

Business ethics

Within this chapter:

- 26** Corporate Governance
- 26** Governance
- 27** Compliance
- 32** Responsible marketing
- 34** Interactions with health systems
- 36** Suppliers
- 36** Supply chain standards
- 39** Mica supply chain
- 41** Human rights
- 43** Bioethics
- 48** Clinical studies
- 53** Animal welfare

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 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 in both our Corporate Responsibility strategy (**CR strategy**) and our Group-wide guidelines. These guidelines comprise **charters and principles** 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** on Business and Human Rights. Our Group-wide **Social and Labor Standards Policy** reflects the labor standards of the International Labour Organisation (ILO). Our **EHS-Policy** (Corporate Environment, 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**.

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. These standards 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 as well as define goals, actions and responsibilities. These systems are based on standards such as the internationally

recognized quality management standard ISO 9001, good working practices (GxP) in the pharmaceutical industry, and ISO 14001 for environmental management. Our company regularly undergoes **ISO 14001** and **ISO 9001** certification, which is conducted by an independent auditing firm. We hold group certificates for both standards.

We support the following responsible governance initiatives:

- We have been a member of 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, health, and safety.
- As a member of the **Together for Sustainability (TFS)** network, we are dedicated to improving the supply chain with respect to environmental, compliance and social standards.
- We are also a member of **Initiative Chemie³**, a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE). The partners 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

Part of the non-financial report

First and foremost, responsible entrepreneurship means acting in accordance with the law, a practice commonly known as compliance. All our activities must adhere to laws, regulations and international ethical standards around the world. Compliance violations would not only result in possible legal prosecution but could also seriously compromise our reputation as an employer and as a business partner.

Our approach to compliance

Compliance is one of our primary considerations worldwide. As an international company with operations in low- and middle-income countries, we have very stringent requirements for effective compliance management. In our view, however, compliance means much more than simply adhering to regulatory provisions. We aspire to always act in accordance with the principles set forth in 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 manages the core topics of anti-corruption, healthcare compliance, antitrust, anti-money laundering, third-party due diligence, data privacy, transparency reporting, and dawn raid preparedness. To cover these core compliance topics, we have **Group-wide policies**, procedures and processes in place that ensure our business activities align with the relevant laws, regulations and international ethical standards. Other compliance related issues, including respective internal regulations and guidelines (such as **Pharmacovigilance**, **Export and Import Controls**, and **Environment, Health, Safety, Security, Quality**), are managed by the responsible functions.

Supported by our Group Compliance function, our Group Compliance Officer is responsible for our compliance program, which consists of the following elements:

- Risk Assessment
- Policies & Procedures
- Compliance Committee
- Training & Awareness
- Programs & Tools
- Monitoring & Reporting
- Case Management
- Continuous Improvement
- Whistleblowing hotline (our SpeakUp Line for anonymous and non-anonymous reporting of potential breaches of rules and regulations).

Our compliance program is regularly updated to reflect new requirements, such as those resulting from amendments to legislation, relevant industry codes or changes within our company.

Our Group Compliance Officer reports to the Executive Board every six months on the status of our compliance activities, possible risks and serious compliance violations. In turn, the Executive Board updates our supervisory bodies at least twice a year on key compliance issues. As part of regular reporting processes, we annually compile a comprehensive **compliance and data privacy report** for the Executive Board detailing the status of our compliance program, updates that have been made, compliance and data privacy cases and training figures. Additionally, we prepare an update at the mid-year mark to highlight current developments and the status of relevant projects and initiatives.

Our Group Compliance Officer oversees approximately 85 Compliance Officers around the world, who implement our compliance program within their respective areas of responsibility. These Compliance Officers receive guidance from our Group Compliance Programs and Support team, a centralized body that drives the design and update of our compliance program across all business sectors and Group functions and is responsible for initiating necessary measures.

Our global Transparency Operations team is responsible for incorporating current and upcoming transparency **reporting requirements in the health sector** – such as those of the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) and the United States Physician Payments Sunshine Act.

Various Compliance Ambassador programs exist in all our regions to take the different needs and cultures throughout our Group into account. In general, the main objective of the Compliance Ambassador programs is to spread the culture of compliance across the local organizations. The ambassadors act as the primary points of contact for their own teams in compliance aspects. They are not compliance representatives and do not replace the work of the Compliance Officers. The Compliance Ambassadors aim to influence the behavior of their colleagues on a daily and permanent -basis, using different compliance-related activities specifically designed for their teams. From the Compliance Offices across the world we encourage and support the development of these programs as they are an excellent way to increase accountability and ownership of **business ethics** across our businesses and functions.

Clear chain of command for reporting violations

Reports of potential compliance violations that we receive via our SpeakUp Line are reviewed by the Compliance Investigations and Case Management team and appropriate investigative steps are initiated. Exposed cases with a certain risk profile are additionally presented to the Compliance Case Committee, which consists of 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 through appropriate measures. If, during the investigation, a root cause is identified that could lead to further **compliance violations**, it is continuously monitored and preventive or corrective actions are taken. An associated sub-committee advises on disciplinary action, if necessary.

Conflicts of interest

We take all potential conflicts of interest seriously. Employees must strictly avoid situations where their professional judgment may come into conflict with their personal interests. Also, they must disclose every potential conflict of interest to their manager and document the disclosure. Such issues are usually resolved directly between the employee and his or her manager, but can also be routed to Human Resources or other relevant functions. Furthermore, we have implemented a specific governance process that includes the Executive Board and ensures that shareholders and related parties are regularly provided with **information on potential conflicts**.

Beyond this, our processes for handling conflicts of interest are detailed in our [Annual Report](#).

Data Privacy integrated into Group Compliance

Our Data Privacy unit is part of our Group Compliance organization. As required by law, this unit acts independently and submits **frequent data privacy updates** in addition to compiling a regular comprehensive data privacy report as a part of the compliance report. Besides a central Group Data Privacy Officer, we also have local Data Privacy Officers at various sites around the world.

Integration of Versum Materials and Intermolecular

Both Versum Materials and Intermolecular have robust compliance programs in place. We will be implementing our compliance program and the corresponding processes step-by-step until December 2020.

Our commitment: guidelines and standards

Our compliance program builds on our company values and integrates these into our compliance framework, which contains Group-wide guidelines for entrepreneurial conduct that are mandatory for all our employees:

- Our **Code of Conduct** guides our people in conducting business ethically – in accordance with our values and the law. It is available to all employees worldwide in 22 languages, both electronically and as a print brochure.
- Our **Human Rights Charter** supplements our Code of Conduct with globally recognized principles regarding human rights.
- Our **Anti-Corruption Policy** stipulates that all business activities must be conducted in accordance with legally applicable anti-corruption standards. All forms of bribery – whether giving or receiving – are strictly prohibited.
- Our **Pharma Code** for prescription medicines as well as underlying policies and additional guideline documents set out key principles for interactions with our partners in the health industry.
- Our Group-wide **Antitrust and Competition Law Policy** sets forth that all business activities across the Group are to be conducted in compliance with applicable competition regulations at all times. We acknowledge the importance of fair competition and expect the same of contract organizations 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 global **Money Laundering Prevention Policy** defines and describes the internal global processes and assurance measures in place to protect our company from being misused by third parties for money laundering purposes.

We use an **online confirmation process** to send Group-wide policies to relevant managers and employees, including Group Legal and Compliance colleagues. Recipients confirm receipt of the policies and commit to adherence and appropriate implementation at the relevant sites.

Rules for the provision of healthcare items

Our company occasionally provides healthcare professionals with items of medical utility or **informational and educational materials**. We require the provision of such items to be for legitimate and lawful purposes, in accordance with our Code of Conduct as well as applicable policies, laws and codes. The rules on such provisions are laid out in our Healthcare Items Policy, which was updated in 2019 to include EMD Serono, Allergopharma and the Foundation sponsored by Merck KGaA, Darmstadt, Germany within its scope.

Requirements we place on 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 Business Partner Risk Management** process governs interactions with sales partners, such as sales agents, distributors, dealers and wholesalers. We expect all our business partners worldwide to comply with our compliance principles. We only collaborate with partners who pledge to comply with all applicable laws, reject all forms of bribery and adhere to environmental, health and safety guidelines. Furthermore, we contractually require our business partners to demonstrate a commitment to internationally recognized **human rights and labor standards** as well as to our own compliance requirements. We also monitor adherence to these standards for existing business relationships with a certain risk-level via our established global Business Partner Risk Management process – typically every three years or ad hoc when new risks are identified.

Requirements of our business partners

We employ a global approach for responding to Code of Conduct acknowledgment requests from our business partners. The framework guiding this practice is laid out in our internal Corporate Responsibility Letter, which was reviewed and updated in 2019.

Harmonizing data privacy Group-wide

Our Policy for Data Protection and Personal Data Privacy defines our standards for processing, saving, using and transmitting data. This approach allows us to achieve a **high level of protection** for the data belonging to 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, which also entails the EU General Data Protection Regulation (EU GDPR). We also consider local data privacy requirements, as not all requirements at all sites are covered by EU standards.

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 Code of Conduct 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 2019, we assessed 50 operations for corruption-related risks.

As of 2020, Versum Materials will be part of the annual audit plan of Group Internal Auditing. In January, a “post day 1 audit” was performed. Further audits, such as of Versum Materials Korea or Delivery Systems and Services, are also part of the **2020 Internal Audit Plan** as approved by our Executive Board.

Compliance training

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

In June 2019, we completed the full global roll-out of our **business sector-specific Code of Conduct e-learning program** by publishing it in 20 new languages in addition to German and English, which were already launched in 2018. The training complements our Code of Conduct brochure “What guides us,” by providing practical guidance on how to act ethically in the workplace. In 2019, 50,461 employees and contractors had been trained as part of the program, which we conduct regularly for all new employees and contractors.

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. One example is the e-learning course on our Anti-Corruption Policy, which is available in 15 languages. In total, 35,425 employees and contractors have completed this training since the introduction of the program, which is also being updated for the 2020 training cycle.

In response to the European General Data Protection Regulation (EU GDPR), we redesigned our regular Data Privacy e-learning course, rolling it out in 17 languages in late 2018. In the meantime, a total of 47,650 employees and contractors have completed this course. Additionally, Compliance Officers complement the execution of our Group-wide training plan by conducting mandatory local and business-specific e-learning courses.

SpeakUp Line for potential compliance violations

We encourage all Group employees to report potential compliance violations to their superiors, 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. Based on recommendations from the Compliance Investigation Team or the Compliance Case Committee, disciplinary actions may also be taken against employees who have committed a compliance violation, where necessary. These actions may range from a simple warning to dismissal, depending on the severity of the violation. In May 2019, the SpeakUp Line was also made 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, and information on transparency and data privacy for external audiences.

To continuously strengthen employees' awareness of the SpeakUp Line, we rolled out a **global SpeakUp Line communication campaign** in May 2019, using digital and internal print channels.

Both the number of reports of suspected compliance violations and the number of actual compliance cases was stable compared with the previous year. In 2019, we received 75 compliance-related reports via the SpeakUp Line and other channels that **led to investigations**. In 2019, there were 30 confirmed cases of violations of the Code of Conduct or other internal and external rules.

Risk analysis: Compliance Risk Reporting and Self-Monitoring

In 2019, the Compliance Programs and Support team launched a **redesigned compliance risk management process**. We adapted the process for risk evaluation and added a new self-monitoring component. The risk management process for compliance-related topics consists of two major core elements: Compliance Risk Reporting and Self-Monitoring.

Compliance Risk Reporting:

Compliance Risk Reporting is the process where compliance risks are evaluated. The Compliance Officer of the respective legal entity or department evaluates designated risks based on the business sector. The risk evaluation is conducted by determining a monetary impact and the extent to which the risk is likely to occur. In line with the best practice for risk evaluation, the Compliance Officers assess the **inherent risk followed by the residual risk**.

Self-Monitoring:

The new 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 business head of a department in scope is provided with specific risk-mitigating statements that must be attested to on an agreement scale.

Once the process is completed, the collected data will be further analyzed and specific risk and control reports will be generated. Based on the results, follow-up activities will be initiated to further enhance our Compliance Management System.

Management of business partners

We apply a risk-based approach to selecting business partners for sales activities. The greater we estimate the risk to be regarding a certain country, region or type of service, the more in-depth we examine the company before entering into a business relationship. For these risk assessments, we use the **Corruption Perceptions Index (CPI)** maintained by Transparency International and assess potential partners based on other parameters such as the nature of the intended business and sales volume. We also explore background information from various databases and information reported by the business partners themselves, for instance, on their own compliance programs.

If we encounter compliance violations, we decide whether to reject the potential business partner, terminate the existing relationship or impose conditions to mitigate identified risks. However, our partners are generally willing to adapt their structures and processes in line with our strict compliance requirements. Since launching this process in 2013, we have assessed more than 3,700 business partners. In 2019, we used this process to assess more than 300 business partners.

Ensuring data privacy and information security

We operate a data privacy management system as part of our Group Compliance function. This system is harmonized across the whole Group. Furthermore, it is necessary to protect our information systems, their contents and our communication channels against criminal activities of any kind, like e-crime and cyberattacks, including unauthorized access, information leakage and misuse of data or systems. Our Group Security and IT Security units implement organizational, process-related and technical information security countermeasures based on recognized international standards. We **harmonized our electronic and physical security measures** (e.g. access control) to bolster our ability to handle sensitive data such as trade secrets. Aside from active security monitoring, our Group Internal Auditing verifies that we are implementing and complying with our data privacy policy and data security programs.

Our data privacy management system applies the **PDCA principle** (plan, do, check, act) to ensure that data privacy policies and tools (plan), data privacy training (do), inspections and assessments (check) and incident and issue management processes (act) are all in place.

To support local Data Privacy Officers at our sites, we have introduced **standardized data privacy consulting services** that can be requested by data controllers and processors as needed. We also implemented a central IT tool to provide a single source for data privacy processes like answering data privacy questions, registering data processing activities and reporting potential data privacy incidents. We had zero sanctioned complaints or incidents

concerning breaches of customer privacy leaks, thefts or losses of customer data in 2019. In one case, a minor personal data breach was reported to the supervisory authority which was not sanctioned.

EFPIA Transparency Initiative

Members of the Transparency Initiative of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are required to publish all contributions to medical professionals and organizations in the health sector, along with the names and addresses of individual recipients. Beyond this initiative, several countries have introduced legislation to further increase transparency in the pharmaceutical industry. We comply with these requirements and additional standards governing interactions with health systems and include them in our transparency reporting.

Alliance for Integrity

We are a member of the Alliance for Integrity Steering Committee. 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 a corruption-free business world in low- and middle-income countries. Its activities focus on Latin American countries, Ghana and Asian countries, in particular India and Indonesia. The Steering

Committee leads the decision-making process for developing measures in the countries, while local advisory groups oversee implementation at country level. Our company has chaired the advisory group of Ghana since 2018. 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 2019, we engaged stakeholders in dialogue primarily through our memberships in various associations. Among other organizations, we are members of the German Chemical Industry Association e. V. (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 e. V. (BME), and the International Association of Privacy Professionals (IAPP).

Responsible Marketing

Part of the non-financial report

We mainly focus our pharmaceutical business on prescription medicines. The well-being of patients is always our primary consideration when marketing such products. This is why pharmaceutical marketing is regulated by both statutory requirements worldwide as well as a variety of internal guidelines that shape our business conduct.

Our approach to responsible marketing

We strictly adhere to all regulations concerning pharmaceutical marketing. In most markets, manufacturers are only permitted to advertise prescription drugs to medical professionals such as physicians and pharmacists. These advertisements must always disclose the active ingredients, adverse effects and contraindications of the drug. Our internal guidelines governing marketing and advertising are part of our Group-wide compliance program, which requires us to always conduct business in compliance with the law and **in line with the highest ethical standards**. This is complemented by our internal guidelines and various voluntary commitments that, in many cases, exceed the applicable statutory regulations. We regularly review all our internal guidelines and revise them as required in response to any new developments.

How we conduct ethical marketing

Our Group Compliance unit is responsible for setting up internal overarching compliance policies to help ensure that our business activities adhere to the statutory regulations applicable to our sales and marketing activities. This unit is supported by other functions that provide topic-specific expertise, offer detailed guidance and report on the processes in their units that are relevant to compliance. For instance, our Global Regulatory Affairs unit has established a dedicated policy and corresponding process document on the review and approval of our promotional materials. The necessary training and communications are carried out by the units responsible for each of the respective policies. 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. Our Group Internal Auditing unit regularly conducts **risk-based reviews** of these activities.

Details on how we help ensure compliance with statutory regulations worldwide can be found under [Compliance](#).

Our commitment: Code of Conduct and industry-wide regulations

Our Group-wide Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations defines the relevant standards for our ethical marketing practices. It also governs our interactions with physicians, medical institutions and patient advocacy groups.

Between 2017 and 2019, we revised our Biopharma compliance policies to ensure we provide the required up-to-date compliance guidance to the business. We also extended the scope of this policy to our Healthcare business in the United States (operating under the name of EMD

Serono), to Allergopharma and to the Foundation sponsored by Merck KGaA, Darmstadt, Germany. This will help enable them to effectively adhere to our compliance principles and guidance around the world while maintaining the necessary flexibility to implement **specific local policies or procedures** that additionally comply with local regulations.

Through our Principles of Review and Approval of Promotional Materials and Other External Communications, we help ensure that all promotional materials conform to our rigorous standards. All employees involved in creating promotional materials have received training on updates made to the principles and the associated standard processes.

In addition to local laws and our own 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](#)). This code was revised in May 2018 and became effective on January 1, 2019. Similarly, the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) updated its [Code of Practice](#) in 2019. We simultaneously revised our internal Items Provided to Healthcare Professionals policy to harmonize our internal guidance with [IFPMA Code of Practice](#) requirements. We are also a member of the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), which has defined its own code of conduct regarding collaboration between physicians and the pharmaceutical industry.

Reviewing marketing material Group-wide

Our aim is to review all promotional material end-to-end to ensure that it meets our standards as well as local regulations, which is why we apply a harmonized **Group-wide review and approval system**. Approximately 2,200 Healthcare employees use a centralized platform that allows us to streamline the review and approval process while also providing a better overview of global marketing data. This also helps us identify opportunities for improvement.

Addressing violations of standards and regulations

We have a number of channels for reporting wrongful marketing practices to the industry associations in which we are members. For instance, when members of the FSA or third parties suspect a violation of the FSA Code, they can file complaints directly with the respective Arbitration Board. In 2019, no significant complaints of this kind were sustained against our company worldwide.

In May 2019 we made our [SpeakUp Line](#) for anonymously reporting potential compliance violations available to

external stakeholders. If our marketing or advertising rules of conduct are breached, we have a committee in place to take immediate countermeasures. In 2019, we had no significant cases of non-compliance regarding regulations and voluntary codes.

Regular employee training

Employees who are responsible for our pharmaceutical advertising receive regular training on current guidelines. This particularly applies to individuals working in sales, marketing and drug registration. Such seminars are either conducted locally in a classroom setting or as e-learning courses.

We ask new company employees to participate in **onboarding training** on the topic of Review and Approval of Promotional Materials and Other External Communications. Additionally, employees in charge of marketing and the promotion of pharmaceutical products can also access our respective compliance guidelines via our intranet.

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,

and we only pursue DTC campaigns in these areas. In these countries, we use DTC advertising to help increase people's awareness of certain diseases and the therapies that are available, thus empowering patients to **make informed decisions** about their own treatment.

Marketing chemicals

We approach the marketing of our chemical products with the deepest sense of responsibility. For instance, we only supply our chemicals to commercial customers with proven expertise and provide them with detailed information on the safe handling and use of our products. We have an extensive safety and security network in place to prevent the **misuse of dual-use products**. This network features standardized export control guidelines for these products, which are monitored by our central Export Control and Customs Regulations unit as well as by trade and export control officers at our local subsidiaries. If we suspect or are informed of misuse, we terminate our business relationship with that customer. When necessary, we work with the responsible authorities to prevent illegal use.

interactions with health systems

Part of the non-financial report

It is essential that research institutes, healthcare professionals, patient advocacy groups and other key players in health systems have access to up-to-date information on diseases and treatments. We help facilitate this access by sponsoring independent initiatives and medical capacity advancement programs. We also support outstanding research projects, for example through our Global Grants for Innovation. Transparency is our top priority in everything we do.

Our approach to interacting with health systems

We support health systems by providing information to professional medical associations, patient advocacy groups, university clinics, and other hospitals, following **specific approval requirements** and procedures and in accordance with applicable laws and codes. In countries that have statutory or industry obligations regarding the disclosure of transfers of value to health systems, we comply with these obligations.

How we ensure transparency and compliance at an organizational level

For all interactions with healthcare stakeholders, Group Compliance establishes internal policies and related **review processes** to ensure adherence to statutory requirements and transparency obligations. Group Compliance also provides the necessary training for all applicable employees and handles the respective communications. The Global Transparency Operations team serves as a center of excellence, providing support for **transparency reporting** and our end-to-end management process for interactions with healthcare professionals, healthcare organizations, patients, caregivers, and patient advocacy groups.

Our Group Internal Auditing function monitors the local implementation of these initiatives. Before entering into a collaboration with a third party that is not a healthcare stakeholder, we also apply a selection process based on a policy and standard operating procedure. This is part of our Business Partner Risk Management compliance program, which is conducted by Group Compliance. More details can be found under [Compliance](#).

Our commitment: Group-wide guidelines and industry standards

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 longstanding 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 being compliant during their interactions with patients, patient opinion leaders and patient organizations.

In 2019, we updated our Items Provided to Healthcare Professionals policy, which guides our employees in providing these key stakeholders with items such as medical or educational materials. We want to help ensure that this is done for legitimate and lawful purposes in accordance with our [Code of Conduct](#) as well as with applicable policies, laws and codes.

Transparent reporting

In 2019, we continued to publish all financial and non-financial contributions that we made to European medical professionals and organizations in the health industry. As required by the [EFPIA Disclosure Code](#), 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 also adhere to all statutory transparency requirements worldwide, such as the Transparency Code of the German Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA). Specific national laws and requirements are implemented by our local units. We consistently adhere to the applicable data privacy legislation and endeavor to ensure the full compliance of our partners.

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.

Collaborating with patient advocacy groups

Patient advocacy groups support patients, family members and caregivers, providing them with information on disease management. We also made it our goal to improve patient quality of life, which is why we support the vitally important work of these organizations. 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](#).

Transparently promoting medical research and education

We sponsor research and medical education around the world so that we can contribute to medical advances that will benefit patients. Through our Global Grants for Innovation, in 2019 we selected two new winners for Grants of Growth Innovation (**GGI**) and three new winners for the Grants of Multiple Sclerosis Innovation (**GMSI**). A total of 104 research proposals have been selected to receive research grants through the Global Grants for Innovation program since 2009.

Through our Global Medical Education and External Relations department, we organize non-promotional Medical Education Programs, either directly or by providing grants to Third Party Medical Education Providers to fund independent medical education programs. This enables the development and delivery of advanced medical training aimed at increasing the scientific knowledge and competence of scientists, physicians, nurses, pharmacists and other healthcare professionals in order to enhance medical practice and **improve patient outcomes**. As with our other partnerships, we take an entirely ethical, transparent and responsible approach aimed at providing fair, balanced and objective content that is designed to allow the expression of diverse theories and recognized opinions.

All direct and indirect financial support aligns with the principles of the **EFPIA Code of Practice**. According to our internal Medical Education Funding Policy and our Programs Policy, all requests for medical education funding are

channeled through an approval process that falls under our R&D and Compliance functions. 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.

In 2019, we continued our partnership with the International Pharmaceutical Alliance for Continuing Medical Education (**iPACME**). This group of 20 professionals from 17 different companies from around the world engages in continuous discussions on improving and harmonizing **quality standards** for continuing medical education. We also contributed to updating the EFPIA Code of Practice issued by the EFPIA Medical Education Working Group.

We continue to support research and education in and for low- and middle-income countries through a series of programs, with a focus on **schistosomiasis and malaria**.

Healthcare-specific Code of Conduct training

In 2019, we worked on a Code of Conduct-related training curriculum on dealing with dilemmas in healthcare-specific situations. We piloted the project in China, where 21 leaders participated in a very comprehensive training course. The aim was to improve their awareness and understanding of Code of Conduct-related dilemmas in healthcare-specific situations, for example when overhearing a conversation that may or may not constitute attempted bribery. This training will be rolled out in other countries in 2020.

suppliers

supply chain standards

Our company procures many raw and packaging materials, technical products, components and services from across 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 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. Our supply chains are diverse and differ in their characteristics. While some supply chains are automated, others, especially in the service sector, are labor-intensive. Our risk-based supplier selection and management approach takes this diversity into account, which helps our sourcing employees to identify required mitigation actions with relevant suppliers and work on improvements.

The approach for our **strategic suppliers**, which account for approximately 43% of our total spend, includes the identification, monitoring and assessment of supply security risks with four main elements:

- **Supplier Risk Assessments:** to capture the overarching risks at supplier legal entity level, including multiple risk domains. In 2019, we enhanced the data scoping and quality, adding NGOs and new financial information providers to our pool of data sources.
- **Alert system:** to notify our Procurement unit when any of our suppliers faces a potential disruption.
- **Material Risk Assessments:** to capture the risks of relevant materials that make up our most significant finished products.
- **Risk Response Tracker:** to create and monitor risk mitigation activities. They will be applied after testing in 2020.

We calculate risk factors for suppliers and raw materials by multiplying risk probability and risk impact. We consider 29 risk titles such as Economic freedom, Social unrest, Unfair business practices, and Poor labor practices.

Additionally, for suppliers that are above a certain spend threshold, we have expanded our risk assessment methodology by integrating further factors such as country, industry and supplier risks as well as the impact on our business. We have also included criteria to identify supplier relationships impacted by **key sustainability risks** such as mineral sourcing or animal welfare.

In 2019, we consolidated the Risk Management approach described above and our sustainability activities into a single supply security program in order to gain a more holistic view of our supply chain. In this way, we aim to further strengthen corporate responsibility (CR) within our standard procurement process.

How we implement corporate responsibility standards in the supply chain

Group Procurement is responsible for integrating corporate responsibility (CR) 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 and regularly updated on our **guidelines and CR requirements** through internal communications and training.

Also in 2019, our training activities (such as our Procurement Training Academy) for Group Procurement employees included sessions on sustainability.

Integration of Versum Materials and Intermolecular

The acquisition of Versum Materials and Intermolecular resulted in a change to our supplier portfolio. The procurement processes described in this report do not yet fully apply to Versum Materials and Intermolecular. We are currently reviewing their existing processes and will align them as needed.

Until the integration is complete, Versum Materials will continue to apply its existing policies and processes. Versum Materials issues a conflict mineral report pursuant to Rule 13p-1 under the Securities Exchange Act of 1934 and has a conflict minerals policy and the respective due diligence processes in place.

We are currently in the middle of developing a company-wide due diligence process for Responsible Minerals Sourcing according to OECD guidance, which will incorporate and further develop measures already implemented in our business sectors. In the second half of 2019, we established a working group with representatives from business sectors and Group functions that also includes a

representative from Versum Materials. At the end of 2019, elements of a conflict minerals management system were drafted and will be further defined in 2020.

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**

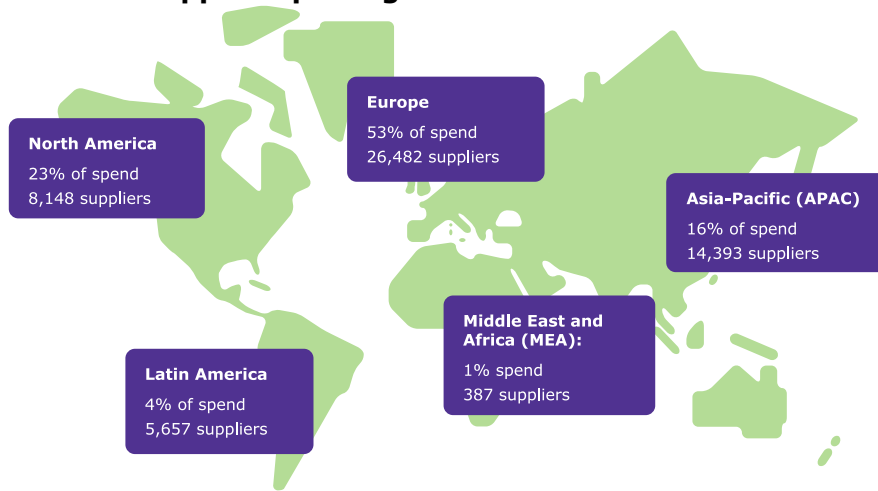
the labor, social and environmental standards defined in our **Responsible Sourcing Principles** and to ensure that their subcontractors do likewise.

All modifications to legal frameworks are incorporated and appropriate measures are initiated where necessary. In 2019, we reviewed our Supplier Management Procedure, which came into effect at the end of 2019. We now take the suppliers' Corporate Responsibility programs into consideration when selecting key vendors and review their Corporate Responsibility progress as part of supplier performance evaluations.

Global procurement

In total, the goods and services we purchased in 2019 from **more than 55,000 suppliers** in almost 150 countries amounted to around € 7.5 billion, versus approximately € 7.4 billion in 2018, representing an increase of 2%. Of these (including R&D services), we purchased 23% from suppliers based in North America, 53% from suppliers based in Europe, 16% from suppliers based in the Asia-Pacific region, 1% from suppliers based in the Middle East and Africa, and 4% from suppliers based in Latin America.

Purchase volume and suppliers per region – 2019^{1,2}



¹⁾ For data processing reasons, 3% of our purchase volume (1,434 suppliers) is currently not assigned to any purchase region.

²⁾ The figures exclude Versum Materials and Intermolecular since the integration process is still underway. For more information, see [report profile](#).

Ambassadors for more sustainable supply chains

In October 2019, the Together for Sustainability (TfS) initiative published The Sustainable Procurement Pledge on the social network LinkedIn. This platform addresses all procurement professionals, academics and students who want to become a sustainability ambassador and drive a responsible procurement agenda through personal engagement. As a member of TfS, many of our Procurement employees have already signed the pledge.

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 CR audits on suppliers.
- Regarding our **mica supply chain**, we engage with a global consultancy to conduct audits and the Indian organization **IGEP** to conduct inspections.

In 2019, we decided to expand the scope of accepted **CR certifications and audits**. We now also accept audits conducted in line with the Pharmaceutical Supply Chain Initiative (**PSCI**) and in line with the Sedex Members Ethical Trade Audit (**SMETA**).

TfS supplier assessments and audits

Under TfS, suppliers are assessed either on information obtained during audits, or on the basis of self-reported and publicly accessible information provided by **EcoVadis**, an independent rating agency. EcoVadis assesses suppliers from 155 countries and 198 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 competition law. Strategically speaking, TfS activities focus heavily on achieving demonstrable improvements in supplier sustainability standards. In 2019, TfS changed its KPI portfolio to measure member activities with a stronger focus on progress and improvement rather than the quantity of assessments and audits.

We conducted several internal webinars and invited suppliers to join a TfS training session in Shanghai (China).

Through the TfS initiative, we have access to more than 1,600 assessments from our suppliers. In 2020, we will intensify our analysis of assessment results and implement comprehensive mitigation activities.

Conducting our own audits

We continuously conduct our own audits in select cases based on business requirements. In 2019, 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.

Local suppliers

We have no internal guidelines stipulating that preference be given to local vendors in allocating contracts and therefore do not collect this type of data. We generally procure our goods and services globally. In some cases, however, local vendors do have an advantage, as products bought locally may be less expensive due to a reduction in additional transport costs. Country-specific regulations such as import duties and licenses also help us decide whether to source our goods locally or globally. In some countries local laws require contracts to be awarded to regional suppliers.

Supplier diversity

In the United States, we have a specific supplier diversity program in place that has grown significantly. Within the Small Business Program, the spend with small businesses grew by 146% in 2019 versus 2018, with growth of 294% in small women-owned companies. We focused our efforts on different internal awareness campaigns, supplier diversity days, training seminars for our sourcing managers, and investment in tools to increase our small and diverse vendor database.

Mica supply chain

Mica is an important raw material of our effect pigments, which are used in automotive and 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 livelihood. We only source the raw material from suppliers acting in formal working environments and monitor compliance with our standards, including our ban on child labor.

Our mica suppliers have been 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

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. Whenever non-compliance with our standards is identified, 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 a ban on child labor. Our Responsible Sourcing Principles also form 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 regular inspections by employees of Merck KGaA, Darmstadt, Germany and third parties used for this purpose, we conduct comprehensive announced audits as well as frequent, unannounced check visits in the region.

Regular audits

Environmental Resources Management (ERM), an international management consulting services company, conducts

regular audits of all 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.

When shortcomings are not rectified, we take further actions up to freezing relations with the respective company or even terminating the business relationship altogether.

Unannounced inspections

Since 2013, the [IGEP Foundation](#), a local non-government organization, has been arranging regular unannounced visits to check the working standards along the supply chain. During these visits, IGEP monitors occupational safety as well as **compliance on child labor**. In 2019, these inspections focused on the upgrade of personal protective equipment and training sessions on proper use.

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. All schools go up to at least sixth grade. In 2019, two schools introduced a seventh grade. Tailoring and carpentry courses are also offered. At a fourth school run by one of our mica suppliers, we provide scholarships for 200 children.

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.

Stronger together: Joint action in the mica supply chain

We are a founding member of the Responsible Mica Initiative (RMI), which was established as a multi-stakeholder group. Our company held the presidency of the organization in 2019. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply chain by **joining forces across industries**. In 2019, we continued to actively support the RMI's work on its three main goals:

- **Responsible workplace standards:** In 2019, RMI held several training sessions on workplace standards for local businesses.
- **Community empowerment:** Building on the first community empowerment program in 2018, which reached 40 villages, in 2019 RMI launched a second program covering a further 40 villages. 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 in drafting future

policies to help ensure sustainable mica mining while eradicating the root causes of child labor.

In 2019, the RMI participated in **multiple local and global stakeholder meetings**, such as the **OECD Forum on Responsible Mineral Supply Chains** in Paris (France). The goal of the event was to assess and facilitate progress on minerals sourcing globally with a special focus on conflict minerals. The RMI also attended the event marking the publication of the National Commission for Protection of Child Rights (NCPCR) study on education and child welfare in the Indian mica mining regions of Bihar and Jharkhand. Also in 2019, RMI signed a **Memorandum of Understanding (MoU)** with the **Responsible Minerals Initiative** to help prevent child labor and improve working conditions in mica industry supply chains globally.

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 2019, a considerable amount of our mica was obtained from Brazil, where we have also established oversight mechanisms to monitor and audit adherence to our CR standards. Furthermore, we manufacture effect pigments based on synthetic substrates as an alternative to pigments based on natural mica.

HUMAN rights

All nations are called upon to uphold and protect human rights and basic freedoms. As an international corporate group, we have a duty to respect human rights worldwide and to ensure that they are not compromised by our business activities. We are constantly working to integrate human rights due diligence into our processes in an effort to minimize the risk of human rights violations and to protect these rights within our sphere of influence. We will not tolerate any business activities or relationships leading to violations of human rights.

Our approach to human rights due diligence

We are committed to upholding and protecting human rights. To this end, we must first understand the **potential human rights impact** of our business activities and relationships, as well as identify the human rights due diligence measures already in place at our sites. This knowledge helps us adapt our Group-wide efforts to local circumstances and to the respective risk profiles. In this way, we can develop support programs, strategies and processes to overcome particular challenges.

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 with other companies to share lessons learned as well as successes in implementing human rights due diligence.

How we promote respect for human rights

Ultimate responsibility for upholding human rights within our organization lies with our Executive Board, which obliges our managing directors of our subsidiaries to meet this responsibility.

Our Group Corporate Responsibility unit is responsible for coordinating all human rights due diligence processes and activities. Progress and measures are regularly discussed at **CR Committee meetings**, while subject matter experts within our Group functions, business sectors and local units are in charge of initiating the necessary actions.

Moreover, we established an interdisciplinary Human Rights Working Group in 2019. Its objective is to develop and conduct **joint, cross-functional actions** that will enable us to meet our responsibility to respect human rights. The group meets three to four times a year. Four meetings were held in 2019.

Our commitment: Guiding principles, charters and laws

Our **Human Rights Charter** aligns with the **UN Guiding Principles** on Business and Human Rights. It underscores our commitment to respecting human rights while also defining the relevant requirements for our company. The charter interlinks and complements all existing rules and regulations pertaining to human rights, including, for example, our **Code of Conduct**, our **Group Environment, Health and Safety Policy**, and our **Charter on Access to Health in Developing Countries**. In 2019, we updated our Human Rights Charter, availing ourselves of **expertise from external stakeholders** such as trade unions, industry associations

and representatives of potentially impacted groups. We also adopted a Group-wide **Social and Labor Standards Policy**, which reflects the labor standards of the International Labour Organization (ILO). Among other topics, the policy covers forced labor, modern slavery, human trafficking, child labor, freedom of association, and collective bargaining rights. In 2019 we also initiated the update of various aspects of our Group-wide Site Security Standard, including human rights.

At the end of 2016, the German federal government adopted a national action plan for implementing the **UN Guiding Principles** on Business and Human Rights. We welcome this plan and are steadily working to implement it across our organization.

In the United Kingdom, the UK Modern Slavery Act requires us to report on the steps we are taking to counter forced labor and human trafficking. In 2019, we issued our third **UK Modern Slavery Statement**, which has been endorsed by our Executive Board and is available on our **website**.

Continually improving our management processes

In order to mitigate human rights risks and prevent their negative impacts, we are working to integrate human rights due diligence even more firmly into our operational processes. With these risks in mind, we are focusing on external manpower, product and service sourcing, and collaboration with contract partners. We are currently creating a **Group-wide overview** of the use of external manpower, above all in high-risk countries such as China, Vietnam and the Philippines. Based on these findings, we intend to execute risk-based measures.

Our **Compliance Risk Reporting & Self-Monitoring process** also covers human rights topics. In 2019, we broadened our risk assessment of human rights and modern slavery. Initial results will be available in 2020.

In 2019, we also began reviewing human rights aspects within the scope of our Site Security Risk Assessments to determine whether site security has any connection to human rights risks, initiating the appropriate actions as necessary.

In addition, in 2019 we opened our **SpeakUp Line** to external stakeholders. Previously it was only accessible to employees. Grievances can now also be reported via our **website**.

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 factors such as environment, health and safety. When it comes to investment projects, we are also bound by our Code of Conduct, which stipulates compliance with the **principles** of the UN Global Compact and therefore also with the core labor standards of the International Labour Organization (**ILO**), such as the prohibition of child and forced labor.

Creating awareness

In 2019, we took further steps to raise awareness of certain human rights risks.

While revising our Human Rights Charter and introducing our Social and Labor Standards Policy in 2019, we

launched an e-learning course targeted to all managing directors and senior leaders reporting to the Executive Board. The course requires them to implement both of these guidelines in their areas of responsibility.

As in the previous year, the EHS StartUp! onboarding course 2019 offered in Darmstadt (Germany) for all new EHS managers addressed the topics of human rights and modern slavery.

Additionally, we ran training activities (such as Procurement Training Academy) for new Procurement employees including sessions on sustainability and human rights in 2019 and conducted webinars for our Procurement staff. Lastly, we invited Chinese suppliers to attend a **TFS training session** in Shanghai (China).

Our employees can find information about human rights on our intranet.

Bioethics

Part of the non-financial report

Bioethics guides us in how to use the rapidly advancing power of life science and technology 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 topics and issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. We are strongly committed to conducting this research in an ethical manner. **Patient well-being and benefit** is always our number one priority, both during treatment with our drugs and when our products are distributed 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 the highest ethical standards.

How we assess bioethical topics and issues

The Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP), co-chaired by a senior executive biomedical expert from our company and the Head of our Global Health Institute, gives clear guidance on bioethical topics and issues, which steers our actions and entrepreneurial conduct. The MBAP consists of renowned international experts in the fields of **bioethics, theology, science, and law** from the United States along with countries across Europe, Asia, and Africa. 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 yearly and also spontaneously, if required, in response to emerging urgent bioethical issues. We publish a summary of the discussions from each meeting on our internal electronic collaboration platform. Our employees can ask MBAP members for advice and are able to report concerns on ethical 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.

These panels are responsible for the operational implementation of our stance and are empowered to make decisions about specific questions on individual projects. Formed in 2011, the 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.

In 2019, we additionally established the Digital Ethics Board (DEB) as a sub-committee of the MBAP. Its purpose is to guide our new digital business models with a strong focus on health. One member of the DEB will join the MBAP as a digital expert.

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 disrupted the realm 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 furthermore 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.

Bioethics Advisory Panel discussions

From November 2018 to March 2019, we held internal workshops on **Artificial Intelligence (AI)** ethics to create a baseline on all Advanced Machine Learning (AML) and AI projects at our company and to identify potential (bio-)ethical issues resulting from these projects. In particular, we produced eight guiding ethical aspects to evaluate projects that might be ethically problematic. This improves our ability to develop new technologies responsibly and address potential ethical issues arising from the usage of AI early on. Currently, no ethical questions or problem statements have arisen from our ongoing and planned AML and AI projects.

As a result of these workshops and of new digital health business models that we are developing, the MBAP addressed the topic of digital ethics in 2019. Since these business models involve enabling access to and exchange of patient data, core guidance and foundational ethics must be established in order to gain stakeholders' trust, which is critical for their success. Another major topic discussed by the panel was our genome editing principle.

Other topics included new developments in the Stem Cell Research Oversight Committee and the Global Health Institute.

The members of our Bioethics Advisory Panel (MBAP)

We discuss with external international experts to give guidance on bioethical topics and issues



Prof. Yimtubezinash Woldeamanuel Mulate



Microbiology

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



Prof. Jochen Taupitz

Medical law, bioethics



Former Vice-Chair German
Ethics Council



Prof. Nikolaus Knoepffler

Philosophy, Theology, Ethics



University Jena



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. Jeanne Loring

Molecular Biology, Stem Cells



Formerly Scripps Research
Institute La Jolla
(Advisor)



Prof. Daniel Fu-Chang Tsai

Bioethics, Medicine



National Taiwan University

Digital Ethics Board

As a result of the MBAP discussions on digital ethics in 2019, we decided to create the Digital Ethics Board (DEB) to deal with all **ethical questions resulting from our Digital (Health) Businesses**, especially from the intended joint venture **Syntropy** (with Palantir). The DEB is designed as a sub-board of the MBAP, and its chair will join the MBAP as a digital expert. The DEB will consist of world-leading experts in digital health business models as well as experts in ethics and medicine. The first step will be to develop a Digital Code of Ethics to address questions and scenarios that may arise from our new Digital Businesses. The DEB will play a pivotal role in ensuring that we develop new technologies responsibly and address potential ethical issues arising from the usage of digital health technologies early on. We strive to be the “ethical digital health company”, adhering to the highest ethical standards in crucial areas such as patient data handling.

Biotechnology and genetic engineering

We utilize genetically modified organisms (GMOs) in our research and development work and have been manufacturing biotech products using GMOs since the 1980s. Without this technology, the **major medical advances** of past years would not have been possible.

Our most important research hubs for medical biotechnology are Darmstadt (Germany), Boston (Massachusetts, USA), Beijing (China), and Tokyo (Japan). Major biotech production sites are located in Martillac (France), Aubonne (Switzerland) and Corsier-sur-Vevey (Switzerland), which is one of the largest biopharmaceutical production sites in Europe.

Across our Group, we manufacture our biotech products in accordance with the highest standards, and all our biotech activities are subject to strict statutory regulations worldwide. Compliance with these regulations is monitored by our **biological safety officers**. We continuously track 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.

Our **Genome Editing Technology Principle** provides a mandatory ethical and operational framework for our employees, setting 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. This principle includes background information on the topic and explains our stance on genome editing.

Following the critical debate surrounding the announcement that a Chinese researcher’s work had led to the birth of the first babies from genome-edited embryos, global discussions emphasized the need for profound bioethical debate and meaningful governance of genome-editing research in the human germline. The topic was presented in detail by the Taiwanese member of the MBAP, and potential regulatory consequences were discussed by the panel, including the implications for our company as a provider and user of this technology. Our Principle on Genome Editing, published in 2017, addresses the subject of human germline editing, taking a strict stance against it.

Bioethical views on germline editing (GE) have been evolving for years in academic and societal discussions. Once the safety profile of the use of GE on embryos has been made fully accessible through clinical studies, and once the benefits significantly outweigh the risks, there may be cases where the use of GE on embryos could be ethically acceptable. Even the **German Ethics Council** took a similar position. One example of this cystic fibrosis, a monogenetic disease.

Considering the progress in genome editing and evolving ethical views, such as the German Ethics Council’s perspective, the MBAP agreed that we needed to update our Genome Editing Principle. Sections on background information, the wording on germline genome editing, and the section on artificial gametes subsequently underwent minor revisions. 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

We currently 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 select 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.

In 2019, the SCROC started developing a new Informed Consent Form for the use of induced pluripotent stem cells (iPSCs). iPSCs are identical to embryonic cells and can generate any type of cell in the human body. They are used in many research projects, but, in most cases, do not require specific approval by the SCROC. The SCROC also decided to support the generation of organoids derived from adult stem cells under the precondition that stem cells derived from fetal tissue should be avoided.

To date, we have not supported research aimed at producing artificial gametes. Any support on our part would have to comply with the German Embryo Protection Act and our **Fertility Principle**.

The topic of producing artificial gametes will be revisited by the SCROC in order to follow up on ongoing developments.

Fertility research

We develop treatments for infertility and seek to improve the success rate of in vitro fertilization, so 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 standard operating procedures and a policy in place that define our principles and processes for human biosample management during and after clinical studies.

Biological samples, including tissue and body fluids, are stored in biorepositories together with the corresponding encrypted patient and specimen data.

Clinical studies

We discover and develop innovative medicines that meet patient needs. In doing so, we adhere to all relevant statutory and regulatory requirements, as well as scientific and ethical standards. For clinical studies, these standards particularly include the **Declaration of Helsinki**, in which the World Medical Association formulated ethical principles for medical **research involving human subjects**, and the Good Clinical Practice (GCP) of the International Council for Harmonisation (ICH). More details can be found under **Clinical studies**.

Off-label use

We **endeavor to drive scientific and medical progress**, often doing so in close collaboration with medical professionals. We regularly receive inquiries about the off-label use of our products, such as indications for which the drug was not originally approved. While each medicine is authorized for specific indications, cases do arise in which a physician wishes to prescribe a drug to treat a disease for which it is not approved. Such applications can benefit patients. However, to use a drug in this way, solid evidence must exist showing that it can be effective and safe in the treatment of the specific disease.

Our principles for disseminating information regarding the off-label use of our products are set out in corresponding policies that apply Group-wide. In 2018, we included a statement regarding requests on off-label use in the new compliance policy concerning **interactions with patients**. We only market our medicines within the scope of the drug's marketing approval; we never share information on off-label use for commercial ends but provide such information to healthcare professionals for medical purposes only and only upon direct, unsolicited request. The information must be backed by scientific evidence and factually balanced. Our employees are not permitted to make any sort of treatment recommendations for individual patients.

Parliamentary discussion on genome-editing

In May 2019, we hosted a Dialogue on Ethics of Genome Editing for German policymakers in the form of a parliamentary breakfast discussion. It was attended by 45 political stakeholders, including elected state officials, members of the German federal parliament, and other high-profile German politicians. Participants engaged in an open debate on the ethics of genome-editing one day after the publication of the German Ethics Council's new position paper on germ cell genome-editing.

Panel discussion on ethical implications of new technologies in the health sector

In November 2019, in collaboration with the Brussels Representation of the State of Hesse, we hosted a panel

discussion (representing academia, the European Parliament and Commission, and our company) on ethical implications of new technologies in the health sector, addressing ethical questions on both digital health and genome editing technology. It was attended by 100 European political stakeholders, including elected officials, Members of the European Parliament (including a vice president), representatives from various governmental and non-governmental organizations, and representatives from the pharmaceutical and biotech industries, all of whom engaged in an open debate with the panelists.

At both events, the Bioethics Advisory Panel's recent work had a significant impact on the respective discussions, which in turn generated valuable input for the continuation of the debate.

clinical studies

Part of the non-financial report

Our company 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. These studies generally run for several years. 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, wellbeing, 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 intentionally 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, furthermore the following 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

Pharmaceutical development and the related governance process are the responsibility of our Head of Global Research and Development, who co-chairs the Development Decision Group (DDG) with the Global Head of Innovative Medicine Franchises. **Decision-makers from all relevant functional areas sit** on this biopharmaceutical committee, helping to ensure a cross-functional approach to the governance of drug development.

Under the umbrella of the DDG, two further committees oversee our clinical studies. The Integrated Clinical Study Committee (ICSC) is responsible for the studies performed by the company in pharmaceuticals 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. The ICSC is also supported by our Therapeutic Area Review Boards, which conduct thorough scientific assessments of new study concepts. 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 profile. We only take the critical step of a first-in-human clinical trial after diligently conducting extensive preclinical testing. The decision resides 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 agreements

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 health authorities to ensure compliance with the applicable laws and guidelines. We also conduct our own **quality assurance audits**. These are planned by the Research and Development Quality function, based on a quality risk assessment approach to identify areas for internal and external auditing. In both cases, we respond immediately to any issues found by defining and implementing corrective and preventive actions to improve our processes accordingly.

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. All participants are given ample time and opportunity to inquire about details before deciding whether to participate. All questions are answered by the clinical investigator or another qualified healthcare professional familiar with the study. 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 2019, once again, 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 for 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 mental 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. The program aims to develop, register and provide access to a **pediatric formulation** of praziquantel for treating schistosomiasis in children younger than six years of age. Due to the lack of clinical data as well as a suitable pediatric formulation of praziquantel, this age group currently goes untreated. Following the successful completion of Phase I bioavailability studies with healthy adults in South Africa and the swill-and-spit taste study in children aged six to eleven in Tanzania, Phase II was concluded in November 2018 in Ivory Coast. The results confirmed the validity of lozenges (orodispersible formulation) as dosage form to be pursued to registration. The pivotal Phase III trial, which is being conducted in Kenya and in Ivory Coast, started in September 2019.

The clinical program was designed in line with the recommendations of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for pediatric development. It was planned and is being implemented in close cooperation with regulatory authorities and a panel of international experts, including clinicians from endemic countries. Further details can be found under ["Health for all"](#).

Teaming up to get results

To provide a broad, in-depth basis for the development of new medicines, we frequently conduct clinical studies in collaboration with external **partners in academia and industry**, as well as with medical-scientific advisory boards, service providers and vendors. We expect all our partners to abide by the same set of high standards when conducting clinical research. This especially applies to contract research organizations (CROs) performing studies on our behalf.

In our collaboration with CROs, we follow established processes of selection, approval, contracting and monitoring defined in comprehensive manuals. We expect their services to comply with the highest quality level including roles and responsibilities as specified in detailed quality agreements. Vendors are audited regularly based upon a risk assessment approach. This is to ensure that they comply with all applicable regulations, guidelines and the requirements defined in the aforementioned manuals and agreements. The same applies to study centers (for example, hospitals) involved in our clinical studies. In 2019, these audits again reveal no indications of systematic or significant non-compliance with the standards mentioned above. One individual critical observation was raised with respect to computerized systems. The root cause was identified and addressed with relevant corrective and preventive actions.

We are a member of TransCelerate, a consortium of 20 pharmaceutical companies seeking to drive the **efficient, effective and high-quality delivery of new medicines**. In this context, we are currently leading an initiative related to decentralized (virtual) clinical trials.

Close dialogue with patients and advocacy groups

We want to ensure the voice and **needs of patients and their caregivers** are adequately taken into consideration when developing and conducting clinical studies. We, therefore, 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 centrality in everything we do. In 2019, we made further strides towards delivering this ambition by executing the first PAB in Asia.

Furthermore, we are involved with multiple organizations that focus on this relevant aspect of **patient centrality in clinical studies**. 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. In Europe, we are involved in the European Patients' Academy on Therapeutic Innovation (EUPATI), a public-private partnership within the Innovative Medicines Initiative (IMI). We extended our participation, which initially ran from 2012 to 2017, until the end of 2019. EUPATI is a pan-European project led by the European Patients' Forum (EPF). It features partners from patient advocacy groups, universities and not-for-profit organizations, along with a number of pharmaceutical companies.

Responsible data sharing

We support professional circles in advancing **medical and scientific knowledge**, thereby allowing for 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

In 2019, we did not receive any substantiated complaints from patients, participants or regulatory bodies concerning breaches of privacy in the context of our clinical studies.

Disclosure of clinical studies and publication of results

We are obliged to disclose findings from our clinical studies, which we do 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. In 2019, we provided participants of 11 studies with Lay Patient Summaries of clinical study results, which explain the results in plain language. Since November 2019, we have been providing clinical study report synopses and Lay Patient Summaries 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.

Immuno-oncology: Major clinical research milestones

Immuno-oncology investigates the extent to which the body's immune system can be activated or boosted to

mount an immune response against cancer cells. As part of our **strategic alliance** with the U.S. pharmaceutical company Pfizer, we are developing Bavencio[®] (avelumab), an investigational anti-PD-L1 antibody that we initially discovered and developed as a potential treatment for different tumors. Under this collaboration, in 2015 we launched JAVELIN, our comprehensive international clinical study program in which we investigate the potential therapeutic benefit of avelumab in multiple tumor types. By the end of 2019, more than 12,200 patients had participated in this program.

By the end of 2019, avelumab had gained marketing authorization in 50 countries, including the EU member states, Japan and the United States, for the treatment of **patients with metastatic Merkel cell carcinoma (mMCC)**, a rare and aggressive form of skin cancer. Furthermore, avelumab was granted regulatory approval in three countries for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) following platinum-containing chemotherapy. UC is a malignant tumor of the urothelium lining the urinary tract.

In addition, avelumab, in combination with axitinib, gained **FDA** approval and European Commission authorization in 2019 for treating patients with advanced renal cell carcinoma. Meanwhile, avelumab continues to be evaluated in several ongoing registrational Phase III studies across different tumor types, including lung and head and neck cancers, as well as the first-line therapy of urothelial carcinoma.

In 2019, we entered into a **global alliance** with the company GlaxoSmithKline to co-develop and co-commercialize Bintrafusp alfa, a bifunctional fusion protein for immunotherapy. Currently in clinical development, including pivotal studies, it could be used to treat multiple difficult-to-treat cancers.

Enabling early access to new medicines

Not all patients have the opportunity to take part in a clinical study and so must 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. We published position papers on **Early Access** and **Post-Study Access** 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 Principles**, published on our website in 2018, define 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 and our corresponding policy and standard operating procedure.

Coming to terms with the past

In the 1950s and 1960s, pharmaceutical companies in Germany supplied their drugs to various institutions for clinical trials conducted typically by university clinics or general practitioners, but in certain cases, also in children’s care homes. Since 2015, we have been giving researchers access to the files in our historical archives at our global headquarters in Darmstadt (Germany) and supporting them in the comprehensive historical research of this topic. We maintain **full transparency**. When their work is completed, their findings can be used for the final assessment of this complex topic.

ANIMAL welfare

From both an ethical and scientific perspective, animal studies for medical purposes and chemical safety are indispensable and furthermore mandated by law. We comply with strict animal welfare standards that meet and frequently exceed applicable laws. Moreover, we oblige our suppliers, contract research organizations and other partners to meet our high expectations with respect to animal welfare.

Our approach to animal welfare

Animal studies enable us to test both the safety of our medicinal and chemical products, and the efficacy of our pharmaceuticals. We conduct animal studies within our Healthcare business sector as part of the official drug approval process, for chemical safety (REACH) and for biological quality control. Animal welfare is also of importance to the Life Science business sector, where laboratory animals are kept, for instance, for the generation of antibodies. Our subsidiary BioReliance conducts animal studies within the scope of contract research work for third parties.

Our Group-wide Policy on the Use, Care and Welfare of Laboratory Animals sets forth our commitment to consistently uphold the highest ethical standards regarding the housing, care and feeding of laboratory animals. When conducting animal studies, we pursue well established methods that ensure high-quality results. We strive to replace animal studies with alternative methods wherever possible and permissible by law. We, therefore, subscribe to the internationally recognized **3Rs for animal-based research**:

- 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

With our internal 3Rs Award, we recognize best practice and further strengthen our commitment to apply and actively promote the 3Rs in our animal studies.

We also promote the 3Rs outside our company. Under the International Consortium for Innovation and Quality in Pharmaceutical Development (**IQ Consortium**), for instance, we joined forces with other pharmaceutical companies to introduce the **Global 3Rs Awards Program**. In partnership with the Association for Assessment and Accreditation of Laboratory Animal Care International (**AAALAC International**), the IQ Consortium recognizes **innovative contributions** to the 3Rs of animal studies to advance ethical science in academia and industry.

How we ensure animal welfare

Through our Corporate Animal Science and Welfare unit, we endeavor to create uniform high-quality animal welfare standards. To ensure adherence to these standards, we initiate **animal welfare audits** within both our company and our partners. Our animal science and welfare officers

and experts regularly interact through our global laboratory animal science network, sharing best practices and lessons learned. This supports the animal welfare units at our sites as well as all projects and processes related to animal science and welfare.

Our Group Animal Welfare Council is made up of representatives from all our business sectors and meets twice a year. The council discusses relevant developments, advises the Chief Animal Welfare Officer and makes decisions regarding our Animal Welfare Strategy.

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

All our animal sites are subject to national regulations. In order to assess the quality of animal husbandry practices and ensure compliance with our standards as well as all statutory requirements, we appoint **animal welfare officers** and establish **animal welfare councils** across our Group, even where not required by law.

Work with committees and associations

As part of our efforts to improve animal welfare, we are involved in several organizations such as the European Federation of Pharmaceutical Industries and Associations (**EFPIA**), the German Association of Research-based Pharmaceutical Companies (**vfa**) and **Interpharma**, a federation of research-based pharmaceutical companies in Switzerland. As a member of Interpharma, we have joined a continuous dialogue with **Swiss Animal Protection** to identify common interests and find synergies regarding the 3Rs.

Our Chief Animal Welfare Officer is a member of various committees and takes an active role in order to advocate our position on animal welfare. Moreover, he represents EFPIA on the **AAALAC International** Board of Delegates. In 2019, he was appointed Vice Chair Elect to the Board of Directors of AAALAC International, entailing a four-year commitment (2021 Vice Chair, 2022 Chair, and 2023 Immediate Past Chair). He is also a member of the German Federal Animal Welfare Commission. Our animal welfare officers are members of the National Committee pursuant to section 15 of the German Animal Welfare Act, the German professional veterinary commission for laboratory animals and the German federal professional veterinary commission for animal welfare, for example.

Our commitment: Group-wide methodology and standards

Through our Group-wide Policy on the **Use, Care and Welfare of Laboratory Animals**, we have expressed our commitment to global animal welfare principles and the highest possible ethical standards in animal studies. The policy further sets out principles on the housing, care and feeding of laboratory animals. We strive to provide our animals with the **best quality of life possible** and consistently seek ways to make improvements. This ethos applies equally to the contracted animal study services we offer third parties such as contract research organizations, academia or partnerships and to those services we contract from these third parties. In addition to our policy, our Group-wide Animal Science and Welfare manual describes the requirements for implementing, maintaining and improving animal welfare practices. Moreover, our standard entitled Housing and Husbandry Practices for Common Laboratory Animals also applies to our external partners. Our Vendor Qualification Standard describes our criteria for evaluating the quality of animal welfare practices in our suppliers and partners.

Legal requirements

Animal testing is only permitted if there are no recognized alternative methods available. In many fields, however,

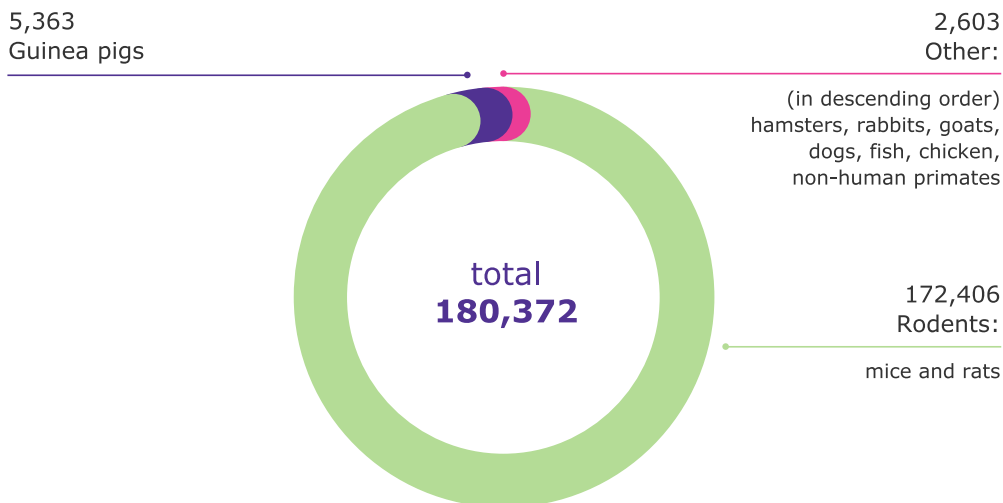
animal studies are indispensable and legally mandated by **ICH guidelines** or **REACH**, which place priority on the **safety of humans**. Laws and regulations govern all aspects of animal testing, such as the housing conditions of laboratory animals, the conduct and approval of studies and the reliability and expertise of all involved individuals.

Number of laboratory animals used for medical study purposes

In 2019, 180,372 animals were used at our company. This represents an increase of 8% compared to 2018. This is attributable mainly to the Life Science business sector, specifically the subsidiary BioReliance. This increase is directly related to government-required safety testing of the compounds of our customers, in particular the testing and determination of clinical toxicological safety profiles.

The majority (96%) of the laboratory animals we use are rodents (mice or rats). In addition, around 10,240 animals were used by contract research organizations (CROs) on our behalf and in collaboration with academia, which represents a decrease of 5% compared to 2018. Regulatory agencies sometimes require the safety of investigational drugs to be investigated in non-rodent species. This allows researchers to identify potential adverse effects with the necessary accuracy and include them in the **risk assessment** of a substance.

Animal types



Auditing our research facilities

We perform regular audits on our animal testing facilities to ensure adherence to our animal welfare standards. In 2019, three internal audits (sites in Israel and Scotland) and one authority visit in Darmstadt were conducted. Where necessary, we initiated the relevant corrective measures. No critical shortcomings were identified during these audits.

We strive to adhere to the highest international animal welfare standards. All our Healthcare laboratory animal facilities and one of our Life Science laboratory animal facilities in the United States were accredited to the standards of [AAALAC International](#).

Collaborating with partners and suppliers

We perform the majority (95%) of animal studies ourselves and procure the animals required from specialized breeders. Sometimes, however, we also hire contract research organizations (CROs) to conduct animal studies on our behalf. Furthermore, we work with academic institutions. Whenever collaborating with such organizations, we expect them to share our high standards, as set out in our Use, Care and Welfare of Laboratory Animals Policy and in the Group standard entitled Animal Welfare CRO, CMO and Supplier Qualification.

Regularly auditing our partners

We verify compliance with our animal welfare policy and standards through a risk-based qualification procedure together with regular audits of our animal breeders and contract research organizations. As part of our collaboration with Interpharma, we worked with other member companies to develop a **cross-company audit concept**. 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. In 2019, the association conducted three audits in Germany, France and the United Kingdom, respectively. We, ourselves, conducted one audit at a CRO in Israel.

In October 2019, one of our CROs in Germany conducting animal studies was accused of having violated our animal welfare and legal animal protection regulations. Following a comprehensive internal investigation, we decided not to commission any further animal studies from this CRO. The last study activities ended in December 2019. If this legally required study had been terminated earlier, it would have had to be repeated elsewhere with other animals. To protect the animals and minimize any potentially harmful impacts, our experts oversaw the completion of the study. Through our rigorous and diligent on-site supervision at the laboratory we could ensure full compliance with all applicable animal protection standards and statutory regulations.

In consultation with the authorities, we work with recognized animal welfare organizations to find appropriate accommodation for the remaining laboratory animals. You can find more information in our [NEWS](#) section online (only in German).

Comprehensive employee training

We regularly train all employees who work with laboratory animals. This way we want to ensure that animal studies are conducted according to the latest scientific standards and that animals receive the best care possible. We held training sessions in Darmstadt (Germany), and at several U.S. sites. The training covered topics such as roles and responsibilities of Institutional Animal Care and Use Committees (IACUCs) and clinical care of animals. The nature and scope of the training courses are based on national, international and local legislative requirements.

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).

How we implement the 3Rs

We implement the 3Rs by way of various measures – both within our own company and as part of industry associations. In 2019, for example, we established the use of less invasive imaging technologies (magnetic resonance imaging and ultrasound) for longitudinal and individual investigations in preclinical studies in rodents.

We also put in place an innovative group housing concept for rabbits and rats at one of our sites. By keeping animals together in groups, they are generally healthier and less stressed. Wherever possible, we adopt out our animals and employ a special re-homing program using recognized animal welfare organizations that specialize in laboratory animals.

Further, our scientists continuously develop alternative methods for animal studies and received numerous accolades for their efforts.

In 2019, we invited once again to apply for our 3Rs Award. The internal award honors employees who provide innovative ways of implementing the 3Rs principle for animal-based research.

We actively support the development of **alternative testing methods** and their official recognition at an inter-

national level. There is serious need for action here because animal studies can only be truly reduced if a new methodology is internationally accepted. Without this global recognition, both, animal studies and alternative testing have to be conducted in parallel when developing pharmaceuticals intended for worldwide distribution.

To help improve this situation, we support the European Partnership for Alternative Approaches to Animal Testing (EPAA). This collaboration between the European Commission, European trade associations and companies from various industry sectors seeks to pool knowledge and resources to accelerate the development of alternative approaches to animal use in regulatory studies. Through our membership in the German Association of Research-based Pharmaceutical Companies (vfa), we also support the German set Foundation, which is dedicated to finding and developing new alternatives in animal experimenting and seeks to **reduce and replace animal testing**. To achieve this objective, the foundation funds projects that conduct research into alternative methods. Our Chief Animal Welfare Officer is currently Vice Chair of the set Foundation Board of Trustees.