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** – for patients, customers and business associates – and find solutions for the world of tomorrow.

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 have integrated these requirements into our sustainability strategy and our Group-wide guidelines. These guidelines comprise **charters and principles** that are valid for the entire company as well as specific standards and procedures for individual business sectors and sites.

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

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

Roles and responsibilities

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

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

We support the following responsible governance initiatives:

- We have been a participant in the United Nations Global Compact since 2005 and are committed to complying with its principles. Our annual progress report illustrates how we live our responsibility in our day-to-day actions.
- As a signatory to the chemical industry's Responsible Care® Global Charter, we voluntarily go above and beyond what is required by law and have adopted mandatory standards for product responsibility, environmental impact mitigation and health and safety.
- As a member of the **Together for Sustainability** (TfS) network, we are dedicated to improving the supply chain with respect to environmental, compliance and social standards.
- We are a member of the Pharmaceutical Supply Chain Initiative (PSCI), which aims to continuously improve health, safety and environmental aspects throughout the supply chain.
- We are also a member of the Chemie^3 initiative, a collaboration between the German Chemical Industry Association (VCI), the Federal Employers' Association (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 take steps 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 global company, we have stringent requirements for effective compliance management. Importantly, we seek to emphasize compliance by acting in line with our company values and believe that profitable business operations should go hand in hand with the highest ethical standards.

Roles and responsibilities

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

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

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

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

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

employee feedback, setting aligned and harmonized goals. We also ensure that our organizational structure is up to date and meets business needs.

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

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

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

Our commitment: Guidelines and standards

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

- Our **Code of Conduct** guides our people in conducting business ethically – in line with our values and the law. It is available to all employees worldwide in 22 languages.
- Our **Human Rights Charter** supplements our Code of Conduct with globally recognized principles on human rights.
- Our **Anti-Corruption Policy** stipulates that all business activities must be conducted in line with legally applicable anti-corruption standards. All forms of bribery are strictly prohibited.
- Our global **Money Laundering Prevention Policy** defines and describes the internal global process and assurance measures to protect our company from being misused by third parties for money laundering activities.
- Our **Conflict of Interest Policy** sets a framework to explain the nature of a Conflict of Interest and the related risks. It explains how to prevent these kinds of situations or if prevention is not possible, sets rules for identifying, disclosing, mitigating and managing the risks that could arise from a conflict of interest situation**.**
- 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 partners acting on our behalf.
- Our **Compliance Reporting and Investigation Policy** includes the basic steps for an internal compliance investigation. Its purpose is to ensure an appropriate, timely and thorough response to compliance-related reports of potential misconduct relating to any kind of internal or external regulations or policies.
- Our **Dawn Raid Policy** defines courses of action, sets out general rules of conduct, and advises on rights and obligations during unannounced investigations, searches and seizures by authorities on our premises.

- Our **Healthcare Ethical Guiding Principles** provide our healthcare employees with ethical guidance for decision making and activities, while taking the particular challenges and responsibilities of this business sector into consideration. See the Responsible interactions with health systems section for more details.
- Our **Pharma Code** for prescription medicines as well as underlying policies and additional guideline documents define key principles for interactions with stakeholders in the health industry.
- Our **Standard on Local Compliance Standards** implements a review and approval process for local governance documents in areas under the responsibility of the Group Compliance function. This helps to ensure a uniform approach, while retaining sufficient flexibility to address stricter or more specific requirements and needs at a local level. In this way, our local teams can adhere to our compliance principles and guidance while implementing **specific local policies or procedures** that comply with local regulations.

Risk assessment

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

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

Conflicts of interest

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

In 2021, we further raised employees' awareness of conflicts of interest by establishing a **dedicated global interactive training program** and enhancing our communication.

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

Management and requirements of our business partners

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

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

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

Compliance training

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

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

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

Anti-money laundering

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

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

Reporting potential compliance violations

We encourage all employees worldwide to report potential compliance violations to their supervisors, Legal, HR or other relevant departments. Globally, they can also use our central whistleblowing “compliance hotline” **free of charge and anonymously** to report violations in their local language by telephone or via a web-based application. Reports of potential compliance violations that we receive via our “compliance hotline” are reviewed by the Compliance Investigations and Case Management team. Cases with a certain risk profile are presented to the Compliance Case Committee, which comprises senior representatives from our Compliance, Corporate Security, Data Privacy, Human Resources, Internal Auditing, and Legal departments.

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

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

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

Compliance audits

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

Our audit planning aims to provide **comprehensive risk assurance** through the best possible audit coverage of our processes. We take a risk-based approach to our annual audit planning process, considering factors such as sales, employee headcount, systematic stakeholder feedback and the Corruption Perceptions Index (CPI) published by the non-governmental organization Transparency International. If an internal audit gives rise to recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the recommended corrective actions. In 2021, Group Internal Auditing conducted 84 internal audits that included bribery and corruption-related risks, thereof 55 operational and 28 IT audits as well as one special audit (for example incident specific internal investigations).

Engaging stakeholders

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

Data protection & privacy

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.

Our approach to data privacy

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

Roles and responsibilities

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

Our Data Privacy Management System

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

Our DPMS applies similar elements as the compliance portfolio but adapted to the needs of data privacy. These include policies and procedures, risk assessment and documentation, training and awareness, programs and tools, individual requests, monitoring and reporting, incident management, and continuous improvement.

Ensuring IT security

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

Our commitment: guidelines and standards

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

Data privacy training

In line with the EU GDPR and our global approach to data privacy, we regularly conduct e-learning training courses in ten languages. We launched a content update to this training course in May 2021. Additionally, Local Data Privacy Officers support the execution of our Group-wide training plan by conducting training for specific target groups, on request.

IT tools for documentation

We maintain a central IT tool to provide a single source for data privacy processes, such as registering data processing activities and reporting potential data privacy incidents. In 2021, we began implementing a new, enhanced tool, which is expected to go live in 2022. Additionally, we use our corporate intranet for further communication, including answering data privacy questions and providing standardized templates. We registered no sanctioned complaints or incidents concerning breaches of customer privacy, data leaks, theft or loss of customer data in 2021. In three cases, minor personal data breaches were reported to the supervisory authority. These were not sanctioned.

Responsible interactions with health systems

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

Our approach to interacting with health systems

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

We adhere to all regulations concerning the promotion of pharmaceutical products. In most markets, pharmaceutical companies are permitted to advertise prescription medicines only to healthcare professionals, such as physicians and pharmacists. These promotional activities must always disclose the active ingredient, potential adverse effects and contraindications of the medicine. Our internal governance documents on the promotion of pharmaceutical products are part of our Group-wide program, which requires us to conduct business in compliance with the law, industry obligations and **in line with the highest ethical standards**. Our internal governance documents and various voluntary commitments exceed the applicable statutory regulations in many cases. 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 (where we share scientific information but not with the intention of promoting or increasing sales of pharmaceutical products) and promotional activities (activities with the clear intention of promoting or increasing sales of pharmaceutical products performed only by the Commercial organization), in line with industry standards. This differentiation implies various internal policies and standard operating procedures, responsible functions and review and approval levels, depending on the intention of the activity.

Direct-to-consumer advertising only in certain countries

Direct-to-consumer (DTC) advertising for prescription medicines is permitted in some countries, such as the United States. In line with applicable local laws, we use DTC advertising in these countries to help increase people’s awareness of certain diseases and the available therapies. In doing so, we empower patients to **make informed decisions** about their own treatment.

Roles and responsibilities

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

Our Global Regulatory Affairs unit has established a dedicated standard and corresponding process document on the review and approval of our promotional materials. At the operational level, the relevant business and all employees involved in our sales and marketing activities must adhere to our internal policies, standards and procedures.

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

Our commitment: Group-wide guidelines and industry standards

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

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

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

Our **Healthcare Ethical Guiding Principles,** introduced in October 2020, supplement the Pharma Code and provide our Healthcare employees with six ethical guiding principles for decisions and activities specific to the particular challenges and responsibilities of this business sector. In 2021, we rolled out an e-learning course for Healthcare employees worldwide. The course introduced the principles and showed how they provide quick and efficient guidance in relevant situations.

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) and sponsorships to participate in events.

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

Collaborating with patient advocacy groups

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

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

Supporting medical education

In order to contribute to medical advances that benefit patients, we organize non-promotional global medical education programs worldwide through our Global Medical Education and Academic Organization Relations department. We offer an Integrated Medical Education Portfolio comprising company-led or independent and continuing medical education programs funded by third-party organizations (medical education providers, medical societies, academic organizations, etc). We take an **ethical, transparent and responsible approach** aimed at providing fair, balanced and objective content. This is designed to allow the expression of a diverse range of theories and recognized opinions.

All requests for medical education funding are channeled through an approval process that falls under our R&D and Compliance functions, in line with our Standard on Medical Education Funding and our Company-led Programs Policy. This process ensures that all funds available for medical education programs are granted according to established internal guidelines and criteria, while also complying with all applicable laws and industry codes.

We also partner with industry associations, such as Global Alliance for Medical Education (GAME), International Alliance for Continuing Medical Education, (iPACME), European Federation of Pharmaceutical Industries and Associations (EFPIA) and Medical Affairs Professional Society (MAPS). Together with these associations, we discuss how to improve and harmonize quality standards for medical education.

Transparent reporting

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

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 2021, we continued with the international roll-out of our Code of Conduct-related training curriculum on dealing with **dilemmas in healthcare-specific situations**. This is a comprehensive and interactive training course that seeks to improve participants' awareness and understanding of such dilemmas, for example when overhearing a conversation that may or may not constitute attempted bribery. We plan to further implement this training program in all countries where our Healthcare business sector operates. The success of this program has prompted us to introduce a similar program in our Life Science and Electronics business sectors.

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

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 via 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 trainings on our policies and guidelines as well as important changes to the reporting requirements of 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 within Merck KGaA, Darmstadt, Germany. Group Tax is generally responsible for tax matters of Merck KGaA, Darmstadt, Germany and provides tax standards for the whole 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. Certain tax tasks are managed by other units of Merck KGaA, Darmstadt, Germany or the Group´s Business Services unit (MBS).

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

At the subsidiary level, the local CFO is generally responsible for tax matters, managed either by local tax units, by external advisors, or, for Germany and our U.S. subsidiaries, by Group Tax. The local CFOs report to the regional CFO. The regional CFO ultimately reports to the Head of MBS, 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 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 was issued by the Executive Board and applies to the entire Group. We review it at least once a year and modify it if necessary. In the event of extraordinary events, 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 modifications are discussed and coordinated with the Group CFO.

Suppliers

Sustainable supply chain management

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

Our approach to sustainable procurement

One of the goals of our supplier management endeavors is **compliance with fundamental environmental and social standards**, in addition to high-quality, reliable delivery and competitive prices. We have introduced relevant strategies, processes and guidelines that we are continuously improving in order to prevent violations of supply chain standards and improve our sustainability performance.

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

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

We view our approach to supply chain sustainability as a journey and are continuously working to improve and further develop our policies and processes. While doing so, we ensure that all legal requirements are taken into account and that corresponding measures are initiated where necessary. For this purpose, in 2021 we set up an internal working group tasked with ensuring that we are compliant with the German Supply Chain Due Diligence Act.

Supplier Decarbonization Program

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

We set up a cross-functional Supplier Decarbonization Program team within Group Procurement to define our strategy and drive the execution of a ten-year program plan. We also started to provide training sessions and materials for procurement managers and sourcing teams. We intend to approach our suppliers in waves and contacted the first target group with a letter from our Chief Procurement Officer, information about our aspirations and a questionnaire to assess their current decarbonization status. Our sourcing managers collect relevant supplier data in a global monitoring database.

We are developing an automated carbon accounting tool to manage the large quantities of data on the CO_2 emissions of our suppliers. It will be available by end of 2022.

More information on our climate-related targets can be found here.

Risk management process

To ensure supply security, we select our suppliers based on various criteria, such as country risk, material risk and supplier risk, and their strategic importance to the business. This helps our sourcing managers to identify potential mitigation actions with relevant suppliers and support them in making improvements. The approach towards our **strategic suppliers,** which account for approximately 53% of our total spend, includes the identification, monitoring and assessment of supply security risks. It comprises four main elements:

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

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

Due diligence process for responsible sourcing of minerals

Our company sources and sells products that contain minerals commonly summarized under the term “3TG” (tin, tungsten, tantalum, gold – collectively also known as conflict minerals). Minerals can be extracted, traded, handled, and exported from conflict-affected and high-risk areas (CAHRAs) associated with the risk that these minerals could originate from mines or smelters controlled by armed militia contributing to human rights violations.

Our overall aim is to source materials in a **responsible and conflict-free manner** and not to contribute to adverse impacts through our sourcing activities. Therefore, we developed a comprehensive due diligence program and respective practices to address minerals originating from CAHRAs. Our program framework is in alignment with applicable laws and international standards.

Our Responsible Minerals Sourcing Charter forms the basis of our due diligence program. It clearly communicates our company’s expectations regarding responsible sourcing to our suppliers and promotes responsible sourcing of minerals. We are continuously working to improve our due diligence practices and ensure conflict-free sourcing of 3TG.

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. In order to address 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. RMI uses third-party auditors to audit smelters and refiners and to investigate working conditions as well as environmental, health and safety issues. In the event that sufficient RMI-based information is not obtained, we conduct further research to determine whether an appropriate level of due diligence is ensured.

Roles and responsibilities

Group Procurement is responsible for integrating sustainability requirements into the relevant stages of our sourcing and supplier management processes. Our Center of Excellence for Supply Security coordinates the relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives. Sourcing managers responsible for selecting and contracting suppliers are made aware of and regularly updated on our **guidelines and sustainability requirements** through internal communication channels and training.

Our commitment: Guidelines and standards

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

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

Moreover, we support the Compliance Initiative of the German Association for Supply Chain Management, Procurement and Logistics (BME) and have endorsed the BME Code of Conduct. In particular, this code sets out rules for combating corruption, antitrust violations and child labor, upholding human rights, protecting the environment and public health, and promoting fair working conditions.

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

We invite our suppliers to let us or trusted partners conduct assessments or audits to increase our supply chain transparency and identify fields of activity in order to improve sustainability performance or mitigate infringement risks. Regarding our mica supply chain, we engage with a global consultancy to conduct audits and with the Indian organization IGEP to conduct inspections. Further information can be found in the corresponding chapter.

Further information on assessments and audits conducted in the reporting year can be found here.

Supply chain assessments and audits

Together for Sustainability supplier assessments and audits

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

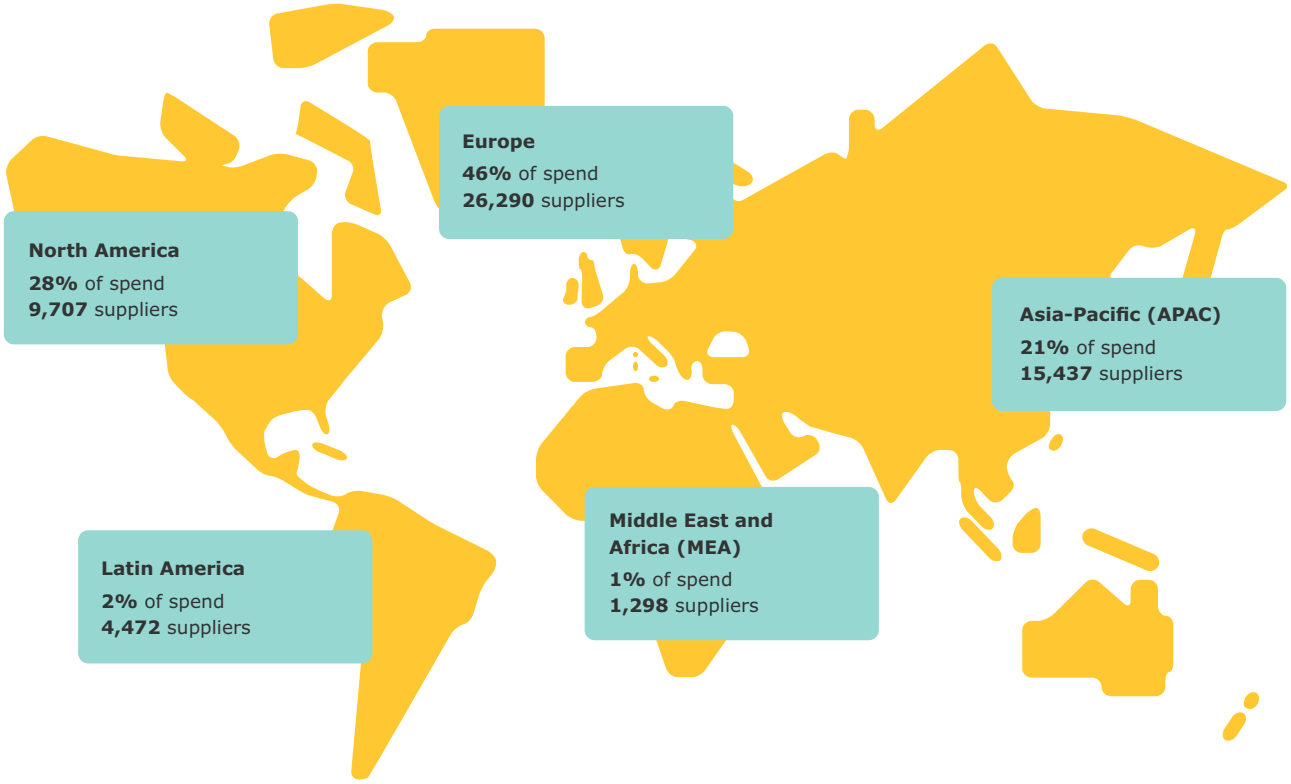
Through the TfS initiative, we have access to more than 1,460 valid scorecards on the assessment of our suppliers, 882 of which completed a new assessment or re-assessment in 2021. In some cases, these were initiated by us and in other cases by other TfS members.

In the context of “Grow & Deliver”, the strategic framework set by TfS for the period 2020-2025, we collaborated closely with member companies to drive **capacity building within our supply chain**. In 2021, we thus conducted several webinars on sustainability assessments and audits and on how to improve supply chain transparency and sustainability performance. These webinars were prepared and hosted in collaboration with TfS and EcoVadis and offered to our sourcing managers and suppliers in all regions. We also contributed to the new best practice sharing session series “TfS Talks”. As part of our contribution as a TfS member, we supported the development of a capability-building concept and implemented a training platform for sustainability knowledge and related skills. This platform will be available in several languages and for all our sourcing managers and suppliers of the 33 TfS member companies from 2022 onwards.

Global Procurement

The total value of the goods and services we purchased in 2021 from approximately **57,000 suppliers** in more than 140 countries amounted to around € 8.6 billion, compared with approximately € 7.9 billion in 2020, representing an increase of 8.9%. Of these (including R&D services), we purchased 28% from suppliers based in North America, 46% from suppliers based in Europe, 21% from suppliers based in the Asia-Pacific region, 1% from suppliers in the Middle East and Africa, and 2% from suppliers in Latin America.

Purchase volume and suppliers per region – 2021[1]



[1)] For data processing reasons, 3% of our purchase volume (1,245 suppliers) is currently not assigned to any purchase region.

Supplier diversity

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

Ambassadors for sustainable procurement

Since becoming established on the social network LinkedIn in 2019, the Sustainable Procurement Pledge (a TfS initiative) has evolved to become a knowledge exchange platform for procurement professionals, academics and other stakeholders. The platform has hosted various online best practice exchange events. We actively participate in the Sustainable Procurement Pledge.

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 taken special measures to comply with high social and environmental standards in our mica supply chain.

Our approach to responsibility in the mica supply chain

By procuring mica from the Indian states of Jharkhand and Bihar, where political instability, poverty and child labor are widespread, we are supporting this region by safeguarding local employment and livelihoods. We source the raw material only from suppliers acting in formal working environments and monitor compliance with our standards, including the prohibition of child labor.

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

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

Roles and responsibilities

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

We have established direct business relationships with suppliers that handle the mica supply chain in India. 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 Responsible Sourcing Principles, we set out our expectations for our suppliers in terms of sustainability and human rights, including prohibition of child labor. Our Responsible Sourcing Principles are also an integral part of our supplier contracts.

Auditing our mica supply chain

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

External audits

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

Unannounced inspections

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

Evaluating and tracking mica sources

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

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

Community outreach in the mica supply chain

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

In addition to our support for education, we are also helping to improve **access to healthcare**. We are fully funding an IGEP-operated health center 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). In 2021, we retained the presidency of the organization. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply chain by **joining forces across industries**.

During the reporting year, we continued to support the RMI's work on its three main program pillars:

- **Responsible workplace standards**: In 2021, the RMI developed and issued an updated version of the workplace standards, supplemented by training for local mica processors.
- **Community empowerment**: Building on the first community empowerment program in 2018, the RMI has expanded its programs to cover 130 villages, reaching more than 11,000 households in 2021. The goal is to address the root causes of child labor and improve livelihoods within the local community.
- **Advocacy**: Through continuous advocacy work, the RMI is recognized as an important partner for drafting future policies to help ensure sustainable mica mining, while eradicating the root causes of child labor.

Human rights

As an international corporate group, we have a duty to respect human rights worldwide within our sphere of influence and to ensure that our business activities do not infringe upon them. By fulfilling our human rights due diligence obligations, we meet the increasing expectations of our shareholders. 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, not only at our own sites but also along our entire supply chain. That is why we integrate human rights due diligence into our business processes. Our approach to human rights due diligence encompasses six main components.

Our human rights due diligence process

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

Roles and responsibilities

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

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

The interdisciplinary human rights working group (HRWG) is developing **cross-functional measures** that we are using to meet our responsibility to respect human rights. In addition, it discusses activities and current developments regarding business and human rights. The HRWG meets three to four times per year.

Within the German Global Compact Network, we are a member of the Business & Human Rights Peer Learning Group, a working group in which we engage in dialogue with other companies to discuss challenges, current issues, experiences and successful approaches in exercising human rights due diligence.

Our commitment: Guiding principles, charters and laws

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

The charter interlinks and complements our existing rules and regulations pertaining to human rights, including our Code of Conduct, Social and Labor Standards Policy, EHS Policy (Corporate Environment, Health and Safety Policy), Responsible Sourcing Principles, Responsible Minerals Sourcing Charter, and the Charter on Access to Health in Developing Countries. Our standards cover a broad range of topics related to human rights. These include, for instance, product safety, occupational health and safety, equal opportunity, fair pay, freedom of association and collective bargaining as well as the exclusion of child and forced labor.

Identifying actual and potential impacts on human rights

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

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

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

In the reporting period, we analyzed our activities designed to implement human rights due diligence in order to identify **potential for improvement**. We took both stakeholder and regulatory requirements into consideration. The analysis showed that we need a uniform, Group-wide process in order to better evaluate the effectiveness of our human rights due diligence. Above and beyond this, we want to further strengthen the HRWG, for instance by involving our business sectors more intensively.

Measures to protect human rights

Auditing our suppliers and sites

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

In addition, we review human rights aspects at our sites through site security risk assessments. In 2021, we formalized the assessments as security audits, which will be implemented at regular intervals in line with the audit plan in the future. The audits are one control mechanism of our security governance framework. Increased risk transparency and centralized CAPA tracking allows us to ensure that out sites meet **security-relevant human rights aspects**.

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

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. In 2021, we integrated human rights topics into the decision-making process for mergers and acquisitions.

Creating awareness among our employees

To embed respect for human rights even more strongly throughout the company, we are continuously expanding our internal communication and awareness training on human rights and modern slavery.

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

Training courses for our suppliers

As part of our membership of TfS, in 2021 we helped develop a concept for a sustainability management training platform, which is scheduled for rollout in 2022. It will be available globally, in multiple languages to all buyers and suppliers of the 31 TfS member companies.

We also participated in the #TfSTalks by sharing our conflict minerals approach, among other things. This new, interactive webinar format allows companies to exchange and discuss best practice approaches.

Our reporting practices

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

Our complaint mechanisms

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

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

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

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

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

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

Patient-focused drug development

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

Clinical studies in low- and middle-income countries

We conduct all our clinical studies in accordance with local laws and regulations, and we adhere to all relevant international scientific and ethical standards, irrespective of the region or country. We are deliberately expanding our medicinal product development to more diverse markets in order to address pressing healthcare needs in low- and middle-income countries and support the development of their healthcare systems.

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

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

Roles and responsibilities

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

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

We have established two internal committees to oversee our clinical studies. The Development Studies Committee is responsible for the studies performed by the company on medicines that are under clinical development, while the Global Medical Decision Board is responsible for our own studies with approved medicines, as well as for all studies performed by independent investigators and supported by us (so-called investigator-sponsored studies). Both bodies consist of medical-scientific **experts and executives with long-standing experience** in clinical research. Our development and study teams present clinical study concepts to the appropriate committee. Each committee meets regularly to conduct a comprehensive review of the proposed concepts and ascertains that our studies are scientifically sound, have a legitimate scientific purpose, and are performed in accordance with the latest standards and best practices.

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

We continuously analyze potential **risks for study participants** before and during our clinical studies. Our Medical Safety and Ethics Board (MSEB) oversees the safety of subjects participating in our clinical studies and, as necessary, reviews the benefit-risk profiles of investigational drugs. You can find further information on the MSEB under Patient safety.

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

Our commitment: International guidelines and requirements

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

- The Good Clinical Practice (GCP) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- The Declaration of Helsinki, published by the World Medical Association
- The Belmont Report by the U.S. Office for Human Research Protections
- Good Pharmacovigilance/Laboratory/Manufacturing/Distribution Practices (GVP/GLP/GMP/GDP)
- The International Ethical Guidelines for Health-related Research Involving Humans, published by the Council for International Organizations of Medical Sciences (CIOMS)
- The Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japan Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA)
- The Principles for Responsible Clinical Trial Data Sharing, published by EFPIA and PhRMA, and the IFPMA Principles for Responsible Clinical Trial Data Sharing

Regular supervision of clinical studies

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

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

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

Conducting clinical studies responsibly

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

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

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

Conducting clinical trials in vulnerable populations

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

Teaming up to get results

The clinical trial investigators participating in our clinical studies by enrolling and caring for patients are critical to the successful development of new medicines. Furthermore, in order 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 all our partners to abide by the same set of high standards in terms of ethical conduct and quality in clinical research.

As a member of TransCelerate, a consortium of 21 pharmaceutical companies, we are currently collaborating on several initiatives 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 when developing and conducting clinical studies. That is why we have established the Patient Advisory Boards (PAB) as one of our crucial communication channels. Our PAB Charter describes how to involve patient advocacy groups in our clinical research process. During Advisory Board meetings, patients, caregivers and representatives from patient advocacy groups are invited to share their experiences and perspectives related to clinical trials. We use this opportunity to discuss multiple aspects of the drug development process, including but not limited to protocol design, educational materials, technology and innovative approaches to clinical trials.

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

Responsible data sharing

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

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

Disclosure of clinical studies and publication of results

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

We publish results from our clinical studies in **medical journals** in line with applicable laws and industry codes. In this way, we adhere in particular to the current version of the Good Publication Practice (GPP3) and follow the recommendations of the International Committee of Medical Journal Editors (ICMJE). Our Medical Publications Policy ensures compliance with all relevant standards, and we use defined standard procedures for scientific publications on our products. In addition, we reference our clinical trial publications on our website. Our Standard on Clinical Trial Data Transparency underscores our strong commitment in this matter.

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

Enabling early access to new medicines

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

Supporting independent human subject research

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

Animal welfare

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

Our approach to animal welfare

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

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

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

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

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

Roles and responsibilities

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

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

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

In 2021, we established **multidisciplinary boards** in Europe and the United Kingdom that review and approve all work conducted by or on behalf of our company involving the use of animals. They are known as Animal Usage Review Boards. In the United States and Israel, these boards already exist as Institutional Animal Care and Use Committees (IACUC, in accordance with the U.S. ILAR Guide).

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

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

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

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

Comprehensive employee training

With our new Animal Affairs Academy we will define training specifications and oversee and provide staff training on practical work, rules, and regulations.

Our employees also regularly participate in external **continuing education** programs.

Work with committees and associations

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

Our commitment: Group-wide standards

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

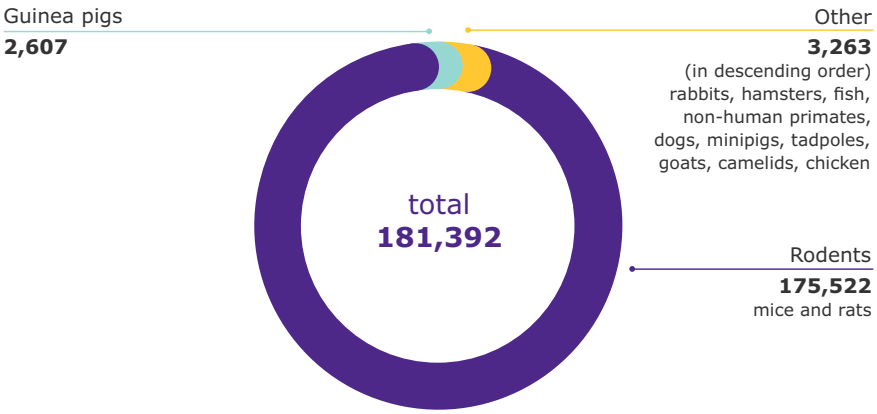
Our standards and procedures entail, for example, the housing and husbandry standards that also apply to external partners, and how we monitor them, including audit procedures. The Animal Using Vendor Management standard describes the requirements for the approval of contract research organizations and suppliers. Further documents, including guidance for our 4R efforts, incident reporting, and risk management, augment the governance framework.

We are convinced that the right level of **transparency** has the potential to improve the scientific outcome and value of animal testing and to create benefit for society, for patients, and for animal well-being. We committed ourselves to transparency by signing the German Transparency Initiative in 2021. The objective of this initiative is to drive forward an open discussion on animal research. It aims to provide easily accessible information and insights into husbandry and animal testing techniques and facilitates sharing of experiences.

Number of laboratory animals used for medical study purposes

In 2021, a total of 181,392 animals were used within the scope of our business activities, either in our own vivaria or on the premises of organizations contracted on our behalf. This represents an overall increase of 1% compared with 2020. Rodents (mice or rats) comprised 97% of all animals used in 2021, compared with 95% in 2020. Regulatory agencies sometimes require studies of the safety of investigational drugs in non-rodent species. This allows researchers to identify potential adverse effects accurately and include them in the risk assessment of a substance.

Animal types



Collaborating with partners and suppliers

We perform the majority (87%) of our animal studies ourselves and procure the required animals from specialized breeders. We also hire 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 2021, two vivaria were audited. Furthermore, we **improved Corporate Animal Affairs' oversight** of internal animal work with regards to aspects such as animal usage, purpose and incidents. In the reporting year we selected a digital solution that will promote this and further support the monitoring of our key indicators. We aim to implement this IT tool in 2022.

An integral part of our strategy is the qualification of all animal-using vendors we conduct business with. We completed the implementation of an auditing strategy and developed procedures to identify and train auditors. In 2021, a total of 58 vendor audits were performed, 19 of them on-site, 39 virtually due to the pandemic.

4R Award for animal welfare

We want to motivate all our employees to contribute to the 4R principle. With the biannual 4R Award, we recognize best practices in animal work as well as pioneering mindset to **Reduce, Replace or Refine** or leading by example in proving **Responsibility**.

To further promote the 4R principle throughout our company we initiated an annual 4R Day. The 2021 event focused on the new Corporate Animal Welfare Strategy and gave an overview of current 4R activities.

Bioethics

Scientific advances can spark controversy over bioethical issues. We want to responsibly bring to bear the growing potential of the life sciences to create maximum benefit for both humankind and other living beings. For us, it is important to clarify our own position on bioethical approaches.

Our approach to ethical business conduct

As a global company, it is crucial for us to identify and take up new bioethical trends and issues early on so that we can define our own position on such matters. Although we align all our operations with international and national laws, many discussions on bioethics pose questions that go far beyond the framework set forth by current legislation. We therefore also seek advice from external experts.

In our work, we encounter various bioethical issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. Our goal is to conduct this research in an ethical manner. We develop frameworks that guide us in making informed decisions to meet the most rigorous ethical standards. **Patient benefit and well-being** is always our top priority, whether in clinical studies, treatment with our medicines, or the distribution of our products to academic researchers and the biopharmaceutical industry. We carefully evaluate our position when it comes to controversial topics.

Roles and responsibilities

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

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

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

Our commitment: Guidelines and standards

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

Our Genome Editing Principle is complemented by additional guidelines that shape our approach to ethically conducted research and business. Our Stem Cell Principle sets the ethical boundaries for the use of human stem cells in our research. Our Fertility Principle guides our research in fertility treatment and in-vitro-fertilization by setting a clear framework for practices that reflect the most rigorous ethical standards. Our principles for disseminating information on the off-label use of our products are set out in corresponding policies that apply Group-wide.

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

Topics currently being discussed by the MEAP

The MEAP last convened in October 2021 and dealt with topics such as the animal welfare strategy we adopted in 2020 as well as our approach to vaccinating and testing employees for Covid-19. Panel members also addressed our ethical duty to go beyond the statutory requirements in terms of transparency on animal studies. In addition, the MEAP discussed our ethical responsibility with regard to the non-intended use of our products, especially those in our Life Science portfolio.

Members of our Ethics Advisory Panel (MEAP)

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

Jeremy Sugarman
Bioethics, Medicine
Johns Hopkins University

Jochen Taupitz
Medical law, bioethics
Former Vice-Chair German Ethics Council

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

Nikolaus Knoepffler
Philosophy, Theology, Ethics
University Jena

Daniel Fu-Chang Tsai
Bioethics, Medicine
National Taiwan University

Christoph Rehmann-Sutter
Philosophy, Ethics, Biology
University Lübeck
Former Chair Swiss National Advisory Commission on Biomedical Ethics

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 accordingly, thus ensuring compliance with all statutory requirements.

Using genome-editing techniques

We are a leading supplier of technologies such as CRISPR/Cas9, which can be used to target and modify specific genes, a process known as **genome editing**. CRISPR/Cas9 opens up new possibilities in genetic engineering research that could bring about major advances in the treatment of serious diseases or in “green genetic engineering”, which is the use of genome editing techniques in plant cultivation. Laws in different countries allow for a varying degree of latitude in applying this technique. Bioethical views on germline editing have been evolving for years through academic and social discourse. Our position on human germline editing is as follows:

“Our company does not support the use of genome editing in human embryos and clinical applications of germline interventions in humans in accordance with the German Embryo Protection Act. Our company recognizes that there may be value in responsibly conducted related research.”

Stem cell research

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

Digital ethics

People, machines, data, and processes are becoming increasingly interlinked, with technological advances transforming our society and posing new ethical challenges. Digital ethics provides us with a framework for responsibly handling data, algorithms and artificial intelligence.

Our approach to corporate digital responsibility

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

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

Roles and responsibilities

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

Our commitment: Guidelines and standards

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

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

The CoDE consists of five core principles: autonomy, justice, beneficence, non-maleficence, and transparency. These principles in turn provide a clear structure for assessing ethical issues and moreover guide our business sectors and individual employees through sensitive situations that are not (yet) covered by laws or other types of regulations. The CoDE not only serves as the basis for assessing the ethical risks posed by existing activities, but also enables us to evaluate the ethical aspects of newly emerging digital solutions. We are currently rolling out the code in the first batch of areas.

In December 2021, the German Association for the Digital Economy (BVDW) and the Bavarian company Bayern Innovative presented us with the Corporate Digital Responsibility Award in recognition of our Code of Digital Ethics. We took first place in the “New Business Models” category.

Strategic partnership for innovative therapeutic solutions

Since 2021, the DEAP has also been addressing questions arising from Syntropy, a digital joint venture between Palantir Technologies and our company. This partnership aims to leverage data to advance the discovery of medicines to treat cancer and other diseases. Syntropy enables us to collect data, collaborate and develop new discoveries in a safe, trust-based environment while also ensuring that the institutions that provide the data retain ownership of it. This partnership will facilitate new types of collaboration within the global scientific community in order to drive innovation in cancer research.