BUSINESS ETHICS

Corporate governance

Governance

For more than 350 years, responsibility has been an integral part of our corporate identity. It is one of our six company values, alongside courage, achievement, respect, integrity, and transparency. We seek to balance environmental, social and governance aspects and find solutions for the world of tomorrow. Our actions serve all people who need our medicines or medical treatment, the companies we supply and the people or partner firms we collaborate with.

Our approach to responsible 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 integrate requirements such as these 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 standard entitled Corporate Chemicals Regulations Governance describes the processes and management structures required to ensure global complianc with the pertinent chemical and product safety regulations.

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.

We use **management systems** to steer processes as well as 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 is conducted by an independent auditing firm. We hold group certificates for both standards.

We support the following responsible governance initiatives:

- We have been a participant in the **United Nations Global Compact** since 2005 and are committed to complying with its principles.
- As a signatory to the chemical industry's **Responsible Care® Global Charter**, we voluntarily go above and beyond what is required by law and have adopted mandatory standards for product responsibility, environmental impact mitigation and health and safety.
- As a member of the **Together for Sustainability** (**TfS**) network, we are dedicated to improving the supply chain with respect to environmental, compliance and social standards.
- We are a member of the Pharmaceutical Supply Chain Initiative (**PSCI**), which aims to continuously improve health, safety and environmental aspects throughout the supply chain.
- We are also a member of **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**). The partners involved this globally unique alliance seek to make sustainability a core part of the chemical industry's guiding principles and to jointly drive the sector's position within the German economy as a key contributor to sustainable development.

Compliance management

Responsible entrepreneurship starts with compliance. We aim to ensure that all our activities adhere to relevant laws, regulations and ethical standards around the world. This also helps us to protect our reputation as an employer and business partner.

Our approach to compliance

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 framework of the following core topics: the Merck Code of Conduct, anti-corruption and anti-bribery (including healthcare compliance, third-party due diligence, transparency reporting), anti-money laundering, antitrust, and conflicts of interest.

To cover these topics, we have **Group-wide policies, standards** and procedures in place that ensure our business activities comply 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; perform internal and external reporting
- **Case Management:** Timely response to reports of misconduct and implementation of corrective actions
- **Continuous Improvement:** Based on and applicable to all compliance program elements

We continuously review our compliance portfolio and update our initiatives and programs where necessary. This approach reflects new requirements as well as internal and external risks, such as those resulting from amendments to legislation, relevant industry codes or changes affecting our company. We discuss current compliance matters, trends and goals with our stakeholders, both internally within our compliance organization and externally. We keep the focus on **our people** by ensuring the availability of appropriate resources and skills, maintaining clear roles and responsibilities and based on employee feedback, setting aligned and harmonized goals. We also ensure that our organizational structure is up to date and meets business needs.

Our Chief 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 Chief Compliance Officer oversees all Compliance departments and the underlying Compliance Officers and Compliance experts around the world. The Compliance Officers implement our compliance program within their respective areas of responsibility (adapting to local regulations) 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.

As part of the Group Compliance Center of Expertise, our global team for coordinating transparency reporting is responsible for implementing current and upcoming transparency **reporting requirements in the Healthcare business sector** – including those of the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) and the United States Physician Payments Sunshine Act. More information on our Healthcare governance and compliance activities can be found in the **Responsible interactions with health systems** section.

Our commitment: Guidelines and standards

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

- The **Merck Code of Conduct** guides our people in conducting business ethically – in line with our values and the law. It is available to all employees worldwide in 22 languages.
- Our **Human Rights Charter** supplements our Code of Conduct with globally recognized principles on human rights.
- Our **Anti-Corruption Standard** stipulates that all business activities must be conducted in line with applicable anti-corruption regulations and standards. All forms of bribery are strictly prohibited.
- Our global **Anti-Money Laundering Group Standard** defines and describes the internal global process and assurance measures to protect our company from being misused by third parties for money laundering or terrorist financing activities.
- Our **Conflict of Interest Policy** sets a framework to explain the nature of a Conflict of Interest and the related risks. It advises how to prevent these kinds of situations or how to set rules for identifying, disclosing, mitigating and managing the risks that could arise from such situations**.**
- Our Group-wide **Antitrust and Competition Law Policy** states that all business activities across the Group must be conducted in compliance with applicable competition regulations at all times. We acknowledge the importance of fair competition and expect the same of parties acting on our behalf.
- Our **Compliance Reporting and Investigation Policy** includes the basic steps for an internal compliance investigation. Its purpose is to ensure an appropriate, timely and thorough response to compliance-related reports of potential misconduct pertaining to any kind of internal or external regulations or policies.
- Our **Dawn Raid Policy** defines courses of action, sets out general rules of conduct, and advises on rights and obligations during unannounced investigations, searches and seizures by authorities on our premises.
- Our **Standard on Local Compliance Standards** implements a review and approval process for local governance documents in areas under the responsibility of the Group Compliance function. In this way, our local teams can adhere to our compliance principles and guidance while implementing **specific local policies or procedures** that comply with local regulations.
- Furthermore, we developed a new **Supplier Code of Conduct** (SCoC) in 2022. It took effect in and is implemented as of January 2023, thus replacing our Responsible Sourcing Principles. The SCoC will lay out the minimum standards our suppliers and business partners are expected to fulfill regarding human rights, health and safety, business integrity, environmental protection, continuous improvement, and management of their respective suppliers.

To maintain compliance, we annually review and compile a list of changes to the applicable laws and regulations and update the policies, standards and procedures accordingly. While for major countries we rely on external legal counsel to stay abreast of these changes, for other countries, we rely on our Compliance Officers. Our annual reviews also identify whether any corrective actions from investigations or internal audits require us to update our policies, standards or procedures.

Risk assessment

Proper compliance risk management is crucial to identify undetected risks and ensure our company remains protected. For this purpose, we are implementing a compliance risk identification process. We started this initiative by launching a global compliance risk process for all our business sectors to improve objectivity and enable a more data-driven risk approach. In addition, we established a **comprehensive risk matrix** that focuses on bribery and corruption risks, illustrated through in-depth risk categorization and risk scenarios. As a next step, in 2022, we started conducting country-based risk assessments. This approach considers gross and net risks while looking at tangible risk scenarios for the respective business. During this process, Group Compliance works closely with the businesses to enhance their risk awareness and create a better understanding of compliance risks. The first round of this process includes high-risk countries.

Furthermore, in 2022, we updated our **country risk segmentation** approach. With it, we determine the risk exposure of the countries where our company is actively operating. The primary aim of this analysis is to classify countries in terms of their risk exposure relating to bribery and corruption by applying objective and consistent criteria. We then use the resulting outcome as a basic model to prioritize projects and initiatives and support or intensify activities in countries with specific risk levels.

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 supervisor and document the disclosure. Such issues are typically resolved directly between the employee and the supervisor but can also be routed to Human Resources, Legal, Compliance, or other relevant functions.

In 2022, we further raised employee awareness of conflicts of interest by establishing a **dedicated global e-learning course** and enhancing our communication.

In addition, as described in the Annual Report under **Avoidance of conflicts of interest**, Executive Board and Supervisory Board members are exclusively committed to the company’s objectives and neither pursue personal interests nor grant unjustified advantages to third parties.

Management and requirements of third parties

For compliance management to be effective, it must not be restricted to the boundaries of our own company. While our **supplier management processes** focus on vendor compliance with our standards, our **global Third Party Risk Management** process governs interactions with sales parties, such as commercial agents, distributors and dealers. We expect our third parties worldwide to adhere to our compliance principles. We collaborate only with parties 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 select the third parties with whom we do business. The greater the estimated risk regarding a particular country, region, or type of service, the more in-depth we examine the third party before entering into a business relationship. We also explore background information from various databases and information reported by third parties.

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

Compliance training

We provide regular compliance classroom and online training courses on our Code of Conduct, anti-corruption, antitrust, data privacy, anti-money laundering, 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.

We introduced a new Conflicts of Interest e-learning module that explains what conflicts of interests are and how these should be managed within our company. The course is available in nine languages. Furthermore, we launched a new e-learning course to provide an overview of our Third-Party Risk Management and to emphasize the importance of Third-Party Risk Assessments.

We also regularly update our training curricula and adapt it to new developments. These ongoing efforts ensure we continuously educate our employees on existing and new compliance requirements, guidelines and projects.

As part of our targeted awareness campaigns, our two Anti-Money Laundering and Anti-Corruption standards were rolled out to senior management in 2022 via our internal communication channels.

Anti-money laundering

We have implemented a global **anti-money laundering** (AML) program consisting of a global Anti-Money Laundering Group Standard, training and a dedicated process to report and investigate red flags as well as any high-risk transactions. Suspicious transactions are reported to the German Financial Intelligence Unit or other authorities as required.

We aim to continuously improve our AML program. Following a worldwide risk assessment in 2021 to identify jurisdictions imposing the strictest legal and regulatory frameworks applicable to our businesses, we initiated in-depth AML risk assessments for higher-risk jurisdictions. Based on these assessments and constant review of changes in the legal environment, we are implementing stricter local AML programs where 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 certain compliance 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 the risk of 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**.

The number of suspected compliance violations reported remained stable compared with the previous year, while the number of confirmed compliance violations decreased. In 2022, we received 79 compliance-related reports via the compliance hotline and other channels that were processed as cases. 28 violations of the Code of Conduct or other internal and external rules were confirmed.

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 units also check for violations of our Code of Conduct and our Anti-Corruption Standard.

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 2022, Group Internal Auditing conducted 79 internal audits involving bribery and corruption-related risks, including 52 operational and 24 IT audits and 3 special audits which may, for example, be initiated as part of incident-specific internal investigations.

Engaging stakeholders

We are members of various organizations, including the German Chemical Industry Association (**VCI**), the German Institute for Compliance (**DICO**), the European Federation of Pharmaceutical Industries and Associations (**EFPIA**), the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), the International Federation of Pharmaceutical Manufacturers and Associations (**IFPMA**), the **Alliance for Integrity**, the German Association for Supply Chain Management, Procurement and Logistics (**BME**), and the International Association of Privacy Professionals (**IAPP**).

Data protection & cyber security

Compliant handling of information is highly important for a leading innovative, science- and technology-driven company. When using personal data, the individuals' rights must be appropriately protected. We strive to safeguard the rights of any person whose data we process, including but not limited to our employees, patients, customers, and healthcare professionals. When it comes to cyber security, our company understands the importance of protecting our business from cybercrime and ensuring our information is secure from any associated internal and external risks.

Our approach to data 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 ensuring compliance with relevant data privacy laws globally. Group Data Privacy also contributes to creating value for the development of digital business models.

Our approach to cyber security

It is of critical importance for our business that we protect our information systems, their contents, and our communication channels against any criminal or unwanted activities. These include e-crime and cyberattacks, such as unauthorized access, information leakage and misuse of data or systems.

Roles and responsibilities

Group Data Privacy is an independent function, organizationally integrated into Group Compliance and Data Privacy. 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 and their respective teams act independently and without receiving internal or external instructions. Group Data Privacy regularly prepares **data privacy updates** and a comprehensive data privacy report. This report is submitted to the Executive Board and the Supervisory Board.

Cyber Security is part of our Group Corporate Security Office. In addition, we have a Group Chief Information Security Officer and a network of Information Security Officers within the business sectors, each in turn supported by dedicated networks. The individual sectors hold risk ownership and act as our first line of cyber security defense. Our Global Cyber Security function acts as a second line of defense and has responsibilities regarding cyber security risk governance and oversight. Our third line of defense comprises internal audits.

Our Data Privacy Management System

Our goal is to complete the implementation of a global and consistent data privacy management system (DPMS) by mid-2023. Our DPMS applies similar elements as the **compliance portfolio** but adapted to the needs of data privacy. These include policies and procedures, risk assessment and documentation, training and awareness, programs and tools, individual requests, monitoring and reporting, incident management, and continuous improvement.

New Cyber Security organization

At the beginning of 2022, we created a new Cyber Security organization with a mandate to improve trust and strengthen resilience against cyberattacks and data breaches.

Our Cyber Security team defines policies and standards for cyber security (including data security) while providing oversight, tools and systems to manage and monitor our overall cyber security risk exposure. The team is also responsible for providing 24/7 cyber security monitoring and incident response capabilities across the entire company environment as well as training employees across the organization on how to protect data appropriately.

Our commitment: Guidelines and standards

Data Privacy Framework

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 are also taking steps to meet local data privacy requirements, where these are stricter than our Group-wide standards.

Cyber Security Framework

Our Group Cyber Security governance framework comprises organizational, process-related and technical information security countermeasures based on recognized international standards. In addition, we **apply harmonized electronic and physical security controls** (e.g. access control and security monitoring) to bolster our ability to handle sensitive data, such as trade secrets.

Data privacy training

In line with the EU GDPR and our global approach to data privacy, we regularly conduct **e-learning training courses** in ten languages. In 2022, the completion rate for our e-learning courses was 98%. Additionally, Local Data Privacy Officers support the execution of our Group-wide training plan by conducting training for specific target groups on request.

IT tools for documentation

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 2022, we rolled out a new data privacy tool. Additionally, we use our corporate intranet for further communication, including answering data privacy questions and providing standardized templates. In 2022, we registered **no sanctioned complaints** or incidents concerning breaches of customer privacy, data leaks, theft, or loss of customer data. In three out of 57 cases, minor personal data breaches were reported to the supervisory authority. These were not sanctioned.

Cyber Security Awareness

The Cyber Security organization has established multiple campaigns – in addition to the mandatory IT Security Awareness e-learning training – to ensure a high level of awareness among internal and external employees. One example is the **cyber hero campaign**, which features a series of videos demonstrating how to apply information security effectively through real-life examples. In addition, all employees receive monthly phishing e-mail simulations to learn how to identify and report potential attempted breaches in an interactive way.

Responsible interactions with health systems

It is important that healthcare stakeholders, such as research institutes, healthcare professionals and patient advocacy groups, have access to up-to-date information on diseases and treatments while safeguarding their independence at the same time. We help to facilitate this access. We also support cutting-edge research projects.

Our approach to interacting with health systems

We support health systems by providing information to our healthcare stakeholders, such as professional medical associations, patient advocacy groups, university clinics and other institutions that provide healthcare. 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 aim to comply with these obligations.

We are committed to adhering to all regulations concerning the promotion of pharmaceutical products. In most markets, pharmaceutical companies are permitted to advertise prescription medicines only to healthcare professionals, such as physicians and pharmacists. These promotional activities must always disclose the active ingredient, potential adverse effects and contraindications of the medicine. Our internal governance documents on the promotion of pharmaceutical products are part of our Group-wide program, which requires us to conduct business in compliance with the law and industry obligations. Our aim is to apply **high ethical standards**. We regularly review all our internal governance documents and revise them as required in response to any new developments.

We clearly differentiate between information-sharing activities and promotional activities. The former are activities where we share scientific information but have no intention of promoting or increasing the sales of pharmaceutical products. The latter are activities with a clear intention to promote or increase sales of pharmaceutical products. The differentiation is critical for various internal policies and standard operating procedures, responsible functions, and levels of review and approval.

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. In doing so, we empower patients to **make informed decisions** about their own treatment.

Roles and responsibilities

For all interactions 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 for our Healthcare business sector. 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**. In our Healthcare business sector, we use a single global software tool. This has enabled us to unify, simplify and monitor the review and approval process for promotional materials and monitor that process in accordance with the dual-control principle. If the material has promotional intent and is product-related, a review is conducted by our Medical, Legal and Regulatory functions. This also helps us identify opportunities for improvement. All employees involved in creating, reviewing and approving promotional materials undergo training on the current process for reviewing, approving and decommissioning promotional materials based on our principles and standards.

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 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**).

We are also members of various local industry associations, such as the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA) and the U.S. Pharmaceutical Research and Manufacturers of America (**PhRMA**). Our activities adhere to the associations' codes for collaboration between healthcare professionals and the pharmaceutical industry.

Our Group-wide Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations (Pharma Code) defines the general compliance for our activities in the Healthcare sector. It provides high-level and overarching principles that govern our interactions with physicians, medical institutions, and patient advocacy groups, along with our promotional practices.

Our **Healthcare Ethical Guiding Principles** supplement the Pharma Code and guide our Healthcare employees with six ethical principles for decisions and activities specific to the particular challenges and responsibilities of this business sector.

Under the umbrella of our Pharma Code and Healthcare Ethical Guiding Principles, we have specific governance documents, procedures and tools for different types of interactions with healthcare stakeholders, covering topics such as service engagements, hospitality, payments (at fair market value), donations and sponsorships to participate in events.

Our **Standard on Medical Activities** provides the general principles and requirements that must be respected in all medical activities, including interactions with healthcare providers. The specific governance for the different types of activities and interactions is detailed in further policies and standards, standard operational procedures and other governance documents.

Collaborating with patient advocacy groups

Our Policy on Interactions with Patients, Patient Opinion Leaders and Patient Organizations provides a comprehensive framework for our interactions with these key stakeholders. Our guideline entitled Good Practice and Process Guidance: Engagement with Patients, Patient Opinion Leaders and Patient Organizations provides additional guidance for our interactions with these stakeholders. It reflects our commitment to prioritizing patient well-being and guides appropriate patient/caregiver engagement that enables our patient-directed approach. Through this policy, the supplementary guideline and specific local policies, we provide a robust guidance structure to support our employees in remaining compliant throughout their interactions with patients, patient opinion leaders and patient organizations.

We seek to improve patients' quality of life, which is why we support the work of patient advocacy groups. In turn, these groups provide patients, family members and caregivers with information on disease management and educational and advocacy resources.

Supporting medical education

To contribute to medical advances that benefit patients, we organize non-promotional medical education programs worldwide through our Global Medical Education and Academic Organization Relations department. We offer an Integrated Medical Education Portfolio by funding independent third-party medical education providers such as medical societies and academic organizations. We also offer company-led medical education programs. We take an **ethical, transparent and responsible approach**, providing fair and balanced content that allows the expression of a diverse range of theories and recognized opinions.

All requests for medical education funding are subject to an approval process through our R&D and Compliance functions, in line with our Standard on Medical Education Funding and Policy on Company Programs. This process ensures all funds granted for medical education programs comply with our internal guidelines and criteria as well as all applicable laws and industry codes.

In addition, we partner with industry associations, such as the Global Alliance for Medical Education (GAME) and the International Alliance for Continuing Medical Education (iPACME). We are also an active member of the relevant working groups established by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Medical Affairs Professional Society (MAPS). Together with these associations, we discuss ways to harmonize and improve quality standards for medical education.

Transparent reporting

We publish the financial and non-financial contributions we make 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, their addresses, the purpose, and the contributed amount or value as required by the applicable laws and codes. In addition, before publishing, we secure all necessary informed consent forms, as required by the applicable data privacy regulations.

In addition to disclosing monetary transfers of value on an individual level, we continue to **publish overall spending** on our **research and development** activities, as required.

Apart from disclosing transfers of value to healthcare professionals and healthcare organizations as required, we ensure transparency on our voluntary unsolicited donations to European patient organizations by publishing the contribution details on our **website**. The report is updated annually and includes all amounts, recipients and the purpose of each transfer of value, thus also meeting **our obligation** as an **EFPIA** member.

Regular employee training

We are continuing our Code of Conduct training curriculum on managing **dilemmas in sector-specific situations**. This comprehensive and interactive training course seeks to improve participants' awareness and understanding of relevant dilemmas, such as overhearing a conversation that may or may not constitute attempted bribery. We plan to further implement this training program in all countries in which our Healthcare business sector operates. In addition, the success of this program has prompted us to further implement the program in our Life Science and Electronics business sectors.

Employees who are responsible for the promotion of our pharmaceutical products receive regular training on current guidelines. This applies to individuals in sales, marketing and functions who work directly with healthcare providers. We conduct these seminars either locally in a classroom setting or as e-learning courses.

Depending on their roles and responsibilities, new employees, participate in **onboarding training** dealing with the review and approval of promotional materials. Additionally, employees in charge of marketing and promotion of pharmaceutical products can also access our respective guidelines on our corporate intranet.

Based on their roles and responsibilities and to remain up-to-date, employees participate in mandatory e-learning courses and classroom training on our policies and guidelines, as well as important changes to the reporting requirements for transfers of value.

Tax governance

Our company operates in a complex legal environment and is subject to various tax obligations due to its domestic and foreign business activities. It is our responsibility to ensure compliance with tax legislation in all countries in which we operate and to be transparent. To this end, we have a tax organization in place that clearly defines responsibilities, processes and controls.

Our approach to taxes

We believe that fair taxation serves as a backbone of any functioning society. Therefore, we expect public authorities to take transparency, predictability and non-discrimination into consideration when implementing taxation measures. We understand that tax is embedded in almost every aspect of commercial operations and our company therefore acts as a **responsible taxpayer** with respect to the following objectives:

- Ensuring timely and proper execution of tax obligations;
- Securing material correctness of tax positions determined in the annual financial statements and tax declarations;
- Ensuring effective tax **risk management** and tax monitoring;
- Avoiding inappropriate structuring leading to benefits not provided for by tax law.

Roles and responsibilities

Taxes are managed in different units. Group Tax is generally responsible for tax matters of Merck KGaA and provides tax standards for the Merck Group – with the exception of customs, consumption tax and wage tax. The Export Control and Customs Regulations unit within the Corporate Sustainability, Quality and Trade Compliance (SQ) function is responsible for customs and consumption tax. Human Resources is responsible for wage tax.

The Group Chief Financial Officer (CFO) is responsible for the Group Tax function. He delegates his tasks related to tax matters to the Head of Group Tax. The Head of Group Tax is also responsible for defining the organizational structure of the function, for monitoring it on an ongoing basis and for adapting it if necessary. In addition, the local tax unit in the United States reports directly to the Head of Group Tax.

At the subsidiary level, the local CFO is generally responsible for tax matters, managed either by local tax units, by external advisors, or, for Germany and our U.S. subsidiaries, by Group Tax. The local CFOs report to the regional CFO. The regional CFOs ultimately report to the Head of Merck Business Services, who reports to the Group CFO. If no local CFO is assigned, the tasks are undertaken by a designated employee in the Finance unit.

Tax-related compliance topics can also be reported through our **compliance hotline**, our Group-wide whistleblowing system.

Our commitment: a tax principle

Our **Tax Principle** is part of our tax **internal control system**. It represents the framework and minimum requirements for all tax-relevant processes, methods and structures within our company. This principle

- outlines the tax compliance culture within the Group;
- defines our tax compliance objectives;
- specifies the organizational framework for tasks, roles and responsibilities, which ensures compliance with tax rules within the Group;
- establishes basic rules for the exchange of tax-relevant information.

The Tax Principle is issued by Group Tax and applies to the entire Group. It is reviewed it at least once a year and modified if necessary. Should extraordinary events occur, such as changes to the business strategy, organizational structures or risk management processes, the principle is reviewed on an ad hoc basis and adapted as appropriate. The Head of Group Tax is responsible for annual and ad hoc reviews as well as modifications to the principle. Any material modifications are discussed and coordinated with the Group CFO.

Suppliers

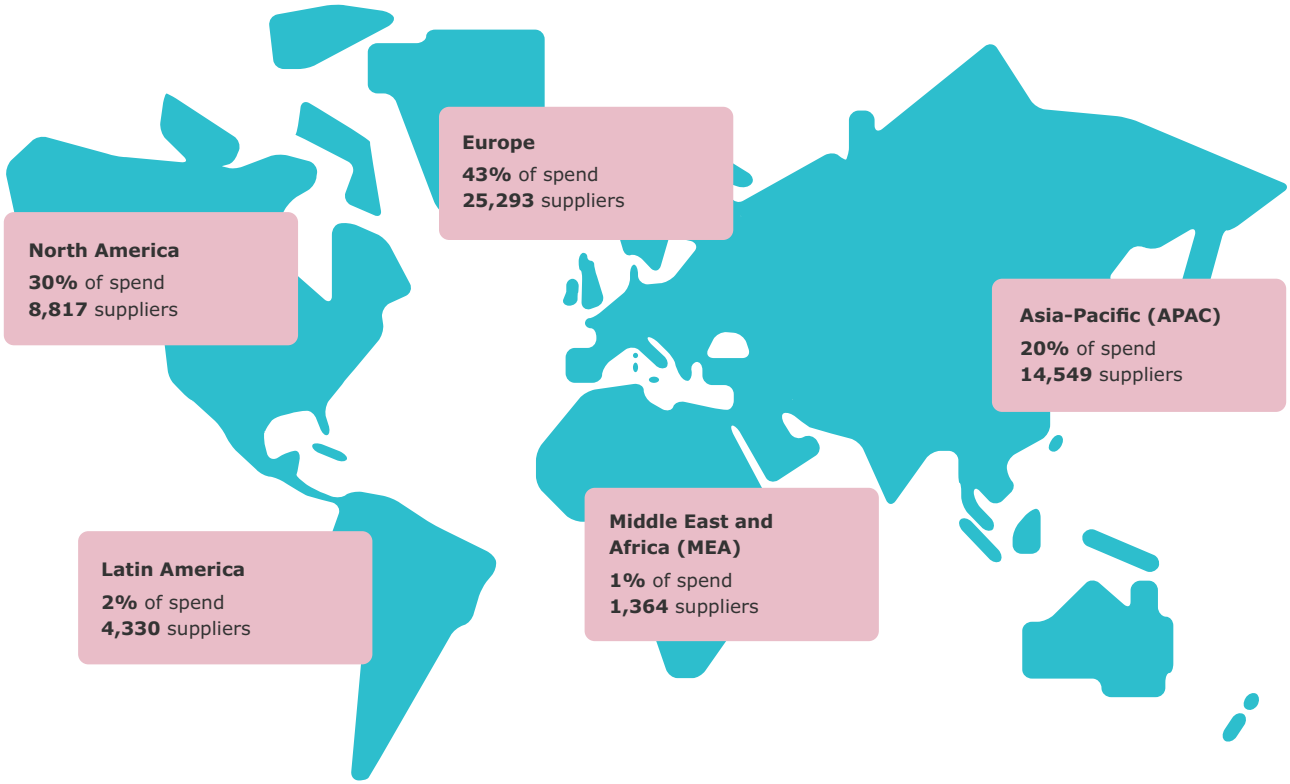
Sustainable supply chain management

Our company procures many raw and packaging materials, technical products, components, and services from around the world. We aim to promote supply chain stability while providing our customers with high-quality products and services. We expect our suppliers to respect our ethical, social and compliance standards and apply these to their own supply chains.

Our approach to sustainable procurement

In 2022, the total value of the goods and services we purchased from around **54,000 suppliers** in more than 140 countries was approximately € 10.2 billion, compared with approximately € 8.6 billion in 2021, representing an increase of 18.5%.

Supplier spend and suppliers per region – 2022[1]



[1] For data processing reasons, 2% of our suppliers (1,203 suppliers) are currently not assigned to any purchase region. This equates to 4% of our supplier spend.

With our supplier management endeavors, we aim for **compliance with fundamental environmental and social standards** in addition to high quality, reliable delivery and competitive prices. Therefore, we have introduced relevant strategies, processes and guidelines to prevent violations of supply chain standards and continuously improving our sustainability performance. Unless stated otherwise, the approaches presented apply to direct suppliers. Furthermore, our supplier management activities include special measures particularly for indirect suppliers working in the area of conflict minerals.

To achieve our **sustainability goals**, our Group Procurement team is working closely with our suppliers. We aim to create transparency in all our sourcing regions and fully integrate sustainability into all our value chains. To this end, we have defined two key indicators to 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 significant percentage of our supplier spend (at least 50%). For the risk evaluation, we previously used the risk data provided by **EcoVadis**. For the country risk, we have developed our own more comprehensive country risk score in 2022.

In 2022, 46% (2021: 33%) of our relevant suppliers were covered by a valid **sustainability assessment**; 82% (2021: 74%) of our spend generated from these suppliers were covered by suppliers with a valid sustainability assessment. To achieve comparability of our key indicators over the years, we applied this new country risk score also retrospectively for 2021 data, the starting point of our measurement.

We view our approach to supply chain sustainability as a journey and continuously work to improve and develop our policies and processes. While doing so, we consider all applicable legal requirements and initiate corresponding measures where necessary. For this purpose, in 2022, we implemented measures to operate compliant with the **German Supply Chain Due Diligence Act**. Among other things, the Head of Corporate Sustainability, Quality and Trade Compliance has been appointed as Human Rights Officer.

Our Supplier Decarbonization Program is a key element of achieving our **Science Based Target**. Through the program, we aim to **reduce greenhouse gas emissions** associated with purchased goods and services as well as capital goods. More details on this program can be found **here**; more information on our climate-related targets can be found in the **Climate action chapter**.

Risk management process

To ensure security of supply, we select our suppliers based on criteria such as country risk, material risk, supplier risk, and their strategic importance to the business. This process helps our sourcing managers identify potential mitigation actions with relevant suppliers and supports them in making improvements. The approach towards our **strategic suppliers which account for approximately 49% of our total supplier spend** includes the identification, monitoring and assessment of supply **security risks**. It comprises four main elements:

- **Supplier Risk Assessments:** to capture the overarching risks at the supplier level, considering multiple risk domains.
- **Alert system:** to notify our Procurement organization about risk events arising with any of our suppliers.
- **Material Risk Assessments:** to identify and mitigate the risks of the materials used in our most significant finished products.
- **Risk Response Tracker:** a system to create and monitor risk mitigation activities in inter-disciplinary teams.

We calculate risk factors for suppliers and raw materials by multiplying risk probability and risk impact. We have simplified our risk methodology to focus on the ten most relevant risk categories - including but not limited to

economic freedom, social unrest, unfair business practices, and poor labor practices - grouped into three risk domains. We also include criteria for identifying supplier relationships impacted by **key sustainability risks,** such as mineral sourcing and animal welfare. In 2022, numerous initiatives were developed to ensure our supply continuity including second source qualifications, regionalization of supply and financial support to suppliers under special circumstances, among others.

Due diligence process for responsible sourcing of minerals

We source and sell products that contain minerals commonly referred to as “3TG” (tin, tungsten, tantalum, gold – collectively also known as conflict minerals). These minerals involve the risk of being extracted, traded, handled, and exported from conflict-affected and high-risk areas (CAHRAs) where human rights are not always respected and violations thereof need to be prevented.

Our company operates in global and complex supply chains, in many cases with several tiers of suppliers between us and the original sources of the minerals used in our products. To address the risk of this complexity, 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.

Our aim is to source materials in a responsible and conflict-free manner and not to contribute to adverse impacts through our activities. Therefore, we have a due diligence program that applies across all our business sectors and is in line with applicable laws and international standards.

In order to continuously improve our due diligence practices, we have a system to store and maintain supplier information across our business sectors. This system supports increased transparency of our supply chain. In addition, we are working on the integration of further control mechanisms into our due diligence framework for high-risk suppliers. Furthermore, we are in constant exchange with suppliers, industry peers and cross-company collaborations to enhance regulatory compliance.

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. Sourcing managers responsible for selecting and contracting suppliers are made aware of and regularly updated on our **guidelines and sustainability requirements** through internal communication channels and training.

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**. We expect our suppliers to ensure that their subcontractors respect the same rules. In the reporting year, we have developed a **Supplier Code of Conduct** which details our expectations towards suppliers and business partners regarding human rights, health and safety, business integrity, environmental protection, continuous improvement, and management of their respective suppliers more comprehensively. It replaces our Responsible Sourcing Principles as of January 2023.

Our **Responsible Minerals Sourcing Charter** demonstrates our commitment to responsible sourcing of minerals from conflict-affected and high-risk areas. It applies to all our legal entities and subsidiaries worldwide. The charter complements the requirements set out in our Supplier 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. For example, we are a member of Together for Sustainability (**TfS**), the Pharma Supply Chain Initiative (**PSCI**), the Responsible Mica Initiative, and the Responsible Minerals Initiative (**RMI**). We call on our suppliers to let us or trusted partners conduct assessments or audits to increase our supply chain transparency and identify fields of activity to improve sustainability performance or mitigate infringement risks. Regarding our **mica supply chain**, we engage with a global consultancy firm to conduct audits and the Indian organization **IGEP** to conduct inspections.

Supply chain assessments and audits

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**. On top of the assessments, suppliers are also monitored through a 360-degree news watch. The results are shared among TfS member companies in compliance with all restrictions stipulated by antitrust law.

Through the TfS initiative alone, we have access to more than 1,700 valid scorecards on the **assessment** of our suppliers, more than 1,100 of which completed a new assessment or re-assessment in 2022. In some cases, these were initiated by us and in other cases by other TfS members.

In 2022, we collaborated closely with member companies in TfS workstreams focusing on sustainability **capacity building and supplier decarbonization**. We supported the development of a capability-building concept and deployed the TfS Academy. This training platform offers sourcing managers, interested employees and suppliers of TfS member companies 165 courses in up to nine languages on topics such as sustainable procurement, environment, health and safety, as well as labor and human rights. We also contributed to several best practice sharing and collaboration formats such as the TfS Talks as well as TfS Coordinator Roundtable. Furthermore, we supported the development and launch of the **TfS Product Carbon Footprint (PCF) Guideline**, which harmonizes PCF calculation methodology across the industry, and led the development of decarbonization training materials for TfS member companies and their suppliers.

Supplier Decarbonization Program

Our cross-functional Supplier Decarbonization Program team within Group Procurement is driving the execution of a ten-year program as part of the decarbonization strategy that was defined in 2021. In 2022, we continued to provide **training sessions and materials** for procurement managers and sourcing teams and engaged further with suppliers by sharing information about our climate targets. Follow-up discussions were again held regarding the supplier decarbonization questionnaire to assess the current decarbonization status and progress made since last year. This allows our sourcing managers to collate relevant supplier data in a global monitoring database.

We have also developed an **automated carbon accounting tool** to manage the large quantities of data on the CO_2 emissions of our suppliers. It has been available since the beginning of 2022 and we will continue adding new functionalities in the coming years.

Supplier diversity

In the United States, we have specific supplier diversity programs in place to comply with local legislation. We are focusing our efforts in the United States on enhancing our current **supplier locator tool** by broadening the rollout among sourcing managers to improve our ability to connect with and potentially award business to a wide range of vendors. Additionally, we continue to work on internal awareness campaigns and training seminars for our sourcing managers and are investing in tools to expand our database of small and diverse vendors. Starting in 2023, we plan to expand these efforts beyond the current focus on the sourcing category marketing & sales.

Ambassadors for sustainable procurement

We are active participants and contributors to the **Sustainable Procurement Pledge**, a TfS initiative established out of the social network LinkedIn in 2019. Since then, it has evolved to become a knowledge exchange platform for procurement professionals, academics and other **stakeholders**, hosting various online best practice exchange events.

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 plastics. We procure the majority of our mica from the Indian states of Jharkhand and Bihar. We have special measures in place to comply with high social and environmental standards in our mica supply chain.

Our approach to responsibility in the mica supply chain

By procuring mica from the Indian states of Jharkhand and Bihar, where social and economic factors contribute to poor working conditions, including child labor, we are supporting this region by safeguarding local employment and livelihoods. We source the raw material only from suppliers operating in formal working environments and we 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 **Supplier Code of Conduct** (formerly 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, we would terminate the business relationship immediately. We are driving initiatives and taking measures to improve the conditions of mica sourcing based on our high standards. We continuously review our monitoring processes to improve their effectiveness.

Roles and responsibilities

Group Procurement has overall responsibility for sourcing mica. A steering committee is in place to involve the relevant functions and inform the respective Board members about significant developments.

We have direct business relationships with suppliers for our mica supply chain in India in place. Our procurement unit is in direct contact with suppliers to reiterate the importance we place on ethical, social and environmental standards.

Our commitment: Compliance with guidelines and standards

As a signatory to the **United Nations Global Compact**, we are actively involved in working to abolish child labor. Our **Human Rights Charter** underscores this commitment. In our **Supplier Code of Conduct** (formerly Responsible Sourcing Principles), we set out our expectations for our suppliers in terms of sustainability and human rights, including prohibition of child labor. Our Responsible Sourcing Principles are also an integral part of our supplier contracts.

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 our company’s employees, regular inspections are conducted by third parties, who conduct comprehensive announced audits as well as frequent, unannounced verification visits.

External audits

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. Findings concerning the ventilation of workplaces and fire prevention were successfully addressed. Our employees in Kolkata (India) and Darmstadt (Germany) take action to address any identified issues. If the corrective measures are not respected, we may suspend or even terminate our business relationship.

Unannounced inspections

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 and **compliance with laws preventing child labor**. In 2022, its inspections focused on checking the availability of physical examinations for workers and conducting mock fire drills. Additionally, we regularly optimize the escalation process together with IGEP, which holds bi-weekly review meetings with representatives of our company to assess suppliers. These meetings help to identify any required actions, which our sourcing teams then discuss and implement with our suppliers. As a result, our suppliers have successfully improved the working conditions at these 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.** We also use this tracking system to monitor productivity of our mica sources. Based on written records of the daily extraction quantities, we review the volumes of mica reported and supplied to the processing facilities. Furthermore, we use a digital traceability solution to increase transparency in the mica supply chain.

To maintain accuracy, our processes undergo constant review and improvement. We are also evaluating other mica sources in accordance with our quality, social and environmental standards, both in India and other regions. For example, in 2022, we sourced a considerable amount of mica in Brazil, where we have also established oversight mechanisms to monitor and audit adherence to these standards.

Community outreach in the mica supply chain

We are working to improve the **living conditions of the families** in mica mining areas. Since 2012, our educational efforts in Jharkhand include funding three schools with currently around 500 students as well as five vocational training centers, all run by our local partner, the NGO IGEP. At a fourth school operated by one of our mica suppliers, we provide on an annual basis scholarship for 200 children out of the 450 enrolled at the school.

In addition to our support for education, we are also helping to improve **access to healthcare**. For example, we are fully funding an IGEP-operated health center in Sapahi, Bihar, that serves approximately 20,000 residents in the local region.

Stronger together: Joint action in the mica supply chain

We are also a founding member of the multi-stakeholder group Responsible Mica Initiative (**RMI**). Since 2017, we have held the presidency of the organization. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply chain by **joining forces across industries**.

During the reporting year, we continued to support the RMI's work, as described below.

Responsible workplace standards:

- The RMI conducted training sessions with supervisors and workers in several Mica processing units.

Community empowerment:

- The RMI has further expanded its programs to include 50 additional villages. The scope now comprises 180 villages, reaching more than 16,000 households in 2022. The RMI's goal is to address the root causes of child labor and improve livelihoods within local communities.
- In 2022, an external and independent impact assessment of RMI's Community Empowerment Program has assessed the conditions in 40 villages, which have received support over the last 3 years. The vast majority of families in these villages have reported increased school attendance.

Human rights

As an international corporate group, we have a duty to respect human rights worldwide within our respective sphere of influence and to ensure that our business activities do not infringe upon these rights. By fulfilling our human rights due diligence obligations, we meet our responsibility to society. At the same time, this enables us to remain competitive over the long term.

Our approach to human rights due diligence

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 as far as possible, 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. Our approach to human rights due diligence encompasses six main components.

Our human rights due diligence process

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 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 respect human rights.

Our Group Corporate Sustainability unit is responsible for coordinating all human rights due diligence activities across the Group. 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.

The cross-sectoral human rights working group exchanges information on activities and the latest developments in the areas of business and human rights. In 2022, two meetings were held.

Within the **UN Global Compact Network Germany**, we are a member of the **Business & Human Rights Peer Learning Group**. In this context, we discuss challenges, current issues, experiences, and successful approaches in exercising human rights due diligence with other companies.

Our commitment: Guiding principles, charters and laws

Our **Human Rights Charter** aligns with the **UN Guiding Principles for Business and Human Rights**. It is our overarching human rights governance document and defines the relevant requirements for our company. These requirements cover a broad range of topics related to human rights, including, for instance, product safety, clinical studies, occupational health and safety, equal opportunity, fair pay, freedom of association and collective bargaining as well as the exclusion of child and forced labor. The charter interlinks and complements our existing rules and regulations pertaining to human rights. These include, for example,

- our **Code of Conduct**,
- our **Social and Labor Standards Policy**,
- our **EHS Policy** (Corporate Environment, Health and Safety Policy),
- our **Supplier Code of Conduct** (formerly Responsible Sourcing Principles),
- our **Responsible Minerals Sourcing Charter**, and
- our **Charter on Access to Health in Developing Countries**.

We expect our employees as well as our suppliers and all companies with which we have business ties to comply with this charter.

In 2022, we further developed our existing approach to human rights due diligence, prompted by the specific requirements of the new German Supply Chain Due Diligence Act. We strengthened the existing processes for risk identification in order to fulfill our due diligence obligations even better. Among other things, we appointed the Head of Corporate Sustainability, Quality and Trade Compliance as human rights officer to monitor compliance with human rights due diligence requirements and the implementation of processes throughout the Group in the future.

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. We track human rights risks through our strategic supplier risk process. More information on how we engage with suppliers can be found under **Sustainable Supply Chain Management**.

We also meet our human rights due diligence obligations when **deploying new technologies**. Our **Code of Digital Ethics** 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**.

Measures to protect human rights

Auditing our sites and suppliers

Our **Global Social and Labor Standards Policy** stipulates the social and labor standards at our sites. We regularly check compliance with the requirements using a risk-based approach. Among other things, this takes into account risks that may arise if relevant laws and regulations change or if there are violations of internationally recognized labor rights by governments and companies, as assessed by the **International Trade Union Confederation** and documented in the annual ITUC Global Rights Index. If we identify a violation during the audit, we define remedial actions together with the responsible Managing Director and/or local HR staff.

In addition, we review human rights aspects at our sites through security audits. The audits are one control mechanism of our security governance framework. Increased risk transparency and centralized CAPA tracking allows us to ensure that our sites meet **security-relevant human rights aspects**.

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

Human rights and investment decisions

When projects exceed a certain cost threshold, our Investment Committee must approve the expenditure. In its decision, the committee considers various aspects related to the project, including environmental impact and health and safety. Furthermore, our Code of Conduct is binding where investment decisions are concerned. We also integrate human rights topics into our decision-making processes regarding mergers and acquisitions.

Creating awareness among our employees

To train our Managing Directors and senior management, we offer an **e-learning course** on implementing the requirements of our Social and Labor Standards Policy in their areas of responsibility. Our **onboarding training** for all new EHS managers continues to cover the topic of human rights, with a particular focus on the issue of modern slavery. In addition, the Supervisory Board received training on the requirements and implementation of the new German Supply Chain Due Diligence Act in 2022.

To embed respect for human rights even more strongly throughout the Group, we are continuously expanding our internal communication and awareness training on human rights and modern slavery. Through our global sustainability network, for example, we held a webinar on human rights in the corporate context in 2022. In addition, **virtual information events on the implementation of the German Supply Chain Due Diligence Act** were offered to selected target groups.

Training courses for our suppliers

Together with TfS, we rolled out the TfS Academy training platform in 2022. The platform offers employees of TfS member companies and their suppliers 165 courses in up to nine languages. The module on human rights due diligence, for instance, covers the topics of child labor, forced labor, human trafficking, discrimination, and harassment. We also participated in the #TfSTalks, an interactive webinar series.

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 **Merck Australia Modern Slavery Statement** in 2022. Both have been signed by the Chair of the Executive Board and published on our website.

Our complaint mechanisms

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 via this Group-wide whistleblowing system in their respective national language, free of charge and anonymously, either by telephone or a web-based application. We thoroughly investigate all complaints that we receive and take countermeasures if necessary. More information on the compliance hotline can be found under **compliance management**.

In 2022, there were **no indications** from our compliance hotline of child or forced labor or violations of the right to collective bargaining or freedom of association within our own global business operations. Regarding forced labor, we were informed that we offered rubber gloves for which a manufacturer is accused of labor abuses including forced labor in Malaysia. The matter is being investigated further. Our supplier has already terminated business relations with the manufacturer. Consequently, our company also no longer has any business ties to the manufacturer in the affected supply chain.

Clinical studies

Before obtaining regulatory approval for our medicines, we conduct clinical studies with patients and, if necessary, also with healthy volunteers to investigate the safety and effectiveness of our products. We also perform extensive preclinical research, including animal testing, to demonstrate that our treatments pose no unacceptable risks to humans.

Our approach to safe and transparent clinical studies

Our aim is to conduct high-caliber clinical research that always is in compliance with applicable laws and regulations. As a responsible company, we set Group wide requirements to ensure that the **highest ethical and scientific standards** worldwide are met when conducting clinical trials.

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 participants 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.

Based on our **Standard on Human Research** we aim to design and plan our studies to ensure that diverse patient populations who are expected to use a product when approved are adequately represented. Study participants shall not be discriminated against due to e.g. gender, ethnic origin, religion, disabilities, sexual orientation 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. At every level of our organization, we are additionally educating staff about the value of a close, 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. We are deliberately expanding our medicinal product development to more diverse markets in order to address pressing healthcare needs in low- and middle-income countries and support the development of their healthcare systems.

When performing clinical studies in low- and middle-income countries, where there is usually a lower level of healthcare and limited healthcare infrastructure, the following also applies:

- We only do so in an environment in which the principles of Good Clinical Practice can be upheld.
- We only investigate diseases and innovative medicines that are relevant to the local population.
- We only conduct clinical studies in countries where we expect that the drug being tested will be submitted for marketing authorization and made available to patients after we have proven its efficacy and safety.

Roles and responsibilities

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

We review the progress of new drug development at defined milestones, and make decisions about the continuation, modification or discontinuation of development, depending on the results of clinical studies.

We have established two internal committees to oversee our clinical studies. The Integrated Protocol Review 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. Our development and study teams present clinical study concepts to the appropriate committee. Each committee meets regularly to conduct a comprehensive review of the proposed concepts and ascertains that our studies are scientifically sound, have a legitimate scientific purpose, and are performed in accordance with the latest standards and best practices.

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 (MSEB) oversees the safety of the participants in our clinical studies and, as necessary, reviews the benefit-risk profiles of investigational drugs. You can find further information on the MSEB under **Patient safety**.

Issues may be submitted to the relevant committees by product teams or other committees (as defined in relevant standard operating procedures or committee charters). If individual employees wish to seek advice or report concerns on ethical questions, they can contact the members of a committee directly.

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.

A hybrid auditing approach combining remote and on-site audits was successfully implemented and most of the audits of the Annual Audit Plan 2022 were completed as planned.

Conducting clinical studies responsibly

Prior to enrolling participants, every clinical trial must first be assessed and approved by a qualified **independent ethics committee**. Furthermore, all regulatory authorizations required in the respective country must be obtained. In accordance with Good Clinical Practice guidelines (ICH-GCP), all study participants must give their explicit informed consent before enrolling in a clinical study. Participants are fully informed about all aspects of the clinical trial in a language that they understand. This includes the potential risks and benefits from participating in the study and the opportunity to inquire about details. As far as possible, non-interventional (observational) studies are also assessed by an ethics committee.

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 2022, regulatory authority inspections did not unveil issues which had a significant impact on patient rights, patient safety, or the data integrity of a study.

We continuously collect and communicate **safety data on our investigational drugs** and promptly provide clinical investigators with important new findings relevant to the safety of the study participants. In this way, we help to ensure the safe use of our medicines. Potential adverse effects and risks are taken into consideration to evaluate the benefit-risk ratio of our products and manage any risk. Product information, including the investigator's brochure and information for study participants, is updated accordingly. More information is available under **Patient safety**.

Conducting clinical trials in vulnerable populations

The implementation of clinical studies in vulnerable populations, such as children or people with disabilities, requires **special attention and care** to comply with the highest ethical and scientific standards. The well-being of the individual is our highest priority. For this reason, we only conduct studies with participants from vulnerable population groups if scientifically justified and if there is no other way to achieve conclusive results. When performing such studies, especially when informing study participants and obtaining their consent, we take statutory regulations into account.

Teaming up to get results

The clinical trial investigators participating in our clinical studies by enrolling and caring for patients are critical to the successful development of new medicines. Furthermore, to achieve a broad, in-depth basis for the development of new treatments, we seek advice from medical-scientific advisory boards and frequently conduct clinical studies in collaboration with external **partners in academia and industry**. We also rely on the support of contract research organizations (CROs) and other service providers and vendors. We expect from our partners that they apply the same high standards in terms of ethical conduct and quality in clinical research.

As a member of **TransCelerate**, a consortium of 20 pharmaceutical companies, we are currently collaborating on several initiatives to improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

Close dialogue with patients and advocacy groups

We want to ensure that the voices and **needs of patients and their caregivers** are adequately heard and taken into consideration through the entire lifecycle of our medicines. We have a strong internal policy as well as compliance guidance documents, which provide a clear frame to ensure that such engagements take place within an ethical framework. In addition, we established the Patient Advisory Boards (PAB) as one of our crucial communication channels. Our PAB Charter describes how to involve patients and caregivers in our clinical research process. During Advisory Board meetings, patients, caregivers and representatives from patient advocacy groups are invited to share their experiences related to clinical trials. We use this opportunity to discuss multiple aspects of the drug development process, including but not limited to protocol design, educational materials, technology and innovative approaches to clinical trials.

Furthermore, we are involved in multiple activities that focus on this relevant aspect of **patient centricity in clinical studies**. For example, in the United States, we are an active member of the Clinical Trials Transformation Initiative (**CTTI**), which focuses on quality and efficiency in clinical trials.

Responsible data sharing

We support professional circles in advancing **medical and scientific knowledge**, thereby enabling informed healthcare decisions for the benefit of patients. Upon request, we provide qualified researchers with study protocols, anonymized individual patient data, study data, and clinical study reports. We share data and information in a manner that is consistent with the joint **Principles for Responsible Clinical Trial Data Sharing** of the **EFPIA** and **PhRMA**:

- Safeguarding the privacy of patients
- Respecting the integrity of national regulatory systems
- Maintaining incentives for investment in biomedical research

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. Our clinical study designs and results are made public in the international **ClinicalTrials.gov** database run by the U.S. National Institutes of Health (**NIH**), which can also be accessed via the World Health Organization's International Clinical Trials Registry Platform (**ICTRP**). Furthermore, in accordance with EU regulations, we publish results from our clinical studies in the EU Drug Regulating Authorities Clinical Trials (**EudraCT**) database, which is run by the European Medicines Agency (**EMA**). If required by local laws and regulations, we publish study results on other publicly accessible platforms. We provide clinical study report synopses and summaries of study results in plain language on our **clinical trials website**.

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 Medical Publications Policy ensures that we consider relevant standards, and we use defined standard procedures for scientific publications on our products. In addition, we reference our clinical trial publications on our **website**. Our **Standard on Clinical Trial Data Transparency** underscores our strong commitment in this matter.

These ongoing efforts to increase the transparency of our clinical studies have received credit from **Bioethics International**. The organization ranks bio-pharmaceutical companies and new drugs based on ethics and public health performance criteria, focusing on issues that are critical to patients. In 2021, we ranked in equal first place among seven of the 42 pharmaceutical companies that were rated.

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. **Position papers** on **early access** and **post-study access** are available on our website.

Supporting independent human subject research

In addition to conducting our own clinical research programs and studies, we also support studies proposed by independent investigators, so-called investigator-sponsored studies (ISS). Our **ISS Principle** defines ISS as unsolicited request for funding and/or supply of an investigational or marketed product by independent investigator/institution that initiates and conducts a scientific investigation as the regulatory sponsor. By granting **financial or material support** for independent human subject research, we seek to stimulate the advancement of clinical and medical knowledge and patient care in our therapeutic areas of interest and support the safe and effective use of our products. We give priority to research that is innovative and has the potential to address specific unmet medical or scientific needs. Our principles, framework and standards for granting support for ISS and our collaboration with independent investigators are specified in our ISS Principle, which is available on our **website** and in our corresponding policy and standard operating procedure.

Animal welfare

International and national legislation mandate animal testing of medicinal compounds and chemicals during their development and prior to their approval for commercial use. In addition, from an ethical and scientific perspective, animal research is indispensable based on the current state of knowledge. We perform animal-using activities in all three of our business sectors.

Our approach to animal welfare

Our long-term aspiration is to be a pioneer in phasing out animal use and replacing animal work with better, cutting-edge alternatives. We aim to outperform as the leader in non-animal-derived products and testing in the life science and healthcare industries. Our business sectors develop individual strategic roadmaps, priorities and timelines towards this aspiration.

Animal testing will be an unavoidable necessity for many more years, especially in drug development to ensure the safety and efficacy of medical devices, medicines and vaccines. As long as animal usage cannot be completely avoided, we are committed to applying the **highest ethical and animal welfare standards** related to the housing, husbandry and veterinary care of all animals involved in our work. We ensure comprehensive **transparency** and ongoing assessment, monitoring, auditing, and improvement of all work involving the use of animals by our company and by trusted third parties. We continuously improve our animal testing processes, striving to enhance the animals' quality of life. We always use as few animals as possible and replace their use whenever feasible with alternative methods. In addition, we advocate for the global acceptance of replacement methods. To this end, we join forces with industry and academia.

We subscribe to the internationally recognized **3Rs for animal-based research** and have added **Responsibility** as our fourth animal welfare principle in line with the ethical considerations published in 2019 by David DeGrazia and Tom Beauchamp in **Principles of Animal Research Ethics**:

- **Replacement** – replacing animal studies with non-animal systems
- **Reduction** – using the minimum number of animals required
- **Refinement** – minimizing distress or discomfort before, during and after testing
- **Responsibility** – accepting responsibility for all animals in our reach internally and among our business partners

Within our **Life Science** business sector, animal activities include required regulatory safety testing of our own products and on behalf of customers. The Life Science product portfolio also includes various materials needed for research that are derived from animals or by-products from food production, such as blood, plasma, or serum, or items specifically produced in animals, such as antibodies. Our **Healthcare** business sector conducts animal testing as a mandatory part of the drug and medical devices development process and conducts biological quality control in animals. Our **Electronics** business sector conducts animal tests as required by applicable chemical regulations. In line with the EU Cosmetics Regulation, no animal tests are conducted for cosmetic ingredients.

Roles and responsibilities

Our Corporate Animal Affairs unit governs the implementation of the Corporate Animal Welfare strategy. The unit acts globally and locally, setting and overseeing guardrails for the use of laboratory animals based on four pillars:

- Animal Welfare
- Animal Using Vendor Management
- Merck Vivarium Oversight
- The 4R principle

Our **Group Animal Welfare Council**, sponsored by the CEO of our company, comprises representatives from all business sectors and meets quarterly. The council acts as sounding and advisory board, assessing which of our services and product innovations can help to avoid animal testing in the future. Moreover, it consults on business-critical issues, adopts key indicators and serves as an escalation body.

In 2022, we established the Merck Animal Usage Review (MAUR) boards in Europe by utilizing existing internal decision-making animal welfare bodies that review and approve all internal animal work conducted by our vivaria, where available. In the United States and Israel, these tasks are performed by already existing comparable company-owned boards such as the Institutional Animal Care and Use Committees (IACUC, in accordance with the **U.S. ILAR Guide**). In addition, these global MAUR / IACUC boards now also review and approve any animal-based activities at all our vendors, contract research organizations and academic partners.

Global and local **animal welfare officers** supporting the local business report directly to Corporate Animal Affairs and are advocates of the animals. Their tasks entail animal science and welfare management as well as acknowledging the individual skills and abilities of all personnel working with animals. Furthermore, they regularly inspect the animal facilities as well as review and approve protocols.

The **Animal Using Vendor Management** unit qualifies our suppliers with regard to animal science and welfare. The group also continuously monitors our contract research organizations, suppliers and business partners.

If employees identify an issue regarding animal welfare, they can report it directly to Corporate Animal Affairs, to local and global animal welfare officers or via our compliance hotline.

The **4R team** and cross-functional workstreams develop and guide projects to implement our 4R principles. The 4R team regularly reports progress made with the 4Rs to the Group Animal Welfare Council. It also coordinates the 4R Award, with which we recognize contributions to the Replacement, Reduction, Refinement of, and Responsibility for our animal work.

Comprehensive employee training

With our new Animal Affairs Academy, we define a holistic training concept for our entire company, provide training sessions on animal welfare, and oversee and provide staff training on practical work, rules and regulations. All employees involved in animal activities receive appropriate training and continuing education. For example, through our Vivarium Rotation Program, employees of each of our vivaria visit another vivarium every year to exchange knowledge and share best practices. The program has been successful, and the University of Heidelberg in Germany has expressed its interest in collaboration.

Additionally, our employees regularly participate in external **continuing education** programs.

Work with committees and associations

As part of our efforts to improve animal welfare, we are involved in several organizations and initiatives, including the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) and **Interpharma**, a federation of research-based pharmaceutical companies in Switzerland. Interpharma conducts audits at contract research organizations and animal breeders together with selected member companies.

We are a member of the European Animal Research Association (**EARA**), a communications and advocacy organization representing both public and private institutions in the biomedical sector. We are also involved with the Association for Assessment and Accreditation of Laboratory Animal Care International (**AAALAC**). This private, nonprofit organization promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. In 2022, one of our employees served as the chair of the AAALAC International Board of Directors.

Our commitment: Group-wide standards

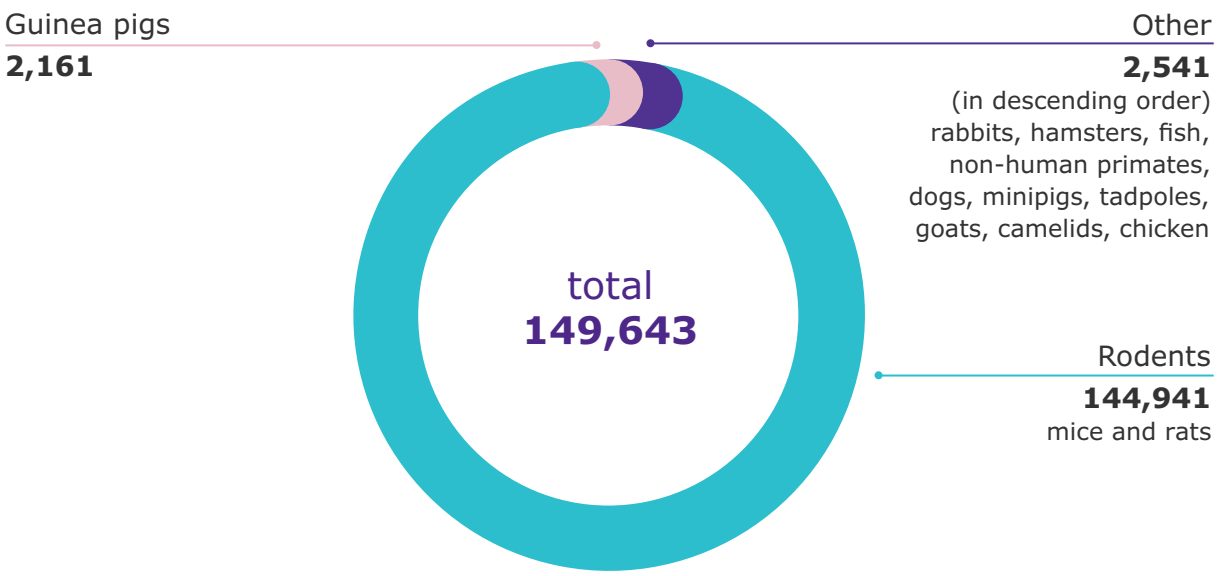
Beyond compliance with all applicable laws and regulations, we are committed to our own set of internal guidelines. Our **Animal Affairs Policy**, our Group animal welfare standards and our procedures for animal testing conducted internally and by trusted third parties corroborate a comprehensive and stringent governance framework based on our four pillars of animal use governance.

Our standards and procedures entail, for example, the housing and husbandry standards that also apply to external partners, and how we monitor them, including audit procedures. The Animal Using Vendor Management standard describes the requirements for the approval of contract research organizations and suppliers. Further documents, including guidance for our 4R efforts, incident reporting and risk management, augment the governance framework. In 2022, we implemented further company-wide standards such as the Global Blood Sampling Standard (GBSS), which defines parameters and methods for blood collection, maximum blood sampling frequencies and volumes in a given time frame. We are convinced that the right level of **transparency** has the potential to improve the scientific outcome and value of animal testing and creates benefits for society, patients and animal well-being. After joining the German Transparency Initiative in 2021, we were awarded the Seal of Quality for Best Practice in Animal Research communication particularly for our achievements in communicating transparent and open about animal experiments in research.

Number of laboratory animals used for medical study purposes

In 2022, a total of 149,643 animals were used within the scope of our business activities, either in our own vivaria or on the premises of organizations contracted on our behalf. This represents an overall decrease of 17% compared with 2021. Rodents (mice or rats) comprised 144,941 of all animals used in 2022, compared to 175,522 in 2021. Regulatory agencies sometimes require studies of the safety of investigational drugs in non-rodent species. This allows researchers to identify potential adverse effects accurately and include them in the risk assessment of a substance.

Animal types



Collaborating with partners and suppliers

We perform the majority (94%) of our animal studies ourselves and procure the required animals from specialized breeders. We also commission contract research organizations to conduct animal studies on our behalf. Furthermore, we work with academic institutions. Whenever we collaborate with such organizations, we require them to comply with our standards.

Conducting animal welfare audits

Corporate Animal Affairs conducts an audit of each of our vivaria every three years. In 2022, two vivaria were audited. Furthermore, we **improved Corporate Animal Affairs' oversight** of internal animal work regarding aspects such as animal usage, purpose and incidents. In the reporting year, we implemented a digital solution that monitors our key indicators.

An integral part of our strategy is the qualification of all animal-using vendors we conduct business with. We completed the implementation of an auditing strategy and developed procedures to identify and train auditors. In 2022, a total of 45 vendor audits were performed, 38 of them on-site and 7 virtually due to the Covid-19 pandemic.

4R Award for animal welfare

We aim to motivate all our employees to contribute to the 4R principle. Therefore, with our biannual 4R Award, we recognize best practices in animal work, such as pioneering better solutions to **Reduce, Replace or Refine** or leading by example in **Responsibility**.

Our annual 4R Day in 2022 focused on the new Corporate Animal Welfare strategy and gave an overview of current 4R activities, highlighting company-wide project submissions representing each of the 4R categories. The grand prize was split evenly between two outstanding projects representing the Replacement and Reduction categories.

Bioethics

Scientific advances can spark controversial debates over bioethical issues. We want to make responsible use of the growing potential of the life sciences to create maximum benefit for both humankind and other living beings. For us, it is important to adopt our own position on bioethical issues.

Our approach to ethical conduct

As a global company, it is critically important for us to identify and address emerging bioethical topics and issues early on so that we can define our own position. Although we do align all our operations with international and national laws, many discussions on bioethics pose questions that extend far beyond the framework set forth by current legislation. We therefore also seek advice from external experts.

In our work, we encounter various bioethical issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. Our goal is to conduct research in an ethically responsible manner and to develop ethical frameworks that guide us in making forward-looking business decisions. **Patient benefit and well-being** are 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 positions when it comes to controversial topics.

Roles and responsibilities

Since 2010, the Merck Ethics Advisory Panel for Science and Technology (MEAP) has been issuing clear recommendations on scientific and technology topics involving ethical questions as well as issues extending beyond pure bioethics, in line with our transformation into a science and technology company. Co-chaired by two of our leading scientific experts from our senior management team, the MEAP provides recommendations that guide our actions and business activities. In addition to renowned international experts from the fields of **bioethics, medicine, philosophy, law, and the natural sciences**, the panel also consists of **technology and sustainability** experts. The MEAP receives its mandate from the Executive Board.

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 recommendations issued by the MEAP. Our employees can also submit topics for discussion to the panel. In addition, they may report ethical concerns through our **compliance hotline** or by reaching out to our Bioethics team.

Our Stem Cell Oversight Committee (SCROC) was established on the recommendation of the MEAP back in 2011. This committee reviews and approves all planned in-house research activities involving the use of **human stem cells**, and ensures to compliance with legal requirements as well as our ethical guidelines. This also includes joint projects with external partners. The committee consists of internal experts from our business sectors as well as external professionals from the fields of bioethics, medicine and law.

In 2022, we expanded the range of consulting services on ethics issues. Our goal is to also take ethics perspectives into account when making forward-looking business decisions. To this end, we launched the Ethics Foresight project, in which external experts and selected MEAP members support our employees from the business units on strategically relevant ethical issues. In contrast to the MEAP, the experts will not develop concrete recommendations in the future but will determine the respective ethical risk for various scenarios and map several decision paths instead.

Our commitment: Guidelines and standards

Our **Genome Editing Principle** provides a mandatory ethical and operational framework for our employees. It sets clear boundaries for us both as a supplier of customized nucleases and genetically modified cell lines, and as a user of genome editing technologies for scientific research. This principle includes background information on the topic and explains our position on genome editing. Moreover, it specifically addresses the subject of human germline editing.

This is complemented by additional guidelines that define how we conduct research and business in an ethical manner. Our **Stem Cell Principle** sets the ethical boundaries for the use of human stem cells in our research. Our **Fertility Principle** regulates our research in fertility treatment and in-vitro fertilization. It sets a clear framework for practices that reflect the most rigorous ethical standards. Our principles on whether information on the off-label use of medicines may be passed on are based on Group-wide guidelines.

Biological samples obtained from patients during clinical studies are indispensable to the development of new targeted treatments and advanced diagnostic methods. We have defined our approach to managing human biospecimens in our Fertility Principle and in standard operating procedures. Accordingly, we handle these samples in a responsible and ethical manner; in doing so, we adhere to all regulatory requirements and abide by the consent given by patients for the use of their samples. This may include an optional consent that provides permission to use the biospecimens for **further medical research beyond the clinical study**.

Topics currently being discussed by the MEAP

The MEAP last convened in May 2022 and dealt with ethical issues surrounding cell culture media that could be used in the fertility sector. In addition, the panel completed the revisions of the Stem Cell Principle, the Genome Editing Principle and the Fertility Principle, thus harmonizing them with the Guidelines of the International Society for Stem Cell Research (**ISSCR**), which were updated in 2021. These address scientific advances and the related ethical, social and political changes since 2016. The basic tenets of our positions remain unchanged, with some details now adapted to the new guidelines. In addition, we marked the tenth anniversary of MEAP with a symposium in 2022. To mark this occasion, MEAP members produced a commemorative publication; the contributions contained therein discuss both past and future bioethical issues and their significance for science and practice.

MEAP members

Yimtubezinash Woldeamanuel Mulate

Microbiology
Addis Ababa University
Board member and Secretary of Pan-African Bioethics Initiative

Jeremy Sugarman

Bioethics, Medicine
Johns Hopkins University

Jochen Taupitz

Medical law, bioethics
Former Vice-Chair German Ethics Council

Jeanne Loring

Molecuar Biology, Stem Cells
Formerly Scripps Research Institute La Jolla (Advisor)

Nikolaus Knoepffler

Philosophy, Theology, Ethics
University Jena

Daniel Fu-Chang Tsai

Bioethics, Medicine
National Taiwan University

Christoph Rehmann-Sutter

Philosophy, Ethics, Biology
University Lübeck
Former Chair Swiss National Advisory Commission on Biomedical Ethics

Rafaela Hillerbrand

Philosophy, Physics, Technic ethics
Karlsruher Institute for Technology

Biotechnology and genetic engineering

Within the Group, we manufacture our biotech products in accordance with rigorous standards at all sites. All these activities are subject to strict statutory regulations worldwide, and compliance with these regulations is monitored by our **biological safety officers**. We continuously track local regulatory changes that relate to biotech products and adapt our processes accordingly, thus ensuring compliance with all statutory requirements.

Using genome-editing techniques

We are a leading supplier of technologies such as CRISPR/Cas9, which can be used to target and modify specific genes, a process known as **genome editing**. CRISPR/Cas9 opens up new possibilities in genetic engineering research that could bring about major advances in the treatment of serious diseases. Laws in different countries allow for a varying degree of latitude in applying this technique. Bioethical positions 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, we do not support the use of genome editing in human embryos and clinical applications of germline interventions in humans. We recognize that there may be value in responsibly conducted related research.”

Stem cell research

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 SCROC has reviewed the respective project and given approval. In 2022, review and approval were granted in one case. 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.

Digital ethics

People, machines, data, and processes are becoming increasingly interlinked, with technological advances transforming our society and posing new ethical challenges. Our digital ethics activities describe how we responsibly handle data and algorithms.

Our approach to corporate digital responsibility

As it is our aim to develop and use **new digital technologies** responsibly, we promptly identify any ethical issues that may arise from algorithm-driven and data-based business models. Since 2021, the **Merck Digital Ethics Advisory Panel (DEAP)** has been focusing on complex ethical issues surrounding digital technologies and supports that our digital business model follows a holistic, ethical approach.

Roles and responsibilities

The DEAP discusses **ethical issues** arising from our digital applications and business activities, especially in the healthcare sector. One of its main tasks is to help ensure that we develop digital innovations responsibly while addressing potential digital ethics questions that could result from collecting and processing data as well as from the use of these digital technologies.

The panel, which issues recommendations on our actions as a company, consists of external international science and industry experts from the fields of **digital ethics, law, Big Data technologies, digital health, medicine,** and **data governance**. In addition, we involve bioethics experts as well as representatives from patient organizations as needed. The DEAP receives its mandate from the Executive Board and our employees may submit topics for the panel to discuss. Summary minutes of DEAP meetings and the recommendations made will be available on our intranet from 2023 onwards, provided that they do not contain any confidential business information. The panel held four meetings in 2022, focusing on ethical challenges that could result from our business model for bioelectronics.

Our commitment: Guidelines and standards

As a company, we want to position ourselves with respect to digital ethics. We are therefore developing clear ethical standards in this new field, primarily for critical areas, for instance handling health data, doing so in collaboration with various stakeholders and experts.

Together with the DEAP, we apply our Code of Digital Ethics (**CoDE**), in order to address issues pertaining to the **ethical use 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 recommendations.

It is based on five core principles: **justice, autonomy, beneficence, non-maleficence,** and **transparency**. These principles in turn provide a clear structure for assessing ethical issues. Moreover, they support our business sectors and individual employees in difficult situations for which laws or other types of regulations do not (yet) exist. The CoDE not only helps us to assess the ethical risks posed by existing activities, but also enables us to evaluate the ethical aspects of newly emerging digital solutions. We have already tested this in initial application areas.

As one of our overarching governance documents, the CoDE applies to all employees and is publicly accessible. In 2022, we developed an employee training course on the CoDE, which we plan to roll out in 2023. The CoDE was developed together with a scientific partner as part of a structured process. In 2022, we published articles on the scientific development process and the legal implications of the CoDE in the journals **AI & Society** and RDi - Recht Digital.

Strategic partnership for innovative therapeutic solutions

In 2022, the DEAP mainly addressed questions arising from **Syntropy**, a digital joint venture between our company and **Palantir Technologies**. This partnership aims to leverage patient data to advance the discovery of medicines to treat cancer and other diseases. Syntropy makes it possible to collect and process these data in a secure environment in order to develop new insights from them.Â At the same time, Syntropy ensures that the ownership of the data remains with the institutions from which they originated. This partnership allows the scientific community to collaborate in new ways and achieve shared objectives in cancer research.

Identifying risks

Since the end of 2022, our Life Science Data Intelligence and Analytics unit ACE has been working to record the potential ethical risk of projects in a structured way. It analyzes data from the Life Science business sector in order to obtain insights for our business.

The tool, which is currently under development, is expected to enable the **early identification of ethical risks**. To this end, a scoring system has been developed to generate a risk assessment for each project. The risk score has implications for product development. The ACE unit is currently working on 700 projects, reviewing them for ethical risks at all decision-making points throughout the product life cycle.