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 include: Our **Human Rights Charter** aligns with the **UN Guiding Principles on 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 compliance with the pertinent chemical and product safety regulations.

We endeavor to 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 employ **management systems** to steer processes and define goals, actions and responsibilities. These systems are based on standards such as the internationally recognized quality management standard ISO 9001, good working practices (GxP) in the pharmaceutical industry, and ISO 14001 for environmental management. Our company regularly undergoes **ISO 14001** and **ISO 9001** certification, which 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 of companies, 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: our Code of Conduct, anti-corruption and anti-bribery (including healthcare compliance, third-party due diligence, transparency reporting), anti-money laundering, and conflicts of interest.

To cover these topics, we have Group-wide policies, standards and procedures in place to 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
- **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. Moreover, 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 want to 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 subordinate 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.

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:

- Our **Code of Conduct** guides our workforce 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 new **Whistleblowing and Investigations Standard**, effective since July 2023, reinforces our commitment to maintaining and strengthening our “speak up” culture. The standard provides guidance on reporting potential violations and our procedures for investigating reports of misconduct while ensuring confidentiality and protecting whistleblowers.
- Additionally, we introduced a new **Supplier Code of Conduct** (SCoC) in January 2023 to replace our Responsible Sourcing Principles. The SCoC outlines our expectations and standards for suppliers and business partners regarding human rights, health and safety, business integrity, environmental protection, continuous improvement and managing 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 have a compliance risk assessment process covering all of our business sectors. The assessment is based on a **comprehensive risk matrix** that improves objectivity and enables a data-driven risk approach. It focuses on bribery and corruption risks, illustrated through in-depth risk categorization and risk scenarios. It also utilizes country risk segmentation, classifying countries where we actively operate in terms of their risk exposure regarding bribery and corruption by applying objective and consistent criteria. We use the outcome as a model to prioritize initiatives and intensify activities in countries with higher risk levels.

The risk assessment follows a staggered approach focusing on global business units first, extending to high-risk countries and finishing with low-risk countries. After completing risk assessments in all countries, we align the top risks per country with our Global Mitigation Plan and Compliance Monitoring Scope to ensure we address all identified high-level risks with appropriate mitigation measures. In addition, we perform regular antitrust risk assessments in a separate process.

Conflicts of interest

We take all potential conflicts of interest seriously. Employees must avoid situations where their professional judgment could 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 2023, our conflict of interest e-learning course had a 95% completion rate.

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.

We also actively prevent bribery by enforcing strict value limits for gifts and entertainment. These limits are embedded in the company tool we use to reimburse travel and expenses. All submissions are subject to an approval process, which includes an additional internal review if they exceed certain cost thresholds. Additionally, we have specific rules and procedures for dealing with healthcare professionals, as outlined under **Responsible interactions with health systems**.

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, dealers, and high-risk vendors. 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.

In 2023, we started implementing a new workflow-based process for third-party risk management. In addition to the existing high-risk categories, we introduced new general categories to strengthen our due diligence and legal compliance in all countries

Compliance training

We provide regular compliance training (both classroom and online) on our Code of Conduct and critical compliance topics such as anti-corruption, conflict of interest, 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 also continually update our training curricula and adapt them to new developments. These efforts ensure we continuously educate our employees on existing and new compliance requirements, guidelines and projects.

In 2023, we launched a new Anti-Corruption, Anti-Bribery and Anti-Money Laundering e-learning course based on the updated Global Anti-Corruption and Anti-Money Laundering standards introduced in 2022.

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 and any high-risk transactions. Suspicious transactions are reported to the German Financial Intelligence Unit or other authorities as required.

We continuously work to improve our AML program. Following in-depth AML risk assessments of jurisdictions with stricter regulatory frameworks than our AML program, we implemented additional local AML programs where required.

Reporting potential compliance violations

We encourage all employees worldwide to report potential compliance violations. Depending on the type of misconduct and the reporting person’s preference, they can choose from various reporting channels. We recommend using one of our central channels that are directly received and reviewed by a dedicated, independent and qualified team within Group Compliance. Depending on the nature, content and type of report, Compliance may investigate a submission directly or assign it to another responsible function for further investigation. One central reporting channel is our global whistleblowing compliance hotline, which can be used **free of charge and anonymously** to report violations. It is available in several languages by telephone or a web-based application.

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

Compliance-relevant cases with a particular risk profile are presented to the Compliance Case Committee, comprising senior members of our Compliance, Legal, Data Privacy, Internal Auditing, and Human Resources departments. The Committee’s duties include assessing and classifying specific compliance issues and addressing identified issues using appropriate measures.

In all Compliance-relevant cases, based on the investigation outcome and recommendations from Compliance or the Compliance Case Committee, we aim to take **appropriate remediation measures**. These can include disciplinary actions against employees who have committed a compliance violation. If the investigation identifies a root cause that could lead to the risk of further compliance violations, we take additional preventive and corrective actions.

Both the number of new Compliance-relevant cases and the number of cases with confirmed compliance violations increased compared with the previous year. In 2023, 106 Compliance-relevant new cases with reports via the compliance hotline and other channels were created. In 32 concluded cases, it was confirmed that the principles of the Code of Conduct or other internal or external guidelines had been violated.

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, Anti-Corruption Standard, Anti-Money Laundering Group Standard, and Antitrust and Competition Law Policy.

Our audit planning aims to provide **comprehensive risk assurance** through the best possible audit coverage of our processes, countries and projects. 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 2023, Group Internal Auditing conducted 80 internal audits involving bribery and corruption-related risks, including 52 operational and 27 IT audits and 1 special audit which may be conducted to meet legal requirements.

External Certification of Compliance Management System

In 2022, we initiated an external review and certification of our Compliance Management System (CMS). The focus is on anti-bribery, anti-corruption and anti-money laundering to identify potential areas of improvement and to assess whether the measures we have taken ensure that regulations, policies and processes are adhered.

The CMS assessment started in November 2022 and will cover three phases until August 2025. The first two phases, pre-assessment and adequacy assessment, were completed by the second quarter of 2023 with positive results. They indicate that the processes and measures in our CMS are adequately designed and implemented to manage our compliance risks. We have also designed and implemented our CMS to identify significant rule breaches in advance and prevent any violations during assessments. The third phase, effectiveness assessment, will be conducted region by region until 2025.

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 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 data privacy management system

In mid-2023, we completed the implementation of the core elements of our global and consistent data privacy management system (DPMS). Our DPMS applies similar elements to the **compliance portfolio** but adapted to our data privacy needs, including policies and procedures, risk assessments and documentation, training and awareness, programs and tools, individual requests, monitoring and reporting, and incident management as well as continuous improvement.

Our approach to cyber security

It is of critical importance to our business to 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.

Information security risk assessments are conducted as part of our project management process for all relevant projects. Additionally, existing applications classified as "severe" or "high-impact" assets undergo this kind of risk assessment. The results are monitored by the Cyber Security organization through an internal cyber risk register. If cyber risks are identified, risk treatment strategies are agreed together with the respective asset owners and tracked until completion. Identified cyber security risks are reported in aggregated form to the Executive Board twice per year through our enterprise risk reporting.

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 and Group functions who hold risk ownership, act as our first line of cyber security defense and are supported by dedicated networks. 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 consists of internal audits.

Our Cyber Security organization strengthens resilience against cyberattacks and **data breaches**. It 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 organization is also responsible for providing cyber security monitoring and incident response capabilities across the entire company. Additionally, we train our employees on how to protect data properly.

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 contains 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 controls and security monitoring) to bolster our ability to securely handle sensitive data, such as trade secrets.

Data privacy training and IT tools for documentation

In line with the EU GDPR and our global approach to data privacy, we regularly conduct **e-learning training courses** in ten languages. In 2023, the completion rate for our **e-learning courses** was 99%. Additionally, local Data Privacy Officers support the execution of our Group-wide training plan by conducting training for specific target groups on request. Furthermore, we reinforced the importance of data privacy to all employees by promoting Data Privacy Day in 2023 via our internal communication channels.

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 2023, we reported seven cases of minor personal data breaches to the supervisory authority. One of them related to identified data leaks, theft, or loss of customer data. However, none of these cases were 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 help them 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 and carer organizations, have access to up-to-date information on diseases and treatments while safeguarding their independence at the same time.

Our approach to interacting with health systems

We support health systems by collaborating with our healthcare stakeholders, such as professional medical associations, patient and carer organizations, 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 aim is to apply **high ethical standards**. Our internal governance documents on the promotion of pharmaceutical products are part of our Group-wide healthcare program, which requires us to conduct business in compliance with the law and industry obligations. 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.

In some countries we inform consumers directly. For example, in the United States direct-to-consumer (DTC) advertising for prescription medicines is permitted. 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 aim to 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. Thereby, we want 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 also strive to 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 are aligned with 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 and carer organizations, 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 and carer organizations

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

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.

Supporting medical education

To contribute to medical advances that benefit patients, we support non-promotional medical education programs worldwide by funding independent third-party medical education providers including medical societies and academic organizations. We also organize 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 independent 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. 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

In 2023, we continued 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. The training program was successfully implemented in all countries in which our Healthcare business sector operates.

Moreover, 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 that 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 in order 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, Darmstadt, Germany and provides tax standards for the 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. She delegates her 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 Group's 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

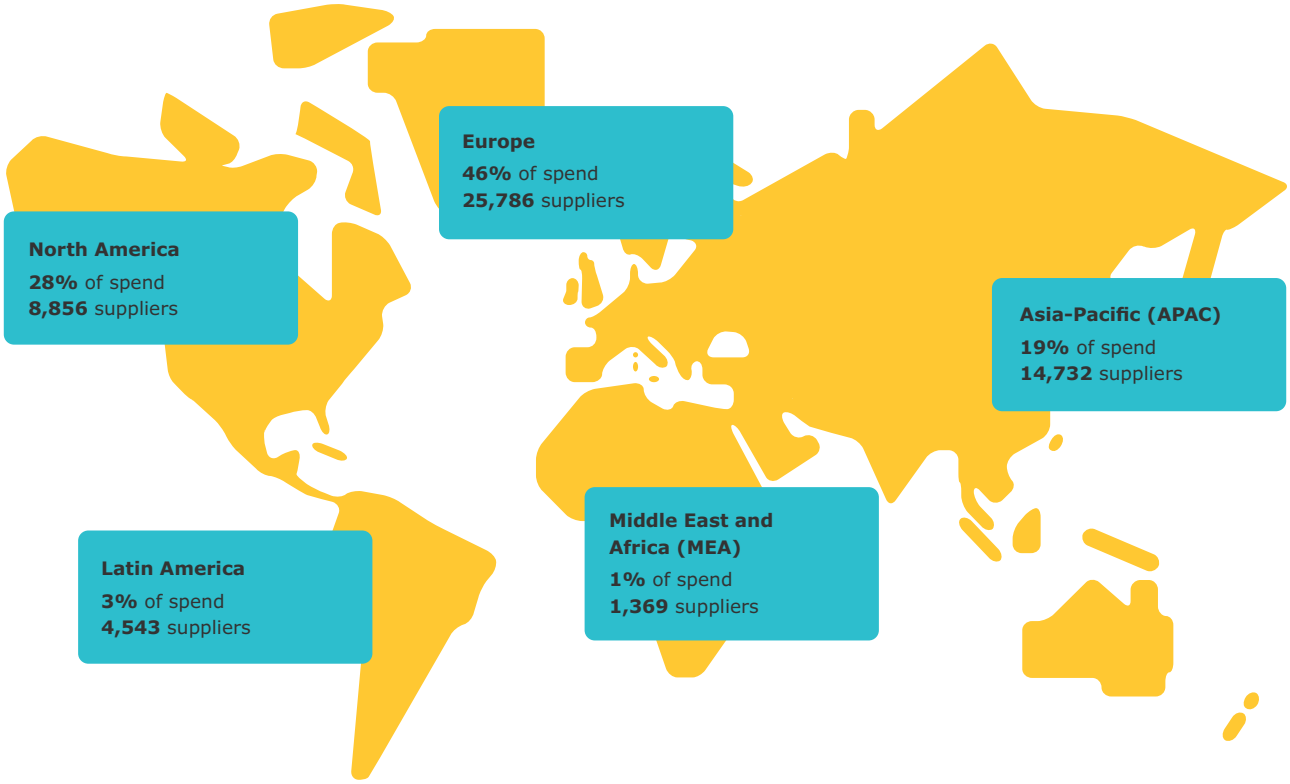
Sustainable supply chain management

Our company procures many raw and packaging materials, technical products, components, and services from around the world. We 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 2023, the total value of the goods and services we purchased from around **55,000 suppliers** in more than 140 countries was approximately € 9.8 billion, compared with approximately € 10.2 billion in 2022, representing a decrease of 4.5%.

Supplier spend and suppliers per region – 2023[1]



[1)] For data processing reasons, 2% of our suppliers (1,161 suppliers) are currently not assigned to any purchase region. This equates to 3.5% 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 tier-1 suppliers, i.e. direct suppliers. Furthermore, our supplier management activities include special measures particularly for tier-n suppliers, i.e. indirect suppliers, working in the area of conflict minerals.

To achieve our **sustainability goals**, our 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 reviewing the **sustainability performance of our relevant suppliers** based on 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. In accordance with our risk management approach, we define relevant suppliers as suppliers, which either indicate a specific country and/or industry risk or contribute to a significant percentage of our supplier spend (at least 50%). For the country risk evaluation, we have developed our own comprehensive country risk score.

In 2023, 66% (2022: 46%) of our relevant suppliers were covered by a valid **sustainability assessment**; 94% (2022: 82%) of our spend attributable to these suppliers was covered by suppliers with a valid sustainability assessment.

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, such as the German Supply Chain Due Diligence Act, and initiate corresponding measures where necessary. Among other things and in conjunction with the implementation of the German Supply Chain Due Diligence Act, we have implemented a risk management approach focusing on human rights and environmental risks along our supply chain. This risk assessment is conducted annually and ad-hoc when required.

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 under **Climate action**.

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 Category Sourcing teams to identify potential mitigation actions with relevant suppliers and supports them in making improvements. Our risk management approach comprises four main elements:

- **Supplier Risk Assessments**: to capture the overarching risks at the supplier level we consider 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. This element focuses on our business sector Life Science. In 2023 we conducted assessments for more than 2,500 of our critical materials.
- **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 according to current human rights risk standards. We also include criteria for identifying supplier relationships

impacted by **key sustainability risks**, such as mineral sourcing and animal welfare. In 2023, we conducted further initiatives to support 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 takes into account applicable laws and international standards. Additionally, we have engaged an external auditing firm to carry out an **independent assessment** in 2023 in order to verify our compliance with regard to the requirements of the EU Conflict Minerals Regulation (EU) 2017/821.

As part of our continuous improvement efforts, we worked on the recommendations from the audit and refined our procedures. Additionally, we established a supply chain traceability system that further increases our supply chain transparency. For our tin imports, which make up the majority of our conflict minerals imports, additional control mechanisms were implemented. These mechanisms include supply chain mapping, information on the country of origin of the mineral, request of audit reports from smelters and refiners, and the revision of agreements, including audit rights, with our suppliers. After careful analysis of the potential risks, no specific risks could be identified that would have required the development of an action plan. We remain in constant contact with our suppliers, industry colleagues and cross-company collaborations to improve the transparency and effectiveness of the framework.

Roles and responsibilities

Procurement is responsible for integrating sustainability requirements into the relevant stages of our sourcing and supplier management processes. Our Center of Excellence for Sustainability coordinates the relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives. Category Sourcing teams 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. For this purpose, our **Supplier Code of Conduct** 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.

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 on the basis of 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 allow us or trusted partners to conduct assessments or audits to increase the transparency of our supply chain 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 175 countries and more than 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 1,860 valid scorecards on the assessment of our suppliers (2022: 1,700), almost 1,790 of which completed a new assessment or re-assessment in 2023 (2022: 1,100). In some cases, these were initiated by us and in other cases by other TfS members.

In 2023, we continued our collaboration with member companies in TfS workstreams. We contributed to several best practice sharing and collaboration formats such as the TfS Talks as well as TfS Coordinator Roundtable. We also introduced the **TfS Product Carbon Footprint (PCF) Guideline** and rolled it out to employees of TfS member companies, our employees, our suppliers and other stakeholders. This comprehensive guideline harmonizes PCF calculation methodology across the industry. We helped to establish the pilot system of the TfS PCF data-sharing solution. This digital platform enables TfS members and their business partners to safely share product carbon footprint data.

Supplier Decarbonization Program

Our cross-functional Supplier Decarbonization Program team within Procurement is driving the execution of a ten-year program as part of the decarbonization strategy that was defined in 2021. In 2023, we continued to provide training sessions and materials for Category Sourcing Teams and engaged further with suppliers by sharing information about our climate targets. Follow-up discussions were again held based on the supplier answers to our supplier decarbonization questionnaire to assess the current decarbonization status and progress made since last year. To obtain more detailed information from our suppliers taking part in the program, we developed a **new supplier questionnaire** in 2023. This allows our Category Sourcing Teams to collate relevant supplier data in **a global monitoring database**.

In order to manage the large quantities of data on the CO_2 emissions of our suppliers, we have an automated carbon accounting tool in place to which we continuously add new functionalities. We offer our suppliers access to solutions to reduce their Scope 2 emissions. This includes a r**enewable electricity supplier toolkit** with tips and in-house best practices on renewable electricity, which is available for free download from our **website**. In

addition, **we joined the Energize program** as a new sponsor. Energize is a collective initiative by a group of industry-leading pharmaceutical and fine chemical companies that have committed themselves to engaging their suppliers to support the adoption of renewable energy and reduce greenhouse gas emissions within their common supply chains. We offer all our suppliers the opportunity to join the program for free and to find out more about renewable electricity options leading to reduced Scope 2 emissions.

Supplier diversity

In the United States, we have a specific supplier diversity program in place to not only comply with local legislation, but also to enhance our company culture. 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 expanding our database of small and diverse vendors in collaboration with our tool provider. In the reporting year, we were able to increase the proportion of orders placed with suppliers classified as diverse. At the beginning of the program, we focused on the sourcing category Marketing & Sales and the category Procurement of Services in the USA. We have since expanded the program to all three business units, including the logistics category. We intend to include additional countries and direct spend categories (e.g. raw materials) in the coming years.

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

In 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**. 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. For example, we have contractually agreed with our suppliers to pay at least living wage to mine workers and workers in the processing units. Furthermore, 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**, we set out our expectations for our suppliers in terms of sustainability and human rights, including prohibition of child labor. Our Supplier Code of Conduct is 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 monitoring.

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 safety of electrical installations and installing proper emergency exit signs 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 monitoring to review labor standards throughout our supply chain. During these visits, IGEP officials monitor occupational safety and **compliance with laws preventing child labor**. In 2023, 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 the 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, we source a considerable amount of mica from Brazil. To monitor our suppliers' adherence to these standards, we have conducted an audit through a third party.

Implementing living wages

We have contractually agreed with our suppliers a monthly wage of 17,500 Indian rupees for mine workers and workers in the processing units for their labor. In 2023, the workers in processing units and mines in our supply chain already received the aforementioned fixed salary, independent of mica volumes harvested or processed. This salary is a living wage that contributes to a reasonable living standard for workers and their families while helping to eliminate the root cause of child labor.

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 470 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 supporting the RMI's work, as described below.

Responsible workplace standards:

- The RMI conducted training sessions with supervisors and workers in several mica processing units.
- An RMI-facilitated audit program on workplace standards continued in 2023. We actively supported this audit program and provided assurance that the processing units we source from would participate throughout 2023.

Community empowerment:

- The RMI aims to address the root causes of child labor and improve livelihoods within local communities. The RMI's scope covers 180 villages and reached over 16,000 households with 90,000 beneficiaries in 2023.
- In 2023, the RMI set the goal for its members to implement a living wage for all mica workers in the States of Jharkhand and Bihar by 2030.

Human rights

As an international corporate group, we have a duty to respect human rights worldwide within our respective sphere of influence and we strive 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 and for adhering to legal requirements, for instance the German Supply Chain Due Diligence Act. 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 such as the planned EU directive on human rights due diligence.

Roles and responsibilities

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

Our Human Rights Officer from the Group function Corporate Sustainability, Quality and Trade Compliance (SQ) is responsible for monitoring due diligence obligations concerning human rights and environmental matters. The Executive Board is informed at least once a year of the work of the Human Rights Officer and the implementation status of risk management and of the due diligence processes.

Those responsible for the issue in the Group functions, business sectors and local units are tasked with implementing our human rights due diligence processes in operations by integrating human rights due diligence into existing processes, for instance.

The cross-sectoral human rights working group exchanges information on activities and the latest developments in the areas of business and human rights. In 2023, 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 directive 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 instance, our

- **Code of Conduct**
- Human Rights Due Diligence standard
- **Social and Labor Standards Policy**,
- **EHS Policy** (Corporate Environment, Health and Safety Policy),
- **Supplier Code of Conduct**,
- **Responsible Minerals Sourcing Charter** and
- **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 2023, our Executive Board approved our Group Policy Statement on Compliance with Human Rights and Environmental Due Diligence Obligations in accordance with the German Supply Chain Due Diligence Act. It applies to our own business operations, in other words to our entire workforces, as well as to our suppliers. The

statement describes how we undertake to comply with our human rights and environmental due diligence obligations and provides information on the risks identified.

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 strive to 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

Risk analyses to determine human rights and environmental risks

We conduct special analyses to identify human rights and certain environmental risks. This enables us to identify potential risks, weight them appropriately and prioritize them. These risk analyses are carried out annually and on an ad hoc basis for our own business operations.

Our **Social and Labor Standards Policy** defines the corresponding commitments and principles as they relate to specific topics and 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.

We also assess human rights aspects at our sites through security audits and as part of the risk analysis. The audits are one control mechanism of our security governance framework. Through increased risk transparency and central follow-up of corrective and preventive actions (CAPA) we help ensure that our sites comply with **safety-related 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

An **online course** trains our Managing Directors and senior management in how to meet the requirements of our Social and Labor Standards Policy in their area of responsibility.

We are constantly expanding our internal communication to better enshrine our commitment to human rights across the Group. In doing so, we are raising awareness of 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

In collaboration with Together for Sustainability (TfS), we offer our employees training modules from the TfS Academy. Through the platform, employees of TfS member companies and their suppliers can access a total of 181 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 and measures as well as the results of our human rights due diligence. We provide information on this annually in our Sustainability Report. Under laws in Australia, the United Kingdom and Norway, we are additionally required to publish information in these countries on our measures to combat forced labor and human trafficking. Apart from the **UK Modern Slavery Statement** and the **Australia Modern Slavery Statement**, we also published the Norway Transparency Statement for the first time in 2023.

Our complaint mechanisms

We have set up a Group-wide whistleblowing and complaints system that can be used to report potential violations of human rights, legal provisions and environmental issues, among other things. Our compliance hotline is a central element of this. 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 are committed to 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 addition, we published **Rules of Procedure**. These apply to tips or complaints that refer to human rights and certain environmental risks or violations at our company and along the supply chain in line with the German Supply Chain Due Diligence Act. In the reporting year, 184 violations of the Social and Labor Standards Policy were reported to us in our own business operations, 60 of which were confirmed. Furthermore, based on the complaint channels specified in the Rules of Procedure, there were **no indications** of child or forced labor or violations of the right to collective bargaining or freedom of association in our own business operations or in the supply chain in 2023.

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 is in compliance with applicable laws and regulations. We set Group-wide requirements that aim to ensure that **high ethical and scientific standards** are met when conducting clinical trials.

We only conduct clinical studies to investigate issues relevant to patients, healthcare professionals or society, and only when our established methodology finds the given medicines show significant therapeutic promise and a **positive benefit-risk ratio**. Accordingly, to ensure patient safety and avoid interrupting the development of promising products, we carefully select patients based on known risk factors. These include age and comorbidities, which we reflect in the design of our clinical studies. Notably, we only enroll the specific number of patients needed to answer the posed scientific and medical questions. We reconcile and review the safety reports from our clinical studies and marketed products and immediately address any unforeseen risks. Senior boards such as the Pharmacovigilance Advisory Board and the Medical Safety and Ethics Board maintain oversight of any emerging safety concerns. In addition, cross-functional Benefit Risk Assessment teams adapt the benefit-risk assessment and development strategy of each product to ensure it delivers maximum safety and efficacy to our patients. In addition, a sound, established scientific methodology must be available to investigate these scientific or medical 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. **Data privacy** is also very important to us, and we maintain a strong focus on data protection and confidentiality in compliance with statutory regulations.

Diversity, equity and inclusion in clinical trials

Based on our **Standard on Human Research,** we aim to conduct clinical studies that adequately represent the diverse patient populations expected to use our products once they are approved. To ensure fair, balanced and scientifically justified study representation, we cemented our commitment to Diversity, Equity and Inclusion (DE&I) in clinical trials by collaborating with healthcare providers and community advocates to eliminate common barriers to clinical trial participation. We have also reviewed our internal processes to enable more inclusive research practices. Additionally, to publicly disclose our views on DE&I, including in clinical trials, we published our very first DE&I report in 2023. It reinforces our commitment to ensuring study participants face no discrimination due to factors such as their gender, ethnic origin, religion, disability, gender identity, or socio-economic status.

Our ongoing efforts to increase diversity in our clinical studies have been formally recognized by **Bioethics International**. In 2023, we received a gold badge and ranked equal first among seven of the 25 rated pharmaceutical companies. The rating considered important factors in oncology studies, including the fair and equitable representation of diverse patient populations.

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 and based on the function, we are additionally either offering or mandating to educate 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 our clinical studies in accordance with local laws and regulations, and we aim at adhering to the **relevant international scientific and ethical standards**, irrespective of the region or country. We are deliberately expanding our medicinal product development to more diverse markets 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 directives also apply:

- We only do so in an environment where the principles of Good Clinical Practice can be upheld.
- We only investigate diseases and innovative products that are relevant to the local population.
- We only conduct clinical studies in countries where we expect that the product 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 development, including clinical studies and their related governance processes, 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 product 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 products that are under clinical development, while the Global Medical Decision Board is responsible for our own studies with approved products 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. The committees meet regularly or as needed to conduct a comprehensive review of the proposed concepts and ascertain 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 product 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 products**. Further information on the MSEB can be found under **Patient safety**.

Emerging issues related to a clinical study may be submitted to the relevant committees by product teams or other committees, as defined in relevant standard operating procedures or committee charters. Also, 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 Quality Policy defines the strategic framework that ensures our products, services and systems deliver high quality, safety and efficacy to our patients. It details the most relevant laws and codes, criteria and guidance (e.g. for product development and manufacturing), and our senior management's responsibility to ensure quality is embedded in everything we do.

Our Standard on Human Research provides the framework for conducting clinical studies and helps ensure we adhere to all applicable **legal, ethical and scientific standards**. Further quality documents detail for instance the strategic direction of all quality related activities or disclose our position on data privacy. In addition to the relevant national laws and regulations, these documents 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
- 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**), 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 and Risk Management (RDQRM) 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 (e.g., investigator sites and vendor audits). We respond immediately to observations made 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. As planned, in 2023, RDQRM concluded most of the audits of the Annual Audit Plan.

Conducting clinical studies responsibly

Prior to enrolling participants, every clinical trial must first be assessed and approved by a qualified **independent ethics committee**. Additionally, 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 study 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 **high 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. As in the previous year, in 2023, none of the regulatory inspections conducted on our clinical research activities resulted in regulatory action.

We continuously collect and communicate **safety data on our investigational products** and promptly provide clinical investigators with important new findings relevant to the safety of study participants. In this way, we help to ensure the safe use of our products. 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 study investigators participating in our clinical studies by enrolling and caring for patients are critical to the successful development of new products. 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 22 pharmaceutical companies, we are currently collaborating on several initiatives to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines.

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 throughout the entire lifecycle of our products. We have a strong internal policy as well as compliance guidance documents, which provide clarity on how 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 guidance document 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 studies. We use this opportunity to discuss multiple aspects of the product development process, including but not limited to protocol design, educational materials, technology and innovative approaches to clinical studies.

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. For instance, in 2023 we engaged with the CTTI to develop industry recommendations for increasing diversity in clinical trials, as mentioned above.

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 strive to do this publicly in a complete, accurate, balanced, transparent, and timely manner as laid out in our Standard on Clinical Trial Data Transparency. 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**). Additionally, new applications for clinical studies in scope of the EU Clinical Trials Regulation were submitted through the **Clinical Trials Information System** (CTIS) and will be published on the public **CTIS portal**. We will transition all ongoing studies to CTIS by January 2025. 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 particular, we adhere to the current version of the Good Publication Practice (**GPP3**) and align with the recommendations of the International Committee of Medical Journal Editors (**ICMJE**). Our Medical Publications Policy helps us to consider relevant standards and use defined standard procedures for scientific publications on our Healthcare's products. In addition, we reference our clinical study publications on our **website**. Our **Standard on Clinical Trial Data Transparency** underscores our strong commitment in this area.

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 products. 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 products 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 entirely dispense with work involving the use of animals and to replace it with better, cutting-edge alternatives. We aim to outperform as a leader in non-animal-derived products and testing in the life science and pharmaceutical 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 certain medical products, 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. Our definition of "highest possible standards" goes beyond the legal requirements and is specified in our internal quality documents. For example EU Directive 2010/63 on cage and kennel sizes is also applied in theUnited States. In addition, the ILAR Guide also applies to mice and rats. Moreover, we are aiming to ensure comprehensive **transparency** as well as ongoing assessment, monitoring, auditing, and improvement of all work involving the use of animals by our company and by trusted third parties. We aim to continuously optimize our animal testing processes, striving to enhance the animals' quality of life. We use as few animals as possible and replace their use with alternative methods wherever feasible. In addition, we advocate for the global acceptance of replacement methods. To this end, we collaborate with other companies and scientific institutions.

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, serum, or items specifically produced in animals such as antibodies. Our **Healthcare** business sector conducts animal testing as 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. According to the EU Cosmetics Regulation, no animal tests are allowed 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
- Vivarium Oversight
- The 4R principle

The **Group Animal Welfare Council**, sponsored by the CEO of our company, comprises representatives from all business sectors and usually meets three times per year under the leadership of Corporate Animal Affairs and may meet more often if required. The council acts as a 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 Europe, the Group's Animal Usage Review (MAUR) board reviews and approves all internal animal work planned for our vivaria. In the United States and Israel, these tasks are performed by comparable company boards such as the Institutional Animal Care and Use Committees (IACUC, in accordance with the **U.S. ILAR Guide**). In addition, a global MAUR/IACUC board reviews and approves all animal-based activities at all our vendors, contract research organizations and academic partners. We use digital systems for both processes, namely internal review by MAUR or IACUCs as well as externally commissioned studies. Those responsible for internal animal testing or those who commission external activities involving animals enter information relevant to an audit of our animal welfare standards. The data records entered enable transparency and allow us to reliably collect and monitor our key figures.

Global and local official representatives and **animal welfare officers** who are independent of the business report directly to Corporate Animal Affairs and see themselves as 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 plans the review and carries out the qualification of our suppliers and business partners with regard to aspects relevant to laboratory animal science and animal welfare. It uses a digital system with an integrated approval process that also allows the monitoring of suppliers, universities, contract research institutes, and business partners. This system is an important part of our efforts to collaborate exclusively with qualified external institutions.

If employees identify an animal welfare problem, they can use various routes to report it either 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

Through our new Animal Affairs Academy, we offer a holistic training program for the entire company. We conduct courses on animal welfare and animal testing, and we supervise and support training for the workforce on practical work as well as on the applicable rules and regulations. Employees involved in animal activities receive appropriate training and continuing education. Initiated in 2022, our Vivarium Rotation Program enables individual employees from each of our vivaria to visit another vivarium every year to exchange knowledge and share best practices. To promote ongoing dialogue outside the program as well, the Vivarium Rotation Program community was formed; it meets once per quarter.

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

Work with committees and associations

We are involved in several organizations and initiatives, including as Vice Chair in the Research and Animal Welfare Group (RAW) of the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) and as well at **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 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 2023, one of our own employees served as Immediate Past Chair of the AAALAC International Board of Directors. We continue to support the European Partnership for Alternative Approaches to Animal Testing (**EPAA**) and participate in its working groups developing alternatives to animal testing. In 2023, we were appointed Chair of the Leadership Coalition of the Marseille Declaration for 2024. Moreover, we participated in the Germany REACH Roundtable – Industry, established and led by the Humane Society International, the objective of which is to reduce the number of animals used in chemicals testing.

Our commitment: Group-wide standards

We consider compliance with statutory **animal welfare requirements** to be a matter of course. However, the standards that we define in our **Animal Affairs Policy** go beyond this and are based on species-specific basic needs. We have defined our set of rules based on these and strictly monitor compliance with them. This also applies to tests carried out for us by third parties.

Our standards and procedures entail, for example, the housing and husbandry standards that also apply to external partners, and how we monitor them, for instance through audits. The Animal Using Vendor Management standard governs the qualification process when working with contract research organizations and suppliers. The Global Blood Sampling Standard (GBSS) sets parameters and methods for drawing blood samples as well as maximum blood sampling frequencies and quantities within a defined time period. Further documents, for instance guidance on our 4R efforts, incident reporting and risk management, augment the governance framework.

In 2022, we initiated the Marseille Declaration in order to advance the global implementation of high animal protection standards. This is voluntary commitment by companies with commercial animal husbandry activities and extends beyond local legislation. Further companies became signatories in 2023.

We are convinced that the right level of **transparency** can lead to better scientific outcomes, increase the value created by animal testing and significantly improve animal health and welfare. In addition, it can create benefits

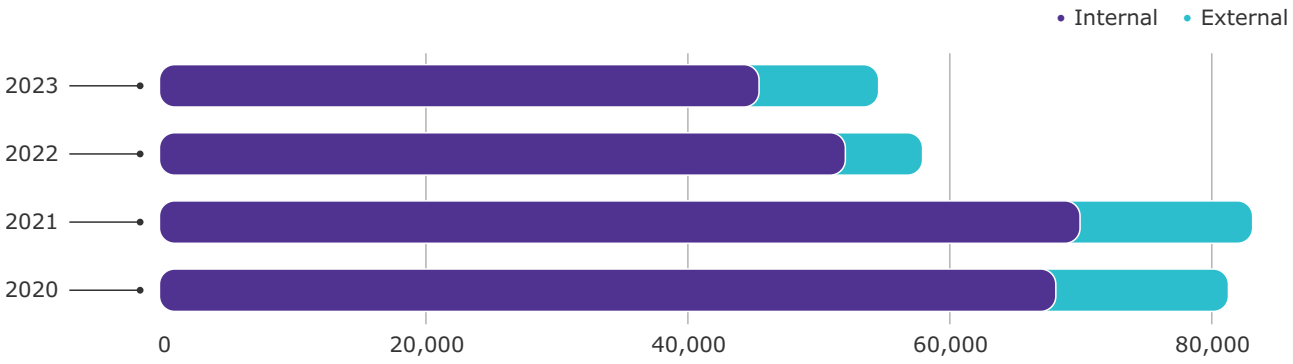
for society, patients and animal well-being. We therefore conducted several activities in 2023 in line with the commitments of the Transparency Initiative Germany, of which we are a signatory. Noteworthy examples include the presentation by our Chief Veterinary Officer at the 12th World Congress on Alternatives to Animal Testing in the Life Sciences and the interview by our Executive Board in the Frankfurter Allgemeine Zeitung on the abolition of animal testing.

Number of laboratory animals used for medical study purposes

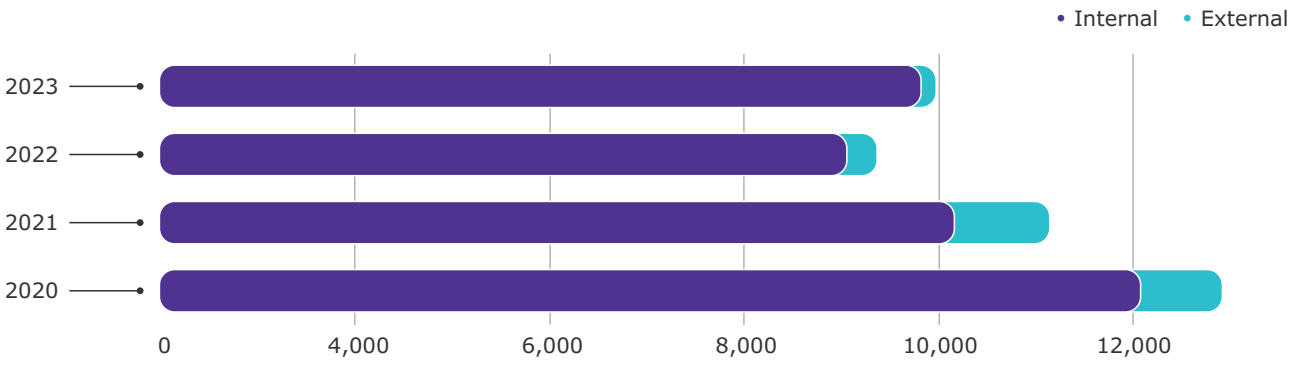
We want to increase transparency regarding the laboratory animals we use by reporting both the number of laboratory animals used by the entire company as well as the numbers used by the Life Science and Healthcare business sectors separately. In Life Science, as well as the absolute number of laboratory animals, we also show the number in relation to sales because in this business sector, we perform animal-using activities on behalf of customers. In the pharmaceutical industry, it is stipulated by legislation that animal testing must be carried out to determine the efficacy and adverse effects of medicines.

In addition to the absolute number of laboratory animals, we show this for Life Science in relation to sales, as in this business area we carry out activities in animals on behalf of customers, as there is a direct correlation between profits and animal numbers. In the pharmaceutical sector, on the other hand, animal experiments are primarily carried out in preclinical research to test the efficacy and safety of drugs that are still in development. Accordingly, the number of animals is not directly related to the sales generated by approved drugs.

Number of laboratory animals in Healthcare and Electronics



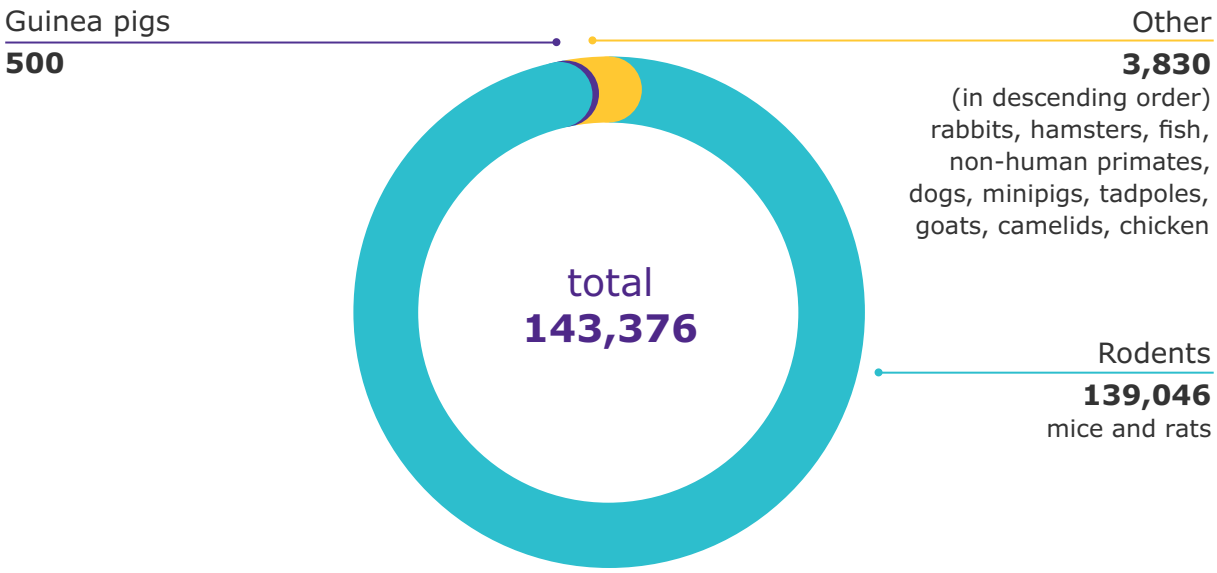
Number of laboratory animals in Life Science relative to sales



In 2023, we used a total of 143,376 animals for animal testing within the meaning of Directive 2010/63/EU. Of this total, we used 132,522 animals in our own vivaria; organizations contracted on our behalf as well as academic partners used 10,824 animals. In our Life Science business sector, 87,144 animals were used in our own vivaria; 1,703 animals were used by organizations contracted by our customers and for production. For our Healthcare business sector, we used 45,408 animals in our own vivaria and 7,577 animals were used by contract organizations and academic partners. Of this total, Healthcare used 1,544 animals to test chemical safety on behalf of our Electronics business sector.

Regulatory agencies sometimes require studies of the safety of investigational drugs in nonrodent 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 (92%) of animal testing in our own animal husbandry facilities. We source our laboratory animals from specialized animal breeding operations. We also commission contract research organizations to conduct animal studies on our behalf. Furthermore, we work with academic institutions. Whenever collaborating with such organizations, we require them to abide by our standards.

Conducting animal welfare audits

Corporate Animal Affairs conducts an audit of each of our vivaria every three years. In 2023, two vivaria were audited, namely in Billerica, Massachusetts (USA) and in Darmstadt, Germany. Additionally, we further **improved Corporate Animal Affairs' oversight** of internal animal work regarding aspects such as animal usage, purpose and incident reporting.

An integral part of our strategy is the qualification of all vendors who conduct work with animals on our behalf. Quality assurance of these qualifications is based on our established and robust audit process well as on an existing process to select and train our auditors. In 2023, a total of 37 vendor audits were performed, 33 of them on-site, and 4 virtually.

4R Day in 2023

We want to firmly embed the 4R principle in our company and to motivate our employees to contribute to it. To this end, we hold an annual 4R Day and with our biannual 4R Award worth € 10,000, we recognize best practices in animal-using activities, such as innovative alternatives to **reduce, refine and replace** animal testing. In addition, we honor exemplary behavior that demonstrates how we meet our **responsibility for animal well-being**. The next 4R Award will be granted in 2024.

The theme of our 4R Day in 2023 was "Compassion Fatigue and Culture of Care". This dealt on the one hand with the symptoms of fatigue that can arise when working with animals and on the other hand about fostering a culture of appreciation towards living beings. Both internal and external experts held presentations on these topics.

Bioethics

Scientific advances can spark controversial debates over ethical questions. We want to make responsible use of the growing potential of the life sciences to maximize benefit for both humankind and other living beings. In this context, it is important to us that we adopt our own position on bioethical questions.

Our approach to ethical business conduct

As a science and technology company with a broad spectrum of research activities, it is critically important for us to identify and address emerging bioethical topics and questions early on so that we can define our own position. Although we align all our operations with international and national laws, many technological developments raise new ethical questions that extend far beyond the framework set forth by current legislation. Our goal is to conduct research in a responsible manner, which is why we develop ethical guidelines – also in close collaboration with external experts – in order to make well-founded decisions for responsible research.

In our work, we encounter various topics of ethical relevance such as animal testing, clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. Moreover, we discuss in our committees the ethical aspects of providing products such as organoids for both academic research purposes and the biopharmaceutical industry.

We carefully evaluate our position when it comes to controversial topics. We always prioritize the well-being of and benefit for various groups of patients, whether in clinical studies or during treatment with our medicines.

Roles and responsibilities

Since 2010, our Ethics Advisory Panel for Science and Technology (MEAP) has been making clear recommendations on ethical questions in science and technology as well as on questions extending beyond the field of traditional bioethics, in line with our transformation into a science and technology company. The recommendations of the MEAP guide our actions and business activities.

The members of the MEAP are renowned international experts from the fields of **bioethics, medicine, philosophy, law, and the natural sciences** as well as **technology** and **sustainability**. The MEAP has its mandate from the Executive Board and is chaired jointly by the two members of the Executive Board with responsibility for the Healthcare and Life Science business sectors.

The MEAP meets multiple times a year and can also be convened on an ad-hoc basis in response to emerging urgent ethical questions. The meeting minutes can be accessed on our intranet, along with the recommendations given by the MEAP. Our employees can submit topics for the MEAP to the Bioethics team. If necessary, we involve further external experts. In addition, all employees may address their concerns to the Bioethics team via our **compliance hotline** and a dedicated e-mail address (accessible via the intranet).

A further board, the Stem Cell Oversight Committee (SCROC), reviews and decides on all planned in-house research activities involving the use of human embryonal or pluripotent stem cells, ensuring compliance with legal requirements as well as our ethical guidelines. This also applies to joint projects with external partners. Up until the end of 2022, the SCROC consisted of internal experts from our business sectors as well as external advisors from the fields of bioethics, medicine, and law. In 2023 and in line with a resolution by the MEAP, we transformed the SCROC into a primarily internal board. The reason for this is that research plans that call for

separate committee approval pursuant to the SCROC charter are currently not being carried out within the company. However, we will continue to involve external experts in the decision-making process should especially complex issues call for this.

Furthermore, for ethical questions arising for instance in the context of forward-looking business decisions, targeted Ethics Foresight projects can be initiated. We specifically engage external experts to work on these projects. In contrast to the MEAP, no specific recommendations result from Ethics Foresight projects, but the respective ethical risk for various scenarios is determined and several decision paths are mapped instead. In addition, the projects map potential consequences of various decisions. No Ethics Foresight projects were commissioned in 2023.

Our commitment: Guidelines and standards

Our **Genome Editing Principle** provides a binding ethical and operational framework for our employees. Apart from our position on genome editing, it includes information on human germline editing. It sets clear boundaries for us both as a supplier of customized CRISPR/Cas nucleases and genetically modified cell lines and as a company that uses genome editing technologies in our research.

This is complemented by further guidelines that form the ethical framework of our research and business activities. Our **Stem Cell Principle** sets the ethical boundaries for the use of human stem cells in our research. Our **Fertility Principle** regulates our fertility treatment and in-vitro fertilization research activities.

Biological samples are indispensable to the development of new targeted treatments and advanced diagnostic methods. We have defined our principles and processes for managing human biospecimens in standard operating procedures. Accordingly, we handle these samples in a responsible and ethical manner; in doing so, we adhere to relevant regulatory requirements and abide by the consent given to us by donors for the use of their samples.

Topics currently being discussed by the MEAP

In 2023, the MEAP met in May and October and discussed ethical questions of organoids, among other things. These are organ-like microstructures that can be produced artificially in the laboratory, for example from induced pluripotent stem cells.

The use of organoids is increasingly opening up the possibility of partially replacing and fundamentally reducing animal testing. This is in line with our commitment to animal welfare (see **Animal welfare**). In addition, it is becoming apparent in research and practical application that organoids could offer scientific advantages over animal models – one of the reasons why the use of organoids is currently increasing rapidly. This growth raises urgent bioethical questions, for example with regard to cell donation. The MEAP recommended that future donors should be more fully informed about the use of their cells, including any commercial uses. We want to review and further develop the design of consent forms in this regard.

The MEAP also addressed the legal and ethical classification of human embryo-like models recently created for the first time, as documented in the scientific literature. This discussion placed particular emphasis on the context of the German Embryo Protection Act and its possible implications for our work.

The MEAP also recommended examining how ethical standards can best be upheld for global health issues. This concerns mass drug administration (MDA), where participants must be informed and informed consent obtained. One focus was on MDA projects that are carried out with local partners or international organizations; the aim is to implement such actions effectively within the agreed areas of responsibility.

MEAP members

Jeremy Sugarman
Bioethics, Medicine
Johns Hopkins University

Jochen Taupitz
Medical law, Bioethics
University Mannheim

Nikolaus Knoepffler
Philosophy, Theology, Ethics
University Jena

Rafaela Hillerbrand
Philosophy, Physics, Technic ethics
Karlsruher Institute for Technology

Maria-Elena Torres-Padilla
Epigenetics, Stem cells
Helmholtz Center Munich

Thomas Douglas
Medicine, Philosophy
Oxford Uehiro Centre for Practical Ethics

Ruipeng Lei
Bioethics, Philosophy
Huazhong University of Science and Technology

Maria de Jesús Medina-Arellano
Bioethics, Medical law
National Autonomous University of Mexico

Biotechnology and genetic engineering

Throughout 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 if necessary. This helps us to ensure that all legal requirements are known and complied with.

Using genome-editing techniques

We are a leading supplier of technologies such as CRISPR/Cas, which can be used to target and modify specific genes, a process known as **genome editing**. CRISPR/Cas 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 or 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 allow the use of human embryonic stem cells only 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 fiscal 2023, no projects required the approval of the SCROC (2022: one project). 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 define how we responsibly handle data and algorithms.

Our approach to corporate digital responsibility

As it is our aim is to develop and use **new digital technologies** responsibly, we evaluate ethical issues that may arise from algorithms, artificial intelligence (AI) and data-based business models in an early stage. Since 2021, our **Digital Ethics Advisory Panel (DEAP)** has been focusing on complex ethical issues surrounding digital technologies.

Roles and responsibilities

One of the main tasks of the DEAP is to support us in developing digital applications responsibly while addressing ethics questions that could result from collecting and processing data as well as from the use of these innovative technologies. It issues recommendations for our entrepreneurial activities.

The panel comprises 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 has its mandate from the Executive Board; our employees may submit topics for the panel to discuss. As in the previous year, the panel held four meetings in 2023. These focused on issues concerning the use of generative AI. Summary minutes of the DEAP meetings have been accessible on our intranet since 2023 insofar as they do not contain any business secrets. They also document the recommendations issued.

Our commitment: Guidelines and standards

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

Together with the DEAP, we apply our **Code of Digital Ethics (CoDE)** in order to address questions pertaining to the **ethical use of data and algorithms**. The CoDE serves as a guideline for our digital business models, as a tool for analyzing ethical challenges, and a basis for practical DEAP recommendations. As one of our overarching governance documents, it applies to all employees and is publicly accessible as well.

The CoDE is based on five core principles: **justice, autonomy, beneficence, non-maleficence,** and **transparency.** These principles provide a clear structure for assessing ethical issues. Moreover, they support our business sectors as well as 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. To this end, we apply a **principle-at-risk analysis** (PaRA), which is based on the CoDE. We use the PaRA to examine ethical issues resulting from our

business as well as from the development of internal applications and new products. The DEAP uses the results of the PaRA as a basis for discussion. The PaRA method was described in the scientific journal Minds and Machines in 2023.

Developments in the field of generative AI, for instance ChatGPT, are growing in importance. All our business sectors are developing applications based on generative AI. To apply these innovative technologies responsibly and to the benefit of all, an ethical framework is currently being developed. The DEAP is intensively evaluating the guidelines. The aim is to roll out this framework company-wide in 2024.

Training on the ethical use of data and algorithms

In June 2023, online training on the CoDE was assigned to approximately 12,000 managers with personnel responsibility who can access the training in eight languages via our internal training platform. In addition, an advanced training course is available specifically for employees working in the fields of data science, AI and other digital areas of specialization. The course serves to illustrate the importance of the CoDE and empowers participants to make responsible decisions concerning the ethical aspects of data use and algorithms in digital products and business models. This course is also available to external stakeholders via our publicly accessible **website**.

Identifying risks

Since 2022, we have been looking at potential ethical risks that could result from projects by the Analytics Center of Excellence (ACE) of our Life Science business sector with the aim of developing suitable processes. The unit analyzes data from the business sector in order to obtain insights for our business.

In this connection, in June 2023, we launched a tool developed in-house for the **early identification of ethical risks** in ACE project management activities. This Group’s digital ethics check is a semi-automated analysis mechanism. It uses existing project features to calculate ethical risks and proposes potential measures to mitigate them. The basis for this is a scoring system that creates a risk assessment for each project. Depending on the risk score, the ACE unit can draw conclusions for product development. In doing so, it includes all decisive stages in the product life cycle and examines them for their ethical risks. As of January 2024, every new project in the Life Science business sector is to be analyzed in accordance with our scoring system. The aim is to expand the Group’s digital ethics check to projects across the entire company.