Business ethics

Within this chapter:

corporate governance

Governance

Part of the non-financial report

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. These core values guide us in our daily work, defining how we interact with our customers and business partners. We endeavor to give our best for patients and customers – 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 and the regulations, external initiatives and international guidelines to which we are committed. 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.

How we live responsible governance

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

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

We support the following responsible governance initiatives:

- We have been a participant in the United Nations Global Compact since 2005 and are committed to complying with its principles. 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 supply chains with respect to environmental, compliance and social standards.
- We are also a member of **Initiative Chemie[3],** a collaboration between the German Chemical Industry Association (VCI), the Federal Employers' Association for the German Chemical Industry (BAVC) and the German Mining, Chemical and Energy Industrial Union (IG BCE). The partners of 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

Part of the non-financial report

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

Compliance is one of our primary considerations worldwide. As an international company with operations also in low- and middle-income countries, 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.

How we ensure compliance

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, 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 Committees/forums:** Platform for compliance-related discussion and decision-making that includes relevant key functions
- **Training & Awareness:** Appropriate training and additional measures to educate and keep awareness high
- **Programs & Tools:** Comprehensive compliance programs and supporting tools that contribute to internal controls and overall governance, such as third-party risk management
- **Monitoring & Reporting:** Tracking of compliance-related data as well as performance of 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 elements of our compliance program

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 drive regular and targeted **communication** and exchange internally within our compliance organization and externally with our stakeholders and business partners to discuss current compliance matters, trends and goals. 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 always up to date and suitable for our 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 bodies every six months at a minimum. As part of our regular reporting processes, we compile a comprehensive **compliance and data privacy report** annually for the Executive Board, detailing 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 95 Compliance Officers and Compliance experts around the world. The Compliance Officers implement our compliance program within their respective areas of responsibility (with local necessary adaptions if legally required) and receive guidance from our Group Compliance Center of Expertise, a centralized body that drives the design and updating 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 incorporating current and upcoming transparency **reporting requirements in the healthcare 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.

Integrating acquisitions into our compliance system

The implementation of our compliance program at legacy Versum Materials has been completed. Legacy Versum Materials entities and sites will sometimes be referred to separately to address specific needs but are now included as part of the Performance Materials organization for our future compliance program evolution. Two role-dependent e-learning training courses will be targeted to legacy Versum Materials employees in 2021. These programs, entitled Global Anti-Corruption Standards and Understanding Global Antitrust and Competition Laws, will supplement our company´s Code of Conduct training they have already received.

As of 2020, Versum Materials and Intermolecular are part of the annual audit planning process of Group Internal Auditing. In January 2020, a "post day 1 audit" and in October 2020, an "Integration 12 months post Day 1 audit" for Versum Materials was performed. Further audits, such as those carried out at Versum Materials Korea or Intermolecular, are part of the **2021 Internal Audit Plan**, as approved by our Executive Board.

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, which 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 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 new **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 set out key principles for interactions with stakeholders in the health industry.
- Our new **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 on a local level. Our local teams can thus adhere to our compliance principles and guidance while implementing **specific local policies or procedures** that comply with local regulations.

Impact of the Covid-19 pandemic on our compliance mechanisms

Due to travel restrictions and in order to keep our employees safe, we had to conduct audits from Darmstadt. Audits were either postponed or adapted so that they could be performed remotely from Darmstadt.

The number of virtual meetings held by our employees grew significantly due to the pandemic, increasing compliance complexity as regards data privacy and IFPMA, EFPIA as well as local pharmaceutical industry code requirements. We responded by providing appropriate guidance on how to comply with international and local regulations in the fast-changing virtual environment and we are adapting our requirements and procedures accordingly.

We contributed to the fight against the Covid-19 pandemic by donating protective equipment to healthcare organizations as well as other organizations around the world. We also defined **global processes and requirement**s to ensure these kinds of donations are made in line with our compliance principles as well as international and local codes and regulations.

Risk assessment

Proper compliance risk management is crucial to identify undetected risks and keep our company protected. In 2019, we rolled out a new overarching cross-sector compliance risk management process. This "**Compliance Risk Reporting & Self-Monitoring Process**" comprises two components. Compliance Risk Reporting is the component in which compliance risks are evaluated. The risk evaluation is conducted by the Compliance Officer, who determines the monetary impact and the extent to which the risk is likely to occur, starting with the inherent risk, followed by the residual risk evaluation. The self-monitoring component allows us to monitor the effectiveness of our compliance program within a business. The respective Managing Director of the legal entity or head of department is provided with specific risk-mitigating statements that must be confirmed on an agreement scale from "fully agree" to "fully disagree".

After completing the first cycle in the previous year, in 2020, we focused on the key risks identified by running different analyses and dedicated follow-up activities for risk mitigation. Additionally, we also started to run sector-specific risk assessments to highlight specific business sector risks and take a targeted approach to risk reduction that help us to continuously adjust our compliance program.

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 manager but can also be routed to Human Resources or other relevant functions.

To further enhance the existing process, a new Policy and Procedure as well as a new tool for transparent documentation of potential conflicts of interest, including decisions and mitigations taken, was rolled out in 2020.

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 existing adverse 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 forums

This year, Group Compliance reinforced compliance awareness and encouraged compliance discussions by establishing a dedicated platform for local Compliance forums or committees. This platform enables discussion of updates and alignment on certain matters in order to maintain a high standard of corporate compliance throughout the global organization. At the same time, they make it possible to **remain agile** when new business and compliance challenges arise. Group Compliance has developed them using a structured methodology framework to enhance consistency and complementation across the globe, which will further support our risk assurance. Each local forum contributes to our consistent compliance framework approach and has sufficient flexibility to cater to their local sector-specific needs.

Compliance training

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

In 2020, we rolled out two new mandatory e-learning training courses. The training courses are assigned to all relevant employees. We launched an updated version of our anti-corruption e-learning training course in 13 languages. In 2020, 28,805 employees completed the training course. We also rolled out a new money laundering prevention e-learning training course, which is available in eight languages. The final rollout took place in November 2020 and 12,829 employees completed the training in 2020.

In September 2020, we migrated to a **Group-wide learning management platform** to simplify learner accessibility.

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.

Compliance monitoring and reporting activities

In 2020, we further enhanced our monitoring and reporting activities. Since we have different tools within Compliance, our efforts were targeted to create a single platform that displays all relevant information (KPIs and metrics for trend analysis) from the various tools. Therefore, we initiated a new governance and monitoring project that ensures a more efficient tracking of compliance-related KPIs and metrics.

Reporting potential compliance violations

We encourage all employees worldwide to report potential compliance violations to their supervisors, Legal, HR, or other relevant departments. Worldwide, they can also use our central whistleblowing SpeakUp Line **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 SpeakUp Line 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 Compliance, Corporate Security, Data Privacy, Human Resources, Internal Auditing, and Legal.

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 SpeakUp Line is also available to external stakeholders. The relevant information can be found in the Compliance and Ethics section of our website, where we consolidate key compliance information, such as our values, Code of Conduct (CoC) and information on transparency and data privacy for external audiences.

Both the number of reports of suspected compliance violations and the number of actual compliance cases were stable compared with the previous year. In 2020, we received 81 compliance-related reports via the SpeakUp Line and other channels that **led to investigations**. There were 41 confirmed cases of violations of the CoC or other internal and external rules.

Compliance audits

As part of operational audits, our Group Internal Auditing function regularly reviews relevant matters at our sites to determine the **effectiveness of the respective compliance guidelines**, processes and structures in place. The unit also checks for violations of our CoC and our Anti-Corruption Policy and reviews 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. Our annual audit planning process is risk-based and includes 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 produces recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the prescribed corrective actions. In 2020, we assessed 52 operations for corruption-related risks.

Alliance for Integrity

We are a member of the Alliance for Integrity Steering Committee, which was established by the German Society for International Cooperation (GIZ), the German Global Compact Network (DGCN) and the Federation of German Industries (BDI). This initiative aims to achieve corruption-free business in low- and middle-income countries. Its activities focus on Latin America, Ghana, and Asian countries, particularly India and Indonesia. The Steering Committee leads the decision-making process for developing national measures, while local advisory groups oversee implementation at country level.

Our local compliance organizations also collaborate with these groups and offer **training to small and medium-sized companies**. Beyond these efforts, we continuously assist the Alliance for Integrity through business-to-business workshops and training courses and by sharing best practices on how to develop and implement effective corruption prevention systems.

Engaging stakeholders

In 2020, we conducted stakeholder dialogues primarily through our memberships of various associations. 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 privacy

Part of the non-financial report

For a leading innovative, science- and technology-driven company such as ours, compliant handling of information is of utmost importance. When using personal data, the individuals' rights must be appropriately protected. In this regard, we strive to safeguard the rights of any person whose data we process, including but not limited to our employees, patients, customers, healthcare professionals, suppliers, visitors, and other business partners.

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 build our employees' capacity to handle data correctly and with clear accountability and it safeguards our company by providing data privacy risk assurance. Group Data Privacy also contributes to creating value for the development of digital business models.

How we ensure data privacy

Group Data Privacy is part of our global Group Compliance and Data Privacy function. As required by law, this unit acts independently. As part of our compliance reporting, it prepares **frequent data privacy updates** as well as a regular, comprehensive data privacy report. This report is part of the compliance report submitted to the Executive Board and the Supervisory Board. In addition to the Group Data Privacy unit with a Group Data Privacy Officer who reports centrally, we also have a network of Local Data Privacy Officers at various sites Group-wide.

Our goal is to establish a fully 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 will consist of eight key processes and topics broken down into 26 detailed sub-elements, thus covering all elements of a functioning DPMS in line with legal requirements and industry standards.

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's requests, monitoring and reporting, incident management, and continuous improvement.

Ensuring IT security

It is essential for our business that we also 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 measures** (e.g. access control) 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 and standards 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 ensure data privacy, we regularly conduct e-learning training courses in ten languages. An update to this training course is planned for the first quarter of 2021. Additionally, Local Data Privacy Officers complement the execution of our Group-wide training plan by conducting training for specific target groups.

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. This tool will be redesigned in 2021. Additionally, we use our company 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, leaks, thefts, or losses of customer data in 2020. In three cases, minor personal data breaches were reported to the supervisory authority which were not sanctioned.

Responsible interactions with health systems

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It is important that healthcare stakeholders, such as research institutes, healthcare professionals, patient advocacy groups, and other key players have access to up-to-date information on diseases and treatments while safeguarding their independence. We help facilitate this access by sponsoring independent initiatives and medical capacity-building programs. We also support outstanding research projects through our Global Grants for Innovation, for example. Transparency is one of our top priorities in everything we do.

Our approach to interacting with health systems

The well-being of patients is always our primary consideration when promoting pharmaceutical products, which is why we support health systems by providing information to our healthcare stakeholders, such as professional medical associations, patient advocacy groups, university clinics, and other hospitals. We follow **specific approval requirements** and procedures for each type of interaction in accordance with applicable laws and codes. In countries that have 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, manufacturers and distributors are permitted to advertise prescription drugs only to healthcare professionals, such as physicians and pharmacists. These promotional activities must always disclose the active ingredients, potential adverse effects and contraindications of the drug. Our internal governing documents on drug promotion are part of our Group-wide program, which requires us to always 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 (activities in which 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.

How we ensure transparency and compliance

For all engagements with healthcare stakeholders, we have established internal policies, **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 policy 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 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, there is a review by medical, legal and regulatory functions. This also helps us identify opportunities for improvement.

Direct-to-consumer advertising only in certain countries

Direct-to-consumer (DTC) advertising for prescription drugs is permitted in some countries, such as the United States. In accordance 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.

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 industry organizations, such as the Code of Practice published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice.

We are a member of the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), which has defined its own Code of Conduct for collaboration between physicians and the pharmaceutical industry.

Our Group-wide Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations defines the relevant general compliance for our activities in the Healthcare sector. It also governs our interactions with physicians, medical institutions and patient advocacy groups along with our promotional practices.

Our new **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.

We introduced new **Healthcare Ethical Guiding Principles** in October 2020 to provide our Healthcare employees with ethical guidance for decisions and activities specific to the particular challenges and responsibilities of this business sector. They complement our other policies by providing an accessible general guide for responsibility towards patients, the independence of safeguarding mechanisms, scientific integrity, responsible promotional activities, responsible interaction with healthcare stakeholders, and organizational responsibility and accountability. We have specific governance documents, procedures and tools for different types of interactions with healthcare stakeholders, covering topics, such as engagements, hospitality, payments (at fair market value) and sponsorships to participate in events.

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 research and education

Through our Global Grants for Innovation, we sponsor research and medical education worldwide in order to contribute to medical advances that benefit patients.

We organize non-promotional medical education programs through our Global Medical Education and Academic Organization Relations unit. We deliver these either directly as Medical Education Programs from Merck KGaA, Darmstadt, Germany or by providing grants to third-party medical education providers to fund independent and continuing medical education programs. We take an **ethical, transparent and responsible approach** aimed at providing fair, balanced and objective content, 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 Medical Education Funding and our Programs Policies. 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 2020, we continued to publish financial and non-financial contributions that we made to healthcare stakeholders in the health industry where required according to local laws and codes. As required by applicable laws and codes, this information includes the names of individual recipients and their addresses as well as the purpose and amount of the transfer. 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.

We **ensure transparency** on our voluntary unsolicited donations by publishing the details of contributions to European patient organizations on our website. The report is updated annually and includes all amounts, recipients and the purpose of each transfer of value, thus fulfilling our obligation as a member of EFPIA.

Regular employee training

In 2020, we rolled out our Code of Conduct-related training curriculum on dealing with **dilemmas in healthcare-specific situations** to several countries after piloting the project in China in 2019. This is a comprehensive 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 implement this training program in all countries where our Healthcare business sector operates.

In 2020, we also rolled out a Healthcare Ethical Guiding Principles training for our leadership teams, explaining the principles and discussing how they can be used in different scenarios. The goal is to enable our employees to make ethical decisions relating to scenarios that are not clearly defined in other governance documents, where necessary. For 2021, an e-learning course is planned for all Healthcare employees.

Employees who are responsible for the promotion of our pharmaceutical products receive regular training on current guidelines. This applies to individuals working in sales, marketing and drug registration in particular. We either conduct these seminars 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 intranet.

Relevant employees participate in mandatory e-learning courses and classroom seminars to stay up-to-date on our policies and guidelines and important changes to transfer of value reporting requirements.

Tax governance

We are aware that our company operates in a complex legal environment and incurs various tax obligations with 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. For this we have a tax organization 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:

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

How we organize our tax governance

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 Group Environment, Health, Safety, Security, Quality (EQ) 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. Group Tax consists of five units. 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 the 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 taken over by a designated employee in the Finance unit.

Our SpeakUp Line, i.e. our general whistleblowing system, is also open for tax topics.

Our commitment: a tax principle

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

- 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 case 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 if required. The responsibility for annual and ad-hoc reviews as well as modifications to the principle lies with the Head of Group Tax. Modifications to the principle are discussed by the Executive Board.

suppliers

supply chain standards

Part of the non-financial report

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, as set out in our Responsible Sourcing Principles, and to apply these within their own supply chains as well.

Our approach to making our supply chains more sustainable

One of the goals of our supplier management endeavors is **compliance with fundamental environmental and social standards**, alongside high-quality, reliable delivery and competitive prices. To achieve this, we have introduced relevant strategies, processes and guidelines that we are continuously improving to prevent violations of supply chain standards. To ensure supply security, we select our suppliers based on diverse criteria such as country risk, material risk, supplier risk, and business criticality. This helps our sourcing employees to identify potential mitigation actions with relevant suppliers and work on improvements.
The approach towards our **strategic suppliers,** which account for approximately 43% of our total spend, includes the identification, monitoring and assessment of supply security risks. It comprises four main elements:

1. **Supplier Risk Assessments**: to capture the overarching risks at supplier legal entity level, including multiple risk domains.
2. **Alert system:** to notify our Procurement organization when any of our suppliers faces a potential disruption.
3. **Material Risk Assessments:** to determine the risks of relevant materials that make up our most significant finished products.
4. **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 2020, we extended this program to include more suppliers. Additionally, we are streamlining the criteria and integrating other relevant topics in order to arrive at a more comprehensive and solid evaluation. We expect to implement this project by the middle of 2021. Amid the Covid-19 pandemic, our Procurement team also successfully secured the supply of raw materials, services and finished goods. It achieved this predominantly through effective supplier relationships.

We have developed a company-wide **due diligence process** for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas, according to OECD guidance, which will integrate and strengthen existing measures used in our business sectors. A working group manages and implements this process. It comprises various business sector and Group function representatives.

We understand 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 make sure that all legal requirements are considered and corresponding measures are initiated where necessary. In this context, we are closely monitoring the developments relating to a potential supply chain law and the resulting requirements.

Learn more about our efforts to reduce our scope 3 emissions in the Climate action chapter.

How we implement sustainability standards in the supply chain

Group Procurement is responsible for integrating sustainability requirements into the relevant stages of our sourcing and supplier management processes. It is a global organization with direct accountability and resources in procurement-relevant local subsidiaries. Our Center of Excellence for Supplier Security coordinates the relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives. Sourcing employees responsible for selecting and contracting suppliers are aware of and regularly updated on our **guidelines and sustainability requirements** through internal communication channels and training.

In 2020, we introduced a TfS training course in Asia. We invited our Procurement employees to participate in various Ecovadis webinars. Part of the training program deals with TfS assessments and audits. In addition, we are in the process of developing a global training program for purchasers and suppliers together with TfS.

Our commitment: Guidelines and standards

We expect all our suppliers and service providers to comply with environmental and social standards, which are primarily derived from the core labor standards of the International Labour Organization (ILO) and the UN Global Compact.

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, as well as for upholding human rights, protecting the environment and public health and promoting fair working conditions.

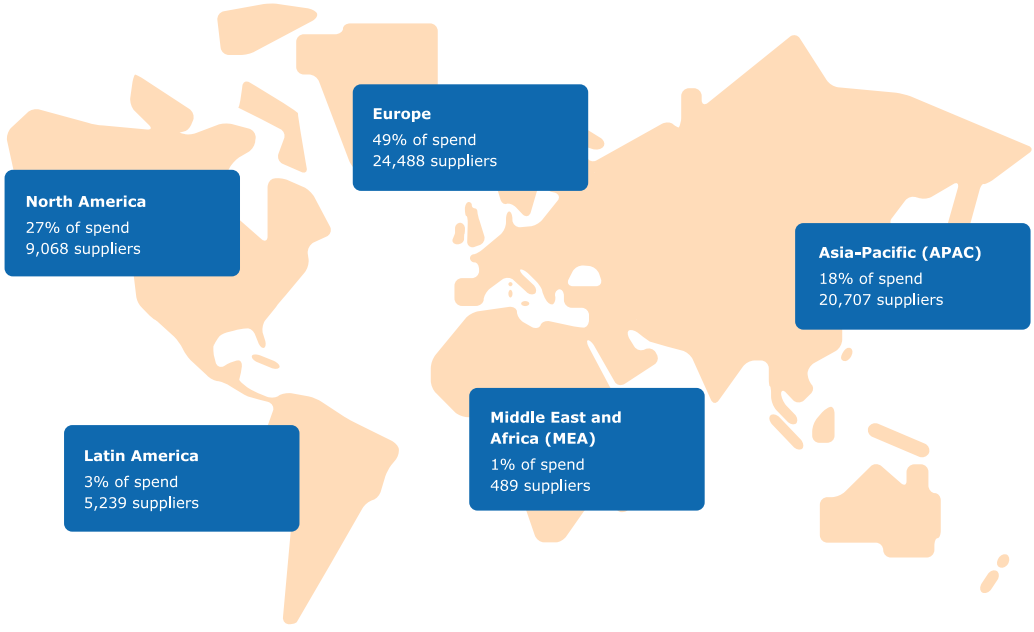
We seek to conduct our business activities in compliance with labor, social and environmental standards while also respecting human rights. Additionally, we abide by the standards set out in our Code of Conduct and our Human Rights Charter. We expect our suppliers to **comply with the labor, social and environmental standards** defined in our Responsible Sourcing Principles and to ensure that their subcontractors do the same.

We recognize that risks of significant adverse impact may be associated with extracting, trading, handling, and exporting minerals from conflict-affected and high-risk areas ("CAHRAs"). We have a responsibility to respect and safeguard human rights and not to contribute to conflicts. That's why we published our commitment to responsible sourcing of minerals from CAHRAs with our Responsible Minerals Sourcing Charter in 2020. This complements the requirements set out in our Responsible Sourcing Principles. The primary focus of the Responsible Minerals Sourcing Charter is on mined material such as tin, tungsten, tantalum, gold (also known as the "3TGs"), and cobalt sourced from CAHRAs. This Charter is also intended to cover CAHRA-related risks in other supply chains, as identified by our internal risk evaluation processes. This Charter applies to all our entities and subsidiaries worldwide, all employees as well as any third party acting on behalf of our company.

Global Procurement

The total value of the goods and services we purchased in 2020 from approximately **60,000 suppliers** in almost 160 countries amounted to around € 7.9 billion, compared with approximately € 7.5 billion in 2019, representing an increase of 5%. Of these (including R&D services), we purchased 27% from suppliers based in North America, 49% from suppliers based in Europe, 18% from suppliers based in the Asia-Pacific region, 1% from suppliers based in the Middle East and Africa, and 3% from suppliers based in Latin America.

Purchase volume and suppliers per region – 2020[1]



[1] For data processing reasons, 3% of our purchase volume (1,196 suppliers) is currently not assigned to any purchase region.

How we monitor our supply chain

A number of different approaches are used to keep track of our suppliers and ensure compliance with our standards and values. These are generally based on the risk the suppliers pose and combine the factors of country risk, industry risk and impact on business.

- Under the **Together for Sustainability** (TfS) initiative launched by companies in the chemical industry, we encourage our suppliers to be assessed either on self-reported information or via audits. We have been a member of TfS since 2014.
- In selected cases, we conduct our own sustainability audits of suppliers.
- Regarding our mica supply chain, we engage with a global consultancy to conduct audits and with the Indian organization IGEP to conduct inspections.

TfS supplier assessments and audits

Under TfS, 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 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. From a strategic perspective, TfS activities focus on achieving demonstrable improvements in supplier sustainability standards. In 2020, we began rolling out a new strategic framework, "Grow & Deliver", which defines TfS activities for the next five years. Our core objective is to move from measuring and monitoring to delivering a substantial positive impact in the chemical supply chain.

Through the TfS initiative, we have access to more than 1,250 valid scorecards on the assessment of our suppliers, 717 of which took part in a new assessment or re-assessment in 2020. In some cases, these were initiated by us and in other cases by other TfS members.

TfS also began a pilot for a more inclusive audit process in 2020. As a TfS member, we can use SQAS, SMETA and PSCI audits in addition to TfS audits, as they are now accepted as equivalent.

Conducting our own audits

We continuously conduct our own audits in selected cases based on business requirements. In 2020, none of these revealed indications of violations of the right of association, the right to collective bargaining or cases of child labor, forced labor or compulsory labor.

Supplier diversity

In the United States, we have a specific supplier diversity program in place to comply with regional legislation. We focused our efforts 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 diverse 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 small and diverse vendor database.

Ambassadors for more sustainable supply chains

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. At our company, we actively participate in the Sustainable Procurement Pledge.

Mica supply chain

Part of the non-financial report

Mica is an important raw material for our effect pigments, which are used in automotive, industrial coatings and plastics, as well as in the cosmetics and food industries. We procure the majority of our mica from India, specifically the north-eastern states of Jharkhand and Bihar. This region suffers from political instability and poverty, with widespread child labor. We've taken special measures to comply with our social and environmental standards.

Our approach to responsibility in the mica supply chain

In procuring mica from northeast India, 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 our 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. **We do not tolerate child labor** and contractually prohibit our suppliers from employing children. Hence, we are driving initiatives and taking measures to improve the conditions of mica sourcing based on our high standards. We constantly review our monitoring processes and work on improving their effectiveness.

How we organize our mica supply chain

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

We have established direct business relationships with those suppliers who handle the mica supply chain in India. Our procurement unit is in direct contact with the suppliers to reiterate the importance we place on ethical, social and environmental standards. In case of non-compliance with our standards, we work with suppliers to ensure the appropriate implementation of corrective measures.

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 corporate responsibility 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 through a system that monitors and audits compliance 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 check visits.

External audits

Environmental Resources Management (ERM), a leading global provider of environmental, health, safety, risk, 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) then follow up to work on resolving any identified issues.

If shortcomings are not rectified, we take further action, up to freezing relations with the respective company or even terminating the business relationship altogether if necessary.

Unannounced inspections

Since 2013, the IGEP Foundation, a local non-government organization, has been arranging regular unannounced inspections to check labor standards along the supply chain. During these visits, IGEP monitors occupational safety as well as **compliance on child labor**. In 2020, the inspections focused on the availability of first aid kits with sufficient medicine, medical health check-ups for workers and health and safety training. Due to an improved escalation process, our suppliers have successfully improved the working conditions on the sites.

Tracking system for 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 companies.

Community outreach in the mica supply chain

The states of Jharkhand and Bihar are among the most impoverished regions in India. Together with IGEP, we are working to improve the **living conditions of the families** in the mica mining areas. The literacy rate and the number of children who attend school are far below the Indian national average, according to a study conducted in 2016 and a report published in 2018 by the organization Terre

des Hommes and the Centre for Research on Multinational Corporations.

As part of our efforts, we are funding three schools in Jharkhand run by our partner IGEP, which are attended by nearly 500 children and adolescents. In 2020, two schools introduced an eighth grade. Tailoring and carpentry courses are also offered in vocational training centers nearby the schools. In the reporting year, we also assessed the feasibility offering new options for vocational trainings such as plumber or electrician. At a fourth school run by one of our mica suppliers, we provide scholarships for 200 children out of 450 enrolled at the school.

In addition to our education efforts, we are committed to improving **local access to healthcare**. To this end, we have established a health center operated by IGEP to serve the 20,000 residents in the region. Two medical professionals work at the center and also provide regular health services to schools. This center provides an important contribution to improving the medical care of the population in the region, particularly during the Covid-19 pandemic, which continues to have a significant impact on the Indian economy and society.

Stronger together: Joint action in the mica supply chain

We are a founding member of the multi-stakeholder group Responsible Mica Initiative (RMI). In 2020, we once again held the presidency of the organization. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply chain by **joining forces across industries**. During the reporting year, we continued to actively support the RMI's work on its three main program pillars:

- **Responsible workplace standards**: In 2020, RMI held training sessions on workplace standards for local businesses.
- **Community empowerment**: Building on the first community empowerment program in 2018, the RMI has expanded the programs to cover 80 villages, reaching more than 5,800 households in 2020. The goal is to address the root causes of child labor and to 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.

In 2020, the RMI further developed its **multi-stakeholder consultations,** including representatives from processors, local authorities and non-government organizations. An important outcome of this is the "Ranchi principles," which represent a cornerstone for alignment among all key players at a local level. They are a set of principles intended to help create a sustainable mica eco-system in the Indian mica region.

The RMI responded rapidly to the Covid-19 outbreak. At the outset, the RMI funded community kitchens in the Giridih district until local authorities took over. These community kitchens supplied two meals per day, prioritizing vulnerable groups, such as the elderly, migrant workers and underprivileged families. At a later stage, the RMI organized e-consultations so that all its stakeholders were able to continue the dialog on sustainable mica.

New sources of mica

Our processes undergo constant review and improvement. We are evaluating other sources for mica according to our quality, social and environmental standards both in India and in other regions. In 2020, we obtained a considerable amount of our mica from Brazil, where we have also established oversight mechanisms to monitor and audit adherence to these standards. In addition, we manufacture effect pigments based on synthetic substrates as an alternative to pigments based on natural mica.

Human rights

As an international corporate group, we have a duty to respect human rights worldwide within our sphere of influence and to ensure that they are not compromised by our business activities. Upholding human rights is indispensable and non-negotiable for us, which is why we also expect our business partners to guarantee that human rights are respected. By meeting our human rights due diligence obligations, we fulfill our social responsibility and secure our social license to operate. At the same time, this helps 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 reduce the risk of human rights violations as far as possible, not only at our own sites but also along our entire supply chain. That is why we are continuously integrating human rights due diligence more firmly into our business processes.

Our approach to human rights due diligence encompasses six main components.

Our human rights due diligence process

We view human rights due diligence as a **continuous process**, which we constantly adapt and improve. We closely monitor regulatory developments – for example, the National Action Plan (NAP) on Business and Human Rights of the German federal government on the implementation of the UN Guiding Principles and the planned EU directive on human rights due diligence. Regulations such as these prompt us to continually review our approach to human rights due diligence.

How we promote respect for human rights

To ensure that human rights are respected in our sphere of influence, we have defined clear responsibilities.

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

Our Group Corporate Sustainability (CS) unit is responsible for coordinating all human rights due diligence activities and processes. Specific need for action, progress and measures are regularly discussed at CS Committee meetings. The persons responsible for these issues in the respective Group functions, business sectors and local units implement the measures decided.

The interdisciplinary Human Rights Working Group is developing **cross-functional measures** that we are using to meet our responsibility to respect human rights. This group meets three to four times per year. In 2020, it defined internal focus areas that build on our approach to human rights due diligence. Within these focus areas and based on the specific risk situation, we will implement further measures in order to better comply with human rights due diligence obligations.

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 all 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, for example, our Code of Conduct, Social and Labor Standards Policy, EHS Policy (Group Environment, Health and Safety Policy), Responsible Sourcing Principles as well as 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 labor.

In 2020, we also added human rights aspects to our Site Security Standard. In doing so, we want to ensure that these aspects are also included in the selection of security service providers, for instance.

In addition, we developed a Conflict Minerals Charter in 2020. This regulates responsible sourcing of minerals from conflict and high-risk regions.

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. The following risk assessments enable us to derive the corresponding strategies and measures:

Within the scope our Group-wide Compliance Risk Reporting & Self-Monitoring process, we monitor and evaluate **compliance risks**. This has included human rights issues since 2019. In 2020, the consolidated results showed a low risk of human rights violations throughout the Group.

Furthermore, we also track human rights risks through our **strategic supplier risk process**. We plan to extend our risk assessment of the selection of new suppliers regarding modern slavery.

We are currently developing a new approach through which we aim to identify whether our **external manpower** is at risk. We are thus broadening the scope of the pilot project we conducted in 2019. Within the scope of this project, we conducted a Group-wide analysis of the work conditions of external manpower, especially in high-risk countries, such as China, Vietnam and the Philippines.

We take responsibility when **deploying new technologies** and comply with our human rights due diligence obligations. We are currently compiling an overview of the technologies we use in the company and are evaluating the human rights risks, if any, that are associated with them.

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 can be found under Compliance management.

In addition, we have been reviewing human rights aspects at our sites through site security risk assessments since 2019. Starting in 2021, these will be formalized as security audits and implemented at regular intervals in line with the audit plan. The audits are one control mechanism of our security governance framework and are thus a central element of it. We derive appropriate measures from the results. This allows us to ensure that our 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. For selected suppliers, we conduct our own sustainability audits. To prevent modern slavery and human trafficking, we will regularly review our supplier

assessment and audit processes and are devising long-term measures together with our suppliers to this end.

Human rights and investment decisions

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

Creating awareness among our employees

To embed respect for human rights even more strongly throughout the company, we are 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, all new EHS managers took the "EHS StartUp!" onboarding course, which has been covering the topics of human rights and modern slavery since 2018. Our employees can find information about human rights on our intranet.

Training courses for our suppliers

In 2020, we introduced a TfS training course in Asia. We invited our Procurement employees to participate in various Ecovadis webinars. Part of the training program deals with TfS assessments and audits, which include compliance with human rights as an essential audit component.

In addition, we are in the process of developing a global training program for purchasers and suppliers together with TfS. This is to include training on human rights.

Transparent reporting

We use various formats to 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, in the United Kingdom, the UK Modern Slavery Act requires us to publish the steps we are taking to counter forced labor and human trafficking. In 2020, we published our fourth UK Modern Slavery Statement. It has been endorsed by our Executive Board and is available on our website.

Our complaint mechanisms

Our SpeakUp Line is the most important channel for reporting complaints about potential human rights violations. Both our employees and all external stakeholders can report suspected cases in their respective national language, free of charge and anonymously, either by telephone or a web-based application. We thoroughly investigate all complaints that we receive and take countermeasures if necessary. In 2020, 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.

Bioethics

Part of the non-financial report

Bioethics guides us in how to use the rapidly advancing power of life science and the resulting technologies responsibly and ethically to the ultimate benefit of society, humans and other living beings. However, factors such as diverse cultural backgrounds have led to heated debates on divisive bioethical topics and issues arising from the explosive progress in science. In light of this situation, we feel the need to clarify our own position on bioethical approaches.

Our approach to ethical business conduct

In our work, we encounter various bioethical and digital ethics topics and issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, use of health data, and the potential impact of new genome editing techniques such as CRISPR/Cas. We are strongly committed to conducting this research in an ethical manner. **Patient well-being and benefit** is always our number one priority. This applies to clinical studies as well as to treatment with our drugs and distribution of our products to academic researchers and the biopharmaceutical industry. We carefully evaluate our position on controversial topics so that we can develop frameworks and make informed decisions that meet rigorous ethical standards.

How we assess bioethics and digital ethics

The Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP), co-chaired by two of our senior executive scientific experts, gives clear guidance on bioethical topics and issues, which steers our actions and entrepreneurial conduct. The MBAP consists of renowned external international experts in the fields of **bioethics, theology, science, and law.** The panel's composition reflects the fact that the evaluation and assessment of bioethics are strongly contingent on cultural and regional factors. The bioethical assessment of topics must be viewed holistically. The MBAP meets once per year but can also be convened on an ad-hoc basis, if required, in response to emerging urgent bioethical issues. We publish a summary of the discussions and resulting guidance from each meeting on our intranet. Our employees can ask MBAP members for advice and are able to report concerns on bioethical issues through channels such as our SpeakUp Line or by reaching out to the Bioethics Office.

Our dedicated guidance panels for genome editing and stem cell matters operate under the overarching MBAP. Using our internal guidelines as a basis, they make recommendations on issues relating to specific topics and are informed by the operational teams about the progress made with respect to implementation. Our Stem Cell Research Oversight Committee (SCROC) performs tasks such as verifying all internal research proposals that employ **human stem cells** and ensuring compliance with our ethical guidelines and any legal requirements. This also includes collaboration with external partners.

Our Digital Ethics Advisory Panel (DEAP) guides our new digital business models with an initial focus on digital health. The DEAP consists of world-leading experts in digital health business models as well as experts in ethics and medicine. It plays a pivotal role in ensuring that we develop new digital technologies responsibly and address potential digital ethics issues arising from the usage of digital technologies and data-driven business models at an early stage.

Our commitment: Identifying topics and issues early on

As a global company, it is crucial for us to promptly identify and address new developments concerning bioethical topics and issues in order to define our own stance. Although we align all our business activities with international and national legislation, many bioethical discussions raise questions that far exceed the current scope of legislators, which is why we also seek the advice of external experts.

The birth of the first babies from genome-edited embryos in China significantly challenged the field of bioethics in 2019. This breach of law, ethics and academic self-regulation led to marked global criticism. Subsequent discussions emphasized the need for profound **bioethical debate** and meaningful governance of genome-editing research in the human germline. Statements and positions were issued by the National Academy of Sciences, the Royal Society and the German Ethics Council. This led to the creation of the World Health Organization (WHO) expert advisory committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Regulation in this research field is expected to emerge in the following years.

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

The Genome Editing Principle is complemented by additional principles 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 aligned with highest ethical standards. Our principles for disseminating information regarding the **off-label use of our products** are set out in corresponding policies that apply Group-wide.

Topics currently being addressed by our Bioethics Advisory Panel

The Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP) convened in October 2020 to discuss important topics such as the use of genome editing tools in agriculture. We sought the MBAP's input in light of the heterogeneity of regulatory frameworks across regions along with calls to reform from the scientific community and the ongoing public controversy around genetically modified foods. The panel also addressed the sourcing of human biosamples: The need in pre-clinical development for this material is growing and requires a framework on donor consent as well as an understanding of ethical implications of its usage. Further topics of discussion included the off-label use of products and how we can provide appropriate information and obtain authorization for the treatment of children in large-scale public health programs such as our Praziquantel Donation Program (informed consent).

Our Bioethics Advisory Panel (MBAP) members

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

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

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

Prof.
Jeremy Sugarman
Bioethics, Medicine
Johns Hopkins University

Prof.
Nikolaus Knoepffler
Philosophy, Theology, Ethics
University Jena

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

Prof.
Daniel Fu-Chang Tsai
Bioethics, Medicine
National Taiwan University

Digital Ethics Advisory Panel

Our ethics horizon extends beyond bioethical questions. We also strive to be the "digital ethics company", adhering to rigorous ethical standards in critical areas such as health data handling. In 2019, we therefore created the Digital Ethics Advisory Panel (DEAP) to deal with all **ethical questions resulting from our Digital (Health) Businesses**, especially from the joint venture Syntropy with Palantir. It held four sessions in 2020. Together with the DEAP and additional academic partners, we currently develop a Code of Digital Ethics (CoDE). The CoDE is to serve as a guideline for our digital business models, a tool for analyzing ethical challenges, and a basis for practical DEAP guidance.

Biotechnology and genetic engineering

Across our Group, we manufacture our biotech products in accordance with the highest standards. All related activities are subject to strict statutory regulations worldwide. 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 we adhere to 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. Statutes in different countries allow for a varying degree of latitude in applying this technique. Bioethical views on germline editing have been evolving for years in academic and societal discussions. Our statement on human germline editing is as follows:

> "Merck KGaA, Darmstadt, Germany 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 of 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. We do, however, use human embryonic stem cells in our research and offer our customers several selected stem cell lines. Thus, our Stem Cell Principle ensures compliance with our ethical approach. All projects are reviewed and approved by the SCROC before any stem cells are used for research purposes. We only use cell lines approved by the United States National Institute of Health (NIH) and allowed under the German Embryo Protection Act and the German Stem Cell Law. The SCROC did not hold any meetings in 2020 as no pressing matters had to be discussed.

Fertility research

We develop treatments for infertility and seek to improve the success rate of in vitro fertilization. As a result, we are frequently confronted with various related **bioethical issues**. Our legislative point of reference for these issues is the German Embryo Protection Act, and we are guided by our Fertility Principle, which was developed based on input from the MBAP.

Biosampling and biobanking

Biological samples obtained from patients within clinical studies are indispensable to the development of new precision treatments and advanced diagnostic methods. We handle these samples in a responsible and ethical manner, in compliance with all regulatory requirements and according to the consent given by patients for the use of their samples. This may include the permission to use biospecimens for **further medical research** beyond the clinical study through an optional consent. Since 2017, we have had a policy and standard operating procedures in place that define our principles and processes for human biosample management during and after clinical studies.

clinical studies

Part of the non-financial report

Our company discovers and develops medicines that help people with serious diseases. Before obtaining regulatory approval, we conduct clinical studies with patients and, if necessary, also with healthy volunteers to investigate the safety and efficacy of these products. Before they begin, extensive preclinical testing must be performed to demonstrate that the drug poses no unacceptable risks. This typically includes procedures such as animal studies.

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 number of participants required to answer each of the 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.

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

How we govern clinical studies

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

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 (DSC) is responsible for the studies performed by the company on medicines that are under clinical development, while the Global Medical Decision Board (GMDB) 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 according to the latest standards and best practices.

Before administering a new drug to human subjects, 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 the course of 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 SOPs 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 procedures are regularly inspected by the relevant regulatory authorities to verify compliance with the applicable laws and guidelines. The Covid-19 pandemic had only a minimal impact on inspections by the regulatory authorities. They continued to carry out their inspections, yet virtually.

Our Research & Development Quality unit identifies areas for auditing based on a quality risk assessment approach. We perform **quality assurance audits** internally within Healthcare R&D as well as externally among our partners (for example, at vendors' sites and investigational sites). We respond immediately to any issues found during audits by defining and implementing corrective and preventive actions to improve processes and promote compliance. Due to the Covid-19 pandemic, we paused business travel and postponed various on-site audits to 2021. We also developed virtual auditing concepts and suitable alternatives for the postponed audits.

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 study follows precisely defined procedures to ensure that it is conducted to the **highest quality standards** in line with good working practices for the development and manufacture of drugs (GxP), the ethical principles of the Declaration of Helsinki and other international guidelines and regulations. In 2020 there were no significant issues which had any impact on patient rights, patient safety or data integrity of a study raised by third parties or regulatory agencies.

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 pharmaceuticals. Potential adverse effects and risks are taken into consideration in an effort 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** in order 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.

Under our leadership and in collaboration with a consortium of partners, the Pediatric Praziquantel Program has conducted clinical trials with vulnerable populations in low- and middle-income countries. Our aim is to develop, register and provide access to a **pediatric formulation** of praziquantel for treating schistosomiasis in children younger than six years of age. The program is currently in Phase III of clinical development.

We collectively designed the clinical program in line with the recommendations of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for pediatric development. Planning and implementation were undertaken in close cooperation with regulatory authorities and a panel of international experts, including clinicians from endemic countries. Further details can be found in the Health for all chapter.

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 20 pharmaceutical companies, we seek to drive the **efficient, effective and high-quality delivery of new medicines.** In this context, we are currently leading an initiative to modernize clinical trials with innovative solutions such as telemedicine, direct to patient medication, home health nursing services and others.

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 experience 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. Our Global Clinical Operations (GCO) unit values and leverages such information in multiple ways, with a clear focus on prioritizing patient centricity in everything we do.

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 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 Lay Patient Summaries, which explain the 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.

Our standard on clinical trial data transparency underscores our strong commitment in this matter.

Enabling early access to new medicines

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

Joining forces to combat the pandemic

The Covid-19 pandemic presented a major challenge for healthcare systems and clinical research in 2020. Researchers from academia, industry and supranational organizations initiated numerous research projects in an effort to find effective and safe therapies to treat Covid-19, the disease caused by the SARS-CoV-2 virus. We supported these initiatives by donating up to 300,000 units of Rebif® (interferon beta-1a) for use in Covid-19 clinical studies. This helped to enable the implementation of **three major clinical trials** with thousands of patients worldwide: the Solidarity trial performed by the World Health Organization (WHO), the Discovery trial undertaken by the French research institution INSERM, and the ACTT 3 trial initiated by the Unites States National Institute of Allergic and Infectious Diseases (NIAID). In addition, we are supporting several Covid-19-related studies performed by independent researchers. We have established a dedicated task force within our Healthcare R&D function to oversee the collaboration with independent external institutions and investigators studying Rebif® as a potential Covid-19 treatment.

We have also initiated our own Phase II randomized, controlled clinical study to evaluate the efficacy and safety of our investigational product M5049 in patients suffering from Covid-19 pneumonia. M5049 blocks the activation of two innate immune sensors that detect single-stranded RNA from viruses such as SARS-CoV-2. The activation leads to immune cell activation and inflammation, which when not properly controlled, can cause severe immunopathology. The aim of the study is to determine whether M5049 can reduce the life-threatening complications of Covid-19, including severe respiratory symptoms that often necessitate further medical interventions such as mechanical ventilation.

Managing the crisis

Soon after the news about the Covid-19 pandemic had been published around the world, it became apparent that the situation could have a major impact on our clinical research activities. First and foremost, our focus has been on the safety and well-being of the patients participating in our clinical studies and the continuity of their treatment and care.

A task force was established within Healthcare R&D in March 2020 to continuously monitor the impact of the Covid-19 pandemic on our ongoing and planned clinical studies, to guide the investigators, monitor clinical trial participants' well-being, and safeguard the integrity of our clinical studies during the pandemic.

animal welfare

In our Healthcare and Performance Materials business sectors, we conduct animal studies as part of the official drug development process and, as required by law, for chemical safety and biological quality control. Animal testing enables us to verify the safety of our medicinal and chemical products and the efficacy of our pharmaceuticals. Our Life Science business sector uses animals to, for instance, generate substances essential for in vitro methods or to generate antibodies for diagnostics.

Our approach to animal welfare

As part of our internal due diligence, all work by our company involving the use of animals was subjected to a stringent internal audit conducted from the end of 2019 to the beginning of 2020. In 2020, we adopted a new animal welfare strategy in response to the audit and the improvement potential it had identified. The new strategy aligns with our high ethical standards. It enables our company to meet the **most rigorous** animal welfare standards and to adopt a consistent and transparent Group-wide approach. We already started implementing the organizational changes and the new processes in 2020 and expect to complete this work by the end of 2021.

Our long-term ambition to replace all our animal use with non-animal alternatives is firmly embedded in the strategy. Until then, 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. These standards also apply to the quality of all animal work as well as related activities, such as data assessment. 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 always use as few animals as possible and replace their use whenever feasible with alternative methods. We continuously improve our animal testing processes, striving to enhance the animals' quality of life.

We subscribe to the internationally recognized **3Rs for animal-based research and have now added Responsibility as our fourth animal welfare principle**:

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

With our internal 4Rs Award, we recognize best practice and further strengthen our commitment to apply and actively **promote the 4Rs** in our animal work. The 2020 winners were recognized for their project "Organ-on-a-chip", which stands to deliver improved, predictable and translational cell culture models for the liver and intestine and their application in the drug development process. Furthermore, we plan to hold an internal virtual 4Rs Day in early 2021.

In addition, we advocate for the global acceptance of replacement methods. To this end, we join forces with industry and academia, communicate with authorities and the public. Our aim is to launch products and processes to replace, reduce or refine the use of animals in our work.

How we ensure animal welfare

Based on our new corporate Animal Welfare strategy, which has been endorsed by the Executive Board and all Group entities, we are introducing fundamental organizational changes in line with our corporate sustainability strategy.

In 2020, we reformed our existing Animal Science and Welfare governance and set up a new Animal Affairs unit with clear roles and responsibilities. The unit will deliver a comprehensive corporate **framework of rules** and implement organizational changes and processes to enable the businesses to conduct animal testing in line with our requirements.

Within the new Animal Affairs unit, we reorganized our Animal Science and Welfare governance and sectoral compliance under four thematic pillars:

- Animal Welfare and Veterinary Care
- Vivarium Oversight
- Animal Using Vendor and Supplier Qualification
- The Group-wide 4Rs program

Our **Group Animal Welfare Council**, chaired by the Vice Chair of the Executive Board and Deputy CEO of Merck KGaA, Darmstadt, Germany, is comprised of representatives from all our business sectors and meets at least twice annually. The council steers the Animal Affairs unit and acts as a decision-making and escalation body as needed.

Currently, all work involving the use of animals by our company is overseen by designated regional bodies or committees. As part of our organizational changes, independent, cross-sectoral and multidisciplinary **Animal Usage Review Boards** will be implemented Group-wide in 2021. These boards will be responsible for approving all work involving the use of animals conducted by or on behalf of our company.

If employees identify an issue regarding animal welfare, they can report it directly to the **Animal Affairs** unit, to local Animal Welfare officers or via our SpeakUp Line.

Comprehensive employee training

Along with the establishment of the new Animal Affairs unit, we launched our Animal Affairs Academy in 2020. The Animal Affairs Academy will ensure regular, comprehensive, high-quality, and up-to-date staff training on practical work and governance documents.

Our employees also regularly participate in external **continuing education** programs, such as accredited laboratory animal science courses offered by the Federation of European Laboratory Animal Science Associations (FELASA), the American Association for Laboratory Animal Science (AALAS), the Society of Laboratory Animal Science, the Laboratory Animal Science Association (LASA) and the Interessengemeinschaft Tierpfleger (Community of Animal Technicians).

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). The goal is to create efficiencies and learn from one another regarding the improvement of animal welfare. Activities include joint auditing processes, knowledge exchange and shared responsibility when phasing out animal use and fostering the approval of alternative methods.

As part of our collaboration with Interpharma, a federation of research-based pharmaceutical companies in Switzerland, we also worked with other member companies to develop a **cross-company audit concept for suppliers of animal studies and animal breeders**. The results are shared among Interpharma member companies and treated confidentially. Based on the audit results, it is up to the discretion of each company whether or not to collaborate with the respective suppliers.

Our commitment: Group-wide standards

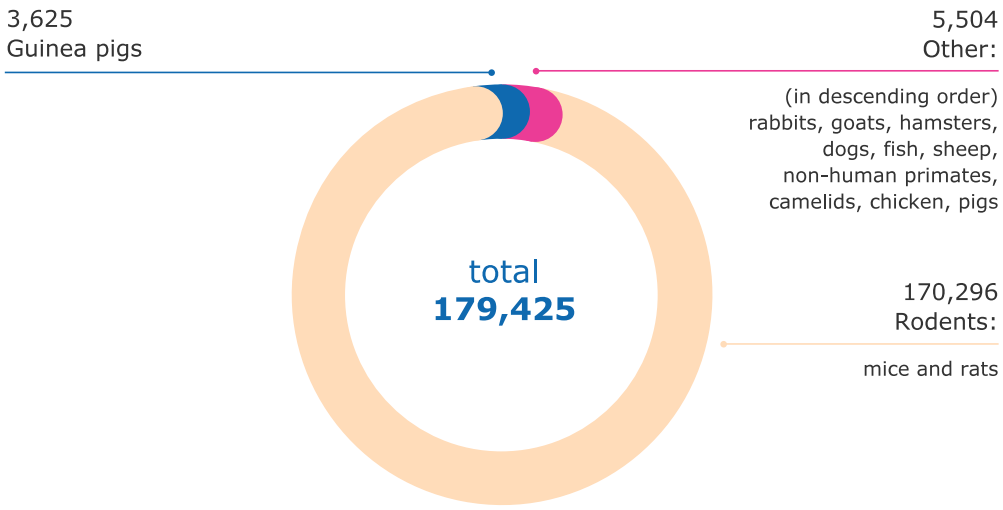
Beyond compliance with all applicable laws and regulations, we are committed to following our own internal guidelines. In 2020, as part of our strategic realignment, we adopted a new **Animal Affairs Policy** and rewrote our Group animal welfare standards and procedures for animal testing conducted internally and by trusted third parties. These guidelines corroborate a comprehensive and stringent governance framework based on our four pillars of animal use governance.

Our new standards and procedures entail, for example, the definition of housing and husbandry standards that also apply to external partners. The Animal Using Vendor Management standard describes the requirements from planning to the approval of vendors and suppliers by Animal Affairs. The standard entitled "Audit Management of Animal Affairs and of Animal Using Vendors" defines how we evaluate the quality of animal welfare practices employed in our own vivariums and by our suppliers and partners. Further documents, including guidance for our 4Rs efforts and our risk management, augment the Animal Affairs governance framework.

Number of laboratory animals used for medical study purposes

In 2020, a total of 179,425 animals were used within the scope of our business activities, either in our own vivariums or on the premises of organizations contracted on our behalf. This represents an overall decrease of 5.9% compared with 2019. Rodents (mice or rats) comprised 95% of all animals used in 2020, compared with 96% in 2019. 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 (89%) of animal studies ourselves and procure the required animals from specialized breeders. We also hire CROs 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.

Covid-19 and animal welfare

In 2020, it was our policy to restrict travel on a Group-wide scale as part of our Covid-19-related measures to protect our employees. Therefore, only limited audits could be performed in the reporting year. With the help of partners, we were able to perform a total of 11 on-site audits of CRO facilities. Additionally, we set up five **remote audits** by carrying out virtual facility tours either with photos or with pre-casted videos. In the future, the Animal Using Vendor governance team will perform regular audits every three years to assess all animal testing vendors.

Employee safety and animal well-being remained our highest priorities throughout the pandemic. Employees of all vivariums worked alternate shifts, for example, to reduce the number of contacts and to protect our teams. We began new studies only if they were indispensable for the business, for example to ensure the ongoing supply of medicines for patients.