often, while significant violations can increase the frequency. In 2021, we commissioned a total of 51 audits, which were conducted either virtually or on site (in 2020, only 10 audits were conducted because of Covid-19). All audited sites received either a "good" or "satisfactory" rating and no site was rated as "critical".

Reporting incidents and violations

To review critical situations, near misses and environmental incidents as quickly as possible and take countermeasures, we have a set of reporting procedures in place that allow us to track the respective incident, its degree of severity and all risk mitigation efforts. We record all incidents Group-wide and report them to the Executive Board on an annual basis.

In the event of a major occurrence, our digital Rapid Incident Report System (RIRS) promptly notifies the Executive Board as well as SQ and Group Communications functions. Major incidents could include fatalities, accidents with multiple casualties, incidents that impact neighboring communities, or natural disasters such as earthquakes and flooding. Through the RIRS, we can quickly coordinate with all those involved and inform the other sites immediately of the respective event. In addition, employees can report any violations of our standards to Group Compliance. As in 2020, we recorded no significant violations of environmental laws or regulations Group-wide in 2021.

ISO 14001:2015 Group certificate

Since 2009, our company has held an ISO 14001 Group certificate that requires all production sites with more than 50 employees to implement an environmental management system with predefined indicators such as greenhouse gas emissions and water consumption. Other facilities are not obligated to undergo certification. The annual internal audit reports and management reviews carried out under the Group certificate give us a better overview of how all our sites are performing. In 2021, 90 of our sites worldwide were covered by the **ISO 14001** certificate.

Every year, we contract a third party to perform a certification audit. In 2021, a sampling of eight sites underwent an audit for our Group certificate, with all audited facilities passing. Beyond undergoing external inspections, we also conduct internal audits to ensure Group-wide compliance with our requirements.

Climate action

We want to do our part to preserve the climate and achieve the Paris Agreement on Climate Change. In 2020, we drew up new objectives: By 2030, we intend to lower our direct (Scope 1) and indirect (Scope 2) greenhouse gas emissions by 50% compared with 2020. This is to be achieved by reducing process-related emissions, implementing energy efficiency measures, and purchasing more electricity from renewable sources. We are also aiming to cover 80% of our purchased electricity with renewables by 2030.

Moreover, we plan to lower our indirect emissions along our entire value chain (Scope 3) by 1,500 metric kilotons of CO_2 equivalents (CO_2eq) by 2030. By 2040, we intend to have achieved climate-neutral operations throughout our entire value chain, a target that covers our Scope 1, 2 and 3 emissions.

In November 2021, our company decided to join the Science Based Targets initiative. In becoming part of this effort, we have committed ourselves to taking concrete steps to reach the Paris Agreement targets.

Roles and responsibilities

Corporate Sustainability, Quality, and Trade Compliance is responsible for overseeing all climate action efforts throughout the Group, with our individual sites and business units worldwide implementing the necessary measures at the local level.

Our commitment: Standards and legal frameworks

We have three EHS standards in place to manage energy and process-related emissions consistently across the Group, specifically “Energy Management”, “Emissions”, and “Emissions of Refrigerants”. We utilize an internal audit process to randomly check compliance with all EHS standards.

Emissions reduced

In 2021, we emitted approximately 1,843,000 metric tons of CO_2 equivalents (CO_2eq) (2020: 2,028,000 metric tons). Our direct emissions (Scope 1) totaled 1,522,000 metric tons of CO_2eq, with process-related emissions accounting for 1,261,000 metric tons of CO_2eq and fuel use accounting for the remainder. Indirect emissions (Scope 2) totaled roughly 321,000 metric tons calculated according to the market-based method (approximately 385,000 metric tons according to the location-based method, which does not specifically take renewable energy sources into account). Greenhouse gas emission intensity (Scope 1 and 2) amounted to 0.09 kg of CO_2eq per € of net sales in this period.

In 2020 and 2021, we focused on creating more transparency on our Scope 3 emissions. The Greenhouse Gas Protocol defines 15 categories for Scope 3 emissions from upstream and downstream activities. In 2021, our emissions totaled 5,716,000 metric tons of CO_2eq. Categories 1 and 2 (Purchased Goods and Services and Capital Goods) accounted for the lion's share, representing 68% of our total Scope 3 emissions in this period.

Total greenhouse gas emissions (Scope 1 and 2 of the GHG Protocol)[1,2]

metric kilotons	2018	2019	2020[3]	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total CO_2eq[4] emissions	**636**	**621**	**2,028**	**1,843**	**153**
thereof:					
direct CO_2eq emissions (Scope 1)	332	341	1,706	1,522	115
indirect CO_2eq emissions[5] (Scope 2)	304	280	322	321	38
Biogenic CO_2 emissions	**13**	**13**	**13**	**15**	**0**

[1] In line with the Greenhouse Gas Protocol, for all previous years greenhouse gas emissions were calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

[2] Baseline for our emission targets is 2020.

[3] Includes Versum Materials as of 2020.

[4] eq = equivalent

[5] The figures presented here have been calculated in accordance with the market-based method.

We have included the following gases in our calculation of direct and indirect CO_2eq emissions:
Direct CO_2 emissions: CO_2, HFCs, PFCs, CH_4, N_2O, NF_3, SF_6.
Indirect CO_2 emissions: CO_2.

Other relevant indirect greenhouse gas emissions (Scope 3 of the GHG Protocol)[1]

	2018	2019	2020	**2021**
Total gross other indirect emissions (metric kilotons CO_2eq[2])	**348**	**339**	**5,030**	**5,716**
Purchased goods & services (category 1)[3]	n/a	n/a	3,040	3,572
Capital goods (Category 2)[3]	n/a	n/a	293	291
Fuel- and energy-related emissions, not included in Scope 1 or 2 (category 3)	131	127	102	143
Upstream transportation & distribution (category 4)[4]	n/a	n/a	264	264[5]
Waste generated in operations (category 5)	47	50	85	79
Business travel (category 6)[6,7]	104	87	32	26
Employee commuting (category 7)	66	75	90	94
Upstream leased assets (category 8)[8]	0	0	0	0
Downstream transportation & distribution (category 9)[4]	n/a	n/a	8	8[5]
Processing of sold products (category 10)[9]	0	0	0	0
Use of sold products (category 11)[4]	n/a	n/a	1,091	1,213
End-of-life treatment of sold products (category 12)[4]	n/a	n/a	23	23[5]
Downstream leased assets (category 13)	0	0	2	2
Franchises (category 14)[10]	0	0	0	0
Investments (category 15)	n/a	n/a	0	1

[1] In line with the Greenhouse Gas Protocol, for all previous years greenhouse gas emissions were calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

[2] eq = equivalent

[3] The reported figures contain 95-97% of our total spend. The difference stems from smaller sites that are not integrated in our Group-wide purchase volume data. 2020 data are slightly over-reported (approx. 3%) as the currency conversion factor (USD to EUR) from 2021 was used. Non-categorized spends are distributed pro rate to category 1 and 2.

[4] Compared to other Scope 3 categories, the screening of the emissions in this category contains more uncertainties. Their impact cannot be estimated more precisely at this time. We are working on improving the accuracy of these data.

[5] Due to high efforts for data preparation, we reference 2020 data for 2021.

[6] Since 2021, we have applied a new calculation approach for 2021 and 2020. The figure for 2020 was therefore adjusted retrospectively.

[7] Air travel, hotel stays, rental car travels, rail travel (German Railway)

[8] Already covered under Scope 1 and 2 emissions

[9] Our company produces a huge variety of intermediate products for various purposes. Due to their many applications and our customer structure, the associated greenhouse gas emissions cannot be tracked in a reasonable fashion.

[10] This category is not relevant for us as we do not operate franchises, i.e. businesses operating under a license to sell or distribute another company's goods or services. Out-licensing in the pharmaceutical sector is not regarded as franchising.

Biogenic emissions (Scope 3), if present, are not being recorded.
Details on the calculation (methodology, assumptions, uncertainties) of the Scope 3 categories can be found in the **Scope 3 document**.

Significant spills

	2018	2019	2020	**2021**
Total number of significant spills	0	0	0	0

Energy efficiency

In 2021, a variety of energy efficiency initiatives helped us save around 1,700 metric tons of CO_2eq at our global headquarters in Darmstadt. For instance, we updated heating, ventilation and air conditioning systems, implemented energy-saving lighting concepts.

As part of the energy and water efficiency program of our Life Science business sector, we rolled out new tools in 2021 to help us assess projects for saving energy and water. In addition, we trained 40 employees from sites outside of Germany on energy management.

Slight rise in energy consumption

We consumed 2,454 gigawatt hours of energy in 2021, versus 2,374 gigawatt hours in 2020. Our energy intensity relative to sales totaled 0.12 kWh/€ in 2021.

Energy consumption[1]

In GWh	2018	2019	2020	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total energy consumption	**2,158**	**2,178**	**2,374**	**2,454**	**628**
Direct energy consumption	**1,261**	**1,288**	**1,266**	**1,318**	**564**
Natural gas	1,194	1,222	1,179	1,232	556
Liquid fossil fuels[2]	33	33	52	48	8
Biomass and self-generated renewable energy	34	33	35	38	0
Indirect energy consumption	**897**	**890**	**1,108**	**1,136**	**64**
Electricity	749	745	945	958	64
Steam, heat, cold	148	145	163	178	0
Total energy sold	**0.0**	**0.1**	**0.2**	**0.1**	**0.0**
Electricity	0.0	0.1	0.2	0.1	0.0
Steam, heat, cold	0.0	0.0	0.0	0.0	0.0

In TJ					
Total energy consumption	**7,770**	**7,839**	**8,546**	**8,834**	**2,261**
Direct energy consumption	**4,541**	**4,637**	**4,558**	**4,745**	**2,030**
Natural gas	4,298	4,399	4,244	4,435	2,002
Liquid fossil fuels[2]	119	119	187	173	29
Biomass and self-generated renewable energy	124	119	126	137	0
Indirect energy consumption	**3,229**	**3,202**	**3,989**	**4,090**	**230**
Electricity	2,696	2,682	3,402	3,449	230
Steam, heat, cold	533	520	587	641	0
Total energy sold	**0.0**	**0.5**	**0.7**	**0.4**	**0.0**
Electricity	0.0	0.5	0.7	0.4	0.0
Steam, heat, cold	0.0	0.0	0.0	0.0	0.0

[1] In line with the Greenhouse Gas Protocol, for all previous years energy consumption has been calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

[2] Light and heavy fuel oil, liquefied petroleum gas (LPG), diesel, biodiesel, gasoline and kerosene

At 15 sites we use photovoltaics to produce power.

We currently only record purchased secondary energy – this is primarily electricity and, to a lesser extent, heat/steam/cold. Details on the local energy mix, including the respective percentage of primary energy, renewable energy, etc. are not available. Data on local energy efficiency in electricity or heat generation are not available either. Our production sites are located in countries with a widely varying energy mix.

In 2021, we increased our focus on purchasing electricity from renewable sources. In this period, we sourced 30% of our purchased electricity from renewable energies (2020: 27%). Renewables represented 13% of our total energy consumption.

Plant, process and transport safety

We seek to minimize manufacturing process hazards wherever possible in order to avoid workplace accidents, production outages, and chemical spills, which is why we regularly review our approach to plant and process safety and continuously gauge it using our EHS performance indicators.

Moreover, all our shipments are to reach our customers and sites safely, undamaged and with the required safety information. Several of the materials we store and transport are classified as hazardous. The storage of such dangerous goods and the transport thereof – whether by road, rail, air, or water – are governed by global regulations. To minimize risks to people and the environment, we apply strict safety requirements across the Group that also comply with applicable laws. We conduct regular reviews to ensure our own warehouses as well as those of third parties comply with these regulations.

Roles and responsibilities

Overriding responsibility for plant, process and transport safety lies with Corporate Sustainability, Quality and Trade Compliance (SQ), which coordinates plant and process safety for the company and defines Group-wide EHS standards and regulations.

Our commitment: Internal standards and international rules

To ensure safe operation throughout the lifetime of a plant, our Group-wide EHS standards contain specific rules for production plants and processes. These include specifications that determine how special risk analyses and hazard assessments are to be carried out. We have also defined measures for the event of accidental release of chemical substances and for fire protection.

Our Group-wide EHS standards stipulate the safety levels for the storage of hazardous materials at our sites. Along with supplementary standard operating procedures and best practice documents, these EHS standards describe the technology, equipment and organizational infrastructure needed to achieve the appropriate safety levels. Contract warehouses must also adhere to our strict safety requirements. Before we sign a contract with an operator, they must submit a statement detailing how they meet our prerequisites. Our Group-wide EHS standards also define the technical and organizational requirements for such warehouses.

Our Group Transport Safety Standard is based on the United Nations Recommendations on the Transport of Dangerous Goods. This guideline is especially important for sites in countries with insufficient local regulations covering the transport of hazardous materials.

Assessing potential risks

Before commissioning a plant, we draft a safety concept and that is subject to continuous review throughout the entire lifetime of the facility and, when necessary, updated until the facility is decommissioned. This safety concept contains an overview of potential risks and specifies corresponding protective measures. After any alterations are made to a plant, we also reassess the hazard and risk situation.

Our Risk Management Process guides all our sites in identifying and assessing risks and is used to devise further measures to minimize them.

We use internal EHS audits to complement the inspections conducted by our EHS and dangerous goods managers in order to ensure that our sites comply with process, plant, transport, and storage safety regulations. Normally, these audits are conducted every three years at productions sites and every four years at warehouse and distribution sites. If major shortcomings are identified, we re-audit the site the following year. Conversely, we may decide to extend the period between audits at facilities where, based on the findings from previous audits, we deem the potential risk to be low. Our sites are required to rectify any deficiencies discovered during the audit, with the auditor subsequently checking whether the specified corrective actions have been taken.

In 2021, we conducted 51 EHS audits in accordance with our Group-wide EHS standards. Our own warehouse locations accounted for 19 of these audits and interfaces to third-party warehouses for a further 7. Due to the Covid-19 situation, all audits were conducted remotely.

Keeping a close eye on safety

We track EHS performance indicators at all production and warehouse facilities, as well as at major research sites, including both accidents and near misses. We investigate each individual incident and then devise appropriate countermeasures in an effort to reduce the likelihood of such events reoccurring in the future. EHS performance indicator data are reported once a month within each business sector, with the Executive Board receiving reports on the topic once a year. Four indicators are particularly important to us here:

- Under our EHS Incident Rate (EHS IR), we track and evaluate all major and minor accidents and incidents as well as further EHS-relevant incidents. The EHS IR covers both our own employees as well as those of contractors. To calculate it, we put the number of incidents and the severity of the event in proportion to the number of hours worked. The lower the EHS Incident Rate, the safer the site is. Our EHR IR in 2021 was 3.9 (2020: 3.4).
- The EHS IR also includes our Loss of Primary Containment (LoPC) indicator. In 2021, we recorded no significant incident-related spills at any of our production, research or warehouse sites Group-wide.
- A further important indicator is the EHS Leading Rate (EHS LR), which reflects the number and the results of the analyses of near misses and critical situations. Some of our individual business sectors have also defined their own annual targets for EHS IR and EHS LR.
- In 2021, we set ourselves a new goal for the Lost Time Injury Rate (LTIR) (number of accidents Group-wide resulting in at least one missed day of work per million hours worked). We aim to bring our LTIR below 1.0 Group-wide by 2025. In 2021, our LTIR was 1.2 (2020: 1.3).

Chemical product safety

Product safety is one of our top priorities. Starting at the product launch stage, we investigate the potential adverse impacts that chemical substances may have. Along the entire value chain of our products – from raw materials to manufacture and commercialization – we provide relevant information on their hazardous properties and how to deal with them. These instructions facilitate the safe handling and use of our products in line with all regulatory requirements. We publish this information primarily on the relevant digital channels. Paper safety data sheets are still common in some countries and we can also provide these upon request through our customer service.

Roles and responsibilities

Our Life Science, Healthcare, and Electronics business sectors have organizational structures in place to implement our product safety strategy taking into account respective businesses requirements and customer needs. This approach includes registering chemicals, classifying hazardous substances and highlighting risks via the use of safety data sheets, labels, and digital communications.

Our Group standards provide a framework for governing the setup of effective operational processes for product safety, hazard communication and chemicals regulatory compliance throughout our business sectors. Our Group Chemicals Regulations Council monitors relevant regulatory developments.

This approach also applies to innovative fields of development such as nanomaterials, which we use with the greatest care in line with the precautionary principle. Furthermore, our Group-wide **Policy for Use and Handling of Nanomaterials** provides the necessary guidance on the use of these materials.

Legal requirements and internal guidelines

Our internal guidelines define the roles, responsibilities, and basic processes required to comply with national and international regulations. In addition, we have also endorsed general voluntary commitments of the chemical industry such as the **Responsible Care® Global Charter**. Using the **Globally Harmonized System** for Classification and Labelling of Chemicals (GHS) for hazard communication allows us to streamline our internal processes and provide consistent, harmonized, and high-quality information to our customers

In 2021, there were no incidents of non-compliance with regulations, specifically concerning potential health and safety impacts and the labeling of our chemical products.

Safety analysis during product launch

Safe and sustainable by design implies that product safety starts with development. Therefore, at an early stage in our product launch process, we analyze innovations in terms of their impacts on human health and the environment. We also evaluate the intrinsic hazards of both our existing and new products to create relevant product safety information in line with all applicable rules.

Product safety information

Chemical product safety is all about protecting human health and the environment from adverse impacts resulting from the use of chemical products throughout their life cycle. To achieve this, we provide all relevant information to our customers and the public, which helps raise awareness of the hazards and build a greater understanding of how to mitigate risks and use the products safely.

To obtain all the relevant information on hazard profiles, we use industry-standard digital tools that gather all information available on the substances we use.

Employee-related matters

Attracting and retaining talent

We believe that curiosity can make great things happen. Therefore, we aim to provide an environment that gives our employees plenty of scope for creativity and sparks their desire to innovate. Our **employer brand** communicates this mindset to the outside world. Through our slogan “Bring Your Curiosity to Life”, we show applicants what they can expect and what they can contribute when they join our company.

Diversity, equity and inclusion are integrated in our attraction and selection activities. We train our recruiters to avoid unconscious bias during interviews and ensure that all new employer branding campaigns follow diversity criteria.

In 2021, we started using a new technology to support gender-neutral language, for example when creating job advertisements. Additionally, we included a dedicated “diversity” section in our interview guide, helping hiring managers to keep inclusivity top-of-mind.

We work across countries to understand cultural norms that allow our colleagues to bring their best selves to work. Attracting applicants with diverse backgrounds remains a top priority for us because we believe this gives us a competitive advantage as we expand our employee base.

Total number of employees[1]

As of Dec. 31	2018	2019	2020	**2021 Group**	**2021 thereof: Merck KGaA, Darmstadt, Germany**
Total number of employees	51,749	57,071	58,127	60,348	8,081
Men	29,006	32,531	33,204	34,274	5,292
Women	22,743	24,540	24,923	26,074	2,789

[1] The Group also has employees at sites that are not fully consolidated subsidiaries. These figures refer to all people directly employed by the Group and therefore may deviate from figures in the financial section of this report.

Employee age by region

As of Dec. 31

Number of employees	Worldwide	North America	Europe (including Germany)	Merck KGaA, Darmstadt, Germany	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
2020							
Up to 29 years old	8,570	1,906	3,193	1,161	2,800	472	199
thereof: women	4,018	825	1,525	420	1,307	260	101
30 to 49 years old	34,974	6,615	15,416	4,458	9,669	2,323	951
thereof: women	15,268	2,841	7,076	1,505	3,776	1,161	414
50 or older	14,583	4,791	7,978	2,959	1,049	592	173
thereof: women	5,637	1,861	3,142	839	342	209	83
Average age	**41.7**	**44.4**	**43.1**	**43.4**	**37.0**	**40.7**	**39.1**
Total employees	**58,127**	**13,312**	**26,587**	**8,578**	**13,518**	**3,387**	**1,323**
2021							
Up to 29 years old	9,129	2,219	3,341	1,125	2,912	482	175
thereof: women	4,359	961	1,598	415	1,437	265	98
30 to 49 years old	36,157	6,939	15,653	4,288	10,260	2,404	901
thereof: women	15,888	2,958	7,224	1,550	4,081	1,225	400
50 or older	15,062	4,912	8,223	2,668	1,113	643	171
thereof: women	5,827	1,881	3,276	824	356	231	83
Average age	**41.6**	**43.9**	**43.1**	**43.1**	**37.1**	**40.8**	**39.7**
Total employees	**60,348**	**14,070**	**27,217**	**8,081**	**14,285**	**3,529**	**1,247**

Internationality of employees

As of Dec. 31	2018[1]	2019[2]	2020	**2021 Group**	**2021 thereof: Merck KGaA, Darmstadt, Germany**
Number of nationalities	136	139	141	142	89
Number of nationalities in management positions (Role 4 or above)	70	73	75	79	39
% of non-Germans in management positions (Role 4 or above)	64	64	66	66	13

[1] In 2018, the position assessment had not yet been carried out for employees of all Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma.

[2] In 2019, the position assessment had not yet been carried out for employees of Versum Materials as well as of Allergopharma.

New employees

As of Dec. 31	2018	2019[1]	2020	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total number of new employee hires	**7,129**	**7,924**	**6,669**	**8,960**	**504**
by age group					
up to 29 years old	2,967	3,432	2,889	3,679	263
30 to 49 years old	3,728	4,055	3,347	4,610	225
50 or older	434	437	433	671	16
by gender					
Women	3,401	3,622	3,016	4,101	215
Men	3,728	4,302	3,653	4,859	289
by region					
Europe	2,560	2,529	2,160	2,567	504
North America	1,524	1,733	1,789	2,855	not applicable
Asia-Pacific (APAC)	2,222	2,729	2,206	2,803	not applicable
Latin America	583	578	396	579	not applicable
Middle East and Africa (MEA)	240	355	118	156	not applicable
Rate of new employee hires[2] (%)	**14**	**14**	**11**	**15**	**6**
by age group[3]					
up to 29 years old	42	43	43	41	52
30 to 49 years old	52	51	50	51	45
50 or older	6	6	7	8	3
by gender[3]					
Women	48	46	45	46	43
Men	52	54	55	54	57
by region[3]					
Europe	36	32	32	29	100
North America	21	22	27	32	not applicable
Asia-Pacific (APAC)	31	34	33	31	not applicable
Latin America	8	7	6	6	not applicable
Middle East and Africa (MEA)	3	5	2	2	not applicable

[1] These figures exclude the approximately 2,400 Versum Materials and Intermolecular employees who are not classified as new hires because they joined the Group as part of the acquisitions.

[2] Formula for calculating the rate of new employee hires: Total number of new employee hires divided by number of employees at the end of the fiscal year.

[3] Formula for calculating the rate of new employee hires by age/gender/region: New employee hires of the focus group divided by the total number of new employee hires.

Staff turnover[1,2]

	2018	2019	2020[3]	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total turnover rate	**9.09**	**9.07**	**8.22**	**10.82**	**2.37**
Turnover rate by gender					
Men	9.03	8.69	8.22	10.69	2.45
Women	9.18	9.54	8.22	11.00	2.22
Turnover rate by age group					
Up to 29 years old	14.24	13.13	11.30	16.64	2.59
30 to 49 years old	8.53	8.90	7.74	10.05	1.95
50 or older	7.39	7.03	7.52	9.22	2.95
Turnover rate by region					
Europe	5.73	5.72	5.64	6.00	2.37
North America	9.90	11.02	9.79	15.44	not applicable
Asia-Pacific (APAC)	14.51	13.18	10.60	14.66	not applicable
Latin America	15.41	13.47	11.40	12.95	not applicable
Middle East and Africa (MEA)	9.77	12.14	11.80	16.57	not applicable
Total number of leavers	**4,613**	**4,863**	**4,721**	**6,354**	**201**
by gender					
Men	2,578	2,621	2,697	3,575	139
Women	2,035	2,242	2,024	2,779	62
by age group					
Up to 29 years old	1,061	1,042	974	1,451	30
30 to 49 years old	2,649	2,898	2,677	3,545	86
50 or older	903	923	1,070	1,358	85
by region					
Europe	1,457	1,500	1,490	1,601	201
North America	1,064	1,264	1,281	2,078	not applicable
Asia-Pacific (APAC)	1,468	1,484	1,394	2,015	not applicable
Latin America	522	459	398	449	not applicable
Middle East and Africa (MEA)	102	156	158	211	not applicable

[1] The table contains unadjusted turnover rates. The rate excludes employees who pause due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

[2] The employee turnover rate is calculated as follows: Total number of leavers from the past 12 months divided by the average employee headcount multiplied by 100.

[3] The figures do not reflect the approximately 500 Allergopharma employees, who were not included in the employee turnover rate due to the divestment of the business.

In 2021, the average length of service for employees Group-wide was 9.5 years (2020: 9.6 years), with 15.7 years (2020: 16.2 years) for employees of Merck KGaA, Darmstadt, Germany.

Roles and responsibilities

The Human Resources (HR) department is responsible for advising all business sectors and Group functions on matters concerning our human capital. The HR team addresses the needs of our employees, organizational topics, and company culture. Across all our sites, HR employees work together with leaders from various functions and business sectors to employ strategies to engage our people in line with Group-wide HR guidelines and requirements, including attractive compensation models and benefits. Every two to three years, we carry out internal audits to check that the guidelines are being implemented.

The Chair of the Executive Board and CEO is responsible for Group Human Resources. Our Chief HR Officer, who leads the HR function and oversees all our HR activities, including Diversity, Equity & Inclusion (DE&I), reports directly to her. Our Business Services unit oversees the operational tasks of human resources work, such as drafting contracts and payroll accounting. The Chief Financial Officer has responsibility for this unit.

The Engagement and Inclusion unit within our HR organization is responsible for employee engagement, diversity, equity, and inclusion and also develops and manages our employee surveys.

Our commitment: Group-wide policies and guidelines

We are dedicated to upholding the appropriate and fair labor and social standards stipulated in our Group-wide **Social and Labor Standards Policy**. It complements the provisions of our **Human Rights Charter** and our **Code of Conduct** with respect to labor and social standards. These include the fundamental Conventions of the **International Labour Organization** (ILO), which cover freedom of association and collective bargaining, forced labor, child labor, anti-discrimination, equal opportunity, equal pay, working hours, occupational health and safety, and the prevention of abuse and harassment. The Social and Labor Standards Policy outlines that we do not tolerate any form of discrimination, physical or verbal harassment or intolerance in the workplace. In this way, it creates the framework for fair and respectful interaction. We conduct internal audits to ensure that our local subsidiaries comply with these principles.

Performance-based pay and social benefits

To ensure a competitive compensation structure, we regularly review our compensation policy based on data analyses and benchmarks. In doing so, we take internal factors and market requirements equally into account. Before adapting our compensation structure, we consult with key stakeholders, such as employee representatives. The pay structures within our company are based on defined criteria, such as job requirements and performance. We make no distinctions based on gender or other diversity criteria.

Diversity, equity and inclusion

At our company, diversity drives progress. It strengthens our ability to innovate and contributes to our success in science and technology. We encourage employees, patients and customers to be their individual, curious and unique selves. The more diverse our people, the better we can succeed in business while making a difference in people's lives.

In 2021, we strengthened and expanded our commitment to diversity. While we have always been a diverse organization – today spanning 66 countries, with more than 60,000 employees – we recognize that the success of our organization depends on our ability to foster an environment that promotes equity and cultivates inclusion.

Together, we are building one culture in which we care about one another and are solidifying a sense of belonging for all so that our different voices are heard to drive better business outcomes. Ultimately, we are creating opportunity and enabling advancement for employees around the globe.

To reflect our expanded DE&I commitment, we are focused on three critical priority areas:

Gender

We are aiming for gender parity in leadership positions by 2030. In 2021, we increased the share of women in leadership roles to 36% (2020: 35%) and maintained a stable 43% proportion of women in the global workforce.

Culture and ethnicity

By 2030, we plan to increase the proportion of colleagues who are members of underrepresented racial and ethnic groups in our United States leadership teams from 21% to 30%. We continue to pursue self-identification efforts to help us further understand our organizational structure in regard to culture and ethnic representation.

With 23% of our employees based in the United States, it is crucial that we become an employer of choice among racial and ethnic minorities in this market. We continually listen and learn from our colleagues in the market to ensure our workforce reflects the talent currently available in the marketplace.

Additionally, due to our current performance and future growth in Asia, Latin America and the Middle East and Africa (MEA), accounting for 40% of our Group sales, we aim to increase the global share of nationals from Asia, Latin America, and MEA in leadership positions from 16% to 30% by 2030.

Inclusion

For us, inclusion means creating a culture and environment where everyone can reach their full potential and is able to add value. Our leaders are key to achieving this. In 2021, we began rolling out a Group-wide program to help leaders reflect on how they can lead more inclusively. All leaders, including new ones, are required to actively participate. In the reporting period, 37% of our leaders participated in this inclusion training. We also monitor progress using our Employee Engagement Survey inclusion score. Additionally, countries and sectors can focus on further diversity dimensions such as LGBTQI+, different abilities, age diversity, or veteran/military status.

A cornerstone of our DE&I strategy is to foster an inclusive culture in partnership with over 40 employee resource groups (ERGs) across the globe. With nearly 4,500 employees involved in one or more ERGs, we are able to build awareness of matters impacting our diverse workforce through programs and open dialogue. Our ERGs range from Women in Leadership to our Black Leaders Network and our Leaders of Ethnicity Allies and Faith.

Number of employees by hierarchical level[1]

As of Dec. 31	2018[2]	2019[3]	2020	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total employees	**51,749**	**57,071**	**58,127**	**60,348**	**8,081**
Senior management (Role 6+)	193	190	193	194	70
Middle management (Role 4 & 5)	3,095	3,352	3,637	3,831	824
Low management (Role 3)	9,019	9,499	10,286	10,880	2,077
Other employees (below Role 3)	39,442	44,030	44,011	45,443	5,110
% of women (total)	**44**	**43**	**43**	**43**	**35**
thereof: in senior management (Role 6+)	36	39	42	49	18
thereof: in middle management (Role 4 & 5)	1,025	1,146	1,284	1,413	257
thereof: in low management (Role 3)	3,795	4,029	4,352	4,669	773
thereof: other employees (below Role 3)	17,888	19,326	19,245	19,943	1,741
% of men (total)	**56**	**57**	**57**	**57**	**65**
thereof: in senior management (Role 6+)	157	151	151	145	52
thereof: in middle management (Role 4 & 5)	2,070	2,206	2,353	2,418	567
thereof: in low management (Role 3)	5,224	5,470	5,934	6,211	1,304
thereof: other employees (below Role 3)	21,554	24,704	24,766	25,500	3,369
by age group					
Up to 29 years old (%)	**15**	**15**	**15**	**15**	**14**
thereof: in senior management (Role 6+)	0	0	0	0	0
thereof: in middle management (Role 4 & 5)	5	8	6	8	2
thereof: in low management (Role 3)	211	190	199	241	65
thereof: other employees (below Role 3)	7,279	8,362	8,365	8,880	1,058
30 to 49 years old (%)	**61**	**60**	**60**	**60**	**53**
thereof: in senior management (Role 6+)	69	69	68	63	25
thereof: in middle management (Role 4 & 5)	1,829	1,933	2,032	2,172	512
thereof: in low management (Role 3)	6,206	6,516	6,926	7,298	1,336
thereof: other employees (below Role 3)	23,536	25,859	25,948	26,624	2,415
50 years or older (%)	**24**	**25**	**25**	**25**	**33**
thereof: in senior management (Role 6+)	124	121	125	131	45
thereof: in middle management (Role 4 & 5)	1,261	1,411	1,599	1,651	310
thereof: in low management (Role 3)	2,602	2,793	3,161	3,341	676
thereof: other employees (below Role 3)	8,627	9,809	9,698	9,939	1,637

[1] The Group also has employees at sites that are not fully consolidated subsidiaries. These figures refer to all people directly employed by the Group and therefore may deviate from figures in the financial section of this report.

[2] In 2018, the position assessment had not yet been carried out for employees of all Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. In the facts and figures, these employees are included under “other employees (below Role 3)”.

[3] In 2019, the position assessment had not yet been carried out for employees of Versum Materials as well as of Allergopharma. In the figures, employees whose positions have not been assessed have been allocated to “other employees (below Role 3)”.

Roles and responsibilities

Our Chief Diversity, Equity and Inclusion Officer is responsible for our global Diversity, Equity and Inclusion (DE&I) strategy and steering related activities. In this role, she reports directly to the Chair of the Executive Board, whose responsibilities include Group Human Resources.

We have a centralized Diversity Council that consists of high-ranking executives from all our business sectors and select Group functions. In addition, all business sectors and major Group functions have various working groups at management level that implement the Diversity, Equity and Inclusion strategy in their area of responsibility.

Our commitment: Industry-wide initiatives and regulations

Our **Social and Labor Standards Policy** spells out that we do not tolerate any form of discrimination, physical or verbal harassment, or intolerance. To underscore our commitment to equality, fairness, inclusion, and tolerance in the workplace, we also participate in industry-wide initiatives

Meeting statutory requirements

The German Law for the Equal Participation of Women and Men in Leadership Positions in the Public and Private Sector has been in effect in Germany since 2015. Owing to our legal form as a KGaA (corporation with general partners), this law also applies in part to us.

With a 37.5% share of women (six out of 16 members), our Supervisory Board already meets the stipulations of German gender quota legislation. As a KGaA, we are not required to set targets for our Executive Board. Our Executive Board currently has a 20% share of women (1 out of 5). Detailed information can be found in the **Statement on Corporate Governance**.

Rooting out unconscious bias

We seek to raise awareness of unconscious bias among our managers and employees, also through Group-wide training courses on this topic. Since 2021, we have been using new technologies in the context of recruitment in order to support the use of gender-neutral language, for example when creating job advertisements. This is intended to reduce unconscious bias in the hiring process and ensures that our job advertisements are attractive to diverse talent.

Pay Equity Analysis

Our commitment to pay equity is an important aspect of our DE&I strategy. In order to create transparency on unexplained pay gaps and their underlying root causes, we conducted a pay equity analysis in 2021. In this first step, we analyzed our top ten countries covering roughly 80% of our employees. The focus of the analysis was on pay gaps based on gender. The detailed data analysis had not yet been completed at the end of 2021. Based on the initial findings, we continue to create a detailed action plan and work on business alignment to ensure fair pay for all our employees.

Taking action against discrimination

We do not tolerate any kind of discrimination at our company. This is stipulated with binding effect in our **Code of Conduct** and our **Social and Labor Standards Policy**. Should employees experience harassment or discrimination in the workplace, they can report the issue via various channels. Their first points of contact are either their supervisor or our Human Resources (HR) or Compliance teams. Alternatively, employees throughout the Group have the possibility to call our **Compliance Hotline** anonymously. As part of our “Group Compliance Case Committee”, HR coordinates suspected cases relating to human resources topics. In 2021, seven suspected cases of discrimination were reported via the compliance hotline and other channels. Of these reports, six incidents were confirmed.

Health and safety

We seek to promote the health and well-being of our employees and sustain their ability to perform over the long term, which necessitates a safe workplace. We are therefore constantly working to take our health and safety culture to the next level.

The lost time injury rate (LTIR) is the indicator used to gauge the success of our occupational safety efforts. This figure is a global measure of the number of accidents resulting in at least one day of missed work per

one million hours worked. We track the LTIR globally for both employees and supervised temporary staff. In 2021, we set a new workplace accident reduction target, specifically to bring our LTIR below 1.0 by 2025.

Before starting any activity worldwide, we perform a hazard assessment to identify risks and do everything possible to eliminate them before commencing the activity or commissioning a plant. If this is not feasible, we put measures in place to minimize the chances of problems arising and their potential impacts. Such hazard assessments are the responsibility of our individual sites and are therefore conducted by them.

We have developed a performance indicator system based on data, such as the health-related responses from our annual anonymous Employee Engagement Survey. We use this survey to calculate our work-balance index and our healthiness index, which should reflect the general state of health of our workforce worldwide and their ability to manage the demands of their professional and personal lives. These indices allow us to assess the data at team level (groups of at least ten), a minimum threshold that enables us to protect people's anonymity. In 2021, we introduced an overarching health question to the survey to document and track our company's health culture and its development in the coming years.

Roles and responsibilities

Our Environment, Health and Safety (EHS) management system is the responsibility of Corporate Sustainability, Quality, and Trade Compliance, which reports to the Chair of the Executive Board. This Group function sets objectives, globally oversees the respective initiatives, and conducts internal EHS audits, while local EHS managers and their teams see to it that our individual sites comply with all occupational health and safety laws and regulations. They are also responsible for local projects, campaigns and programs.

Employees worried about their health or safety are permitted to temporarily step back from their work until the issue has been resolved. Across the Group, they are encouraged to report such concerns via our **compliance hotline**.

Our commitment: Policies and company agreements

Defining our principles and strategies for Environment, Health and Safety (EHS), our Corporate **EHS Policy** is an integral part of our EHS management system, which undergoes an external ISO 45001 audit every year. As part of a group certificate, our occupational health and safety management system was ISO 45001-certified at 46 sites at the end of 2021.

Our Group Health Policy details our approach to ensuring workplace safety for our employees while also promoting their health and well-being. This document sets out our Group-wide approach to health and safety management, which is aimed at preventing workplace accidents and occupational illnesses.

To complement this policy, our Contractor EHS Management standard helps us ensure that our contractors adhere to environment, health, and safety requirements throughout the entire process, from starting a job to completion.

Accident rates

Our employees are required to immediately report any relevant occupational accidents to Corporate Sustainability, Quality and Trade Compliance, where the incidents are assessed. If necessary, we then implement additional safety measures at our sites. This procedure is an integral practice across all of our production facilities around the world.

We track the following occupational safety data across our sites worldwide:

- The LTIR measures the accidents resulting in at least one day of missed work per one million hours worked. In 2021, our LTIR was 1.2, an improvement over 2020 (1.3). The majority of incidents resulting in lost time were slips, trips and falls, along with contusions and lacerations from the operation of machinery and equipment. In 2021, we once more recorded no fatal accidents.
- We use our Environment, Health and Safety Incident Rate (EHS IR) to **track accidents**.
- Alongside this indicator, we also use the Occupational Illness Rate in the United States to monitor work-related illnesses and their long-term effects.

Work-related accidents[1]

	2018	2019	2020	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Lost Time Injury Rate (LTIR = workplace accidents resulting in missed days of work per one million hours worked)	**1.2**	**1.6**	**1.3**	**1.2**	**2.5**
by region					
Europe	1.8	2.6	2.4	2.1	2.5
North America	1.1	1.0	0.8[2]	1.2	not applicable
Asia-Pacific (APAC)	0.3	0.2	0.1	0.1	not applicable
Latin America	1.5	1.7	0.8[2]	0.4	not applicable
Middle East and Africa (MEA)	0.7	0.0	0.4	0.0	not applicable
Number of deaths	**0**	**0**	**0**	**0**	**0**
by region					
Europe	0	0	0	0	0
North America	0	0	0	0	not applicable
Asia-Pacific (APAC)	0	0	0	0	not applicable
Latin America	0	0	0	0	not applicable
Middle East and Africa (MEA)	0	0	0	0	not applicable
by gender					
Women	0	0	0	0	0
Men	0	0	0	0	0

[1] Including supervised temporary staff

[2] Figure retroactively adjusted

A work-related accident is an injury that results from the type of work, in the course of doing said work, and that has no internal cause. Work-related accidents are considered relevant if they occur on the premises, on business trips, during goods transport, as a result of external influences (e.g. natural disasters), or due to criminal acts involving personal injury. Commuting accidents and accidents during company sporting activities are not included. First-aid incidents are generally not included in the LTIR since these usually do not result in more than one day of missed work.

Clear rules of conduct

Group-wide, all new EHS managers must complete a three-day EHS onboarding that covers topics such as occupational health and safety as well as our BeSafe! safety culture program. Through this initiative, we raise employee awareness of workplace dangers and teach them rules for safe behavior. Despite the ongoing pandemic, in 2021 we managed to integrate four legacy Versum sites into BeSafe! and conducted the training online. In addition, we regularly provide occupational safety training at our sites covering both legal requirements as well as the specific local risks.

Social matters and respect for human rights

Responsible supply chain

One of the goals of our supplier management endeavors is compliance with fundamental environmental and social standards, in addition to high-quality, reliable delivery and competitive prices. We have introduced relevant strategies, processes and guidelines that we are continuously improving in order to prevent violations of supply chain standards and improve our sustainability performance. We ensure that all legal requirements are taken into account and that corresponding measures are initiated where necessary. For this purpose, we set up an internal working group in 2021 tasked with ensuring that we are compliant with the **German Supply Chain Due Diligence Act**.

To achieve our corporate sustainability goals, our Group Procurement team works closely with our suppliers. We aim to create transparency in all our sourcing regions and fully integrate sustainability into all our value chains.

Therefore, we have set two new key indicators that will measure our journey towards increasing this transparency by evaluating the sustainability performance of our relevant suppliers with valid sustainability assessments. Our definition of valid sustainability assessment includes assessments carried out over the last three years and performed by a reliable, approved source. Relevant suppliers either indicate a specific country and industry risk or contribute to a major part (50% minimum) of our purchase volume. For the risk evaluation, we apply the risk data provided by **EcoVadis** for almost our complete purchase volume (98%). For the calculation of our purchase volume, we consider sourcing-relevant third parties (excluding expenses such as taxes and customs, as well as fees and memberships). We measure these key indicators using two equally weighted metrics: coverage in terms of purchase volume (2021: 65%), and the number of suppliers (2021: 21%).

Supplier Decarbonization Program

Our Supplier Decarbonization Program is a key element contributing to reduce our emissions in line with our decision to join the Science Based Targets initiative. Through the program, we aim to reduce greenhouse gas emissions associated with purchased goods and services as well as capital goods.

Risk management process

To ensure supply security, we select our suppliers based on various criteria, such as country risk, material and supplier risk, and their strategic importance to the business. This helps our sourcing managers to identify potential mitigation actions with relevant suppliers and support them in making improvements.

The approach towards our strategic suppliers, which account for approximately 53% of our total spending, includes the identification, monitoring and assessment of supply security risks. It comprises four main elements:

- Supplier Risk Assessments: to capture the overarching risks at supplier legal entity level, including multiple risk domains.
- Alert system: to notify our Procurement Organization in the event of a risk or production issue arising with any of our suppliers.
- Material Risk Assessments: to determine the risks of relevant materials used in our most significant finished products.
- Risk Response Tracker: to create and monitor risk mitigation activities.

We calculate risk factors for suppliers and raw materials by multiplying risk probability and risk impact. For the supplier evaluation, we consider 29 risk titles, including, but not limited to economic freedom, social unrest, unfair business practices, and poor labor practices. We have also included criteria for identifying supplier relationships impacted by key sustainability risks, such as mineral sourcing or animal welfare. In 2021, we further developed our supplier risk assessment, focusing on the more relevant risk titles and thus sharpening our approach.

Due diligence process for responsible sourcing of minerals

Our company sources and sells products that contain minerals commonly summarized under the term "3TG" (tin, tungsten, tantalum, and gold – collectively also known as conflict minerals). Our overall aim is to source materials in a responsible and conflict-free manner and not to contribute to adverse impacts through our sourcing activities. Therefore, we developed a comprehensive due diligence program and respective practices to address minerals originating from conflict-affected and high-risk areas (CAHRAs). Our program framework is in alignment with applicable laws and international standards.

Our **Responsible Minerals Sourcing Charter** forms the basis of our due diligence program. We are continuously working to improve our due diligence practices and ensure conflict-free sourcing of 3TG.

We are a member of the Responsible Minerals Initiative (**RMI**). RMI provides us with tools and resources to make sourcing decisions that improve regulatory compliance and support responsible sourcing of minerals from CAHRAs. RMI uses third-party auditors to audit smelters and refiners and to investigate working conditions as well as environmental, health and safety issues. In the event that sufficient RMI-based information is not obtained, we conduct further research to determine whether an appropriate level of due diligence is ensured.

Roles and responsibilities

Group Procurement is responsible for integrating sustainability requirements into the relevant stages of our sourcing and supplier management processes. Our Center of Excellence for Supply Security coordinates the relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives.

Our commitment: Guidelines and standards

We expect all our suppliers and service providers to comply with our environmental and social standards, which are primarily derived from the **core labor standards** of the International Labour Organization (**ILO**) and the **UN Global Compact**. These are defined in our **Responsible Sourcing Principles**. We expect our suppliers to ensure that their subcontractors respect the same rules.

Our **Responsible Minerals Sourcing Charter** demonstrates our commitment to responsible sourcing of minerals from CAHRAs. It applies to all our legal entities and subsidiaries worldwide, all our employees as well as any third party acting on our behalf. The charter complements the requirements set out in our **Responsible Sourcing Principles**.

Moreover, we support the Compliance Initiative of the German Association for Supply Chain Management, Procurement and Logistics (**BME**) and have endorsed the BME Code of Conduct.

To ensure that we work based on industry standards and can rely on comparable data analytics and expert analysis, we collaborate with our peer companies in industry initiatives. We are member of both Together for Sustainability (**TfS**) and the Pharma Supply Chain Initiative (**PSCI**).

We invite our suppliers to let us or trusted partners conduct assessments or audits to increase our supply chain transparency and identify fields of activity in order to improve sustainability performance or mitigate infringement risks.

Together for Sustainability supplier assessments and audits

Through the TfS initiative, suppliers are assessed either based on information obtained during audits or based on self-reported and publicly accessible information provided by EcoVadis, an independent rating agency. EcoVadis assesses suppliers from more than 160 countries and 200 sectors across the four categories of Environment, Labor and Human Rights, Ethics, and Sustainable Procurement. The results are shared among TfS member companies in compliance with all restrictions stipulated by antitrust law.

Through the TfS initiative, we have access to more than 1,460 valid scorecards on the assessment of our suppliers, 882 of which completed a new assessment or re-assessment in 2021. In some cases, these were initiated by us and in other cases by other TfS members.

Our approach to responsibility in the mica supply chain

Mica is an important raw material for our effect pigments, which are used in automotive, cosmetic, and industrial coatings, as well as in plastics. We procure the majority of our mica from the Indian states of Jharkhand and Bihar. By procuring mica from these areas, where political instability, poverty, and child labor are widespread, we are supporting this region by safeguarding local employment and livelihoods. We source the raw material only from suppliers acting in formal working environments and monitor compliance with our standards, including the prohibition of child labor.

Our mica suppliers are informed of our standards and have confirmed that they adhere to the principles of our **Human Rights Charter** as well as the requirements of our **Responsible Sourcing Principles**. In the event of non-compliance with our standards, we work with suppliers to ensure the appropriate implementation of corrective measures.

We do not tolerate child labor and contractually prohibit our suppliers from employing children. If one of our suppliers were found to be using child labor, our company would terminate the business relationship immediately. We drive initiatives and take measures to improve the conditions of mica sourcing based on our high standards. We continuously review our monitoring processes to improve their effectiveness.

Auditing our mica supply chain

We have implemented a series of oversight mechanisms using a system that monitors and audits conformity with our social and environmental standards. In addition to visits by Group employees, regular inspections are conducted by third parties, who conduct comprehensive announced audits as well as frequent, unannounced verification visits.

Environmental Resources Management (**ERM**), a leading global provider of environmental, health, safety, risk, and social consulting services, conducts external audits of mines and processing plants, investigating working conditions as well as environmental, health and safety issues. The audit reports document any identified shortcomings in this respect and propose corrective actions. Our employees in Kolkata (India) and Darmstadt (Germany) take action to address any issues identified. If the corrective measures are not respected, we may suspend or even terminate our business relationship.

Since 2013, IGEP Consult, an Indian non-governmental organization, has conducted regular unannounced inspections to review labor standards throughout our supply chain. During these visits, IGEP officials monitor occupational safety as well as compliance with laws preventing child labor. In 2021, its inspections focused on medical check-ups for workers as well as the implementation of health and risk assessment concepts and safety training. In addition, IGEP has revised and improved the escalation process: Biweekly review meetings are now held with Group representatives to assess suppliers. These meetings help identify any required actions, which our sourcing teams then discuss and implement with our suppliers. Our suppliers have successfully improved the working conditions on the sites.

Evaluating and tracking mica sources

We use a tracking system to help ensure that the mica we purchase is derived from sources qualified by our company and to monitor their productivity. Based on written records of the daily extraction quantities, we review the volumes of mica reported and supplied to the processing facilities.

Our processes undergo constant review and improvement. We are also evaluating other sources for mica in accordance with our quality, social and environmental standards both in India and in other regions. In 2021, we obtained a considerable amount of our mica from Brazil, where we have also established oversight mechanisms to monitor and audit adherence to these standards. In addition, we manufacture effect pigments based on synthetic substrates as an alternative to pigments based on natural mica.

Human rights

We are committed to upholding human rights, which is why we became a signatory to the UN Global Compact back in 2005. We endeavor to prevent the risk of human rights violations, not only at our own sites, but also along our entire supply chain. That is why we integrate human rights due diligence into our business processes.

We view our human rights due diligence as a continuous process, which we constantly adapt and improve. This also prompts us to continually review our approach. We closely monitor regulatory developments – for example, the German Supply Chain Due Diligence Act and the planned EU directive on human rights due diligence.

Roles and responsibilities

Our Executive Board has ultimate responsibility for human rights within our sphere of influence. The Executive Board exercises this responsibility by requiring our Managing Directors to comply with human rights.

Our Group Corporate Sustainability unit is responsible for coordinating all human rights due diligence activities. The persons responsible for these issues in the respective Group functions, business sectors and local units implement the specific measures, for instance by integrating human rights due diligence into existing processes.

Our commitment: Guiding principles, charters and laws

Our **Human Rights Charter** aligns with the **UN Guiding Principles on Business and Human Rights**. It is our overarching human rights directive and defines the relevant requirements for our company. We expect our employees as well as our suppliers and business partners to comply with this charter.

Identifying actual and potential impacts on human rights

We perform risk assessments to understand the potential impacts our operations and business relationships could have on human rights. For instance, we investigate human rights risks at our sites as well as risks related to product and service sourcing. These risk assessments enable us to derive the corresponding strategies and measures.

Furthermore, we also track human rights risks through our strategic supplier risk process. More information on how we engage with suppliers can be found under **Responsible supply chain**.

We also meet our human rights due diligence obligations when deploying new technologies. In 2021, we adopted the **Code of Digital Ethics**. This defines digital ethics principles and forms the basis for the work of the Digital Ethics Advisory Panel. More information can be found under **Digital ethics**.

In the reporting period, we analyzed our activities designed to implement human rights due diligence in order to identify potential for improvement. We took both stakeholder and regulatory requirements into

consideration. The analysis showed that we need a uniform, Group-wide process in order to better evaluate the effectiveness of our human rights due diligence. Above and beyond this, we want to further strengthen the human rights working group, for instance by involving our business sectors more intensively.

Auditing our suppliers and sites

We use internal audits to check whether the workplace requirements of our Human Rights Charter are being observed at our sites. More information on internal audits can be found under **Compliance management**.

In addition, we review human rights aspects at our sites through site security risk assessments. In 2021, we formalized the assessments as security audits, which will be implemented at regular intervals in line with the audit plan in the future. The audits are one control mechanism of our security governance framework.

Increased risk transparency and centralized corrective and preventive actions tracking allows us to ensure that out sites meet security-relevant human rights aspects.

Through the Together for Sustainability (**TfS**) initiative, we determine whether our strategic suppliers comply with human rights standards.

Creating awareness among our employees

To train our Managing Directors and senior leaders reporting directly to the Executive Board, we offer an e-learning course on the requirements of our Human Rights Charter and our Social and Labor Standards Policy and the implementation thereof in their areas of responsibility. In addition, the onboarding course for all new EHS managers covers the topics of human rights and modern slavery. In addition, during the reporting period the regional Security Academy meetings elaborated on current developments in the areas of human rights and modern slavery. The Security Academy is a training platform for our local, national and regional Security functions. It addresses security-relevant topics and is coordinated by our Corporate Security Group function.

Our reporting practices

We inform the public about our approaches, measures and results of human rights due diligence. We provide information on this annually in our Sustainability Report. Additionally, legislation in Australia and the United Kingdom requires us to publish the steps we are taking to counter forced labor and human trafficking. Apart from the **UK Modern Slavery Statement** we also published our first **Australia Modern Slavery Statement** in 2021. Both have been signed by our Executive Board Chair.

Our complaint mechanism

Our compliance hotline is the most important channel for reporting complaints about potential human rights violations. Our employees as well as external stakeholders can report suspected cases in their respective national language, free of charge and anonymously to our Group-wide whistleblowing system, either by telephone or a web-based application through our compliance hotline. We thoroughly investigate all complaints that we receive and take countermeasures if necessary. In 2021, we noted no violations, either with respect to child or forced labor or with respect to the right to collective bargaining or freedom of association. More information on the compliance hotline can be found under **Compliance management**.

Human rights violations[1]

	2018[2]	2019[2]	2020	**2021**
Number of reported violations of Social and Labor Standards Policy	-	-	108	121
Number of confirmed Violations of Social and Labor Standards Policy	-	-	29	41
thereof: number of incidents of discrimination	-	-	2	6

[1] In 2020, we modified our reporting structure for human rights violations. Previously, we reported on such violations in the "Reported compliance violations" table. Since 2020, we report on violations of our Social and Labor Standards Policy, which was drafted and rolled out across the entire Group in 2019.

[2] Due to our revised reporting practices, we have decided not to report the data from previous years.

Patient safety

Through a rigorous benefit-risk management process, we help to ensure that the benefits of our medicinal products always outweigh the risks for patients. Every new medicine goes through a series of precisely defined development stages. Before any medicinal product is administered to human subjects, we conduct extensive preclinical testing both in vitro and in vivo.

During clinical development, we diligently use all the collected data to continuously evaluate the medical product's benefit-risk profile. If we consider the medical product's benefit-risk profile to be positive, we then submit an application for marketing authorization to the relevant regulatory authorities.

Continual monitoring

Once we launch a new medicinal product, the number of patients being treated with it increases significantly. In rare circumstances, there may be adverse and potentially serious effects that were not detected during clinical development, which is why we continuously monitor and manage the benefit-risk profiles after its market release. Pharmacovigilance includes the process of monitoring a medical product on an ongoing basis to detect and assess safety signals as part of signal management activities. Continuous monitoring of adverse effects allows us to proactively and transparently minimize and communicate any risks. In addition, we always provide healthcare professionals and patients with the latest information on the safety of all our marketed medicinal products. The scope of continuous safety monitoring includes the entire life cycle of a product, ranging from development, market launch, and commercialization to expiration of the marketing authorization.

Roles and responsibilities

Our Global Patient Safety unit is responsible for pharmacovigilance. It continuously collects current safety data from a wide variety of sources across the globe, including clinical studies, early access programs, spontaneous reports on adverse effects, patient support programs, and articles published in medical and scientific journals.

Our experts help to ensure all information on the risks and adverse effects of our medical products is properly documented, tracked, and reported to the respective health authorities in accordance with regulatory requirements. Our Global Patient Safety unit analyzes all data and reassesses the benefit-risk profile based on these data, where required. We then inform regulatory authorities, healthcare professionals and patients about new risks, additional risk mitigation measures, and potential changes in the benefit-risk profile.

In order to implement our R&D Strategy 2023, our Global Patient Safety unit is on a journey of transformation. Our vision is to embed a deep knowledge of safety into early decision-making as we evolve to practice predictive safety. In 2021 we continued to refine our approach to benefit-risk assessments. For example, we applied a scoring system based on safety aspects and used it to determine the prioritization levels of our products. We also redesigned our pharmacovigilance processes using a business process management model that ensures cross-functional alignment between our corporate functions. We expect to complete the implementation of these processes in 2022.

Our Global Patient Safety unit hosts a Pharmacovigilance Intelligence Council that focuses on changes in pharmacovigilance legislation and its impacts on our global and local pharmacovigilance systems. This initiative enables us to make strategic decisions and govern changes in our pharmacovigilance requirements, ensuring continuous compliance with regulatory requirements.

Our Medical Safety and Ethics Board

Our Medical Safety and Ethics Board (MSEB) oversees the safety and benefit-risk assessments of our medicinal products throughout their clinical development and commercialization. It endorses appropriate measures to minimize risks, such as updates to product information. This board is chaired by our Chief Medical Officer and comprises experienced physicians, scientists and experts from our company. Throughout a medicinal product's entire life cycle, the MSEB reviews and assesses important medical safety risks and benefit-risk issues and reviews human-related ethical matters as appropriate.

Our commitment: Guidelines and statutory requirements

We follow international guidance and standard procedures, such as the International Council for Harmonisation (**ICH**) guidelines and the Good Pharmacovigilance Practices (GVP) established by the European Medicines Agency (**EMA**) and national health authorities. In addition, we comply with all new statutory pharmacovigilance regulations in the countries where we market our products.

Monitoring drug safety

Regulatory authorities conduct periodic inspections to verify that we comply with statutory requirements as well as our own internal pharmacovigilance standards. We follow up on the findings of health authority inspections and take necessary actions to ensure the ongoing compliance of our pharmacovigilance system. In 2021, we had eight pharmacovigilance inspections.

Furthermore, we perform audits to ensure that all our units and subsidiaries involved in pharmacovigilance consistently meet all global requirements. In 2021, we conducted a total of 18 pharmacovigilance audits and found no significant deviations in our pharmacovigilance systems from these requirements and standards. We also audit our vendors and licensing partners involved in pharmacovigilance, which helps us improve our pharmacovigilance processes and comply with regulatory requirements.

Redefining our approach to benefit-risk assessments

We have developed an improved benefit-risk strategy to help us transform from a reactive and compliance-driven organization into a proactive and benefit-risk-focused organization. By truly understanding the benefit-risk profiles of our products, we can enable early decision-making within the organization to protect the safety of patients. Ultimately, the aim is to be able to provide the right medicine to the right patient at the right time. As part of this initiative, we have also developed the concepts and principles for conducting benefit-risk assessments at each stage of product development and post-marketing.

We have concluded the pilot phase of our new benefit-risk strategy and are now following up with incremental implementation by the end of 2022.

Up-to-date labeling and product information

Our product information explains to healthcare professionals and patients how to correctly use the respective product and make informed treatment decisions.

We review and update all product information documents, such as package leaflets, to ensure our medicinal products contain the latest information on safety, efficacy, and pharmaceutical formulation. In accordance with regulatory requirements, we submit all modifications to our leaflets to the respective regulatory authorities for

approval. In 2021, there were no incidents of non-compliance with regulations concerning the labeling of our medicinal products.

Internal and external training

Our pharmacovigilance experts are regularly trained so that they gain the experience and knowledge required to carry out their activities. We manage our training via a global learning platform and verify compliance with training our requirements by producing training completion reports.

All our approximately 23,000 Healthcare employees receive basic pharmacovigilance training once a year that covers the procedure for reporting adverse effects or special circumstances associated with the use of our products.

Product-related crime

Our company develops and manufactures pharmaceutical and chemical products of the highest quality. We take resolute action against product-related crime in order to protect our patients and customers from the harm caused by illegal products. For this purpose, we have implemented a Group-wide strategy, which focuses on identifying and responding to the availability of counterfeit medicines as well as ensuring the integrity of our products and supply chains. Moreover, we are committed to collaborating both with government authorities and with national and international organizations. Together, we want to tackle product-related crime and raise awareness of the issue among stakeholders as well as the wider public.

By the end of 2022, we will introduce a Group-wide security audit management program, which is intended to further increase transparency and the security level performance within our organization and prove our compliance with security requirements. For this purpose, we are developing key figures to support this process. These key figures will be supplemented by the existing audit management tool.

Roles and responsibilities

The Corporate Security unit coordinates our approach to tackling product-related crime on the strategic level. A cross-functional team supports the operational implementation of the strategy. The team comprises experts from various units, including Legal/Trademarks, Product Security, Export Control, Supply Chain, Patient Safety, Regulatory Affairs, and Quality Assurance. Furthermore, all our sites have product crime officers who serve as central, local points of contact and act as the interface between both local and global stakeholders, internal and external alike.

Our commitment to Group-wide policies and standards

Globally applicable regulations are a key part of our approach to effectively and efficiently tackling product-related crime. The Group-wide guideline entitled “Illicit Trade & Product Crime Prevention” describes our goals and measures for reducing product-related crime and minimizing its impact. Our Group-wide Product Crime Incident Management standard sets out mandatory requirements for effectively managing incidents of product-related crime.

Detecting counterfeit drugs and withdrawing them from circulation

A team of experts examines, evaluates, and processes every notification we receive regarding suspected counterfeit medicines. Our response always complies with both the regulatory requirements and our own wider objectives for tackling counterfeit products. We pro-actively conduct investigations both online and offline in order to identify and disrupt the availability of illicit products in legitimate and illegitimate channels. We document all incidents using a central, Group-wide reporting system. Moreover, we support the prosecution of criminals by working closely with the authorities. As a member of the Pharmaceutical Security Institute (**PSI**), we routinely share intelligence about product crime with other pharmaceutical companies.

Tracking system for chemical substances

We monitor chemicals that could be misused to produce illegal weapons, explosives, or narcotics, tracking through an internal system that flags suspicious orders or orders of sensitive products. These are released only once we have confirmed the existence of a verified end-user declaration.

In addition to fulfilling the duties defined in the statutory provisions on export control, we also report suspicious orders and inquiries to the competent authorities. Through these efforts, we are honoring a voluntary commitment of the German Chemical Industry Association (VCI) and meeting the terms of the Guideline for Operators published by the European Commission. In 2021, we reported 745 orders placed for relevant substances. In addition, we helped to resolve six inquiries from authorities regarding specific suspected cases. We evaluate the effectiveness of our measures for avoiding product misuse based on, among other things, the number of incidents suggested to us by the authorities and solved.

Raising awareness of product-related crime

We aim to continuously raise awareness of product-related crime among our business partners and employees, educating and training our people Group-wide on the subject to strengthen their competencies. All staff involved in security, such as product crime officers, participate in appropriate training programs. We are continuously evolving these programs and adapting them to new trends.

Prices of medicines

To help ensure that all patients have access to the most effective medicines for their needs, we are working to prevent cost from becoming a barrier to treatment. Therefore, we adapt our medicine prices according to people's ability to pay in different geographical or socioeconomic segments.

We are committed to fair, flexible and sustainable pricing – both within and across countries. We therefore adapt our prices based on local market considerations, such as unmet medical and treatment needs, health system capacity, infrastructure, and education standards. This approach involves working closely with governments and other stakeholders. In addition, we continuously monitor dynamic healthcare environments and markets, pricing and reimbursement systems as well as legal and regulatory guidelines, adjusting our prices as necessary.

We conduct price analyses annually to validate price thresholds and provide guidance on local pricing to our subsidiaries for the following year to ensure they meet patient access needs, taking a consistent, data-driven approach. We also make our products affordable to patients in low- and middle-income countries with an equitable value and access strategy that includes participating in government tenders, providing flexible pricing, establishing high-quality affordable brands or branded generics, and operating patient access programs.

Furthermore, we support innovative risk-sharing agreements and are working to improve data efficiency in health systems in order to achieve an optimal distribution of funds and resources.

Roles and responsibilities

Our Global Market Access and Pricing unit evaluates market launch prices in coordination with the respective franchises. The team reports directly to a member of our Healthcare Executive Committee. The GMAP unit systematically evaluates and applies our medicines portfolios for equal access initiatives. Our local affiliates are responsible for managing prices and adapting them to evolving local conditions in compliance with our pricing governance and the defined price approval process.

Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition. Our medicine pricing adheres to the stipulations of our overarching **Access to Health Charter** and is defined in detail in an internal guideline. Additionally, our Patient Access Programs Policy sets out standards for offering medicines at affordable prices.

Value-based contracting models

We are committed to advancing value-based healthcare through pricing and contracting mechanisms that fully comply with all applicable local laws and regulations. In collaboration with payers, such as health insurance companies, we have developed various product- and market-specific reimbursement and contracting models. These help to provide patients with prompt access to our innovations. In addition, we aim to pilot outcome-based contracting models in one or two markets for our fertility product portfolio by the end of 2022.

Equitable value and access approaches to serve low- and-middle-income patients

We work in close partnership with governments and other stakeholders on innovative, differential medicine pricing schemes. We developed an equitable and value access strategy and by 2023, want to test it with pilot programs for two products of our innovative product portfolio in at least two low- and middle-income countries. In addition, we supply products at affordable prices to certain countries in Africa, Asia, Latin America, and the Middle East.

Our Biopharma tender excellence initiative offers a strategic tender framework. This includes a web-based system that helps country teams increase quality and agility in tender decisions, while improving performance tracking and collaboration.

For some of our existing high-quality products, we have created second brands at affordable prices, particularly in countries with a large percentage of patients with very low incomes.

We operate patient access programs that enable us to offer certain products at affordable prices in several countries.

Clinical studies

We conduct high-caliber clinical research that always complies with applicable laws and regulations. When performing clinical studies, we adhere to the highest ethical and scientific standards worldwide.

We only conduct clinical studies to investigate issues that are relevant to patients, healthcare professionals, or society, and only when the medicines being tested show significant therapeutic promise and have a positive benefit-risk ratio. In addition, a sound, established scientific methodology must be available to investigate these scientific or medical questions. We only enroll the specific number of participants required to answer each of these questions.

Protecting the safety, well-being, dignity, and rights of the patients and healthy volunteers participating in our clinical studies is of utmost importance to us. We do not intentionally expose study subjects to undue risk or irreversible harm. Personal data privacy is also very important to us, and we maintain a strong focus on data protection and confidentiality in compliance with statutory regulations.

We assure that no subject enrolling in a clinical study is discriminated against on the basis of ethnic origin, gender or socio-economic status.

Patient-focused drug development

We are improving our approach to research and development by committing to patient-focused drug development that more actively involves patients, caregivers, and their advocates in our work. Their valuable insights into disease and treatment management will help us make more informed decisions at each stage of the medicine development process. We aim to make our studies easy for patients to understand while ensuring all participants have positive experiences as they contribute to our understanding of the particular disease and its treatment. We are also working to further develop the way in which our research work is communicated and how it can improve the healthcare people receive. At every level of our organization, we are additionally educating staff about the value of closer, more consistent patient interaction and the requirements to protect our patients' independence and privacy.

Clinical studies in low- and middle-income countries

We conduct all our clinical studies in accordance with local laws and regulations, and we adhere to all relevant international scientific and ethical standards, irrespective of the region or country.

Roles and responsibilities

Clinical drug development, including clinical studies and the related governance process, are the responsibility of the Global Development unit. The Head of Global Development reports to the CEO Healthcare, who is a member of the Executive Board.

We have established two internal committees to oversee our clinical studies. The Development Studies Committee is responsible for the studies performed by the company on medicines that are under clinical development, while the Global Medical Decision Board is responsible for our own studies with approved medicines, as well as for all studies performed by independent investigators and supported by us (so-called investigator-sponsored studies). Both bodies consist of medical-scientific experts and executives with long-standing experience in clinical research.

Before administering a new drug to humans, there must be sufficient evidence that it offers a potential therapeutic benefit, is sufficiently safe for use in humans, and has a positive benefit-risk ratio. We only take the critical step of a first-in-human clinical trial after diligently conducting extensive preclinical testing. The decision lies with a separate committee, the Human Exposure Group, chaired by our Global Chief Medical Officer.

We continuously analyze potential risks for study participants before and during our clinical studies. Our Medical Safety and Ethics Board oversees the safety of subjects participating in our clinical studies and, as necessary, reviews the benefit-risk profiles of investigational drugs.

Our commitment: International guidelines and requirements

Our Human Subjects Research and Development Policy provides the framework for conducting clinical studies and helps ensure that we adhere to all applicable legal, ethical and scientific standards. In addition to the relevant national laws and regulations, these standards also include:

- The **Good Clinical Practice** (GCP) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**)
- The **Declaration of Helsinki**, published by the World Medical Association
- The **Belmont Report** by the **U.S. Office for Human Research Protections**
- Good Pharmacovigilance/Laboratory/Manufacturing/Distribution Practices (GVP/GLP/GMP/GDP)
- The **International Ethical Guidelines for Health-related Research Involving Humans**, published by the Council for International Organizations of Medical Sciences (**CIOMS**)

- The **Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases** and the **Joint Position on the Publication of Clinical Trial Results in the Scientific Literature**, published by the International Federation of Pharmaceutical Manufacturers & Associations (**IFPMA**), the European Federation of Pharmaceutical Industries and Associations (**EFPIA**), the Japan Pharmaceutical Manufacturers Association (**JPMA**), and the Pharmaceutical Research and Manufacturers of America (**PhRMA**)
- The **Principles for Responsible Clinical Trial Data Sharing**, published by EFPIA and PhRMA, and the IFPMA Principles for Responsible Clinical Trial Data Sharing

Regular supervision of clinical studies

Our clinical study processes and procedures are regularly inspected by relevant regulatory authorities to verify their compliance with applicable laws and guidelines.

The Research & Development Quality unit applies a risk-based identification strategy to determine areas that need to be audited. Quality assurance audits are performed internally within Healthcare R&D (for example, process audits) and externally (for example, at vendors' sites and investigational sites). We respond immediately to observations during audits by investigating their root causes and, according to their criticality, defining and implementing corrective and preventive actions to improve processes, prevent reoccurrence of irregularities and ensure compliance.

Due to the Covid-19 pandemic, we postponed some audits from 2020 to 2021. However, for all audit types we successfully implemented a remote audit approach. As a result, we were able to largely implement the audit plan for 2021, shifting only a small number of audits to 2022.

Conducting clinical studies responsibly

Every clinical study follows defined procedures to ensure it is conducted to the highest quality standards in line with good working practices (GxP) for the development and manufacturing of drugs, the ethical principles of the Declaration of Helsinki and other international guidelines and regulations. In 2021, regulatory authority inspections did not unveil significant issues which had any impact on patient rights, patient safety, or the data integrity of a study.

Disclosure of clinical studies and publication of results

We are obligated to disclose findings from our clinical studies. We do this publicly in a complete, accurate, balanced, transparent, and timely manner as laid out in our Clinical Trial Disclosure Policy. We publish results from our clinical studies in medical journals in line with applicable laws and industry codes. In this way, we adhere in particular to the current version of the Good Publication Practice (GPP3) and follow the recommendations of the International Committee of Medical Journal Editors (**ICMJE**). Our **Standard on Clinical Trial Data Transparency** underscores our strong commitment in this matter.

Enabling early access to new medicines

Not all patients have the opportunity to take part in a clinical study and must therefore wait for a new pharmaceutical product to be approved. Through our Early Access Program, we can, under specific circumstances, enable patients to gain early access to new, potentially life-saving medicines. The offer is aimed at people with serious conditions who have already received all available therapies without success. It allows them to be treated with medicines that have already been clinically tested but have not yet been approved. Furthermore, we offer patients who participated in one of our clinical studies post-study access to the investigational product, provided that certain conditions are met. Here, too, we meet stringent statutory, ethical, and scientific standards. By performing a thorough assessment of all available data, we ensure that the potential benefits outweigh the potential risks for patients.

Bioethics

Our goal is to conduct this research in an ethical manner. We develop frameworks that guide us in making informed decisions to meet the most rigorous ethical standards. Patient benefit and well-being is always our top priority, whether in clinical studies, treatment with our medicines, or the distribution of our products to academic researchers and the biopharmaceutical industry. We carefully evaluate our position when it comes to controversial topics.

Roles and responsibilities

For around ten years, the Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP), appointed by the Executive Board, provided guidance on bioethical questions. To tackle a broader array of topics going forward, in May 2021 we transformed this body into the Ethics Advisory Panel for Science and Technology of Merck KGaA, Darmstadt, Germany (MEAP). The new committee provides clear recommendations on science and technology topics and issues that go beyond pure bioethics. Co-chaired by two of our leading scientific experts, the MEAP provides recommendations that steer our actions and business activities. In addition to renowned international specialists from the fields of bioethics, theology, law, and science, the panel also features technology and sustainability experts.

The MEAP meets multiple times a year and can also be convened on an ad-hoc basis in response to emerging urgent ethical issues. The meeting minutes can be accessed on our intranet, along with the guidance resulting from each meeting. Our employees can submit topics for the MEAP to discuss and can furthermore report ethical concerns through our compliance hotline or by reaching out to our Bioethics team.

Our dedicated committees on genome editing and stem cell research operate under the overarching MEAP. Using our internal guidelines as a basis, they make recommendations on issues relating to specific topics. Our Stem Cell Research Oversight Committee (SCROC) verifies all internal research proposals that employ human stem cells, ensuring compliance with legal requirements as well as our ethical guidelines. This also includes joint projects with external partners.

Our commitment to policies and standards

Our **Genome Editing Principle** provides a mandatory ethical and operational framework for our employees. It is complemented by additional guidelines that shape our approach to ethically conducted research and business. Our **Stem Cell Principle** sets the ethical boundaries for the use of human stem cells in our research. Our **Fertility Principle** guides our research in fertility treatment and in-vitro-fertilization.

Use of genome-editing technologies

CRISPR/Cas9 opens up new possibilities in genetic engineering research that could bring about major advances in the treatment of serious diseases or in “green genetic engineering”, which is the use of genome editing techniques in plant cultivation. Laws in different countries allow for a varying degree of latitude in applying this technique. Bioethical views on germline editing have been evolving for years through academic and social discourse. Our position on human germline editing is as follows:

“In accordance with the German Embryo Protection Act, the Group does not support the use of genome editing in human embryos or clinical applications of germline interventions in humans. We recognize that there may be value in responsibly conducted research in this area.”

Stem cell research

At the present time, we neither participate in clinical programs that utilize human embryonic stem cells or cloned human cells for the treatment of diseases, nor do we pursue such approaches ourselves. However, we use human embryonic stem cells in our research and offer our customers several select stem cell lines. In both applications, we only allow the use of human embryonic stem cells if clearly defined conditions have been met. For instance, we only utilize stem cells for research purposes if our Stem Cell Research Oversight Committee (SCROC) has reviewed the respective project and given approval. We exclusively make use of cell lines that have been approved by the United States National Institutes of Health (**NIH**) and are allowed under the German Embryo Protection Act as well as the German Stem Cell Law. At its October 2021 meeting, the SCROC revised our Stem Cell Principle to align it with the new guidelines published by the International Society for Stem Cell Research (ISSCR) in 2021.

Digital ethics

Having made it our mission to develop new digital technologies responsibly, we identify any ethical issues that may arise from either using this technology or from applying algorithm-driven and data-based business models at an early stage.

Established in 2021, the new Digital Ethics Advisory Panel of Merck KGaA, Darmstadt, Germany (DEAP) focuses on complex ethical issues surrounding digital technologies. Ensuring that our digital business model follows a holistic, ethical approach, its efforts complement the work of our Ethics Advisory Panel for Science and Technology (MEAP). Launched in 2010, the MEAP provides guidance on ethical issues pertaining to our business activities and research.

Roles and responsibilities

The DEAP deals with all ethical issues arising from our digital businesses, especially digital health. It plays a pivotal role in ensuring that we develop digital innovations responsibly and address potential digital ethics questions that could result from the use of these digital technologies. Making recommendations on our actions as a company, the panel consists of external United States' and European science and industry experts from the following fields: digital ethics, law, Big Data technologies, digital health, medicine, and data governance. Furthermore, if necessary, we draw on bioethics experts as well as representatives from patient organizations. As with the MEAP, the DEAP is appointed by the Executive Board. All employees may submit topics for the panel to discuss. The minutes from DEAP meetings as well as their recommendations will be accessible on our intranet. The panel held four meetings in 2021. One DEAP session focused on our company's role and responsibility in terms of how (patient) data is collected and handled by customers who utilize our digital products and services.

What we are committed to: Policies and standards

We aim to position ourselves as the "digital ethics company", meeting rigorous ethical standards in critical areas such as health data handling.

In 2021, we worked with the DEAP and other partners from academia and science to draft our Code of Digital Ethics (**CoDE**), a document that governs our approach to the ethical management of data and algorithms. The CoDE serves as a guideline for our digital business models, a tool for analyzing ethical challenges, and a basis for practical DEAP guidance. In March 2021, the Executive Board decided to classify the CoDE as a charter; this is our company's highest category for quality control documents and one that also includes our Code of Conduct and our company values. As such, the CoDE applies to all employees, is publicly accessible, and will become part of the employee training curricula.

Data protection and privacy

The mandate and goal of our Group Data Privacy unit is to mitigate risks and create a global framework for data privacy-compliant business operations. This unit helps to train our employees to handle data responsibly and with clear accountability. It safeguards our company by providing data privacy risk assurance and compliance with relevant data privacy laws globally. Group Data Privacy also contributes to creating value for the development of digital business models.

Roles and responsibilities

Group Data Privacy is part of our global Group Compliance and Data Privacy function. In addition, we have a Group Data Privacy Officer and a network of local Data Privacy Officers at various sites Group-wide. In line with external regulations, the Data Privacy Officers act independently. As part of our compliance reporting, Group Data Privacy regularly prepares data privacy updates as well as a comprehensive data privacy report. This report is part of the compliance report submitted to the Executive Board and the Supervisory Board.

Our Data Privacy Management System

Our goal is to establish a global and consistent Data Privacy Management System (DPMS) by the end of 2022. It will be based on the following three pillars: Data Privacy portfolio, people, and communication. The Data Privacy portfolio consists of eight key elements, covering all parts of a functioning DPMS, in line with legal requirements and industry standards. In 2021, we rolled out the revised Data Privacy Policy and Data Breach Standard and updated the e-learning environment amongst other deliverables.

Ensuring IT security

It is vital for our businesses that we protect our information systems, their contents, and our communication channels against criminal or unwanted activities of any kind, such as e-crime and cyberattacks, including unauthorized access, information leakage, and misuse of data or systems. Our Group Security and IT Security units maintain organizational, process-related and technical information security countermeasures based on recognized international standards. We employ harmonized electronic and physical security controls (e.g. access control, security monitoring) to bolster our ability to handle sensitive data, such as trade secrets.

Our commitment: Guidelines and standards

Our Data Privacy Policy and the corresponding standards and procedures define our principles for processing personal data. This approach allows us to achieve a high level of data protection for our employees, contract partners, customers and suppliers as well as patients and participants in clinical studies. Our Group-wide understanding of data privacy is based on European legislation, in particular the European Union General Data Protection Regulation (EU GDPR). We also take steps to meet local data privacy requirements, where these are stricter than our Group-wide standards.

Training and IT tools

In line with the EU GDPR and our global approach to data privacy, we regularly conduct e-learning training courses in ten languages. We launched a content update to this training course in May 2021.

We maintain a central IT tool to provide a single source for data privacy processes, such as registering data processing activities and reporting potential data privacy incidents. In 2021, we began implementing a new, enhanced tool, which is expected to go live in 2022.

We registered no sanctioned complaints or incidents concerning breaches of customer privacy, data leaks, theft, or loss of customer data in 2021. In three cases, minor personal data breaches were reported to the supervisory authority. These were not sanctioned.

Data Privacy

	2018	2019[1]	2020	**2021 Group**	**2021 thereof: Merck KGaA, Darmstadt, Germany**
Reported violations of Data Privacy Guidelines	1	1	3	3	1
Customer Privacy[2]					
Total number of substantiated complaints received from outside parties	0	0	0	0	0
Total number of complaints from regulatory bodies	0	1	0	0	0
Total number of identified leaks, thefts, or losses of customer data	1	1	0	0	0

[1] Since 2019, our reported figures have excluded the Consumer Health business, which was divested on December 1, 2018.

[2] These data only reflect incidents classified as significant.

Anti-corruption and anti-bribery

Compliance management

As a global company, we have stringent requirements for effective compliance management. Importantly, we seek to emphasize compliance by acting in line with our **company values** and believe that profitable business operations should go hand in hand with the highest ethical standards.

Roles and responsibilities

Our Group Compliance function is responsible for the policies on the following core topics: anti-corruption and anti-bribery (including healthcare compliance, third-party due diligence, transparency reporting), anti-money laundering, antitrust, conflict of interest, and dawn raid preparedness.

To cover these compliance topics, we have Group-wide policies and procedures in place that ensure our business activities align with the relevant laws, regulations, and international ethical standards. Other compliance-related issues, including the respective internal regulations and guidelines, such as **Pharmacovigilance**, Export and Import Controls, and **Environment, Health, Safety, Security, Quality**, are managed by the responsible functions.

Our Group Compliance function is responsible for our compliance portfolio, which consists of the following elements:

- Risk Assessment: Identifying internal and external critical risks in regular business operations
- Policies & Procedures: Global policies, procedures and standards to mitigate identified risks (see the “Our commitment: guidelines and standards” section for more details)
- Compliance Committee/Forums: Platform for compliance-related discussion and decision-making, including relevant key functions
- Training & Awareness: Appropriate training and additional measures to educate and keep awareness high
- Programs & Tools: Comprehensive compliance programs and supporting tools contributing to internal controls and overall governance
- Monitoring & Reporting: Tracking of compliance-related data; performing internal and external reporting
- Case Management: Timely response to reports of misconduct and implementation of corrective actions
- Continuous Improvement: Based on and applying to all compliance program elements

Our Group Compliance Officer reports on the status of our compliance activities, potential risks and serious compliance violations to the Executive Board and Supervisory Board twice a year at a minimum. As part of our regular reporting processes, we compile a comprehensive compliance and data privacy report annually for the Executive Board. This includes the status of our compliance program, continuous improvement initiatives and key figures on compliance and data privacy cases. Additionally, we prepare a mid-year update to highlight ongoing developments and the status of relevant projects and initiatives.

Our Group Compliance Officer oversees approximately 94 Compliance Officers and Compliance experts around the world. The Compliance Officers implement our compliance program within their respective areas of responsibility (adapting to local legislation, if legally required) and receive guidance from our Group Compliance Center of Expertise. This is a centralized body that drives the design and evolution of our compliance program across all business sectors and Group functions.

Our commitment: Guidelines and standards

Our compliance program builds on our company values and integrates these into our compliance framework, which contains Group-wide policies and procedures for entrepreneurial conduct. The following are mandatory for all our employees:

- **Code of Conduct of Merck KGaA, Darmstadt, Germany**
- **Human Rights Charter**
- Anti-Corruption Policy
- Money Laundering Prevention Policy
- Conflict of Interest Policy
- Antitrust and Competition Law Policy
- Compliance Reporting and Investigation Policy
- Dawn Raid Policy
- Healthcare Ethical Guiding Principles
- Pharma Code
- Standard on Local Compliance Standards

Risk assessment

Proper compliance risk management is crucial in order to identify undetected risks and keep our company protected. In 2021, we launched a global, redesigned risk identification process for all our business sectors. The new process enables objectivity and a more data-driven risk approach. We established a comprehensive risk matrix that focuses on bribery and corruption risks, which are illustrated through in-depth risk categorization and risk scenarios. The matrix consists of a questionnaire to detect the risk exposure level of the business sectors and another mitigation questionnaire that checks the implementation of the compliance program. These risk questionnaires are primarily answered by the business heads.

We are implementing the risk identification process in a staggered, top-down approach. We started the risk assessment with global functions in 2021. In a second step, we will conduct country-specific assessments in 2022.

Conflicts of interest

We take all potential conflicts of interest seriously. Employees must avoid situations where their professional judgment may come into conflict with their personal interests. They must also disclose every potential conflict of interest to their manager and document the disclosure. Such issues are typically resolved directly between the employee and the manager but can also be routed to Human Resources, Legal, Compliance, or other relevant functions.

In 2021, we further raised employees' awareness of conflicts of interest by establishing a dedicated global interactive training program and enhancing our communication. In addition, as described under "**Avoidance of conflicts of interest**", Executive Board and Supervisory Board members are exclusively committed to the interests of the company and neither pursue personal interests nor grant unjustified advantages to third parties.

Management and requirements of our business partners

Our global Third Partner Risk Management process governs interactions with sales partners, such as agents, distributors, and dealers. We expect our business partners worldwide to adhere to our compliance principles. We collaborate only with partners who pledge to comply with relevant laws, reject all forms of bribery and adhere to environmental, health, and safety guidelines.

We apply a risk-based approach to selecting business partners. The greater the estimated risk regarding a certain country, region, or type of service, the more in-depth we examine the company before entering into a business relationship. We also explore background information from various databases and information reported by our business partners.

If we encounter compliance concerns, we further analyze and verify the relevant information. Based on the outcome, we decide whether to reject the potential business partner, impose conditions to mitigate identified risks, or terminate the existing relationship.

Until the end of 2023, we plan that all subsidiaries of our company will have a Third Partner Risk Management process and tool that follows a risk-based approach to conduct business only with legally compliant third parties. To enable stepwise implementation, we already launched this new process and tool in selected pilot countries in 2021..

Compliance training

We provide regular compliance classroom and online training courses on our Code of Conduct, anti-corruption, antitrust, data privacy, money laundering prevention, and healthcare compliance standards. We require employees to take these courses based on their exposure to risk. Some courses also apply to independent contractors and supervised workers, such as temporary employees.

In 2021, we launched two new versions of our antitrust e-learning training courses: a fundamental and an advanced course. Both courses are available in ten languages. 12,560 employees completed the fundamental training. In addition to the fundamental training, 6,057 employees with potentially higher risk exposure took the advanced training course. The mandatory training courses must be completed by all relevant employees.

We regularly update our training plan and adapt it to new developments to continuously educate our employees on existing and new compliance requirements, guidelines, and projects.

Anti-money laundering

We have implemented a global Anti-Money Laundering (AML) program consisting of a global policy, training, and a dedicated process to report and investigate red flags as well as any high-risk transactions and to report suspicious transactions to the German Financial Intelligence Unit.

It is our aim to continuously improve our AML program. In 2021, we conducted a worldwide risk analysis to identify jurisdictions that impose the strictest AML legal and regulatory framework applicable to our businesses, so that we can improve our AML program accordingly. Based on this analysis, we initiated in-depth AML risk assessments for high-risk jurisdictions, where we can implement a stricter AML program, if required.

Reporting potential compliance violations

We encourage all employees worldwide to report potential compliance violations to their supervisors, Legal, HR or other relevant departments. Globally, they can also use our central whistleblowing compliance hotline free of charge and anonymously to report violations in their local language by telephone or via a web-based application. Reports of potential compliance violations that we receive via our compliance hotline are reviewed by the Compliance Investigations and Case Management team. Cases with a certain risk profile are presented

to the Compliance Case Committee, which comprises senior representatives from our Compliance, Corporate Security, Data Privacy, Human Resources, Internal Auditing, and Legal departments.

The Committee's duties include assessing and classifying ethical issues, investigating their background and addressing these issues using appropriate measures. Based on the investigation outcome and recommendations from the compliance investigation team or the Compliance Case Committee, appropriate disciplinary action may be taken against employees who have committed a compliance violation. If, during the investigation, a root cause is identified that could lead to further compliance violations, we take preventive and corrective actions.

The compliance hotline is also available to external stakeholders. The relevant information can be found in the Compliance and Ethics section of our **website**.

Both the number of suspected compliance violations reported and the number of actual compliance cases were stable compared with the previous year. In 2021, we received 79 compliance-related reports via the compliance hotline and other channels that led to investigations. There were 42 confirmed cases of violations of the Code of Conduct or other internal and external rules.

Reported compliance violations

	2018	2019	2020	2021 Group	2021 thereof: Merck KGaA, Darmstadt, Germany
Total number of reported compliance violations					
Number of reported compliance incidents	72	75	81	79	6
Number of confirmed cases	19	30	41	42	3
Confirmed cases by category					
Bribery and corruption	3	9	6	1	0
Violation of cartel laws and fair competition rules	1	0	0	0	0
Fraudulent actions against the Group	5	8	11	6	0
Other violations of the Group Compliance Principles for the relations with business partners	1	4	0	0	0
Other violations of Group values, internal guidelines or legal requirements	9	9	24	35	3

Compliance audits

Compliance is ensured by Group Compliance and Group Internal Auditing as the second and third lines of defense. As part of the audits, Group Internal Auditing regularly reviews functions, processes, and legal entities worldwide. These reviews include an assessment of the effectiveness of the respective compliance guidelines, processes, and structures in place. The unit also checks for violations of our Code of Conduct and our Anti-Corruption Policy. Moreover, they request and check a self-assessment of the workplace requirements set out in our Human Rights Charter.

Our audit planning aims to provide comprehensive risk assurance through the best possible audit coverage of our processes. We take a risk-based approach to our annual audit planning process, considering factors such as sales, employee headcount, systematic stakeholder feedback, and the Corruption Perceptions Index (**CPI**) published by the non-governmental organization **Transparency International**. If an internal audit gives rise to recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the recommended corrective actions. In 2021, Group Internal Auditing conducted 84 internal audits that

included bribery and corruption-related risks, thereof 55 operational, 28 IT and one special audits (for example, incident-specific internal investigations).

Interactions with health systems

The well-being of patients is our primary consideration when promoting pharmaceutical products. We support health systems by providing information to our healthcare stakeholders, such as professional medical associations, patient advocacy groups, university clinics, and other healthcare providing institutions. We follow clearly defined internal approval requirements and procedures for each type of interaction, in line with applicable laws and codes. In countries with statutory or industry obligations on the disclosure of transfers of value to healthcare stakeholders, we comply with these obligations.

Direct-to-consumer advertising only in certain countries

Direct-to-consumer (DTC) advertising for prescription medicines is permitted in some countries, such as the United States. In line with applicable local laws, we use DTC advertising in these countries to help increase people's awareness of certain diseases and the available therapies.

Roles and responsibilities

For all engagements with healthcare stakeholders, we have established internal policies and review processes and tools, such as record-keeping systems, to ensure adherence to statutory requirements and transparency obligations.

Our Global Regulatory Affairs unit has established a dedicated standard and corresponding process document on the review and approval of our promotional materials. At the operational level, the relevant business and all employees involved in our sales and marketing activities must adhere to our internal policies, standards and procedures. To ensure that all promotional materials meet our standards as well as local regulations end-to-end, we apply a harmonized Group-wide review and approval system.

Our commitment: Group-wide guidelines and industry standards

In addition to applicable laws and our own internal standards, we comply with the codes of conduct of various international and local industry organizations, such as the **Code of Practice** published by the International Federation of Pharmaceutical Manufacturers & Associations (**IFPMA**) and the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) or the regulations of the U.S. Pharmaceutical Research and Manufacturers of America (**PhRMA**).

Moreover, we apply various specific internal rules and regulations:

- Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations (Pharma Code)
- Healthcare Ethical Guiding Principles
- Standard on Medical Activities
- Policy on Interactions with Patients, Patient Opinion Leaders, and Patient Organizations
- Guideline Good Practice and Process Guidance: Engagement with Patients, Patient Opinion Leaders, and Patient Organizations.

Transparent reporting

In 2021, we continued to publish financial and non-financial contributions that we made to healthcare stakeholders in the healthcare industry, such as healthcare professionals and healthcare organizations, as appropriate and in accordance with local laws and codes. The published information includes the names of individual recipients and their addresses as well as the purpose and amount of the transfer, as required by the applicable laws and codes. Before publishing, we secured all necessary informed consent forms, as required by the applicable data privacy regulations.

Regular employee training

In 2021, we continued with the international roll-out of our Code of Conduct-related training curriculum on dealing with dilemmas in healthcare-specific situations. Employees who are responsible for the promotion of our pharmaceutical products receive regular training on current guidelines. New employees participate in onboarding training dealing with the review and approval of promotional materials. Based on their roles and responsibilities and in order to remain up to date, employees participate in mandatory e-learning courses and classroom trainings on our policies and guidelines as well as important changes to the reporting requirements of transfers of value.

Other topics

Sustainable innovation and technology

The sustainable innovation that we envision or drive forward must align with and support the three goals of our **sustainability strategy**. We define sustainable innovation as new or improved products, services, technologies, or processes that generate economic benefits and have positive environmental and social impacts. Therefore, we develop long-term solutions for our innovation and research activities long-term solutions that consider the entire value chain and evaluate each product's impact over its lifecycle.

Research and development (R&D) play an essential role in further improving our sustainability performance. They are critical elements that determine the sustainability impact of our products, from their initial conception to market launch. Our business sectors create tailored sustainability strategies to develop products that benefit patients and customers. We are also improving the way we measure our progress, which includes the introduction of sustainability criteria within our product development processes.

In 2021, we partnered with the well-established patent information platform LexisNexis® PatentSight® to assess the sustainability impact of our intellectual property. Building on this, we will start disclosing the share of newly published sustainability-related patent families as of the 2022 reporting year.

Roles and responsibilities

The organizational set-up of our R&D activities reflects the overall structure of our company. All three of our business sectors operate independent R&D units that pursue their own innovation strategies. Group Corporate Sustainability supports our business sectors and group functions to advance and integrate sustainability within our R&D and innovation processes in line with our shared goals.

Our new Group Science & Technology Office leads the implementation of our combined strategy for innovation and "data & digital", enabling innovation across our business sectors while harnessing the power of highly advanced data and digital capacities. It aims to identify and integrate transformative technology trends into our business sectors while maintaining a company-wide view of our tech roadmap and innovation portfolio. In addition, it ensures the strategic fit of our innovation fields. Fostering data & digital is key to accelerating sustainable innovation and enabling rapid action and personalized offerings. Innovation projects are incubated either through our corporate innovation teams or in the business sectors.

Lastly, we are also investing in sustainable solutions via **M Ventures**, our strategic corporate venture capital fund. It complements our Life Science, Healthcare and Electronics business sectors by focusing on investments in two areas of high strategic relevance to our company: digital technology and sustainability.

Our commitment: Aiming for circularity

Within our R&D processes, we continuously improve and integrate sustainability KPIs to measure the sustainability performance of our products and portfolio. For example, our Life Science business sector developed Design for Sustainability (DfS) as well as the DOZN™ tool to enable the creation of more sustainable products for our customers. In addition, several circular economy initiatives are underway throughout the organization, some of which are in collaboration with external partners.

Reporting in accordance with the EU Taxonomy Regulation

Fundamentals

The EU taxonomy for sustainable activities (hereinafter "EU taxonomy") is a classification system that translates the climate and environmental objectives of the European Union (EU) into criteria for sustainable economic activities. For this purpose, the EU taxonomy defines various key figures and qualitative information that the Group must disclose. The disclosure obligation under Article 8 of Regulation (EU) 2020/852 of the European Parliament and of the European Council dated June 18, 2020 on establishing a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088 (hereinafter "EU Taxonomy Regulation") and the delegated acts adopted in this regard is being carried out in two phases:

- For 2021, key figures will be stated only for so-called taxonomy-eligible economic activities and will be limited to those that make a significant contribution to climate change mitigation or climate change adaptation as defined by the EU Taxonomy Regulation. An economic activity is considered taxonomy-eligible provided that it is within the scope of the EU taxonomy.

- As of 2022, four further environmental objectives of the EU will be included in the disclosure obligation: 1) sustainable use and protection of water and marine resources, 2) transition to a circular economy, 3) pollution prevention and control, and 4) protection and restoration of biodiversity and ecosystems. In addition to the degree of taxonomy eligibility, the share of taxonomy alignment of the identified economic activities will then also be disclosed. According to the EU taxonomy, an economic activity is considered taxonomy-aligned if it makes a significant contribution to at least one of the six environmental objectives while ensuring that such an activity does no significant harm to the remaining objectives or the social minimum safeguards.

For the environmental objective "pollution prevention and control," which is to be disclosed for the first time for the 2022 reporting period, the Group expects a higher share of taxonomy-eligible economic activities than for the objectives "climate change mitigation" and "adaptation to climate change" that are reported for the 2021 reporting period. This assessment is based on proposals for technical assessment criteria by the "Technical Working Group of the EU Platform on Sustainable Finance" dated August 3, 2021, which, with respect to the environmental objective "pollution prevention and control", list the production of chemicals, pharmaceutical and chemical products, and pharmaceutical preparations without further specification as taxonomy-relevant economic activities. These proposals will flow into the development of the delegated act through which the European Commission will define the technical evaluation criteria in 2022.

Approach

To ensure the timely and legally compliant fulfillment of its disclosure obligations, the Group established an interdisciplinary project team that is analyzing the existence of taxonomy-eligible activities in close coordination with the representatives of the business sectors and various Group functions. The identification of the taxonomy-eligible economic activities for the first two environmental objectives proceeded in line with a top-down approach using structured inquiries submitted to the relevant departments. The results of this analysis were confirmed by supplementary big-data supported analyses as part of a bottom-up approach. Among other things, information was used that can also be found in connection with the requirements of the REACH regulation as well as in the context of customs declarations.

The three key figures net sales, capital expenditure and operating expenditure were mainly derived from existing financial reporting systems. Double counting is excluded by the very nature of the procedure.

Accounting principles

To review the taxonomy-eligibility of an economic activity, for manufacturing-related activities, the Group applies an end-product oriented approach. This means that the end product must result from one of the economic activities named in the delegated act. In the case of chemical products, the corresponding economic activities are only considered taxonomy-eligible if the end product is an organic basic chemical within the meaning of the delegated acts for the environmental objectives “climate change mitigation” and “climate change adaptation”. The manufacture and distribution of specialty chemicals, which represent the core activities of the Life Science and Electronics business sectors, are not covered by this definition.

Furthermore, the Group only takes into consideration the manufacturing activities named in the delegated act if these are linked to a significant transformation process. In our interpretation, products that are merely passed on for sale, repackaged or mixed do not qualify as taxonomy-eligible within the meaning of the EU Taxonomy Regulation. In particular in the Life Science business sector, net sales from the sale of organic basic chemicals or plastic products are not taxonomy-eligible in the vast majority of cases due to the lack of a manufacturing process.

The economic activities specified in the delegated act are also considered taxonomy-eligible with respect to capital expenditure and operating expenditure if they are only performed for company-internal purposes and do not generate any sales with third parties. For example, this means that in the viewpoint of the Group, capital expenditure and operating expenditure incurred in conjunction with the renovation of buildings for own use are also within the scope of the EU Taxonomy Regulation. By contrast, the Group considers neither economic activities in the context of the construction of new buildings nor the acquisition and ownership of buildings to be taxonomy-eligible.

The definition of relevant net sales for the purposes of the EU Taxonomy Regulation corresponds to the definition of net sales in the consolidated financial statements (see Note (9) “**Net sales**" in the notes to the consolidated financial statements). Within the Group and within the meaning of the EU Taxonomy Regulation, capital expenditure in the reporting period comprises additions to property, plant and equipment (IAS 16), rights of use assets from leases (IFRS 16), and intangible assets (IAS 38) with the exception of goodwill. Apart from the additions, advance payments for the named assets are also included. Operating expenditure relevant within the scope of reporting under the EU Taxonomy Regulation include direct, non-capitalized research and development costs, low-value leases, building renovations, maintenance and repair, and all other direct internal and external expenses related to the day-to-day maintenance of property, plant and equipment that are necessary to ensure the continuous and effective functioning of these assets.

Key figures and qualitative information

The following overview presents the share of net sales, capital expenditure and operating expenditure attributable to taxonomy-eligible economic activities in respect of the environmental objective “Climate change mitigation”.

Environmental Objective "Climate Change Mitigation"

Key Performance Indicator	Reference value in the reporting period 2021 (in € million)	Share of the taxonomy-eligible economic activities (in %)	Share of the not taxonomy-eligible economic activities (in %)
Net sales	19,687	< 1%	> 99%
CapEx	1,817	< 1%	> 99%
OpEx[1]	2,692	< 1%	> 99%

[1] The EU taxonomy only defines a certain portion of all operating expenses as a baseline for operating expenses.

The lower share of taxonomy-eligible net sales, capital expenditure and operating expenditure in connection with the environmental objective “climate change mitigation” is mainly due to the very limited conformity of the business activities of the Group with the economic activities stated in the EU Taxonomy Regulation. The low amount of net sales from taxonomy-eligible economic activities was generated in the manufacture of energy efficiency equipment for buildings. The share of taxonomy-eligible operating and capital expenditures was largely attributable to the renovation of existing buildings.

Research and development expenses accounted for € 2,408 million of the presented operating expenditure with € 1,712 million of this being attributable to the Healthcare business sector.

No additional taxonomy-eligible net sales, capital expenditure or operating expenditure were identified for the environmental objective “climate change adaptation”.