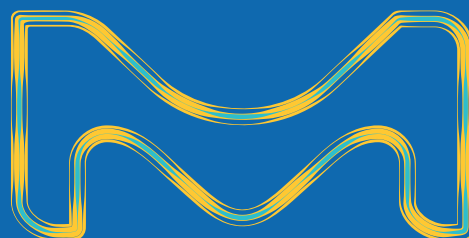


Merck KGaA
Darmstadt, Germany

CORPORATE RESPONSIBILITY Report 2018



5 STRATEGY & MANAGEMENT

- 6** Company profile
- 9** CR strategy
- 11** Stakeholder dialogue
- 14** Materiality analysis

20 BUSINESS ETHICS

- 21** Corporate Governance
 - 21** Governance
 - 22** Compliance
 - 27** Responsible marketing
 - 29** Interactions with health systems
- 31** Suppliers
 - 31** Supply chain standards
 - 34** Mica supply chain
- 36** Human rights
- 38** Bioethics
- 41** Clinical studies
- 45** Animal welfare

48 PRODUCTS

- 49** Innovation and digitalization
- 53** Sustainable products
 - 53** Sustainable product design
 - 56** Packaging and recycling
- 58** Health for all
 - 58** Global strategy
 - 61** Focus programs
 - 64** Open innovation sharing
 - 66** Pharmaceutical supply chain
 - 68** Prices of medicines
 - 70** Health awareness
- 73** Product safety and quality
 - 73** Chemical product safety
 - 76** Patient safety
 - 79** Product-related crime
 - 82** Transport and warehouse safety

84 EMPLOYEES

- 85** Attractive employer
- 90** Diversity
- 94** Health and safety
- 97** Employee engagement
- 99** Good leadership

101 ENVIRONMENT

- 102** Environmental stewardship
- 105** Climate action
- 108** Waste and recycling
- 110** Water management
- 113** Plant and process safety
- 115** Biodiversity

116 COMMUNITY

- 117** Community involvement
- 119** Global Health
- 121** Broad Minds

124 FACTS & FIGURES

- 125** Report profile
- 127** Indicators
 - 127** Economics
 - 128** Business ethics
 - 132** Employees
 - 145** Environment
 - 151** Community
- 153** Goals
- 165** Recognition and rankings
- 168** Sustainable Development Goals
- 173** Non-financial report
- 180** GRI content index
 - 180** General disclosures
 - 185** Economic Standards
 - 188** Environmental Standards
 - 191** Social Standards
- 198** Global Compact CoP
- 202**

Letter from the CEO

Ladies and gentlemen, friends of Merck KGaA, Darmstadt, Germany,

In 2018 we ran an [employee campaign](#) called “350 Good Deeds”. The name says it all – to commemorate our 350th anniversary, we rolled up our sleeves to support good causes across 60 countries. We made donations to charitable initiatives, launched new projects and volunteered our time. Our employees poured great effort into helping people with disabilities; they renovated hospitals and cooked meals with disadvantaged children. Starting this year, our workforce across the globe will be permitted to take up to two days of paid leave per year to volunteer for charitable activities spearheaded or supported by our company.

While I am proud to be part of a company that is so deeply dedicated to community outreach, corporate responsibility means so much more to us. Indeed, our entire business model is founded on this sense of responsibility.

We aspire to be a leading science and technology company, which also means developing technological advances that benefit all humankind. This ranges from treatments for serious diseases, to products and services that make research and biomanufacturing faster and more reliable, through to materials for the technologies of tomorrow. We are leveraging the great potential presented by genome editing, big data and artificial intelligence while living up to the massive responsibility that arises from utilizing such technologies. To keep our moral compass aligned, we discuss complex ethical issues in our [Bioethics Advisory Panel](#), consisting of internal and external experts from a variety of fields and cultures, and comply with the clear-cut recommendations they make.



Last but not least, responsible conduct involves respecting the interests of our employees, customers and investors. In line with this ethos, we are deeply committed to the [United Nations Global Compact](#) and its principles on human rights, labor standards, environmental protection, and anti-corruption.

In 2018 we realigned our [corporate responsibility strategy](#) to reflect a **shared value** approach that centers more heavily on creating long-lasting added value for both our company and society. We also narrowed the focus of our three strategic spheres of activity.

Under **Global Health**, we partner with other actors to support a variety of initiatives that improve access to health services particularly for people in low- and middle-income countries. The non-profit Foundation sponsored by Merck KGaA, Darmstadt, Germany is likewise focused on achieving this goal. For me personally, the greatest proof that we are on the right track is our fourth-place ranking in the [Access to Medicine Index](#), where we beat out some of the giants in the pharmaceutical industry. It is also reflected in our advances in malaria and antimicrobial research, our continued fight against the tropical disease schistosomiasis, and our many awareness campaigns such as "Embracing Carers".

Yours,



Stefan Oschmann

Chairman of the Executive Board and CEO

Sustainable Solutions covers everything that we at the company do to ensure that our processes, products and services contribute to sustainability, specifically in terms of climate and environment. Thanks to our liquid crystals, for instance, energy-efficient smart windows can block sunlight and help reduce the energy needed for air conditioning by up to 40%. Another example is [Design for Sustainability](#), a system our Life Science team uses to analyze and enhance products at the development stage in a bid to conserve resources from cradle to grave.

Broad Minds embodies our tradition of promoting STEM education, scientific research and culture. We are on a quest to spark enthusiasm for science among the next generation. In 2018, we were therefore thrilled to host the German national "Jugend forscht" young researchers competition for the third time. As someone who lives and breathes research, I thoroughly enjoyed interacting with so many curious, talented up-and-coming scientists and discussing their ideas and projects.

We absolutely believe that progress thrives on the nourishment of creative minds. The wide-ranging examples contained in this report illustrate that we do more than pay mere lip service to responsibility – we live it every day. For us, scientific research and responsible entrepreneurship go hand in hand, a principle that will guide us today, tomorrow and beyond.

strategy & Management

Within this chapter:

6 Company profile
9 CR strategy

11 Stakeholder dialogue
14 Materiality analysis

company profile

Part of the non-financial report

We are Merck KGaA, Darmstadt, Germany, a vibrant science and technology company. Science is at the heart of everything we do. It drives the discoveries we make and the technologies we create. Our work makes a positive difference in millions of people's lives every day. In line with our strategic direction, in Healthcare, we discover unique ways to treat the most challenging diseases such as multiple sclerosis and cancer. Our Life Science experts empower scientists by developing tools and solutions that help deliver breakthroughs more quickly. And in Performance Materials, we develop science that sits inside technologies and changes the way we access and display information.

Everything we do is fueled by a belief in science and technology as a force for good. A belief that has driven our work since 1668 and will continue to inspire us to find more joyful and sustainable ways to live. We are curious minds dedicated to human progress.

Who we are

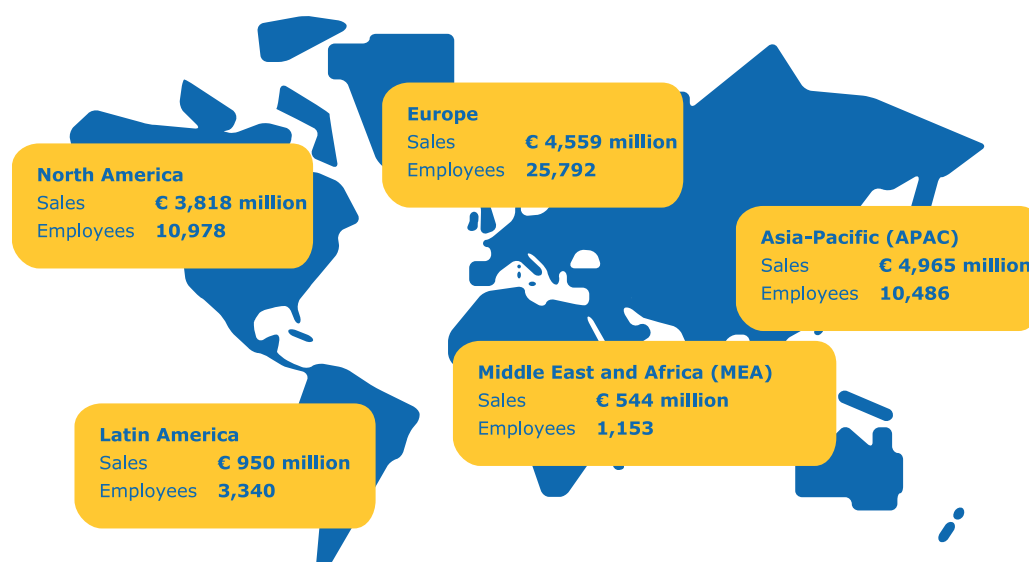
We hold the global rights to the "Merck" name and brand. The only exceptions are Canada and the United States. In these countries, we operate as EMD Serono in the biopharmaceutical business, as MilliporeSigma in the life science

business and as EMD Performance Materials in the high-tech materials business.

Apart from our three business sectors, our financial reporting presents the five regions Europe, North America, Asia-Pacific (APAC), Latin America as well as Middle East and Africa (MEA). As of December 31, 2018, we had 51,749 employees worldwide, which compares with 52,941 on December 31, 2017.

In 2018, our 207 subsidiaries with employees in 66 countries generated sales of € 14.8 billion. Our 90 production sites are located across 21 countries.

Employees and sales by region – 2018



Group structure

Merck KGaA, Darmstadt, Germany comprises three business sectors: Healthcare, Life Science, and Performance Materials. Our Healthcare business sector – the biggest among our three business sectors – comprises the two businesses Biopharma and Allergopharma. On December 1, our Consumer Health business transferred to Procter & Gamble (P&G).

Our Biopharma business discovers, develops, manufactures and markets innovative pharmaceutical and biological prescription drugs to treat cancer, multiple sclerosis (MS), infertility, growth disorders as well as certain cardiovascular and metabolic diseases. Biopharma is the larger of our **Healthcare** businesses and operates in four franchises: Oncology, Neurology & Immunology, Fertility and General Medicine & Endocrinology. Our R&D pipeline positions us with a clear focus on becoming a global specialty innovator

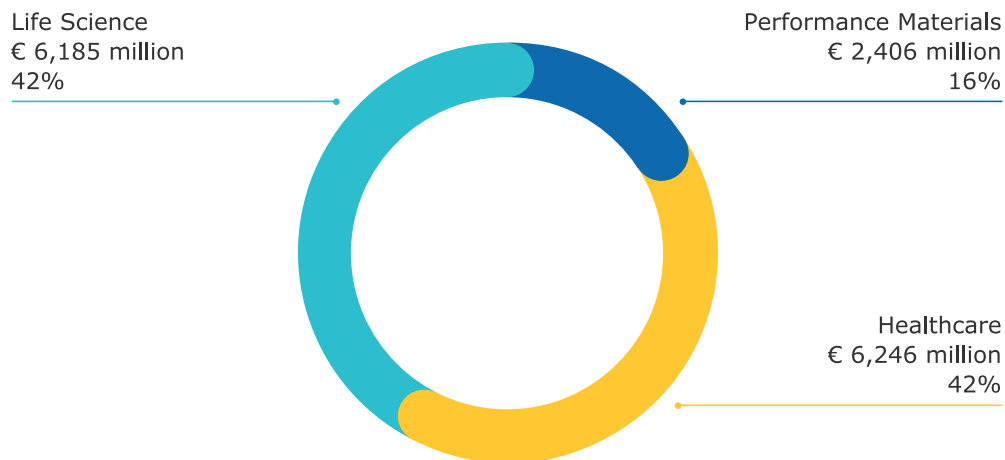
in oncology, immuno-oncology and immunology including MS. Our allergy business Allergopharma is one of the leading companies in the field of allergy immunotherapy (AIT) in Europe. For high-precision, effective allergy therapy, we offer comprehensive diagnosis solutions as a basis for individual treatment concepts. Our AIT products concentrate on causal treatment of type 1 allergies such as allergic rhinitis (for example, hay fever) and allergic asthma to meet patients' needs.

In **Life Science**, we are a leading, global supplier of tools, high-grade chemicals, and equipment for academic labs, biotech and biopharmaceutical manufacturers, as well as the industrial sector. We make scientific discovery easier and faster with technologies like CRISPR for gene editing; and we provide drug manufacturers with process development expertise that make medicines safer and more effective for patients. We offer both testing kits and services to ensure that our food is safe to eat and water is clean to drink. Our portfolio comprises more than 300,000 products ranging from lab water systems to genome-editing tools, antibodies, and cell lines, as well as end-to-end bioprocessing systems to support the manufacturing needs of both emerging biotech and large pharma companies. For example, our Life Science business sector has built the expertise to further develop our BioReliance® End-to-End

Solutions, a service offering for process development and manufacturing for emerging biotechs. Another example is BrightLab™, our digital ecosystem for complete lab management.

Our **Performance Materials** business sector comprises the specialty chemicals of our company and supplies solutions for displays, computer chips and surfaces of all kinds. Since April 1, 2018, Performance Materials comprises three business units: Display Solutions, Semiconductor Solutions and Surface Solutions. If we compare Performance Materials with a smartphone, Display Solutions represents the user interface, Semiconductor Solutions the intelligence and Surface Solutions the aesthetics. Our Display Solutions business unit comprises the liquid crystals, OLED (organic light-emitting diodes), photoresists and liquid crystal windows businesses. Semiconductor Solutions, the second-largest business unit in Performance Materials, supplies products for integrated circuits, microelectronic systems, for antireflection coatings, and for the miniaturization of transistor structures. Deposition materials and conductive pastes for semiconductor packaging round off the portfolio. In the Surface Solutions business unit our goal is to help customers with our materials and solutions to make innovative surfaces of all kinds more beautiful, more resistant or even more intelligent.

Net sales by business sector – 2018



Governance

Based in Darmstadt, Germany, our company operates in the legal form of a corporation with general partners (Kommanditgesellschaft auf Aktien – KGaA). The general partner E. Merck KG, Darmstadt, Germany holds around 70% of the total capital of Merck KGaA, Darmstadt, Germany (equity interest); the shareholders hold the remainder, which is divided into shares (share capital). Our shares have been included in the DAX[®] 30, the blue-chip index of the Deutsche Börse, since 2007. In September 2008, our company was added to the FTSE4Good Index, a sustainability index that assesses the social, ecological and ethical conduct of companies.

Group strategy

Throughout the past years, our company has grown significantly through a series of strategic moves that have enabled us to develop into the vibrant science and technology company we are today. We have systematically and continuously strengthened and focused our portfolio of innovative science and technology throughout our business sectors. In Healthcare we divested our Generics business (2007) to focus on highly specialized products and acquired Serono (2007) to expand our pipeline and strengthen our business.

This focused approach has continued until today with the divestments of the Biosimilars business (2017) and Consumer Health business (2018), so that we can increase our efforts on our Oncology, Immuno-oncology and Immunology franchises. Within Life Science, we have significantly transformed to become a diversified industry leader through the acquisition of Millipore (2010) and Sigma-Aldrich (2015). During the last years, Performance Materials has continued to deliver profitable growth and a significant cash contribution, and we evolved this business further into attractive science and technology areas such as semiconductor materials through the acquisition of AZ Electronic Materials (2014), which also helped us further diversify our product portfolio that was strongly driven by liquid crystals. Our Group Strategy considers certain foundational elements such as, first and foremost, a risk diversification strategy that ensures that we are not over-exposed to any single customer, industry or geography. We want to be a forward-thinking company generating long- term sustainable value. We focus our efforts and activities on innovative areas to add maximum value to the future of science and technology.

You can find more information on our strategy in our [Annual Report 2018](#).

CR strategy

Part of the non-financial report

Major global trends such as a growing population, increasing life expectancy, resource scarcity, and digitalization are transforming our society and our lives. To cope with these challenges and changes, policy makers and civil society must join forces with the private sector to find solutions. For us, this transformation is driving the development of sustainable, personalized and interconnected products.

Our approach: Looking, listening and doing better

We are aware that as a leading science and technology company our business operations impact our environment and the people around us. We have therefore made **responsible conduct** a pillar of our corporate culture, the bedrock of our sustained success. Through our innovative top-quality products within our Healthcare, Life Science and Performance Materials business sectors, we help resolving global challenges while also bolstering our own financial performance.

Our **Group strategy** aims to maximize our success, which goes hand in hand both with respecting the interests of our employees, customers, shareholders, and communities, as well as mitigating the ethical, economic and social risks. Our corporate responsibility (CR) strategy is underpinned by our Group strategy, and we focus our resources on those areas where we can have the greatest impact. All our CR activities fall under the heading of “responsible governance”, which for us most importantly means looking, listening and doing better.

We take responsibility for our products, the environment and the people around us – especially for our employees and the communities in which we operate. Through our products,

we endeavor to **meet people’s current and future needs**. In doing so, safety and ethical aspects matter just as much to us as business success. In our production activities, we seek to impact the environment as little as possible, which requires safe manufacturing techniques, high environmental standards and strict quality management. Furthermore, we strengthen our company by recruiting, developing and motivating talented employees. We strive to set an example for ethical conduct and actively contribute to the communities we live in.

To quickly identify **new global trends and challenges**, we **engage in dialogues** and initiatives, share lessons learned and best practices with other companies in our industry, and evaluate media coverage. This allows us to minimize risks while also leveraging business opportunities that arise.

In 2018, we realigned our CR strategy, focusing more heavily on generating **sustainable added value** for ourselves as a company and for society. To achieve this, we are taking a shared value approach. In revising our strategy, we modified our three strategic spheres of activity to bring them more in line with our businesses. Our focus areas are now “Global Health”, “Sustainable Solutions” and “Broad Minds”.

Our CR strategy



Global Health

An estimated 400 million people in low- and middle-income countries lack access to adequate, affordable primary healthcare. Hand in hand with our partners, we help provide local solutions and develop treatments for neglected tropical diseases. For instance, we are fighting schistosomiasis using the active ingredient praziquantel. Through our Global Health Institute, we are developing diagnostics, therapies and preventive solutions to address infectious diseases such as malaria and schistosomiasis. Moreover, we are working on therapeutic challenges such as antimicrobial resistance. You can find more information under "[Health for all](#)".

Sustainable Solutions

We are constantly working to improve the sustainability footprint of our products – even during their use phase – which helps our customers achieve their own sustainability goals. To this end, we have established systematic approaches for product development such as our Design for Sustainability program. A program of our Life Science business sector, this initiative allows us to assess the sustainability of products under development through techniques such as life cycle analyses. You can find more information under "[Sustainable product design](#)".

Broad Minds

As a science and technology company, we endeavor to excite people about science, inspire curiosity and help their creativity take flight. Our goal is to bolster our reputation in the field of science, especially in those areas where we have particular expertise. We not only support educational programs for schools, but also back pioneering research at institutes of higher learning. Because music and literature inspire people, we moreover promote a number of cultural initiatives worldwide. Creativity and curiosity are the bedrock of science, culture and art and also underpin our holistic approach. You can find more information under "[Broad Minds](#)".

Corporate responsibility entwined with governance

Our CR strategy is approved by our Executive Board, which meets regularly to make decisions regarding our CR goals and reporting. Also tasked with overseeing corporate responsibility, our Group function Corporate Affairs reports to the chairman of the Executive Board. We moreover have

a CR Committee in place to steer the implementation of our CR strategy and submit recommendations regarding CR goals to the Executive Board. While our Executive Board chairman bears overall responsibility for this body, it is chaired by the head of our Group CR Group unit and consists of representatives from our business sectors as well as from relevant Group functions such as EQ, HR, Compliance, and Procurement.

Our CR Committee also reviews our CR strategy to ensure that it covers the issues material to our company. In doing so, we draw on regular input from our [stakeholders](#) as well as the results of [materiality assessments](#). This council also defines measures to enact our CR strategy and assesses the success of these efforts. In addition, it ensures that the initiatives of our business sectors, Group functions and subsidiaries align with our Group-wide CR strategy. The measures adopted by the CR Committee are implemented by our line managers as well as by interdisciplinary project teams.

In 2018, the CR Committee met three times a year, with its sessions focusing on human rights, environmental and social standards in the supply chain, animal welfare, bioethical principles, and community involvement. Updating our CR strategy was also on the agenda.

Greater focus on UN Sustainable Development Goals (SDGs)

Our CR activities align with the United Nations Sustainable Development Goals (SDGs). The [materiality analysis](#) we conducted this year assessed the contribution our key material topics made to the SDGs. In this analysis, we investigated our direct and indirect impact on the **17 goals and 169 targets** of the SDGs. In general, we particularly focus our CR efforts on those objectives that best reflect our business ethos. You can find more information on our support for these goals under "[Sustainable Development Goals](#)".

Understanding and improving the impacts of our operations

We work to mitigate the ethical, financial and legal risks of our business activities, thereby ensuring our social license to operate. To this end, we have put comprehensive structures and systems in place to ensure compliance with legal requirements, along with ethical, social and ecological standards, all of which are explained in detail in the individual sections of this report.

stakeholder dialogue

Our business activities converge with the interests of many people, which is why engaging with our various stakeholders is particularly important to us. We aim to unite divergent interests as far as possible, as well as build and sustain trust. Through this dialogue, we communicate our decisions and actions transparently in an effort to ensure social license to operate.

Dialogue at various levels

Our key stakeholders include our employees, customers and business partners, patients, the Merck family, and our suppliers. We maintain continuous contact with these groups through a variety of channels such as stakeholder surveys, issue-specific dialogues, roundtable discussions, and information forums. We also engage stakeholders through our advocacy work and industry coalitions.

Our stakeholders



Regular stakeholder dialogue

We regularly conduct surveys among our employees, customers and business partners, as well as other relevant stakeholder groups. We want to know which issues they consider to be of importance to our company now and in the future, along with how they rate our performance in addressing individual issues. We also seek to understand their expectations of us as a responsible company. Our CR report reflects the results of these surveys and presents the actions we have taken in response.

In October 2018 we conducted a **Group-wide employee survey** in 22 languages. Around 45,000 employees took part, representing an 86% response rate.

Issue-specific dialogue

Our business operations in the areas of healthcare, life science and performance materials intersect the interests of various social groups, whom we engage via questionnaires, workshops and seminars, as well as at major conferences. Our departments organize such forms of exchange at the local, national and international level, depending on the topic and degree of importance. Beyond this, we are also involved in industry networks and participate in symposia. In 2018, we intensified our efforts in the following areas:

Protecting public health and safety: We partner with the Pharmaceutical Security Institute ([PSI](#)), a non-profit organization whose main objectives are to protect public health and safety by sharing information on pharmaceutical counterfeiting and initiating enforcement actions via the appropriate authorities. We take an active role in this work through participation in conferences and PSI network meetings. In September 2018 we hosted both the PSI Europe, Middle East and Africa (EMEA) regional meeting and the PSI Technical Forum. The aim of these conferences was to coordinate new actions and share efficient analytical methods and techniques for the forensic identification of counterfeits. Among the participants were safety and analysis experts from 27 pharmaceutical companies, as well as government officials. You can find more information under [Product-related crime](#).

Protecting aquatic ecosystems from trace substances: In 2018, we participated in the second phase of the "Handling trace substances" dialogue through our membership in industry coalitions. A joint effort with non-governmental organizations, other companies, the German Federal Environment Agency, and the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, this dialogue aims to unite divergent interests and identify measures to minimize trace substances in order to prepare a German federal government strategy to protect aquatic ecosystems. You can find more information under [Water management](#).

Towards a responsible mica supply chain: In 2018, we continued to support and promote the work of the Responsible Mica Initiative ([RMI](#)), whose goal is to improve traceability along the Indian mica supply chain through collaborating on specific cross-industry actions. We took part in RMI events with various interest groups and also attended symposia. In April 2018, for instance, we partic-

ipated in the [Terre des Hommes](#) Mica Stakeholder Event in the Hague (Netherlands), which centered around discussions scrutinizing the relevance of mica in the automotive and electronics supply chains. In March 2018 we furthermore attended the Child Labor Platform (CLP) of the International Labour Organization ([ILO](#)) in Paris (France), which focused on eliminating child labor in sandstone and mica mines as well as on cacao plantations. You can find more information under [Mica supply chain](#).

350 years of curiosity: To mark our 350th anniversary, we assumed sponsorship of the Curious2018 – Future Insight Conference. Held in July in Darmstadt, a group of renowned scientists, including six Nobel laureates, presented their research to some 1,300 guests. We also chose the conference as a platform to launch the Future Insight Prize, with which we hope to stimulate the creation of groundbreaking scientific solutions to solve existential challenges facing humanity. The Future Insight Prize will be presented for the first time in 2019, for work on a pandemic protector that can analyze emerging pathogens. You can find more information under [Innovation and digitalization](#).

Roundtables and informational forums

We have set up roundtable discussions and informational forums for local residents at our major facilities. Since 1994, we have been holding an annual public planning forum in Darmstadt to discuss the development of our site with members of the city council, local authorities and the community. In 2018, the forum focused on future worlds of work, for instance how we can create modern workplaces and attract talented employees.

Advocacy groups and industry coalitions

We actively participate in the political process and advocate our views by engaging policy makers in a direct dialogue as well as through our work with industry coalitions. Below are several examples of major national and international industry associations in which we are members and hold positions:

- German Chemical Industry Association e. V. ([VCI](#))
- European Chemical Industry Council ([Cefic](#))
- German Association of Research-based Pharmaceutical Manufacturers e. V. ([vfa](#))
- European Federation of Pharmaceutical Industries and Associations ([EFPIA](#))
- International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)).

Examples of positions held by members of our [Executive Board](#) include:

Stefan Oschmann, Executive Board Chairman and CEO:

- European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)), President
- German Chemical Industry Association e. V. ([VCI](#)), Member of the Executive Committee

Udit Batra, Executive Board member and CEO Life Science:

- [Greater Boston Chamber of Commerce](#), Board member
- [Massachusetts High Technology Council \(MHTC\)](#), Board member
- [University of Delaware, Department of Engineering](#), member of the Advisory Council
- [Princeton University, Department of Engineering](#), member of the Advisory Council

Kai Beckmann, Executive Board member and CEO Performance Materials:

- [German Federation of Chemical Employers' Associations \(BAVC\)](#), President
- [Darmstadt Rhein Main Neckar Chamber of Industry and Commerce \(IHK\)](#), Vice President
- [Fraunhofer Institute for Computer Graphics Research \(IGD\)](#), Chairman of the Advisory Board
- [Confederation of German Employers' Associations \(BDA\)](#), Vice President

Belén Garijo, Executive Board member and CEO Healthcare:

- [Pharmaceutical Research and Manufacturers of America \(PhRMA\)](#), Board member

Marcus Kuhnert, Executive Board member and Chief Financial Officer:

- [German Chemical Industry Association e. V. \(VCI\)](#), Vice Chairman of the Hessian Chapter

Involvement in initiatives

We collaborate with an array of civically engaged organizations such as the [Goethe-Institute](#), the Joint Conference Church and Development (GKKE) (pharma dialogue) and the World Environment Center ([WEC](#)). Furthermore, we are also involved in [initiatives and projects](#) that share our interpretation of responsible entrepreneurial conduct. This is why we support, for instance, the [Code of Responsible Conduct for Business](#) and are members of the [Chemie³](#) and [Responsible Care[®]](#) initiatives.

Political donations

We do not make donations in the form of financial contributions or services to political parties or related organizations. Donations to holders of political office or candidates for such, as well as to political initiatives, must always comply with the statutes in force in the recipient's country. This approach is stipulated in our internal guidelines. In the United States, political action committees (PACs) have been set up through which our employees can donate money to support political candidates and organizations. Such donations are not made by or on behalf of the company; they are reported to the [U.S. Federal Election Commission](#) and publicly disclosed.

Materiality analysis

Part of the non-financial report

Which topics – in terms of our corporate responsibility – are of particular significance to our long-term success? What expectations do our various stakeholders have of us? And in which areas do we contribute to a more sustainable development? In an effort to answer these questions, in 2018, we again conducted a materiality assessment, thereby fulfilling the requirements of the Global Reporting Initiative (GRI) and the German CSR Directive Implementation Act.

Realignment

To decide which topics to include in our report, we regularly conduct comprehensive materiality assessments. With our 2018 Corporate Responsibility (CR) Report, we took this process a step further: Looking at a **broad range of issues**, we considered the topics on which the business activities of our company have a material impact and, conversely, the impact these topics have on our business activities.

Materiality process



Identifying our topics

We first assessed the topics from previous materiality assessments in terms of their relevance before comparing them against the **United Nations Sustainable Development Goals** to determine the impact they have on these goals. As a next step, we discerned which additional sector-specific issues to include.

Analyzing external expectations and requirements

For each of the identified issues, we evaluated various external factors and assessed the impact they have on our business. Such aspects include relevant regulations, our competitors, the financial market, new requirements

of non-governmental organizations (NGOs) on the chemical and pharmaceutical industries, and our economic setting. In conducting this analysis, we drew on relevant legislation, NGO reports and ESG ratings.

Analyzing our own impacts

As well as analyzing external factors, we also evaluated our company's contribution to **sustainable development**. For each of the topics identified, we reviewed the following:

- the influence of the industries in which we operate
- our own positioning as a company
- the number of value chain steps affected
- the importance for our worldwide sites

Results of the analysis

We identified **35 topics** that are of significance to our CR strategy and reporting and weighted them according to their relevance. The results were then discussed, validated and adopted by our [CR Committee](#).

The issues rated as material form the focus of this CR Report. Since our stakeholders also expect information and transparency from us regarding less significant issues, we also report on these, albeit in less detail.

Identifying topics for non-financial disclosure

The German CSR Directive Implementation Act obliges us to review the "double materiality" of topics according to

Section 289 (3) of the German Commercial Code. The **principle of double materiality** requires companies to disclose non-financial information when the following two criteria are met: Firstly, the information is necessary to understand the company's business performance, business results and financial situation. And secondly, the information makes it possible to understand how the company's business activities affect non-financial aspects.

We have reviewed the double materiality of the topics identified. Those that fall within the scope of this definition are marked in the materiality matrix. The topics are linked to the respective chapters in this report.

Material topics

Resource efficiency <ul style="list-style-type: none"> <input type="checkbox"/> Waste and recycling <input type="checkbox"/> Water management 	Product safety and quality <ul style="list-style-type: none"> <input type="checkbox"/> Patient safety <input type="checkbox"/> Chemical product safety <input checked="" type="checkbox"/> Product-related crime <input checked="" type="checkbox"/> Transport and warehouse safety 	Supply chain standards <ul style="list-style-type: none"> <input type="checkbox"/> Supply chain standards
Environmental protection <ul style="list-style-type: none"> <input type="checkbox"/> Emissions <input type="checkbox"/> Plant and process safety <input type="checkbox"/> Energy efficiency and renewable energies <input type="checkbox"/> Greenhouse gas emissions <input checked="" type="checkbox"/> Biodiversity 	Health for everyone <ul style="list-style-type: none"> <input type="checkbox"/> Prices of medicines <input type="checkbox"/> Access to health <input checked="" type="checkbox"/> Health awareness 	Ethical conduct <ul style="list-style-type: none"> <input type="checkbox"/> Bioethics <input type="checkbox"/> Clinical studies <input checked="" type="checkbox"/> Animal welfare
Sustainable products <ul style="list-style-type: none"> <input type="checkbox"/> Sustainable products (including design, packaging and recycling) 	Human rights <ul style="list-style-type: none"> <input type="checkbox"/> Human rights 	Good business practice <ul style="list-style-type: none"> <input type="checkbox"/> Compliance <input type="checkbox"/> Data security <input type="checkbox"/> Advocacy <input type="checkbox"/> Responsible marketing <input checked="" type="checkbox"/> Interactions with health systems <input checked="" type="checkbox"/> Community involvement
Technology <ul style="list-style-type: none"> <input type="checkbox"/> Digitalization <input type="checkbox"/> Innovation and R&D 	Attractive employer <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Health and safety <input type="checkbox"/> Good leadership <input type="checkbox"/> Employee engagement <input type="checkbox"/> Employee development <input type="checkbox"/> Attracting, recruiting and retaining employees <input type="checkbox"/> Diversity and equal opportunity <input checked="" type="checkbox"/> Work 4.0 	

☒ Very high importance
 ☒ High importance
 ☒ Medium importance
 Part of the non-financial report

Material issues in our value chain

The following table shows where our material issues fall within the value chain: upstream in our supply chain, in the course of our own activities, or downstream with our customers and patients. Moreover, we have listed the issues to show the breakdown of materiality by business sector and stakeholder group.



Product safety and quality

Chemical product safety

	✓	✓	✓	✓
--	---	---	---	---

Material for: Customers, Merck family, Shareholders, Government agencies, NGOs, Commercial and business associates

Patient safety

	✓			✓
--	---	--	--	---

Material for: Merck family, Shareholders, Government agencies, NGOs, Health systems, Patients

Product-related crime (formerly Counterfeit products)

	✓			✓
--	---	--	--	---

Material for: Customers, Merck family, Shareholders, Federations and policy makers, Government agencies, NGOs, Commercial and business associates, Health systems, Patients

Transport and warehouse safety

✓		✓	✓	✓
---	--	---	---	---

Material for: Customers, Government agencies, Suppliers, Commercial and business associates, Communities

Ethical conduct

Bioethics

	✓	✓		✓
--	---	---	--	---

Material for: Customers, Federations and policy makers, Government agencies, NGOs, Media, Scientists

Clinical studies

✓	✓			✓
---	---	--	--	---

Material for: Merck family, Shareholders, Federations and policy makers, Government agencies, NGOs, Media, Suppliers, Scientists, Patients

Animal welfare

✓	✓	✓	✓	
---	---	---	---	--

Material for: Government agencies, NGOs, Media, Suppliers, Scientists

Good business practice

Compliance					
Material for:	Employees, Merck family, Shareholders, Government agencies, NGOs, Suppliers, Commercial and business associates, Health systems, Competitors				
Responsible marketing					
Material for:	Customers, Federations and policy makers, Media, Commercial and business associates, Health systems, Patients				
Community involvement					
Material for:	Merck family, Employees, NGOs, Media, Communities				
Interactions with health systems					
Material for:	Federations and policy makers, Government agencies, NGOs, Health systems, Patients				
Governance					
Material for:	Employees, Employee representatives, Merck family, Shareholders, Government agencies, Suppliers, Commercial and business associates, Customers				
Data protection					
Material for:	Employees, Employee representatives, Suppliers, Commercial and business associates, Customers, Patients				

Health for all

Access to health					
Material for:	NGOs, Media, Commercial and business associates, Health systems, Patients				
Prices of medicines					
Material for:	Merck family, Shareholders, NGOs, Media, Commercial and business associates, Health systems, Patients				
Health awareness					
Material for:	NGOs, Media, Commercial and business associates, Health systems, Patients, Communities, Competitors				

Supply chain standards

Supply chain standards

✓	✓	✓	✓	✓
---	---	---	---	---

Material for:

Customers, Merck family, Shareholders, Federations and policy makers, NGOs, Media, Suppliers, Competitors

Human rights

Human rights

✓	✓	✓	✓	✓
---	---	---	---	---

Material for:

Customers, Federations and policy makers, NGOs, Media, Suppliers, Communities, Employees

Sustainable products

Sustainable product design

		✓	✓	✓
--	--	---	---	---

Material for:

Customers, Scientists

Attractive employer

Diversity

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives, Merck family, Media

Attracting and retaining employees

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives, Merck family, Shareholders, Competitors

Employee development

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives

Good leadership

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives

Employee engagement

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives

Health and safety

✓	✓	✓	✓	
---	---	---	---	--

Material for:

Employees, Employee representatives, Government agencies

Work 4.0 (formerly Digitalization of the world of work)

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Employee representatives

Technology

Innovation and R&D

✓	✓	✓	✓	✓
---	---	---	---	---

Material for:

Customers, Merck family, Shareholders, Scientists, Health systems, Patients

Digitalization

✓	✓	✓	✓	✓
---	---	---	---	---

Material for:

Scientists, Commercial and business associates, Customers, Patients

Resource efficiency

Waste and recycling

	✓	✓	✓	✓
--	---	---	---	---

Material for:

Government agencies, NGOs, Communities, Customers

Water management

	✓	✓	✓	✓
--	---	---	---	---

Material for:

Government agencies, NGOs, Communities

Environmental protection

Energy efficiency and renewable energy

	✓	✓	✓	✓
--	---	---	---	---

Material for:

Federations and policy makers, NGOs, Customers

Greenhouse gas emissions

✓	✓	✓	✓	✓
---	---	---	---	---

Material for:

Customers, Federations and policy makers, Government agencies, NGOs, Media, Suppliers

Plant and process safety

	✓	✓	✓	
--	---	---	---	--

Material for:

Employees, Shareholders, Merck family, Government agencies, Media

Biodiversity

	✓	✓	✓	
--	---	---	---	--

Material for:

Federations and policy makers, Government agencies, NGOs

Emissions

	✓	✓	✓	
--	---	---	---	--

Material for:

Federations and policy makers, Government agencies, NGOs

Business ethics

Within this chapter:

21	Corporate Governance	34	Mica supply chain
21	Governance	36	Human rights
22	Compliance	38	Bioethics
27	Responsible marketing	41	Clinical studies
29	Interactions with health systems	45	Animal welfare
31	Suppliers		
31	Supply chain standards		

corporate Governance

Governance

Part of the non-financial report

Alongside Courage, Achievement, Respect, Integrity, and Transparency, Responsibility is one of our six core values and has been an integral part of our corporate identity for 350 years. These core values guide us in our daily work, defining how we interact with our customers and business partners. We research and develop products to enhance life in all its diversity, from the great questions facing humanity to the little everyday pleasures. We endeavor to give patients and customers the best – and find solutions for the world of tomorrow.

Our approach to responsible governance

Our [Values](#) along with the external regulations and initiatives to which we are committed give rise to requirements for responsible governance that are integrated in both our [Corporate Responsibility 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.

Take for example our [Corporate Environment, Health and Safety \(EHS\) Policy](#), which forms the basis for implementing the chemical industry's Responsible Care® Global Charter within our company. Or our Safety Policy for chemical products, which defines product safety processes along with the corresponding management structures.

How we live responsible governance

Derived from the provisions contained in charters, principles and policies, our internal standards give specific guidance to those responsible for operational processes. They are constantly updated by the relevant departments and are available on our Intranet. Our managers implement these standards in their respective areas of responsibility and ensure that they are adhered to. We moreover 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. We regularly undergo [ISO 14001](#) and [ISO 9001](#) certification, which is

conducted by an independent auditing firm, and hold Group certificates for both.

We support the following responsible governance initiatives:

- Since 2005, we have been a member of the [United Nations Global Compact](#) 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 a member of [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. This initiative has developed a system of [40 indicators](#) to measure the progress of sustainable development within the chemical industry.

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 because compliance violations don't just result in possible legal prosecution but could also seriously compromise our reputation as an employer and business partner.

Our approach to compliance

Compliance is one of our primary considerations worldwide. As an international company with operations in developing and emerging countries, we have extremely stringent requirements for effective compliance management. For us, however, there is more to compliance than simply adhering to regulatory provisions. We consistently aspire to act in accordance with the principles defined in our [Values](#) and believe that profitability 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, fraud prevention, 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, are managed by the responsible functions (such as [Pharmacovigilance](#), [Export and Import Controls](#) and [Environment, Health, Safety, Security, Quality](#)).

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

- Efficient solution-oriented systems and processes
- Enabling policies
- Monitoring and controls
- Investigations and case management
- Whistleblowing hotline (SpeakUp Line for anonymous and non-anonymous reporting)
- Continuous improvement tailored to business risks
- Target-group focused training

Our compliance program is regularly updated to reflect new requirements such as those resulting from amendments to legislation, relevant industry codices 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, an update is prepared at the mid-year mark to highlight current developments and the status of relevant projects and initiatives.

Our Group Compliance Officer oversees 77 Compliance Officers around the world, who are assigned to business sector teams and implement the measures of our compliance program within their respective areas of responsibility. In executing their tasks, 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 has the responsibility of 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.

We have successfully integrated our compliance framework more closely within our business sectors. For example, a new holistic concept is being developed, which combines the existing monitoring controls into a single system, providing a dashboard view of potential compliance risks across the organization. Compliance requirements specific to each business sector are also integrated into employee training material.

Designated Compliance Ambassadors support local compliance implementation and operate independently of our Compliance Organization. Located in the various regions in which we operate, these Compliance Ambassadors are global compliance representatives who support compliance initiatives across our businesses and functions, increasing accountability and ownership of business ethics.

Our Compliance Ambassadors are located in the following regions:

- **Europe:** Austria, Germany, Switzerland
- **Africa:** Algeria, Angola, Botswana, Egypt, Ghana, Kenya, Mauritius, Morocco, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Tunisia, Uganda
- **Middle East:** Bahrain, Iran, Iraq, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen
- **Asia Pacific:** China, Japan, Korea
- **Latin America:** Argentina, Chile

Clear chain of command for reporting violations

Any reports of potential compliance violations that we receive via our whistleblowing hotline "SpeakUp Line" are reviewed by the Compliance Investigations and Case Management team and appropriate investigative steps are initiated. Exposed cases showing 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. Duties of the committee include assessing and classifying ethical issues, investigating their background and terminating these issues through appropriate measures. If during the investigation a root cause is identified that could lead to further compliance violations, it is monitored continuously, and preventive or corrective actions are applied. An associated sub-committee advises on disciplinary action if necessary.

Conflicts of interest

We take all potential conflicts of interest seriously, which is why we have dedicated a section of our Anti-Corruption Policy to this topic. It states that employees must strictly avoid situations where their professional judgment may come into conflict with their personal interests, that they disclose every potential conflict of interest to their superior and that they document the disclosure. Such issues are usually resolved directly between the employee and their manager but can also be routed to superordinate HR or employment law functions. We have therefore implemented a specific governance process that also includes the Executive Board and ensures that shareholders and related parties are regularly provided information on potential conflicts.

Beyond this, our commitment to an appropriate conflict of interest process is documented in our [Annual Report](#).

Data Privacy integrated into Group Compliance

Our Data Privacy unit is integrated into our Group Compliance organization. As required by law, this unit acts independently and submits frequent data privacy updates as well as 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.

Our commitment: Guidelines and standards

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

- Our [Code of Conduct](#) provides our people with a tool that promotes ethical business practices. In 2018, we completed the roll-out of an updated version called "What guides us". This version is closely linked to our Values and includes newer topics such as data protection, supplier

due diligence and bioethics. The code has been provided to all employees worldwide both digitally and as a print brochure. Available in 22 languages, it explains the principles for interacting with business partners, employees and the communities in which we operate.

- Our [Human Rights Charter](#) supplements our Code of Conduct with globally valid principles regarding human rights, as well as the core labor standards of the International Labour Organization (ILO).
- 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. We have reinforced our policy by adding and updating relevant corruption prevention sections. One example is the changes made to the gifts and hospitality section. Additionally, we have created guidelines on local limits and thresholds in giving or receiving gifts and hospitality (especially transportation and accommodation) to or from third parties (including public officials and external business partners).
- Our Pharma Code (for prescription medicines) and our Consumer Health Code (for over-the-counter 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 guideline stipulates that all business activities across the Group are to be carried out 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.

We use an **online confirmation process** to send Group-wide policies to relevant managers, Group Compliance and Legal. Recipients then confirm not only receipt of the policies, but also that they are being adhered to and implemented appropriately at the relevant sites. This confirmation process was also used to roll out our Code of Conduct. With this initiated process, we are striving to draw the attention of all our managers and employees to take note of the updated Code of Conduct.

Guidelines for new business units

Where necessary, we update our policies according to external requirements. Our Medical Devices and Services unit falls under the scope of existing Biopharma Compliance policies and we have separate legal and compliance guidance for business interactions with our key stakeholders. We recognize the fact that we are increasingly interacting with patients and patient organizations and have therefore revised our corresponding compliance policy. More information on our commitment to our Code of Conduct and healthcare compliance regulations can be found under [Responsible marketing](#).

Requirements for our business partners

To be effective, compliance management must not be restricted to the boundaries of our own company, which is why 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, adhere to environmental, health and safety guidelines and refuse to tolerate discrimination. 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 via our established global Business Partner Risk Management process – usually every three years, or ad hoc when new risks are identified.

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 and wholesalers. Our Business Partner Risk Management approach is integrated in our Anti-Corruption Policy.

In general, we are not able to negotiate social and environmental responsibility, compliance or integrity issues with each of our customers individually. We therefore employ a global approach for responding to external Code of Conduct acknowledgment requests. To implement this framework, the Corporate Responsibility Letter of Merck KGaA, Darmstadt, Germany and a correlation clause were introduced in 2017.

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) that came into effect in May 2018. We also consider local data privacy requirements, as not all requirements at all sites are covered by EU standards. When in doubt, the respective national legal obligations take precedence.

Compliance audits

As part of operational audits, our Group Internal Auditing function regularly reviews relevant matters at our sites to determine which compliance guidelines, processes and structures are in place and how effective they are. 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 2018, 54 operations were assessed for corruption-related risks.

Compliance training

We provide regular compliance training in the form of classroom and online courses that cover our Code of Conduct, anti-corruption, antitrust awareness, data privacy, and healthcare compliance standards. Employees are requested to attend these courses based on their risk indication, and some are also extended to independent contractors and supervised workers (such as temporary staff). We regularly update our training plan and adapt it to new developments. In 2018, our training concept was reviewed thoroughly with a special focus on formats, media usage, target groups, and frequency, and a refresher concept was included to **strengthen learning measures**. Additionally, a large amount of the training material was reviewed to make sure it addresses the compliance topics in a way that allows employees to better connect to their working environment.

In 2018, we started the roll-out of our business sector-specific e-learning program that is centered on our new Code of Conduct and aims to make employees aware of the consequences of compliance violations. 10,421 people have already been trained as part of the program, which will be made available to all new employees on a regular basis.

Using global slide deck materials that can be adapted for local use according to business and country-specific regulations and situations, local Compliance Officers are now providing classroom **training sessions on the Code of Conduct**. We specifically develop some seminars on special topics with certain roles in mind. When participating in pharma-specific training, for example, employees in our Healthcare business sector also receive training on relevant compliance issues.

We continually educate our employees on new compliance requirements, guidelines and projects. One example is an online course on our Anti-Corruption Policy, which is available in 15 languages. In 2018, a total of 11,404 employees and contractors took part in [anti-corruption training](#).

Also in 2018, in response to the European General Data Protection Regulation (EU GDPR), we redesigned our regular Data Privacy eLearning course, rolling it out in 17 languages.

“Compliance. Because we care”

Our internal “Compliance. Because we care” initiative aims to increase awareness of compliance throughout our Group. Harnessing the power of emotion, this communications campaign engages our employees in the key compliance aspects and thus heightens their sensitivity to and understanding of these issues. Launched in 2017, the initiative is being implemented gradually Group-wide. This style of communicating has also been incorporated in the Code of Conduct and was used to enhance our compliance training materials during 2018.

In addition to providing training via webinars, Skype meetings and on-site events, we inform our staff about compliance issues through a variety of media, including our Intranet, newsletters, posters and our employee magazine “pro”. **Video clips** from all board members strengthen the tone from the top and have been in use since 2018 across different channels including our Compliance Learning Management Platform.

SpeakUp Line for potential compliance violations

All Group employees are encouraged 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, where necessary, by the responsible superiors against employees who have committed a compliance violation. These actions may range from a simple warning to dismissal, depending on the severity of the violation. Our business partners who have undergone the Business Partner Risk Management Process can also use the SpeakUp Line to report violations of internal or external rules.

Both the number of reports of suspected compliance violations and the number of actual compliance cases has increased last year. In 2018, 72 compliance-related reports that led to investigations were received via the SpeakUp Line and other channels. In 2018, there were 19 confirmed cases of violations of the Code of Conduct.

Risk analysis and management of business partners

We apply a risk-based approach to selecting sales-related business partners. The greater we estimate the risk to be regarding a certain country, region or type of service, the closer and more carefully we examine the company before entering into a business relationship with them. For these risk assessments, we use the **Corruption Perceptions Index (CPI)**, which is maintained by Transparency International, and assess potential partners against other parameters such as the nature of the intended business and sales volume. We also tap into 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 3,500 business partners, and in 2018, we used this process to assess 335 business partners.

Ensuring data privacy and information security

We operate a data privacy management system as part of our Group Compliance function. This system has been harmonized across the whole Group. Furthermore, it is necessary to protect our information systems, their contents and our communication channels against criminal activities (eCrime, cyber-attacks) of any kind, including unauthorized access, information leakage and misuse of data or systems. Our Group Security and IT Security units implement organizational, process and technical based information security countermeasures based on recognized international standards. We have harmonized 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 have also implemented a central IT tool to provide a single source for data privacy processes, e.g. 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 2018. In one case, a minor personal data breach was reported to the supervisory authority, which was not sanctioned.

EFPIA and other transparency initiatives

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 developing and emerging countries. Its activities are concentrated in Argentina, Brazil, Ghana and India. The Steering Committee leads the decision-making process for developing measures in these countries, while local advisory groups oversee implementation at the country level. In 2018, our company was elected chair of the advisory group of Ghana. Our local Compliance organizations also collaborate with these groups and offer **training to small and medium-sized companies**. We furthermore support anti-corruption conferences such as the Global Conference of the Alliance for Integrity, which takes place once a year. 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 2018, we engaged stakeholders in dialogue primarily through our memberships in various associations. Amongst 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

Pharmaceutical marketing is regulated by legislation worldwide. In marketing our pharmaceuticals, the wellbeing of patients is always our primary consideration. A variety of internal guidelines shape our business conduct. Since November 2018, we mainly commercialize prescription medicines. In order to strategically focus on innovation-driven businesses, we divested our over-the-counter Consumer Health business.

Our approach to responsible marketing

We adhere strictly to all regulations concerning pharmaceutical marketing. In Germany, for instance, manufacturers are only permitted to advertise prescription drugs to medical professionals such as physicians and pharmacists. These adverts 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 ensure our business activities adhere to the statutory regulations that are applicable to our sales and marketing activities. This unit is further supported by other functions that provide topic-specific expertise to offer further detailed guidance and processes for review. 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 our sales and marketing activities. You can find more details on how we ensure compliance with statutory regulations worldwide 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.

In 2018, we revised ten 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 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 ensure that all promotional materials conform to our rigorous standards. All our 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. We simultaneously revised our internal policy "Items Provided to Healthcare Professionals" 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 industry.

Reviewing marketing material Group-wide

Our aim is to review all promotional material end-to-end to ensure that it meets our standards, 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 more efficiently, 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 where 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 2018, no significant complaints of this kind were sustained against our company worldwide.

We have also established an internal SpeakUp Line that allows our employees to anonymously report potential

compliance violations. If our marketing or advertising rules of conduct are broken, we have a committee in place to take immediate countermeasures. Any violations are dealt with using **appropriate corrective action**. In 2018, we experienced 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. These seminars are conducted locally in a classroom setting but are also offered online and as e-learning courses.

During 2018, we asked newcomers to our company to participate in an **onboarding training** on the topic of "Review and Approval of Promotional Materials and Other External Communications". More than 1,100 employees already took part in a similar training course in 2017. Additionally, employees in charge of marketing and the promotion of pharmaceuticals can also access our respective compliance guidelines via our Intranet.

Direct marketing only in certain countries

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

and we only pursue DTC campaigns in these areas. We use direct advertising to try and 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 also 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 we 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 the customer. When necessary, we work with the responsible authorities to prevent illegal use. In 2018, there were eight attempts to obtain our products for illegal purposes. The business relationship with these customers was terminated.

interactions with health systems

Part of the non-financial report

It is essential that research institutes, physicians, patient advocacy groups and other key players in health systems have access to detailed and up-to-date information on diseases and treatments. We help facilitate this access by sponsoring independent initiatives and medical capacity advancement programs, as well as by donating money and supplies. We also promote outstanding research projects, for example through our Global Grants for Innovation. In all our endeavors, transparency is our number one priority.

Our approach to interacting with health systems

We support health systems by providing information, making monetary contributions and donating supplies to professional medical associations, patient advocacy groups, university clinics and other hospitals. These contributions are absolutely not intended to influence decisions regarding treatment, prescriptions or purchasing. We have therefore committed ourselves to providing **complete transparency**. We prepare detailed reports on our donations that align with industry-wide codes and with statutory requirements such as those governing data protection, and we comply with all applicable laws and industry codes on transparency. In countries that have statutory or industry obligations regarding the transfers of values to health systems, we comply with these and are transparent in our reporting.

How we ensure transparency and compliance at an organizational level

In all interactions with health systems, 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 and communication to all applicable employees. The Global Transparency Operations team of Group Compliance 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 and patient advocacy groups.

Our Internal Audits unit monitors the local implementation of these initiatives. Before entering into a partnership or collaboration with a third party, 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. The [Compliance](#) chapter of this report provides more details on how we implement legal requirements across the Group.

Our commitment: Group-wide guidelines and industry standards

Our "Interactions with Patients, Patient Opinion Leaders and Patient Organizations" policy provides a comprehensive framework for our prescription medicines business. This policy was updated in April 2018 to include more **guidance for interactions with patients and patient organizations** and is directly applicable to our Biopharma business,

Allergopharma and the Foundation sponsored by Merck KGaA, Darmstadt, Germany. Our guideline "Good Practice and Process Guidance: Engagement with Patients, Patient Opinion Leaders and Patient Organizations" provides additional guidance for our interactions with patients and patient advocacy groups. It reinforces our belief that patient well-being is always a top priority. 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. We are also active in the enhancement of self-regulation within the industry, such as in the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) subgroup discussions with patient organizations and industry representatives on delivering guidelines on patient compensation.

Transparent reporting

In 2018, 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 & development activities](#), as required by the EFPIA Disclosure Code. In 2018, EFPIA issued further guidance on the **disclosure of non-interventional studies** (NIS) differentiating between retrospective NIS and prospective NIS for different reporting methods, either on an individual level or in aggregate amount. We have adopted the new requirement in our preparation of reporting from 2018 onward. When the EU General Data Protection Regulation ([GDPR](#)) became effective in May 2018, we revised our global agreement templates with healthcare professionals, healthcare organizations, patients and patient organizations, and the related disclosure consent templates, in relevant countries to ensure all clauses and processes related to transparency reporting are aligned with the requirements of the regulation.

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), the stipulations of the Sunshine Act in the United States and the Loi Bertrand in France. 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.

In 2018, we registered an increase in the number of countries adapting new transparency disclosure rules, including Canada and Saudi Arabia. The province of Ontario (Canada) has passed the Health Sector Payment Transparency Act, which came into effect on January 1, 2019. This makes it the first province in Canada to formally address the transparency of payments made by pharmaceutical and medical device companies. In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) introduced new transparency reporting rules that were implemented on October 1, 2018.

Relevant employees participate in **mandatory online training and classroom seminars**, so that they stay informed about our interactions guideline and policy, and important changes to reporting requirements for transfers of value.

Partnering with patient advocacy groups

Patient advocacy groups support patients, family members and caregivers, providing them with information on disease management. We have 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 donations** by publishing the details of contributions to European patient organizations on our [website](#). The report is updated annually and includes all donation amounts, recipients and the purpose of each donation, thus fulfilling our obligation as a member of EFPIA.

Transparently promoting medical research and education

We sponsor research and continuing medical education around the world so that we can contribute to medical advances that will benefit patients. Through our Grants for Innovation, for example, we support research projects in [fertility](#), [multiple sclerosis](#), [oncology](#) and [growth disorders](#). As of 2018, a total of 99 research proposals have been selected to receive research grants through the Global Grants for Innovation program since its inauguration in 2009.

Through our Global Medical Education and External Relations unit we also provide grants to continuing medical

education providers, enabling them to develop and deliver advanced medical training to scientists, physicians, nurses, pharmacists, and other healthcare professionals. As with our other collaborations, we take an entirely transparent approach to this. All direct and indirect financial support aligns with the principles of EFPIA. According to our internal "Medical Education Funding Policy", all requests for medical education funding are channeled through an **evaluation process** under the responsibility of our R&D and compliance functions. This process ensures that all funds for medical education programs are granted according to established internal guidelines and criteria while also complying with all applicable laws and industry codes.

In 2018, 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 for improving and harmonizing **quality standards for continuing medical education**.

We continue to promote research and education in and for developing countries through a series of programs, with a focus on malaria and schistosomiasis. These research programs, involving African post-doctoral fellows, include, for example, the sponsorship of three PhD fellowships in support to the governmental malaria control programs in Namibia, Botswana and Zambia.

Other examples of research programs enhancing local expertise include collaborations with the University of Cape Town and Medicine for Malaria Venture ([MMV](#)) to identify new potential anti-malarial drug candidates. We also work with the Kenya Medical Research Institute ([KEMRI](#)) to study the impact of schistosomiasis infection on the severity of malaria co-infection in children, and with the European and Developing Countries Clinical Trials Partnership ([EDCTP](#)) in a fellowship program on clinical practices and management.

Introduction of a new compliance tool

In May 2018, we introduced a new compliance tool called Quantum Connect, which replaced our previous tools for supporting the planning, review and confirmation of compliant interactions with healthcare professionals, healthcare organizations, patients, and patient organizations. Quantum Connect stands as a single global tool that is applied to all markets in which we operate. The new software encompasses elements to determine the **appropriate compensation for service engagement** and ensures agreements are compliant with applicable laws and codes, such as the EU General Data Protection Regulation ([GDPR](#)).

suppliers

supply chain standards

Our company procures many raw materials, packaging materials, technical products, components and services from across the world. The overarching goal of Group Procurement, in close collaboration with our supply chain departments of each business sector, is to protect the stability of these supply chains and always provide our customers with the best possible products and services at optimal quality. In this fast-paced world, we believe that secure supply chains are the key to our success. We expect our suppliers to adhere to the same ethical, social and compliance standards as we do.

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've 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. If the risk probability exceeds our risk appetite, we take further actions. For example, we ask the supplier to conduct a sustainability assessment or an audit. This additional step helps our sourcing employees to identify required mitigation actions with relevant suppliers and work on improvements.

We further developed our **supplier and material risk management** and launched a new program in 2018. This program covers our key suppliers and aims to identify, assess, respond, and monitor third-party risks that could have an impact in our supply continuity. It has four main elements:

- **Supplier Risk Assessments:** to capture the overarching risks at supplier legal entity level, including multiple risk domains. This system was tested and implemented in 2018.
- **Alert system:** to notify our Procurement unit when any of our suppliers face a potential disruption. The system was implemented in 2018.
- **Material Risk Assessments:** to capture the risks of relevant materials that make up our most significant finished products. The Material Risk Assessments were aligned with our business in 2018.

- **Risk Response Tracker:** to create and monitor risk mitigation activities. The Risk Response Tracker is currently under development.

A "risk factor" for the Supplier and the Material Risk Assessments is calculated by multiplying risk probability and risk impact. Risk probability considers 29 risk titles such as "Economic freedom", "Social unrest", "Unfair business practices" or "Poor labor practices" throughout the five "risk domains": financial, geo-political, compliance, operations, and sustainability. Risk impact is calculated by considering supplier spend and the number of our businesses impacted. The aspect of risk impact will be further refined to take into consideration the impact to our finished products and our customers.

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 Sustainability** coordinates all relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives. Our Procurement employees in all countries are kept up to date on these guidelines and processes through internal communication channels such as our company intranet. Sourcing staff are responsible for the supplier selection process and collaborate closely with the stakeholders in each business sector. All new Sourcing staff are trained on those sustainability aspects that are of importance for procurement.

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.

Our Group Procurement Policy stipulates **expectations for our suppliers** and specifies how we monitor compliance with our standards. This policy reflects both internal and external guidelines, such as our [Code of Conduct](#), our [Human Rights Charter](#), our [EHS Policy](#) (Environment, Health

and Safety Policy), ISO 14001, and the BME Code of Conduct. In our [Responsible Sourcing Principles](#) we set out these expectations for our suppliers and formally oblige them to apply these standards to their own vendors.

All modifications to legal frameworks are incorporated and appropriate measures are initiated where necessary.

Global procurement

In total, the goods and services we purchased in 2018 from **more than 60,000 suppliers** in almost 150 countries amounted to around € 7.4 billion compared with € 7.0 billion in 2017, representing an increase of 4.8%. Of these (including R&D services), we purchased 50% from suppliers based in EU countries and 35% from vendors based in [OECD](#) countries outside the EU. The share of goods and services sourced from suppliers based in non-OECD countries outside the EU increased from 14.8% in 2017 to 15% in 2018.

Share of overall goods and services purchased



Material use

We primarily use **chemical and pharmaceutical raw materials** for our manufacturing operations, in addition to operating supplies and packaging materials such as folding boxes, glass bottles and ampules. We utilized 487.6 metric kilotons of material in 2018, a slight increase compared to 2017. We only record the weight of the materials that are directly used in our pharmaceuticals and chemicals.

How we monitor our supply chain

A number of different approaches are used to keep track of our suppliers and ensure adherence to our standards and values. These are generally based on the risk they pose, combining the factors of country risk, product category and sales.

- 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.
- 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.

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 150 countries and 190 sectors across the four categories of **Environment, Social, Ethics, and Sustainable Procurement**. The results are shared among TfS member

companies in compliance with all restrictions stipulated by competition law. The strategic focus of the TfS activities concentrates strongly on the initiative's demonstrable improvements of supplier sustainability standards. We've been a member of TfS since 2014.

Via a collaborative platform, we now have access to **evaluated supplier self-assessments of more than 10,700 suppliers** and audit reports from over 1,000 suppliers, partially initiated by our company and partially by other TfS members. Based on all the audits and assessments conducted since joining the TfS initiative, in 2018 we focused on scorecard improvements of our suppliers rather than additional new assessments and audits.

Conducting our own audits

We continuously conduct own audits in selected cases based on business requirements.

Neither our audits nor those of TfS revealed indications of violations of the right of association, the right to collective bargaining, 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.

Mica supply chain

Mica is the primary raw material of our effect pigments, which are used in automotive and industrial coatings and plastic mass coloration, as well as in the cosmetics and food industries. Although it occurs naturally in many places, we mainly procure mica from India, specifically the north-eastern states of Jharkhand and Bihar. This region suffers from political instability and poverty, with widespread child labor, so we've taken special measures to meet compliance with our social and environmental standards.

Our approach to responsibility in the mica supply chain

In procuring mica from north-east India, we are supporting this region by safeguarding local jobs and livelihood. We only source the raw material from formal working environments, such as mines qualified by our company, as this is the only way to monitor compliance with our standards including our ban of 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 mica mining and processing 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 the ban of child labor.

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 self-inspections, we conduct comprehensive announced audits at mica mines and processors, as well as unannounced check visits.

Annual audits

The international consultancy firm Environmental Resources Management (ERM) conducts annual 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.

In 2018, ERM conducted six audits. Identified defects primarily involved occupational safety precautions and gaps in the implementation of management systems. When violations are discovered, we work **together with the suppliers** on corrective measures. When breaches are not rectified, we take further actions up to freezing relations with the respective company or even terminating the business relationship altogether.

Monthly inspections

Since 2013, the [IGEP Foundation](#), a local non-government organization, has been arranging monthly unannounced visits to check the working standards in the mines and at the processors. In 2018, three mica mines and three processing plants were regularly checked. During these visits, IGEP monitors productivity and occupational safety as well as **compliance with the ban on child labor**. They also check whether our suppliers have held mandatory training sessions for their employees. In October 2018, IGEP - supported by one of our EHS specialists - held a workshop on workplace health and safety for our suppliers.

Tracking system for mica sources

We use a tracking system to ensure mica that is supplied to us comes from **mines qualified by our company** and to monitor the productivity of the mines. All mine owners record the daily extraction volume of their mines in a logbook, and we review the volumes of mica reported in the logbook 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 in 2016 and a [report](#) in 2018 by the organization [Terre des Hommes](#) and the [Centre for Research on Multinational Corporations](#).

As part of our efforts, we are financing three schools run by our partner IGEP in Jharkhand, which are attended by a total of almost 500 children and adolescents. All three schools introduced a sixth grade in 2018. This change will contribute to school attendance of **children and younger students**. 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, in 2010 we established a health center operated by IGEP to serve the region's 20,000 residents. Two medical professionals work at the center and also provide regular health services to schools. Previously there was no healthcare of any kind in this region.

In August 2018 we supported a health checkup camp that was run in collaboration with the Indian hospital chain Medanta at two different locations in the state of Jharkhand (India). The first took place in Jhumri Telaiya in the Koderma district with the second one in Tisri in Giridih district. These health camps were visited by more than 1,000 people and gave them access to up-to-date diagnostic tools and doctors without charge. Patients were then provided with initial treatment. The follow-up will be done by our health center. The camps are regarded as starting point for further health camps in the communities.

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 following the Mica Summit 2016. From January 2018 to January 2020, our company holds the presidency of the organization. The initiative aims to eradicate child labor and unacceptable working conditions in the Indian mica supply

chain by **joining forces across industries**. In 2018, we actively supported the RMI's work to improve traceability along the Indian mica supply chain: "Responsible Mica specifications" have been developed and pilot tests on the field have been conducted. To build sustainable living conditions in local communities, the RMI started a community empowerment program in the mica mining area. The goal is to address the root causes of child labor and to improve the livelihood of the local community. In 2018, 40 villages in Jharkhand and Bihar (India), were selected for the program.

We participated in **dialogues with various stakeholders** and at conferences in 2018, such as the Child Labor Platform (CLP) of the International Labour Organization (ILO) in Paris (France), the Mica Stakeholder Event in The Hague (Netherlands) organized by Terre des Hommes and the OECD Forum on Responsible Mineral Supply Chain in Paris. During these meetings, approaches on fighting child labor were critically reviewed and best practices were shared.

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. Part of our mica, for example, is obtained from Brazil. This helps us to secure supply over the long term and avoid potential bottlenecks. We also manufacture effect pigments based on synthetic substrates as an alternative to pigments based on natural mica.

HUMAN rights

First and foremost, all nations have a duty to establish a regulatory framework to protect human rights. As an international enterprise, we in turn also have a duty to uphold human rights, taking steps 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.

Our approach to human rights due diligence

We are committed to upholding and protecting human rights. To this end, we must better understand the potential impact of our business activities and relationships on human rights, as well as identify the practices already in place at our sites that fulfill the function of human rights due diligence. This knowledge helps us adapt our Group-wide human rights due diligence efforts to **better meet local needs** and adapt our processes in response to the respective risk profiles. In doing so, we can develop support programs, strategies and processes to overcome particular challenges. At the same time, we are working to identify the opportunities presented by the positive impacts of our operations.

Within the German Global Compact Network (DGCN), 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

Our Executive Board bears ultimate responsibility for upholding human rights within our organization. Our Group Corporate Responsibility unit handles the **coordination of activities** and processes relating to human rights due diligence. 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.

In 2018, we formed an internal, cross-functional human rights working group that has two overarching objectives. First, it helps us meet our obligation to respect human rights through joint, cross-functional actions. And secondly, it is intended to establish an ongoing dialogue on the subject. The group meets three to four times a year, with the first meeting having been held in November.

In 2018, we also added the topic of human rights to our manual for new managing directors in an effort to heighten awareness at the executive level. The manual is primarily intended to consolidate all the legal and compliance-related responsibilities of a managing director into one document.

Our commitment: Guiding principles, charters and laws

Our [Human Rights Charter](#) affirms our commitment to respecting human rights while also defining the relevant requirements for our company. This charter furthermore

unites and complements existing policies and guidelines on human rights such as our [Code of Conduct](#), our [Corporate Environment, Health and Safety Policy](#), our [Responsible Sourcing Principles](#), and our [Charter on Access to Health in Developing Countries](#). In 2018, we started the process of updating our Human Rights Charter, **partnering with external stakeholders** such as trade unions, business federations and representatives of potentially impacted groups. Additionally, we are currently drafting a Group-wide Social and Labor Standards Policy. Aligning with the core labor standards of the International Labour Organization (ILO), this policy is scheduled for publication in 2019.

At the end of 2016, the German federal government adopted a national action plan for implementing the [UN Guiding Principles](#) for Business and Human Rights. We welcome this plan, which reflects the UN Guiding Principles and sets out the duty of states to protect human rights as well as the responsibility of companies to uphold them. It furthermore provides specific guidance on how the German federal government and German businesses can do so. Through our current efforts and initiatives, such as evaluating our existing grievance mechanisms, we are on the right track to fulfilling the requirements stipulated in the national action plan.

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 2018, our company once again issued our [UK Modern Slavery Statement](#), which has been endorsed by our Executive Board and is available on our [website](#).

Creating awareness

In 2018, we started to implement measures based on the findings from the Group-wide human rights self-assessment of our subsidiaries, which included initiating steps to raise awareness of certain human rights risks. In 2018, we hosted a **workshop on modern slavery**, which was attended by representatives from the Group functions Environment, Health, Safety, Security, Quality (EQ), Procurement, Human Resources, Compliance, and Corporate Responsibility. Human rights and modern slavery were also on the agenda of our annual Global Security Network Meeting in Darmstadt and our Environment, Health, Safety (EHS) forums in Tokyo and Shizuoka (both Japan) and Corsier-sur-Vevey (Switzerland). They were also part of "EHS StartUp!", our EHS orientation program for all new EHS managers in Darmstadt.

Launched in 2017, our Group-wide online course on our Human Rights Charter was successfully completed by 194 people in 2018. This course was mandatory Group-wide for all managing directors as well as all leaders from the first managerial level below Executive Board. In addition to this, Procurement executives from the second and third managerial tiers were also required to take the course, which focuses on modern slavery and the increasing regulatory requirements for companies such as those set out in the national action plan and the UK Modern Slavery Act. By taking the course, participants confirm that they have read and understood our Human Rights Charter and are working to promote its values.

Continually improving our management processes

We are continuing our efforts to further integrate human rights into our operational processes, reviewing our approach to human rights risks and their impacts and working to improve them. We focus on external manpower, product and service sourcing, and collaboration with contract partners. We are currently working to obtain an overview of the use of external manpower Group-wide. Building on these findings, we intend to execute risk-based measures to increase awareness of modern slavery at the local level as well. To support these efforts, in 2018, we developed an interactive database for human rights risks and issues that also covers specific risks in individual countries.

Our annual compliance risk reporting covers human rights issues. In 2018, our Compliance Group function started updating their compliance risk reporting process with human rights and modern slavery now featuring more prominently in our risk reporting and our newly created self-monitoring process.

To reinforce human rights due diligence within our company, in 2018 we reviewed our existing grievance mechanisms, focusing particularly on their scope and effectiveness. Based on the results, in 2019 we decided to open up our SpeakUp Line, previously only accessible to employees, to external stakeholders as well. Grievances can now be reported via a link on our external website.

Human rights and investment decisions

When projects exceed a certain cost threshold, our Investment Committee must approve the expenditure. The committee's decision 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.

Keeping employees informed

We use a variety of channels to educate our employees on human rights, including topical Intranet sites and other articles featuring employees explaining how their work intersects with human rights.

Bioethics

Part of the non-financial report

Bioethics guide us in how to use the rapidly advancing power of life sciences 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 issues arising from the explosive progress in science and particularly molecular biology. In light of this situation, we feel the need to clarify our own position on these issues.

Our approach to ethical business conduct

In our work we encounter various bioethical issues, including animal testing and clinical research, stem cell use, the use of genetically modified microorganisms, and the potential impact of new genome editing techniques such as CRISPR/Cas. We are strongly committed to conducting this research in an ethical manner. **Patient wellbeing 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 biopharma industry. We carefully evaluate our position on controversial topics so that we can make informed decisions that meet the highest ethical standards.

How we assess bioethical issues

The Bioethics Advisory Panel of Merck KGaA, Darmstadt, Germany (MBAP), co-chaired by a senior executive biomedical expert of our company and the Head of our Global Health Institute, gives clear guidance on bioethical issues, which steers our behavior and entrepreneurial conduct. It consists of renowned international experts in the fields of **bioethics, theology, science, and law**. The MBAP meets once a year 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.

We continuously adapt the organizational structure of the MBAP to reflect the current requirements of bioethical issues in all three of our business sectors. In 2018, two experts from Africa and Asia became standing members, having previously had guest status. This has enabled us to further integrate the important views of these regions in our bioethical discussions.

Our dedicated guidance panels for genome editing and stem cell topics continue to 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. Since it was formed in 2011, the Stem Cell Research Oversight Committee (SCROC), for example, has been verifying all internal research proposals that employ **human stem cells** and ensuring compliance with our ethical guidelines and any legal requirements. This also includes collaboration with external partners.

Our commitment: Identifying issues early on

As a global company, it is crucial for us to promptly identify and address new developments concerning bioethical 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.

Bioethics Advisory Panel discussions

In 2018, the MBAP addressed, for the first time, the topic of **Artificial Intelligence (AI)** and related ethical issues. The recommendation was to develop a supervisory board that includes roles and responsibilities for the highly sensitive data that is used in clinical and other applications of AI.

Other topics included new developments in [stem cell research](#), [genome editing](#) and [animal welfare](#).

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 (MA, United States), Beijing (China) and Tokyo (Japan). Major biotech production sites are located in Martillac (France) and Aubonne, as well as Corsier-sur-Vevey (both in Switzerland), which is one of the largest biopharmaceutical production facilities in Europe.

Across our Group, we manufacture our biotech products according to 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 current stance on the technology.

In 2018, the MBAP re-examined the current possibilities and ethical boundaries of genome editing systems and agreed that our Principle did not need to be updated. It was determined to understand more fully the advances in genome editing in agriculture, as well as gene drive technologies, and the associated ethical and country-specific legal implications. A number of MBAP members and scientists of our company pooled their insights to co-author a paper entitled, "**Ethical Considerations in the Manufacture, Sale, and Distribution of Genome Editing Technologies**", which was published in the American Journal of Bioethics. The paper shows that we have become a thought leader in the scientific discussion on genome editing innovations and that we are committed to fostering a broader dialogue in a bid to create lasting buy-in and acceptance for this promising technology.

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. Thereby, 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 that are allowed under the German Embryo Protection Act and the German Stem Cell Law.

During 2018, the SCROC continued discussions on a new Informed Consent Form for the use of induced pluripotent stem cells (iPSCs), which is expected to be finalized in 2019. iPSCs are identical to embryonic cells and can generate every 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.

So far, we do not support 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, and 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 steered by our **Fertility Principle**, which was developed based on guidance from the MBAP and came into force in October 2017.

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, a policy and standard operating procedures have defined our principles and processes of 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. While these are extremely important to our research, their storage and use for research purposes requires us to adhere to stringent ethical standards and all current legislation.

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 has 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, i.e. indications for which the drug was not originally approved. While each medicine is authorized for specific indications, cases do arise in which a physi-

cian 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 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 globally applicable policies. 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 and we never share information on off-label use for commercial ends but provide such information to healthcare professionals only for medical purposes 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.

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 subjects to test the safety and efficacy of these products. These studies generally run for multiple 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 testing.

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 as a whole, and only when the medicines being tested show great 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 extremely important to us, and the confidentiality of all data and information collected is ensured in compliance with statutory regulations.

Clinical studies in developing 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 the healthcare needs in various regions and countries and to support the **development of their healthcare systems**.

In performing clinical studies in developing countries where there is usually a lower level of healthcare and the healthcare infrastructure is less developed, we adhere to all relevant scientific and ethical standards at all times. When we perform studies in developing countries, we also:

- Only do so in an environment in which the principles of Good Clinical Practice can be upheld.
- Only investigate diseases and innovative medicines that are relevant to the local population.
- 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.

- 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. The DDG replaces the former Development Operations Committee (DOC). Decision makers from all relevant functional areas sit on this biopharma committee, thus ensuring 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 studies in pharmaceuticals that are under clinical development, while the Global Medical Affairs Decision Board (GMADB) is responsible for studies involving approved medicines. 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 drug/pharmaceutical 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 has to verify 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**. This important step of exposing humans to an investigational drug is governed by the Human Exposure Group chaired by our Global Chief Medical Officer.

Potential risks for subjects are carefully and continuously analyzed before and during the course of our clinical studies. Our Medical Safety and Ethics Board (MSEB) over-

sees 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](#).

Our commitment: International guidelines and agreements

We have renamed our Clinical Research Policy and extended its scope. The now so-called Human Subjects Research and Development Policy provides the framework for conducting clinical studies and ensures 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](#) from the [Office for Human Research Protections](#), USA
- 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

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 internal **quality assurance audits**. These are planned by the Biopharma Research & 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 subjects must give their explicit informed consent before enrolling in a clinical study. Subjects 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. The subjects are further provided with detailed information.

Every study follows precisely defined procedures to ensure that studies are 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. This approach ensures in particular that studies are designed, conducted, recorded, and reported in line with all applicable requirements. In 2018, once again, no significant issues regarding these clinical study procedures were 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 subjects. In this way, we 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 Subject Information, is updated accordingly. You can find more information 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. As the well-being of the individual is our absolute priority, we involve vulnerable populations only when there is a scientific justification 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.

The Pediatric Praziquantel program led by our company within a [consortium of partners](#) has been implementing clinical trials in developing countries and involving vulnerable populations. The program aims at developing, registering and providing access to a **pediatric formulation** of praziquantel for treating schistosomiasis in children younger than six years of age. Due to a lack of clinical data and no suitable pediatric formulation of praziquantel, this age group currently goes untreated. Following the successful completion of the 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 with children aged younger than six years. The current results confirm the formulation and the dose that will be pursued by the consortium until

registration. Phase III is due to start in 2019 with children in the target age group in Kenya and Ivory Coast.

The clinical program was designed in line with the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) recommendations for pediatric development. It was planned and is being implemented with the support of 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 applies especially to contract research organizations (CROs) performing studies on our behalf.

We have established processes defining the requirements for selection, approval, contracting and oversight-monitoring of CROs. In addition to comprehensive collaboration manuals with a contracted vendor, expectations on the highest quality level of the provided services including roles and responsibilities are specified in detailed quality agreements. Based on a risk assessment approach, vendors are audited regularly against applicable regulations, guidelines and the above-mentioned manuals and agreements. This also applies to study centers (for example hospitals) involved in our clinical studies. In 2018, once again, these audits did not reveal significant non-compliance with the above-mentioned standards.

Close dialogue with patients and advocacy groups

We want to ensure the **voice and needs of patients** are adequately taken into consideration when developing and executing clinical studies. To this end, we have established Patient Advisory Boards (PABs). Our Patient Advisory Boards Charter describes the process on how to involve the Patient Advocacy Groups in our clinical research. During Advisory Board meetings, caregivers and representatives from patient advocacy groups are invited to share their experience and particular perspective related to our clinical trials, plus multiple aspects including but not limited to protocol design, educational materials, and others. This advice and wealth of valuable insight applies to both the design of the clinical trial and its operational implementation. We use this information to render clinical development and clinical studies more patient-centric by sharing the outcomes of the PABs internally. Our Global Clinical Operations organization uses such information in multiple manners with a clear focus on patient centricity in everything we do.

Furthermore, we are involved in the European Patients' Academy on Therapeutic Innovation (EUPATI), a public-private partnership within the Innovative Medicines Initiative (IMI). It initially ran from 2012 to 2017 but we have extended our participation until 2020. EUPATI is a pan-Euro-

pean 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. This partnership has created a suite of resources that is available to better inform patients on the **development process** and the importance of their involvement while also offering them a way to incorporate their needs into the development of clinical studies. EUPATI also aims to improve the availability of objective and reliable information for the public.

Responsible data sharing

We support professional circles in advancing **medical and scientific knowledge**, thereby allowing for informed healthcare decisions for the benefit of patients. To this end, 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 following joint Principles for Responsible Clinical Trial Data Sharing of the EFPIA and PhRMA:

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

Disclosure of clinical studies and publication of results

We are obliged to disclose information 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 United States 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 European Union 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 2018, we provided participants of ten studies with Lay Patient Summaries, which explain clinical study results in plain language.

We make sure that results from our clinical studies are published in medical journals in line with applicable laws and industry codes. In doing so, 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 have 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 strengthened

to mount an immune response against cancer. As part of a strategic alliance with the U.S. pharmaceutical company Pfizer, we are developing **avelumab (Bavencio®)**. This is an investigational anti-PD-L1 (programmed cell death ligand 1) 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 are investigating the potential therapeutic benefit of avelumab in multiple tumor types. As of the end of 2018, more than 9,000 patients have been evaluated within this program.

In 2018, avelumab has continued to gain marketing authorization in several countries including Argentina, Australia, Brazil, Chile, Israel, Lebanon, Mexico, Saudi Arabia, and Taiwan for treatment in patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive form of skin cancer. Previously, we successfully started to market the medicine in the EU, Japan and the USA. Subsequently, avelumab has also been granted regulatory approval in Canada and Israel for the treatment of patients with locally advanced or metastatic urothelial carcinoma (a malignant tumor of the urothelium that lines the urinary tract) that had progressed following platinum-containing chemotherapy. Meanwhile, avelumab continues to be evaluated in several ongoing registrational Phase III studies across multiple different tumor types, including lung, gastric, ovarian, renal cell, and head and neck cancers. Positive top-line results were shown in 2018 in renal cell carcinoma.

Enabling early access to new medicines

Not all patients can take part in a clinical study and so must wait for a new pharmaceutical product to be approved. Through our Early Access Program, we are, under specific circumstances, enabling patients to gain early access to new, potentially life-saving medicines. The offer is aimed at people with serious conditions who have already used all the available therapies without success. It allows them to obtain medicines that have already been clinically tested but not yet obtained marketing approval. 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 have published a [position paper](#) on the Early Access Program on our website.

Support of 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 areas of therapeutic 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, drugs from various manufacturers were tested on children living in institutions in Germany, often in collaboration with (university) hospitals and general practitioners. In 2015, we made files in our **historical archives** at our global headquarters in Darmstadt (Germany) available to researchers, in order to help understand and come to terms with this episode in the history of science. When their work is completed, their findings can be used to make a final assessment of this complex issue. We guarantee full transparency and will do everything necessary to help the affected institutions come to terms with the past.

Animal welfare

From both an ethical and scientific perspective, animal research is indispensable and is furthermore mandated by law. We enforce stringent animal welfare standards that meet and frequently exceed applicable laws and extend these high expectations to our suppliers, contract research organizations and other partners.

Our approach to animal welfare

Animal studies enable us to test both the safety of our chemical and medicinal products, and the efficacy of our pharmaceuticals. We conduct animal testing within our Healthcare business sector as part of the official drug approval process and for biological quality control. Animal welfare is also a prominent issue for our Life Science business sector, where laboratory animals are kept, for instance, for the production of antibodies. Our subsidiary BioReliance conducts animal testing as part 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 research, we pursue well established and tested methods that ensure high-quality results. We strive to replace animal testing 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 required animals
- Refinement - minimizing distress or discomfort before, during and after testing
- Replacement - replacing animal studies with non-animal systems

In 2018, we launched our internal 3Rs Award, which is open to all our employees and which further strengthens our commitment to apply and actively promote the 3Rs in our animal research activities.

We also promote the 3Rs outside our company. Under the International Consortium for Innovation and Quality in Pharmaceutical Development ([IQ Consortium](#)), for instance, we have joined forces with other 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 research to advance ethical science in academia and industry.

How we ensure animal welfare

Through our Corporate Animal Science and Welfare (EQ-A) 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. In 2018, we expanded the

animal welfare auditing team in order to accommodate for increased auditing and AAALAC International reaccreditation demands. All our animal science and welfare officers and experts regularly interact through our global laboratory animal science network. This platform for sharing best practices and lessons learned 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 convenes twice a year to support and advise the Chief Animal Welfare Officer. This council discusses relevant developments and makes decisions regarding our Animal Welfare Strategy. If an employee identifies an internal issue regarding animal welfare, they can file an incident report which will be sent directly to the Chief Animal Welfare Officer or report it via our SpeakUp Line.

In most cases, our sites are subject to additional 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 sits on 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, where he ensures **adherence to European standards**. He has been appointed to the Board of Directors of AAALAC International since the end of 2016 for a three-year term. He is also a member of the German Federal Animal Welfare Commission.

Our commitment: Group-wide methodology and standards

Through our Group-wide [Policy on the Use, Care and Welfare of Laboratory Animals](#), we have made a commitment to global animal welfare principles and the highest possible ethical standards in animal research. In 2017, we

updated this policy to include the work of our Group Animal Welfare Council. The policy further sets out principles on the housing, care and feeding of laboratory animals. We strive to provide our animals with **high-quality living conditions** and consistently seek ways to make improvements. This ethos applies equally to the contracted animal research 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. In 2018, we implemented the Vendor Qualification Standard, which describes our criteria for evaluating the quality of animal welfare practices in our suppliers and partners.

Legal requirements

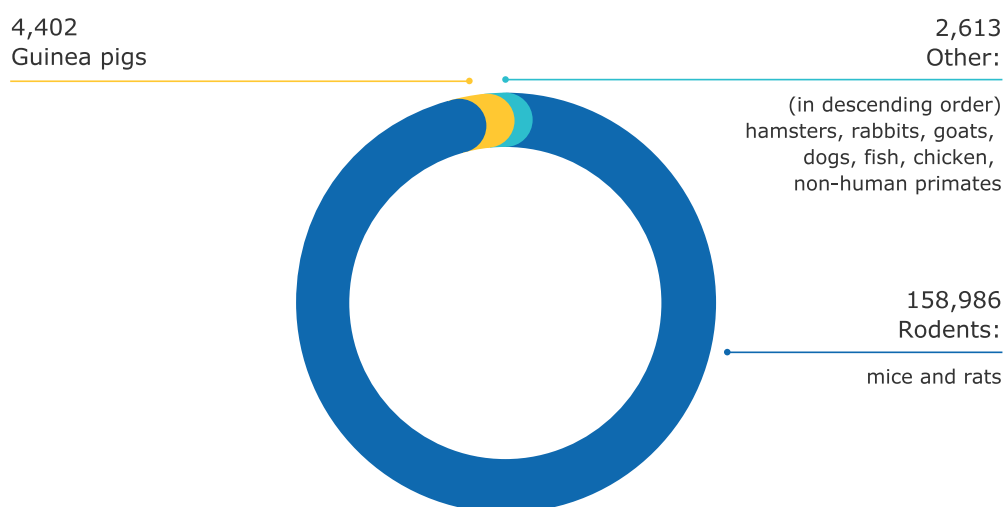
Animal research is only permitted if there are no recognized alternative methods available. In many fields, however,

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 research, such as the housing conditions of laboratory animals, the conduct and approval of studies and the reliability and expertise of all involved individuals.

The majority of laboratory animals are rodents

In 2018, around 166,000 animals were used at Merck KGaA, Darmstadt, Germany. This represents a decrease of 12% compared to 2017. The majority (96%) of the laboratory animals we use are rodents (mice or rats). In addition, approximately 10,800 animals were used by contract research organizations (CROs) in our name and in collaborations with academia. Regulatory agencies sometimes require investigational drugs to be safety tested on 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 research facilities to ensure adherence to our animal welfare standards. In 2018, ten internal audits and ten authority visits occurred. We have initiated the relevant corrective measures where necessary. No critical shortcomings were identified during these audits.

We adhere to the **highest international animal welfare standards** at all times. All our Healthcare laboratory animal facilities and one of our Life Science laboratory animal facilities in the United States have been accredited to the standards of [AAALAC International](#).

Collaborating with partners and suppliers

We perform the majority (95%) of animal studies ourselves and procure our animals from specialized breeders. Sometimes, however, we also hire **contract research organi-**

zations (CROs) to conduct animal research on our behalf. Furthermore, we work with both the private sector and, to a much lesser degree, academic institutions. However, when collaborating with such organizations, we expect them to adhere to comparably high standards as we do, as set out in our Use, Care and Welfare of Laboratory Animals Policy. We verify compliance with this policy through a **risk-based qualification procedure** and, where necessary, conduct audits, typically every three years.

Regularly auditing our partners

We perform regular audits on our animal breeders and contract research organizations to ensure compliance with our animal welfare standards. As part of our work with Interpharma, we have worked with other member companies to develop a **cross-company audit concept** that concentrates on those partners that are relevant to the

maximum possible number of companies involved. The results are shared among Interpharma member companies and treated confidentially. Based on the results of the audits, it is up to the discretion of each company whether or not to collaborate with the respective suppliers. In 2018, the association conducted two audits in Denmark, one in France and one in the United Kingdom.

Comprehensive employee training

We regularly train all employees who work with laboratory animals, thereby ensuring that animal studies are conducted according to the latest scientific standards and that animals receive the best care possible. The nature and scope of this training is 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). The respective local, national and international regulatory authorities monitor our activities to ensure compliance.

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. To minimize discomfort and distress to animals before, during and after testing (refinement), in 2017 and 2018 we successfully implemented our own 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 rehoming program using accepted animal welfare organizations that specialize in laboratory animals. In 2018, for example, we closed down our own dog breeding colony and gave the animals away for adoption.

We actively support the development of **alternative testing methods** and their official recognition at an international level. There is a serious need for action here because animal research 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 sectors seeks to pool knowledge and resources to

accelerate the development of alternative approaches to animal use in regulatory testing. Through our membership in the German Association of Research-based Pharmaceutical Companies ([vfa](#)), we also support the [set](#) Foundation dedicated to researching and developing new alternatives in animal experimenting, which 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 Chairman of the set Foundation Board of Trustees.

Our own scientists are also working on developing alternative methods and have received numerous accolades for their efforts, which includes being presented with the 2018 Animal Welfare Research Award by the Hessian government in Germany. One of our Global Research & Development teams was recognized for demonstrating how animal welfare and cutting-edge research can go hand in hand through the use of innovative housing systems for rabbits and rats that are used in legally required animal experiments when developing medication to treat arthritis.

Other awards that our teams have received include:

- 2014: The Hessian Animal Welfare Research Prize for Alternative Methods to Replace or Reduce Animal Testing
- 2010: The IUTox Bo Holmstedt Scientists Award for Alternative Test Strategies according to the 3Rs
- 2009: The Eurotox Gerhard Zbinden Young Scientists Award
- 2008: The Eurotox Bo Holmstedt Young Scientists Award for Alternative Test Strategies according to the 3Rs
- 2007: The Hessian Animal Welfare Research Prize for Alternative Methods to Replace or Reduce Animal Testing
- 2006: The German Animal Welfare Research Prize awarded by the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) for alternative methods to replace or reduce animal studies
- 2005: The Eurotox Gerhard Zbinden Young Scientists Award

In 2018, we also launched an internal 3Rs Award, which is open to all our employees. The **three winning teams** in 2018 were recognized for providing innovative ways of implementing the 3Rs for animal-based research. One of the winning teams is based in Israel. It found a way to produce monoclonal antibodies using an in-vitro method instead of the animal itself, which has the added benefit of achieving higher yields than conventional production methods. A bio-monitoring team in France was awarded for developing a pyrogene test that does not need to use rabbits as test subjects. This project is currently awaiting regulatory approval. We moreover recognized a team from Italy that developed an in-vitro method, which replaces mandatory growth hormone testing on animals.

products

Within this chapter:

49	Innovation and digitalization	66	Pharmaceutical supply chain
53	Sustainable products	68	Prices of medicines
53	Sustainable product design	70	Health awareness
56	Packaging and recycling	73	Product safety and quality
58	Health for all	73	Chemical product safety
58	Global strategy	76	Patient safety
61	Focus programs	79	Product-related crime
64	Open innovation sharing	82	Transport and warehouse safety

Innovation and digitalization

Part of the non-financial report

We develop products and technologies that enrich people's lives and are constantly on the lookout for ground-breaking developments and trends. Research and development (R&D) and innovation are the cornerstones of our success. In 2018, we spent around € 2.2 billion on R&D, corresponding to 15% of our net sales. New technology and the advance of digitalization in particular enable us to create innovative technologies, products, services and pioneering business models. At the same time, digitalization is decreasing the time-to-market for new ideas, which creates opportunities we intend to leverage.

Research and development costs by business sector¹ – 2018



¹ Not presented: Research and development costs of € 47 million allocated to Corporate and Other.

Our approach to innovation and digitalization

Our three business sectors Healthcare, Life Science and Performance Materials, have established strategies to drive new product developments for the benefit of patients and our customers. The diversity of these business sectors provides us with a breadth of technologies and depth of market know-how, giving us a competitive advantage in developing new products.

When deciding where to invest, we analyze current megatrends to determine the innovation fields in which we see potential for new business. We endeavor to identify innovation projects that transcend our current portfolio and develop them from the initial idea all the way to a functioning business model. This can only succeed if our business sectors work closely together and if we are open to external momentum. Our **end-to-end innovation process** seeks to achieve exactly that.

Our Group function Strategy and Transformation facilitates innovation between the individual business sectors and beyond our current business scope. It oversees an end-to-end process that ranges from **setting the innovation direction**, through ideation, incubation and growth of projects to establishing long-term business models.

We push the progress of promising projects as quickly as possible from the brainstorming and idea generation stage to an incubation and growth phase, where we provide project teams with a suitable environment to develop their business models and scale-up. Projects are monitored in a lean, gate-based process, with strict criteria applied at each gate to evaluate progress. All activities are **supported by experts** in business model design, business development, market research and agile methodologies. The objective is that, after market launch, the new products or services will make a measurable contribution to our business success.

Driving digital innovations

A major focus of our innovation efforts is digitalization, and we want to leverage related opportunities to boost our business performance. We therefore increasingly form new strategic partnerships with organizations that offer different perspectives. The following areas are those in which we expect to see progress:

- **Research and development:** Digital technologies enable us to access and quickly analyze large volumes of data, thereby accelerating our research and development activities. This is especially the case in our Health-care business sector, where we are working to advance the development of new drugs to provide patients with faster access to effective medicines.
- **Supply chain management:** Digital technologies help us to better manage our supply chain. Collating all data centrally gives us access to crucial real-time data. This enables us to predict supply bottlenecks around the world and respond promptly to make sure medicines reach their destination when needed.
- **Production:** We set up the infrastructure to capture data throughout all stages of our production processes and apply advanced data science methods to optimize our manufacturing methodologies.
- **Digital product innovations:** Digitalization enables us to broaden our existing product portfolio to include, for instance, new digital services. We also promote health awareness and improve disease awareness and patient treatment through innovative e-health offerings such as our Diabetes Online Risk Assessment ([DORA](#)).
- **Interactions with customers:** Thanks to modern data collection and analysis methods, we can make more efficient use of customer-relevant data. This information allows us to adapt our products and services where necessary.

You can find more information on research and development in our [Annual Report 2018](#).

How we drive innovation

The organizational set-up of our research and development activities reflects the overall structure of our company. All three of our business sectors operate their own independent Research and Development (R&D) units, which are aligned with their individual innovation strategies. In 2018, our Group function Strategy and Transformation **developed a new end-to-end process** that covers innovation both between and beyond current business sectors and is responsible for implementation. This function reports directly to the CEO and Chairman of the Executive Board.

Our Innovation Committee (IC) oversees the implementation of innovation projects both between and beyond our business sectors. It is tasked with ensuring that the decision-making process for selecting innovation projects is both transparent and consistent and reviews the progress of ongoing efforts. The committee consists of senior executives from our Group functions and our three business sectors. For projects requiring larger-scale investments, the IC consults our Executive Board.

INFO

OUR THREE INNOVATION FIELDS IN THE INNOVATION CENTER

Bio-Sensing and Interfaces

This innovation field focuses on the interface between the biological and digital world. The goal is to utilize data analytical tools to enable faster and more accurate (remote) monitoring and treatment of health in numerous areas.

Clean Meat

This field concentrates on the biotechnology required to produce meat in laboratories so that it is healthier, more efficiently produced, ethical, and environmentally sustainable.

Liquid Biopsy technologies

This area focuses on non-invasive alternatives to traditional tissue-based diagnostics like liquid biopsy, thereby reshaping methods of detecting and managing various diseases.

Whilst we are open to innovation around the world, many potential partners for these projects are based in Silicon Valley (California, USA), which is one of the key sites in the global high-tech industry. We are therefore currently building an innovation hub in Silicon Valley to be closer to innovation partners there, be it companies or institutions. The Silicon Valley Innovation Hub aims to scout new technological opportunities and establish partnerships and projects within our three innovation fields.

Discovering new technologies through collaboration

In 2018, our Silicon Valley Innovation Hub signed a partnership agreement with, among others, the Bao Group at Stanford University. Using our liquid crystals as the enabling technology, Bao is working on Liquid Crystal Elastomers, often referred to as **artificial muscle**, making it the most promising candidate for developing wearable haptic sensor-actuator systems.

Our China Strategy and Transformation Group is responsible for driving our strategy in this fast-evolving market. The China Innovation Hub was set up in 2018, with the mission to **boost innovation through collaboration** between current businesses, and cooperate with Chinese start-ups, academic institutions, business partners and local governments to explore new innovation fields. In spring 2019, the first batch of start-ups will be hosted by the China Innovation Hub.

M Ventures is our strategic, corporate venture capital arm. It invests in innovative technologies and products with the potential to significantly impact our core business areas. M Ventures has a significant focus on **early stage**

investing and company creation, including the creation of spin-offs to leverage our science and technology base, and takes an active role in its portfolio companies. The fund has a total volume of € 300 million and has the mandate to invest in the areas of Healthcare, Life Sciences, Performance Materials and New Businesses.

Our commitment: Protecting innovative ideas

We are committed to ensuring the confidentiality of sensitive information, especially of intellectual property in digitalization projects, and to protecting our innovative ideas. Our Policy for Data Protection and Personal Data Privacy defines the standards that govern how we process, save, use, and transfer data. You can find more information on data protection under [Compliance](#).

Spotlight on the Innovation Center

We completed the construction of our new Innovation Center in Darmstadt (Germany) and moved into the premises in early 2018. It was officially inaugurated during our 350th anniversary celebrations on May 3, 2018 which were attended by German Chancellor Angela Merkel.

The Innovation Center offers our people and external partners an optimal environment in which to cultivate their ideas and scale them up to viable new business. We provide the infrastructure needed to advance **cutting-edge projects**, along with state-of-the-art methods and tools. It currently hosts 22 innovation projects. In September 2018, the Innovation Center was nominated for the National German Sustainability Award.

Our bi-monthly Innovators' Club brings together a diverse range of external and internal experts to share insight and debate about a range of topics, from curiosity research and new work order to novel innovation methodologies. These events are open to anyone with an interest in innovation, from start-ups to company experts and other interested employees, and even other organizations.

Synergizing external ideas: Start-ups and cross-industry collaboration

Numerous start-ups around the world are working on new technologies and innovative business models. Our Accelerator program supports selected enterprises in their development, with a focus on initiatives that align with our business sectors and other current trends. In return, we gain insights into the innovative start-up scene and are able to identify **emerging market trends** early on. Our primary goal is to link these start-up companies with our innovation projects or our business sectors for future collaboration. In 2018, we accepted ten start-ups into the Accelerator at our Darmstadt headquarters. Following the end of this three-month program, we are already working on an innovation project with one of the start-ups and are in talks with eight others regarding future collaboration.

In 2018, we started our Africa Satellites program in Nairobi (Kenya), Lagos (Nigeria) and Cape Town (South Africa). These satellite engagements will enable us to foster our network in the African founders' scene and to scout cutting-edge start-ups for our Accelerator program. As part of the program we organized a hackathon in Cape Town

(South Africa). Also in 2018, we started to accept applications to our China accelerator program, which will be run by the China Innovation Hub from 2019 onwards.

Our Accelerator is complemented by hackathons, two of which were carried out at the Innovation Center in 2018. One of them was a so-called Makerthon in collaboration with Deutsche Telekom. Over three weeks in late 2018, almost 80 young students and professionals provided hardware solutions to different challenges where **healthcare and technology intersect**. At a final pitch event at our Innovation Center, the teams were offered the opportunity to present their solutions to the two host companies.

We support the start-up program HIGHEST 1877, which is run by the Technical University (TU) of Darmstadt (Germany). We were Silver Sponsors of the Startup and Innovation Day held in October 2018 and also participated as jury members.

In 2018, we continued our two-year partnership with the European Space Agency (ESA) through which we hope to leverage synergies in areas such as innovation, digitalization and materials research. We hosted astronaut Thomas Reiter, who gave a speech to our R&D employees about research options in space, and we took part in the panel discussion "Space Meets Non-Space" at the ILA Berlin, a leading aviation industry exhibition. We were also a partner of the "Space Exploration Masters", initiated by the European Space Agency (ESA), which annually awards the best business ideas that bring the benefits of space exploration closer to society by way of products and services.

Channeling internal ideas to generate innovation projects

We want to maximize the innovative power within our company, which is why we give our employees around the world the opportunity to present their ideas to us via various channels. Our objective is to identify ideas between our business sectors and beyond our current scope that have the potential to become viable new businesses. Our **Innospire** (innovation and inspiration) initiative encourages employees to submit ideas for new products, services and business models. The best suggestions are then developed into business plans in a multi-stage process. More information on this topic can be found under [Employee engagement](#).

The most promising ideas that are sourced through channels such as Innospire become innovation projects, and we offer employees the chance to focus on their innovation project by hosting them in the Innovation Center. In addition to financial backing we provide a protected ecosystem and dedicated support, as well as clear governance and decision-making to efficiently grow and scale innovation projects into sustainable future businesses.

Our **Innovator Academy** strives to unleash the innovation potential of idea-givers, internal project teams, members of Think Tanks and start-ups. It offers a wide range of development programs, methodologies and online and offline trainings. Besides an online training platform, webinars are offered introducing employees to the topics and contents of the Innovation Center through practical examples.

Third Displaying Futures Award

The aim of our annual Displaying Futures Award, run by our Performance Materials business sector, is to support teams from academic and institutional backgrounds. In 2018, the target topic area was **"smart medical devices"**. Submitted by creative minds and start-ups from 19 countries, the number of ideas we received rose from 69 in 2017, to 97 in 2018. A panel of judges selected the three winning teams by considering important criteria such as innovativeness, business potential and social impact. The winners enter into a year-long partnership with our company, which will culminate in a final event in summer 2019 where they will be able to pitch their ideas to investors.

Maximizing the opportunities of digitalization

Through our strategic partnership with Palantir Technologies, a company based in California (United States), we are able to use their data analysis capabilities to improve and accelerate the development, commercialization and delivery of new medicines. The access to Palantir technology has enabled us to create tools that help to improve patient retention, increase sales rep efficiency and aid in strategic targeting to deliver effectively on our product launches. We can also now integrate and analyze large amounts of data to improve our operational excellence.

Syntropy

Syntropy is a joint venture being formed by Merck KGaA, Darmstadt, Germany and the California software company Palantir Technologies. The partnership aims to give scientists and research centers access to a technology platform that integrates different types of datasets across an organization into a singular point of access. In this way, experts can collaborate more effectively on research on cancer and many other diseases.

Advances in medical research over decades have created a wealth of knowledge about diseases and how to treat them. This includes biomedical data. Massive amounts of this data are trapped within silos and between institutions and are inaccessible to the scientists and clinicians who need it to advance their research. Syntropy will **create a network** that drives discovery and improve human lives.

Improving customer experience through artificial intelligence

We are currently developing **chatbots**, which are text-based dialogue systems that enable people to ask computer systems questions in natural language – exactly as they would write messages to another person. This means we are available to answer questions from our customers 24 hours a day. In the future, for example, patients with multiple sclerosis will be able to order refills for their RebiSmart® injection device via chatbot. Future chatbots may even be capable of reminding patients to order a refill. Chatbots are more cost-effective for us than traditional customer services.

Development of a Global Data Science Team

In 2018, we built up a global data science team of around 30 data scientists to leverage the huge potential in advanced analytics and machine learning. The team works with eCommerce data to provide insights to our customers and business teams in Life Science, using **image recognition techniques** to support the work of clinicians and researchers in our Healthcare sector, and assisting in the research and innovation process in Performance Materials. In addition, we have established a global data science community, bringing together over 250 analytics professionals from around our company. One milestone of this development was when around 120 employees participated in our first internal Data Science conference in June 2018.

Promoting visionary research

During our 350th anniversary year we were the main sponsor of the Curious2018 - Future Insight Conference. The conference, which took place in July in Darmstadt (Germany), brought together top scientists from around the world to discuss the future of science and technology. More than 60 renowned speakers, including **six Nobel laureates**, presented their work to around 1,300 invited guests. We intend to establish Curious Future Insight as a flagship conference, a forum at which the brightest minds in science and entrepreneurship can share their work and develop visionary solutions to tackle global challenges. The conference will take place again in July 2020.

During the conference we also launched the **Future Insight Prize** to stimulate innovative solutions enabled by ground-breaking science. We want to help drive the development of what we call dream products. These are products that don't yet exist but that might solve some of the existential challenges to mankind. We plan to grant up to € 1 million every year for the next 35 years to researchers who contribute to making these dream products a reality. The first Future Insight Prize will be awarded in 2019, for achievements in the field of pandemic preparedness.

In 2018, we also held the **Innovation Cup Anniversary Edition**, which brought together some of the brightest students from all over the world with experienced professionals to develop new ideas into convincing business plans. A jury made up of top scientists and entrepreneurs selected the best business plan and awarded € 20,000 to the winning team. In addition, in 2018, we started a series of science competitions and rolled out the **350th anniversary research grants**.

Rewarding inclusive innovation

In September 2018, we hosted the European final of the "Inclusive Innovation Challenge" in Darmstadt (Germany) as the exclusive European partner. The competition was initiated by the Massachusetts Institute of Technology (MIT) Initiative on the Digital Economy and aims to **accelerate technology-driven solutions** enabling greater economic opportunity for employees around the world. The challenge awards over US\$ 1 million in prize money. Organizations and companies from around the world can take part with technological solutions to shape the future of work.

sustainable products

sustainable product design

Respect for the environment is at the heart of sustainable conduct. We see it as our duty to not only conserve resources when developing our own products, but to also help our customers increase the sustainability of theirs. Our Life Science business sector develops solutions to make research and biotech production simpler, faster and more efficient, while our Performance Materials business sector focuses on solutions for the electronics market, for example semiconductor or display materials.

Our approach to sustainable product design

Our individual business sectors take different approaches to sustainable product design. In our Life Science business sector, we aim to reduce the impact of our products on health and the environment. This applies to the **entire life-cycle**, from manufacture and use to disposal. At the same time, we seek to make our products more efficient and user-friendly, asking ourselves right at the start of product development how to best reconcile these requirements.

Our Performance Materials business sector develops and produces numerous products that in turn help our customers manufacture sustainable and environmentally compatible goods. Our aim is to develop smart products that allow people to save energy in everyday life. The avoidance of hazardous materials is a principle that is embedded in the product development process.

How we include sustainability in product design

The Corporate Responsibility (CR) unit within our Life Science business sector is responsible for coordinating and driving product-related sustainability. This includes our Design for Sustainability (DfS) program for **eco-friendlier life science products** as well as **DOZN™**, a web-based tool for assessing greener alternatives.

Our Performance Materials business sector has its own CR Committee comprising representatives from all Performance Materials business units and other relevant internal units. The committee functions as a platform to discuss CR issues and meets three to four times per year.

The responsibilities described here also apply to product **packaging and recycling**.

Our commitment: Chemicals and product policies

To meet the product safety regulations relevant to our company, our **Regulatory Affairs Group Policy** details Group-wide processes for managing and implementing product safety, including the necessary management structures.

Our processes for sustainable product design

Within our Life Science business sector, a variety of approaches help our experts to drive sustainability improvement during the development of products and packaging:

- With our Design for Sustainability (DfS) program, we have developed a comprehensive approach to increasing the sustainability of Life Science products through the analysis of different sustainability criteria.
- Our Life Science researchers are using a green chemistry assessment tool to develop innovative solutions in line with the 12 Principles of Green Chemistry developed by chemists Paul T. Anastas and John C. Warner.
- Our in-house-developed **web-based tool DOZN™** enables us to assess the green alternatives of various chemicals, thereby creating transparency for our customers.

The following guidelines also set out **requirements** for sustainable product design within our Performance Materials business sector:

- The Green Product Policy ensures that we adhere to all national and international laws and statutes (e.g. **REACH** and the European Union **RoHS Directive**), as well as to industry and customer-specific requirements.
- Our raw materials for the cosmetics industry fulfill the high standards of the Cosmetics Directive and are produced in line with Good Manufacturing Practices for Cosmetic Ingredients (**EFfCI GMP**). As part of a regular process we reviewed the EFfCI GMP in 2018 and communicated the results to the plant managers operating in the field of Surface Solutions. A new manual for cosmetic suppliers was also made available in 2018.

Sustainable product design in the Life Science business sector

Through our Design for Sustainability (DfS) program, we have developed a comprehensive approach to increasing the sustainability of Life Science products. The DfS program provides our product developers with a range of tools that enable them to analyze the impact of the product on the following areas: materials, energy and emissions, waste, water, packaging, usability and innovation. For each of these areas we have developed several sustainability criteria that are noted on a **scorecard**. When developing a new product, our aim is to improve on as many of these criteria scores as possible. We conduct product life cycle analyses to understand the potential environmental impacts within different stages of the product life cycle. The findings of these analyses show us how we can improve our products

and are incorporated into subsequent development stages. During this process, experts from R&D, Product Management, Quality, Procurement and other departments are in constant contact with one another. By the end of 2018, 27% of these product development projects met three or more product sustainability criteria.

We are currently working on enhancing our DfS program, with the aim of helping our development teams better account for environmental impacts during the product development process and improving communication of sustainability attributes to our customers. In 2019, we intend to integrate the changes to the program into our product development process. The improvements will especially **involve our suppliers**, with specific criteria aiming at encouraging the majority of them to participate in the [Together for Sustainability](#) industry initiative. In 2018, we ran a first product development pilot project for which we engaged 10 suppliers of consumable parts who represent more than 85% of the manufacturing cost of the product.

Green chemistry assessment tool

In addition to DfS, our Life Science researchers are developing innovative solutions in line with the twelve Principles of Green Chemistry developed by chemists Paul T. Anastas and John C. Warner. These aim to make research **as environmentally compatible as possible** and to minimize negative impacts on human health. More than 750 greener alternatives to conventional products have been made available so far.

Our in-house-developed [web-based tool DOZN™](#) enables us to assess the green alternatives of various chemicals, thereby creating transparency for our customers. Under DOZN™, the twelve Principles of Green Chemistry provide a framework for rating our products **in three major stewardship categories**, namely "Improved resource use," "Increased energy efficiency" and "Reduced human and environmental hazards." The system calculates scores on each substance based on a range of data that includes the Globally Harmonized System of Classification and Labelling of Chemicals ([GHS](#)) as well as the Material Safety Data Sheet information. To date, we have used this matrix to assess and improve more than 40 products. It is our goal to make the tool available to our customers in 2019, so that they can evaluate the environmental footprint of their activities.

Wide range of solutions

Our Life Science portfolio comprises a broad array of products, each with different properties that are taken into consideration when applying our DfS approach and the Principles of Green Chemistry. The following examples illustrate the results.

Greener laboratory filters

We have significantly reduced the environmental footprint of our [EZ-Fit™ Manifold](#) laboratory filter, and it now requires 47% less raw material than its predecessor, the Hydrosol Manifold. The packaging is 100% recyclable cardboard and, overall, 99% of its parts are recyclable. Because the heads can be easily removed for cleaning, it is no longer necessary

to autoclave the whole device, which saves energy and results in a 91% reduction in the carbon dioxide emissions produced during cleaning.

Greener chemistry

Our greener, **bio-based solvent** Cyrene™ is derived from waste cellulose. This solvent is used as a more sustainable alternative to substances such as dimethylformamide (formic acid), which is classified as teratogenic. Through Cyrene™ and other [greener solvents](#), we are helping our customers make their production processes safer and more environmentally sustainable. Cyrene™ was shortlisted for the "innovation of the year" at the Ethical Corporation's 9th Annual Responsible Business Awards in 2018. We've teamed up with leading institutions and start-ups to co-develop other green solvents. In contrast to conventional solvents, these are based on natural resources such as corn cobs and sugar cane bagasse, making them eco-friendlier, more biodegradable and easier to recycle.

Eco-friendly lab water use

In mid-2017, we launched Milli-Q® IQ 7000, a new lab water purification and monitoring system. It uses mercury-free UV oxidation lamps and has a hibernation mode to save energy while still preserving system water quality. We were able to reduce the system footprint by 25%, and the cartridges by 33%, all of which **cut down on the amount of plastic used**, packaging and transportation, as well as waste levels.

Current product examples from Performance Materials

Our Performance Materials products help boost sustainability in a variety of ways:

Energy-efficient displays

Our [liquid crystals](#) provide high picture quality in LCD TVs, computer monitors and many more electronic devices, while also making them more power efficient. Self-aligned vertical alignment (SA-VA) is the next-generation liquid crystal (LC) technology and was launched in 2018. SA-VA helps conserve resources and is **even more environmentally sustainable** because less energy and solvent for the orientation layer are required to manufacture the displays. Moreover, its manufacture is more efficient as it requires fewer process steps. Furthermore, since SA-VA technology can be processed at lower temperatures, it is also suitable for sensitive materials such as those used in premium products, or for forward-looking applications such as flexible displays. Our [reactive mesogen](#) materials can also be used for ultra-thin optical films to improve the visual performance of LC and OLED displays, making them suitable for potential new flexible-type displays.

Mobile-device displays have increasingly high resolutions yet are still expected to be as energy-efficient as possible. This is where our liquid crystals for touchscreen applications come in. Based on ultra-brightness FFS technology ([UB-FFS](#)), these liquid crystals provide displays with 15% more light transmission. This can reduce the energy consumption of smartphones and tablets by around 30%,

thereby **prolonging battery life**. UB-FFS also enhances picture resolution. Devices with the innovative UB-Plus liquid crystal technology and with a significant reduction in energy consumption are expected to enter the market in 2019.

Switchable windows

Windows that can be darkened in a matter of seconds are now a reality thanks to our **liquid crystal window** (LCW) technology. These darkened windows regulate the heat generated by direct sunlight. The LC material was commercialized under our **licrivision®** brand, and in October 2018 a new brand for the product was launched under the name **eyrise™**. Initial estimates show that this technology can lower the energy consumed by building climate control systems by up to 40%, thus replacing conventional sun shading. We have invested € 15 million in the construction of a facility in the Netherlands to manufacture these switchable glass modules, which began deliveries in 2018. In response to market demand, we prioritized solar control during 2018, and we have three sophisticated architectural projects in the pipeline to be fitted with solar control LCWs.

We were able to realize the first commercial project in October 2018: large solar control windows for the company Orkla in Oslo (Norway). Furthermore, we presented a selection of these innovative architectural solutions at the trade fair "BAU 2019", where we focused on our **eyrise™** technology. Among other things, we showed an iconic building design by renowned Brazilian architect Oscar Niemeyer. The building is currently being constructed for the company Kirow Ardelt in Leipzig (Germany). We also help partner companies build their own window production using our liquid crystal materials.

OLEDs – organic light emitting diodes

Organic light-emitting diodes (OLEDs) increase the energy efficiency of displays while also providing brilliant colors and razor-sharp images. To further enable unique display applications and efficient production of large-area OLED displays, we are developing high performance OLED materials for vacuum evaporation methods and printing processes.

Our OLED production is designed with cost and resource efficiency in mind. Here, we also work together with our customers: When OLED materials are installed, some production material always remains in the used containers and machinery. Our customers can collect this residual

production material and send it back to us. We then prepare it so that it reaches its original quality again and can be reused. This approach saves **valuable resources** and benefits the environment.

Life cycle approach to benefit our customers

At the plants where our effect pigments are produced, we focus on saving energy and reducing CO₂-output. In 2018, this led to an 18% overall CO₂-reduction for plants, which operate for our Surface Solutions portfolio. This is especially relevant for those customers who want to reduce their upstream **CO₂ footprint**. We also conducted a gap analysis on the origin transparency of raw materials, the sustainability in product development and product sustainability. In the Surface Solutions area of our Performance Materials business sector, we use around 600 metric tons of renewable materials for the production of commercial products. This is mainly by extracting the natural compound glycerol from a variety of plant-derived oils.

More natural-based cosmetics

Responding to the ever-growing popularity of natural cosmetics, we are working closely with our customers in the cosmetics industry. Our cosmetic formulations comply with strict criteria and by the end of 2018, 68 of our cosmetic pigments and actives were certified according to Ecocert's COSMOS standard for organic and natural cosmetics. We also obtained **halal certificates** for our **Eusolex T** and UV-Titan product ranges. Our aim is to develop more natural-based raw materials for use in cosmetics in the future.

Alternative to plastic microbeads

We manufacture mineral-based pigments and functional fillers that are used by the cosmetics industry. Our **RonaFlair® functional fillers** series provides an alternative to plastic microbeads that are used in skin care products. Through this range of 27 innovative products, we are supporting initiatives such as the declaration of Cosmetics Europe, which advocates a phase-out of microplastics in rinse-off products by 2020. Microbeads are tiny, non-biodegradable polymer particles that cannot be filtered out by wastewater treatment plants. They end up in marine and terrestrial ecosystems, where they can harm the organisms living there. We are continuing to develop other functional fillers that don't make use of microbeads.

packaging and recycling

Packaging protects our products from external influences and ensures that they reach the customer undamaged. Packaging must therefore remain intact across the entire product life cycle to guarantee safety. We are working to reduce the amount of material we use, as well as increasingly utilizing eco-friendly materials where possible. We have also put recycling programs in place to help our customers properly dispose of and recycle our products and packaging.

Our sustainable packaging strategy

We aim to deliver our products in packaging that is safe and easy for customers to handle, and as sustainable as possible. With more than 300,000 products in our Life Science portfolio – ranging from biochemicals to lab chemicals, from filter materials and systems to instruments – we face a variety of challenges when it comes to packaging. We strive to improve the sustainability of this packaging to help both us and our customers reduce the environmental impact. To achieve this, we have developed a sustainable packaging strategy for Life Science that is built on the three pillars of optimizing resources, using more sustainable materials and designing for **circular economy**. In 2018, goals and targets were defined in collaboration with internal stakeholders from Sourcing, Distribution and the Global Packaging Material group. In December 2018, we started implementing and internally communicating our sustainable packaging plan.

We have set four goals that build on these three pillars:

- Reduce amount of packaging
- Achieve zero deforestation
- Improve plastic sustainability
- Maximize recycling

Internal targets relating to these goals have been defined up to the year 2022 and we have identified initiatives that will be implemented in order to achieve them.

Design for Sustainability program

Our Design for Sustainability (DfS) program supports our Life Science business sector in creating products with reduced life cycle impacts. This process focuses on utilizing recyclable or reusable materials that can be easily recovered or separated. Through DfS, we are continuously working to reduce the **ecological footprint** of our products and make disposal as easy as possible for our customers.

Making packaging more sustainable

A great deal of our packaging is fiber derived from wood. We are constantly working to increase the proportion of corrugated cardboard boxes certified to the standards governing **sustainable forestry**, including the Sustainable Forestry Initiative (SFI), the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC). As part of reaching our “zero deforestation” goal by ensuring that none of our fiber-based packaging materials contribute to deforestation, we are currently defining new procedures on how to track the percentage of wood- and fiber-based packaging materials that are certified

by at least one of these standards, so that we can report this figure in the future.

Cellulose and air cushions replace polystyrene and foam

In the past, glass reagent bottles were secured using expanded polystyrene (EPS) molded foam to prevent them from breaking during transport. While EPS, also known as Styrofoam®, is an excellent cushioning material, it is manufactured from non-renewable petrochemicals and difficult to recycle. By contrast, molded pulp components can be easily recycled with other paper materials and compacted together for storage and transport. We employ a substitution program in which we replace EPS as far as possible with molded components made of cellulose and recycled paper pulp.

We are already using molded pulp inserts to pack some of our 4x4 liter, 4x2.5 liter and 6x1 liter bottles in shipping boxes, thereby replacing around two million EPS parts per year. We are currently conducting safety tests on new pulp designs for shipping other bottles of various sizes. Overall, we used approximately 669 metric tons of molded pulp packaging material in 2018.

We seek **eco-friendly alternatives** to ship our products safely, which is why we are also working with a specialist biotech company to develop a more sustainable bulk-packaging design to transport our Millistak+® Pod Disposable Depth Filter. A life cycle assessment showed that we achieved a 24% reduction in used corrugated cardboard, which translates to a 17% decrease in greenhouse gas (GHG) emissions from the life cycle of the packaging materials. Moreover, 70% less time is required at our customers in the processing of products and their packaging.

More cardboard instead of plastic

Whilst solvents are usually packed in plastic bottles, we use Titripac® because it offers a more eco-friendly alternative. The cardboard carton and plastic liner with an integrated withdrawal tap have made the packaging **more recyclable** while also cutting its weight by more than half. As a result, the greenhouse gas emissions arising across the entire product life cycle are 61% lower than for plastic bottles. Because the withdrawal tap protects the product against contamination, the contents can be used to the very last drop, thereby reducing chemical waste.

Reusing expanded polystyrene (EPS) boxes

Many of our Life Science products need to be kept cool during shipping and are therefore packed in special EPS boxes. To mitigate waste, we offer our customers in the

United States the option of returning these boxes to us. If they are still fully functional, we reuse them. In 2018, this amounted to more than 14,000 boxes being reused at least once, making up around 5% of shipments leaving the three distribution centers where this type of packaging is being used.

Integrating stainless steel canisters in production

In China, Korea and Taiwan, our Performance Materials liquid crystal mixtures are delivered to display manufacturers in stainless steel canisters. Our customers utilize these standard canisters from our company directly on their production lines without decanting. The empty canisters are then sent back to us and cleaned. In 2018, 1,374 standardized canisters were in circulation within this closed system, which allows them to be reused over multiple years.

Steel instead of glass

Thanks to our bulk product delivery system, our solvents are delivered to Life Science customers based in the United States in special **reusable** steel containers such as the EMD ReCycler®. Our customers can return empty stainless-steel containers to us for refilling, enabling us to significantly reduce the consumption of primary packaging materials. In 2018, we filled more than 14,000 reusable containers.

In Europe, we also utilize reusable stainless-steel containers to deliver solvents that are required in bulk for preparative chromatography. Our customers send the empty containers back to us, where they are properly cleaned and then reused. Approximately 32,000 of these serialized stainless-steel containers are currently in circulation. The rate of return is at around 90%.

New sustainable membrane packaging for cut disc filters

With the objective of helping customers meet their own sustainability goals, we have redesigned membrane boxes

for our cut disc filters. The membrane box packaging has been re-engineered for usability and reduced environmental impact. The newly redesigned membrane box packaging is manufactured using 22% less plastic and replaces polystyrene with polypropylene that has a 43% lower global warming potential than polystyrene. Other environmental impact enhancements include elimination of foam inserts and **local sourcing** of materials, resulting in less transportation and fewer emissions. This new design also reduces GHG emissions by 180 metric tons per year across the entire product life cycle. A life cycle assessment conducted on this new packaging design features the following sustainability improvements over the previous design:

- 22% reduction in weight of product packaging
- 33% reduction in GHG emissions
- 27% reduction in non-renewable energy

Recycling program updated

In cooperation with a waste-management company based in Massachusetts (United States), we employ a comprehensive recycling program for our Life Science customers in the United States. Product waste from their research labs and biopharmaceutical manufacturing operations is collected, sanitized and recycled into plastic lumber. This material can be used in many industries, such as construction, landscaping, transportation and marine construction. The program includes our [Biopharma Recycling](#) and Ech2o Collection **Recycling Programs**.

We are continuing to expand this program throughout the United States and are exploring options in other regions such as Europe and Asia. The program now serves twelve customers. Since launching the program, we have recycled 2,738 metric tons of waste generated from the use of our products, including 1,218 metric tons in 2018 alone.

Health for all

Global strategy

Two billion people across the globe do not have adequate access to health. We are striving to make health solutions affordable, raise awareness of diseases and teach people how to manage them. We are working with committed partners to tackle this complex challenge by researching innovative solutions, developing new approaches and improving existing programs to help people at the point of care.

Our approach to improving healthcare of underserved populations

Our aim is to create a healthier future for all: for individuals, communities and countries. We want to use innovation in science and technology to improve the health of underserved populations in low- and middle-income countries. To achieve this, we are leveraging our expertise from all business sectors and collaborating closely with a wide range of partners. We also participate in industry-wide initiatives and work with other businesses to develop new approaches.

In 2018, we refined our **Global Health strategy** for addressing the global needs that impact access to health. Our strategy is designed to overcome access barriers for underserved populations and communities in developing countries in a business-integrated and sustainable manner, thereby creating "shared value." For us, creating shared value means developing business models that increase the value and competitiveness of our company and at the same time solve unmet health needs and bring value to underserved populations, thereby creating a win-win-situation for us and society.

In order to address unmet needs whilst strengthening health systems and our position in the market, we follow three core operating principles:

- **Developing innovative solutions:** we take a leading role in the elimination of schistosomiasis, and we create new integrated drug, diagnostic and vector control solutions for infectious diseases.
- **Engaging cross-sector partners:** we participate in multi-stakeholder global health platforms to help achieve the Sustainable Development Goals. We utilize access alliances for our solutions and create locally based opportunities where possible.
- **Creating business opportunities via a shared value approach:** we help sustainably improve the health of underserved populations by drawing our portfolio from across all three of our business sectors.

We have created focus programs to address our priority areas. We want to be instrumental in the elimination of schistosomiasis and fight malaria and other infectious diseases whilst helping to build local capacity across the value chain and positioning our company as a leading and reliable partner.

Activities within our strategy for global access to healthcare are generally related to one of four areas:

- **Availability:** we research, develop and refine health solutions that address unmet needs, tailoring them to local environments. For example, we are committed to the [Drugs for Neglected Diseases initiative](#).
- **Affordability:** we seek to provide assistance to those who are unable to pay for the health solutions they need, for example through our [Patient Access Programs](#). This also includes addressing challenges surrounding pricing and intellectual property.
- **Awareness:** we help raise awareness for diseases and therapies by empowering medical professionals, communities and patients to make informed decisions. One way to do this is through our [global awareness campaigns](#).
- **Accessibility:** we promote initiatives that strengthen supply chains and develop localized health solutions. Medicines should reach the people who need them quickly and safely, as demonstrated in our [NTDeliver project](#).

How we are improving access to healthcare

Our Global Health unit coordinates the implementation of our strategy for global access to healthcare. Several teams work on ways to investigate and reduce the barriers that make it difficult for underserved populations to receive healthcare.

Our Global Health unit is responsible for Group-wide initiatives, programs and sponsorships that relate to global health topics. Our experts collaborate closely with the Healthcare, Life Science and Performance Materials business sectors to effectively leverage their strengths and competencies.

Integrated into our Global Health unit, the Global Health Institute seeks to provide **research and development capabilities** in order to engage in health system strengthening programs and develop a sustainable portfolio of treatments, diagnostics and preventive measures against infectious diseases. The Institute operates as a social business enterprise, using innovative financial mechanisms to deliver innovations for those who are most vulnerable: women and children in the developing world.

Our Access to Health subunit investigates the factors that make it more difficult for underserved populations to receive healthcare, working with various partners to develop ways to remove these barriers.

Our Praziquantel Donation Program, the third subunit, coordinates our efforts to [eliminate schistosomiasis](#) together with our external partners.

Our commitment: Providing a solid basis for access to healthcare

To demonstrate our commitment to access to healthcare, we publish a dedicated [Access to Health Charter](#) on our website. This charter sets out guidelines on the following:

- Our approach
- Pharmaceutical product donations
- Fake medicines
- R&D for infectious diseases
- Pharmaceutical product pricing
- Intellectual property rights

Every two years, the [Access to Medicine Foundation](#) publishes the [Access to Medicine Index](#), in which it benchmarks 20 of the world's largest research-based pharmaceutical companies on activities and initiatives that experts consider most relevant for access to medicine, ranging from donations, and patents to capacity-building. We use the ranking to inform and, in certain cases, guide our access to health strategy and approach.

We endorsed the [London Declaration on Neglected Tropical Diseases](#) when it was launched in 2012. Participating companies, governments and private organizations promise to help control or even eliminate the top ten most prevalent infections. We are particularly engaged in the fight against schistosomiasis.

Access to Medicine Index Ranking 2018

We have maintained our ranking of **4th place** in the 2018 Index, a recognition of our company's integrated strategy on access to medicine, our efforts across the whole value chain to address the needs of unserved and underserved populations, and our commitment to shared value.

The company has been particularly recognized by the Access to Medicine Foundation for leading practices such as:

- Establishing the Global Health Institute to accelerate R&D, incorporate access provisions and build capacity for [projects and initiatives targeting schistosomiasis, malaria and bacterial infections](#)
- Joining the Drugs for Neglected Diseases initiative's NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis as part of company's commitment to [Open Innovation](#)
- Improving access to better therapies in diabetes, cancer, hypertension, and fertility in underserved regions through our Capacity Advancement Program.
- Joining "[Access Accelerated](#)", a global initiative with multiple programs including our Capacity Advancement Program, which affirms our commitment to measuring impact and sharing results publicly via the Access Observatory
- Disclosing publicly the patent statuses for small molecules in scope via the [Pat-INFORMED](#) platform with 20 leading research-based pharmaceutical companies and in collab-

oration with the World Intellectual Property Organization (WIPO)

The 2018 Access to Medicine Index ranking and the report card for our company can be accessed here: www.accesstomedicineindex.org

Partnering to develop clinical capacity and skills

In order to advance global access to healthcare, it is necessary to develop trained and **professional clinical personnel**. We are collaborating with the European & Developing Countries Clinical Trials Partnership (EDCTP), which supports international fellowship programs for post-doctoral researchers from developing and emerging countries. In addition to receiving training on clinical aspects such as clinical trial practices and clinical management, research fellows are also given the opportunity to work for a period of up to 24 months at a number of leading pharmaceutical enterprises, including our own company. They are then able to return to their home countries and academic institutions with the knowledge they need to implement their research in line with international regulatory requirements and standards, as well as to train other local students to also help them enhance own their skills.

Engaging Stakeholders

Partnerships and dialogue are important instruments for improving access to healthcare, and we aim for stakeholder dialogues that have a large-scale relevance and impact. Our partners include multinational organizations, government agencies and NGOs, as well as academic institutions, health industry associations, private sector companies and independent experts on global health topics.

Alliances for better access to health

We are a member of the Business for Social Responsibility (BSR) initiative and have also endorsed the [BSR Guiding Principles on Access to Healthcare](#), which provide a framework for us to refine and enhance our Global Health efforts.

In 2017, we joined forces with 21 other leading pharmaceutical companies to launch [Access Accelerated](#), a global initiative that seeks to improve both the treatment and prevention of non-communicable diseases in low- and middle-income countries.

Our Access Dialogue Series

Our [Access Dialogue Series](#) were launched in 2013, as a multi-stakeholder platform for sharing information and **exchanging best practices** on broadening access to healthcare. We are always looking for opportunities for collaborative actions. The outcomes of the series inform and drive our access strategy, plan of action and engagements. This process is intended to be an open space for insightful and critical dialogue on how we and our partners can best use our respective capacities, experience, expertise and competencies to sustainably address access barriers. In 2018, we hosted an event on open innovation and intellectual property as well as supply chain and delivery.

Discussions at a global level

We participated in many events in 2018, that had a global reach or relevance. To position ourselves as a key player for global health, we continued to engage major stakeholders in a dialogue on infectious diseases, and to deepen collaborations with the scientific community through publications and primary roles at international scientific conferences and events. We were also part of stakeholder groups including the [Swiss NTD Alliance](#) and the [Swiss Malaria Group](#).

Selection of events and initiatives:

- International Society for Neglected Tropical Diseases ([ISNTD](#)) conferences in London (United Kingdom) in March and June 2018
- World Malaria Day, including a 'Malaria Screening Campaign and a Scientific Forum' attended by the First Lady of Ghana in Accra (Ghana) in April 2018
- Multilateral Initiative on Malaria (MIM) – 7th Pan African Conference on Malaria, in Dakar (Senegal) in April 2018
- World Health Assembly in Geneva (Switzerland) in May 2018
- 15th [International Symposium on Schistosomiasis](#) in Rio de Janeiro (Brazil) in August 2018
- 9th European & Developing Countries Clinical Trials Partnership ([EDCTP](#)) Forum 2018 in Lisbon (Portugal) in September 2018
- World Health Summit in Berlin (Germany) in October 2018, panel on "Access to Essential Medicines"
- 67th American Society of Tropical Medicine and Hygiene ([ASTMH](#)) in New Orleans (United States) in October/November 2018
- Access Dialogue Series: Supply Chain & Delivery in January 2018 and Innovative Intellectual Property and Access in November 2018
- Hosted Fellows from the African Public Health Leaders Fellowship at our Vevey manufacturing site in November 2018

FOCUS programs

So-called neglected tropical diseases are concentrated almost exclusively in impoverished populations in the developing world. Barely known in industrialized nations, they attract little public attention and research funding. One poignant example is schistosomiasis. Our aim is to help in providing urgent action to prevent and control these neglected diseases, as well as more familiar ones such as malaria.

Strategy for preventing and treating infectious diseases

Our strategy is to not only develop and provide medicines, but also to improve diagnosis, counter disease transmission, increase disease control and strengthen local health systems. We seek to improve healthcare in developing countries by creating **novel and integrated health solutions** for infectious diseases and by ensuring the sustainable implementation of these innovations, many of which are led by our Global Health Institute. Our Group-wide initiatives and programs particularly address the medical needs of women and children.

Our comprehensive Global Health portfolio includes the following programs:

- Development of a pediatric formulation for praziquantel to treat schistosomiasis in children under the age of six
- Development of a new active ingredient to treat and prevent malaria
- Screening of our compound library in search of potential new active ingredients to treat schistosomiasis and malaria
- Development of diagnostic kits for schistosomiasis and malaria
- Development of products and technologies to enhance prevention of disease infection and re-infection

In addition, we engage in activities that address bacterial infections and antimicrobial resistance, for example by developing assets for antibiotic quality and laboratory capacity to detect antimicrobial resistance, improving the use of antibiotics by healthcare providers and patients, and helping define industry-wide guidelines for the control of antibiotics.

Our fight against schistosomiasis

Schistosomiasis, also known as bilharzia, is one of the most prevalent parasitic diseases in Africa, placing a great burden on public health and the local economy. The disease affects over **200 million people worldwide**, with more than 90% of cases occurring in Sub-Saharan Africa. Around 10% of those affected are preschool age children. An estimated 200,000 people die every year from the effects of schistosomiasis, such as liver and kidney infections, bladder cancer and blood loss.

In the 1970s, we partnered with Bayer to develop a medicine called praziquantel. Today, praziquantel remains

the standard of care for the effective treatment of schistosomiasis around the world.

We have been partnering with the World Health Organization (WHO) since 2007, regularly providing them with donations of praziquantel tablets. Over time, we have built up a portfolio of pioneering R&D projects on schistosomiasis. These include:

- a new pediatric formulation of praziquantel to treat children under the age of six
- the screening of our proprietary compound library through a dedicated schistosomiasis drug discovery platform
- the development of innovative and highly sensitive schistosomiasis diagnostic methods
- the setup of approaches for vector control
- health education programs that help prevent transmission

Our fight against malaria

According to estimates by WHO, nearly half of the world's population is at risk of malaria. More than **200 million cases of malaria** and over 400,000 related deaths are recorded every year with 70% in children under five years of age. Around 90 different countries are affected by the disease, with approximately 90% of deaths occurring in Africa.

There is an urgent need for new products to overcome the problem of increasing drug resistance and to achieve the goal of complete eradication. Through our Malaria program, we are well positioned to help deliver integrated and sustainable health solutions against malaria (treatments, diagnostics, prevention methods) to endemic countries. In our efforts, we closely collaborate with a wide range of partners in both developed and developing countries.

Schistosomiasis: Over 900 million donated tablets

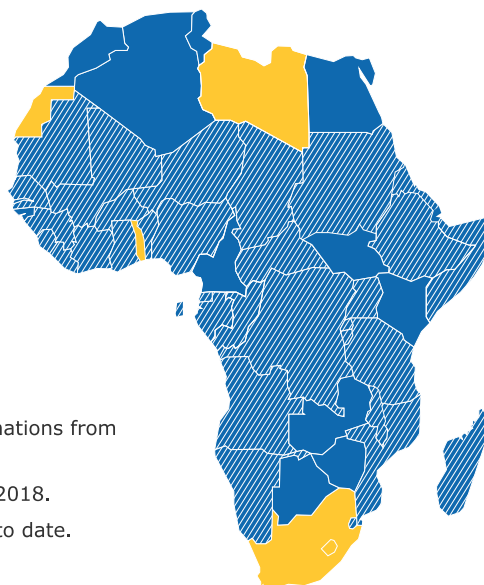
As part of our long partnership with the World Health Organization that dates back to 2007, we agreed to donate praziquantel tablets every year for distribution in African countries. This year, our donation program was expanded to include Burkina Faso, Niger, and Sierra Leone, and now covers a total of 46 countries. In 2018, we donated approximately 200 million tablets for distribution in 34 countries, and we keep our commitment by maintaining production capacities to a level sufficient for manufacturing up to 250 million tablets a year.

Countries that have received donations of praziquantel tablets

Since 2007, we have donated almost **900 million** tablets of praziquantel, which is enough to treat around 360 million school-aged children.

- African countries that started receiving tablet donations from us since 2007*.
- ▨ African countries to which we donated tablets in 2018.
- Countries that have received no donated tablets to date.

* Launch of our Praziquantel Donation Program.



Schistosomiasis Health Education Project

We have been working with the [NALA](#) Foundation since launching the Schistosomiasis Health Education Project in 2017. Through this partnership, we are donating nearly € 300,000 over a period of three years to support the Federal Ministry of Health in Ethiopia in promoting the long-term behavioral change that is needed to help **eliminate schistosomiasis** and other neglected tropical diseases. The project targets a population of 850,000 in Bench Maji, a region in southwestern Ethiopia, with a focus on approximately 260,000 students in 290 schools and includes distribution of customized educational material and improving water sanitation and hygiene facilities through a community-based approach. In 2018, activities were launched in all 74 schools of the Bero and South Bench districts of the Bench Maji region, reaching almost 70,000 students in total. The goal for 2019 is to extend this model to two other districts.

Central platform in the battle against this parasitic disease

Since schistosomiasis is a complex disease, a coordinated, multi-sectoral approach is needed to combat it. We joined forces with international partners from various sectors to address the remaining gaps in the fight against this infection and initiated the Global Schistosomiasis Alliance ([GSA](#)) in 2014, to coordinate and increase the impact of our efforts. The founding members of the GSA include the [Bill & Melinda Gates Foundation](#), the Schistosomiasis Control Initiative ([SCI](#)), the United States Agency for International Development ([USAID](#)) and [World Vision International](#).

In 2018, the GSA acquired additional international stakeholders as new members. As well as organizing several conferences and key meetings, it took part in various projects aimed at driving local efforts to combat schistosomiasis. The GSA is also working to promote and support an **international action plan** to progress schistosomiasis

control and eventually achieve elimination of the disease. The GSA continues with its efforts to raise awareness through campaigns such as [#MakingSchistory](#), which began in 2017.

Partners in schistosomiasis research

The need for a more sensitive diagnostic is crucial in the fight against schistosomiasis. Since 2017, we have been collaborating with the Australian Institute of Tropical Health and Medicine at James Cook University in Townsville (Australia) and with the Baylor College of Medicine in Houston (United States) to research new biomarkers in order to develop diagnostic tools for schistosomiasis. A collaboration with the Bill and Melinda Gates Foundation and the Foundation for Innovative Diagnostics started in 2018, with the objective of developing innovative **rapid diagnostic solutions** for schistosomiasis.

Praziquantel is an effective and well tolerated drug, but it is not active against all development stages of the parasite. Research activities have continued in collaboration with many partners in developing and developed countries. This discovery work searches for new, long-lasting compounds to treat juvenile forms of the parasite, improve efficacy and prevent reinfections. One potential compound has been identified and is currently in the pre-clinical research phase. We also continued supporting academic research into a new genome editing method for **vector control** to combat schistosomiasis.

We have been fostering research and development as well as manufacturing capacities and know-how in endemic countries through collaboration with local academic and public institutions. We have been implementing a series of research programs on schistosomiasis involving African post-doctoral researchers. New initiatives and opportunities were also assessed to tackle female genital schistosomiasis and its impact on HIV/AIDS.

Consortium for the development of Pediatric Praziquantel Formulation

If left untreated at preschool-age, schistosomiasis can have long-term effects such as stunted growth and an impaired learning ability, causing chronic diseases like bladder cancer or genital schistosomiasis. Since July 2012, we have been working within the [Pediatric Praziquantel Consortium](#), with representatives from both the public and private sector including funding organizations, with the goal of developing a pediatric formulation of praziquantel for all children under the age of six.

Following initial Phase I studies and a taste evaluation, we completed a Phase II study in Ivory Coast to assess the efficacy and safety of two different formulations for orodispersible tablets in schistosomiasis-infected children under the age of six. The results indicate that both formulations are well tolerated and confirmed one formulation for further development. The process for the active pharmaceutical ingredient has been developed and is being transferred to a contract manufacturing organization.

In 2018, two new partners joined the Consortium: the Kenya Medical Research Institute (KEMRI) and the Université Félix Houphouët-Boigny in Ivory Coast. Both will play an important role in implementing the **Phase III trial**, which is due to start in the first half of 2019. This trial comprises the confirmatory clinical study in schistosomiasis-infected preschool-age children and is co-funded by the Consortium, the European & Developing Countries Clinical Trials Partnership (EDCTP) and the Global Health Innovative Technology Fund (GHIT Fund). Regulatory submission is planned in 2020, and we expect the product to be available for launch in the first endemic countries in Africa in 2021.

Accurately diagnosing malaria

Malaria is hard to distinguish from other infections that cause a high fever. Reliable diagnostics are needed to correctly identify patients suffering from the disease so that the appropriate treatment can be administered to the right population. We have been working on a kit containing a **novel malaria detection and typing test** adaptable to the MUSE[®] cytometry platform. It aims to accurately diagnose malaria and measure the type of malaria parasite as well as the infection level. This malaria kit was launched for research use in 2018. At the end of 2018, we sold the underlying technology platform developed by our Life Science business sector to the U.S. laboratory supplier Luminex, which is now commercializing the diagnostic kit.

Enabling the treatment of children

We have been developing a new, **innovative drug** for the treatment of malaria since 2015. The new compound is intended to be developed as a single-dose combination treatment to treat and potentially prevent malaria in children. The Phase I study in healthy volunteers in Australia allowed the safety of the compound to be assessed, and a Phase Ib study provided data to support clinical proof of principle. These clinical activities have been supported through a grant by the [Wellcome Trust](#), a biomedical research charity based in London.

The program is progressing towards the next phase, which entails the development of the asset in combination with another anti-malarial compound in acute uncomplicated malaria. The clinical development plan is also being defined with new clinical studies in patients to start in late 2019 or early 2020.

Developing new lead programs

Our strategic collaboration with the University of Cape Town in South Africa has led to the development of a new research and development platform. In 2018, this collaboration, including our collaboration with the Medicines for Malaria Venture, was extended to continue screening activities with the aim of identifying **new therapeutic solutions** for malaria while building research capacity in and for Africa. This program continues to leverage our proprietary chemical library of almost 100,000 compounds to identify new lead programs for the treatment of malaria, targeting liver-stage forms of the parasite and long-lasting compounds to improve post treatment prophylaxis. This program is co-funded by the [German Federal Ministry of Education and Research](#).

A separate collaboration involving two research centers in Portugal, Instituto de Biologia Experimental e Tecnológica (IBET) and Instituto de Medicina Molecular (IMM), saw progression in the development of a new cell model of liver-stage malaria infection. This model could serve as a screening tool for novel anti-malaria drugs.

Preventing and controlling transmission

To help prevent the spread of malaria, we are working to improve access to insect repellent as a vector control method. Through internal and external collaborations, we are working towards demonstrating the **efficacy of IR3535[®]** against malaria in Africa. IR3535[®] is used in insect repellents for complementary prevention from vector borne diseases, such as malaria, dengue fever, Zika, Chikungunya, and Lyme disease. The repellent has the major advantage of being very safe for all age groups including children as well as for pregnant women and lactating mothers.

In 2018, we entered a partnership with the [Infanta Malaria Prevention Foundation](#) and with [ASPIRx](#), a Ghanaian bio-pharmaceutical manufacturer. This supports the National Malaria Control Program of the Ghana Health Service by exploring development of solutions based on IR3535[®] for malaria prevention in vulnerable communities.

Addressing the global health challenge caused by antimicrobial resistance (AMR)

In order to address the growing emergency of increased bacterial resistance, we have been implementing new collaborative programs to assess the degree of resistance of identified bacterial pathogens. We also focus our efforts on the development of new technological platforms to speed up assessment of the type of infections. A Master's program is currently being run at Makerere University (Uganda) where students are researching ways of tackling the three AMR areas of prevention, detection and management.

open innovation sharing

We consider it our duty and responsibility to share core technological advances in the battle for global access to healthcare. This level of transparency, however, requires a solid, transparent and reliable legal framework to protect the intellectual property rights of pharmaceutical companies and enforce patents, in order to provide time and protection to balance the cost of research and development.

Our approach to sharing and protecting intellectual property

The approach that we and other pharmaceutical manufacturers take to our intellectual property impacts access to healthcare. We often refrain from filing or enforcing patents in developing countries. In markets where we do register product patents, we are transparent and committed to sharing data to the greatest possible extent and improving public access to clinical study data. We report on the patent status of our products via a **publicly accessible database**. Furthermore, we support voluntary licensing agreements of all kinds, including non-exclusive voluntary licenses, legally binding non-assertion covenants and clauses that aim to widen access to health. Moreover, we support the concept of patent pools, but believe that these should be structured to improve access to medicines, prevent anti-competition behavior and overcome geographic limitations. We consider joining patent pools when they are relevant to our portfolio and meet all our efficacy, quality and safety requirements. We are currently only active in the [Medicines Patent Pool](#), which recently extended its scope to include HIV, hepatitis C and tuberculosis.

The responsible treatment of intellectual property does not pose a barrier to health, but rather guarantees **safety and high quality** for patients worldwide. Nearly all medicines that address the highest burden of disease in developing countries are not protected by patents. Studies found that between 90% and 95% of the [WHO Model List of Essential Medicines](#) are off-patent. We provide 46 essential medicines and products, of which 27 are on the WHO Essential Medicines List and 29 are considered to be first line treatments.

Through our initiatives and partnerships, we provide access to patent information. In some cases, we even give access to parts of our compound libraries. This is true for open innovation research projects and collaborative research programs for novel R&D platforms in the search of new active substances.

How we organize access and control of our intellectual property

The [Open Innovation](#) initiative of Merck KGaA, Darmstadt, Germany, is a collaborative and cross-functional effort led by the Access to Health and the Patents teams. It aims to **mitigate affordability issues** by sharing our intellectual property to accelerate early discovery in diseases that have

high unmet needs, where we do not have expertise. We hope to foster the discovery of new generations of health solutions that tackle the needs of the poorest, with a first focus on neglected tropical diseases (NTDs).

In 2015, we established the Open Innovation Committee to provide technical expertise, strategic guidance and decision-making on our open innovation activities, collaborations and strategy. The Open Innovation Committee is co-chaired by the heads of our Access to Health subunit and the globally acting Patents Healthcare unit and is part of the Open Innovation Initiative.

Our commitment: supporting transparent and reliable frameworks

Our approach to intellectual property is based on the principles set out in our [Access to Health charter](#).

We support [TRIPS](#), an international agreement administered by the World Trade Organization (WTO) that addresses trade-related aspects of intellectual property rights, along with TRIPS addenda such as the Special Declaration on the TRIPS Agreement and Public Health, also known as the 2001 DOHA Declaration. This extends the deadline for the least-developed countries to apply TRIPS provisions to pharmaceutical patents until 2033.

Initiative improves access to patent information

We are a founding member of the Patent Information Initiative for Medicines ([Pat-INFORMED](#)), which was established by 20 leading research-based biopharmaceutical companies. Pat-INFORMED acts as a global gateway to medicine patent information, offering new tools and resources to determine the existence of patents that are relevant to products sought by national and international drug procurement agencies. This transparency should make it easier for drug procurement agencies to access a basic body of patent information necessary to implement **disease management strategies** and other activities that address public health needs. Pat-INFORMED features patent information for small molecule drugs within oncology, hepatitis C, cardiovascular, HIV, diabetes and respiratory therapy areas and any products on the WHO Essential Medicines List that are not within these therapy areas. The initiative is backed by the World Intellectual Property Organization ([WIPO](#)) and the International Federation of Pharmaceutical Manufacturers and Associations ([IFPMA](#)).

Pat-INFORMED currently houses information on over 14,000 individual patents, for 600 patent families and 169 so-called INNs, unique names that are globally recognized and used to identify pharmaceutical substances or active pharmaceutical ingredients within medicines that cover a wide range of conditions. The initiative will soon extend to other therapeutic areas and explore the inclusion of complex therapeutics such as biologics.

Open innovation collaboration: WIPO Re:Search

Established in 2011, [WIPO Re:Search](#) is a public-private partnership administered by the World Intellectual Property Organization (WIPO) in collaboration with BIO Ventures for Global Health ([BVGH](#)). We are one of more than 100 members of the WIPO Re:Search platform. The mission is to accelerate the discovery and product development of medicines, vaccines and diagnostics to create **new solutions** for people affected by neglected tropical diseases, malaria

and tuberculosis, by making intellectual property and know-how available to the global health research community. Through the WIPO Re:Search platform we are working on the extension of the collaboration with the University of Buea (Cameroon) and University of California, San Diego (United States) to find potential cures for onchocerciasis, leishmaniasis, Chagas disease and African sleeping sickness.

Drugs for Neglected Diseases initiative

In 2017, we formed a partnership with the Drugs for Neglected Diseases initiative ([DNDi](#)), under which we are involved in the Drug Discovery Booster project for neglected tropical diseases. This project pursues an open innovation approach in which the participating companies simultaneously search for new treatments for leishmaniasis and Chagas disease. We are joined in this project by six other companies (Astellas, AstraZeneca, Celgene, Eisai, Shionogi and Takeda).

pharmaceutical supply chain

In many parts of the world, medicines are not always available where and when they are urgently needed. We want patients in low- and middle-income countries to have fast, safe and affordable access to our products. We believe that this can be accomplished through efficient supply chain management and by utilizing local manufacturing. Our actions in this area reflect our high standards for improving access to healthcare for underserved populations.

Our approach to local supply chain solutions

During product development and manufacturing we favor approaches that enable us to control the cost of goods and allow for local supply chains that strengthen the local economy. This is the model applied in the context of the [Pediatric Praziquantel Consortium](#), for instance, in which the manufacturing and supply are planned to be undertaken locally.

We partner with pharmaceutical companies and other supply chain stakeholders to improve supply chains in developing countries and to guarantee the targeted supply of medicines. We manufacture some of our products directly in the regions where they are needed in order to **build local capacity**, reduce travel time and distance, and achieve cost savings that can be passed on to the consumer.

Our pharmaceutical supply chains are organized efficiently to ensure that our products reach the right place in the right condition and quantity, at an affordable price and on time. **Modern supply chain solutions** allow us to monitor our inventory and current deliveries, as well as to predict expected demand for medicines, partly in real time.

How we organize our supply chains

The Global Planning unit is responsible for our efficient medicine supply chains and is part of Biopharma Supply Network Operations within our Healthcare business sector. Global Planning collaborates with our [Global Health unit](#) and consults experts from other business sectors as needed.

Our commitment: High quality standards for pharmaceutical production

All our pharmaceutical production plants operate to the same high standard of quality worldwide. This ensures full compliance for us and our contract manufacturers with the internationally harmonized guidelines Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

In 2018, we refined our "Right First Time" (RFT) concept, which aims to reduce the number of temperature excursions that happen during transportation worldwide. At the same time, we encourage shipping sites and receiving units worldwide to improve their processes together with freight forwarders and carriers.

Our **uniform quality assurance system** ensures that our quality standards are universally adhered to. It comprises training courses, quality control monitoring and technologies that are tailored to each site. The results of all audits conducted by health authorities are published Group-wide, allowing the respective units to share lessons learned and benefit from the improvements of others.

Through our Virtual Plant Teams, we support our contract manufacturers in complying with quality standards. Our external partners in Africa, Asia and Latin America are each assigned a production expert from our company to act as a **virtual site leader** who is able to provide guidance. This approach was again recognized as a best practice in the [2018 Access to Medicine Index](#).

Leveraging technological possibilities for efficient market access

Accurate business forecasts are the foundation of efficient supply chain management. We use harmonized Biopharmaceutical business planning processes across our Group, including a special software platform that enables us to plan centrally for specific demand for medicines. The data generated by the software platform is used to manufacture and deliver medicines according to demand, which allows us to prevent local inventories from running out or expiring.

We employ a software-based solution for our customers in northwestern Africa, which gives them continuous access to our e-shop so that they can quickly and easily order medicines approved by the respective regulatory authorities. The system makes demand more transparent whilst reducing lead times and miscommunications. Combined, both systems enable us to react more quickly to local demands, including in developing markets, than ever before.

Working with partners to achieve more

Our collaborations and partnerships are founded on the Group-wide exchange of centrally stored information, which allows us to organize shared supply chains in a more efficient manner.

Shared data platform for medicine donations

NTDeliver is our digital information tool, which facilitates **transparency in supply chains** for medicine donations that are created through public-private partnerships. Deliveries from companies running donation programs are clearly displayed – from purchase orders made by the World Health Organization (WHO) through to delivery to the first warehouse in the destination country. This improves the coordination of our efforts and provides WHO, the local experts and us with a more transparent overview of the in-country inventory. Following a pilot in 2017, where we tracked deliveries all the way to the treatment point in the destination country, we fully implemented the system in 2018. We started using NTDeliver last mile tracking as a standard reporting tool in the school-based deworming program for schistosomiasis in Kenya. This system is now fully functional

in collecting and consolidating field information and has helped us reach out to more than 12,000 teachers throughout Kenya. In addition to supply chain data, we have started to integrate the first level of impact data requests from the teachers, such as the number of children treated.

Further partnerships

We are a founding member of the Accessibility Platform, which meets to discuss local supply chains during our [Access Dialogues](#). This is an informal effort spearheaded by the private sector to raise awareness of supply chain issues as part of the access to health challenge. It seeks to **increase knowledge-sharing** and information exchange through open, multi-stakeholder dialogue, and to identify opportunities for collective action. We also share best practices with other companies and partners on efficient, end-to-end, secure supply chains. The Accessibility Platform was recognized by the [Access to Medicine Foundation's white paper](#) on "Shortages, stockouts and scarcity: the issues facing the security of antibiotic supply and the role for pharmaceutical companies." In the paper, the Foundation acknowledges that companies have a strong role to play in helping to address supply chain complexities and recognizes the Accessibility Platform as a best practice in information sharing through partnerships.

Promoting local production

Having started to supply pharmaceutical products in 2017, our production facility in Nantong (China) increased its production volume to full capacity in 2018, in order to serve local markets. In addition, we manufacture drugs for diabetes, cardiovascular conditions and diseases of the lower respiratory tract in India and Indonesia. This local capacity building supports local economies and allows us to supply medicines faster and more affordably here and in neighboring countries such as Sri Lanka and Myanmar. In 2018, we further expanded the scope of local production with a contract manufacturing organization (CMO) in Russia.

CURAFA

In 2017, we started the project [CURAFA™](#). The name is derived from the Latin word 'curare', which means care, and the Swahili word 'afya', which means health. CURAFA™ facilities serve as points of care for integrated primary healthcare services and are run by local pharmacists and nurses, who provide **pharmaceutical and clinical services**, medicine, digital health solutions, insurance and financing schemes. The staff is supported by a modern facility with WiFi access and charging stations, tablet PCs and TVs, refrigerators for cold chain medicines, and solar power.

We created the project as part of our vision to achieve primary healthcare for everyone everywhere. Our mission is to address inequalities in primary healthcare access in emerging economies and to enable accessibility, availability and affordability of primary healthcare. We also aim to leverage on-the-ground learning to build a sustainable business model for primary healthcare and provide a space for co-creation with fellow innovators. The project was implemented in collaboration with the non-governmental orga-

nization [Amref Health Africa](#) and benefits patients as well as communities. In 2018, five primary healthcare points were opened in the Kenyan counties Kajiado, Kiambu and Machakos.

Fight against falsified medicines

According to a [WHO report](#) published in 2017, more than 10% of all medicines in developing and emerging countries are counterfeit or substandard, creating a major health risk. The Global Pharma Health Fund (GPHF) is a non-profit initiative funded by our company that is fighting counterfeit medicines with its GPHF Minilab™.

The GPHF Minilab™ is a **portable, compact laboratory** that fits into a tropics-resistant suitcase and can detect fake medicines quickly, easily and cheaply. Around 90 chemical substances can be tested for their authenticity. The GPHF develops these Minilabs, supplies them at cost and provides training on how to use them. The WHO report cites the Minilab as one of the most important tools for detecting poor quality and falsified medicines. As part of a study published in this report, over 20,000 pharmaceutical samples were tested using the Minilab™, with more than 1,000 of them identified as falsified. An [international study](#) conducted by the Difäm-EPN Minilab Survey Group in 2017 also highlighted how the GPHF Minilab™ has helped ensure access to safe medicines in developing countries. The Minilab is currently the only product of its kind.

The majority of Minilabs are deployed in countries in Africa and Asia. These test kits are primarily utilized by national health agencies, often in partnership with the labs of governmental drug inspection centers or within multilateral health interventions led by various UN bodies, aid organizations in the United States and Germany, faith-based networks or the incoming goods inspection unit in the medicines supply chain in all kinds of healthcare facilities, for example medical stores and major hospitals.

Through our Global Health Institute, we are also co-developing a new user-friendly technology that will enable users to detect falsified medicines at the qualitative and quantitative level. Initial models will focus on measuring the presence and quantity of the active pharmaceutical ingredient for malaria and other bacterial infections.

Expanding Minilab use

In 2018, the GPHF developed testing methods for five additional active ingredients, effectively covering a total of 90 active agents from the essential medicines list. Test protocols for ten more active pharmaceutical ingredients were developed and 30 existing protocols reviewed. All test protocols will be put together into a single volume in 2019, and made available in three languages in 2020. By 2020, the Minilab will then cover **100 active ingredients**, ranging from antipyretic, antimalarial and antiviral, to antibacterial and antimycobacterial medicines.

Since 1998, the GPHF has supplied a total of 843 Minilabs to nearly 100 countries, with seven new Minilab shipments made in 2018. The GPHF and its partners held three official seminars for Minilab users in 2018 with 60 participants.

prices of Medicines

Part of the non-financial report

In OECD (Organization for Economic Cooperation and Development) countries, prescription drug costs currently account for between 6% and 29% of total healthcare spending. However, advances in the research and development of innovative medicines are dramatically transforming the healthcare landscape, allowing chronic diseases – the greatest cost drivers – to be treated more effectively and affordably.

Our approach to pricing medicines

We want to ensure that all patients have access to the most effective medicines for their needs, which is why we are working to prevent cost from becoming a barrier to treatment. We are committed to **flexible and fair pricing** – both within and across countries. We therefore adapt our prices based on local market access, also taking into account factors such as health system capacity and financial standing, geographic circumstances and existing infrastructure, statutory requirements, unmet medical needs, and socioeconomic aspects such as the ability of patients to pay. This approach involves working closely with governments and other stakeholders. In addition to these considerations, we continuously monitor dynamic healthcare environments and markets, pricing and reimbursement systems and legal and regulatory guidelines, adjusting our prices as necessary.

We review our prices on an annual basis to ensure they meet patient access needs. To assist this process, we use a consistent, data-driven approach to monitor our local pricing. We also make our products affordable to patients in certain countries by participating in government tenders, establishing second low-price brands or branded generics and operating patient access programs.

Moreover, we support risk-sharing agreements and are working to improve data efficiency in health systems in order to achieve an optimal distribution of funds and resources.

Setting medicine prices

Our Global Pricing and Market Access unit sets initial prices in coordination with the respective businesses. Following a reorganization in 2018, this team now reports to the Chief Operating Officer of our Healthcare business sector. Our individual subsidiaries are responsible for managing prices and continually adapting them to local environments.

Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition, which includes increasing [accessibility](#), availability and awareness. Medicine pricing adheres to the stipulations of our overarching [Access to Health Charter](#) and is defined in detail by our [Pricing of Medicines](#) guideline. Our Patient Access Programs Policy furthermore sets out standards that enable us to offer medicines at reduced prices.

Customer-centric contracting models

We are dedicated to advancing value-based healthcare through pricing and contracting mechanisms that comply fully with all local laws. In collaboration with payers such as health insurance companies, we have developed various product- and market-specific reimbursement and contracting models with the aim of providing patients with prompt **access to our innovations**. For instance, we have entered into a risk-sharing agreement in the United Kingdom that provides immediate access to Mavenclad® for patients with multiple sclerosis (MS); under this agreement, the National Health Service only has to pay for medicines for those patients who respond to the drug. Since the start of 2018, under this scheme 488 patients in the United Kingdom have been reimbursed for the cost of the drug.

We have also created contracting models for our oncology drug Erbitux®, our MS drug Rebif® and our growth hormone Saizen® to make it easier for patients to access these medicines. In this vein, we have also capped per patient costs in certain countries and have formed risk-sharing agreements there.

Pricing schemes to serve low-income patients

We work in close partnership with governments and other stakeholders on innovative, differential medicine pricing schemes and furthermore supply products at **reduced prices** to certain countries in Africa, Asia, Latin America and the Middle East. In India, for instance, we are working with public sector representatives such as Bharat Heavy Electricals Limited ([BHEL](#)) and the Oil and Natural Gas Corporation ([ONGC](#)) to develop alternative models for low-income patients and patients who have a limited ability to pay.

Moreover, we regularly participate in government tenders for products that are used in public hospitals serving low-income patients. Many of these tenders take place in developing countries.

Low-price second brands

We have established low-price second brands for some of our existing brands, particularly in countries with a large percentage of **very low-income patients**. In Brazil, for instance, twelve of our products are available as a lower priced version. Other examples of countries where we have established low-price second brands include Mexico, the Philippines, Poland, and South Africa.

Generics

Hand in hand with our partners, we offer branded generics particularly in developing countries to meet the local need for affordable, high-quality medicines that are required to treat the diseases endemic to these nations. In doing so, we ensure better access to reliably high-quality medicines at lower prices. In the Philippines, for instance, four branded generics have been launched to date.

Patient access programs

Worldwide, we operate patient access programs that allow us to offer certain products at **more affordable prices** in several countries. Examples include efforts in China to expand access to our oncology drug Erbitux[®], which is used to treat conditions such as colorectal cancer. Geared

primarily toward low-income patients who receive the drug free of charge, our Erbitux[®] donations have so far benefited around 11,500 patients in China.

We run similar assistance programs in other countries such as India, where we also offer Erbitux[®] at discounted prices. Over 1,700 patients have participated in the initiative. In nations such as China, Peru and the Philippines, we offer free-of-charge biomarker screening that determines whether Erbitux[®] would be a suitable treatment.

In addition to our oncology initiatives, we offer access programs for our drugs Rebif[®], Gonal-F[®] and Saizen[®]. In China, for instance, we operate the Gonal-F-Baby Fund, an access program that provides financial assistance for fertility treatments to low-income couples who have lost their only baby.

Health awareness

Many people are ill but do not realize it. This means that, although effective medicines and therapies are available, these individuals either do not receive treatment or do not receive it in time. To try and prevent this, we conduct global campaigns to raise awareness and improve knowledge of diseases, their symptoms and treatment options. Ultimately, healthcare professionals, communities and patients can only make informed decisions if they have the right knowledge and information.

Our approach to raising health awareness

Awareness plays a key role in our [approach to improving access to healthcare](#). We seek to empower communities, medical professionals and patients with appropriate tools, information and skills so that they can make **high-quality, informed decisions** on prevention, diagnosis, treatment, care, and support.

We often join forces with committed partners to conduct educational campaigns for prevention, early diagnosis and awareness, which also helps to build the capacities of medical professionals working in the fields of research, technology and healthcare.

How we build awareness

The strategic direction and the output of all awareness activities are aligned with our respective businesses. This means that the different business units plan and implement our diverse awareness projects either on a global level or through their local offices, with projects organized according to the **specific needs of the local area**. The offices are also responsible for local mobilization during our global campaigns.

Our commitment: Access to health through awareness

Our strategy for addressing access to healthcare incorporates the topic of awareness and is laid out in our [Access to Health Charter](#). Our awareness campaigns are also subject to the respective [marketing principles](#) set out in guidelines such as our "Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations." In addition, they are governed by internal policies and guidance for reviewing our [interactions with health systems](#) and by the review processes for communication materials.

Global awareness campaigns

We regularly conduct campaigns, often in collaboration with patient advocacy groups, to raise awareness of various diseases across the globe. We focus on those diseases that align with **our core competencies**, expertise and experience along the health value chain, in particular cancer (specifically colorectal as well as head and neck), thyroid disorders, diabetes, and multiple sclerosis. During 2018, we conducted or participated in multiple campaigns that enabled us to reach millions of people.

Awareness and knowledge transfer for thyroid disorders

Throughout 2018, we continued our work to raise awareness of thyroid disorders. At the global level, we supported the International Thyroid Awareness Week in May 2018 for the tenth time. This annual awareness campaign, which we run jointly with the Thyroid Federation International (TFI), aims to highlight some of the lesser-known aspects of thyroid disorders.

To mark this year's International Thyroid Awareness Week, we commissioned an international survey, together with the TFI, among hypothyroidism patients in six countries. The results suggest that getting diagnosed can be difficult and distressing for many of those affected by thyroid disorders, with 70% of surveyed patients saying that they found the road to diagnosis stressful.

We hosted a number of our own events during the week, with more than half targeted specifically at healthcare professionals. These events connected us with almost 35,000 people, including around 11,000 healthcare professionals. Furthermore, we reached three million people through our own social media activities in 23 countries and an additional 35 million people were touched by news coverage, social media and events.

At the regional level, we launched an awareness and action campaign with the Vietnam National Hospital of Endocrinology, which highlighted the fact that although many women suffer from thyroid disorders, an estimated 50% go undiagnosed. The campaign offered free screening for thyroid diseases in 15 hospitals nationwide, with around **50,000 screenings** taking place under the supervision and management of our company's Vietnam representative office.

Awareness campaigns for cancer

Each year in September, we support the Head and Neck Cancer Awareness Week, an initiative by the Make Sense Campaign that is run by the European Head and Neck Society (EHNS). We align with the Make Sense Campaign's three-year theme, "Supporting Survivorship," and demonstrate our commitment to the head and neck cancer community through our own "Stand Up for Survivors" campaign. Our publicity material included a video in which a head and neck cancer survivor discussed the challenges she faced during remission. Partners were encouraged to translate our materials and leverage them locally with stakeholders in their region. We also asked subsidiaries to show their solidarity with survivors by sharing photos on social media that showed them representing the key theme and standing up for survivors.

World Cancer Day

On February 4, 2018, we again recognized World Cancer Day, an annual initiative driven by the Union for International Cancer Control (UICC). This year, we focused on the future possibilities of cancer care with our campaign "We Can. I Can. Help Shape the Future for Patients." **Teams from around the world** got creative, expressing their hopes and aspirations for the future of cancer care through sculptures made from modelling clay. We received almost 330 images of support from 24 countries and our multi-channel social media activity generated over 15,300 views.

Colorectal Cancer Awareness Month

During March 2018, we backed Colorectal Cancer (CRC) Awareness Month, an initiative to raise awareness of CRC, its symptoms and the importance of early diagnosis. Our "gut strength: Targeting CRC Together" campaign encompassed three key themes: together, strength and support. We united on social media to share a message of support through a Thunderclap, which reached over 162,000 people worldwide. Colleagues also showed their commitment to the CRC community by sharing photos of themselves visually representing the key themes and using the campaign hashtag #gutstrength.

World Multiple Sclerosis Day

We participated in the annual World Multiple Sclerosis Day (WMSD) in May 2018. This year's theme was #bringingus-closer to ending multiple sclerosis (MS), which was selected to celebrate advancements in research and care and to look to the future for further developments. A total of **26 organizations of our company** participated in this initiative of the MS International Federation (MSIF) by showcasing their support and activities.

We also announced a new campaign, #MSInsideOut, to support the MS community and deepen understanding of the disease. The initiative involved a collaboration with the social network Shift.ms, which acted as executive producers of a new documentary, "Interpreting MS", which featured unique perspectives from people with MS. The documentary premiered at the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Berlin (Germany) in October 2018.

To accompany the premiere of the documentary, we published the report "Living with Multiple Sclerosis: The Carer's Perspective", which examines the experiences of those caring for people living with MS. This report was developed in collaboration with the International Alliance of Carer Organizations (IACO) and Eurocarers, the European network that represents informal carers and their organizations. A survey of MS carers across seven countries (Canada, France, Germany, Italy, Spain, the United Kingdom, and the United States) found that almost half of those surveyed became carers when they were 34 years old or younger, and one in three had been caring for somebody for 11 years or more. Furthermore, nearly half reported that their caring responsibilities had negatively impacted their future plans and life goals, while a similar proportion said they suffered from either severe or high stress levels. This emotional toll was compounded by the fact that over half of

the carers surveyed felt that people around them don't truly understand what it means to care for someone with MS. Finally, MS in the 21st Century, an initiative sponsored by our company, launched a [website](#) for discussions between patients and healthcare professionals.

World Malaria Day

Since 2015, we have championed World Malaria Day, held annually on April 25, with campaigns that raise awareness for the disease and through engaging in the activities and efforts of our Malaria program. In 2018, we hosted events in Accra (Ghana), [joining forces](#) with the [Infanta Malaria Prevention Foundation](#) of the First Lady of Ghana and with [ASPIRx](#) to support the Ghanaian National Malaria Control Program. These events, which included a scientific symposium, led to the signing of a Memorandum of Understanding for a consortium to identify and deploy timely and **effective malarial prevention solutions** for vulnerable populations.

World Diabetes Day

We launched a global campaign for World Diabetes Day on November 14, 2018, under the concept: See it. Slow it. Stop it. The aim of the campaign is threefold: helping people spot the risks and symptoms of type 2 diabetes, empowering them take action to slow down progression to type 2 diabetes and ultimately equipping them to help themselves or others prevent type 2 diabetes. We continued our partnership with the International Diabetes Federation (IDF), working on a range of educational activities that aim to raise awareness of prediabetes and diabetes prevention and to globally reduce the rise in type 2 diabetes cases.

Online diabetes campaign

According to the International Diabetes Federation, there were 14 million cases of diabetes in Africa in 2015, a figure expected to more than double by 2040. Moreover, approximately 60% of cases go undiagnosed. Awareness of early symptoms of diabetes is low, even among healthcare professionals. To **improve early diagnosis** and promote awareness of the disease, we joined forces with various partners in March 2015 to launch a digital initiative known as DORA ([Diabetes Online Risk Assessment](#)). DORA aims to expand individuals' knowledge of diabetes by providing free online self-assessment tests to determine their risk of developing the disease. Depending on the outcome of the online test, people have the opportunity to take a free blood test in partnering pharmacies. When this blood test indicates diabetes, they are given a starter pack to help monitor the disease at home. Until recently, DORA had been deployed in Ethiopia, Ghana Kenya, Mauritius, Mozambique, Namibia, and South Africa. During 2018, the program was extended to Angola, Botswana, Tanzania and Uganda. Since its launch, there have been more than one million visits to the DORA website.

Healthy Women, Healthy Economies initiative

Nearly one in four women worldwide are held back from achieving their full economic potential due to preventable causes, including exposure to a wide range of communicable and non-communicable diseases. In addition, they spend

significant time on unpaid work. This has implications for their own health and well-being. To tackle these challenges, we are committed to [Healthy Women, Healthy Economies](#). Under the auspices of the Asia-Pacific Economic Cooperation (APEC), we collaborated with representatives of several governments to launch this public-private partnership that aims to identify and implement policies that advance women's health and well-being to support their economic participation. The initiative has developed a [policy toolkit](#) with recommendations to improve women's health. We have made Healthy Women, Healthy Economies part of our core commitment by **forming collaborations** to make meaningful change and supporting research to quantify the socio-economic impact of health burdens on women.

Our collaborations

We joined forces with the Philippine government and the Philippine Thyroid Association (PTA) to educate more than 2,000 health industry employees on thyroid disorders, a problem that disproportionately affects women. By the end of 2018, our campaign had reached nearly eight million people in the Philippines.

In Jordan, we collaborated with the Royal Health Awareness Society, an NGO that increases awareness among women about thyroid disease and trains health workers on thyroid disorders in women. We reached over 7,000 patients through the Society's thyroid disease website and an accompanying social media awareness campaign, and engaged and educated over 120 healthcare providers during a scientific event.

We also sponsored and undertook several other projects in Brazil, Spain and the United States.

Quantifying the socio-economic impacts of health burdens on women

In Asia we are working to help our local not-for-profit partners better understand the drivers and impacts of the socio-economic dynamics they will be facing locally. In 2018, we commissioned the Economist Intelligence Unit to study

the demographic trends, childbearing choices and family-related policy decisions in China, Japan and the emerging markets of Southeast Asia.

In the United States, we conduct six studies with the March of Dimes Center for Social Science Research to better understand the relationship between economic and employer policies, women's health and productivity and childbirth. Under a collaboration with the Wilson Center, we supported the development of a policy brief titled "The Juggling Act of Caregiving: Balancing Career, Health, and Gender Roles".

We are also conducting research to understand the full range of impacts that multiple sclerosis has on the lives of women who are affected by the disease in Argentina, Brazil, Chile, Colombia, and Mexico. This research builds on the [European report](#) we launched in October 2017.

Embracing Carers initiative

[Embracing Carers](#) is a global initiative that we lead in collaboration with prominent caregiver organizations around the world. Embracing Carers is designed to increase awareness, action and discussion for the often-overlooked needs of caregivers. We believe that the topic of caregiving is one of the most **under-addressed public health issues** of our time. Caregivers spend so much time looking after someone else that they often do not get the recognition and support they need. We raise awareness of the issues caregivers face, activate stakeholders for deeper engagement, establish global best practices and advocacy resources, and endorse the improved integration of carer support into the entire spectrum of care. In 2018, Embracing Carers supported the self-identification of caregivers, extended the reach of the initiative to Brazil and China, established dedicated disease-specific carer resources, and collaborated with carer communities to develop the first-ever Global State in November 2018, which highlights the needs of unpaid caregivers in Australia, Canada, France, Germany, India, Italy, Spain, the United Kingdom, and the United States.

product safety and quality

chemical product safety

Part of the non-financial report

Since many of our chemicals are classified as hazardous substances and mixtures, we must ensure that they pose no risk to people or the environment. We therefore comply with an array of national and international regulatory requirements, statutes and guidelines, an approach that is crucial to our business activities. In addition, we strive to meet the expectations that stakeholders such as customers and employees have of a comprehensive hazard management system.

Our approach to safe chemical products

Product safety is one of our top priorities. Starting at the development stage, we investigate the potential adverse impacts chemical substances may have. Along the entire value chain of our chemicals – **from cradle to grave** – we fulfill all statutory requirements, often even exceeding them. We furthermore publish extensive information on our website so that both our customers and the general public can learn about our products and how to handle them safely.

How we ensure chemical product safety

Our Healthcare, Life Science and Performance Materials business sectors each have their own organizational structures in place to provide guidance on product safety. These units work in close collaboration with our Group-wide governance function Corporate Regulatory Affairs Chemicals (EQ-R) to ensure our products' safety. Their tasks include registering chemicals, classifying hazardous substances and communicating risks by means of safety data sheets and labels.

Our Group Product Safety Committee (GPSC) monitors regulatory requirements worldwide to check for relevant changes, initiating and reviewing the measures needed to integrate these changes into our processes.

Corporate Regulatory Affairs Chemicals (EQ-R) ensures regulatory compliance Group-wide. Reporting directly to the head of our Group function Corporate Environment, Health, Safety, Security, Quality, EQ-R is independent of our business sectors and not subject to any operational commitments. Any necessary corrective or preventive action is carried out by the operating units within each business sector. EQ-R further supports individual units in implementing and harmonizing efficient processes.

Our commitment: statutory regulations and Group-wide guidelines

We have implemented Group-wide guidelines that guarantee compliance with national and international regulatory

requirements, and have also endorsed general voluntary commitments of the chemical industry such as the [Responsible Care® Global Charter](#).

To meet the product safety regulations relevant to our company, we have enacted our Regulatory Affairs Group Policy, which details our Group-wide processes for managing and **implementing product safety**, including the necessary management structures. The statutory requirements applicable to our operations include the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and its implementation in regional and national legislation (such as the CLP regulation in the European Union and HazCom 2012 in the United States), the EU chemicals regulation [REACH](#), the amended U.S. Toxic Substances Control Act (TSCA), and the amended German Federal Banned Chemicals Ordinance (ChemVerbotsV). Our Group-wide policy also incorporates legal norms concerning the transport of hazardous chemicals, biocides, cosmetics, and products used in food and animal feed. In 2018, we furthermore implemented our Group Label Standard, which provides a consistent framework for labeling products according to GHS requirements.

In this period, there were no incidents of non-compliance with regulations or voluntary standards involving chemical product labeling.

REACH registration complete

In 2018, we finished registering all substances covered by REACH, doing so within the allotted time. In the third and final REACH registration phase, to be completed by June 2018, we **evaluated and registered all substances** produced or imported in annual quantities greater than one metric ton. This process also incorporated the substances added to our portfolio through the acquisition of Sigma-Aldrich.

In line with the **Strategic Approach** to International Chemicals Management (**SAICM**), a global policy framework, a growing number of countries are recognizing the requirements for registering and licensing chemicals, such as the Toxic Substances Control Act (**TSCA**) in the United States and the Act on the Registration and Evaluation of Chemicals (**AREC**) in Korea. Thanks to our expertise in implementing REACH, we are well prepared for such a procedure and are already registering chemicals as required.

Transcending laws

In an effort that goes beyond statutory requirements, we support the goals of the Global Product Strategy, an international initiative of the chemical industry. In this vein, we publish product safety summaries for all lead substances that we have registered under **REACH**, making them available on the website of the International Council of Chemical Associations (**ICCA**).

Safety analysis during product development

We believe that product safety starts during the development stage. By conducting hazard, exposure and risk assessments, we work to ensure our chemicals can be safely used later down the road. All our innovations undergo an **EHS analysis**, which examines factors such as their impact on human health and the environment. Before launching a new product, we evaluate all relevant hazardous substance data and classify the product according to the Globally Harmonised System of Classification and Labelling of Chemicals (**GHS**), along with locally applicable regulations such as **CLP** in Europe. In conducting these safety assessments, our employees in our Life Science and Performance Materials business sectors are advised by their respective Regulatory Affairs unit.

Our approach to nanotechnology

Nanotechnology is a highly innovative field of development that researches and uses structures 50,000 times thinner than a human hair. This technology makes it possible to produce **materials with completely new properties and functions** for a myriad of applications.

Nanotechnology opens up many opportunities for our Group. In our Life Science and Performance Materials busi-

ness sectors, we utilize nanomaterials to develop products with new functions and properties, thereby making resource and energy consumption more efficient. In our Healthcare business sector, we collaborate with research institutes and other European companies to explore the use of nanomaterials to improve therapeutic options. Under the auspices of **European research partnerships**, we are also investigating whether nanoparticles are suitable vehicles to deliver active pharmaceutical ingredients to the required site of action.

Despite their promise, the unique structure of nanoparticles may harbor risks, which we assess in line with statutory requirements such as REACH. Moreover, we only utilize this new technology with the greatest care, abiding by the **precautionary principle** and taking nanomaterial safety very seriously. In doing so, we consider Group-wide requirements for safety, environmental stewardship and health impact mitigation, employing our existing product safety processes and systems. Whether using nanomaterials in pharmaceutical and chemical laboratories, production facilities, filling plants, or warehouses, we follow our Group-wide **Policy for Use and Handling of Nanomaterials**.

In the manufacture and processing of our products, we adhere to all statutory regulations along with standards such as those of the German Federal Institute for Occupational Safety and Health (**BAuA**), as well as the German Chemical Industry Association (**VCI**). We also provide our customers **safety data sheets** containing information on the proper handling of nanomaterials during transport, processing, storage, and disposal.

Sharing nanotech knowledge

Over and above our internal efforts, we continuously engage other companies, associations and regulatory agencies in a dialogue on the **opportunities and risks of nanotechnology**. We also take part in committees and working groups, including the Nano Panel of VCI's Technology and Environment committee, as well as Responsible Production and Use of Nanomaterials, a joint technology working group of the Society for Chemical Engineering and Biotechnology (**DECHEMA**) and the VCI. Under the auspices of the VCI, we furthermore review current scientific literature in order to stay abreast of new advances in nanotechnology.

Standardized product safety information

As part of our efforts to communicate the potential dangers of our products, we provide our customers with in-depth informational material on all our chemicals. These brochures contain instructions on **proper use and handling** to prevent them from posing a danger to people and the environment. Our goal is to give our customers product safety information that has been standardized worldwide.

We issue all chemicals classified as hazardous with **safety data sheets**, which, in accordance with UN regulations, follow a globally harmonized format. These sheets contain information on the physicochemical, toxicological and ecotoxicological properties of the agent, and reflect the relevant regulatory requirements of the countries in which they are published. We therefore produce country-specific safety data sheets in 44 languages for our Performance Materials business sector and in 37 languages for our Life Science business sector. Although not mandated by law, we also provide safety data sheets for the non-hazardous materials and finished medicinal products manufactured by our Healthcare business sector. Since all these documents must be kept up to date and consistent, we have automated the majority of our Group-wide hazard communication processes. Within Performance Materials, we draft all safety data sheets Group-wide using a single system.

In 2018, we also automated most of the safety data sheet creation process for our Life Science business sector and also developed an app that provides our Life Science customers with **access to the latest product safety information**. Covering the whole life cycle of the product along its entire supply chain, the information is available

worldwide in the respective national language and accounts for country-specific regulations. To access it, customers need merely scan the product's barcode or enter it manually.



million safety data sheets in total are made available to our customers.

Informing and educating customers

All information on the safe use of our products is also available on our website, where our customers can additionally access the **ScIDeX[®]** program. This tool allows them to check whether they can use chemicals safely within the boundaries of the REACH exposure scenarios.

Taking a more active approach, we also endeavor to **educate people on the safe handling of hazardous chemicals**, providing users with best practice advice and information. To this end, we regularly conduct seminars and information sessions worldwide that teach basic lab safety rules such as the handling of flammable solvents and the storage of hazardous chemicals in safety cabinets and warehouses.

patient safety

Part of the non-financial report

The safety of patients who are treated with our medicines is our absolute priority. Our pharmaceutical products need to be effective in treating the respective disease while also posing as little risk as possible to patients. That is why we consistently monitor risks and any adverse effects that may arise, and take the necessary actions to minimize them. The benefits of our drugs must always outweigh the risks for patients.

Our approach to ensuring patient safety

Through rigorous benefit-risk management, we ensure that the benefits of our drugs always outweigh the risks for patients. Every new medicine passes a series of precisely defined development stages. Before any drug is given to humans, we conduct extensive preclinical testing both in vitro and in vivo. Through toxicological testing, we determine whether an active pharmaceutical ingredient is toxic to living organisms and, if so, at what dosage. This also helps us determine the dose that humans can safely tolerate. Only when this is complete do we perform [clinical studies](#) to investigate the safety and efficacy of the drug when used in humans. During clinical development, we diligently use all collected data to continuously evaluate the drug's **benefit-risk profile** to be positive, we then submit an application for marketing authorization to the regulatory authorities.

Continual monitoring

After a drug is launched, the number of patients being treated with it increases significantly. In certain circumstances, rare adverse and severe effects that go undetected during clinical development may occur, which is why we continually monitor and manage the positive benefit-risk profiles after market launch. Pharmacovigilance is the process of continuously monitoring a drug to detect and assess signals as part of signal management activities. The aim is to track the adverse effects in an effort to take appropriate action to minimize and communicate the risks in a transparent way. We always provide physicians and patients with the **latest information on the safety** of all our marketed drugs. This applies to the entire life cycle of a product, ranging from development, market launch and commercialization to expiration of the marketing authorization.

For new products, educational materials are developed for patients and healthcare providers to communicate the known and potential risks, and ways to minimize them. We assess the effectiveness of these materials in close collaboration with our Benefit-Risk Action Team. If required, we adjust the content of the materials and their distribution, and describe the results from the effectiveness analysis in our periodic safety reports and risk management plans, which we submit to health authorities for evaluation.

How we monitor patient safety

Our Global Patient Safety unit is responsible for pharmacovigilance. It continually collects current safety data from a wide variety of sources across the globe, including clinical

studies, spontaneous reports on adverse effects, patient support programs, and articles published in medical and scientific journals, and furthermore reassesses the benefit-risk profile on an ongoing basis.

Our experts make sure all information on the risks and adverse effects of our medicines is properly documented, tracked and reported to the respective health authorities in accordance with regulatory requirements. The Global Patient Safety unit analyzes all data and uses this as required to reassess the benefit-risk profile. We then inform regulatory authorities, physicians and patients about new risks, additional risk mitigation measures and potential changes in the benefit-risk balance.

Our **Product Quality unit** (MBQ) processes quality complaints relating to our products. When quality defects may have an impact on patient safety or lead to adverse effects, Global Patient Safety gets involved.

Our Medical Safety and Ethics Board

Our Medical Safety and Ethics Board (MSEB) oversees the safety and benefit-risk evaluations of our drugs throughout clinical development and commercialization. It endorses appropriate **measures to minimize risk**, such as package insert updates. This board is chaired by our Chief Medical Officer (CMO) and consists of experienced physicians, scientists and experts from our company. Throughout a drug's entire life cycle, the MSEB reviews and assesses important medical safety risks and benefit-risk issues, and reviews ethical issues if necessary.

Our commitment: Guidelines and statutory requirements

We follow international guidance and standard procedures such as the International Conference of Harmonization (ICH) guidelines and the Good Pharmacovigilance Practices (GVP) established by the European Medicines Agency (EMA). In addition, we adhere to all statutory pharmacovigilance regulations in those countries where we market our products, and we constantly work to incorporate all required changes in our Group-wide standards and processes. In 2018, for instance, we harmonized the **processing of personal data** worldwide according to [new European legislation on data privacy](#).

In November 2017, the EMA implemented a new process for EudraVigilance to monitor the safety of medicines. This newly established approach provides marketing authorization holders with access to data on suspected adverse effects, requiring them to monitor the EudraVigilance data for safety signals and to report these to health authorities.

In response to these new requirements and to the new data transmission format stipulated by ICH guideline E2B (R3), we upgraded our **Global Safety Database** to ensure the technical capabilities needed to support the coordinated exchange of individual [case safety reports](#).

In 2018, we assessed new country-specific regulatory requirements and implemented necessary changes in order to fulfill them. Examples include the Chinese Food and Drug Administration, the new India Pharmacovigilance Guidance for Marketing Authorization for **post-marketing safety reporting** and the new Canadian requirements for safety signal notification.

In addition to adhering to guidelines and regulations, we have introduced a Benefit-Risk guide to our Global Patient Safety unit, which builds on the results of a joint initiative that we are involved in between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). These results helped us in compiling the documentation for the marketing authorization of cladribine and avelumab.

Collecting information and checking processes

Our self-developed mobile app, named agReporter, is used to report any adverse effects arising from the use of our products. Although initially intended for use by field nurses and our sales representatives, in 2018 we introduced an interface designed for non-medically trained users, thus making **patient feedback** the core of our efforts to consistently collect adverse effects data. In 2018, the app became available in a total of eight languages, with a Chinese version currently in the works.

In 2018, we introduced a new pharmacovigilance intelligence process to improve internal data analysis and informational output from our various sources. We have developed new capabilities in the following areas:

- advanced benefit-risk management
- big data analytics
- advanced signal detection technology
- pilot processes in patient-centric adverse effects collection

Supervising drug safety

Regulatory authorities conduct periodic inspections to verify that we are complying both with statutory requirements and our own internal standards for drug safety. In Germany, these are handled by the German Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (the German Federal Institute for Vaccines and Biomedicines (PEI) on behalf of the EMA. In 2018, four **pharmacovigilance inspections** were conducted in Japan, Slovakia, Slovenia, and Turkey. Every inspection has confirmed the proper functioning of our pharmacovigilance system.

Furthermore, we perform audits to ensure that all our departments and subsidiaries involved in pharmacovigilance consistently meet all requirements across the globe. In 2018, we conducted a total of 37 audits and found no significant deviations in our pharmacovigilance system from these requirements. We also audit vendors and licensing

partners involved in pharmacovigilance, which help us hone our pharmacovigilance processes so that they surpass statutory requirements.

Innovative signal detection

In 2018, we successfully launched a new methodology and technical system for analyzing and managing large amounts of data from around the world, such as scientific studies and news about side effects. Through this new tool for signal detection, named Empirica, we intend to become more efficient and proactive and improve risk management. It helps us to comply with regulatory timelines for safety signals and other safety-related factors and will ensure that all signal data, documentation and decisions are captured in one place. This allows easy access to and analysis of our data as well as cross-functional collaboration between Global Patient Safety and other internal and external stakeholders. Furthermore, we established a **new signal detection process** that allows us to detect signals directly from the EudraVigilance Data Analysis System (EVDAS) and enables us to comply with any new requirements set by health authorities.

Up-to-date labeling and product information

Our product information explains to physicians and patients how to properly use the respective drug and allows for an informed decision on the treatment. In accordance with statutory regulations, the **package insert** contains all relevant information such as indication and ingredients, as well as dosage, storage, mode of action, instructions for use, warnings, precautions and possible adverse effects. Should the medicine contain ingredients that may impact the environment, the package insert may also contain information on the proper disposal of the product.

As necessary, we review and update all product information documents such as package inserts, ensuring that our medicinal products contain the latest information on safety, efficacy and pharmaceutical formulation. In accordance with statutory requirements, all modifications to the inserts are submitted to the respective regulatory authorities for approval.

Internal and external training

All employees involved in the safety and quality of pharmaceutical products are trained according to our global training standards. We verify compliance with these requirements by producing training compliance reports and performing regular audits.

Our training is delivered via a **global-learning platform**. All of our 20,000-plus Biopharma employees receive basic pharmacovigilance training once a year that covers the procedure for reporting adverse effects from our products. Other training courses keep employees up to date on their professional expertise as well as internal standard operating procedures and other relevant requirements. This ensures adherence to Good Pharmacovigilance Practice (GVP) requirements.

Sharing expertise with other countries

We endeavor to transfer our drug safety expertise around the world, especially in countries where health workers need to build **their pharmacovigilance expertise**. In 2018, we organized a workshop for 96 students from the School of Medicine of the National University in Guatemala, as reporting of adverse drug reactions is often not sufficiently represented in the curricula of medical students. The participants were already examining patients and prescribing drugs on a daily basis, so they considered the workshop to be relevant and applicable in their daily routine.

We also assist Latin American health authorities in implementing electronic reporting processes for adverse effects. Following a pilot project in Ecuador that ended in April 2018, we are supporting the implementation of elec-

tronic reporting in Argentina, El Salvador and Peru. Health authorities in Mexico and Brazil are also moving towards adopting this technology. This program makes us one of the first companies to participate in global electronic reporting.

Our activities in providing **health for all** include involvement in piloting a **social business healthcare platform** in Kenya named **CURAFA**. As part of this project, in 2018 we provided training to two pharmacies on pharmacovigilance awareness and safety reporting procedures, and introduced our agReporter app to the people working there.

Launched in late 2017, we are continuing the "Afrika kommt!" project in an effort to educate trainees from Africa on the safe use of pharmaceutical products. The ultimate goal is for them to eventually take what they have learned and implement it in their home countries.

product-related crime

Part of the non-financial report

According to the World Health Organization (WHO), a considerable proportion of the medicines in developing countries are illegal, counterfeit or substandard. In industrialized nations, however, such products are also becoming increasingly available on the market through unlicensed internet pharmacies and underground platforms, posing a risk to public health. Moreover, chemical products too can be used for illegal purposes such as the manufacture of illicit drugs.

Our approach to product-related crime

Our company develops and manufactures products of the utmost quality. In order to protect both customers and patients, we secure our products against counterfeiting and are deeply committed to fighting product-related crime. For instance, we collaborate with regulatory and law enforcement agencies **at the regional, national and international level**. When cases of product-related crime are identified, we also cooperate with the law enforcement and public health authorities in the respective countries. In taking preventive action, we furthermore partner with representatives from Interpol and the World Customs Organization. Our guidelines, standards and processes apply to all our business sectors and markets worldwide.

What we mean by product-related crime

1. Counterfeit products: In line with the relevant WHO standard, we define a counterfeit product as “a product that is deliberately and fraudulently produced and/or mislabeled with respect to its identity and/or source to make it appear to be a genuine product.”

This includes products

- with incorrect active ingredients or concentrations thereof
- without any active ingredients
- with dangerous impurities
- with modified/alterd packaging and/or incorrect brand names
- with an authentic active agent, but not one produced under GxP conditions
- that have expired
- that were diverted from the legal supply chain (for example through theft).

2. Illegal diversion of products: This term refers to the diversion of either chemicals or pharmaceuticals from within the legitimate supply chain for illegal export, for use in the production of illicit drugs, weapons or explosives, or for any other illegitimate purpose.

3. Black market crimes: This refers to the sale of counterfeit and/or diverted products via illegal channels such as the Internet, or for illicit purposes.

4. Misappropriation of products: This refers to theft from production sites and warehouses, or while in transit.

How we are tackling product-related crime

Our Group function Corporate Security coordinates all our anti-counterfeiting activities, all of which are overseen by the Chief Security Officer and the head of Environment, Health, Safety, Security, Quality (EQ). Furthermore, all our sites have a product crime officer who investigates potential cases of counterfeiting, acting as the interface between local regulatory and law enforcement authorities, national associations, our Group functions, and our facilities. Depending on the type, allegations are first investigated by the competent unit. In 2018, conference calls attended by all product crime officers were held every two weeks to discuss strategic matters along with local issues and suspected cases of criminal activity.

Group-wide anti-counterfeiting network

Our Anti-Counterfeiting Operational Network (MACON) is responsible for **globally monitoring and executing all anti-counterfeiting measures** for our products. Along with coordinating prevention and the development of security systems, this organization is also responsible for investigations. Comprised of experts from various units such as Legal/Trademarks, Product Security, Export Control, Supply Chain, Patient Safety, and Quality Assurance, this network is coordinated by our Corporate Security unit.

To investigate suspected cases, MACON collaborates with the competent law enforcement agencies and regulatory authorities. This network has allowed us to identify more **cases of counterfeiting** and take decisive action, especially in high-risk countries. In 2018, MACON investigated and pursued numerous incidents including theft, counterfeiting and illegal diversion in both the legitimate and illegitimate supply chain.

Our commitment: Group-wide guidelines and standards

Our Crime Relating to Products Guideline describes our goals and strategies for combating product-related crime. Our Group-wide Product Crime Investigation Standard sets out **mandatory requirements** and defines the knowledge sharing process within our company in an effort to provide a solid legal footing for dealing with illicit products.

Enhanced monitoring and reporting systems

We analyze and document all counterfeit product incidents using a Group-wide reporting system. This approach provides us with a **complete picture of the security situation** and enables us to identify possible links between different cases, thus equipping us to combat similar incidents more effectively going forward. Our standard operating procedure "Data and Documentation Quality Management" details the corresponding process and was used in 2018 to standardize and harmonize data quality and reporting across our organization.

Tracking system for chemical substances

We monitor chemicals that could be misused to produce illegal weapons, explosives or narcotics, tracking them through an **internal system** that flags suspicious orders or orders of sensitive products. These are only released once we have confirmed the existence of a (verified) end-user declaration.

In 2018, the integration of Sigma Aldrich into our organization substantially increased the volume of products to be monitored. In an effort to augment process safety and efficiency, we revised our **internal reporting**.

In addition to fulfilling the duties stipulated by **statutory provisions on export control**, we also report suspicious orders, inquiries and requests to the competent authorities. Through these efforts, we are honoring a voluntary commitment of the German Chemical Industry Association (VCI) and meeting the terms of the Guideline for Operators published by the European Commission.

Reviewing our efforts

We evaluate the effectiveness of our measures according to the number of reported, investigated and solved cases, as well as their severity.

Supporting customers and patients

To protect patients, pharmacies must be able to determine the identity and authenticity of pharmaceuticals. We are therefore rigorous in meeting the requirements of the EU Falsified Medicines Directive and, accordingly, have set a goal for February 2019 to apply a **unique serial number** to the packaging of all the prescription medicines we commercialize in the European Union. We have already concluded the preparatory stage of implementation for 73% of our products covered by the directive. In 2018, 32% of these serialized products were in circulation. We are also transposing similar guidelines in many other countries. In the United States, for instance, we were the first company to comply with the 2018 Food and Drug Administration (FDA) product identification requirement.

In parallel to meeting these provisions, we also pursue our own initiatives:

- We apply the Security M label to some of our products, which enables users to **easily verify the authenticity**

of our products and is considerably harder to counterfeit than commonly used holograms. We take a risk-based approach to identifying the products to be labeled in this manner.

- Using our **Track and Trace** system to track the serial numbers of our products, delivery points (such as pharmacies) and distributors can trace the supplier of the medicine to verify its authenticity. So far, this system has been established in the United States, the European Union, China, Egypt, Colombia, Turkey, and parts of the Middle East, with implementation in Russia still underway. Preparations are currently being made to launch Track and Trace in Indonesia and Malaysia.
- Our free **Check My Meds app** for smartphones allows patients in the United States and Colombia to scan the serial number of their medicines and quickly verify their authenticity.
- In our **Mobile Anti-Counterfeiting System (MAS)** project in Nigeria, we are working closely with one of our suppliers on a text message-based identification system. Patients scratch off a barcode that is printed on the product packaging and then send this code via text message to an assigned number. They immediately receive a response telling them whether their code is authentic.
- We sponsor the non-profit Global Pharma Health Fund (GPHF), which supplies **GPHF Minilabs®** to test the quality of 90 different active ingredients. Used primarily in developing and emerging countries, this compact kit can detect counterfeit medicines quickly, easily and inexpensively. You can find more information on this project under [Pharmaceutical supply chain](#).
- We offer our customers in the pharmaceutical industry **Candurin® pearl effect pigments with** unique color properties that make tablets and capsules more difficult to counterfeit.

Industry-wide exchange

In an effort to fight product-related crime, we have joined forces with organizations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and the German Association of Research-based Pharmaceutical Companies e. V. (vfa). We also support industry-wide initiatives. For instance, we partner particularly closely with the Pharmaceutical Security Institute (PSI), a non-profit organization dedicated to protecting public health by sharing information on pharmaceutical counterfeiting and initiating enforcement actions through the appropriate authorities. We take an active role in this work through participation in [PSI conferences and network meetings](#). Furthermore, we are a member of [Rx-360](#), a consortium of global pharmaceutical manufacturers and suppliers that aims to prevent counterfeit products through a **worldwide quality control system**.

Raise awareness for product-related crime

We endeavor to raise awareness of product crime among our employees and business partners, educating our people Group-wide on the subject.

All staff involved in security, such as product crime officers, participate in **onboarding and training programs** aimed at building their capacities and promoting best practice sharing. We are continuously evolving these programs and adapting them to new trends. In 2018, for instance, we held 40 onboarding sessions for our product crime officers, covering product-related crime, incident reporting, case management, and cooperation with authorities.

In addition to offering training, we contributed to "Schutz vor Arzneimittelfälschungen: Regelungen zur Arzneimittelsicherheit", a book published in July 2018 by Editio Cantor Verlag that **discusses approaches to combating counterfeit drugs**.

Security audits for contract manufacturers and distributors

We regularly check whether our distributors and contract manufacturers are complying with GMP and GDP (Good Manufacturing Practice/Good Distribution Practice). These audits are based on the [EMA ICH Q10](#) pharmaceutical quality assurance standard. In doing so, we also ascertain the extent to which our **security requirements** are being obeyed by contract manufacturers and distributors, conducting special security audits if a concrete need is identified. Such audits are also conducted standardly when we certify external service providers for our Security M label. This applies to both pharmaceutical contract manufacturers as well as print companies that print packaging. The findings from these audits are a key factor in our decision-making process when considering potential external partners. If any critical defects are found, they must be rectified prior to us signing a deal, or a detailed corrective action plan must be submitted for our approval. In 2018, we conducted four security audits of our partners worldwide, who have since remedied the relevant defects.

Transport and warehouse safety

Part of the non-financial report

We transport and store products and materials worldwide such as chemicals and pharmaceuticals, raw materials, intermediates and waste, as well as technical materials and packaging, all of which could pose a hazard to health and the environment if handled incorrectly.

Our approach to safe transport and storage

We strive for all our shipments to reach our customers and sites safely, undamaged and with the required safety information. Several of the materials we store and transport are classified as hazardous. To minimize danger to people and the environment, we therefore adhere to **extremely strict safety regulations across our Group**. The storage of such hazardous goods and the corresponding transport involved – whether by road, rail, plane, or ship – are governed by regulations applicable worldwide. Our standards cover all stipulated safety guidelines, and we ensure compliance through regular audits of our sites along with training for our employees and the leadership of contract warehouses.

How we achieve transport and warehouse safety

Transport and warehouse safety falls under our Group function Environment, Health, Safety, Security, Quality (EQ) (see [Environmental stewardship](#)), which sets Group-wide standards and guidelines. In addition, our individual sites are subject to various national and international regulations governing environmental stewardship and public safety, which **local site directors are responsible** for implementing.

Each of our sites around the world has an EHS manager and a **dangerous goods manager**, a position that equates to the “dangerous goods safety advisor” required by EU regulations. Both of these people advise the site director on the safe storage and transport of hazardous goods while also monitoring compliance with statutory requirements and our own internal standards.

Our EHS managers are also responsible for **monitoring our contract warehouses**. Before signing a contract with a third-party warehouse operator, we assess whether they properly adhere to national and international storage and transport regulations and if they are able to meet our additional requirements. The findings from this audit are summarized in a statement issued by EHS. If off-site warehouses employ additional subcontractors, these are also included in our audit.

Our commitment: Internal standards and international rules

Our **Group-wide safety concepts and standards** govern the safe storage of hazardous substances. Take our Warehouse Safety standard, for instance, which sets out measures to prevent materials from leaking or igniting and requires us to specify the dangers posed by any stored

substance. Moreover, special rules of conduct apply to all warehouse employees.

Third-party warehouses must also adhere to our strict safety requirements. Before we sign a contract, providers must submit a statement detailing how they plan to meet our stringent safety standards, while audits are performed to ensure compliance from both our own warehouses as well as third-party facilities. To this end, in 2018 we drew up a standardized checklist that helps us assess contract warehouse risks. Furthermore, our Group standard “Warehouse Requirements for Third-party Warehouses” defines specific **structural and organizational requirements**.

In Germany, the Technical Rules for Hazardous Substances ([TRGS 510 Storage of hazardous substances in non-stationary containers](#)) govern the **storage of packaged hazardous materials** and apply across all our warehouse and distribution centers worldwide. We are currently working with the Committee on Hazardous Substances ([AGS](#)) of the German Federal Ministry of Labor and Social Affairs to revise these rules. Beyond complying with these requirements, all our sites fulfill the current requirements of the Globally Harmonized System of Classification and Labelling of Chemicals ([GHS](#)).

Our Group Transport Safety standard defines the **safety levels for our facilities** and is based on the United Nations Recommendations on the Transport of Dangerous Goods. This is especially important for sites in those countries with no local regulations covering the transport of hazardous materials. We update our Group standard to reflect current requirements every two years and support our site directors in implementing relevant changes at the local level.

Enhancing transport and warehouse safety

In addition to the inspections conducted by our EHS and dangerous goods managers, we regularly perform **risk-based** audits across our company to ensure that our sites are complying with warehouse and transport safety regulations. We generally conduct these every four years, performing them more frequently at facilities that pose a potentially higher risk. If major shortcomings are identified, we re-audit the respective site the following year. Conversely, we may decide to extend the period between audits at facilities where, based on the findings from previous audits, we deem the potential risk to be low.

In 2018, we audited ten of our warehouse facilities for compliance with our Warehouse Safety and Transport Safety standards. All audit observations were assessed in terms of the areas where we can improve, with the focal points of the observations being scrutinized and addressed. In response to the deficiencies identified by these audits,

we are currently reviewing and optimizing our processes for **safety-related storage time limits**. For instance, specific transport regulations require time limits, as does the use of stabilizers and desensitizers, while plastic packaging has a limited shelf life due to aging. Moreover, we drafted or revised training documents on load securing, safety data sheets, safety signs, and the safe use of pallet units.

Third-party warehouses and contract logistics companies are also regularly audited by our EHS managers. In 2018, we audited 15 third-party warehouses and external logistics providers, developing corrective action plans where deficiencies were identified. To optimize safety communication, we created **additional informational material and distributed it to all our contract warehouses**.

As a member of the SQAS Logistics & Distributors User Group, a service provided by the European Chemical Industry Council (Cefic), we receive additional audit reports on our logistics service providers and evaluate these against our own set of criteria.

In 2018, no incidents that could have significantly impacted the environment or community were recorded at our company, our third-party warehouses or our logistics providers, nor were there any major infringements of international regulations.

Continuously evolving safety concepts

Our local EHS and dangerous goods managers regularly review and evaluate our transport and warehouse activities, informing site directors of shortcomings and opportunities for improvement. Underpinned by a **strength and weakness analysis of each site**, we calculate key performance indicators for transport and warehouse safety that help us determine where to institute additional improvements.

Employee training and best practice sharing

Multiple times a year, our warehouse workers and all employees involved in the transport of goods undergo training on our standards and procedures, as well as on incident management and changes to international requirements. The e-learning concept we've developed for basic management courses on hazardous material transport is mandatory for logistics, EHS and dangerous goods managers. By the end of 2018, the majority of eligible employees had completed such a course. To bolster this

e-learning concept, we offered further **classes on transport and warehouse safety**. All our truck drivers hold a dangerous goods driver's license, while in Germany they complete additional training on securing cargo, along with training required by the German Professional Driver Qualification Act (BKrFQG). Across the globe, we conduct around 1,000 internal and external seminars on transport and warehouse safety every year. In some cases, the managers of third-party warehouses also participate in these sessions.

To further best practice sharing, our EHS managers meet every three years at our **EHS Conference** in Darmstadt (Germany), where they have the opportunity to share lessons learned and participate in transport and warehouse safety training. These topics are also covered in the mandatory three-day orientation seminar for all new EHS managers. The next EHS conference will be held in 2019.

Ensuring correct transport

Our products are primarily delivered to our customers by means of logistics providers. In Germany, we transport the majority of our hazardous waste ourselves, but do sometimes also enlist the services of contractors if necessary. Furthermore, we participate in the German **Transport Accident Reporting and Emergency Response System** (TUIS) operated by the German Chemical Industry Association (VCI). Within this system, we exchange lessons learned and best practices on chemical transport with experts from other chemical companies and also provide hands-on assistance in the event of a chemical transportation accident. When a transportation or warehouse accident occurs, we can use our "TUIS Southern Hesse Measuring Concept" to quickly calculate the rate at which hazardous substances are spilling and spreading.

Making transport vehicles safer

The safe transportation of dangerous goods requires safe vehicles, another factor we take very seriously. Over the past few years, for instance, we have been constantly evolving our **SafeServer truck body technology**. Under this design, the aluminum panels integrated into the side walls of the truck render the walls extremely stable. In 2018, 14 of our trucks were already running with this technology.

Employees

Within this chapter:

85 Attractive employer
90 Diversity
94 Health and safety

97 Employee engagement
99 Good leadership

Attractive employer

Part of the non-financial report

Across the globe, our employees drive next generation advancements in science and technology. As they do so, we encourage every one of them to pursue the professional path that aligns with their individual ambitions, skills and talents. We offer flexible working models that allow our people to adjust to the changing priorities in their lives. To continue down the path of success, we endeavor to attract talent who will bring courage, creativity and curiosity to the table.

Our approach to attracting and retaining talent

We believe that curiosity can make great things happen. We therefore seek to provide an environment that gives our employees plenty of **scope for creativity** and awakens their desire to innovate. Our **employer brand** communicates this mindset to the outside world. Through our motto “Bring Your Curiosity to Life”, we show applicants what they can expect when they join our company. We regularly train our employees, managers and recruiters on the characteristics of our employer brand.

In addition to our recruiting efforts, **career development** also plays a key role in attracting and retaining people. Focusing on their individual strengths, aspirations and skills, we support their personal and professional development, thereby laying the groundwork for an enriching and challenging career with our company.

We endeavor to discover qualified employees at an early stage in their career and develop their talents. Within our **succession management process**, we work with leaders and Human Resources to systematically prepare these select candidates for leadership positions. Our goal is to move suitable candidates into vacancies quickly and efficiently.

We furthermore develop our people by transferring them within the company, for instance from one business sector or function to another. To provide a framework for this practice, our company has a Group-wide job architecture in place called Expanding Horizons, which defines three fundamental career types of equal stature: managers, experts and project managers.

We seek to offer our employees **ideal working conditions** including a retirement plan and flextime models, along with social benefits and an attractive compensation package. Compensation is based on both our company’s success and individual performance.

How we structure our human resources management

Human Resources (HR) supports and advises all businesses and units within our organization. Our Centers of Expertise Talent, Development and Recruiting, Compensation and Benefits, and Engagement and Inclusion develop strategies to promote and advance our employees, organization and corporate culture. These units also coordinate the imple-

mentation of necessary measures. Across all our sites, HR staff execute these measures in collaboration with leadership from the business units in accordance with **Group-wide HR guidelines and requirements**. We perform internal audits every two to three years to ensure that all steps taken comply with these guidelines.

Belén Garijo is the Executive Board member responsible for Group Human Resources. Our Chief HR Officer, in charge of the various HR activities, HR experts and HR business partners, reports directly to her. Our Business Services unit oversees the operational tasks of human resources work, such as drafting contracts and payroll accounting. Marcus Kuhnert, Executive Board member and Chief Financial Officer, is responsible for this unit.

Digital HR

To **harmonize our HR processes Group-wide**, in 2012 we launched the HR4You online platform, which can be accessed by all employees. This platform is used to manage central HR tasks such as development and succession planning, job vacancies, continuing education, and employee performance assessments. It moreover helps calculate compensation and bonus payments.

Our commitment: Guidelines for employee development and working hours

In 2018, we updated our People Development and Learning Policy, which provides a Group-wide framework for continuing employee development. For instance, it specifies guidelines for our development opportunities along with roles and responsibilities. The corresponding processes are described in our People Development and Learning Standards.

Also in 2018, we furthermore started drafting a **Group-wide flexible work guideline** that was adopted by the Executive Board at the end of 2018 and is intended to establish and foster a variety of flexible options for working time and location across our organization.

Group-wide work and social standards

We are dedicated to upholding appropriate labor and social standards. Our **Code of Conduct** is a **compulsory set of rules for our entire workforce**. All employees have been provided with a copy of the Code of Conduct, and new employees are supplied a copy with their letter of offer.

Our Code of Conduct explains the principles for dealings with business associates, general partners, co-workers, and employees, as well as the communities in which we operate. It thus supports all employees in choosing an ethical path. Our [Human Rights Charter](#) supplements the Code of Conduct with global human rights principles such as the fundamental conventions of the International Labour Organization (ILO), which cover topics like freedom of association and collective bargaining, forced labor, child labor, anti-discrimination, equal opportunity, equal pay, working hours, occupational health and safety, and the prevention of abuse and harassment. We conduct internal audits to ensure that our local subsidiaries are complying with these standards.

In 2018, we used a benchmark analysis as the basis for drafting a Group-wide guideline governing adherence to additional ILO labor standards. This new guideline is to be rolled out and implemented worldwide in 2019, underscoring our ambition to make international occupational and social standards a pillar of our organization.

Providing feedback and supporting development

We regularly provide our employees performance feedback through our **Performance and Potential Management Process**, which ensures that, in addition to this ongoing feedback, a meeting is held once a year to evaluate their overall performance. This process is applicable to all employees Group-wide with a Role of 2 or higher, and additionally to all non-exempt staff employed by either Merck KGaA, Darmstadt, Germany or any other subsidiary based in Germany.

Our leaders and subordinates work together to define individual objectives and, in a separate process, create a **detailed development plan** that reflects each employee's core tasks as well as current strategic priorities. In drafting the development plan, all employees have access to the Development Advisor. Building on our [competencies](#), this web-based tool provides a selection of development opportunities that employees can tailor to their own needs, while our digital HR4You platform allows them to create their development plan quickly and easily.

Employees can additionally have their performance assessed by select colleagues and external partners. This **360-degree feedback** helps to identify personal strengths and advancement opportunities. Moreover, our people have access to a real-time feedback tool launched in 2017, that can be accessed via their PC or smartphone, making it easier to give and receive feedback. Intended to help promote a non-hierarchical feedback culture, this instrument has been used since its rollout by 16,183 employees, who have provided feedback 32,743 times. We are constantly updating the tool to make it more user-friendly.

of our employees took part in the Performance and Potential Management Process in 2018, with 70% of our employees creating a development plan.

Employee learning and education

Our **Group-wide advanced training and continuing education program** ensures that our employees develop the skills needed to help us realize our company strategy. We constantly adapt the offerings to meet current learning needs and strategic priorities. Moreover, employees can use our digital HR4YouLearning tool to sign up for events such as seminars and online training courses as set out in their tailored development plan.

In 2018, more than 4,100 employees took part in our Group-wide classroom courses. These courses are flexible, meaning that while the core curriculum is uniform throughout the company, there is still room for adjustments to reflect aspects such as specific local change projects. Along with in-person training, 1,550 employees signed up for **global e-learning courses** and 235 completed online language classes.

Performance-based pay

We endeavor to reward the performance of all our employees and maintain a competitive edge in attracting qualified professionals, which necessitates commensurate compensation. At our company, compensation is based on the requirements of each position as well as each employee's respective performance. In addition to competitive remuneration, we offer attractive fringe and social benefits. Our **benefits4me** package, for instance, encompasses three pillars, namely company-funded benefits including our company retirement plan, health and well-being offerings, and services. To meet the multifaceted needs of our workforce worldwide, we offer **a variety of benefit packages**.

To ensure a **competitive remuneration structure**, we regularly review our compensation policy based on data analyses and benchmarks. In doing so, we take internal factors and market requirements equally into account. When revising this policy, we involve key stakeholders such as [employee representatives](#) in the early stages of the process. The pay structures within our company are gender-neutral and based on defined criteria such as job requirements and performance. Our Group-level analyses show that there is no significant gender-based compensation inequity.

Attracting qualified university graduates

We endeavor to attract top university graduates. As part of our efforts, we partner with the German online network "careerloft". Furthermore, we regularly attend job fairs to inform potential applicants about job opportunities and career tracks within our company. In countries outside of Germany, particularly the United States and China, we likewise use career fairs as a way of making **initial contact with university graduates**.

In addition to recruiting talented students, we also provide them financial assistance, collaborating with organizations such as the German National Academic Foundation and the Foundation of German Business, as well as supporting the Deutschlandstipendium (German national scholarship program).

University graduates can apply for a position with our company directly or complete one of our trainee programs. Our trainees acquire **international experience** in various business sectors and functions, and take part in tailored continuing education offerings.

Inspiring young people to join our company

We employ trainees in units such as Inhouse Consulting, Finance, Production, Marketing, Sales, Human Resources, and Research and Development. In 2018, we launched a trainee program in Procurement.

Our global graduate program GOGlobal enables university graduates to join our company as a trainee. Within 24 months, the entry-level employees get to know various departments and functions while also gaining international work experience. All ten GOGlobal **trainee programs** provide experience in various units, international assignments, custom-tailored continuing education, mentoring, and coaching. Although the initiatives are largely centered around Germany and the United States, we also have trainees at our sites in China, France and Ireland. In 2018, we employed 114 trainees.

To cultivate young talent, we also offer internships in all departments to high school and university students. Through our **Keeping Ties to Students program**, we stay in touch with talented individuals who perform particularly well during their internship. Besides these programs, we also offer university students work-study jobs or the opportunity to pursue their bachelor's degree, master's degree or doctorate. Furthermore, every year we invite students from Austrian, German and Swiss universities to our company to learn about the various career tracks and job opportunities we have. In 2018, we redoubled our contact with students by expanding our Keeping Ties to Students program and augmenting the number of German national scholarships we sponsor.

The foundation: Vocational training

For us, vocational training is a key way to meet the **current and future need for qualified professionals**. In Austria, Germany and Switzerland, we offer apprenticeships across a number of professions, along with cooperative education programs. We continuously invest in new technologies and integrate these into our vocational training. Young adults can also complete their vocational training on a part-time

basis. If after completing their apprenticeship they wish to continue studying while working, we will cover up to 75% of the costs and also allow them to take special leave. Furthermore, apprentices can take part in community outreach projects.

High hiring rate and dual education programs

In 2018, 604 people were enrolled in vocational training programs at our sites in Germany, with 222 beginning their apprenticeship at our company. In total, we offer apprenticeships across 24 occupations, primarily in production, laboratory work and office administration. In 2018, we launched an animal welfare apprenticeship along with an apprenticeship to become a wholesale and international trade specialist. Furthermore, we enable young adults to pursue a dual education program in the fields of business administration, business IT, process engineering (chemical engineering), and mechanical engineering. Apprentices in the Laboratory group begin their training as chemistry or biology lab technicians and, subject to suitability, may receive the opportunity to start a dual education program after six months. Since 2014, we have been offering **permanent employment contracts** to all apprentices and graduates of cooperative study programs in occupations for which we have long-term demand. In 2018, the hiring rate for graduates of these programs – taking voluntary terminations into account – was over 90%.

Special vocational training opportunities

In Darmstadt, our "Start in die Ausbildung" program helps young people who have a high school diploma but have been searching for an apprenticeship for at least one year without success. We offer them the opportunity to complete an eleven-month program with our company, providing **professional experience** and improving their chances of gaining an apprenticeship. In 2018, 21 participants aged 16-25 started this program. Since its launch in 2006, 223 young people have already taken part; 103 of them have successfully completed an apprenticeship, while 55 are still in a vocational training program.

We also have a similar program for **refugees**. In 2018, the "Integrating refugees through training" initiative prepared 12 young refugees for vocational training, thereby opening the door to the German labor market. The project comprises language, technical, cultural, and career-related training. In 2018, we hired four of the participants from the 2017 program as apprentices and placed three others in apprenticeships with other companies. The five remaining participants are now pursuing further studies at schools or universities.

Leveraging the opportunities of digitalization

The digital transformation has long since overtaken the world of work. New, agile approaches to work are increasingly gaining ground, a shift we are actively supporting within our company by offering our people numerous **innovative digital options to perform their tasks**. Take for instance big data applications such as people analytics, which allow us to analyze Human Resources data. Our Manager Self Services and Employee Self Services also

epitomize a state-of-the-art approach to work, enabling employees to manage their own data, access information and handle HR-related tasks on their own.

Using such **big data applications** developed by our People Analytics HR unit, leaders obtain rapid, specific answers to HR-related questions. Besides gleaning conventional master data, this software also collects information on compensation, performance and potential, along with info on engagement and succession planning, interconnecting this data in meaningful ways. Managers thus have access to an extensive trove of data that they may utilize as long as they comply with data privacy. The analyses are based on algorithms and enable us to conduct predictive analytics and make data-driven decisions.

Digitalization is also impacting our vocational training and continuing education programs, where IT skills are becoming increasingly crucial. At the same time, digital media are creating new opportunities for learning, which is why we are increasingly integrating 3D printing, Big Data and artificial intelligence into our curricula. Moreover, we are testing out **novel learning and innovation methods** such as Scrum and Design Thinking.

To learn how to operate plants and machinery, our apprentices also utilize augmented reality glasses while operating the systems, accessing useful additional information via a display.

In 2018, a Group-wide **HR innovation campaign** also gave rise to an initiative entitled "Ad@m", which features a **chatbot**. Accessible to HR business partners and leaders, it provides support for HR-related issues, among other things. Going forward, the chatbot will be taking over standardized tasks so that managers and HR business partners have more time for other matters.

Good standing in employer rankings

Our company is one of the world's best employers, a fact now officially verified by the **Global Top Employer 2018** certificate awarded by the Netherlands-based Top Employers Institute. Every year, this independent institute organizes an international assessment involving an external audit as well as a detailed survey to determine the processes and structures that make up a company's human resources environment.

The success of our efforts is also confirmed by our **ranking among the 100 most attractive employers** for students and experienced scientists in Germany. This index is published annually by the research and consulting firm Universum and involves a survey of more than 5,000 people. In the category of Natural Sciences, our Group ranked fifth in the student survey and seventh among experienced professionals in 2018.

In addition to this recognition, we were also named a 2018 top employer by Science, a leading peer-reviewed scientific journal. Almost 8,000 employees as well as managers from biotech and pharmaceutical companies took part in the magazine's online survey, ranking our company fourth.

Finding work-life balance

We recognize how important work-life balance is for a productive and motivated workforce. With this in mind, at the end of 2018 our Executive Board adopted a Group-wide guideline intended to facilitate the use of a variety of flexible working time and location options in the twelve countries where the majority of our employees work (75% of our workforce). In many countries, we already allow our employees flexibility in setting their own work schedule, with our people making use of **more than 30 different part-time working models**. In Germany and the United States, where around 45% of our workforce is based, we offer parental leave conditions that go beyond the statutory minimum requirements.

Flexible working models

We offer our employees various flexible and innovative working models. Our "mywork" program, for instance, is available to employees at our Darmstadt and Gernsheim sites in Germany along with many other facilities across Europe, Asia and Australia. It is open to both exempt and non-exempt employees. In agreement with their teams and supervisors, employees can freely choose their working hours and location. Together with their respective supervisors, the teams can decide for themselves when and how often fixed physical presence in the office is necessary for all members. Working hours are no longer recorded or monitored. This approach aims to strengthen the **culture of performance and trust** within the company. At the end of 2018, a total of 5,698 employees in Germany were making use of this model.

In 2018, 4.8% of our employees worked part-time, 12.5% of whom were men. We believe that with these flexible working models, we are on the right track to achieving a better balance between the expectations we set as an employer and the home life demands of our employees. Ideally, such a balance should also lead to greater **employee satisfaction** and increase our appeal as an employer.

Supporting mothers and fathers

We endeavor to make it easier for our employees to return to work following parental leave, which is why in 2016, we launched a program for parents in Darmstadt and Gernsheim (Germany). By the end of 2018, 100 employees had signed up for this program, which gives mothers and fathers on parental leave the chance to talk and interact while also helping them keep in touch with the company. Moreover, they can make use of the various **training and networking opportunities**. We have established a similar program in the United States.

In the United States, we offer the female employees in our Life Science and Healthcare business sectors eight weeks of paid maternity leave. In Life Science, fathers are eligible for two weeks of paid paternity leave, which also applies when adopting a child, while Healthcare staff are given five weeks of paid paternity or adoption leave. In 2019, we intend to standardize paternity leave across all our subsidiaries in the United States, setting it at five weeks. By contrast, the statutory minimum only provides for 12

weeks of unpaid parental leave per year. Furthermore, we also reimburse up to US\$ 5,000 in adoption fees.

At our sites in Germany (around 25% of our workforce), 326 employees were on parental leave at the end of 2018, 42% of whom were men. In other key countries, we go **beyond the legal requirements** to offer other kinds of new parent support such as extended leave for employees in Brazil. In India, too, we offer five days of paid paternity leave even though it is not legally required. In offering these benefits, we do not differentiate between full- and part-time staff. Employees with fixed-term contracts may apply for parental leave until the end of their term of employment, with their employment continuing as agreed until the contract terminates.

Daycare support

For 50 years our headquarters in Darmstadt has featured a **daycare center for children** aged 1-12. This facility is funded by the Merck family and offers 150 slots. Since 2013, we've been providing year-round care from 6:30 a.m. to 7 p.m. For the children of our employees in Gernsheim, five places are available at a public daycare center.

Our Darmstadt site also offers **provisional daycare services** to cover times when an employee's regular childcare falls through. During school breaks in the German Federal State of Hesse, we host a number of vacation camps focused on sports, art, research, and nature for up to 450 children. We also provide temporary care for sick children. For up to two days a year, parents throughout Germany can engage the services of an education specialist free of charge to look after their children at home.

Our facility in Mumbai, our main site in India, also has a **daycare center** that our employees can use. In the United States, parents can go to www.care.com to find external childcare. Furthermore, we offer up to ten days of provisional childcare, as well as daycare center slots at special rates and home childcare.

Saving for retirement through a long-term account

We enable our employees in Germany to reduce their working hours before retirement or to retire earlier through

a **long-term account**. For instance, they can deposit part of their salary or comp days into the account. Our company additionally makes contributions to the account to supplement the balance. Employees can then utilize the accrued balance to retire up to three years before they are due to start their regular retirement plan, or to reduce their working hours by 50% for up to six years. In 2018, 9,214 employees made use of this option.

Taking a sabbatical

In essence, all employees of Merck KGaA, Darmstadt, Germany and Merck KGaA, Darmstadt, Germany Real Estate GmbH in Germany (22% of our workforce) can request a **sabbatical**, which allows them a break of up to one year. At the end of 2018, 22 people were on sabbatical. For personal emergencies in which an employee needs to leave immediately, we additionally offer an emergency sabbatical of up to three months in duration.

Assistance with family and elderly care

For our employees in Darmstadt who are caring for family members, we provide **special seminars and family care services**. Moreover, through our "Family leave" model, we offer people throughout Germany the option of taking a short- or long-term break from work, whether partial or complete. We are thus enabling employees to organize and provide care for their loved ones, in line with the German Family Leave Act and the German Home Care Leave Act.

Twice a year, we offer our employees in Germany family care seminars on a range of topics. In 2018, these addressed work-life balance, the financial and legal issues involved when family members require care, and age-related dementia and depression. An external associate provides advice on all issues relating to family care and guides employees in their **search for suitable options**. In Darmstadt, our company health insurance fund also puts people in touch with nurses and, in the United States, our employees can use the online portal care.com to locate family care services.

Diversity

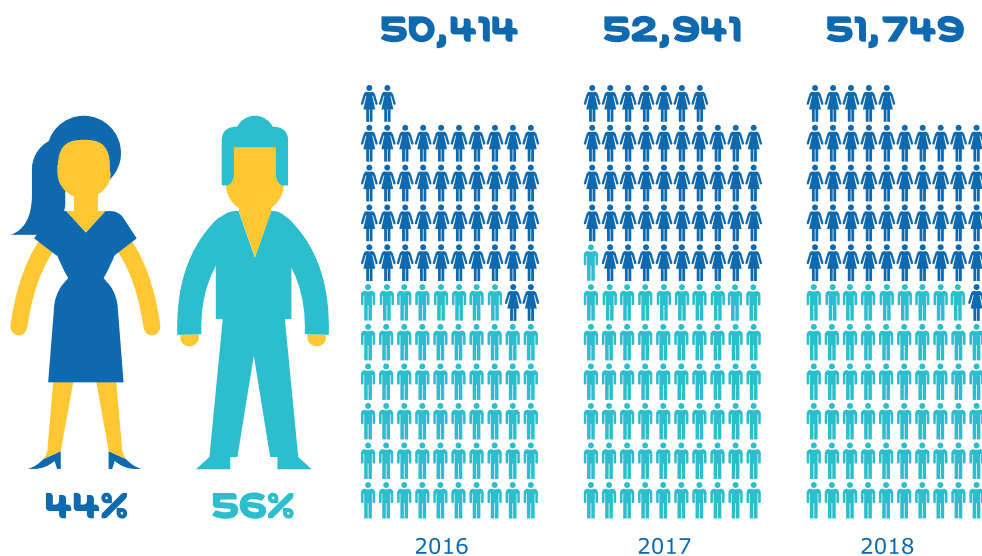
Part of the non-financial report

We are a global science and technology company with employees who represent a varied cross-section of gender identities, nationalities, cultures, religions, and age groups, as well as different sexual orientations. They bring their professional backgrounds, life experience and point of view to the table, incorporating this richness into their work. We believe that a diverse workforce – paired with a respectful corporate culture – strengthens our ability to innovate and contributes significantly to our business success.

Our approach to diversity and equal opportunity

We are dedicated to creating **an inclusive culture** that reflects our values and enables every employee to unlock their potential. Our goal is to further drive diversity across our workforce and offer all our people equal opportunities for advancement.

Our employee numbers



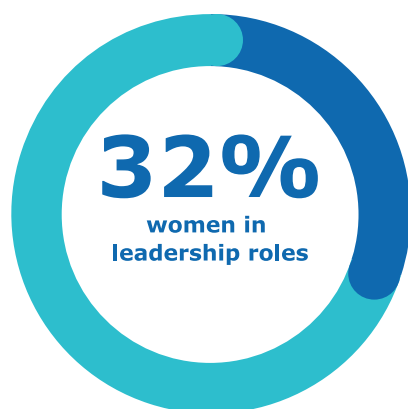
In 2018, we reviewed our **Diversity Strategy** and revised parts of it. Going forward, we will continue to focus on promoting women in leadership roles. Because Asian markets are becoming increasingly important to us, we have set the new goal of offering better opportunities to talent from the Asia-Pacific region. We are also continuing to pursue the other goals of our strategy: cultivating an international work environment, taking action against all forms of discrimination, creating teams with a balanced age structure, and building a diverse base of educational backgrounds and experience.

The strategic competencies that guide our employees and leaders in their tasks are set out in our **Competency Model**, a fundamental element of HR processes such as recruitment, feedback and training for supervisors and

leaders. Building on this model, we defined six leadership behaviors in 2018, and also started to educate our people Group-wide on **unconscious bias**. We endeavor to help leaders recognize and reconsider these thought patterns in their daily routines and interactions as well as their decision making, ultimately making a lasting change to their approach.

In 2018, we also **expanded a variety of HR tools and software** that help leaders manage diverse teams. This allows them to quickly and reliably analyze their personnel and team data in terms of diversity and inclusion, and foster an inclusive culture that helps all team members contribute. Selected data on topics such as diversity are also presented in this report.

Women in leadership roles: Requirements and targets



thereof **19%** in senior management



thereof **33%** in middle management



At the end of 2018, women occupied 32% of leadership roles Group-wide, which means that we exceeded our 2021 target of maintaining a 30% representation of women in these positions. Although these figures are increasing steadily across the company, this is not the case within certain business units, Group functions and hierarchical levels. We are therefore working to further increase the **representation of women** in leadership positions and in those business units where they are still underrepresented. To achieve this objective, in 2018 we formed special teams responsible for developing goals and measures at a departmental level to help us advance female candidates into roles in different areas and hierarchies. In the units where the 30% target has been achieved, we are working to further increase the percentage of leadership positions held by women. In cultivating talent, for instance, we focus on promoting top-performing women in an effort to place more women in leadership positions.

How we are making diversity a pillar of the company

Our Chief Diversity Officer is responsible for overseeing our Group's diversity strategy and reports directly to Belén Garijo, the Executive Board member whose responsibilities include Group Human Resources. Consisting of executives from all our business sectors and select Group functions, our **Diversity Council** performs four key tasks:

- It is responsible for implementing our strategy for greater diversity and inclusion.
- It evaluates and develops proposals to increase diversity submitted by our business sectors, Group functions and employee-organized networks.
- Council members ensure implementation of the Diversity Strategy in their respective areas, monitoring the progress of the initiatives.
- Members act as direct points of contact for the employees in their respective areas.

Group Human Resources (HR) has also implemented a number of programs and processes in order to further enhance diversity within the company. In our business units, work teams assess special requirements and devise a corresponding course of action.

Our commitment: Industry-wide initiatives and regulations

In an effort to drive diversity across our organization and underscore our **commitment to fairness, inclusion and tolerance** in the workplace, we support industry-wide initiatives:

- In 2017, we adopted the new Inclusion Action Plan of the German Mining, Chemical and Energy Industrial Union (IG BCE), which sets out concrete measures and provides guidance for creating a more inclusive workforce for employees with disabilities. In endorsing this plan, we are meeting the requirements of the United Nations Convention on the Rights of Persons with Disabilities.
- In 2015, we signed the IG BCE Equal Opportunity Charter, thereby promising to do everything in our power to achieve gender equality within the company.
- In 2013, we endorsed the German industry-wide "Charta der Vielfalt" (Diversity Charter).
- In 2011, we joined other DAX[®] 30 companies in signing a declaration committing to advance women in leadership roles and have been regularly reporting on our progress.

Meeting statutory requirements

The German Law for the Equal Participation of Women and Men in Leadership Positions in the Public and Private Sector has been in effect in Germany since 2015. Owing to our legal form as a KGaA (corporation with general partners), this law also applies in part to us. Detailed information can be found on our [website](#).

Consisting of 37.5% women (six out of 16 members), our Supervisory Board already meets the stipulations of German legislation on the **gender quota**. Owing to our legal form as a KGaA (corporation with general partners), we are not required to set targets for our Executive Board. For the two management levels below the Executive Board of Merck KGaA, Darmstadt, Germany, however, the Executive Board set the following targets in 2016:

- 21% women on the first management level below the Executive Board
- 26% women on the second management level below the Executive Board

We have set a deadline of December 31, 2021 for reaching these targets.

Revealing unconscious bias

We seek to **raise awareness for diversity and inclusion** among our employees. In a bid to educate people on unconscious bias, in 2018 we conducted pilot projects Group-wide involving a variety of training seminars and plan to roll out this training curriculum Group-wide in 2019. Approximately 380 employees took part in 2018. Through these workshops, we helped participants recognize unconscious thought patterns and stereotypes, thereby preventing any unfair treatment. To support these efforts, in 2018 we developed a new training concept and accompanying programs to drive awareness of unconscious bias across our organization.

In 2018, for instance, we rolled out the Job Analyzer, an online tool that helps us maintain **gender neutrality when communicating with applicants**. The algorithms assist our recruiters and leaders in reducing potential unconscious bias during the hiring process. The online tool is currently available in English, with a German and French version currently in the works.

Promoting women leaders and talent

We support our business units in their efforts to advance more female candidates into leadership roles. Since the end of 2017, we've been utilizing the **Healthy Women, Healthy Economies toolkit**, whose guidelines help us identify methods of promoting the **health of our female employees**.

In 2018, we furthermore hosted a variety of events on the topic:

- Under our Women in Leadership pharmaceutical initiative, we hosted an internal conference for our Healthcare leaders based in Darmstadt, Switzerland and the United States. This workshop aimed to educate people on gender equality in leadership roles.
- Partnering with external organizations, we hosted an event series on "Women in Science and Technology Companies".
- In 2018, our Life Science business sector also organized 14 Diversity Days.

In the United States, we sponsored the **Big Sisters initiative** to commemorate International Women's Day, a program that offers mentoring for **young women from underprivileged communities**. Among the mentors are employees from our company. In mid-2018, we furthermore launched an internship program in Italy for women with MS. On average, women develop multiple sclerosis (MS) twice as often as men. Unique to this program, it not only provides MS patients a stepping stone into the working world, but also helps us understand their needs and expectations concerning working life.

Networks to bolster diversity

Creating an inclusive work environment that promotes mutual respect is a particular focus of our Diversity Strategy. We support specific employee networks in order to foster **exchange among like-minded individuals**. Apart from our internal women's network in various countries, we also promote networks that further the interests of the LGBTIQ (Lesbian, Gay, Bisexual, Trans, Intersex, Questioning) community, Afro-American employees and international staff. Owing to the acquisitions we have made in recent years, there has been a steady increase in the number of our employee networks. Going forward, we intend to better leverage the potential of these networks to benefit our business activities. Networks with similar objectives are to be merged and expanded internationally. Moreover, we want to help establish leadership structures within these networks and define their goals. In 2018, the networks made great strides in sharing lessons learned and synergizing efforts.

- Our **women's networks** offer women within our company a forum to discuss professional possibilities and best practices, providing each other mutual support in building their own competencies and advancing their careers. These networks also seek to identify, consolidate and maximize synergies between the global groups, transcending business sectors and hierarchies.
- Through our **Rainbow Network** for homosexual, bisexual and transsexual employees, we supported the 2018 Christopher Street Day in Frankfurt and Darmstadt (Germany). As well as taking part, we were the official corporate sponsor of the event in Darmstadt. Since 2016, the Rainbow Network has also been active in the United States and Canada, engaged in activities such as internal and external forums.
- Our U.S.-based **Black Leadership Network** is dedicated to advancing and developing African American employees, offering its members advanced training and continuing education programs, tailored career planning and networking opportunities.
- In our **Carer Network**, we bring together employees from across the globe who are caring for family members. The network helps people share lessons learned and best practices, as well as helping them process the personal and professional experiences that arise every day while caring for their loved ones. To raise awareness for the often overlooked needs of carers, the network also supports the general mission "**Embracing Carers**".

Tapping into external networks

We are a corporate partner of the Healthcare Businesswomen's Association (**HBA**), a non-profit organization committed to furthering the **advancement and impact of women** in the healthcare industry. We encourage our female employees to get involved in this network because it gives them access to mentoring programs as well as the opportunity to attend various seminars and conferences at our global headquarters in Darmstadt (Germany), as well as in Lyon (France), Lausanne (Switzerland) and Boston (Massachusetts, USA). Two of our female employees are

board members of HBA Europe. In autumn 2018, 35 of our employees participated in the HBA's European conference in Berlin (Germany) as well as five female employees in its annual conference in Washington D.C. (USA). Moreover, we were the main sponsor of the HBA's European Leadership Summit, which was held in Berlin in 2018.

In 2018, we also sponsored the Women's International Networking (WIN) Conference in Rome (Italy); 16 of our employees attended, with several of them giving talks. The **network connects women in leadership roles** with the aim of helping them gain more influence. In 2018, one of our female employees participated in the Task Force Summit held by the Center for Talent Innovation in New York City (USA).

Taking action against discrimination

As stipulated in our [Code of Conduct](#), we do not tolerate any form of discrimination within our company. If an employee feels they have been discriminated against, they can report the issue **via various channels**. Their first point of contact is either their supervisor or one of three Group functions, namely Human Resources, Legal or Compliance. Alternatively, employees can call our SpeakUp Line anonymously from anywhere Group-wide. Group Compliance is responsible for investigating alleged cases, a process coordinated by the Group Compliance Case Committee. In confirmed cases of discrimination, a subcommittee provides a recommendation for disciplinary action that is implemented by our management team. In this way, we ensure that similar cases are dealt with consistently across the company. Details on alleged cases can be found under [Compliance](#).

Successfully integrating international employees

Our company is becoming increasingly international. We currently employ people from a total of 136 nations, 24% of whom are German citizens. Our leadership (Role 4+) includes representatives of 70 nationalities. In 2018, 64% of leadership positions were held by non-German employees. As of the end of 2018, 74% of our workforce was working outside their home countries.

To best facilitate this international collaboration, we offer **intercultural training for all employees along with suitable online tools**. For instance, our Cultural Navigator helps prepare our staff for international projects and business trips abroad. We also provide the majority of our company-related documents in English, and support employees posted to other countries through language courses and international networks to help them adjust more quickly to their new country. For instance, more than 700 expatriate employees are members of the International Community that meets regularly in Darmstadt.

Addressing demographic change

Another issue we are tackling is demographic change. We expect the average age of our workforce to continue to rise in the coming years. In Germany, we are responding to this trend with various initiatives including our [corporate health management program](#). A case in point is BELS, the tool for strain evaluation we use to design ergonomic work spaces that boost performance. BELS accounts for demographic change by **assessing a range of stressors through the lens of age**. This approach allows us to adapt our workplaces to suit the needs of older individuals. In addition to modifying physical working environments, we also offer innovative shift models and a prevention program for shift workers.

In 2018, our company health insurance fund partnered with our Health Management organization to conduct a **year-long campaign** entitled "I got a check-up". This initiative sought to educate people about metabolic syndrome, a combination of multiple risk factors that can lead to serious conditions such as diabetes, heart attacks or strokes. To raise awareness for the issue, we employed a variety of media such as flyers on mobility, nutrition, stimulants, and relaxation, along with an online self-test. In Darmstadt and Gernsheim (Germany), our Site Medical Center offered check-ups for heart attack and diabetes risk factors, along with blood lipid, blood sugar, body weight, and body composition screening. A total of 900 employees received a check-up.

Health and safety

Part of the non-financial report

When it comes to the health and safety of our employees, we take our responsibility very seriously, doing everything in our power to safeguard them against work-related illnesses and accidents. With our top priorities comprising issues such as stress prevention, nutrition and mobility, we help our employees prevent acute or chronic health issues through steps that are easy to integrate into their daily work routine.

Our approach to preventing accidents and promoting health

We seek to promote the health of our employees and maintain their ability to perform over the long term, for which a safe workplace is paramount. One of our Group-wide objectives is therefore to step up our **safety culture**, with our goal for 2020 to keep our lost time injury rate (LTIR) under 1.5. At all our sites, we conduct hazard assessments even before a new plant is commissioned to minimize or eliminate any potential safety risks to our employees. Furthermore, we are working to make workplace health management a greater part of our corporate culture and leadership.

In 2018, we developed a **key performance indicator management system** to review the effectiveness of our occupational health practices and identify opportunities for improvement. In addition, for the first time we included questions regarding employee health in our 2018 Employee Engagement survey. The input from this survey is used to calculate our company's Healthiness Index, which is due to be published after completing the analysis in 2019. The index should reflect the general state of health of our employees.

Our health projects are tailored to the needs of our employees. In 2018, we refined our objectives, creating a roadmap for the next several years that will concentrate on shift work, office work, mental stress, and demographic change, as well as analyzing key disease occurrence information to draw up appropriate measures. We regularly evaluate the success of our individual efforts.

How we manage occupational health and safety

Our Environment, Health, Safety, Security, Quality (EQ) Group function is responsible for our Environment, Health and Safety (EHS) management system. Since October 2018, this unit has been reporting to Executive Board member Belén Garijo, who took over the position from Walter Galinat on his retirement at the end of September 2018. EQ sets objectives, oversees global initiatives and conducts internal audits, while local EHS managers ensure that each individual site adheres to occupational safety laws and regulations. All new EHS managers are required to complete EHStart-up!, a three-day orientation held in Darmstadt that covers topics such as occupational health and safety as well as our **BeSafe!** safety culture program.

We collect workplace accident data from our sites on a monthly basis. Every facility is required to immediately report relevant accidents to EQ, where the cases are investigated and assessed. If necessary, we implement additional safety measures at our sites. In addition, our German sites in Darmstadt and Gernsheim have an occupational safety committee in place that meets four times a year and makes decisions on current EHS issues. In 2018, their agenda included health management along with relevant accidents and incidents. They also discussed the status of the roll-out of an IT system for hazard assessment and contingency planning processes. Beyond all these safety mechanisms, our Life Science business sector holds monthly safety calls with all local EHS officers to share lessons learned and discuss recommended actions for comparable situations. If employees are worried about their health or safety, they are encouraged to use our global **SpeakUp Line** and are moreover entitled to take a temporary leave of absence.

At our Darmstadt and Gernsheim sites, our Health Management unit helps weave health awareness into our corporate culture. The appropriate strategy, individual focal areas and measures required are developed by an interdisciplinary steering committee consisting of various senior leaders such as the head of Occupational Health & Safety, the chairman of the Works Council, the head of Health Management, and the production heads of our business sectors. Meeting six times a year, the topics discussed include workplace health fundamentals, good leadership and tailored health programs.

On top of their usual tasks, some of our production employees at our sites in Darmstadt and Gernsheim are also responsible for health matters. After completing a training course, these health partners act as a liaison between our employees and Health Management, providing a channel through which they can voice their ideas and suggestions for workplace health management strategy and initiatives. Since our production employees have shown great appreciation for these health partners, we have decided to start introducing this practice in other departments as well.

Our commitment: Policies and bylaws

Our approach to occupational health and safety is detailed in our Corporate Environment, Health and Safety (**EHS**) Policy. This is an integral part of our EHS management system, which undergoes an external OHSAS 18001 audit every year.

Our Group Health Policy defines how we ensure workplace safety for our employees while also promoting their health and welfare. This document details our **Group-wide approach to safety and health management** as well as our comprehensive behavioral modification program to prevent workplace accidents and occupational diseases. One component of the policy is our Global Wellbeing and Health Promotion Framework, which describes the differing requirements in a wide array of countries. Our individual sites are responsible for performing local workplace risk assessments and hazard analyses.

At most of our sites in Germany, we work in partnership with employee representatives to craft comprehensive **bylaws** on occupational health and safety. Our Employee Care bylaw defines processes such as employee care conversations, which help our leaders to promptly identify health risks and mental stress in their employees. In 2017, this bylaw was extended by an additional three years. Introduced in 2017, our Occupational Integration Management bylaw governs the procedure for protracted employee illness and applies to all our facilities in Germany. This bylaw aims to help keep the employee's position open while also helping to prevent adverse health impacts after their return to work.

Renewed safety certification

In 2018, we inspected and recertified the safety management systems at all our Performance Materials production sites. The Healthcare facilities at our Darmstadt site were also recertified, along with those of other units. Furthermore, our Life Science facilities in Bangalore (India), Buchs (Switzerland), Irvine and Haverhill (both in the United Kingdom), and Jerusalem and Rehovot (both in Israel) once again obtained OHSAS 18001 certification. Also in 2018, our site in Arklow (Ireland) was incorporated into our Group certificate, meaning that **31 of our sites are now OHSAS 18001 certified**. At 30 of these sites, 100% of employees are covered by a certified safety management system, with such a system including around 70% of employees at our Darmstadt facility. The certification process helps us pinpoint weak areas, identify opportunities for improvement and take suitable measures. Other sites are also required to apply this standard.

In 2020, we plan to migrate to the **new ISO 45001 certification guideline**, which will replace OHSAS 18001.

Accident rates

The **lost time injury rate** (LTIR) is the indicator used to assess the success of our safety efforts. This figure measures the accidents resulting in at least one day of missed work per one million man-hours. We track the LTIR for both employees and temporary workers. Having achieved the target we set in 2010 for a 2.5 LTIR, in 2015 we set a new ambitious goal of permanently lowering this figure to 1.5 by 2020. After all, we believe that nothing is worth an accident. In 2018, our LTIR was 1.3. The majority of incidents resulting in lost time were slips, trips and falls, along with accidents involving the operation of machinery and equipment. In 2018, there were no fatal accidents.

Clear rules of conduct

Experience shows that most workplace accidents can be prevented by proper conduct. Through our **"BeSafe!" safety culture initiative**, we are working to educate our employees on dangers in the workplace and provide them with rules of conduct that help keep them safe. All production and warehouse sites have now been incorporated into the program. 60% former Sigma-Aldrich facilities have likewise implemented BeSafe! since being acquired by our company in 2015. The rollout at these newly acquired sites will continue until 2020.

In 2018, we conducted **awareness campaigns across the Group** as part of our BeSafe! program. For instance, we once again used a video in German, English and Spanish to increase employee awareness in a bid to further bolster our safety culture. The video forms part of our BeSafe! training and is also available on our Intranet. In 2018, we translated the video into Chinese, French and Japanese in order to reach more of our employees in their local language. In addition, several subsidiaries again held safety competitions. To underscore the importance of safety, in 2010 we launched the Safety Excellence Award, which is presented annually to all production sites that have no workplace accidents on record for the year. In 2018, 62 of 90 facilities achieved this honor. Furthermore, we conducted two refresher courses on key content from our BeSafe! program, as well as occupational safety training in individual countries in accordance with the statutory requirements and specific risks of each country. It is the responsibility of each facility to conduct this training.

Workplace health management

At our Darmstadt and Gernsheim sites, our Health Management unit conducts an array of campaigns and programs to promote the health of our workforce. These activities are based on health indicators derived from sources such as the health report issued by our company health insurance fund, evaluations from our Site Medical Center and, since 2018, our employee surveys. We utilize the findings in the creation of **prevention programs tailored to specific target groups or facilities**. Moreover, our Health Management unit offers specific health programs such as mindfulness courses and workplace ergonomics consultation. Along these lines, we have a standard procedure in place for continuously assessing the working conditions and environment, making state-of-the-art updates wherever needed. If other sites express interest, our Health Management unit will advise on potential improvements or health programs. When requested, we also provide local consultation and operate campaigns by means of an internal service contract.

Since 2013, Site Catering at our Darmstadt facility has held the "Job&Fit Premium" certification from the German Nutrition Society e. V. (DGE). To obtain this certification, a strict set of regulations regarding food selection and meal planning must be met. In 2018, we received the Dr. Rainer Wild Prize for the design and realization of our new employee cafeteria in Darmstadt. In particular, we were praised for the **variety and balance of the food on offer**, as well as for our Job&Fit certification. This prize recognizes outstanding projects, individuals and initiatives that support

and raise public awareness of healthy eating. We also offer a variety of nutritious options for our staff at our other sites.

Our employees have access to a health catalog detailing our Health Management services in both English and German. Created together with our Social Counseling and our Site Medical Center, it contains information on ergonomics, nutrition, stress, and mental health issues.

We hold the "Excellence" certification for our Germany-wide health management efforts. Sponsored by BKK Dachverband e. V., this certification is granted in recognition of companies that have implemented **exemplary health management** programs and met the quality criteria of the European Network for Workplace Health Promotion (ENWHP).

Our **program to minimize chronic back pain** is an integral component of our workplace health management efforts in Darmstadt and Gernsheim. This initiative, which also takes mental health factors into account, is offered in units with demonstrable need, such as a relatively high number of employees suffering from these sorts of symptoms. In 2018, we ran the program over a period of seven weeks at our site in Gernsheim, with 17 logistics employees taking part in an effort to prevent their back pain from becoming a chronic issue. Held weekly, the 90-minute sessions focused on various topics such as exercise, self-management and relaxation. We also offered one-on-one telephone coaching sessions.

Beyond this initiative, throughout Germany we offer our employees services such as our **company fitness program**, which provides them with up to € 195 per year towards health prevention classes. In Darmstadt and Gernsheim, we furthermore run a company sports program that currently features 25 different activities such as tennis, volleyball, strength training, triathlon, yoga, and bouldering.

In an effort to improve our workplace, we regularly analyze the ergonomics of individual workstations, implementing appropriate measures as required. Our workers also receive **training on occupational ergonomics** tailored to specific areas, whether manufacturing, office work or the laboratory. Moreover, we conduct wellness programs at many sites, for instance the Industrial Athlete Program (IAP) we offer to our Life Science employees in Danvers (Massachusetts, USA). Open to all workers who wish to improve their general and physical wellbeing through exercise in small groups, this initiative proved very popular and was attended by 60 people in 2018. Starting in 2019, we will be expanding the services we offer to include individual personal training sessions. This will be aimed in particular at employees with a medical certificate from a physician, but also shift workers who aren't able to take part in group courses.

Training in mobile gyms

In September 2018, we launched and started expanding the Training Island project, which centers around **mobile gyms** located in renovated buses. Featuring state-of-the-art equipment and experienced trainers, participants can work out close to their office twice a week for twelve minutes. The program was designed in particular to prevent musculoskeletal disorders and to motivate employees to exercise. In addition to working out, participants can also receive an individual consultation on topics such as food and nutrition, while screening at the beginning and end of the project highlights personal successes. Initially available to Life Science and Performance Materials employees, the training islands will be open for a period of twelve months. In 2018, 300 employees made use of this offer, with 450 already having registered for 2019.

Weight Watchers at Work for shift workers

From April to July 2018, 31 Life Science and Performance Materials shift workers in Darmstadt and Gernsheim took part in the Weight Watchers at Work – Shift program. Run by Weight Watchers and redesigned in partnership with our Health Management, our company is the first to test this program. Aimed at employees with a body mass index (BMI) equal to or greater than 25, which is considered overweight, Weight Watchers coaches provided in-depth seminars on making **healthy nutritional choices and leading a more active lifestyle**. The course was offered at the workplace and focused particularly on living and coping with shift work, with the schedule planned around the participants' shifts. As well as attending seminars, employees could download the Weight Watchers app to scan the bar codes of packaged food and find out its nutritional information. This tool also provides tips on losing weight and contains thousands of healthy recipes. On average, participants lost seven kilograms during the program.

Testing and supporting our employees

Our Physical Ability Test and Health Preservation process ensures that all employees meet the health requirements for their particular tasks. This test helps us implement targeted intervention as necessary.

Our Travel Health & Medical Advisory Service assists our employees who spend a lot of time abroad on business, providing them with recommendations on necessary vaccinations and advice on hygiene risks.

Employee engagement

Part of the non-financial report

As a science and technology company, we are always looking for new solutions and constantly working to evolve our approaches. Motivated, curious employees are key to our ability to innovate, and therefore also to our success. However, we also need a corporate culture that broadens our employees' knowledge and skills, one that creates exciting opportunities and encourages them to take a proactive role in shaping the development of our company. Open feedback from every individual helps us pinpoint the areas where we can do better.

Our approach to engagement

We strive to create a work environment that empowers our employees to **truly think outside the box**. An environment that is conducive to developing ideas, seeking creative solutions and discovering new market opportunities. To better engage employees, we have set clear goals and defined the steps necessary to achieving them.

We seek to understand the needs of the people who work for us and therefore regularly conduct **employee surveys**, either Group-wide or within individual countries, businesses or projects. These surveys help to facilitate communication between leaders and employees and show us ways we can improve. Moreover, they are paramount to a company culture that values dialogue and employee input.

How we engage our employees

Engagement and Inclusion, a unit within our HR organization responsible for areas such as employee engagement and diversity and inclusion, creates and oversees our employee surveys.

In addition to conducting employee surveys, we regularly include **local employee representatives** in our decision-making processes. Within Germany, 13 of our subsidiaries have employee representation, while in Europe 27 of our subsidiaries have employee representation bodies across eight countries (Austria, Belgium, France, Ireland, Italy, the Netherlands, Spain, and Switzerland). In addition, 63% of all employees of Merck KGaA, Darmstadt, Germany, are subject to collective agreements. Local works councils as well as a Group works council represent our employees, discussing topics such as compensation, working hours and organizational realignment. The Senior Executives Committee represents the interests of our top leaders, while the Euroforum represents our employees at the European level. Focusing on the economic situation, employment rates and significant changes within our company, this body covers all EU countries as well as Switzerland and Norway, although not all countries have their own delegate.

Our commitment: Corporate Volunteering Guideline

At the end of 2018, the Executive Board adopted a Group-wide guideline governing volunteer work, which grants our employees up to two days of **paid leave** per year to volunteer. This time can be used to support the local community through

charitable activities that are offered or supported by our company.

Understanding our employees

To give us a better sense of the situation within our company as a whole and to benchmark against our competitors, we conduct Group-wide employee engagement surveys on an annual basis. These surveys provide a platform for employees, managers and executives to engage in a regular dialogue, sharing ideas and experience. The 2018 employee engagement survey revealed that 61% of employees feel engaged at work, with around 45,000 people (86%) having taken part. In response to the 2016 survey, in 2018 we continued a series of measures to **improve our work environment**, which focused on our IT infrastructure as well as our recruiting and onboarding processes.

In addition to taking the pulse of our workforce, we continued work on our Science Network project. Due to the broad positioning of our company, we do not have a central research and development organization that unites **expertise across our businesses**. In building the Science Network, our primary aim is thus to accelerate the exchange of innovative ideas and facilitate collaboration among all our R&D employees. One of the components of the project is the Continuous Performance Dialogues held between 1,300 employees and their supervisors in order to align performance and potential appraisals with research and development needs.

Encouraging and rewarding innovative ideas

Our company has a long tradition of rewarding ideas. In 1853, we became the first industrial company in the world to introduce a contractual **bonus for employees who made suggestions for improvement**, and approximately 60 years ago we set down bylaws stipulating principles and rules for our ideation efforts. Our idea management program seeks to inspire our employees to think creatively and encourage them to contribute to the continuous evolution of our procedures and processes. We reward all ideas that are successfully implemented by offering employees a bonus based on how much the suggestion enhances our processes or cuts down our costs.

In 2018, our employees submitted approximately 1,500 suggestions for improvement via our **Germany-wide ideation program**. These ideas are expected to yield around € 1.6 million in cost savings in the first year. As a reward for

their proposals, our employees received around € 300,000 in bonuses.

In addition to rewarding good suggestions, we also regularly hold a **Group-wide innovation competition called Innospire** that allows employees to submit ideas for new products, services and business models. Through this competition, we target ideas in specific areas such as biointerfaces and biosensing, enablers of precision farming, and artificial intelligence. However, we also welcome ideas outside of these target areas. In 2017, nearly 900 ideas were submitted. After choosing the top eight proposals at the end of 2017, we held a boot camp in 2018 with the aim of developing these ideas in a quick and agile manner. In May 2018, each team presented its project to the Executive Board. Three winners were then chosen, whose ideas were incubated at our Innovation Center in Darmstadt. Along with the three winning proposals, a further three projects from our Healthcare and Life Science business sectors were selected.

Besides Innospire, we annually present **awards in recognition of outstanding ideas**, teamwork and projects. In 2018, the Executive Board presented four teams consisting in total of 34 employees with awards in the categories of Performance, People, and Technology, along with a special CEO Award. Projects were submitted Group-wide by 80 teams from various countries, Group functions and businesses.

On top of these mechanisms, all employees have the opportunity to submit ideas related to human resources to our **HR innovation campaign**, with a total of 146 proposals submitted in 2018. The ideas are evaluated by a jury of top executives from our various business sectors, who then select the two most interesting approaches to be further explored and advanced by interdisciplinary teams. A prime example of such a proposal is the "**Ad@m**" project, a chatbot developed to support standardized workflows.

Above and beyond our internal initiatives, we also collaborate with the nonprofit organization TED, one of the most distinguished global platforms devoted to **developing new perspectives and innovative ideas**. Through this partnership, we aim to share ideas worth spreading with the world. In November 2017, we joined forces to host a **TED event in London**, featuring talks that have since been watched online by more than eight million people. In November 2018, we again hosted a TED event, this time in Darmstadt. Entitled "The Art of Possibility", ten of our people from a pool of 110 applicants presented their ideas.

Making room for ideas: Our Innovation Center in Darmstadt

Over the last several years, we have undergone a major evolution and grown through acquisitions. We are now transforming our site in Darmstadt into a global headquarters that will bolster our ability to innovate, enabling us to respond **flexibly to growth** while also reflecting our corporate identity.

Opening its doors in early 2018, our **Innovation Center** is the heart of our global headquarters. Replacing the previous modular innovation center, this new facility **gives our employees room to explore their creativity** by joining interdisciplinary teams and collaborating on pioneering projects – all with the aim of cultivating new businesses that transcend our existing ones.

At the end of 2018, 22 project teams were hard at work in the Innovation Center, where they have access to a maker space. Equipped with the resources to quickly develop prototypes, this space is also open to all our other employees. Besides taking part in our Innospire competition, employees from around the world wishing to get involved at the Innovation Center can apply for a three-month think tank program that will allow them to drive innovation beyond our existing businesses. By analyzing current trends and technologies in select fields of innovation, the program aims to generate **new ideas and initial business plans for innovation projects**. Four think tanks were held in 2018 and focused on topics from areas such as biosensing and interfaces, liquid biopsy technologies, and clean meat.

Beyond facilitating cross-collaboration and creativity, the Innovation Center team regularly conducts events, workshops, seminars, and webinars. Through these channels, we introduce our employees to innovation methods such as design thinking and working out loud, which have proved very popular.

Keeping employees informed and encouraging dialogue

We keep our employees up to date and encourage exchange through a number of formats tailored to specific target groups. Take, for instance, our **international collaboration platform EVA** or our international employee magazine "pro", which is published in seven languages and is available in digital format as well as an app. "pro" has a readership covering more than 90% of our approximately 52,000 employees worldwide in their local language. Several subsidiaries also publish local editions of "pro", for example in Germany, Korea, Mexico, and Russia. In addition to these formats, a variety of newsletters is also published by our business sectors.

Our collaboration platform EVA encompasses our global Intranet for all subsidiaries and business sectors and furthermore consolidates numerous collaboration applications in one central location. EVA ranks as one of the most important internal communication media – second only to e-mail – receiving approximately 1.89 million hits per month. In 2018, we rolled out software that automatically translates **news in 22 languages**, thus facilitating digital participation and worldwide understanding.

Moreover, we publish articles on EVA and host various events to raise employee awareness of **corporate responsibility issues**. In 2018, for instance, we ran an internal communication campaign entitled "You're part of it". In addition, employees had the opportunity to engage in community outreach through our [350 Good Deeds project](#).

Deepening employee engagement

SPARK is a global volunteer program in which our Life Science employees conduct scientific experiments with school children around the world in an effort to **ignite a passion for science** in the next generation. Benefiting both urban and rural schools, this initiative also gives our employees the opportunity to pass on their knowledge. You can find more information on SPARK as well as our myriad education projects in the communities in and around our global headquarters under [Community involvement](#).

Good leadership

Part of the non-financial report

We believe it is essential for our leaders to develop and grow so that they can lead all employees Group-wide to the best of their ability. Within our company, many teams collaborate across sites and international boundaries. While the variety of skills, strengths and experience these teams bring to the table creates great potential for our leadership to leverage, global collaboration too plays an increasingly important role in the development of our next generation of leaders.

Our approach to good leadership

Our **strategic competency model** describes core competencies that should underpin the conduct of employees of all levels. Our six core competencies are Purposeful, Future-oriented, Innovative, Results-driven, Collaborative, and Empowering. In our day-to-day work, they play an important role in our success. This model provides the foundation for all development activities within our HR work, including leadership and management programs, talent development

strategies, our [360 degree feedback tool](#), and career management services. It applies to all employees but particularly to our leaders, who act as role models and are therefore key to building employee buy-in for the competency model. In addition, the model defines the leadership culture through which we intend to grow our business. Building on this model, in 2018 we defined six leadership behaviors that outline the way we expect our leaders to act.

Our Competencies



During career advancement discussions, employees and supervisors review specific growth and development needs, as well as the progress of development measures. Through [employee surveys](#), our people moreover have the opportunity to evaluate various factors such as leadership quality within our company.

How we facilitate good leadership

We expect our leaders to be attuned to the needs of our diverse workforce and therefore provide them support in the form of resources and data. At the same time, they can access transparent feedback through specially developed tools in order to track the impact of their decisions.

Management and talent programs for leaders

In recent years, we have initiated three programs to **enhance the skills of our people managers**. The Managerial Foundation Program imparts the basics of leadership, such as communication techniques, leadership styles, conflict management, motivation, and emotional intelligence. The Advanced Management Program covers topics such as change management, self-reflection and resilience. In addition, it teaches coaching methods that help leaders transition from their first management role to positions leading cross-functional and international teams. The third initiative is our Global Leadership program, which focuses on competencies needed to ensure successful international collaboration. In 2018, the Managerial Foundation and Advanced Management programs were offered at several of our sites worldwide, while the Global Leadership program was held in Germany and the United States.

Since 1999, we have been partnering with top international universities to offer an **international and modular University program** for our company. Over a period of

ten months, senior executives take classes on management techniques and strategic business development. To date, a total of 397 executives have completed this program.

Another initiative we have been offering our up-and-coming leaders since the 1990s is our **International Management Program**, where participants work on an interdisciplinary project over a period of eight months. The results are then presented to the Executive Board. In 2018, 26 of our employees took part in this program.

In addition to these various programs, we partner with universities across the globe to enable our employees to obtain qualifications such as an Executive MBA.

In 2015, we launched a Growth Markets Management Program (GMMP) covering business administration topics and content specific to our company for **local leaders** in Africa, China, Latin America, and the Middle East.

By the end of 2018, 59% of our people managers rated Role 3+ had taken part in one of these management and talent programs.

Leveraging growth market potential

In 2018, six of our employees successfully completed "[Afrika kommt!](#)", a one-year scholarship offered by the German Society for International Cooperation (GIZ) that trains young experts and leaders from Sub-Saharan Africa. In supporting this initiative, we aim to build a pool of **regional partners to encourage economic cooperation between Germany and Africa**. 17 former scholarship recipients are now working for us in various specialist and leadership positions, some of them in various countries in Africa and others in Darmstadt. Nine new candidates were chosen for the seventh round of "[Afrika kommt!](#)". They took up their positions at our company in November 2018.

Environment

Within this chapter:

102 Environmental stewardship

105 Climate action

108 Waste and recycling

110 Water management

113 Plant and process safety

115 Biodiversity

Environmental Stewardship

Part of the non-financial report

As a science and technology company with manufacturing operations, our activities have an impact on the environment, generating air emissions, wastewater and waste. Even the materials we utilize could adversely affect the environment if not handled properly. To mitigate these impacts, all our sites meet a strict set of environmental regulations and continually adapt their processes to new regulatory requirements. Moreover, due to the growing scarcity of natural resources, we attach great importance to using energy, water and materials efficiently.

Our approach to environmental stewardship

Minimizing negative environmental impacts and taking meaningful climate action requires a holistic approach. Our goal is to diligently monitor detrimental emissions into the air, water and soil and try to prevent them wherever possible.

How we structure our environmental stewardship practices

On October 1, 2018, Belén Garijo took over from Walter Galinat as the Executive Board member with responsibility for environmental governance, a remit that also covers climate impact mitigation, water management, waste and recycling, and plant and process safety. Our Group function Environment, Health, Safety, Security, Quality (EQ) is in charge of steering all related ecological efforts Group-wide. At our individual sites, each site director is responsible for environmental stewardship as well as occupational safety at the operational level. At larger facilities, the site directors receive day-to-day support and advice from Environment, Health and Safety (EHS) managers, with EHS coordinators performing this role at smaller facilities. These local EHS organizations report to and work hand in hand with EQ.

In 2018, our EHS organization comprised **more than 200 EHS managers** – supported at the local level by other personnel. Our Group function EQ conducts annual EHS seminars at our various sites. All new EHS managers are required to complete EHStart-up!, a three-day training course held at our global headquarters in Darmstadt that covers topics such as our Rapid Incident Report System (RIRS, see below), [energy efficiency](#) and [climate impact mitigation](#), [wastewater](#), [occupational safety](#) and [process safety](#).

The EQ leadership meets with the Executive Board on a regular basis, usually once a month, to report on their environmental stewardship efforts. Every six months, EQ provides the Executive Board with a report on environmental, health and safety issues that also covers climate impact mitigation, water management, waste and recycling, and plant and process safety. The report focuses on our current progress, documenting and assessing the work EHS has accomplished. The Executive Board utilizes this brief as a source of information and as documentation to support ISO 14001 and BS OHSAS 18001 certification.

Our Executive Board is moreover responsible for approving internal guidelines such as our Environmental,

Health and Safety (EHS) Policy. Internal standards are approved by the head of EQ. While standards provide an operational framework, guidelines present an overarching outline of our company's position on a specific issue.

INFO

OUR EQ GROUP FUNCTION ("ENVIRONMENT, HEALTH, SAFETY, SECURITY, QUALITY")

Responsibilities of Group Governance and Service Unit Environment, Health, Safety, Security, Quality (EQ)

- Develop and maintain Group EG strategy
- Performance of environmental and safety audits
- Compliance audits to review adherence to standards
- Implementation of EQ management systems
- Conducting EQ improvement programs
- Consulting for investments, process development and acquisitions
- Conducting training programs

Responsibilities of local operating units with competencies at local sites:

- Wastewater treatment
- Waste management
- Environmental analysis
- Plant safety
- Occupational health and safety
- Fire protection/risk prevention
- Approval procedures

Clearly defined incident reporting procedures

We have established a variety of reporting procedures ([EHS Leading Rate](#)) to review critical situations, near misses and environmental incidents as quickly as possible and take corrective action. These procedures allow us to track the respective incident, its degree of severity and all risk mitigation efforts. All incidents are logged Group-wide and reported to the Executive Board every six months.

In the event of major incidents, our **Rapid Incident Report System** (RIRS) promptly notifies the Executive Board, our EHS Group function and Group Communications. Such incidents may include fatalities, accidents with multiple casualties, or injuries and damage that occur beyond our premises, but also environmental disasters such as earthquakes or floods. Through the RIRS, we can coordinate the responses of all those involved and inform other potentially impacted sites immediately. To make the RIRS faster and more effective, we migrated to an online version of the system at the end of 2018.

Our commitment: Standards and standard operating procedures

Our approach to environmental stewardship is built on our **Group-wide EHS Policy** (Corporate Environment, Health and Safety Policy), which has been endorsed by the Executive Board. This policy is closely aligned with the stipulations of the chemical industry's [Responsible Care® Global Charter](#), as well as with the environmental management standard ISO 14001, and emphasizes the responsibility of our leadership toward environmental stewardship, [health and safety](#). Moreover, it addresses our [suppliers](#), encouraging them to adopt similarly enhanced standards governing environmental sustainability and safety. In doing so, our Corporate EHS Policy complements the [Responsible Sourcing Principles](#) of our Group Procurement function.

The principles of our EHS policy are implemented through internal guidelines, standards and standard operating procedures. For instance, our Group EHS, Security and Quality Manual describes how we **organize environmental stewardship and occupational safety across the company**. In addition to this manual, we have put in place a number of other internal standards that govern environmental stewardship such as our Air Emissions Standard, [Waste Management Standard](#) and [Energy Management Standard](#).

Potential EHS risks posed by acquisitions, divestments or site closures are assessed through due diligence, a process defined in our EHS Due Diligence and Post Merger Transaction Standard. During audits, new sites are given priority.

We regularly review our internal guidelines, standards and standard operating procedures. In 2018, we revised and introduced multiple standards and processes. For instance, we updated our Office and Field Service Safety Standard to increase our focus on safety in areas beyond our production facilities. We also adjusted our Occupational Hygiene Standard. In making these improvements, our aim

is to better recognize and counteract health hazards in the workplace. In addition to these efforts, in 2018 we introduced the [Sustainable Water Management Standard](#). Composed of two parts, it replaces our Water Protection Standard and details wastewater discharge control and monitoring, water use analysis and protective measures against rainwater risks such as contaminated rainwater.

Material investments in environmental impact mitigation

Preventing and monitoring air, water and soil emissions involves large expenditures on the part of our company, as does proper waste disposal. Moreover, we have set aside provisions **for groundwater and soil remediation** to ensure our ability to execute all measures required. In 2018, our [provisions for environmental impact mitigation](#) totaled € 137 million, 94% of which was attributable to Merck KGaA, Darmstadt, Germany. Neither these environmental indicators nor the ones appearing later on in the report reflect data from our Consumer Health business. This is due to the fact that this business was transferred to Procter & Gamble as of December 1, 2018 and, pursuant to IFRS 5, was classified as a discontinued operation as of April 2018.

Parking lot remediation completed

In 2018, we completed our ten-year project to decontaminate a parking lot at our Gernsheim site. The scope of the **environmental remediation** required turned out to be significantly greater than originally anticipated. During the decontamination work, we removed hexachlorocyclohexane (HCH) residue from the soil under the parking lot and properly disposed of it using external incinerators.

Assessing environmental impacts and reporting violations

In general, we conduct risk-based assessments along with **internal and external audits** on all our production facilities every three years with the goal of analyzing and minimizing our environmental footprint. Conducted by EQ, these assessments serve to ensure that our requirements are being met. As needed, we use the results to define a suitable course of action. In addition, grievance mechanisms are in place to identify potential violations of our requirements. In 2018, our corporate EHS audits rated 80% of the 40 sites audited as "good" or "satisfactory". We assess performance on a five-tier scale: "excellent", "good", "satisfactory", "poor", and "critical", which in turn determines how frequently an audit is conducted. If the findings are deemed to be good, a facility will undergo audits less often, while significant violations can increase the frequency.

Aside from using audits to identify issues, we also encourage employees to report potential violations of our standards to our Compliance unit. All of these violations are reported to the Executive Board. In the 2018 period, we recorded no significant violations of environmental laws or regulations Group-wide.

ISO 14001:2015 Group certificate

Since 2009, our company has held a Group ISO 14001 certificate, which means that all production sites with more than 50 employees must implement the requirements of the certificate. Other facilities are not obligated to implement an ISO-certified environmental management system. New sites must gradually establish a corresponding **environmental management system with predefined indicators** for factors such as greenhouse gas emissions and water use, as well as obtaining ISO 14001 certification. The annual internal audit reports and management reviews carried out as part of the Group certificate afford us a better overview of how all our sites are performing.

81

of our sites worldwide are currently covered by the ISO 14001 certificate.

Every year we contract a third party to perform a certification audit. In 2018 a sample of ten sites underwent and passed an ISO 14001 audit, while two facilities were newly incorporated into the Group certificate. Furthermore, we conduct internal audits to ensure compliance with our requirements.

Stakeholder dialogue

By participating in a variety of industry associations, we exchange information and ideas on environmental issues. In 2018, for instance, we took part in discussions between the German Chemical Industry Association e. V. (VCI) and [German legislators](#) on eliminating the thermal value criteria. Until the end of 2018, our company chaired the VCI plant safety working group. Additionally, we contribute to the dialogue on [plant and process safety](#) in our capacity as a member of the [European Process Safety Center](#) and the Commission on Process Safety of the [German Federal Ministry for the Environment, Nature Conservation, Building, and Nuclear Safety](#). Since 2018, we have also been involved in a multi-stakeholder dialogue to develop the Trace Substance Strategy of the German federal government to protect aquatic ecosystems.

Furthermore, we engage residents in the vicinity of our sites in discussions on issues of local relevance.

climate action

Climate change is one of the most pressing challenges of the 21st century. Because our operations also generate greenhouse gas emissions, we endeavor to reduce these emissions to mitigate our impact on the climate, a course of action expected by our customers and stakeholders. Although stricter regulatory requirements may lead to planning and investment uncertainty, burgeoning regulations and rising energy costs are making climate impact mitigation an increasingly smart investment.

Our contribution to climate protection

We are taking action to mitigate our impact on the climate. Our **goal for 2020** is to reduce our direct greenhouse gas emissions (Scope 1) and indirect emissions (Scope 2) by 20% relative to the 2006 baseline, an objective set by the Executive Board in 2009. Scope 1 covers emissions that we produce ourselves, for instance by burning fossil fuels to generate power, while Scope 2 pertains to emissions from the consumption of purchased energy, such as electricity or district heating.

Across the globe, 40 of our sites account for roughly 80% of our greenhouse gas emissions, which is why we are focusing our efforts here.

Energy conservation represents a key component of our climate impact mitigation activities. By adapting and updating our technology, we are improving the **energy efficiency** of our R&D operations, our production processes and our buildings. Just as important for climate impact mitigation is the **reduction of process-related emissions**. Furthermore, we are working to lower the emissions resulting from energy generation. Where financially viable, we additionally make use of renewable energies to generate our own power.

How we structure our climate impact mitigation efforts

Our Group function Environment, Health, Safety, Security, Quality (EQ) is responsible for globally overseeing all climate impact mitigation efforts (see also [Environmental stewardship](#)), with each of our sites handling the actual implementation of the specific measures.

Our commitment: Standards and legal frameworks

Our Corporate Environment, Health and Safety (EHS) standards on energy management and emissions from coolant ensure that energy and process-related emissions are managed consistently across the Group. We audit our EHS processes at random to verify compliance with all EHS standards.

We know that **efficient energy management** plays a major role in climate impact mitigation and is also becoming increasingly important to our customers. With this in mind, 13 of our sites have decided to obtain ISO 50001 certification, the international standard for energy management.

Our company is subject to a wide array of **national and international energy and emissions regulations** such as the German Energy Conservation Act and the German Renewable Energy Sources Act. Our activities are also governed by EU Directive 2012/27/EU, which stipulates that relevant companies must establish energy management systems and regularly audit their energy consumption. The sites subject to these requirements are responsible for implementing them and furthermore undergo audits conducted by internal or external experts.

The **revised EU Emissions Trading System** took effect in April 2018, establishing a legal framework for installations covered by this system for the fourth phase of the trading program (2021 – 2030). Going forward in phase four, we foresee having to purchase the emissions allowances that we are still largely obtaining for free during phase three (2013 – 2020).

Slight increase in energy consumption

We used 2,232 gigawatt hours of energy in 2018, versus 2,194 gigawatt hours in 2017. Our energy intensity relative to sales totaled 0.15 kWh/€ in 2018.

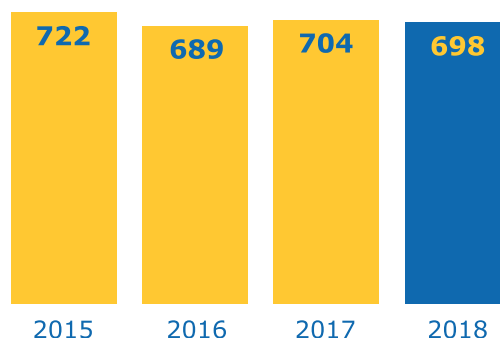
Emissions lowered despite growth

Despite growth in our operating business, we managed to reduce our **greenhouse gas emissions** by 11% relative to the 2006 baseline. We thus lowered our process-related emissions from 111,000 metric tons in 2017, to 95,000 metric tons in 2018. In 2018, we emitted 698,000 metric tons of CO₂ equivalents, versus 704,000 metric tons in 2017. Greenhouse gas emission intensity amounted to 0.047 kg of CO₂eq per euro of net sales in this period.

Between 2006 and 2018 we more than doubled our sales, which means that, relative to sales, our emissions dropped significantly.

Total greenhouse gas emissions (metric kilotons)¹

(Scope 1 and Scope 2 of the Greenhouse Gas Protocol)



¹ In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline), the greenhouse gas emissions have been calculated based on the current corporate structure of the reporting year and retroactively adjusted for acquisitions and divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted). Because it was divested in 2018, emissions from the Consumer Health business are no longer included in these figures.

Strategic climate program

Since 2009, all our measures to **improve energy efficiency and reduce process-related greenhouse gas emissions** have been housed under our strategic Edison program. Within this framework, our Group function EQ collaborates with a working group comprising representatives from all our business sectors. Any site can propose a project to curb CO₂ emissions.

Through the more than 360 Edison projects initiated since 2012, we aim to save around 177,000 metric tons of CO₂ annually in the medium term. Since 2012, these efforts have conserved approximately 89,000 megawatt hours of energy in total, primarily from electricity.

By the end of the year, we had implemented or launched 34 of the 48 Edison projects approved for 2018. These initiatives are expected to achieve savings of around 75,000 metric tons of CO₂ in the medium term. As in previous years, we also accepted new project proposals.

In 2018, the efficiency projects underway focused on optimizing air conditioning and ventilation systems, using and optimizing electric motors, and energy generation at installations mainly located in Germany, the United States and Switzerland.

In 2017, the Executive Board approved a **roadmap** for achieving the remaining savings needed to meet our climate target, and in 2018 they made the decision to purchase more power from renewable sources in an effort to achieve this objective faster.

Investing in renewable energies

Globally, we utilize **photovoltaic plants** with a total output of approximately 2,500 kilowatts. In 2017, we installed a solar voltaic system at our site in Burlington (Massachusetts, USA). It has an installed capacity of 182 kilowatts

and generated 136,000 kilowatt hours of power in 2018, reducing our emissions by roughly 37 metric tons.

Educating employees about climate impact mitigation

We encourage our employees to do their part to preserve the climate and regularly report on our **Group-wide climate action efforts** in our EHS newsletters while also providing helpful information and tips on our Intranet. Moreover, we support employees who prefer greener modes of transportation. For instance, we constantly update our leased vehicle pool with more efficient models so as to reduce the average carbon emissions of our fleet Group-wide by 30% by 2020, relative to 2013.

Subsidies for our employees

In January 2017, we lowered the CO₂ emission rate for newly registered company cars from 150 g/km to a maximum of 135 g/km. We are currently in the process of updating our vehicle emissions limits to the new requirements (test cycle). At our German subsidiaries, we offer a subsidy of € 100 towards monthly lease payments to employees who opt for a **greener car model**.

The average **emission rate of our company fleet** in Darmstadt and Gernsheim is 122 g/km, with about 15% of the fleet being electric.

In the United States, we provide our people with financial incentives to choose greener options. For instance, they receive up to US\$ 1,000 in subsidies towards the construction of a private solar power unit and up to US\$ 100 towards an energy audit for their home. They are also eligible for as much as US\$ 3,500 towards the purchase of a hybrid or electric car. To date, we have helped 55 of our employees install solar panels and motivated 361 employees to switch to a hybrid or electric car.

Recharging facilities at our sites

Our company fleet in Darmstadt and Gernsheim includes 23 **electric vehicles** (as of December 2018) that our employees can use for business purposes, but we also want to encourage our workforce to use electric cars in their private lives. To this end, our Darmstadt headquarters offers ten charging stations in the employee parking garage that recharge electric vehicles using green electricity. Furthermore, this site has six additional charging stations and 15 charging boxes for departmental vehicles. Over the next several years, we intend to continually expand the charging infrastructure at our German and European sites. Charging is processed via a payment platform called eCharge. Employees already registered on the platform also have access to a network across Germany featuring 6,000 charging stations across 740 cities.

In 2018, we installed eight new **charging stations** in the United States and Switzerland. In the United States, we now offer 43 such stations to our employees at 11 sites nationwide. Moreover, we have ten charging stations available (as of December 2018) at our sites in France, Ireland and Switzerland.

Jobticket and carpooling

We offer our workforce in Darmstadt a "Jobticket", an annual subscription to use local public transportation whose cost we partially cover. In 2018, more than 5,800 employees made use of this option. Our people also have access to an online tool that helps them organize carpools.

Bike sharing in Germany

At our German facilities, we also encourage our people to use **eco-friendly forms of transport** through "bike4me", a program enabling them to lease a bike at special rates with payments coming out of their pre-tax income. In 2018, 161 of our employees signed up for the program.

Furthermore, our employees can also use the Deutsche Bahn Call a Bike service throughout Germany and borrow a

bike free of charge for the first half hour. Deutsche Bahn, the German national rail company, has set up further rental stations all around our sites in Darmstadt, and in 2018 we sponsored 100 bikes in the city.

Switching to sea freight

In an effort to lower greenhouse gas emissions resulting from the transport of our products, we **utilize sea rather than air freight** whenever possible. However, this is only an option for products that survive protracted transport times undamaged, and we cannot allow the quality of customer service to suffer due to lengthy transport. The raw material mica, for instance, is transported primarily by ship.

Transparency regarding CO₂ emissions and energy consumption

The organization **CDP** (formerly the Carbon Disclosure Project) assesses the ways in which companies are working to minimize the risks and consequences of climate change, along with their success and strategy for doing so. The rating scale used ranges from A to D-, with A being the top score. In 2018, we received a C (B in 2017). The lower rating is attributable to several factors, including our failure to make progress on our ambitious emissions target in the reference period.

Since 2008, we have been reporting in detail on our climate impact mitigation efforts as stipulated by the CDP. We track our greenhouse gas emissions in line with the **Greenhouse Gas (GHG) Protocol**, an internationally recognized standard, reporting on Scopes 1 and 2 as well as parts of Scope 3. Regarding Scope 3 emissions, we only track emissions from business trips and employee commuting, from waste management, and from the manufacture and transport of fuel. Besides these emissions, we also measure energy consumption at our sites. However, this does not include energy use outside our field of activity such as raw materials production, as we do not have sufficient data available to perform these complex calculations.

waste and recycling

Waste contains valuable raw materials that can be reused in the production stream. However, it can also pose risks to the environment, so we consider it fundamental to both prevent and recycle as much of our waste as possible.

Our approach to waste and recycling

We work to both limit the loss of raw materials and minimize the environmental impacts of our waste disposal processes. To this end, we have set the goal of reducing the ecological impact of our waste by 5% by 2025 (relative to the 2016 baseline).

We generally try to prevent waste, for instance by developing new production processes or optimizing existing ones. Since this is not always feasible, whenever possible we endeavor to reuse the accrued waste to produce materials or generate energy. Through our Waste Scoring System and its objectives, we are supporting the circular economy. By employing measures such as waste separation, for instance, we ensure that **raw materials are recycled**, and that unrecyclable waste is discarded in an environmentally sustainable manner in line with the strictest waste disposal standards. In doing so we comply with local legal requirements, taking into account the available disposal options.

Responsibility for the waste disposal process

As a generator of waste, we are responsible for the ultimate disposal of our waste products and therefore choose our service providers with the utmost care, contractually stipulating disposal requirements. Each of our vendors must prove that they have **properly discarded our waste**, and we perform random audits to verify their compliance with our disposal standards, especially when it comes to hazardous substances.

How we organize our waste management and recycling activities

Our Group function Environment, Health, Safety, Security, Quality (EQ) bears overall responsibility for our waste management and recycling activities, while our EHS managers are in charge of implementing our guidelines and requirements at our individual sites (see [Environmental stewardship](#)). In 2018, we established both a Group-wide and a U.S.-based **Waste Expert Network Group** aimed at

fostering interactions and promoting best practice sharing on waste management. In addition, these groups of experts are responsible for further integrating waste scoring into our company practices.

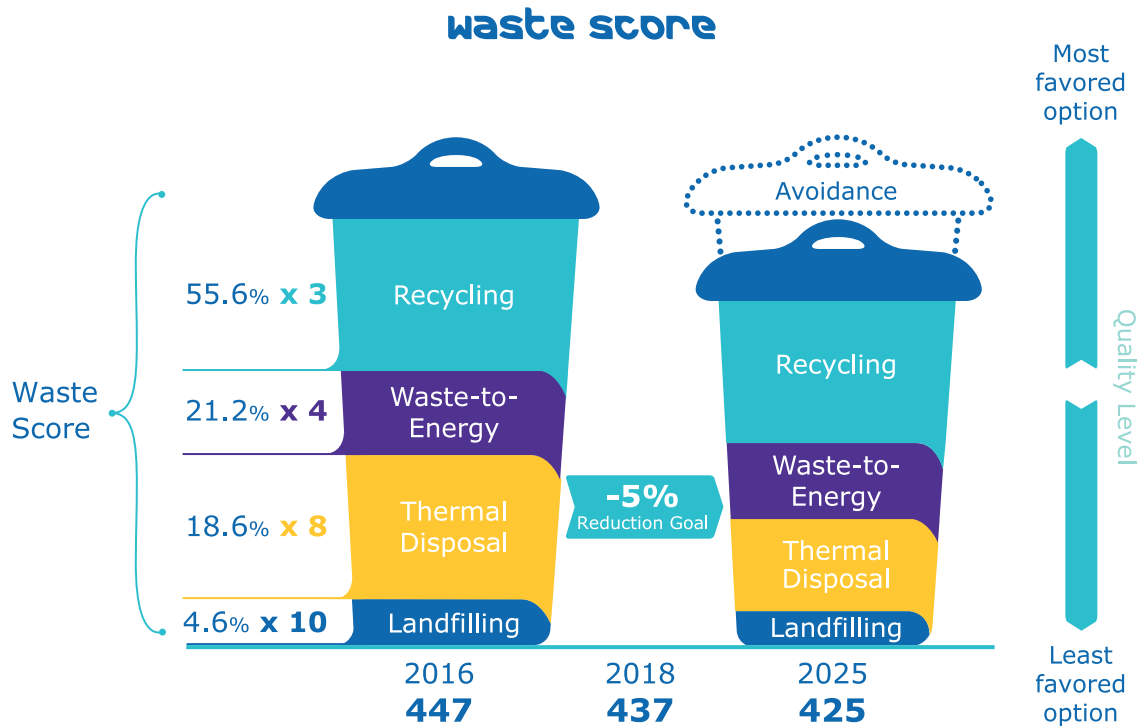
Waste management is part of our Group-wide ISO 14001-certified environmental management system. As well as undergoing external certification, we also conduct internal EHS audits to review our waste management practices. Moreover, in an effort to ensure Group-wide compliance with our environmental standards, we regularly host activities such as EHS forums and conferences to keep our local EHS managers and site directors informed on various waste disposal issues.

Our commitment: Group-wide EHS standard

Our Group-wide EHS Waste Management Standard provides a **consistent framework for waste management across all our sites**, defining organizational structures and minimum requirements. It moreover stipulates that all facilities document their waste by type and quantity, reporting this data to EQ. In 2018, we revised this standard to further reinforce the requirements for achieving our waste disposal targets.

Award for our Waste Scoring System

At our company we use a variety of methods for recycling and disposing of waste, each of which has a different impact on the environment. To account for these impacts in our waste reduction efforts, in 2016 we created a Waste Scoring System that allows us to compare the amount of waste our individual sites are producing and monitor our various waste streams. Under this system, the volume of waste is assigned to one of five categories according to how it is discarded (see diagram) and then multiplied by a factor that increases based on the disposal method's environmental impact. The sum of the scores of each category provides the total Waste Score of our company.



All sites are expected to do their part to reduce waste. The Waste Score excludes construction and demolition debris, along with waste from water treatment plants, because such waste inherently has clearly defined disposal methods that can rarely be circumvented.

In 2018, we were awarded **third place for our Waste Scoring System in the regional Responsible Care competition**. Organized by the German Chemical Industry Association (VCI), this year's competition centered around "Our contribution to the UN Sustainable Development Goals".

Clear target for reducing the environmental impacts of waste

In 2017, we calculated our Group-wide Waste Score for 2016. Taking this as a basis, in 2017 the Executive Board adopted the goal of reducing the environmental impact of our waste by 5% by 2025. To achieve this objective, we constantly examine our production processes and disposal methods to identify potential areas for improvement. In 2018, we furthermore established two Waste Expert Network Groups that meet regularly to discuss best practices, thus facilitating Group-wide exchange among our sites. In addition, these expert groups are responsible for integrating waste scoring into our company practices.

Relative to 2017, the amount of waste we produced in 2018 decreased slightly, coming to 247 metric kilotons. Construction and demolition debris continue to account for the majority of our total waste – 31% in 2018, and 36% in 2017. In particular large quantities of such waste material was generated by the remodeling of our global headquarters in Darmstadt, a process we completed in 2018.

Preventing waste: Sharing instead of discarding

In April 2018 we launched the online platform called "Troc" at our site in Corsier-sur-Vevey (Switzerland). Using this platform, departments can procure consumables, devices and products that other departments were planning to throw away. By involving all our employees at the site in this project, we are also raising awareness on waste minimization.

Preventing waste: Reducing filter waste

In 2015, we switched our multi-step filter process for photoresists to a single-step process, thus decreasing filter waste by 50%-70%. Since 2017, this process has become standard at all our facilities involved in photoresist filtering.

Recycling: From production waste to valuable compost

At our site in Molsheim (France), since 2017 we have been making a concerted effort to achieve our waste disposal target by composting all solid media waste from production activities instead of incinerating it. This method involves filling biodegradable bags with the solid media waste and shipping them to a local composting facility, where the waste is mixed with vegetable and green waste. Once turned into compost, it is used by municipalities and individuals. This method is set to reduce the amount of incinerated waste by 80 metric tons annually.

Recycling the solvent methanol

At our site in Darmstadt, we have initiated various processes to prevent waste and recycle materials. In 2018, for instance, a solvent recycling process enabled us to recycle 211 metric tons of methanol, which is generated in the manufacture of excipients for cosmetic products and the amino acid glycine.

water Management

Worldwide, the number of areas suffering from water scarcity is on the rise, yet our various facilities are dependent on a regular supply of water. At the same time, legislation governing water conservation is growing increasingly stringent. Our wastewater may contain traces of substances such as heavy metals or pharmaceutical active ingredients, which makes sustainable water management a key focus of our environmental stewardship.

Our approach to sustainable water management

For us, sustainable water management means not negatively impacting the aquatic ecosystems from which we obtain freshwater, or into which we discharge purified wastewater.

To bolster sustainable water management practices, we use an assessment tool from the European Chemical Industry Council (Cefic) to evaluate water management practices and progress at our facilities. Based on this assessment, our sites draft a list of steps that need to be taken and implement them gradually. This often brings best practices to light which are then shared throughout the company.

In addition, we have set ourselves the goal of **reducing our water consumption at sites in water stressed areas by 10% by 2020**. To lay the groundwork for this undertaking, we are systematically analyzing our water data utilizing tools such as the [Water Risk Filter](#) of the World Wide Fund For Nature (WWF) and the [Aqueduct Water Risk Atlas](#) of the World Resources Institute (WRI). These instruments help us determine, for instance, whether a site is located in a water-stressed area, i.e. those regions where the demand for water exceeds the amount available.

However, we also encourage efficient water management at facilities in areas of low or moderate water stress, which is why we are expanding our best practice sharing platform for sustainable water management. This tool provides examples of successful measures and enables our EHS officers to share ideas and lessons learned.

At the same time, it is our responsibility to minimize the impact of our wastewater across all our sites, which is why our regular EHS audits **review site-specific water management practices** at our production and development facilities.

Our water management efforts focus more heavily on our manufacturing sites than our administrative facilities because they have the greatest potential for impacting local aquatic ecosystems.

How we organize our water management activities

Our Group function Environment, Health, Safety, Security, Quality (EQ) (see also [Environmental stewardship](#)) bears

overall responsibility for water management. At our individual sites, our engineers work closely with our Environment, Health and Safety (EHS) managers to implement water conservation and wastewater treatment measures.

Our commitment: Standards and guidelines

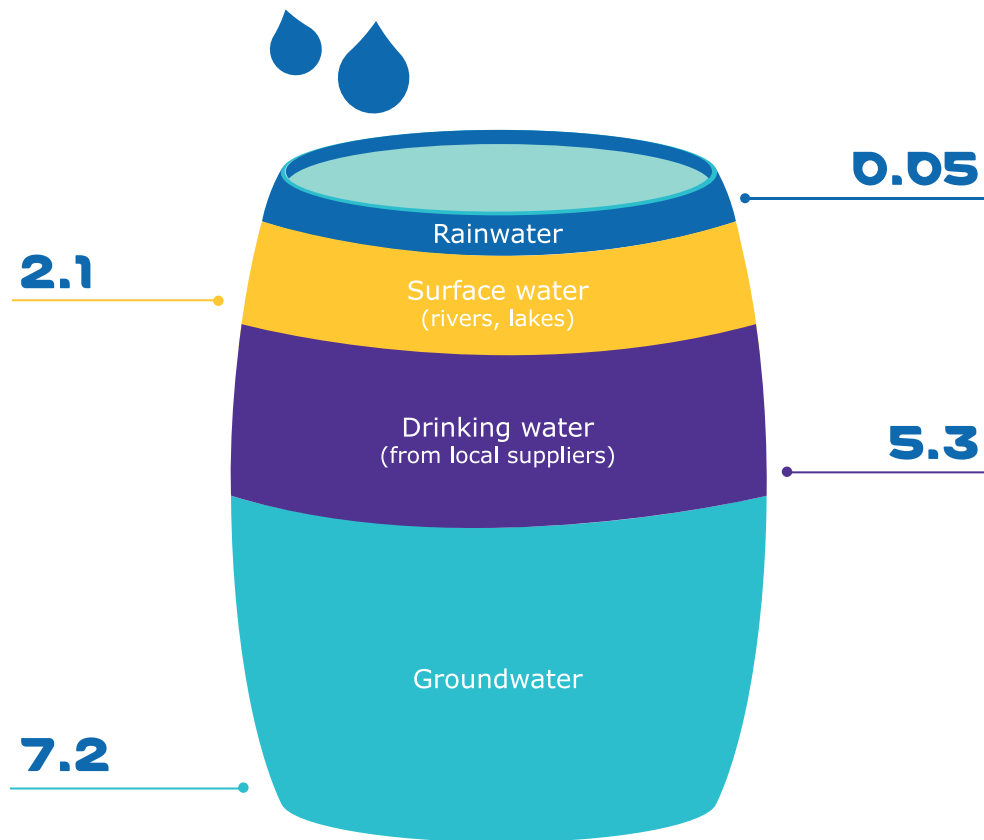
In 2018, we replaced our EHS "Water Protection" standard with two new Group-wide EHS standards: "Sustainable Water Management Part 1 – Waste water" and "Sustainable Water Management Part 2 – Water use and stormwater protection". These two new standards detail the way we are integrating **modern mechanisms of sustainable water management** into our management system. Both are based on the commitments we have made under the global [Responsible Care®](#) initiative. Guided by the "Waste water" standard, over the next several years our company will be rolling out a method of assessing our wastewater discharge into the ecosystem. The "Water use and stormwater protection" standard sets out Group-wide requirements for the responsible stewardship of water as a resource. It moreover establishes a way for us to manage the risks that arise from direct or indirect water abstraction. The standard even covers risks such as contaminated rainwater and flooding. Through internal audits, we verify compliance with our standards. All our sites are required to measure and assess the risks and impacts of the hazardous substances in their wastewater. They are moreover committed to handling water responsibly and to analyzing water abstraction and rainwater risks.

In addition to these measures, we are optimizing our production and purification processes to minimize the amount of pharmaceutical active ingredient residue in our wastewater. What's more, all our pharmaceutical manufacturing facilities have wastewater treatment plants and regularly assess the composition of their wastewater.

Water from our own sources

For the most part, we draw our process water from our own wells and drinking water from local suppliers and never do anything to compromise sensitive water sources. However, in the course of our sustainable water management activities, we keep an eye on trends that could potentially lead to sources being reclassified as sensitive.

Water abstraction (millions of m³) 2018¹



¹ Excludes Consumer Health

The cooling water used for our production processes generally runs in a circular system. Depending on regulatory standards and the energy footprint, we sometimes use fresh water in a once-through cooling system. For certain applications, we treat production wastewater and reuse it. In 2018, we reused a total of 24.4 million cubic meters of water.

New standards and comprehensive analyses

To reach our water management targets, in 2018 we introduced two new standards – “Sustainable Water Management Part 1 – Waste water” and “Sustainable Water Management Part 2 – Water use and stormwater protection”.

We enforce the **Flagship Self-Assessment** of the European Chemical Industry Council (Cefic) and utilized it to survey our sites’ water management practices in 2016 and 2017. In 2018, we evaluated this data and started assessing the environmental impacts arising from our discharged water. We constantly analyze the findings from these assessments to take specific steps at individual sites as needed.

Curbing water use

We seek to minimize our impact on the water situation at our sites. In 2018, we consumed 14,7 million cubic meters of water in total, with 883,213 cubic meters originating in water-scarce areas. Sites in areas of high water stress

must **transparently report their water use** and identify the process steps that require a particularly high volume of water. In response to this information, we execute measures to help our individual facilities lower their water consumption.

This approach applies to our manufacturing sites in Mexico City (Mexico), Mollet del Vallès (Spain), Kankakee (Illinois, USA), and Norwood (Ohio, USA), which consume more than 30,000 cubic meters of water per year. At these sites, we aim to achieve a 10% reduction in annual water use by 2020, relative to 2014. The same goes for our facilities in Savannah (Georgia, USA), Hsinchu and Taoyuan (both in Taiwan), which are at increased risk due to local groundwater conditions or seasonal water scarcity. By the end of 2018, we had curbed our water use in water-stressed areas by approximately 10.8%. In 2018, our site in Savannah (Georgia, USA), for instance, cut water use by 3% by optimizing the pigment washing process in the local pressure drum filters. Our facility in Mollet (Spain) installed a filter system that prospectively will reduce local water use by 3% thanks to improved water circulation.

Grading of our water management practices

In addition to reporting on our [climate action](#) efforts, since 2016 we have also been reporting water-related data to the [CDP](#) (formerly the Carbon Disclosure Project). This initiative collects environmental data from companies once a year,

evaluating their processes and performance on a scale from A to D-. In 2018, we were awarded a "B-" for our water management practices (2017: B).

Water protection measures in India

We also implement measures to minimize our adverse impacts at sites not located in water-scarce regions. Our manufacturing facilities in India, for instance, abide by a zero-discharge policy that requires used water to first be treated before being drained back into the soil. Furthermore, we collect rainwater at our Bangalore site and let it seep back into the soil as well, thereby helping stop the water table from sinking further.

Our wastewater

In 2018, we generated 13.6 million cubic meters of wastewater, consisting of around 9.7 million cubic meters of freshwater which we directly discharged into surface waters, and 3.9 million cubic meters of other water, which afterwards was treated by external treatment plants or discharged through other disposal methods. Approximately 50% of our total wastewater was discharged by four sites. Our Gernsheim site in Germany discharges its purified wastewater into the Rhine, our Savannah (Georgia, USA) facility into the Savannah River and our Onahama site in Japan into the Pacific Ocean. The wastewater generated at our Darmstadt site is purified in our treatment plants before being fed into Schwarzbach-Ried Creek, a tributary

of the Rhine River. In 2018, we discharged a volume of water representing approximately 4% of the average annual discharge of Schwarzbach-Ried Creek. We constantly work to meet the increasingly stringent **quality regulations set forth by law**, coordinating our efforts with the respective authorities.

Continuously monitoring wastewater

The two sustainable water management standards we introduced in 2018 also cover the topic of wastewater. We are in the process of implementing a method that will lay the groundwork for a **comprehensive wastewater assessment**. Our individual sites are responsible for identifying the corresponding areas of improvement and must also comply with the respective requirements imposed by local authorities.

Antibiotic residues in wastewater

We process antibiotic active ingredients on a small scale. The wastewater generated from these activities is subject to an additional purification process before being discharged into the environment. In 2018, we conducted a systematic, Group-wide assessment of our ecological impacts from manufacturing and handling antibiotics. As a follow-up, we inspected the wastewater pretreatment facility at our site in Mollet (Spain). The analysis revealed that on site, antibiotic residues are below the detection limit, meaning that the wastewater has a high degree of purification.

plant and process safety

Part of the non-financial report

The safety of our plants and processes is a key element of our environmental stewardship efforts. This approach allows us to protect both our workforce and the people in the vicinity of our sites. Furthermore, high-performance safety systems help minimize production errors, which in turn lowers the risk of financial losses.

Our approach to plant and process safety

We seek to **eliminate manufacturing hazards** wherever possible in order to prevent workplace accidents, production outages and chemical leaks. We train our employees regularly in an effort to minimize human errors and also to detect technical defects before they have a chance to cause damage.

How we organize our plant and process safety

Our Group function Environment, Health, Safety, Security, Quality (EQ) oversees plant and process safety within our company ([Environmental stewardship](#)), while at the operational level this responsibility falls to our individual sites and their EHS managers. **Fire protection** is paramount to the safety of our plants and processes.

We conduct **internal EHS audits** to review the safety of our plants and processes. During this process we also evaluate selected suppliers based on criteria such as purchasing volumes, type of incoming raw materials and geographic location. If we identify technical or organizational deficiencies pertaining to occupational and plant safety, our vendors are obligated to rectify them, as are our own facilities, with the auditor verifying whether the specified corrective actions have been taken.

Our commitment: Standards and legislation

All our sites are subject to the same requirements for plant and process safety as set forth by our Group-wide EHS Plant and Process Safety standard, which describes the safety rules for all production plants and warehouses. This document encompasses the entire life cycle of a plant from cradle to grave. Before commissioning a plant, we draft a **safety concept** that is subject to continuous review and, when necessary, updated until the facility is decommissioned. This concept contains an overview of potential risks and the corresponding protective measures.

Our Group-wide EHS Spillage Control standard governs the **handling of hazardous materials** and stipulates organizational measures to prevent toxic substances from spilling or leaking during storage and transport. In addition to this standard, our Risk Management Process guides all our sites in identifying and assessing risks. As needed, this process can be used to develop and implement measures to minimize such risks. Since 2016, the Group Procedure Hazard and Operability Study has clearly defined the individuals responsible for pinpointing potential hazards during

a project as well as the manner in which hazards should be identified and documented.

The 2012 EU directive on the control of major accident hazards involving dangerous substances (aka Seveso III) was transposed into German law at the end of 2016 and entered into force on January 14, 2017. Numerous amendments to this directive have affected regulations such as the German Hazardous Incident Ordinance (aka 12th BImSchV). In response to these amendments, in 2017 we updated the existing processes and documents on the **assessment and communication of potential hazards** posed by our production plants and warehouses. On request, members of the public may access our revised safety documentation at any time. We furthermore fulfill our obligation to keep the public informed through forums such as neighborhood meetings, where residents learn about the potential hazards of industrial accidents, common accident scenarios, and the measures needed to prevent or mitigate their consequences. Further information is contained in our Hazardous Incident Brochure, which we update on a three-year basis and send to approximately 17,000 households in the vicinity of our Darmstadt site. The brochure is also available on our [website](#).

Keeping a close eye on safety

Our **EHS performance indicators** make it possible to measure safety and identify opportunities for improvement. We track EHS performance indicators at all our production and warehouse facilities, as well as at major research sites such as Billerica (Massachusetts, USA) and Chilworth (United Kingdom). In doing so, we record both accidents and near misses. We investigate each individual incident before devising appropriate countermeasures in an effort to prevent such accidents from repeating themselves in the future.

When it comes to performance indicators, we attach particular importance to the EHS Incident Rate (EHS IR) for recording and evaluating all minor and major incidents, along with the associated Loss of Primary Containment (LoPC) indicator. Also important is the EHS Leading Rate (EHS LR), which is calculated based on an analysis of near misses and critical situations.

In 2018, the European Chemical Industry Council ([Cefic](#)) and the International Council of Chemical Associations ([ICCA](#)) jointly resolved to tighten the **reporting thresholds** of incidents such as near misses. We expect that this will result in more incidents being reported going forward.

In collaboration with our individual business sectors, we have defined specific targets for our EHS performance indicators. The Executive Board receives semi-annual reports detailing the progress of these indicators.

EHS Incident Rate

Since 2013 we have been tracking the EHS Incident Rate, an indicator that synthesizes the following four categories of data:

- the number of workplace accidents involving our employees and the contractors who work at our sites
- environmentally relevant incidents as defined by the European Chemical Industry Council (Cefic) and the German Chemical Industry Association (VCI), for instance product spills
- the activation of operational safety precautions with no adverse impact on people or the environment, such as preemptive systems shutdowns
- deviations identified during external reviews and audits

The calculation of the EHS Incident Rate includes the number of incidents and the severity of the event relative to the number of man-hours worked. **The lower the EHS Incident Rate, the safer the site** is.

3.1

was our EHS IR in 2018, which represents a slight decrease compared to the previous year's result (2017: 3.4).

In 2018, we recorded no significant incident-related spills across all production, research and warehouse sites.

Risk Management Process

Our Risk Management Process guides all our sites in identifying and assessing risks. As part of this process, for instance, we conducted a comprehensive audit of our Performance Materials site in Suzhou (China) following its acquisition in 2014. We subsequently took steps to address the shortcomings identified in the audit, all of which we successfully completed in the course of 2018.

Training and sharing lessons learned

The safety of our plants and processes is predicated on the **successful interaction between man and machine**, which is why it is crucial for us to educate our employees and provide them with regular training. Our internal continuing education programs for site, production, engineering, and EHS officers also cover plant and process safety. Likewise, we also train newly hired EHS managers in plant and process safety during their onboarding. In 2018, 23 new employees completed the onboarding process.

In the interest of improving safety, it is extremely important to **share best practices and lessons learned**, an approach that enables all our production sites to learn from incidents at other facilities and thereby implement preventive measures. Once a month, for instance, site directors and EHS managers participate in safety leadership calls to share new lessons learned. Additionally, regular discussion rounds are held by the EHS managers at our sites.

Biodiversity

The increasing loss of biodiversity is a global challenge that impacts our company as well. After all, we depend on ecosystems for natural resources such as raw materials. Prime examples include red algae (*Polysiphonia elongata*), whose cytoplasm is used in our cosmetic active RonaCare® RenouMer, and the seeds of the common poppy (*Papaver rhoeas*), whose extracts can be found in our cosmetic active RonaCare® Poppy SE. We therefore have a vested interest in preserving and promoting biodiversity.

Our holistic approach to preserving biodiversity

Across all our sites, we consider the ecosystems in our immediate vicinity with the goal of minimizing our direct impacts. With these considerations in mind, our wide array of **environmental sustainability efforts** such as [water management](#) and [climate action](#) help conserve biodiversity.

Our own production sites are located in established industrial and commercial zones. Before acquiring a company – and thus its sites – we first conduct an ecological risk assessment, taking into consideration information from public sources such as neighbors and non-governmental organizations (NGOs).

How we preserve biodiversity at our sites

Our efforts to protect biodiversity are organized by our Group function Environment, Health, Safety, Security, Quality (EQ) ([Environmental stewardship](#)). In designing new sites and plants, we always include our Environment, Health and Safety (EHS) unit, which is responsible for reviewing the ecological aspects of a project. EHS is on hand to assist all sites with support and advice, and furthermore performs detailed environmental impact assessments for large-scale projects.

Our commitment: Standards and agreements

Substances that compromise biodiversity should not end up in the environment, which is why we design and operate our plants in accordance with our Group-wide safety and environmental requirements. For instance, our Corporate Environment, Health and Safety (EHS) standards define the way we manage [waste](#) and [wastewater](#) treatment as well as how we ensure plant safety. To minimize our impact on the environment, we furthermore adhere to internal standards governing air emissions, water protection and energy management.

The Nagoya Protocol is an international supplementary agreement to the UN Convention on Biological Diversity (CBD), which was transposed into German law in 2015. The aims of the CBD include the **conservation of biodiversity** and the sustainable use of its components. Within our

company, for instance, the Nagoya Protocol plays a key role in our product development efforts, and we always apply the agreement's requirements when using genetic resources originating in countries covered by the protocol.

Nagoya Protocol and access and benefit sharing

We are highly vested in implementing the Nagoya Protocol. A key part of this agreement is access and benefit sharing, which ensures that countries providing genetic resources – generally developing nations – also benefit from their use. In 2018, we developed processes aimed at systematically assessing instances of access and benefit sharing and dealing with them according to common standards. In addition to these efforts, we implemented further requirements of the Nagoya Protocol, establishing a Group-wide standard that details our **approach to genetic resources** originating in countries covered by this agreement.

Biodiversity at our sites

Unsealed surfaces represent an important habitat for plants and animals. At our facilities, however, we are required to seal certain surfaces to minimize the risk of chemicals ending up in the ecosystem. We are working to increase the **percentage of unsealed surfaces** insofar as safety requirements permit.

Our Darmstadt site is a prime example of our commitment to preserving biodiversity. We conduct regular assessments of our facilities there to evaluate the site's nature conservation efforts, using the results to help develop an action plan for improving the surrounding ecosystem for plants and animals. For instance, we have created places of refuge for insects and reptiles, and around 30% of the premises (0.4 square kilometers) have now been greened. Ecologically friendly spaces are not a new idea for us, having developed a green open space concept for our Darmstadt site as early as 1995. Moreover, we have worked with the City of Darmstadt to draft a planning guideline that stipulates the ecological optimization of our site's green areas. In addition, **we survey the environment around potential construction sites** to assess the respective flora and fauna situation there.

community

Within this chapter:

- 117** Community involvement
- 119** Global Health

- 121** Broad Minds

community involvement

We take on social responsibility. Focusing especially on those areas where we can best leverage our expertise, we support health, education and cultural projects. Moreover, we provide disaster relief and assist people in need in the vicinity of our sites and in the countries where we operate.

Our approach to community involvement

Across all our facilities worldwide, we are deeply committed to supporting our communities. In selecting social projects, we choose initiatives that align with our [strategic focus areas](#), namely Global Health and Broad Minds.

We are particularly determined to facilitate access to health for all citizens worldwide. To do so, we take a multi-pronged approach that includes an array of [health projects](#) aimed at strengthening communities. In pursuing these efforts, we apply our competencies, knowledge and experience in the health industry, joining forces with dependable partners to provide people with the help they need.

We view scientific education as a key component of culture - and vice versa. Education can help us understand culture, but culture can also **build a bridge to education**; it can stimulate curiosity, nurture creativity and even inspire scientific discovery. We therefore sponsor [cultural initiatives](#) and support a number of [educational projects](#) aimed at cultivating the next generation of scientists. As part of these efforts, we deploy our expertise to encourage and inspire curious young people who share our passion for science and technology.

Our activities are intended to have a positive, long-lasting effect on the community. We therefore promote many long-term initiatives, which is an approach that strengthens our relationship with our stakeholders and helps reinforce our social license to operate.

How we structure community support

Our Group Corporate Affairs function monitors Group-wide community outreach and oversees a portion of our activities, including the [Praziquantel Donation Program](#), the Global Pharma Health Fund (GPHF) and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany. Beyond these Group-wide efforts, our business sectors also run their own projects such as our educational initiative [SPARK](#), while several of our health initiatives in low- and middle-income countries operate under the auspices of the [Foundation sponsored by Merck KGaA, Darmstadt, Germany](#). Furthermore, our regionally focused activities are planned and executed by our local subsidiaries, who choose for themselves the focus areas of our [Corporate Responsibility \(CR\) strategy](#) they would like to support.

The Merck family has also long been committed to philanthropic work, with its activities falling under the umbrella

of the Family Foundation. This organization takes on social responsibility by supporting projects that bring benefits to the people in the vicinity of our sites, focusing on healthcare and education, promoting citizens' initiatives, development cooperation, intercultural understanding, and non-profit objectives. The foundation moreover cooperates with government and scientific institutions as well as nongovernmental organizations, and especially furthers projects that our employees are privately involved in.

Our commitment: The principles of our community involvement

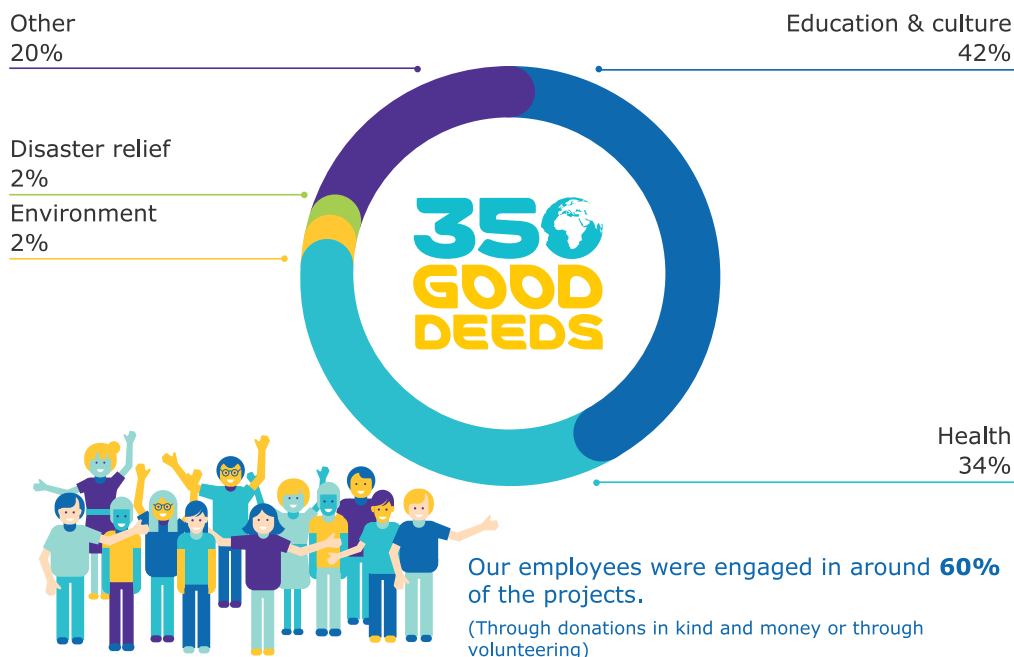
We align our projects with our Group Policy on Contributions to Society, which defines community engagement for our company along with the objectives we pursue. This policy also provides our business sectors and subsidiaries with a framework for structuring their respective activities. Moreover, it sets out roles and responsibilities, emphasizing that our activities should have a **long-lasting, positive effect on the community**. With this in mind, we focus our efforts on long-term projects.

In 2018, the Executive Board adopted a new Group-wide [Corporate Volunteering Guideline](#), which grants our people up to two days of paid leave per year to volunteer in initiatives that are either run or supported by our company. We hope that this guideline will encourage even more of our employees to get involved in the community.

350 years – 350 good deeds

To mark our 350th anniversary, in 2018 we launched 350 Good Deeds, a campaign under which we conducted more than 350 charitable activities in 60 countries worldwide – particularly in the direct vicinity of our facilities. The aim of this campaign was to demonstrate our **social commitment** and give something back to the communities in which we operate. At the same time, it was intended to enhance employee engagement and bolster team spirit by involving employees around the globe in our community outreach efforts. In selecting social projects, we chose initiatives that aligned with our [strategic spheres of activity](#), namely Global Health and Broad Minds. However, we also supported environmental projects and provided assistance to people in need. The 350 good deeds were chosen by the responsible employees at our individual sites.

More than 350 charitable activities in 60 countries worldwide



Actively participating in more than 60% of the projects, our employees showed their support by donating their time as well as money and supplies. Another way they got involved was by voting for their favorite projects, with the four most popular receiving additional funding from our company.

In 2018, we spent a total of around € 36 million on community involvement. This figure does not include contributions from the [Foundation sponsored by Merck KGaA, Darmstadt, Germany](#) or initiatives that primarily served to market our products.

Examples of our 350 Good Deeds engagement

The good deeds promoted through our anniversary campaign covered a wide range of issues, an intentional choice since the campaign reflected the diverse interests of our employees. In particular, these activities addressed **local needs and challenges** that our people are passionate about and which they deemed to be worthy.

During our 350th anniversary year, our employees in Poland took a fitting and unique approach toward community involvement. All the community activities they pursued in their free time were counted and as soon as the number reached 350, we made a financial donation to both the F84

Autism Spectrum Disorder Society and the AVALON Foundation. These two organizations assist people with disabilities and were chosen by the employees who participated.

Hand in hand with the Manos Abiertas foundation, we support an orphanage in Argentina, funding the maintenance of the facility along with equipment to meet the children's everyday needs. Together with our employees, we also donated **food, school supplies, clothing, and toys** in 2018. Our people moreover visited the center regularly to spend time cooking and painting pictures with the children, or to celebrate occasions such as birthdays, Easter or Christmas.

We supported similar volunteering activities in other countries, and many employees have donated items such as books, toiletries and food to social facilities. One example is the Give Back Days held by our people in France. During our 350th anniversary year, they launched two on-site donation drives, the first for clothes and children's books and the second for toys and hygiene products as well as canned goods, collecting an impressive 1.2 metric tons of food in total. The items were then donated to eight local charities.

You can read more about the 350 Good Deeds initiatives under "[Broad Minds](#)" and "[Global Health](#)".

Global Health

We use our expertise to support health initiatives all over the world, particularly concentrating on promoting local healthcare infrastructure, providing vocational training and continuing education for medical professionals, and educating people on health issues.

Our commitment: The principles of our community involvement

As with the other ways we support the community, we align our health activities with our Group Policy on Contributions to Society. In addition, health initiatives are also governed by our Healthcare business sector's policies and our [Access to Health Charter](#) which was updated at the end of 2018. We calculate the value of our pharmaceutical donations according to the World Health Organization (WHO) Guidelines for Medicine Donations.

Volunteering in health initiatives

As part of our [350 Good Deeds campaign](#), in 2018 many of our employees around the world committed to supporting health initiatives and institutions. For example, several hundred employees from ten countries participated in running, cycling, paddling, and hiking events to boost awareness of diseases such as breast cancer and multiple sclerosis, as well as to raise funds for charitable health initiatives.

Our employees were also involved in renovating and decorating healthcare facilities. In Brazil, for instance, 50 of our employees helped remodel a hospital in São Paulo that specializes in the treatment of breast cancer and is a point of contact for women who have experienced sexual violence. Our people painted the walls of the chemotherapy reception area and the outpatient clinic using materials provided by our company.

In Germany, we support the Dr. Mildred Scheel hospital house in Greifswald by donating supplies and providing manpower. Creating a sense of warmth and well-being, this facility provides a place where the families of children with cancer can stay during the difficult treatment phases. In April 2018, our employees helped expand and enhance the grounds around the facility. On **World Children's Day** in June 2018, we also helped out at the organization's summer festival.

Educational initiatives for healthcare professionals

We are dedicated to improving medical care around the world. Every year, our Global Medical Education and External Relations unit initiates and supports a multitude of educational initiatives for healthcare professionals. This includes funding educational programs through independent third-party providers, as well as leading the **development of scientifically and clinically relevant programs**. In doing so, we advance the knowledge of healthcare professionals, sensitize for clinical disease patterns and encourage

familiarization with progressing medical treatment methods, all of which ultimately benefits patients.

In 2018, we supported more than 50 Continuing Medical Education (CME) programs offered by 17 independent medical education providers, and we newly designed 12 Medical Education Programs. More than 320,000 healthcare professionals participated via e-learning platforms and in-person courses.

Health education in India: Fighting anemia together

In India, more than 50% of all women suffer from anemia. As part of our [Healthy Women, Healthy Economies](#) initiative, we launched the Swasth Nari Sashakt Parivar (healthy woman, healthy family) program in March 2018, joining forces with the non-profit organization Doctors For You. Reaching almost 4,800 women in Mumbai aged between 18 and 35, the program tested them for anemia and offered **nutritional counselling and medical treatment** for those with low hemoglobin. Unique to this initiative, the nongovernmental organization not only treats anemia, but also offers skill development courses to the women undergoing treatment. Starting in 2019, around 100 women who have shown improvement and demonstrated an interest in advancing their skills will be able to train as a cosmetician or a seamstress. This opportunity encourages all participants to care for their health and stick to the treatment cycle.

Disease awareness in Brazil

Since rare cancer types are often detected too late and pose a serious threat to the health of individuals, we want to drive the conversation on these diseases and raise awareness for early diagnosis and treatment. To this end, in 2018 we partnered with the Brazilian non-profit "Instituto Vencer o Câncer" to launch a joint social media awareness campaign on rare skin cancer types. Going beyond social media, we supported an event in Brasília to inform citizens about rare forms of cancer. Taking place at the same time as a public hearing on the subject, it was attended by more than 500 guests and served as a **platform for healthcare professionals** to share their knowledge. Initiated in June 2018, a local forum on rare cancers complemented our efforts to bring healthcare professionals and other stakeholders together.

To raise awareness for the neurodegenerative disease multiple sclerosis (MS), around 20 employees in Brazil organized a roadshow featuring an MS mini-simulator and additional interactive information, touring four states in 30 days. Visitors had the opportunity to take a virtual journey through the brain of a patient to better understand the

disease and the challenges patients face in their everyday life. More than 1,000 visitors tried out the mini-simulator. In addition, employees traveled around three Brazilian states with an MS suitcase that lets carers of MS patients experience living with the condition. The suitcase contained items such as gloves that make it difficult to zip clothes and toothbrushes that can create a tingling sensation in the limbs.

To raise awareness of colorectal cancer, we presented our Giant Intestine Exhibition in March 2018 in Brazil. Featuring an inflatable model of the organ large enough for visitors to walk through, the exhibition provided audiovisual information on the human intestine, with more than 1,100 people attending.

Further educational health projects can be found under "[Health awareness](#)".

Improving access to healthcare in Madagascar and India

Through the AR-MADA initiative in Madagascar, we are reaching patients who have inadequate or no access to effective and affordable medical care. Six times a year, volunteer doctors travel to different regions of the island to distribute medicines free of charge and help by providing expertise. We assist the initiative with money and donations. In addition, one of our employees travels there every year to support activities. In 2018, more than 30,000 patients benefitted from the project.

Emergency medical care is also a challenge in some remote parts of India, which is why we are working with several local non-governmental organizations to overcome this issue. In 2018, for example, in India our company donated 15 **motorbike ambulances** to the Ministry of Health in the federal state of Goa. The bikes are equipped with emergency medical care kits and located at strategic sites across the state's major cities. Managed and operated by GVK EMRI, a not-for-profit partner of the Goa government, these bikes can travel faster than standard ambu-

lances in high traffic, thus ensuring quick treatment of patients.

Since 2014, we have also led the River Ambulance Program in India in association with the non-profit organization Narmada Samagra. The River Ambulance transports health workers and provides healthcare solutions to local populations living in the remote region along the Narmada River.

INFO

IMPROVING ACCESS TO HEALTHCARE THROUGH THE FOUNDATION SPONSORED BY MERCK KGAA, DARMSTADT, GERMANY

The Foundation sponsored by Merck KGaA, Darmstadt, Germany is a non-profit organization with limited liability that aims to improve the health and wellbeing of people and advance their lives through science and technology – especially in developing and underserved regions. It is the only foundation of Merck KGaA, Darmstadt, Germany and since 2017 has been overseeing many of our philanthropic activities. Its efforts are primarily focused on improving access to innovative healthcare solutions in underserved communities, building healthcare and scientific research capacity and empowering people in STEM, with a special focus on women and young people.

Broad Minds

Underpinned by a longstanding tradition, the promotion of education and culture is a core element of our commitment to society. By making education and culture accessible, we nurture characteristics that are essential to us as a high-tech company, namely creativity, enthusiasm for new discoveries, curiosity, and the courage to transcend boundaries. To tap into these key drivers, we sponsor educational and cultural initiatives at many of our sites, grant scholarships and facilitate learning in specific subjects.

Our commitment: The principles of our community outreach

When it comes to supporting creativity and inspiration within our communities, we align our efforts with our Group Policy on Contributions to Society, which is detailed under [Community involvement](#).

Promoting education worldwide

We are committed to igniting a passion for science, especially among young people, which is why we have been supporting initiatives such as the "Jugend forscht" competition for more than 35 years. In 2018, we hosted the nationals for the third time. Themed "Jump! #ThinkNew", the contest attracted 182 young scientists from across Germany. We have also been organizing the state-level competition for the German Federal State of Hesse since 1996.

Junior Labs at the Technical University Darmstadt, Germany

We encourage young people to come to our Junior Labs and explore their scientific curiosity. Linking classroom lessons with trending topics and modern methods of research, the initiative encompasses different focus areas. For instance, we partner with the Technical University (TU) of Darmstadt to operate a junior laboratory for chemistry, with approximately 2,500 students conducting research over the course of 2018. We also run the "livfe BioLab", where in 2018 more than 1,000 pupils performed biology experiments under professional guidance.

Continuing education for teachers and expanding school partnerships

As part of our school booster program in Darmstadt (Germany) and the surrounding area, we helped approximately 70 schools conduct experiment-based science projects in 2018. Additionally, around 1,500 students visited research labs and select manufacturing plants at our global headquarters.

Beyond promoting STEM education, in Darmstadt we also support teachers through **continuing professional development** that explores educational concepts and helps them evolve their teaching technique. In 2018, we once more hosted a science conference attended by more than 100 teachers from the region.

Over the years, we have gained a great deal of experience through longstanding school partnerships in the Darm-

stadt area. In an effort to leverage these lessons learned and apply them to other countries, we initiated a pilot project in India in 2017, with subsequent projects launched in Chile, Kenya and Tanzania in 2018. Building on the experience from the pilot, our endeavors here focus on providing teachers with the tools to design exciting lessons that will spark their students' **curiosity in science**. To date, 100 people have taken advantage of this continuing education program. We are working closely with education experts to develop the lesson concepts. Thanks to their knowledge of the cultural landscapes in the respective countries, we can adapt experiments to local environments and introduce our technologies as well as those of our partners. The projects conducted in collaboration with the Kenya Chemical Society provide a good example of this approach. Utilizing a simple education concept for four- to six-year-olds ("Finding out with Fred"), these experiments require little preparation, combine imaginative stories with STEM education, and can be performed with inexpensive materials that are easily available locally.

SPARK: Igniting a passion for science in the next generation

As part of our global volunteer program SPARK, employees around the world from our Life Science business dedicate their time and expertise to engage school children in hands-on learning. The goal is to ignite a passion for science and inspire them to consider a STEM-related career. SPARK activities include our Curiosity Labs™ program, which educates students through exciting, hands-on science lessons. We also offer tours of our production sites, career panel events and more. In addition to providing **materials for interactive lessons**, we collaborate closely with education experts around the world to ensure that SPARK aligns with specific local requirements and complements existing curricula.

In 2018, as part of SPARK, our Life Science business ran its second year-long Curiosity Cube™ tour across North America. Consisting of a shipping container retrofitted into a mobile science lab, the Curiosity Cube™ provides a learning environment that immerses visitors of all ages in specific science topics through hands-on experiments and state-of-the-art technology. Supporting the daily work of teachers by offering tools and resources that most schools lack, the tour focused on schools with **underprivileged students**, which accounted for 94% of the facilities visited. In total, the Curiosity Cube™ traveled 30,000 kilometers across North

America in 2018, and engaged students in 108 communities. Feedback showed that following the visit, 94% of students increased their understanding of life science terminology and 74% expressed interest in being a scientist.

Through the overall SPARK Global Volunteer Program, including the Curiosity Cube™, more than 2,800 of our employees volunteered more than 19,000 hours of their time throughout 2018, engaging over 66,000 students worldwide in science.

Partnering with Seeding Labs

We support [Seeding Labs](#), a non-governmental organization that provides scientists in developing countries with lab equipment, training and opportunities to collaborate with other experts in their field. To date, we have enabled the organization to equip 69 universities in 34 developing countries with 209 metric tons of used but **fully functioning laboratory equipment**, providing access to the global scientific community and helping to accelerate scientific research.

We are the exclusive sponsor of the Seeding Labs new online platform, [TeleScience](#). Featuring educational videos and training sessions led by our Life Science employees, who share techniques and tips on a wide range of science topics, TeleScience has drawn more than 2,000 users from 115 countries since its launch in 2018.

Pioneering hands-on learning

We engage in a signature partnership with Technorama. Located in Switzerland, this organization is the third largest science center in Europe and a pioneer of hands-on, self-directed learning. In 2018, our scientists in Switzerland developed experiments for public school pupils to perform at special Technorama Days. At these events, more than 650 students collaborated with over 50 employees from our local sites to learn how to detect odors and synthesize a simple fragrance. We are also helping in the development and operation of a fully equipped, **state-of-the-art wet lab** that has the appropriate setup to handle various liquid chemicals and reagents. It is expected to receive more than 70,000 visitors annually. Technorama will use this lab to provide science-focused professional training for teachers throughout Switzerland.

Clean water for China

At the celebration of our 350th anniversary, in China our company launched a new partnership program with the One Foundation charity fund, which aims to provide clean water to schools. This is an important cause since over 40 million students across 114,000 rural schools in China lack access to safe drinking water. We donate one Chinese renminbi (approximately US\$ 0.14) a day on behalf of each of our employees in China, which is used to **supply rural schools** with clean drinking water. The money donated in 2018 helped to install drinking water purification facilities for around 15,000 students in 33 rural schools as well as providing water testing machines. We also donated 20 sets of portable water quality testing systems to these schools.

Some of our employees also got personally involved in the action. During the school visit program, 18 employees volunteered 16 hours each, teaching topics such as awareness of water and electricity signs and organizing small scientific experiments for the children. In recognition of our efforts, we received the EU Chamber of Commerce CSR Award in 2018.

Music and literature as ambassadors

Our symphony orchestra

What began in 1966 as a company ensemble is now a professional symphony orchestra. In addition to regularly undertaking international concert tours, the [Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany](#) is also an integral part of cultural life in Darmstadt (Germany) and the surrounding region. Besides giving performances, we also seek to inspire young people and ignite a passion for classical music through orchestra workshops. In 2018, for instance, 37 young musicians took advantage of the opportunity to play in a professional ensemble for the first time. We furthermore held our traditional cushion concerts for children aged four and up.

In 2018, the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany gave its 30th charity concert, raising a total of € 50,000. Via the "Echo hilft!" initiative, the proceeds went to help five community projects in the Darmstadt area. To commemorate our 350th anniversary, our symphony also gave performances in Beijing (China), Boston, MA (United States), Darmstadt (Germany), Saint Louis, MO (United States) and Shanghai (China). In China, our musicians led an orchestra workshop for music students from the University of Beijing, and afterwards gave a hugely successful joint [concert to an audience of approximately 1,700 people](#). Beyond these activities, the orchestra also performed three movie soundtrack concerts at our 350th anniversary celebration for our Darmstadt employees and made a guest appearance at the Millstatt Music Weeks in Austria.



people attended the concerts given by our symphony orchestra in 2018.

Literary awards for bridge builders

As with music, literature is also an important ambassador between cultures. We therefore award five literary prizes worldwide: the Johann Heinrich Merck Award for Literary Criticism and Essay Writing of Merck KGaA, Darmstadt, Germany (since 1964), the Premio Letterario of Merck KGaA, Darmstadt, Germany in Italy (since 2003), the Kakehashi Literature Prize of Merck KGaA, Darmstadt, Germany in Japan (since 2014), the Tagore Award of Merck KGaA, Darmstadt, Germany in India (since 2012), and the Translation Award of Merck KGaA, Darmstadt, Germany in Russia (since 2016). These awards particularly recognize authors who build bridges between cultures, as well as between science and literature.

- Worth € 20,000, the 2018 Johann Heinrich Merck Award for Literary Criticism and Essay Writing of Merck KGaA, Darmstadt, Germany, went to Austrian author and translator Martin Pollack.
- Endowed with € 10,000, our 2018 Premio Letterario was presented to Carl Safina, an American ecologist, writer and professor. Honorable mention went to Italian physicist and science historian Lucio Russo. In Italy, we are

also dedicated to promoting the next generation of literary genius. Besides offering creative writing workshops, we host a youth writing competition called La Scienza Narrata, whose winners are chosen together with the winners of the Premio Letterario.

- With prize money of € 10,000, the 2018 Kakehashi Literature Prize went to Austrian writer Clemens J. Setz and his Japanese translator Ayano Inukai.
- Worth € 4,000, our 2018 Translation Award in Russia went to Nina Fedorova, Ekaterina Aralova and Natalia Stillmark, while Tatiana Zborovskaya received the Goethe Prize.

Translation project in Asia

In 2018, we launched our company's Social Translating project in Korea. Moreover, we sponsored the translation of the German novel "Die Welt im Rücken" (The world at your back) by Thomas Melle into ten Asian languages. As part of this project, we also funded the [Goethe-Institut's](#) innovative approach to translating the book, with ten translators working simultaneously via a digital platform, engaging in a lively discourse with each other and the author.

Facts & figures

Within this chapter:

125	Report profile	168	Sustainable Development Goals
127	Indicators	173	Non-financial report
127	Economics	180	GRI content index
128	Business ethics	180	General disclosures
132	Employees	185	Economic Standards
145	Environment	188	Environmental Standards
151	Community	191	Social Standards
153	Goals	198	Global Compact CoP
165	Recognition and rankings	202	

Report profile

Part of the non-financial report

We take pride in our commitment to corporate responsibility, especially on the occasion of our 350th anniversary. Our long-standing history of giving back to the community has also given rise to a tradition of reporting on our efforts, with this being our tenth Corporate Responsibility Report. Starting in 1993 as a series of environmental reports describing how we meet our obligations to society, in 2003 our reporting evolved into a full-blown compilation released every two years. In 2016, we started publishing the story of our dedication on an annual basis, a practice that continues to this day.

With transparency as a key goal, we aim to extensively inform our stakeholders of our activities and successes, as well as the challenges we face. Our 2018 Corporate Responsibility Report meets the requirements for a combined separate non-financial report as defined in the German Federal CSR Directive Implementation Act. The index to the [non-financial report](#) provides an overview of the relevant content.

This CR Report also documents the progress we have made in implementing the guidelines of the [United Nations Global Compact \(Communication on Progress\)](#) and meets the criteria of the German Sustainability Code (DNK) of the German Council for Sustainable Development (RNE), a body established by the Federal Government of Germany. Our Statement of Compliance with the German Sustainability Code can be accessed via the [DNK database](#).

Reporting framework

This CR report covers fiscal 2018 and pertains to our entire Group including our subsidiaries across 66 countries. Any deviations from this reporting framework are indicated on a case-by-case basis. On December 1, 2018, our Consumer Health business was transferred to Procter & Gamble (P&G) after having been classified as a discontinued operation as of April 2018, pursuant to IFRS 5. Upon completion of the sale in early December, around 3,300 employees were transferred to P&G. Unless otherwise stated, our data incorporate the Consumer Health business pro rata for an 11 month period. The majority of the figures we publish reflect the status as of December 31, 2018. As such, figures calculated as of this date exclude Consumer Health because the sale of this business had been completed entirely by that point in time.

Data collection and consolidation systems

Since 2005, we have been using a Group-wide electronic data acquisition system to collect environmental and occupational health and safety data, which is input locally at our individual sites and approved following review. To maximize the quality of this data, we support the sites in optimizing their collection processes and their corresponding quality assurance measures. Moreover, our Group function Environment, Health, Safety, Security, Quality (EQ) conducts internal EHS audits that review both the processes and the data provided.

We compile environmental performance indicators from all our production sites across the Group, as well as those warehouse and research sites that are relevant in terms of their environmental impact and employee headcount. The scope of consolidation therefore covers all Group sites that have relevant impacts on the environment.

The data on employees and community outreach pertain to our entire Group. All employee master data is continually updated in an SAP database. We use community data management software to log data pertaining to our community involvement at subsidiary level.

Some employee data is only disclosed for select sites or countries, which is accordingly indicated in the respective text passages.

Determining report content

We align the content of our CR Report with the internationally recognized guidelines of the Global Reporting Initiative ([GRI](#)), and the principles of completeness and materiality, as well as input from our stakeholders. This report has been prepared in accordance with the "GRI Standards: Comprehensive" option. Moreover, we have taken into consideration the requirements of the capital market for assessing companies' sustainability performance.

In 2018, we performed a comprehensive materiality assessment to determine the CR topics of relevance to our Group. Experts from our business sectors and relevant Group functions reviewed the findings and validated them. Moreover, as stipulated by Section 289c (2) of the German Commercial Code (HGB), we checked the topics validated in 2018 for "double materiality". We have derived the content of this CR report from the results of the materiality assessment, addressing all issues identified as material. Detailed information on the materiality assessment and the materiality matrix can be found under [Materiality analysis](#).

Our Executive Board has reviewed and approved this report. The content of the non-financial report has also been reviewed by the Supervisory Board in accordance with Section 111 (2) of the German Stock Corporation Act (AktG).

External audit

KPMG AG Wirtschaftsprüfungsgesellschaft has audited the annual financial statements and management report of our company for the fiscal year spanning January 1 to December 31, 2018 and issued an unqualified opinion. Furthermore, after undergoing a limited assurance audit, our company has received an independent audit certificate for the following chapters of this CR report:

- Strategy & management
- Business ethics
- Products
- Employees
- Environment
- Community
- Facts & figures

The additional content provided on the company's websites and external webpages linked in this report is not part of the non-financial report or the information assured by KPMG.

Contact:

We welcome your feedback and are happy to answer any questions.

Merck KGaA, Darmstadt, Germany

Corporate Affairs
Group Corporate Responsibility

Maria Schaad

Frankfurter Str. 250
64293 Darmstadt
Germany

Tel.: +49 6151 72-0
Fax: +49 6151 72-200

The previous CR Report was published in April 2018. Our next CR Report is scheduled for publication in April 2020.

indicators

ECONOMICS

Net sales, operating result (EBIT) and research and development costs, by business sector^{1,2}

€ million	Healthcare	Life Science	Performance Materials	Group
2017				
Net sales	6,190 ³	5,882	2,446	14,517³
Operating result (EBIT)	1,337 ³	834	689	2,423³
R&D costs	1,600 ³	241	225	2,108³
2018				
Net sales	6,246	6,185	2,406	14,836
Operating result (EBIT)	731	1,036	508	1,727
R&D costs	1,686	249	242	2,225

1 As a non-operating segment, Corporate and Other is not shown here as a separate item, but rather under Segment Reporting in our 2018 Annual Report.

2 Figures comprise the continuing operations of the Group excluding the Consumer Health business.

3 Figure retroactively adjusted; see Consolidated Financial Statements in our 2018 Annual Report.

business ethics

Part of the non-financial report

Internal audits on corruption and Human Rights Charter

	2015	2016 ¹	2017	2018 The Group ²	2018 thereof Merck KGaA, Darm- stadt, Germany ³
Number of audits relating to corruption	49	55	50	54	16
% of audits relating to corruption	64	68	65	69	21
Number of audits relating to the workplace requirements of our Human Rights Charter	41	47	45	46	14

1 Includes Sigma-Aldrich as of 2016

2 Consumer Health business has been out of Internal Auditing scope since September 2017.

3 Includes global audits which are conducted at the headquarters in Darmstadt and/or the management of the audited function is reporting into KGaA.

In 2018, we audited 18% of all Group subsidiaries (status June 2018, excluding minority holdings), covering approximately 27% of all sales generated between the third quarter of 2017 and the second quarter of 2018.

In 2018, during 46 of our audits conducted in 27 countries, we additionally reviewed workplace parameters as per our Human Rights Charter. No violations were identified.

Reported compliance violations

	2015	2016 ¹	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
Total number of reported compliance violations					
Number of reported compliance incidents	33	36	39	72	17
Number of confirmed cases	8	12	14	19	7
confirmed cases by category					
Violation of the Human Rights Charter	0	2	0	0	0
Bribery and Corruption	0	2	1	1	0
Violation of the Pharmaceutical Guidelines	2	4	2	2	0
Violation of Data Privacy and Confidentiality Guidelines	1	0	2	3	3
Manipulation of Business Documents	0	2	1	0	0
Violation of cartel laws and fair competition rules	1	0	0	1	0
Infringements in the areas of finance, accounting and banking	0	0	0	0	0
Theft and fraudulent Actions against the Group	2	1	1	5	1
Other violations of Compliance Principles for the relations with Business Partners of the Group	0	1	2	1	0
Other violations of values, internal guidelines or legal requirements	2	0	5	6	3

¹ Includes Sigma-Aldrich as of 2016

Compliance training

	2015	2016 ¹	2017 ¹	2018 The Group ²	2018 thereof Merck KGaA, Darm- stadt, Germany ²
Total number of persons trained on anti-corruption guidelines³	20,404	29,764	17,044	11,404	1,254
Total number of employees trained on anti-corruption guidelines	17,378	25,889	13,345	11,155	1,245
% of employees trained on anti-corruption	43	51	25	22	11
by employee category					
Number of Role 2+ employees trained on anti-corruption	12,747	14,379	7,080	9,257	1,017
% of Role 2+ employees trained on anti-corruption	64	84	27	36	19
% of employees below Role 2 trained on anti-corruption	22	34	23 ⁴	7	4
by region (%)⁵					
Europe	–	54	18	19	11
North America	–	57	46	36	not applicable
Asia-Pacific (APAC)	–	38	25	16	not applicable
Latin America	–	52	19	12	not applicable
Middle East and Africa (MEA)	–	66	29	18	not applicable

1 From 2016 on, these figures include Sigma-Aldrich, however as of Dec. 31, 2017 the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. In the facts and figures, these employees are included under "employees below Role 2".

2 In 2018, our job grading system had not yet been applied to the employees of Sigma Aldrich in Steinheim (Germany), or to those of Allergopharma. In the facts and figures for 2018, these employees are included under "employees below Role 2".

3 Includes contractors, external supervised workers (e.g. temps) and contract partners working on-site who were trained on anti-corruption guidelines (2018: 249).

4 Figure retroactively adjusted.

5 As of 2016, we are also reporting the training rate by region. No such data was tracked for the preceding year.

In order to address the special responsibility held by management personnel, as well as by staff with HR responsibility, these employees are increasingly receiving training on anti-corruption guidelines. This applies to all employees rated Role 2+.

Our compliance and anti-corruption principles are communicated to all our business partners, who undergo a Business Partner Risk Management (BPRM) process.

Training increased in 2016, due to the initial integration of employees of Sigma-Aldrich, a company acquired at the end of 2015.

Legal actions

	2015	2016	2017	2018 The Group ¹	2018 thereof Merck KGaA, Darmstadt, Germany
Total number² of legal actions pending or completed (for anti-competitive behavior, violations of anti-trust or violations of monopoly legislation)	2	2	3	3	2
pending	2	2	3	3	2
completed	0	0	0	0	0

1 Excludes Consumer Health

2 As published in the annual reports, the herein listed total number of legal actions refers to the significant legal risks as per the company's definition. The significance of legal risks is based on potential negative effects on projected financial objectives as well as on the probability of occurrence.

For further information please see our annual reports:

- [Annual Report 2015](#), pages 128-129 and pages 212-213, no. 27
- [Annual Report 2016](#), pages 135-136 and pages 228-229, no. 26
- [Annual Report 2017](#), pages 148-150 and pages 252-254, no. 27
- [Annual Report 2018](#), pages 146-148 and pages 247-251, no. 26

Customer privacy¹

	2015	2016	2017 ²	2018
Total number of substantiated complaints received from outside parties	0	0	0	0
Total number of complaints from regulatory bodies	0	0	0	0
Total number of identified leaks, thefts, or losses of customer data	0	1	0	1

1 This data only reflects incidents classified as significant.

2 Includes Sigma-Aldrich as of 2017

Employees

Part of the non-financial report

Total number of employees

As of Dec. 31	2015	2016	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
Total number of employees	49,613	50,414	52,941	51,749	11,133
Men	28,997	28,848	30,083	29,006	7,036
Women	20,616	21,566	22,858	22,743	4,097

Number of employees by hierarchical level

As of Dec. 31	2015 ¹	2016 ¹	2017 ¹	2018 The Group ²	2018 thereof Merck KGaA, Darm- stadt, Germany ²
Total employees	49,613	50,414	52,941	51,749	11,133
Senior management (Role 6+)	146	181	197	193	94
Middle management (Role 4 & 5)	2,211	2,685	2,927	3,095	1,155
Low management (Role 3)	6,622	8,139	8,904	9,019	2,661
Other employees (below Role 3)	40,634	39,409	40,913	39,442	7,223
% of women (total)	41	43	43	44	37
thereof in senior management (Role 6+)	21	25	30	36	17
thereof in middle management (Role 4 & 5)	611	805	917	1,025	368
thereof in low management (Role 3)	2,636	3,361	3,714	3,795	1,036
thereof other employees (below Role 3)	17,348	17,375	18,197	17,888	2,676
% of men (total)	59	57	57	56	63
thereof in senior management (Role 6+)	125	156	167	157	77
thereof in middle management (Role 4 & 5)	1,600	1,880	2,010	2,070	787
thereof in low management (Role 3)	3,986	4,778	5,190	5,224	1,625
thereof other employees (below Role 3)	23,286	22,034	22,716	21,554	4,547
by age group					
Up to 29 years old (%)	15	15	15	15	14
thereof in senior management (Role 6+)	0	0	0	0	0
thereof in middle management (Role 4 & 5)	5	7	3	5	3
thereof in low management (Role 3)	130	183	194	211	111
thereof other employees (below Role 3)	7,424	7,229	7,479	7,279	1,460
30 to 49 years old (%)	64	62	62	61	54
thereof in senior management (Role 6+)	68	76	72	69	32
thereof in middle management (Role 4 & 5)	1,407	1,670	1,782	1,829	692
thereof in low management (Role 3)	4,770	5,784	6,308	6,206	1,766
thereof other employees (below Role 3)	24,815	23,996	24,733	23,536	3,497
50 years or older (%)	21	23	23	24	32
thereof in senior management (Role 6+)	78	105	125	124	62
thereof in middle management (Role 4 & 5)	799	1,008	1,142	1,261	460
thereof in low management (Role 3)	1,722	2,172	2,402	2,602	784

¹ From 2015 on, these figures include Sigma-Aldrich, however as of Dec. 31, 2017 the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. In the facts and figures, these employees are included under "other employees (below Role 3)".

² In 2018, our job grading system had not yet been applied to the employees of Sigma Aldrich in Steinheim (Germany), or to those of Allergopharma. In the facts and figures for 2018, these employees are included under "other employees (below Role 3)".

Number of employees by hierarchical level

As of Dec. 31	2015 ¹	2016 ¹	2017 ¹	2018 The Group ²	2018 thereof Merck KGaA, Darm- stadt, Germany ²
thereof other employees (below Role 3)	8,395	8,184	8,701	8,627	2,266

1 From 2015 on, these figures include Sigma-Aldrich, however as of Dec. 31, 2017 the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany, or for employees of Allergopharma. In the facts and figures, these employees are included under "other employees (below Role 3)".

2 In 2018, our job grading system had not yet been applied to the employees of Sigma Aldrich in Steinheim (Germany), or to those of Allergopharma. In the facts and figures for 2018, these employees are included under "other employees (below Role 3)".

Average number of employees by functional area¹

	2015	2016	2017	2018 ²
Group	41,511	50,439	52,053	53,809
Thereof women	17,180	21,136	22,353	23,388
Production	11,563	14,829	15,571	16,240
Thereof women	3,642	4,698	5,059	5,359
Logistics/Supply Chain ³	2,581	3,955	3,729	4,014
Thereof women	913	1,459	1,442	1,569
Marketing and Sales/Commercials ³	12,871	14,887	15,115	15,479
Thereof women	5,204	6,401	6,609	6,981
Administration	6,763	8,190	9,286	9,864
Thereof women	3,757	4,421	4,798	5,067
Research and Development	5,097	6,249	6,789	7,245
Thereof women	2,674	3,274	3,591	3,871
Infrastructure and Other	2,636	2,329	1,564	966
Thereof women	990	883	854	541

1 The average employee headcount is calculated by adding up all employees at the end of each of the last 13 months, and dividing this total by 13. Employees of Sigma-Aldrich, a company acquired in November 2015, are only included in the employee headcount calculations as of November 2015.

2 The average employee headcount for fiscal 2018 incorporates the Consumer Health employees on a pro rata basis up until the end of November 2018 due to the divestment of the Consumer Health business as of December 1, 2018.

3 In conjunction with the new job architecture implemented in 2017, some functional areas have been renamed and reorganized. Due to the new structure from 2017 on, it will only be possible to deliver a limited trend forecast in a year-on-year comparison.

Number of employees by region

As of Dec. 31	2015	2016	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
Total	49,613	50,414	52,941	51,749	11,133
Europe	23,429	24,438	25,980	25,792	11,133
women	10,316	10,884	11,627	11,464	4,097
women (%)	44	45	45	44	37
Number of employees with temporary contracts	1,079	1,031	1,279	1,209	483
% of employees with temporary contracts	5	4	5	5	4
North America	9,794	10,037	10,520	10,978	0
women	4,183	4,308	4,518	4,742	not applicable
women (%)	43	43	43	43	not applicable
Number of employees with temporary contracts	22	122	138	148	not applicable
% of employees with temporary contracts	0.2	1	1	1	not applicable
Asia-Pacific (APAC)	11,096	10,754	11,294	10,486	0
women	3,706	3,981	4,298	4,348	not applicable
women (%)	33	37	38	41	not applicable
Number of employees with temporary contracts	1,888	2,231	2,603	2,846	not applicable
% of employees with temporary contracts	17	21	23	27	not applicable
Latin America	4,352	4,140	4,050	3,340	0
women	1,986	1,910	1,896	1,648	not applicable
women (%)	46	46	47	49	not applicable
Number of employees with temporary contracts	43	40	40	62	not applicable
% of employees with temporary contracts	1	1	1	2	not applicable
Middle East and Africa (MEA)	942	1,045	1,097	1,153	0
women	425	483	519	541	not applicable
women (%)	45	46	47	47	not applicable
Number of employees with temporary contracts	127	153	172	189	not applicable
% of employees with temporary contracts	13	15	16	16	not applicable

External contractors are currently not logged in our employee data system, nor do we currently have any plans to integrate them.

Employees by business sector

As of Dec. 31	2015	2016	2017	2018
Healthcare employees	18,566	18,837	19,795	17,456
Thereof women	8,522	9,090	9,656	8,884
Thereof women (%)	46	48	49	51
Life Science employees	18,611	19,178	19,607	20,667
Thereof women	7,883	7,928	8,276	8,837
Thereof women (%)	42	41	42	43
Performance Materials employees	6,228	5,469	5,529	5,278
Thereof women	1,531	1,427	1,455	1,411
Thereof women (%)	25	26	26	27

Employees by contract type

As of Dec. 31	2015	2016	2017	2018
Total employees	49,613	50,414	52,941	51,749
Number of employees with permanent contracts	46,454	46,837	48,709	47,295
% of employees with permanent contracts	94	93	92	91
thereof women	19,034	19,741	20,741	20,545
thereof women (%)	41	42	43	43
Number of employees with temporary contracts	3,159	3,577	4,232	4,454
% of employees with temporary contracts	6	7	8	9
thereof women	1,563	1,744	2,117	2,198
thereof women (%)	49	49	50	49
full-time employees	47,292	48,056	50,498	49,273
% full-time	95	95	95	95
thereof women	18,557	19,457	20,677	20,577
thereof women (%)	39	40	41	42
part-time employees	2,321	2,358	2,443	2,476
% part-time	5	5	5	5
thereof women	2,059	2,109	2,181	2,166
thereof women (%)	89	89	89	87

New employees

As of Dec. 31	2015 ¹	2016	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
Total number of new employee hires	5,710	7,085	7,285	7,129	696
by age group					
Up to 29 years old	2,088	2,930	2,940	2,967	332
30 to 49 years old	3,252	3,736	3,848	3,728	331
50 or older	370	419	497	434	33
by gender					
Women	2,450	3,388	3,412	3,401	298
Men	3,260	3,697	3,873	3,728	398
by region					
Europe	2,119	2,689	3,058	2,560	696
North America	730	1,348	1,603	1,524	0
Asia-Pacific (APAC)	1,913	2,201	1,955	2,222	0
Latin America	780	636	497	583	0
Middle East and Africa (MEA)	168	211	172	240	0
Rate of new employee hires² (%)	14	14	14	14	6
by age group³					
Up to 29 years old	37	41	40	42	48
30 to 49 years old	57	53	53	52	48
50 or older	6	6	7	6	5
by gender³					
Women	43	48	47	48	43
Men	57	52	53	52	57
by region³					
Europe	37	38	42	36	100
North America	13	19	22	21	not applicable
Asia-Pacific (APAC)	33	31	27	31	not applicable
Latin America	14	9	7	8	not applicable
Middle East and Africa (MEA)	3	3	2	3	not applicable

1 These figures exclude the 8,975 Sigma-Aldrich employees who are not classified as new hires because they joined our company as part of the Sigma-Aldrich acquisition.

2 Formula for calculating the rate of new employee hires: Total number of new employee hires divided by number of employees at the end of the fiscal year.

3 Formula for calculating the rate of new employee hires by age/gender/region: New employee hires of the focus group divided by the total number of new employee hires.

Staff turnover^{1,2}

	2015	2016 ³	2017	2018 The Group ⁴	2018 thereof Merck KGaA, Darm- stadt, Germany
Total turnover rate	10.38	12.07	9.05	9.09	2.13
Turnover rate by gender					
Men	10.13	12.87	8.75	9.03	2.21
Women	10.73	10.96	9.46	9.18	1.99
Turnover rate by age group					
Up to 29 years old	17.49	19.20	13.66	14.24	3.51
30 to 49 years old	9.69	11.37	8.38	8.53	1.79
50 or older	8.08	9.19	7.87	7.39	2.10
Turnover rate by region					
Europe	6.22	6.23	6.22	5.73	2.13
North America	12.72	11.50	11.02	9.90	not applicable
Asia-Pacific (APAC)	15.95	22.37	12.53	14.51	not applicable
Latin America	15.29	18.85	13.74	15.41	not applicable
Middle East and Africa (MEA)	12	10.80	11.22	9.77	not applicable
Total number of leavers	4,168	6,087	4,710	4,613	233
by gender					
Men	2,386	3,771	2,596	2,578	153
Women	1,782	2,316	2,114	2,035	80
by age group					
Up to 29 years old	943	1,464	1,058	1,061	56
30 to 49 years old	2,505	3,589	2,713	2,649	106
50 or older	720	1,034	939	903	71
by region					
Europe	1,290	1,490	1,488	1,457	233
North America	638	1,132	1,143	1,064	0
Asia-Pacific (APAC)	1,540	2,543	1,387	1,468	0
Latin America	618	814	570	522	0
Middle East and Africa (MEA)	82	108	122	102	0

1 The table contains unadjusted turnover rates. The rate excludes employees who depart due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

2 Employee headcount is calculated as follows: Total number of leavers from the past 12 months divided by the average employee headcount multiplied by 100.

3 Includes Sigma-Aldrich as of 2016

4 Excludes Consumer Health

In 2018, the average length of service for employees Group-wide was 10 years (2017: 9.8 years), with 14.9 years (2017: 14.6 years) for Merck KGaA, Darmstadt, Germany employees.

Work-related accidents¹

	2015	2016	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
Lost Time Injury Rate (LTIR = work- place accidents resulting in missed days of work per one million man-hours)	1.4	1.3	1.5	1.3	2.8
by region					
Europe	2.6	2.2	2.4	1.9	2.8
North America	0.9	1.1	1.0	1.1	not applicable
Asia-Pacific (APAC)	0.3	0.4	0.3	0.3	not applicable
Latin America	0.7	0.4	1.3	1.5	not applicable
Middle East and Africa (MEA)	0.5	1.6	0.0	0.7	not applicable
Number of deaths	2	0	0	0	0
by region					
Europe	1	0	0	0	0
North America	1	0	0	0	0
Asia-Pacific (APAC)	0	0	0	0	0
Latin America	0	0	0	0	0
Middle East and Africa (MEA)	0	0	0	0	0
by gender					
Women	1	0	0	0	0
Men	1	0	0	0	0

¹ Including supervised workers

Both our employees as well as contractors have been included in the calculation of these indicators.

Through the LTIR, we record work-related accidents that involve at least one day of missed work. A work-related accident is an injury that results from the type of work, in the course of doing said work, and that has no internal cause. Work-related accidents are considered relevant if they occur on the premises, on business trips, during goods transport, as a result of external influences (e.g. natural disasters), or due to criminal acts involving personal injury. Commuting accidents and accidents during company sporting activities are not included. First-aid incidents are generally not included in the LTIR since these usually do not result in more than one day of missed work.

By 2020, we intend to sustainably lower the LTIR to 1.5. The aim is to permanently stabilize or outperform this challenging number, which we achieved for the first time in 2015.

We have defined the LTIR as a key indicator for the Group. Therefore, we do not publish any other indicators such as workplace accidents, lost days or days of absence. The LTIR is not broken down by gender as this differentiation is not relevant to our strategic planning.

For Merck KGaA, Darmstadt, Germany (about 22% of the employees of the Group), we only report work-related illnesses if these have been certified as an occupational illness by the employers' liability insurance association. In 2018 period, two cases of work-induced illness were verified (as of the end of August 2018).

Employees who regularly receive a performance and development evaluation

	2015 ¹	2016 ²	2017 The Group ²	2018 The Group ^{3, 4}	2018 thereof Merck KGaA, Darmstadt, Germany
% of employees who receive a performance and development evaluation	88	97	97	98	100
by gender					
Women	90	97	97	99	100
Men	87	97	97	98	100
by employee category⁵					
Senior management (Role 6+)	100	100	100	100	100
Middle management (Role 4 & 5)	100	100	100	100	100
Low management (Role 3)	100	100	100	100	100
Other employees (below Role 3)	85	96	96	98	100

1 The 2015 data is based on a reporting date of February 29, 2016.

2 From 2016 on, figures include Sigma-Aldrich, but as of Dec. 31 2017, the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany and of Allergopharma. In the facts and figures for 2018, the employees whose positions had not been graded are included under "Other employees (below Role 3)".

3 Excludes Consumer Health

4 In 2018, our job grading system had not yet been applied to the employees of Sigma Aldrich in Steinheim (Germany), or to those of Allergopharma. In the facts and figures for 2018, the employees whose positions had not been graded are included under "Other employees (below Role 3)".

5 In 2017, we switched our job architecture from a Global Grading System to Roles. Figures have been retroactively adjusted for previous years.

Regular feedback and employee performance evaluations are essential to fairly ranking individual performance and to helping all employees follow their own career path. Our globally uniform Performance and Talent Management Process requires annual feedback meetings and performance assessments for all employees rated Role 2 and up in the job grading system that was used since 2017. Figures have been retroactively adjusted for previous years. Apart from evaluating employee performance, this helps us to identify individual development opportunities.

When it comes to applying this process, our individual subsidiaries can decide for themselves whether to include employees rated below Role 2. In Germany, all permanent employees have been participating in the Performance and Talent Management Process since 2013. In 2018, a total of 50,920 employees worldwide were involved in the process. The Performance and Talent Management Process is coordinated via our online platform HR4You.

Internationality of employees

	2015 ¹	2016 ²	2017 ²	2018 The Group ³	2018 thereof Merck KGaA, Darmstadt, Germany
As of Dec. 31					
Number of nationalities	122	129	131	136	90
Number of nationalities in management positions (Role 4 or above)	64	70	65	70	41
% of non-Germans in management positions (Role 4 or above)	61	65	64	64	17

1 These figures do not include the employees of Sigma-Aldrich, a company that was acquired in November 2015. As of December 31, 2015, the job grading system had not yet been implemented there.

2 From 2016 on, figures include Sigma-Aldrich. However, as of Dec. 31 2017, the job grading system had not yet been implemented for employees of Sigma-Aldrich legal entities in Germany or for employees of Allergopharma.

3 In 2018, our job grading system had not yet been applied to the employees of Sigma Aldrich in Steinheim (Germany), or to those of Allergopharma.

Employee age by region

As of Dec. 31

Number of employees	Worldwide	North America	Europe (including Germany)	Merck KGaA, Darmstadt, Germany	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
2017							
Up to 29 years old	7,676	1,438	3,272	1,589	2,257	521	188
thereof women	3,512	608	1,585	634	945	294	80
30 to 49 years old	32,895	5,465	15,680	5,838	8,099	2,913	738
thereof women	14,540	2,423	7,287	2,195	3,074	1,405	351
50 or older	12,370	3,617	7,028	3,250	938	616	171
thereof women	4,806	1,487	2,755	1,069	279	197	88
Average age	41.4	44.1	42.5	42.6	36.9	40.3	39.4
Total employees	52,941	10,520	25,980	10,677	11,294	4,050	1,097

2018

Up to 29 years old	7,494	1,573	3,175	1,574	2,082	470	195
thereof women	3,534	661	1,537	633	966	285	85
30 to 49 years old	31,638	5,636	15,247	5,987	7,616	2,342	799
thereof women	14,238	2,511	7,044	2,281	3,123	1,183	377
50 or older	12,611	3,769	7,370	3,572	788	528	159
thereof women	4,971	1,570	2,883	1,183	259	180	79
Average age	41.7	44.1	42.8	42.9	36.9	40.4	39.2
Total employees	51,749	10,978	25,792	11,133	10,486	3,340	1,153

Age of youngest employee

As of Dec. 31	2015	2016 ¹	2017	2018
Age of youngest employee, excluding apprentices	17	17	18	17

¹ Includes Sigma-Aldrich as of 2016

Voluntary insurance benefits (voluntarily introduced and (co-) financed)

As of Dec. 31	2015	2016 ¹	2017	2018 The Group	2018 thereof Merck KGaA, Darm- stadt, Germany
% of employees with healthcare benefits ²	–	68 ³	68	67	0
% of employees with Group accident insurance ⁴	–	39	42	39	5
% of employees with life insurance ⁵	–	57	58	58	0
% of employees with disability insurance (short-term and long-term) ⁶	–	32	35	37	0

1 Since 2016, we have been reporting voluntary insurance benefits that we offer our employees. No such data was tracked for the preceding year.

2 Any spend on voluntarily introduced and (co-) financed healthcare benefits for employees and possibly their dependents. Not taking into consideration any mandatory social security cover (mostly covered by an insurance policy).

3 Figure retroactively adjusted.

4 Any spend on voluntarily introduced and (co-) financed accident insurance that pays a defined amount in case of death or disability caused by a work-related accident (not taking into consideration any mandatory social security cover, e.g. workman's compensation).

5 Any spend on voluntarily introduced and (co-) financed life insurance cover that pays a defined amount of money in case of natural death (not accidental).

6 Any spend on voluntarily introduced and (co-) financed insurance cover that disability pays for salary continuation in case of inability to work caused by an insured incident.

All our employees are covered by either statutory or voluntary accident and health insurance. Employees of Merck KGaA, Darmstadt, Germany are covered by statutory insurance as stipulated by the regulations in force in Germany.

We offer a company pension in numerous countries along with various programs for supplemental company pensions and survivor's benefits.

The global benefits listed in the table above are designed to provide additional security to our workforce and their families and to improve their quality of life. Benefits represent voluntarily employer-initiated as well as employer-financed assistance to our workforce in addition to the regular compensation package.

Our benefits offer meaningful choices, where possible, to support a diverse workforce and are sensitive to the needs and customs of the employees who use them, regardless of country, age, family status, interests, or values.

Long-term pension obligations and post-employment benefits

€ million	2015	2016	2017	2018
Present value of all defined benefit obligations as of Dec. 31	4,153	4,698	4,707	4,719
Pension expenses	210	226	304	295

Depending on the legal, economic and fiscal circumstances prevailing in each country, different retirement benefit systems are provided for our employees. Generally, these systems are based on the years of service and salaries of the employees. Pension obligations of the Group include both defined benefit and defined contribution plans and comprise both obligations from current pensions and accrued benefits for pensions payable in the future. In the Group, defined benefit plans are funded and unfunded (see our Annual Report 2018, Note on Provisions for pensions and other post-employment benefits).

Flexible working hours in Germany

As of Dec. 31	2015	2016 ¹	2017	2018 ²
% of employees utilizing the "mywork" working model	35	36	40	42

1 Includes Sigma-Aldrich as of 2016

2 Essentially reflects the figures of Merck KGaA, Darmstadt, Germany.

In coordination with their teams and supervisors, employees taking advantage of our "mywork" program can choose when and where they work.

Parental leave in Germany

As of Dec. 31	2015 ¹	2016 ¹	2017 ²	2018 ²
Number of employees with a right to parental leave	317	359	353	308
thereof women (recorded via maternity leave in the respective year)	149	191	151	188
thereof men (recorded via special paternity leave in the respective year)	168	168	202	120
Number of employees who took parental leave ³	485	480	352	500
thereof women	301	303	150	240
thereof men	184	177	202	260
Number of employees on parental leave who worked part time during their leave	102	102	49	128
thereof women	99	95	47	109
thereof men	3	7	2	19
Number of employees who returned from parental leave	183	174	312	312
thereof women	51	62	143	65
thereof men	132	112	169	247
Return to work rate (%)	37.7	36.3	88.6	62.4
thereof women	16.9	20.5	95.3	27.1
thereof men	71.7	63.3	83.7	95.0
Number of employees still working for the Group one year after their return from parental leave	184	190	238	– ⁴
thereof women	55	73	89	– ⁴
thereof men	129	117	149	– ⁴
Retention rate (%)	96.8	95.6	89.8	– ⁴
thereof women	98.2	93.8	85.6	– ⁴
thereof men	96.3	96.8	92.5	– ⁴

1 Figures only pertain to the Darmstadt and Gernsheim sites in Germany (which accounted for around 22% of the employees of the Group in 2018). Figures are calculated on the basis of the data from one entire year, which also includes those employees who took parental leave during the calendar year but who had not returned by Dec. 31.

2 Figures pertain only to Merck KGaA, Darmstadt, Germany (which accounted for around 20% of the employees of the Group in 2017, and roughly 22% in 2018). Figures are calculated on the basis of the data from one entire year, which also includes those employees who took parental leave during the calendar year but who had not yet returned by Dec. 31.

3 Since parental leave can be taken for a period ranging from one month to three years, it is possible for employees to be recorded across a period of up to four calendar years. This explains why the number of employees on parental leave exceeds the number of employees who have a right to it.

4 Figure will be available on Dec. 31, 2019.

Employees with disabilities¹ (%)

As of Dec. 31	2015	2016	2017	2018
Employees with disabilities ¹	4.7	4.5	4.3	4.3

1 Only pertains to Merck KGaA, Darmstadt, Germany (which accounted for around 22% of the employees of the Group in 2018, calculations based on the German Social Code IX - SGB IX).

Apprentices

As of Dec. 31	2015 ¹	2016 ²	2017 ²	2018
Number of apprentices	506	576	588	604
% of apprentices	5.3	4.6	4.4	4.5

1 Only pertains to Merck KGaA, Darmstadt, Germany (roughly 19% of the total employee headcount of the Group in 2015).

2 Only pertains to sites in Germany (approximately 25% of the Group's total workforce in 2016, 2017 and 2018). Essentially reflects the figures of Merck KGaA, Darmstadt, Germany.

Environment

Total greenhouse gas emissions (Scope 1 and 2 of the GHG Protocol)¹

metric kilotons	2006 ²	2015	2016	2017	2018
Total CO₂eq³ emissions	786	722	689	704	698
Thereof					
direct CO ₂ eq emissions	378	391	384	373	354
indirect CO ₂ eq emissions	408	331	305	331	344
Biogenic CO₂ emissions	0	13	14	13	13

1 In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline) the greenhouse gas emissions have been calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions (e.g. Sigma-Aldrich in 2015) or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

2 Baseline for our emission targets is 2006.

3 eq = equivalent

Our response to the Carbon Disclosure Project contains a detailed description of our calculation methods.

We have included the following gases in our calculation of direct and indirect CO₂eq emissions:

Direct CO₂ emissions: CO₂, HFCs, PFCs; CH₄/N₂O negligible; SF₆/NF₃ not available.

Indirect CO₂ emissions: CO₂.

In 2018, we emitted 0.047 kg of CO₂eq per euro of net sales.

Other relevant indirect greenhouse gas emissions (Scope 3 of the GHG Protocol)

	2015 ¹	2016 ^{1,2}	2017	2018 ³
Total gross other indirect emissions (metric kilotons CO₂eq⁴)	349	426	353	380
Fuel- and energy-related emissions, not included in Scope 1 or 2 (category 3)	95	127	118	131
Waste generated in operations (category 5)	123	127	68	80
Business travel - air travel (category 6)	79	103 ⁵	98	103
Business travel - rail travel (category 6) ⁶	0.02	0.02	0.02	0.02
Business travel - rental car travel (category 6)	1.1	0.6	0.6	1.4
Employee commuting (category 7)	51	68	68	66
Upstream leased assets (category 8)	0.0 ⁷	0.0 ⁷	0.0 ⁷	0.0 ⁷
Processing of sold products (category 10)	0.0 ⁸	0.0 ⁸	0.0 ⁸	0.0 ⁸
Downstream leased assets (category 13)	0	0	0	0
Franchises (category 14)	0	0	0	0

1 Because of the characteristics of the Scope 3 emissions data we do not correct these data subsequently.

2 Includes Sigma-Aldrich as of 2016

3 Excludes Consumer Health

4 eq = equivalent

5 This figure covers roughly 95% of the employees of the Group because the data for the employees of Sigma-Aldrich, acquired in November 2015, are only partially available.

6 German Railway

7 Already covered under Scope 1 and 2 emissions

8 The Group produces a huge variety of intermediate products for various purposes. Due to their many applications and our customer structure, the associated GHG emissions cannot be tracked in a reasonable fashion.

No data is available for Scope 3 categories not listed above. Their relevance to the Group is assessed in the [Scope 3 document](#).

Biogenic emissions (Scope 3), if present, are not being recorded.

Emissions of ozone-depleting substances

metric tons	2015	2016	2017	2018 ¹
Total emissions of ozone-depleting substances	2.5	2.2	1.9 ²	1.5
CFC-11eq ³	0.1	0.1	0.1	0.1

1 Excludes Consumer Health

2 Figure retroactively adjusted.

3 CFC-11eq is a unit of measure used to compare the potential of various substances to deplete the ozone. Reference figure 1 indicates the potential of CFC-11 to cause the depletion of the ozone layer.

Substances included: R-12, R-22, R-141b, R-402a, R-409a, R-401a.

Source for the emission factors: Montreal Protocol.

Other air emissions

metric kilotons	2015	2016 ¹	2017	2018 ²
Volatile organic compounds (VOC)	0.3	0.3	0.3	0.3
Nitrogen oxide	0.3	0.2	0.2	0.3
Sulfur dioxide	0.05	0.05	0.03	0.01
Dust	0.06	0.02	0.04	0.01

1 Includes Sigma-Aldrich as of 2016

2 Excludes Consumer Health

The VOC, nitrogen oxide, sulfur dioxide, and dust emissions reported here are attributable to production activities as well as energy generation. These figures do not include emissions from vehicles. Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Transport of finished goods, by means of transportation

	2015 ¹	2016 ²	2017	2018
% Truck	53	71	73	74
% Boat	41	18	15	14
% Airplane	6	11	12	12

1 The figures of 2015 pertain to goods shipped by our Darmstadt, Gernsheim and Hohenbrunn sites in Germany (excluding Sigma-Aldrich).

2 From 2016 on, the figures contain the volumes of the biggest global distribution centers of our Healthcare, Life Science and Performance Materials business sectors. These figures pertain to the total weight of transported products and indicate the primary means of transport.

In shipping finished goods from our production sites to the local warehouses of our subsidiaries, we have been working to reduce the use of air shipping in favor of sea freight. This change aims to both reduce costs as well as lower transport-related CO₂ emissions.

Energy consumption¹

In GWh	2015	2016	2017	2018
Total energy consumption	2,141	2,117	2,194	2,232
Direct energy consumption	1,343	1,330	1,319	1,322
Natural gas	1,200	1,260	1,254	1,256
Liquid fossil fuels ²	110	36	32	32
Biomass and self-generated renewable energy	33	34	33	34
Indirect energy consumption	798	787	875	910
Electricity	702	692	729	761
Steam, heat, cold	96	95	146	149
Total energy sold	0.3	0.3	0.1	0.0
Electricity	0.3	0.3	0.1	0.0
Steam, heat, cold	0	0	0	0

In TJ				2018
Total energy consumption	7,708	7,621	7,898	8,035
Direct energy consumption	4,835	4,788	4,748	4,759
Natural gas	4,320	4,536	4,514	4,522
Liquid fossil fuels ²	396	130	115	115
Biomass and self-generated renewable energy	119	122	119	122
Indirect energy consumption	2,873	2,833	3,150	3,276
Electricity	2,527	2,491	2,624	2,740
Steam, heat, cold	346	342	526	536
Total energy sold	1.1	1.1	0.4	0.0
Electricity	1.1	1.1	0.4	0.0
Steam, heat, cold	0.0	0.0	0.0	0.0

1 In line with the Greenhouse Gas Protocol, for all previous years (up to the 2006 baseline) the energy consumption has been calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

2 Light and heavy fuel oil, liquefied petroleum gas (LPG), diesel and gasoline

At our sites in Billerica (MA, USA), Bedford (MA, USA), Molsheim (France), Tel Aviv (Israel), Rome (Italy), Guatemala City (Guatemala), Shizuoka-ken (Japan), and Shanghai (China), we use photovoltaics to produce power.

We currently only record purchased secondary energy – this is primarily electricity and, to a lesser extent, heat/steam/cold. Details on the local energy mix, including the respective percentage of primary energy, renewable energy, etc. are not available. Data on local energy efficiency in electricity or heat generation are not available either. Our production sites are located in countries with a widely varying energy mix.

Our Darmstadt and Gernsheim sites in Germany consume the most energy, representing 29% of our Group-wide total. Here, fossil energy (coal, gas, etc.) accounts for approx. 50.7%, nuclear energy approx. 12.7% and renewable energies approx. 36.6% of the energy mix. Renewable energies account for a higher share of electricity generation at production sites in Switzerland, with nuclear energy taking the lead in France. Based on an estimated global energy efficiency of 37% for the conversion and distribution of generated electricity, this results in a primary energy consumption of 2,050 GWh for 2018. Based on an estimated global energy efficiency of 85% for heat/steam/cold, this results in a primary energy consumption of 175 GWh for 2018. This yields a total primary energy consumption of 2,225 GWh for 2018. (The calculation is based on factors stated in the "Manual for energy management in practice - Systematically reducing energy costs" published by DENA, 12/2012.)

In 2018, the Group's energy intensity relative to net sales totaled 0.150 kWh/€.

Water consumption

millions of m ³	2015	2016	2017	2018 ¹
Total water consumption	13.7	13.8	14.0	14.7
Surface water (rivers, lakes)	1.8	1.8	1.9 ²	2.1
Groundwater	7.1	7.2	7.3	7.2
Drinking water (from local suppliers)	4.8	4.8	4.8 ²	5.3
Rain water and other sources	0.01	0.01	0.00 ²	0.05

- 1 Excludes Consumer Health
2 Figure retroactively adjusted.

These figures do not include the ground water that we use for safety measures at our Gernsheim site in Germany. Here, the water is fed back directly into natural circulation.

Water reused

millions of m ³	2015	2016	2017	2018 ¹
Water reused	23.0	22.7	22.4	24.4

- 1 Excludes Consumer Health

The recirculating cooling system at our Darmstadt, Germany facility accounts for the majority of reused water as it allows the water to be re-utilized multiple times. The volume of reused water is thus greater than the total volume of consumed water.

Wastewater volume and quality

	2015	2016	2017	2018 ^{1, 2}
Total wastewater volume (millions of m³)	12.5³	12.9³	13.1³	13.5
Chemical oxygen demand (metric tons of O ₃)	1,240 ³	1,535	1,669 ³	1,589
Phosphorous (metric tons)	10	12	8	9
Nitrogen (metric tons)	487	379	234 ³	258
Zinc (kg)	491	448	351	- ²
Chromium (kg)	42	34	34	- ²
Copper (kg)	78	48	61	- ²
Nickel (kg)	29 ³	29 ³	32 ³	29
Lead (kg)	32 ³	31 ³	35 ³	28
Cadmium (kg)	9 ³	7 ³	6 ³	6
Mercury (kg)	2	2	1	0
Arsenic (kg)	5	4	3	- ²

- 1 Excludes Consumer Health
2 In alignment with [ICCA reporting](#) requirements specified by Cefic, we track heavy metal emissions from lead, cadmium, nickel, and mercury. These heavy metals are considered to be directly toxic to organisms and are also hazardous to human health due to their carcinogenic properties and their ability to cause harmful effects even in minute quantities. Due to having adopted ICCA reporting standards, we stopped tracking arsenic, chrome, copper, and zinc as of 2018.
3 Figure retroactively adjusted.

The wastewater volume includes indirect discharge into both public and Group-owned wastewater treatment plants, as well as direct discharge (such as rainwater and cooling water).

The wastewater treatment plant at our Gernsheim, Germany site also treats wastewater from the neighboring municipality of Biebesheim. The communal wastewater from Biebesheim is included in the wastewater volume as well as in the emissions stated in the table.

Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Hazardous and non-hazardous waste

metric kilotons	2015	2016	2017	2018 ¹
Total waste	324²	256²	255²	244
Hazardous waste disposed ³	55	47	43	44
Non-hazardous waste disposed ³	35	38	33 ²	54
Hazardous waste recycled ⁴	77 ²	82 ²	72 ²	74
Non-hazardous waste recycled ⁴	157	89	107 ²	72

1 Excludes Consumer Health

2 Figure retroactively adjusted.

3 Disposed = incineration (without energy recovery) and landfill

4 Recycled = incineration (with energy recovery) and material recycling

Exported/Imported hazardous waste

metric kilotons	2015	2016	2017	2018 ¹
Exported ²	5.1	4.6	4.9	4.5
Imported ³	0.010	0.010	0.005	0.000

1 Excludes Consumer Health

2 Disposal within the EU and the United States.

In 2018, approximately 4% of hazardous waste was shipped internationally.

Waste by disposal method

	2015	2016	2017	2018 ¹
Total waste (metric kilotons)	324²	256²	255²	244
Disposed waste (metric kilotons)	90	85	76²	98
Landfilled waste (metric kilotons)	16	15	13	35
Incinerated waste (metric kilotons)	74	70	63 ²	63
Recycled waste (metric kilotons)	234²	171²	179²	146
Material recycling (metric kilotons)	202 ²	139 ²	149 ²	126
Waste-to-energy (metric kilotons)	32	32	30	20
Recycling rate (%)	72	67²	70²	60

1 Excludes Consumer Health

2 Figure retroactively adjusted.

As in previous years, the total waste generated continues to be heavily influenced by the waste from construction and remodeling activities. Construction, excavation and demolition waste accounted for 31% of our waste in 2018. Around 40 metric kilotons of construction, excavation and demolition waste was recycled.

The following table is part of the non-financial report

Significant spills

	2015	2016	2017	2018 ¹
Total number of significant spills	0	0	0	0

1 Excludes Consumer Health

community

Spending on community involvement

€ million	2015	2016 ^{1,2}	2017	2018 ³
Total spending	100.0	43.0	33.8	35.7

1 Includes Sigma-Aldrich as of 2016

2 From 2016 on, we are separating spending on patient support programs such as our Erbitux® China Patients Assistance Program from our community involvement figures.

3 From 2018 on, we are separating spending on programmes of the Foundation sponsored by Merck KGaA, Darmstadt, Germany from our community involvement figures.

We calculate the value of pharmaceutical product donations according to the WHO Guidelines for Medicine Donations; for other product donations, we apply their fair value.

Community involvement spending by region¹

	Europe	North America	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
2017					
€ million	8.7	2.9	3.2	0.5	18.5
%	26	9	9	1	55
2018					
€ million	10.1	2.2	2.6	0.7	20.1
%	28	6	7	2	57

1 This table presents the regions across the globe in which we support initiatives. For projects that benefit multiple regions, we have calculated the amount per region by dividing the project spending evenly per country.

2 From 2018 on, we are separating spending on programmes of the Foundation sponsored by Merck KGaA, Darmstadt, Germany from our community involvement figures.

Focus of our local community involvement¹

%	2015	2016 ^{2,3,4}	2017	2018 ⁵
Global Health	33	35	38	34
Broad Minds: Education and culture	33	36	43	42
Sustainable Solutions: Environment	7	5	4	2
Disaster relief	6	2	2	2
Other	21	22	13	20

1 Based on number of projects

2 Includes Sigma-Aldrich as of 2016

3 Since 2016, we have integrated our global projects into our community outreach figures, specifically the Global Pharma Health Fund, the Praziquantel Donation Program and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany. This change in approach was due to the increasingly international nature of our efforts. We are spearheading a rising number of global projects that account for a growing percentage of our project portfolio. To ensure maximal accuracy, we are therefore including all international initiatives in our figures as of 2016.

4 From 2016 on, we are separating spending on patient support programs such as our Erbitux® China Patients Assistance Program from our charitable spending figures.

5 From 2018 on, we are separating spending on programmes of the Foundation sponsored by Merck KGaA, Darmstadt, Germany from our community involvement figures.

Motivations for our community involvement¹

%	2015	2016 ^{2,3,4}	2017	2018 ⁵
Charitable activities	3	4	9	7
Community investment	92	87	84	88
Commercial initiatives in the community	5	9	7	5

1 Based on total spending on all projects

2 Including Sigma-Aldrich as of 2016

3 Since 2016, we have been integrating our global projects into our community outreach figures, specifically the Global Pharma Health Fund, the Praziquantel Donation Program and the Deutsche Philharmonie sponsored by Merck KGaA, Darmstadt, Germany. This change in approach was due to the increasingly international nature of our efforts. We are spearheading a rising number of global projects that account for a growing percentage of our project portfolio. To ensure maximal accuracy, we are therefore including all international initiatives in our figures as of 2016.

4 As of 2016, we are separating patient support programs such as our Erbitux[®] China Patients Assistance Program from our charitable spending.

5 From 2018 on, we are separating spending on programmes of the Foundation sponsored by Merck KGaA, Darmstadt, Germany from our community involvement figures.

We categorize the motivations for our activities based on the London Benchmarking Group model as well as the guidelines of the Bertelsmann Foundation for corporate social responsibility. Projects that primarily aim to make improvements within the community are classified as community investment.

Initiatives that are predominantly aimed at company-relevant factors such as image or personnel recruitment are classified as commercial initiatives in the community. Charitable activities cover any other projects that benefit a charitable organization, but cannot be listed under either of the other two motivation categories due to missing data or their narrow scope.

Goals





Part of the non-financial report

Legende:  New Goal  Goal achieved  In Progress  Goal not achieved

Business ethics




Compliance

Goal: Bring Compliance closer to the business

Action(s):	By:	Progress as of end of 2018:	Status:
Quantum LEAP (Lean and Effective Approval and Publication): Develop and introduce an automated, lean process and tool landscape to support transparency reporting requirements and the streamlined processing of interactions with our partners in the Healthcare sector. Build on adapted compliance controls and enhance business ownership and accountability.	September 2018	The Quantum LEAP infrastructure has been successfully implemented in 60+ countries for the core components Quantum Connect and MDM (Master Data Management).	
Business Partner Risk Management Process update: Best practice risk mitigation to meet strict standards and organizational duties.	December 2019	In 2018, a new project has been set up to redesign the existing Business Partner Risk Management Process and to ensure compliance with 5th EU Anti-money Laundering Directive published in June 2018. The new process will fulfill current legal requirements in the areas of anti-corruption, anti-money laundering and fraud prevention.	
New Code of Conduct of Merck KGaA, Darmstadt, Germany: The Code has a strong relation to the company's Values, built on core principles to adhere to. Supported by a business specific roll-out and e-learning.	March 2018	We started the roll-out of our business sector-specific e-learning program centered on our new Code of Conduct.	
Self-monitoring as part of the Compliance Risk Assessment process: Integrate self-assessment of compliance program implementation status in existing Compliance Risk Assessment.	April 2019	We redesigned the existing Compliance Risk Assessment process and will introduce a new technical solution. The self-monitoring process has been added to document the status of the implementation of the compliance program across the Group businesses.	



Supply chain standards

Goal: Ensure that suppliers adhere to ethical, social, environmental, and compliance standards


Action(s):	By:	Progress as of end of 2018:	Status:
Perform a qualitative analysis of the available assessment and audit findings and define potential courses of action.	End of Q2/2019	In 2018, our Procurement unit worked on standard processes for the purchasing unit that describe the implementation of sustainability audits in the supply chain and follow-up measures.	
Development of a due diligence process for Responsible Minerals Sourcing according to the OECD guidance for upstream process and implementation in the working processes of the affected units.	End of Q3/2019	In 2018, we established an interdisciplinary working group, collected data to gain supply chain transparency and conducted first investigations of legal implications.	
Development of a due diligence process for palm oil sourcing according to international guidance and implementation in the working processes of the affected units.	End of 2019	We acquired first data from our Performance Materials business to gain better transparency on the supply chain.	

Animal welfare


Goal: Ensure consistently high quality across our animal facilities

Action(s):	By:	Progress as of end of 2018:	Status:
Inspect Life Science animal facilities in preparation for potential accreditation: Conduct a feasibility study and make a decision about accreditation.	End of 2018	In 2018, we completed the feasibility study. No additional activities are envisioned at this time.	
Re-accredit relevant animal facilities.	Ongoing	In 2018, two sites in the United States were due for re-accreditation (Billerica, MA and Rockville, MD). Both sites completed their re-accreditation and continue operations with full accreditation status. Re-accreditations are conducted every three years.	

Goal: Ensure animal welfare in our supply chain

Action(s):	By:	Progress as of end of 2018:	Status:
Develop and implement an audit plan for suppliers.	Ongoing	The audit plan is in place, audits have been scheduled and undertaken as planned.	

Goal: Promote the 3Rs (Reduce, Refine, Replace)

Action(s):	By:	Progress as of end of 2018:	Status:
Develop a Group-wide 3R program.	Ongoing	We further increased internal awareness for the 3R program through measures like the internal Merck KGaA, Darmstadt, Germany 3Rs Award.	


products

health for all

Global Strategy

We aim to improve access to health for underserved populations in low- and middle-income countries.






Goal: Awareness: Empower health workers, communities and people

Action(s):	By:	Progress as of end of 2018:	Status:
Engage in a dialogue to jointly identify the key access challenges and opportunities for our strategy for global access to healthcare.	End of 2018	In 2018, we conducted an Access Dialogue on the topics of open innovation and intellectual property.	

Focus programs

Hand in hand with our partners, we aim to eliminate the tropical worm disease schistosomiasis worldwide.

Goal: Eliminate schistosomiasis

Action(s):	By:	Progress as of end of 2018:	Status:
Donate up to 250 million praziquantel tablets annually to World Health Organization (WHO) for African school children.	Ongoing	In 2018, we donated almost 200 million tablets for distribution in 34 African countries in partnership with the WHO, and keep production capacities at a level sufficient for manufacturing 250 million praziquantel tablets a year.	
Optimize the praziquantel formulation. Milestone for 2019: complete analysis of bioequivalence study.	End of 2019	In 2018, we completed a first bio-equivalence study, which is currently being analyzed.	
Initiate new partnerships to promote behavioral change in African school children. Milestone for 2019: extend project to two further districts in Ethiopia.	End of 2019	Since 2017, we have been partnering with the NALA Foundation to raise awareness and encourage behavioral change. Together, we are supporting a national health project jointly carried out by the Ethiopian Federal Ministry of Health and the Foundation. The project was started in two districts, extension into two additional ones is planned.	
Position the Global Schistosomiasis Alliance (GSA) as a partner platform for advocacy, implementation, research, communication, and strategy development.	Ongoing	GSA has taken on the role to house and oversee the implementation of the Schistosomiasis Action Plan and adjusted its work program and working groups to drive progress on the Action Plan.	
Provide WHO with educational booklets to teach children about schistosomiasis and ways to prevent it.	Ongoing	The successful development and distribution of the booklets have been completed. The goal will be discontinued. Health promotion to leverage behavioral change will continue to be a central element in our fight against schistosomiasis. We will continue to support health education activities and create synergies with existing efforts and projects, for example the NALA Foundation in Ethiopia.	

We aim to improve global health for underserved populations in low- and middle-income countries, with a focus on combating infectious diseases.

Goal: Availability: Address unmet needs through the research, development and optimization of health solutions

Action(s):	By:	Progress as of end of 2018:	Status:
Develop a pediatric formulation of praziquantel for the treatment of schistosomiasis in children under six. Milestone: entry into Phase III.	2018	The current results from the Phase II study indicate that both developed formulations are well tolerated at all doses tested and confirmed the formulation for further development. Executive board approved decision to move into Phase III in 2018.	✓
Develop a pediatric formulation of praziquantel for the treatment of schistosomiasis in children under six. Milestone 2019: start of Phase III trial.	End of Q2/2019		▶
Develop a new antimalarial (PeEF2 inhibitor). Milestone for 2019: Completion of Phase I/Ib.	End of Q4/2019	The Phase I study in healthy volunteers allowed assessment of the safety of the compound and the Phase I/Ib study provided data to support clinical proof of principle. Additional cohorts were added in 2018, to fully define the profile of the new antimalarial compound	↻
Develop a new diagnostic kit to detect and characterize the type of malaria parasite. Milestone: Start of clinical trial.	End of 2018	In 2018, we introduced a diagnostic set for research purposes. At the end of 2018, we sold the underlying technology platform to the US laboratory supplier Luminex.	✓

Open innovation sharing

Goal: Affordability: Overcome inability to pay

Action(s):	By:	Progress as of end of 2018:	Status:
Establish a partnership to share intellectual property with a non-commercial organization.	End of 2018	Our collaboration with the DNDi NTD Booster moves forward as we have contributed compounds to 10+ screens. We entered into a partnership with the Drug for Neglected Diseases initiative (DNDi), under which we are participating in the Drug Discovery Booster project for neglected tropical diseases.	✓
Participate in at least one partnership with a public-sector partner in an effort to share our intellectual property and expertise in infectious and neglected tropical diseases.	End of 2018	Our collaboration via the WIPO-Re-Search platform moves forward. The University of Buea collaboration has completed the screening phase and is evaluating further options. We entered into a partnership with the University of California San Diego, United States.	✓

Pharmaceutical supply chain

Goal: Accessibility: Strengthen supply chains and provide localized health solutions

Action(s):	By:	Progress as of end of 2018:	Status:
Engage stakeholders in overcoming the challenges in creating an end-to-end secure supply chain and supplying goods in developing countries.	End of 2018	We presented the pharma industry point of view of supply chain challenges at the World Health Assembly that addressed Health Supply Chain and Delivery Challenges.	✓
Host one to two meetings under the auspices of the Accessibility Platform.	End of 2018	We held an Accessibility Platform meeting in 2017, and a Merck KGaA, Darmstadt, Germany Access Dialogue on Supply Chain & Delivery meeting in January 2018.	✓
Form a partnership to improve health-care at the point of care in developing countries.	End of 2019	We partnered with the NGO Business for Health Solutions (BHS) to help strengthen supply chains and delivery effectively at point of care to improve sustainable access to health in developing countries. A dozen Merck KGaA, Darmstadt, Germany Supply Chain employees agreed to provide their Supply Chain competences in supporting local healthcare organizations (mainly distributors from Tanzania) on customer demand planning, stock level management, warehouse operations and cold chain management.	✓
NTDeliver: Reach more than 1,000 schools via a school-based deworming campaign with praziquantel and Albendazole (GlaxoSmithKline).	End of 2018	Implementation has taken place. 12,000 schools were contacted, 8,900 reported back on the number of tablets distributed in 2018.	✓

Through the GPHF Minilab™, we seek to fight counterfeit medicines in developing and emerging economies.





Goal: Provide and further develop the GPHF Minilab™

Action(s):	By:	Progress as of end of 2018:	Status:
Conduct at least two Minilab training seminars, provide at least 30 Minilabs and spread their use.	End of 2018	GPHF and its partners conducted three Minilab trainings in 2018, and provided seven Minilabs. The demand for Minilab consumables for replenishment remained high.	✗
Develop new test methods for ten active ingredients and revise ten existing methods.	End of 2018	The development of ten test protocols for ten new drug compounds plus one new test protocol for an existing drug compound were successfully concluded. The review on further 30 existing test protocols was intensified.	✓
Update the Minilab manuals and consolidate all test methods into one single volume.	End of 2020	A print version of a consolidated English manual is expected to be available end of 2019. Work on French and Spanish versions will follow 2019 and 2020.	🔄

product safety and quality




Chemical product safety

Goal: Use precautionary principle to establish a globally aligned hazard and risk communication system for all our relevant chemical products in the supply chain

Action(s):	By:	Progress by end of 2018:	Status:
Implement REACH: Register substances produced in quantities of 1-100 metric tons per year (phase 3 of REACH implementation) and register non-phase-in substances.	Mid-2018	By June 2018, we had registered all 700 relevant phase 3 substances for the various subsidiaries of our Group.	
Implement the Global Product Strategy: Issue product safety summaries for all hazardous substances registered under REACH.	End of 2020	Because we were heavily focused on completing phase 3 REACH registrations on time, along with the subsequent updates, product safety summaries were not a priority in 2018.	
Projects for hazard communication: Update safety data sheets for non-hazardous materials.	End of 2020	By the end of 2018, we had updated 70% of the safety data sheets for non-hazardous substances within Performance Materials and 80% in Life Science.	
Harmonize safety data sheets to align with a globally uniform standard.	End of 2020	Within Performance Materials, all safety data sheets are drafted using a single system Group-wide, thereby harmonizing the information to the extent permitted by the variations in country-specific regulations. During the integration of Sigma-Aldrich, safety data sheet creation for products assigned to Performance Materials was transitioned to the Performance Materials process. Within Life Science, safety data sheets for all new product launches have been harmonized. Existing substances will be transitioned to the globally harmonized system by 2020.	

Patient safety

Goal: Increase patient safety


Action(s):	By:	Progress as of end of 2018:	Status:
Development of a new methodology and tools for earlier detection of signals and safety issues to ensure safety of our products.	2018	We implemented the new signal detection tool Empirica for safety signals and introduced a new process for the signal detection in the EudraVigilance database.	
Enhance the effective and timely communication to stakeholders in agreement with Health Authorities.	Ongoing	We successfully implemented a project to enhance internal and external communication on quantitative outcomes of benefit-risk analysis and safety profiles of our products. We engaged in stakeholder dialogues with health authorities on crisis communication in order to deliver appropriate information to patients and healthcare professionals concerning patient safety.	
Enhance patient centricity.	Ongoing	We made the mobile patient centric app for reporting adverse effects (agReporter) available in eight languages. In order to promote the patient use of the app to report adverse effects, we implemented a communication campaign called Patient 360 Series.	

Product-related crime


Goal: Integrate security into relevant business processes for our Healthcare and Life Science business sectors

Action(s):	By:	Progress by end of 2018:	Status:
Identify strategic and commercial data that require greater protection; minimize risks by modifying processes.	End of 2018	In 2018, our Healthcare business sector launched a project to standardize security features and thus protect relevant products in key markets. Moreover, we conducted a value chain analysis to identify risks to our Healthcare products. We made security audits a prerequisite for collaboration with contract production and packaging facilities.	





Goal: Step up interdisciplinary collaboration within global security network

Action(s):	By:	Progress as of end of 2018:	Status:
Expand organizational structures and certify employees who deal with product-related crime.	Ongoing	Our product crime officers participate in regular MACON conference calls and face-to-face meetings, thereby continuously improving their ability to combat product-related crime.	

Goal: Educate employees and other target groups on the strategic relevance of counterfeit medicines


Action(s):	By:	Progress as of end of 2018:	Status:
Host conferences and seminars; share best practices and lessons learned through international networks.	Ongoing	In 2018, we jointly organized two MACON conferences, one for countries in Europe, the Middle East and Africa (EMEA) and the other for countries in the Asia-Pacific (APAC) region. In the same period, conference calls attended by all product crime officers were held every two weeks to discuss strategic matters along with local situations and suspected cases of counterfeiting.	

Goal: Develop and implement security technology and solutions for supply chain authentication, identification, integrity, and security

Action(s):	By:	Progress as of end of 2018:	Status:
Support regional activities to counter product-related crime.	Ongoing	The 2018 MACON conferences featured working sessions to develop and implement security technologies, as well as to discuss appropriate solutions. In addition to these sessions, we took part in workshops and seminars to reinforce collaborative efforts with law enforcement agencies, for instance in Germany, Brazil, China, Italy, Colombia, Mexico, Romania, Singapore, and the United States.	
Step up internet searches to detect counterfeit products, illegal parallel imports as well as trademark infringements.	Ongoing	We continually scour the Internet for cases of product crime relating to our company, taking into account new developments, for example the growing importance of social media.	
Monitor counterfeit pharmaceuticals in conventional distribution channels as well as online sales.	Ongoing	In 2018, we enhanced our collaboration with monitoring service providers by systematizing the process for exchanging electronic data with one of them. This approach accelerates our efforts to discover counterfeit versions of our products and initiate countermeasures.	
Participate in and support the Disruption 18 project.	Early 2019	In 2018, we joined forces with other Pharmaceutical Security Institute (PSI) member companies to run Disruption 18, a project to combat online sales of counterfeit medicines. We support this project by providing both financial support and manpower.	

Transport and warehouse safety



Goal: Ensure warehouse and transport safety for our company and our suppliers

Action(s):	By:	Progress by end of 2018:	Status:
Harmonize transport and warehouse safety master data through Group-wide ERP systems.	End of 2022	By the end of 2018, we had finished harmonizing the transport and warehouse safety master data for the products in our Life Science portfolio.	



Employees

Attractive employer



Goal: Consistently fill at least two-thirds of leadership positions (Role 6+) with internal candidates

Action(s):	By:	Progress by end of 2018:	Status:
Use the Talent Management Process to identify suitable employees with leadership potential and optimize the process to systematically advance them.	Ongoing	In 2018, 87% of our vacant leadership positions/the positions (Role 6+) were filled internally.	
Build a high-potential pool that reflects our demographic structure.	Ongoing	We are continuously developing our high-potential pool, which is a reflection of the diversity within our company.	

Goal: Position our Group as an attractive employer for university graduates


Action(s):	By:	Progress by end of 2018:	Status:
Participate in university fairs and organize in-house events for graduates; position our company via employer branding channels.	Ongoing	We are continuously positioning ourselves as an attractive employer for university graduates via editorial articles on careerloft, through event information on e-fellows.net and through trainee and employee films on YouTube. By the end of 2018, all 40 planned trainee slots and direct hires were filled through our employer branding and talent sourcing efforts.	
Approach select target universities.	Ongoing	We have increased our visibility at our target universities through billboards, job advertisements and newsletters. Moreover, we make use of relevant social media channels (Facebook, Twitter, LinkedIn, XING, Instagram, and WeChat). We leveraged the tools available to continue presenting ourselves as an attractive employer for university graduates.	

Goal: Increase the share of employees (Group-wide) with development plans to 70% by 2020

Conduct extensive internal communications and people development campaigns and optimize existing tools.	End of 2020	The percentage of employees with development plans increased from 61% (2017) to 69.9% (2018).	
Create awareness and share knowledge.	End of 2020	To meet this goal, we are taking steps to raise awareness of development plans and help people create a good one. In 2018, these included new training documents and videos, along with printed materials such as the "Development Planning Guideline" and information on counseling career advancement options.	


Diversity

Goal: Our target for 2021 is to maintain a 30% representation of women in leadership roles (Role 4+)

Action(s):	By:	Progress by end of 2018:	Status:
Deploy teams at departmental level to develop goals and measures to move women into positions in various units and hierarchies.	End of 2021	The measures identified by the business sectors were expanded.	


Health and safety

Goal: Reduce the lost time injury rate Group-wide (to 1.5 or less)

Action(s):	By:	Progress by end of 2018:	Status:
Reinforce our safety culture to prevent behavior-related accidents/Roll out our BeSafe! program at all newly acquired sites and monitor ongoing implementation via appropriate performance indicators.	End of 2020	In 2018, we achieved a Group-wide LTIR of 1.3. Through manager training, safety tours and train-the-trainer programs, we continued to sustain a high level of safety awareness in 2018. We took these steps at numerous sites – including 20 newly acquired ones.	


Employee engagement

Goal: Measure and improve employee engagement

Action(s):	By:	Progress by end of 2018:	Status:
Implement a regularly occurring process to measure employee engagement and take actions to improve it.	Ongoing	In 2018, we once again conducted a Group-wide employee survey.	

Good leadership


Goal: Ensure that people managers are enabled to motivate and develop their employees

Action(s):	By:	Progress by end of 2018:	Status:
Have at least 50% of people managers rated Role 3+ take part in a management program.	End of 2018	3,133 of 5,281 people managers had taken part in a management program. In compiling participant data, we include the following programs: Managerial Foundation Program (MFP), Advanced Management Program (AMP), Global Leadership Program (GLP), Merck KGaA, Darmstadt, Germany University (MU), International Management Program (IMP), and Growth Markets Management Program (GMMP).	

Environment






Environmental stewardship

Goal: Incorporate all production sites into our Group ISO 14001 certificate for environmental management systems

Action(s):	By:	Progress by end of 2018:	Status:
At newly acquired production sites, introduce environmental management systems in line with our Group ISO 14001 certificate and certify them accordingly.	Ongoing	In 2018, two sites transferred their environmental management system to our Group certificate. All sites pertinent to the Group certificate have thus been transitioned to the new version of ISO 14001:2015.	


Climate action

Goal: 20% reduction in our direct and indirect greenhouse gas emissions (Scope 1 and 2) relative to the 2006 baseline

Action(s):	By:	Progress by end of 2018:	Status:
Systematically examine the energy consumption at our individual production sites.	End of 2020	In 2018, we conducted an energy audit at a production facility in Hamburg (Germany).	
Training on energy efficiency	End of 2018	In partnership with TU Darmstadt, our Darmstadt site offered day-long workshops on energy efficiency. The six workshops were attended by 80 people who play a major role in enhancing energy efficiency (such as plant engineers).	
Identify and implement potential energy savings.	End of 2020	In 2018, we implemented 34 Edison projects with a view to cutting carbon emissions by 75,000 metric tons in the medium term. Multiple projects had to be postponed until 2019.	
Reduce process-related emissions.	End of 2022	In 2018, we initiated two further projects aimed at lowering process-related emissions, one of which was completed in 2018, and yielded 10,000 metric tons of carbon savings. The second project is scheduled to run until 2022. Based on production volume in 2018, we are expecting to save roughly 40,000 metric tons of CO ₂ in this period. A third project is currently in the planning stages.	
Renewable energy	End of 2020	Full integration of the purchase of electricity from renewable sources is our goal.	



Waste and recycling

Goal: Reduce the environmental impact of our waste disposal (Waste Score of Merck KGaA, Darmstadt, Germany) by 5% by 2025 (baseline 2016)

Action(s):	By:	Progress by end of 2018:	Status:
Establish Waste Expert Network Groups.	End of 2018	We established a Group-wide and a U.S.-based Waste Expert Network Group comprising specialists from various areas who work together to integrate waste scoring and promote best practice sharing.	

Water management

Goal: Introduce a sustainable water management system at 24 of our manufacturing facilities with high water use by 2020

Action(s):	By:	Progress by end of 2018:	Status:
Meet the "progressed" requirements set out in the CEFIC flagship self-assessment tool (stage 2). This involves creating transparency regarding the situation in the vicinity of the respective sites and beginning the evaluation of the sites' influence on their environment.	End of 2018	During stage 2 of the self-assessment, we created transparency regarding the water situation in the vicinity of our individual sites. We successfully analyzed the results by the end of 2018.	
Meet the "advanced" requirements set out in the CEFIC flagship self-assessment tool (stage 3): This will assess our sites' impact on the water situation in the vicinity of each individual site.	May 2020	During stage 3 of the self-assessment, we will assess the environmental impacts arising from our discharged water. This process began in 2018, and will continue until May 2020 without an interim audit.	

Recognition and rankings

The following overview presents a selection of major awards and recognition that we have received or achieved. Information on additional recognition and accolades received by individual businesses or sites can be found in the respective chapter of our 2018 Corporate Responsibility Report, or on our company's website.

CR performance

Access to Medicine Index

In 2018, our company was ranked fourth place in the Access to Medicine Index, a position we have held since 2016, and one that has consistently put us among the top five companies in the listing. Published every two years by the international non-profit Access to Medicine Foundation, this initiative evaluates pharmaceutical companies in areas where they have the biggest potential and responsibility to bring about change in developing countries.

www.accesstomedicineindex.org

CDP climate and water

Since 2008, we've been reporting our climate impact mitigation activities to the CDP (formerly the Carbon Disclosure Project). In 2018, we scored a C in the CDP, versus a B in 2017. The CDP assesses the strategy used and the success achieved by companies in reducing their greenhouse gas emissions, as well as how they address the risks and consequences of climate change.

In addition to reporting on our climate action, since 2016 we have been reporting our water-related performance and processes to the CDP. In 2018, we received a B- for our water management practices, versus a B in 2017.

The CDP evaluates performance in the areas of climate and water on a scale from A to D-, with A being the top score.

www.cdp.net

EcoVadis rating

The independent rating agency EcoVadis evaluates suppliers from 120 countries across the categories of Environment, Labor and Human Rights, Ethics, and Sustainable Procurement. As a member of the Together for Sustainability initiative, we also undergo this assessment and, as in 2017, were once more awarded Gold status in 2018, putting us among the top 1% of all participating companies.

www.ecovadis.com

ESG rating from MSCI

MSCI is one of the world's largest providers of financial services for institutional investors as well as environment, social and governance ratings (ESG). This independent organization assesses companies according to their exposure to industry-significant ESG risks and their ability to manage those risks relative to industry peers. In May 2018, MSCI gave us an "AAA", their highest rating and one that puts us among the top 3% of all companies evaluated. They particularly praised our Group-wide ISO 9001 certification, our collaboration in industry-wide initiatives and our robust quality management system.

www.msci.com/esg-ratings

ESG rating from Sustainalytics

Sustainalytics is a company that rates the sustainability of listed companies based on their environmental, social and corporate governance (ESG) performance. In 2018, this organization awarded us 79 out of 100 points, putting us among the leading pharmaceutical companies. We received particularly high marks in the categories of corporate governance and community outreach, and even our environmental performance earned a high score that far exceeded the average.

www.sustainalytics.com

Good Company Ranking

In 2018, the management consultancy Kirchhoff Consult released its sixth Good Company Ranking, an index that is published every two years. Among the 30 DAX member companies, we took fourth place in this latest round, having moved up six positions from our 2016 rating.

<http://www.kirchhoff-consult.com>

Institute for Ecological Economy Research ranking

In 2018, the Institute for Ecological Economy Research (IÖW) and "future e. V. – verantwortung unternehmen" issued their tenth ranking of sustainability reporting by major German companies. This index assesses factors such as the environmental impacts of production processes, transparent communication and efforts to enhance supply chain sustainability. Our 2017 CR Report achieved a score of 426 in the latest ranking, putting us in sixth place.

www.ranking-nachhaltigkeitsberichte.de/en

oekom-research sustainability rating

In 2018, the sustainability ratings agency oekom research AG gave our company a B- on a scale of A+ (top mark) to D-, once more granting us oekom Prime Status ("good" to "very good") as they did in 2017.

www.oekom-research.com

sustainability indices

Ethibel Sustainability Index (ESI) Excellence Europe and Ethibel EXCELLENCE Investment Register

In 2015, we were added to the ESI Excellence Europe, a sustainability index that includes the 200 top-rated European companies based on their corporate responsibility performance. We are also a member of the Ethibel EXCELLENCE Investment Register.

www.forumethibel.org

Euronext-Vigeo Eurozone 120 Index

Since 2015, we have been members of the Euronext-Vigeo Eurozone 120, an index that features the 120 most successful European companies in terms of their environmental, social and governance practices.

www.vigeo-eiris.com

FTSE4Good Index

Since 2008, we have been included in the FTSE4GOOD Index, a leading international sustainability rating that annually measures the performance of companies in demonstrating strong environmental, social and ethical practices.

www.ftse.com

STOXX® Global ESG Leaders Index

In 2018, our company was once again included in STOXX Global ESG Leaders, a sustainability index that assesses companies based on key environmental, social and governance criteria.

www.stoxx.com

CR awards

Annual Report Competition ARC Awards

In October 2018, our 2017 CR Report won three gold international ARC awards in the categories of Interactive Annual Report, Design/Graphics and Interior Design. MerComm, Inc. has been presenting the ARC Awards since 1987, in an effort to reward and recognize achievements in report design, imagery and content.

www.mercommawards.com

Building Public Trust Award

In October 2018, we received a Building Public Trust Award in the category of "Non-Financial Reporting DAX 30". In presenting this prize, auditing company PricewaterhouseCoopers (PwC) recognized the non-financial reporting required by the German CSR Directive Implementation Act, the first time this organization has done so.

www.pwc.de/en

Econ Awards

Presented by German publisher Econ, the Econ Awards recognize outstanding concepts and practices in corporate communications. In October 2018, we won a Gold Econ Award for our digital 2017 CR Report, with special mention made of its user-friendliness, high-level content and attractive design.

www.econforum.de (German only)

sustainable Development Goals

In 2015, the United Nations adopted the Sustainable Development Goals (SDGs), a set of aspirations aimed at all countries and organizations across the globe. We too are making every effort to help reach these objectives. Recently, for instance, we conducted a materiality analysis to identify the goals with which our daily operations currently align.

Our approach

Underpinned by 17 Sustainable Development Goals, the international community has identified 169 targets aimed at facilitating the actions necessary to accomplishing the mission. We recognize that companies too are duty-bound to support the implementation of the Sustainable Development Goals. In 2018, we examined the SDG targets in an effort to pinpoint the ones where our business activities make the greatest direct impact.

A closer look at our efforts

With our CR commitments we especially support the goals of Good Health & Well-Being (SDG 3), Quality Education (SDG 4) and Affordable & Clean Energy (SDG 7) (see graphic below). However, our contribution towards achieving the SDGs does not limit itself to the strategic spheres of activity established in our [corporate responsibility strategy](#). This means that we not only contribute to solving global challenges within the areas of "Global Health", "Sustainable Solutions" and "Broad Minds", but rather that many of our activities have positive effects that go beyond. This is the case with **seven of the 17 SDGs**. In our 2018 CR-report, for the first time, we show which SDG targets we support with our management approaches and projects. Beyond these seven SDGs, we are also pursuing activities in support of eight other goals, albeit to a lesser extent. For this reason we do not report on them on a target level.



SDG 3: Good health and well-being

Ensure healthy lives and promote well-being for all at all ages.

Across the globe, two billion people lack access to medicines, with an estimated 400 million lacking access to effective and affordable essential health services. Given this reality, we are striving to rectify the situation through our [Global Health Strategy](#). However, recognizing that we cannot solve these challenges alone, we have joined forces with strong partners to work towards a solution.

Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.

- [Access to Medicine Index Ranking 2018](#)
- [Strategy for preventing and treating infectious diseases](#)
- [Joining forces to improve access to health](#)

Target 3.b: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

- [Access to and control of intellectual property](#)
- [Collaborating on open innovation: WIPO Re:Search](#)
- [Drugs for Neglected Diseases initiative](#)
- [Global Health Institute research on neglected tropical diseases](#)

SDG 4: Quality education

Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all.

- [Community outreach in the mica supply chain](#)
- [Igniting a passion for science with the global volunteer program SPARK](#)
- [Scientific junior labs at the Technical University, Darmstadt, Germany](#)
- [Education for teachers and school partnerships](#)

SDG 5: Gender equality

Achieve gender equality and empower all women and girls.

- [Women in leadership roles: Requirements and targets](#)
- [Revealing unconscious bias](#)
- [Networks to bolster diversity](#)

SDG 6: Clean water and sanitation

Ensure availability and sustainable management of water and sanitation for all.

Around the world, the number of areas suffering from water scarcity is on the rise. At our sites, we are dependent on a reliable supply of water. We have made sustainable water management a key focus of our environmental stewardship.

Target 6.3: By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally.

- [High marks for our water management practices](#)
- [Antibiotic residues in wastewater](#)
- [Water protection measures in India](#)
- [Clean water for China](#)

SDG 7: Affordable and clean energy

Ensure access to affordable, reliable, sustainable and modern energy for all.

- Investing in renewable energies
- Subsidies for our employees
- Developing energy-efficient products

SDG 8: Decent work and economic growth

Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all.

We expect all suppliers and vendors to adhere to the same high social standards as we do. These are set forth in the [core labor standards](#) of the International Labour Organization (ILO) and the [United Nations Global Compact](#).

Target 8.4.: Improve progressively, through 2030, global resource efficiency in consumption and production and endeavour to decouple economic growth from environmental degradation, in accordance with the 10-Year Framework of Programmes on Sustainable Consumption and Production, with developed countries taking the lead.

- Our commitment: Guiding principles, charters and laws
- Monitoring our supply chain

SDG 9: Industry, innovation and infrastructure

Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.

We are always on the lookout for pioneering developments and trends. We develop products and technologies that improve people's lives. New technologies, especially advances in digitalization, enable us to create innovative products, services and business models.

Target 9.4: By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities.

- Making packaging more sustainable
- Recycling program updated
- Using biotechnology to produce meat in laboratories (clean meat)
- Material investments in environmental impact mitigation
- Investing in renewable energies
- Recharging facilities at our sites

SDG 10: Reduced inequalities

Reduce inequality within and among countries.

- Shared data platform for increasing the transparency of medicine donation supply chains
- Providing integrated primary healthcare service facilities (CURAFA)
- Low-price second brands
- Generics

SDG 11: Sustainable cities and communities

Make cities and human settlements inclusive, safe, resilient and sustainable.

We take on social responsibility. Focusing especially on those areas where we can best leverage our expertise, we promote health, education and cultural projects. Beyond these efforts, we provide disaster relief and assist people in need in the countries where we operate, particularly in the immediate vicinity of our sites.

Target 11.6: By 2030, reduce the adverse per capita environmental impact of cities, including by paying special attention to air quality and municipal and other waste management.

- ISO 14001:2015 environmental certification
- Clear target for reducing the environmental impacts of waste

SDG 12: Responsible consumption and production

Ensure sustainable consumption and production patterns.

Respect for the environment is the bedrock of our approach to sustainability. We see it as our duty to not only conserve resources when developing our own products, but also to help our customers enhance the sustainability of theirs.

Target 12.4: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.

- Our processes for sustainable product design
- Green chemistry assessment tool
- Registration of chemical compounds
- Safety analysis during product development

Target 12.5: By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse.

- Award for our Waste Scoring System
- Clear target for reducing the environmental impacts of waste

Target 12.6: Encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle.

- Our processes for sustainable product design
- Green chemistry assessment tool
- Our CR strategy
- Yearly sustainability reporting

SDG 13: Climate action

Take urgent action to combat climate change and its impacts.

- Emissions lowered despite growth
- Strategic climate program
- Educating employees about climate impact mitigation
- Switching to sea freight

SDG 14: Life below water

Conserve and sustainably use the oceans, seas and marine resources for sustainable development.

Our wastewater may contain traces of substances such as heavy metals or pharmaceutical active ingredients. For us, sustainable water management means not negatively impacting the aquatic ecosystems from which we obtain freshwater, or into which we discharge purified wastewater.

Target 14.1: By 2025, prevent and significantly reduce marine pollution of all kinds, in particular from land-based activities, including marine debris and nutrient pollution.

- High marks for our water management practices
- Avoid antibiotic residues in wastewater
- Water protection measures in India
- Alternatives to microplastic in cosmetics

SDG 15: Life on land

Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss.

- Biodiversity: Nagoya Protocol and access and benefit sharing
- Biodiversity at our sites

SDG 16: Peace, justice and strong institutions

Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels.

- Clear chain of command for reporting violations
- Responsible governance

SDG 17: Partnerships for the goals

Strengthen the means of implementation and revitalize the global partnership for sustainable development.

- Engaging stakeholder: our approach
- Engaging stakeholders about health for all
- Discussions on an international level
- Engaging stakeholders about compliance
- Engaging stakeholders about environmental stewardship

Non-financial report

Part of the non-financial report

Index for the combined separate integrated non-financial report

Through our combined separate integrated non-financial report, we fulfill the requirements arising from the CSR Directive Implementation Act. The separate non-financial report of the Group has been combined with the separate non-financial report of the parent undertaking, Merck KGaA, Darmstadt, Germany, in accordance with Section 289b (3) sentence 2 in conjunction with Section 298 (2) of the German Commercial Code, and integrated into our Corporate Responsibility Report. The following index provides an overview of the contents of the non-financial report and contains links to the relevant passages in the CR report. External references within our CR Report are not part of the non-financial report.

To provide the type of framework stipulated in Section 289b in conjunction with Section 315c (3) of the German Commercial Code, we have applied the standards of the Global Reporting Initiative (Option: Comprehensive) for this report.

Description of business model

We describe our business model, corporate structure, governance, and Group strategy under [Company profile](#).

Strategic and organizational approach to sustainability

Under [Governance](#), we present external guidelines and initiatives to which we've committed ourselves, along with Group-wide guidelines that are the cornerstone of our responsible governance. Our [CR strategy](#) sets out how we practice corporate responsibility, both in terms of strategy and at the organizational level.

Material aspects and issues

To determine the aspects and issues of relevance to the non-financial report, we conducted a [materiality assessment](#) that identified several issues that could not be assigned to any of the five aspects defined as minimum contents under Section 289c (2) of the German Commercial Code. Along with these five aspects, we have therefore decided to report on the following additional relevant issues:

Aspect	Issue
Environmental matters	<ul style="list-style-type: none"> ■ Environmental stewardship ■ Pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste) ■ Plant and process safety
Employee-related matters	<ul style="list-style-type: none"> ■ Recruiting and retaining employees (incl. Employee development, Work 4.0, diversity and equal opportunities, good leadership, employee engagement as well as health and safety)
Social matters	<ul style="list-style-type: none"> ■ Patient safety ■ Product-related crime ■ Responsible marketing ■ Data protection
Respect for human rights	<ul style="list-style-type: none"> ■ Bioethics (incl. genome editing) ■ Clinical studies
Anti-corruption and anti-bribery	<ul style="list-style-type: none"> ■ Compliance ■ Interactions with health systems
	<ul style="list-style-type: none"> ■ Chemical product safety (incl. labeling of chemicals) ■ Transport and warehouse safety ■ Prices of medicines ■ Innovation and R & D ■ Digitalization

Within our approach to comprehensive risk and opportunity management, we also identify current and potential risks and opportunities in the areas of environment, community and governance. This includes information on the gross risks in terms of potential damage and probability, as well as the residual net risks remaining after mitigation measures have been effected. We did not identify any net risks that fulfill the materiality criteria as set forth by Section 289c (3) no. 3 and 4 of the German Commercial Code. Additional risks are described in the [Report on Risks and Opportunities](#) in the combined management report.

Aspect: Environmental matters

Within our Group, environmental matters fall under environmental stewardship. In the following section, we report on the measures implemented to further environmental stewardship, enhance plant and process safety, and address pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste).

Issue	Concepts incl. due diligence processes and outcome of activities
Environmental stewardship	<ul style="list-style-type: none"> ■ Organizational structure of the Group function EQ ■ Standards and standard operating procedures for environmental stewardship ■ Assessing environmental impacts, auditing our sites and reporting violations ■ ISO 14001 Group certificate and certification of new sites ■ Stakeholder dialogue ■ Goals and progress: Environment
Pharmaceutical and chemical residues in the environment (incl. abandoned hazardous waste)	<ul style="list-style-type: none"> ■ Type and amount of provisions for environmental impact mitigation ■ Remediation of contamination at Gernsheim site
Plant and process safety	<ul style="list-style-type: none"> ■ Organizational structure: Plant and process safety within EQ ■ EHS standards and processes ■ Tracking EHS performance indicators ■ „Risk Management Process“ ■ Employee training and sharing lessons learned ■ EHS Incident Rate ■ Substance spills and environmental impacts

Aspect: Employee-related matters

Within our Group, employee-related matters fall under the purview of Human Resources (HR). Under this aspect, we report on concepts pertaining to recruiting and retaining employees. (incl. „Employee development“, „Work 4.0“, „Diversity and equal opportunity“, „Good leadership“, „Employee engagement“ as well as „Health and safety“).

Issue	Concepts incl. due diligence processes and outcome of activities
Recruiting and retaining employees (incl. employee development, Work 4.0, diversity and equal opportunities, good leadership, employee engagement as well as health and safety)	<ul style="list-style-type: none"> ■ Employer brand and approach to recruiting and retaining employees ■ Organization of HR ■ People Development & Learning Policy, Corporate guideline on “flexwork” and global standards ■ Concept and number of participants: Performance and Potential Management Process ■ Performance-based and gender-neutral pay ■ Qualified university graduates, number of trainees and apprentices, and hiring rates ■ Vocational training ■ Digitalization of work and use of digitalization ■ Finding work-life balance, flexible working models, part-time and parental leave ■ Good standing in employer rankings ■ Goals and progress: Employees ■ Indicators: Employees <ul style="list-style-type: none"> ■ Diversity strategy ■ Organizational structure of diversity ■ Industry-wide diversity initiatives ■ Diversity awareness and trainings on unconscious bias ■ Gender-neutral communication with candidates ■ Networks to bolster diversity and our activities in such areas ■ SpeakUp Line and taking action against discrimination ■ Integration and key figures of international employees ■ Addressing demographic change and health campaigns ■ Indicators: Business ethics <ul style="list-style-type: none"> ■ Structural organization for engagement and inclusion ■ Employee engagement surveys and improvement of the workplace environment ■ Promoting and rewarding innovative ideas, number of participants in such programs 2018, Merck KGaA, Darmstadt, Germany Awards, HR Innovation Campaign and our TED program ■ Innovation center and teams working there ■ Keeping employees informed, encouraging dialogue as well as availability of “pro” and EVA ■ Deepening employee engagement <ul style="list-style-type: none"> ■ Competency model ■ Management and talent programs for leaders, University program for our company and participant numbers ■ Programs in growth markets and number of participants <ul style="list-style-type: none"> ■ Organizational structure of health and safety ■ Policies and bylaws ■ OHSAS 18001 safety certification ■ Safety culture program “BeSafe!” and initiatives, campaigns and awareness-raising measures for the program in 2018 ■ Workplace health management and health projects ■ Reduce the number of accidents

Aspect: Social matters

"Social matters" encompasses our relationship with consumers. Under this heading, we report on concepts relating to patient safety, product-related crime, responsible marketing, and data protection.

Issue	Concepts incl. due diligence processes and outcome of activities
Patient safety	<ul style="list-style-type: none"> ■ Approach to patient safety ■ Pharmacovigilance ■ Infrastructure for patient safety ■ Patient safety guidelines ■ Pharmacovigilance monitoring through inspections and audits ■ Product labeling and changing product labels ■ Internal and external training ■ Share knowledge and pharmacovigilance campaigns
Product-related crime	<ul style="list-style-type: none"> ■ Approach to product-related crime ■ Product-related crime organization ■ Product-related crime guidelines and standards ■ Monitoring and reporting systems ■ Supporting customers and patients: Our approaches ■ Industry-wide exchange ■ Raising awareness of product crime, training sessions and reference book ■ Safety audits for contract manufacturers and distributors as well as findings ■ Goals and progress: Products
Responsible marketing	<ul style="list-style-type: none"> ■ Infrastructure for responsible marketing ■ Code of conduct and industry-wide rules ■ Reviewing marketing material ■ Addressing violations of standards and regulations ■ Employee training and number of participants ■ Direct marketing only in certain countries ■ Marketing chemicals and preventing chemical misuse
Data protection	<ul style="list-style-type: none"> ■ Organization: Integrated into Compliance ■ Policy for Data Protection and Personal Data Privacy as well as European General Data Protection Regulation ■ Data privacy management system ■ Indicators: Business ethics

Aspect: Respect for human rights

Under "Respect for human rights", we report on concepts related to bioethics (including genome editing) and clinical studies.

Issue	Concepts incl. due diligence processes and outcome of activities
Bioethics (including genome editing)	<ul style="list-style-type: none"> ■ Organizational structure for addressing bioethical issues ■ Current discussions within our Bioethics Advisory Panel (MBAP) of Merck KGaA, Darmstadt, Germany ■ Genome Editing Technology Principle ■ Stem Cells Principle ■ Fertility Principle ■ Guidelines and standard operation procedures for biosampling and biobanking ■ Guidelines on off-label use
Clinical studies	<ul style="list-style-type: none"> ■ Fundamental requirements for clinical studies ■ Organizational structure for clinical studies ■ Clinical study guidelines and agreements ■ Supervision of clinical studies ■ Teaming up to get results, auditing contract research organizations and findings ■ Close dialogue with patients and advocacy groups as well as participation in EUPATI ■ Responsible data sharing and data publication ■ Early Access Program and position paper on the program ■ Support of independent human subject research ■ Marketing approval for Avelumab

Aspect: Anti-corruption and anti-bribery matters

Within our corporate structure, anti-corruption efforts fall under Compliance Management, so we report here on compliance and interactions with health systems.

Issue	Concepts incl. due diligence processes and outcome of activities
Compliance	<ul style="list-style-type: none"> ■ Structural organization: Group Compliance ■ Compliance guidelines and standards ■ Compliance audits ■ Compliance training, e-learning course for our code of conduct and number of participants ■ Inform employees, for example through the initiative "Compliance. Because We Care" ■ SpeakUp Line, reported and confirmed cases of non-compliance ■ Business Partner Risk Management, risk analysis and training ■ Alliance for Integrity ■ Goals and progress: Business ethics ■ Indicators: Business ethics
Interactions with health systems	<ul style="list-style-type: none"> ■ Organizational structure for interactions with health systems ■ Group-wide guidelines and industry-wide standards ■ Transparent reporting, new regulations on transparency and publication of an EFPIA transparency report ■ Collaboration with patient advocacy groups ■ Transparent promotion of research and education ■ Introduction of a new compliance tool

Other matters

In the following section, we report on significant issues that are not covered in any of the five minimum aspects stipulated in section 289c (2) of the German Commercial Code:

Issue	Concepts incl. due diligence processes and outcome of activities
Chemical product safety (incl. Labeling of chemicals)	<ul style="list-style-type: none"> ■ Organizational structure for product safety ■ Group-wide and industry-wide guidelines ■ REACH registration ■ Supporting our Global Product Strategy ■ Assessing safety during product development ■ Our approach to nanotechnology ■ Standardized product safety information, number and languages of safety data sheets ■ ScIDeEx ■ Goals and progress: Products
Transport and warehouse safety	<ul style="list-style-type: none"> ■ Structural organization: EQ and dangerous goods manager ■ Globally applicable standards ■ Transport and warehouse safety audits, number and results of audits ■ Strengths and weaknesses profile ■ Employee training and regular discussions ■ Proper transport ■ Transport vehicles ■ Goals and progress: Products
Prices of medicines	<ul style="list-style-type: none"> ■ Structural pricing organization ■ Medicine price guidelines and principles ■ Data-based pricing ■ Customer-centric contracting models and examples ■ Pricing schemes to serve low-income patients and examples ■ Low-price second brands and examples ■ Generics and examples ■ Patient access programs and examples
Innovation and R & D	<ul style="list-style-type: none"> ■ Continuous innovation process ■ Structural organization of research and development as well as strategic partnerships ■ Our three innovation fields in the Innovation Center ■ Innovation Center and projects ■ Start-ups and cross-industry collaboration ■ "Innospire" and "Innovator Academy" ■ Displaying Futures Award ■ Research and development spending ■ M Venture Fund
Digitalization	<ul style="list-style-type: none"> ■ Structural organization of research and development ■ Five strategic focus areas ■ "Inclusive Innovation Challenge" ■ Examples from the strategic focus areas

GRI content index

General disclosures

The CR Report 2018 has been prepared in accordance with the GRI Standards: 'Comprehensive' option. The following GRI content index provides an overview of general disclosures, the GRI Standards and management approaches that were identified to be relevant. It also indicates where the corresponding information can be found. The GRI content index, as a part of the [CR report 2018](#), has received an independent audit certificate after undergoing a [limited assurance audit](#).

GRI Content Index: General disclosures

GRI Standards and Disclosure Number		Comment	Reference
Organizational profile			
102-1	Name of the organization		Company profile
102-2	Activities, brands, products, and services		Company profile Products & Industries
102-3	Location of headquarters		Company profile
102-4	Location of operations		Company profile List of shareholdings
102-5	Ownership and legal form		Company profile
102-6	Markets served		Company profile Macroeconomic and Sector-Specific Environment
102-7	Scale of the organization		Company profile Indicators: employees Indicators: environment Net sales Capitalization Consolidated Balance Sheet
102-8	Information on employees and other workers	Supervised workers such as temps are not logged in our employee data system.	Indicators: employees Attractive employer
102-9	Supply chain		Supply chain standards Mica supply chain Pharmaceutical supply chain
102-10	Significant changes to the organization and its supply chain		Company profile Supply chain standards Fundamental Information about the Group
102-11	Precautionary Principle or approach		CR strategy Environmental stewardship Transport and warehouse safety Health and safety Climate action Plant and process safety Chemical product safety

102-12	External initiatives	CR strategy Governance Compliance Human rights Sustainable Development Goals
102-13	Membership of associations	Stakeholder dialogue Compliance Global strategy Environmental stewardship
Strategy		
102-14	Statement from senior decision-maker	Letter from the CEO
102-15	Key impacts, risks, and opportunities	Letter from the CEO CR strategy Materiality analysis Goals Report on Risks and Opportunities
Ethics and integrity		
102-16	Values, principles, standards, and norms of behavior	CR strategy Governance Compliance Human rights Health for all Diversity Good leadership Bioethics Clinical studies Animal welfare Sustainable products Environmental stewardship
102-17	Mechanisms for advice and concerns about ethics	Compliance Diversity Mica supply chain Human rights Bioethics Clinical studies Animal welfare
Governance		
102-18	Governance structure	CR strategy Management Statement on Corporate Governance
102-19	Delegating authority	CR strategy Procedures of the corporate bodies
102-20	Executive-level responsibility for economic, environmental, and social topics	CR strategy
102-21	Consulting stakeholders on economic, environmental, and social topics	CR strategy Stakeholder dialogue Materiality analysis Compliance Global strategy Environmental stewardship Employee engagement

102-22	Composition of the highest governance body and its committees	Management Statement on Corporate Governance The Executive Board The Supervisory Board Objectives of the Supervisory Board with respect to its composition
102-23	Chair of the highest governance body	Management Statement on Corporate Governance
102-24	Nominating and selecting the highest governance body	Diversity The Executive Board Statement on Corporate Governance Gender quota Diversity policy Objectives of the Supervisory Board with respect to its composition
102-25	Conflicts of interest	Compliance Information on corporate governance practices
102-26	Role of highest governance body in setting purpose, values, and strategy	CR strategy Values and compliance Report of the Supervisory Board
102-27	Collective knowledge of highest governance body	CR strategy The Executive Board Statement on Corporate Governance
102-28	Evaluating the highest governance body's performance	Company profile Board of Partners The Supervisory Board Articles of Association Statement on Corporate Governance
102-29	Identifying and managing economic, environmental, and social impacts	CR strategy Materiality analysis Stakeholder dialogue Compliance Report profile Report on Risks and Opportunities Statement on Corporate Governance
102-30	Effectiveness of risk management processes	CR strategy Report profile Report on Risks and Opportunities Report of the Supervisory Board
102-31	Review of economic, environmental, and social topics	CR strategy Report profile Report on Risks and Opportunities Report of the Supervisory Board

102-32	Highest governance body's role in sustainability reporting		Report profile
102-33	Communicating critical concerns		Compliance Values and compliance
102-34	Nature and total number of critical concerns		Compliance Values and compliance
102-35	Remuneration policies		Compensation report
102-36	Process for determining remuneration		Compensation report
102-37	Stakeholders' involvement in remuneration		Attractive employer Compensation report Voting results Annual General Meeting 2018
102-38	Annual total compensation ratio	Competitive salaries and additional benefits not only increase our attractiveness as an employer; they also motivate our people and build loyalty to the company. The compensation we offer is based on market analyses in the relevant field and the value of the respective position, as well as the employee's skill set and performance. Our Global Rewards Policy defines the framework for compensation and benefits across the entire Group. As far as possible, we strive to offer all our employees comparable compensation structures. Furthermore, we monitor compliance with minimum standards. We do not consider the information required under GRI 102-38 and GRI 102-39 to be relevant to assessing the fairness of our compensation structures.	
102-39	Percentage increase in annual total compensation ratio	Competitive salaries and additional benefits not only increase our attractiveness as an employer; they also motivate our people and build loyalty to the company. The compensation we offer is based on market analyses in the relevant field and the value of the respective position, as well as the employee's skill set and performance. Our Global Rewards Policy defines the framework for compensation and benefits across the entire Group. As far as possible, we strive to offer all our employees comparable compensation structures. Furthermore, we monitor compliance with minimum standards. We do not consider the information required under GRI 102-38 and GRI 102-39 to be relevant to assessing the fairness of our compensation structures.	
Stakeholder engagement			
102-40	List of stakeholder groups		Stakeholder dialogue
102-41	Collective bargaining agreements		Employee engagement
102-42	Identifying and selecting stakeholders		Stakeholder dialogue Materiality analysis

102-43	Approach to stakeholder engagement	Stakeholder dialogue Materiality analysis
102-44	Key topics and concerns raised	Stakeholder dialogue Materiality analysis

Reporting practice

102-45	Entities included in the consolidated financial statements	Report profile Company profile
102-46	Defining report content and topic Boundaries	Report profile Materiality analysis
102-47	List of material topics	Materiality analysis
102-48	Restatements of information	Report profile
102-49	Changes in reporting	Report profile Materiality analysis
102-50	Reporting period	Report profile
102-51	Date of most recent report	Report profile
102-52	Reporting cycle	Report profile
102-53	Contact point for questions regarding the report	Report profile
102-54	Claims of reporting in accordance with the GRI Standards	GRI content index
102-55	GRI content index	GRI content index
102-56	External assurance	Report profile Assurance report GRI content index

Economic standards

GRI Content Index: Economic Standards

GRI Standards and Disclosure Number	Comment	Reference
GRI 201: ECONOMIC PERFORMANCE 2016		
103-1	Explanation of the material topic and its Boundary	Materiality analysis Statement on Corporate Governance
103-2	The management approach and its components	Economic performance Pension schemes
103-3	Evaluation of the management approach	Report on Risks and Opportunities
201-1	Direct economic value generated and distributed	Indicators: community Indicators: employees Indicators: economics Consolidated Income Statement Consolidated Cash Flow Statement Information by business sector /country and region Personnel expenses
201-2	Financial implications and other risks and opportunities due to climate change	We report in detail on various aspects of climate change as part of our participation in the CDP (formerly known as the Carbon Disclosure Project). Climate action Water management Global Compact CoP CDP Report on Risks and Opportunities
201-3	Defined benefit plan obligations and other retirement plans	Indicators: employees Pension schemes
201-4	Financial assistance received from government	Accounting: Property, plant and equipment Property, plant and equipment Research and development costs

GRI 202: MARKET PRESENCE 2016

103-1	Explanation of the material topic and its Boundary		Attractive employer Good leadership
103-2	The management approach and its components		Diversity Employee engagement Materiality analysis
103-3	Evaluation of the management approach		
202-1	Ratios of standard entry level wage by gender compared to local minimum wage	This indicator is not relevant to us, which is why we do not collect data on the ratio of the standard entry level wage compared to local minimum wage. Our Global Rewards Policy applies to all our subsidiaries world-wide and guarantees a systematic compensation structure. Both base pay and short-term variable compensation are oriented to the median base pay of the relevant reference market. Our pay brackets are reviewed on an annual basis and reflect market conditions. It goes without saying that we always adhere to local minimum wage levels.	Attractive employer
202-2	Proportion of senior management hired from the local community	We encourage both local hiring and international appointments across all levels of the company. The percentage of local managers is not recorded as it is not relevant to our strategic personnel planning.	Diversity Good leadership

GRI 204: PROCUREMENT PRACTICES 2016

103-1	Explanation of the material topic and its Boundary		Supply chain standards Mica supply chain Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
204-1	Proportion of spending on local suppliers		Supply chain standards

GRI 205: ANTI-CORRUPTION 2016

103-1	Explanation of the material topic and its Boundary		Compliance Interactions with health systems Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
205-1	Operations assessed for risks related to corruption		Compliance Indicators: business ethics Values and compliance Report on Risks and Opportunities
205-2	Communication and training about anti-corruption policies and procedures		Governance Compliance Responsible marketing Indicators: business ethics
205-3	Confirmed incidents of corruption and actions taken	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Compliance Responsible marketing Indicators: business ethics Report on Risks and Opportunities

GRI 206: ANTI-COMPETITIVE BEHAVIOR 2016

103-1	Explanation of the material topic and its Boundary	Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Indicators: business ethics

Additional material topics

TECHNOLOGY (Innovation and R&D, Digitalization)

103-1	Explanation of the material topic and its Boundary	Innovation and digitalization Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

DATA PROTECTION

103-1	Explanation of the material topic and its Boundary	Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

Environmental standards

GRI Content Index: Environmental Standards

GRI Standards and Disclosure Number		Comment	Reference
GRI 301: MATERIALS 2016			
103-1	Explanation of the material topic and its Boundary	In all our endeavors, we attempt to efficiently utilize materials and recycle as much as possible. Where feasible, we use recycled materials (in packaging, for instance). Overall, our company considers material consumption a major concern. There are few opportunities to use recycled material in our production processes because our business model puts us at the start of the value chain. We therefore do not collect such data at the Group-level. Individual data and measures are reported under the respective chapters.	Sustainable product design Packaging and recycling
103-2	The management approach and its components		Environmental stewardship Waste and recycling
103-3	Evaluation of the management approach		Materiality analysis
301-1	Materials used by weight or volume	See GRI 301: 103	Waste and recycling Sustainable product design Packaging and recycling
301-2	Recycled input materials used	See GRI 301: 103	Waste and recycling Sustainable product design Packaging and recycling
301-3	Reclaimed products and their packaging materials	Owing to the multitude of products we supply and the minimal comparability of our various initiatives, we do not collect quantitative data at the Group level. The individual measures taken by our various businesses are reported in the respective chapters.	Waste and recycling Sustainable product design Packaging and recycling
GRI 302: ENERGY 2016			
103-1	Explanation of the material topic and its Boundary		Environmental stewardship Climate action
103-2	The management approach and its components		Sustainable product design Materiality analysis
103-3	Evaluation of the management approach		
302-1	Energy consumption within the organization		Climate action Indicators: environment
302-2	Energy consumption outside of the organization		Climate action
302-3	Energy intensity		Climate action Indicators: environment
302-4	Reduction of energy consumption		Climate action Indicators: environment
302-5	Reductions in energy requirements of products and services		Sustainable product design

GRI 303: WATER AND EFFLUENTS 2018

103-1	Explanation of the material topic and its Boundary		Environmental stewardship Water management Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
303-1	Interactions with water as a shared resource		Water management Indicators: environment
303-2	Management of water discharge-related impacts		Water management
303-3	Water withdrawal	The amount of seawater, produced water and other water withdrawn and discharged is not significant and is therefore not reported separately.	Water management Indicators: environment
303-4	Water discharge	The amount of seawater, produced water and other water withdrawn and discharged is not significant and is therefore not reported separately.	Water management Indicators: environment
303-5	Water consumption		Water management Indicators: environment

GRI 304: BIODIVERSITY 2016

103-1	Explanation of the material topic and its Boundary		Biodiversity Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
304-1	Operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas	Land use planning takes impacts on biodiversity into account, with appropriate measures being taken on a case-by-case basis.	Biodiversity
304-2	Significant impacts of activities, products, and services on biodiversity		Biodiversity
304-3	Habitats protected or restored		Biodiversity
304-4	IUCN Red List species and national conservation list species with habitats in areas affected by operations	Land use planning takes impacts on biodiversity into account, with appropriate measures being taken on a case-by-case basis.	Biodiversity

GRI 305: EMISSIONS 2016

103-1	Explanation of the material topic and its Boundary		Environmental stewardship Climate action Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
305-1	Direct (Scope 1) GHG emissions		Climate action Indicators: environment
305-2	Energy indirect (Scope 2) GHG		Climate action Indicators: environment
305-3	Other indirect (Scope 3) GHG emissions		Climate action Indicators: environment CDP
305-4	GHG emissions intensity		Indicators: environment

305-5	Reduction of GHG emissions		Climate action Indicators: environment Sustainable product design Packaging and recycling CDP
-------	----------------------------	--	---

305-6	Emissions of ozone-depleting substances (ODS)	This disclosure is not material to the Group.	Indicators: environment
-------	---	---	-------------------------

305-7	Nitrogen oxides (NOX), sulfur oxides (SOX), and other significant air emissions	This disclosure is not material to the Group.	Indicators: environment
-------	---	---	-------------------------

GRI 306: EFFLUENTS AND WASTE 2016

103-1	Explanation of the material topic and its Boundary		Environmental stewardship Waste and recycling Packaging and recycling Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		

306-1	Water discharge by quality and destination	Please note that the effluents-related content in the current GRI 306: Effluents and Waste 2016 Standard has been updated and can be found in GRI 303: Water and Effluents 2018.	
-------	--	--	--

306-2	Waste by type and disposal method		Waste and recycling Packaging and recycling Indicators: environment
-------	-----------------------------------	--	---

306-3	Significant spills		Plant and process safety Indicators: environment
-------	--------------------	--	---

306-4	Transport of hazardous waste		Indicators: environment
-------	------------------------------	--	-------------------------

306-5	Water bodies affected by water discharges and/or runoff	Please note that the effluents-related content in the current GRI 306: Effluents and Waste 2016 Standard has been updated and can be found in GRI 303: Water and Effluents 2018.	
-------	---	--	--

GRI 307: ENVIRONMENTAL COMPLIANCE 2016

103-1	Explanation of the material topic and its Boundary		Environmental stewardship Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
307-1	Non-compliance with environmental laws and regulations		Environmental stewardship

GRI 308: SUPPLIER ENVIRONMENTAL ASSESSMENT 2016

103-1	Explanation of the material topic and its Boundary		Supply chain standards Materiality analysis Mica supply chain
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
308-1	New suppliers that were screened using environmental criteria		Supply chain standards Mica supply chain
308-2	Negative environmental impacts in the supply chain and actions taken		Supply chain standards Mica supply chain

social standards

GRI Content Index: Social Standards

GRI Standards and Disclosure Number		Comment	Reference
GRI 401: EMPLOYMENT 2016			
103-1	Explanation of the material topic and its Boundary		Attractive employer Diversity
103-2	The management approach and its components		Health and safety Human rights Materiality analysis
103-3	Evaluation of the management approach		
401-1	New employee hires and employee turnover		Indicators: employees
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	At Merck KGaA, Darmstadt, Germany (22% of the company's total work-force), part-time employees receive the same job benefits as full-time workers. Employees with temporary contracts, however, are not entitled to all company benefits, such as a company pension.	Indicators: employees Attractive employer
401-3	Parental leave		Attractive employer Indicators: employees
GRI 402: LABOR/MANAGEMENT RELATIONS 2016			
103-1	Explanation of the material topic and its Boundary		Attractive employer Health and safety
103-2	The management approach and its components		Employee engagement Materiality analysis
103-3	Evaluation of the management approach		
402-1	Minimum notice periods regarding operational changes	The regulations on periods of notice vary worldwide. We apply the rules that are in force locally. There is no need for us to track periods of notice at Group level.	

GRI 403: OCCUPATIONAL HEALTH AND SAFETY 2018

103-1	Explanation of the material topic and its Boundary		Health and safety Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
403-1	Occupational health and safety management system		Health and safety
403-2	Hazard identification, risk assessment, and incident investigation		Health and safety
403-3	Occupational health services		Health and safety
403-4	Worker participation, consultation, and communication on occupational health and safety	<p>Occupational health and safety committees are required by law in Germany. All employees of Merck KGaA, Darmstadt, Germany are therefore represented by such committees, which operate at the site level. These employees account for around 22% of our total workforce. The majority of facilities outside Germany also have health and safety committees to represent their employees. Each individual site is responsible for arranging and maintaining such committees.</p> <p>Health and safety issues are governed Group-wide by our EHS Policy. The organizational implementation of the policy is the responsibility of our individual sites and is subject to local laws and regulations. Merck KGaA, Darmstadt, Germany, which accounts for approximately 22% of our total workforce, has bylaws on occupational health and safety in place.</p>	Health and safety
403-5	Worker training on occupational health and safety		Health and safety
403-6	Promotion of worker health		Health and safety
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships		Health and safety
403-8	Workers covered by an occupational health and safety management system		Health and safety
403-9	Work-related injuries	We have identified the lost time injury rate (LTIR) as a key performance indicator for our company.	Health and safety Indicators: employees
403-10	Work-related ill health		Indicators: employees

GRI 404: TRAINING AND EDUCATION 2016

103-1	Explanation of the material topic and its Boundary		Attractive employer Good leadership
103-2	The management approach and its components		Diversity Materiality analysis
103-3	Evaluation of the management approach		
404-1	Average hours of training per year per employee	We do not keep track of the average hours our employees spend on vocational training and continuing education because this indicator does not have any bearing on the quality or success of our efforts.	Compliance Responsible marketing Interactions with health systems Animal welfare Patient safety Product-related crime Transport and warehouse safety Attractive employer Diversity Health and safety Good leadership Environmental stewardship Plant and process safety
404-2	Programs for upgrading employee skills and transition assistance programs		Attractive employer Diversity Good leadership
404-3	Percentage of employees receiving regular performance and career development reviews		Attractive employer Indicators: employees

GRI 405: DIVERSITY AND EQUAL OPPORTUNITY 2016

103-1	Explanation of the material topic and its Boundary		Diversity Attractive employer
103-2	The management approach and its components		Materiality analysis Objectives of the Supervisory Board with respect to its position
103-3	Evaluation of the management approach		
405-1	Diversity of governance bodies and employees	Since there is no globally uniform definition of the term "minority", we do not record this sort of data. Moreover, many countries in which we operate have strict data privacy regulations governing the recording of personal employee data.	Diversity Indicators: employees The Executive Board The Supervisory Board Objectives of the Supervisory Board with respect to its position
405-2	Ratio of basic salary and remuneration of women to men	The salaries we offer are predicated on the respective job description and are based on our Global Job Catalog, which has fixed salary bands that are identical for men and women. Variable salary components that fall under performance-based compensation are paid on the basis of whether mutually agreed targets have been achieved. A performance management system governs this process.	Attractive employer

GRI 406: NON-DISCRIMINATION 2016

103-1	Explanation of the material topic and its Boundary	Diversity Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
406-1	Incidents of discrimination and corrective actions taken	Diversity

GRI 407: FREEDOM OF ASSOCIATION AND COLLECTIVE BARGAINING 2016

103-1	Explanation of the material topic and its Boundary	Supply chain standards Mica supply chain Attractive employer Human rights Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	Supply chain standards Mica supply chain Human rights Attractive employer

GRI 408: CHILD LABOR 2016

103-1	Explanation of the material topic and its Boundary	Supply chain standards Mica supply chain Human rights Attractive employer Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
408-1	Operations and suppliers at significant risk for incidents of child labor	Supply chain standards Mica supply chain Human rights Attractive employer Indicators: employees

GRI 409: FORCED OR COMPULSORY LABOR 2016

103-1	Explanation of the material topic and its Boundary	Supply chain standards Mica supply chain Attractive employer Human rights Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Supply chain standards Mica supply chain Attractive employer Human rights

GRI 412: HUMAN RIGHTS ASSESSMENT 2016

103-1	Explanation of the material topic and its Boundary	Human rights Compliance Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
412-1	Operations that have been subject to human rights reviews or impact assessments	Human rights
412-2	Employee training on human rights policies or procedures	Human rights
412-3	Significant investment agreements and contracts that include human rights clauses or that underwent human rights screening	Human rights

GRI 414: SUPPLIER SOCIAL ASSESSMENT 2016

103-1	Explanation of the material topic and its Boundary	Supply chain standards Mica supply chain Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
414-1	New suppliers that were screened using social criteria	Supply chain standards Mica supply chain
414-2	Negative social impacts in the supply chain and actions taken	Supply chain standards Mica supply chain

GRI 415: PUBLIC POLICY 2016

103-1	Explanation of the material topic and its Boundary	Stakeholder dialogue Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	
415-1	Political contributions	Stakeholder dialogue

GRI 416: CUSTOMER HEALTH AND SAFETY 2016

103-1	Explanation of the material topic and its Boundary	Patient safety Responsible marketing Interactions with health systems Clinical studies Chemical product safety Sustainable product design Plant and process safety Materiality analysis Report on Risks and Opportunities
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

416-1	Assessment of the health and safety impacts of product and service categories		Patient safety Clinical studies Chemical product safety Sustainable product design Plant and process safety
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Report on Risks and Opportunities

GRI 417: MARKETING AND LABELING 2016

103-1	Explanation of the material topic and its Boundary		Patient safety Chemical product safety Responsible marketing Interactions with health systems Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
417-1	Requirements for product and service information and labeling	Within our businesses, product labels are both important and mandatory. All pharmaceuticals and chemicals are subject to reporting and notification requirements that we fulfill. The individual requirements are reported in the respective chapters.	Patient safety Responsible marketing Interactions with health systems Chemical product safety
417-2	Incidents of non-compliance concerning product and service information and labeling		Patient safety Chemical product safety Report on Risks and Opportunities
417-3	Incidents of non-compliance concerning marketing communications	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Responsible marketing Report on Risks and Opportunities

GRI 418: CUSTOMER PRIVACY 2016

103-1	Explanation of the material topic and its Boundary		Clinical studies Compliance Materiality analysis
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data		Indicators: business ethics Clinical studies Compliance

GRI 419: SOCIOECONOMIC COMPLIANCE 2016

103-1	Explanation of the material topic and its Boundary		Compliance Materiality analysis Report on Risks and Opportunities
103-2	The management approach and its components		
103-3	Evaluation of the management approach		
419-1	Non-compliance with laws and regulations in the social and economic area	As applicable, we report on risks from litigation and legal proceedings in our Report on Risks and Opportunities.	Indicators: business ethics Report on Risks and Opportunities

Additional material topics

ETHICAL CONDUCT (bioethics, clinical studies, animal welfare)

103-1	Explanation of the material topic and its Boundary	Bioethics Clinical studies Animal welfare Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

HEALTH FOR ALL (access to health, prices of medicines, health awareness)

103-1	Explanation of the material topic and its Boundary	Global strategy Focus programs Open innovation sharing Prices of medicines Health awareness Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

PRODUCT-RELATED CRIME

103-1	Explanation of the material topic and its Boundary	Product-related crime Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

COMMUNITY INVOLVEMENT

103-1	Explanation of the material topic and its Boundary	Community involvement Global Health Broad Minds Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

WORK 4.0

103-1	Explanation of the material topic and its Boundary	Attractive employer Materiality analysis
103-2	The management approach and its components	
103-3	Evaluation of the management approach	

global compact CoP

2018 Communication on progress (CoP) in implementing the ten principles of the Global Compact

We have been a UN Global Compact participant since 2005. As a signatory of the initiative, we have committed ourselves to ten principles based on key UN conventions regarding human rights, labor standards, environmental protection, and anti-corruption. At the same time, the UN Global Compact calls on its signatories to actively engage in propagating the principles within their own sphere of influence.

The following table summarizes the key measures we took in 2018, to support and implement the principles of the Global Compact.

[undefined]

Link: www.unglobalcompact.org

UNGC-Principleien:	Key measures in 2018:	Relevant GRI disclosures:	Reference:
Human rights			
Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights.	Key measures in 2018: <ul style="list-style-type: none"> Hosted a workshop on modern slavery 194 people managers took part in the online course on our Human Rights Charter Donated nearly 200 million praziquantel tablets to the World Health Organization to treat schistosomiasis, a donation that included Burkina Faso, Niger and Sierra Leone for the first time Formed an internal, cross-functional human rights working group Added the topic of human rights to our manual for new managing directors in an effort to heighten awareness at the executive level Started the process of updating our Human Rights Charter 	Relevant GRI disclosures: 410-1, 411-1, 103-2: 412, 412-2, 413-1, 413-2	Reference: Compliance Human rights Focus programs
Principle 2: Businesses should make sure that they are not complicit in human rights abuses.	Key measures in 2018 <ul style="list-style-type: none"> Took initial steps in response to the human rights self-assessment we conducted at our sites 194 people managers took part in the online course on our Human Rights Charter Conducted internal and external audits, assessments and inspections of suppliers regarding corporate responsibility, and collected self-reported information Added human rights issues to our compliance risk reporting 	Relevant GRI disclosures: 412-3, 414-1, 414-2	Reference: Human rights Compliance Supply chain standards

Labor standards

Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining.	Key measures in 2018: <ul style="list-style-type: none"> ■ Took initial steps in response to the human rights self-assessment we conducted at our sites ■ Conducted internal audits on workplace aspects of our Human Rights Charter ■ Conducted internal and external audits, assessments and inspections of suppliers regarding corporate responsibility, and collected self-reported information 	Relevant GRI disclosures: 102-41, 402-1, 407-1	Reference: Human rights Compliance Employee engagement Supply chain standards
Principle 4: Businesses should support the elimination of all forms of forced and compulsory labor.	Key measures in 2018 <ul style="list-style-type: none"> ■ Conducted internal audits on workplace aspects of our Human Rights Charter ■ Took initial steps in response to the human rights self-assessment we conducted at our sites ■ Issued our UK Modern Slavery Statement, which has been endorsed by our Executive Board and is available on our website ■ Conducted internal and external audits, assessments and inspections of suppliers regarding corporate responsibility, and collected self-reported information 	Relevant GRI disclosures: 409-1	Reference: Human rights Compliance Supply chain standards
Principle 5: Businesses should support the effective abolition of child labor.	Key measures in 2018 <ul style="list-style-type: none"> ■ Took initial steps in response to the human rights self-assessment we conducted at our sites ■ Conducted internal audits on workplace aspects of our Human Rights Charter ■ Assumed the presidency of the Responsible Mica Initiative until 2020, and supported its work ■ Engaged with the Indian organization IGEP to conduct monthly inspections of mica mines and processing plants ■ Conducted internal and external audits, assessments and inspections of suppliers regarding corporate responsibility, and collected self-reported information 	Relevant GRI disclosures: 408-1	Reference: Human rights Compliance Supply chain standards Mica supply chain
Principle 6: Businesses should support the elimination of discrimination in respect of employment and occupation.	Key measures in 2018 <ul style="list-style-type: none"> ■ Reviewed and revised our Diversity Strategy ■ Conducted internal audits on workplace aspects of our Human Rights Charter ■ Identified key measures to achieve our 2021 target of maintaining a 30% representation of women in leadership roles (Role 4+) ■ Expanded internal diversity programs ■ Conducted a pilot training program on unconscious bias 	Relevant GRI disclosures: 102-8, 202-1, 202-2, 401-1, 401-3, 404-1, 404-3, 405-1, 405-2, 406-1	Reference: Human rights Compliance Diversity

Environmental stewardship

Principle 7: Businesses should support a precautionary approach to environmental challenges.	Key measures in 2018 <ul style="list-style-type: none"> ■ Added two new sites to our ISO 14001:2015 Group certificate (Group certificate for 81 facilities) ■ Annually reduced CO₂ emissions (2020 reduction target: 20% versus 2006 baseline) ■ Implemented more than 360 climate impact mitigation projects since 2012 ■ Introduced two new Group-wide water standards ■ Implemented measures to ensure product safety (e.g. REACH, GHS, Global Product Strategy) as well as plant and process safety (e.g. risk management process) ■ Performed internal and external EHS audits ■ Used our Waste Scoring System with the goal of reducing the environmental impact of our waste by 5% by 2025 ■ Established two Waste Expert Network Groups 	Relevant GRI disclosures: 201-2, 301-1, 302-1, 303-1, 305-1, 305-2, 305-3, 305-6, 305-7	Reference: Environmental stewardship Climate action Water management Waste and recycling Plant and process safety Sustainable product design Packaging and recycling Patient safety Chemical product safety Transport and warehouse safety
Principle 8: Businesses should undertake initiatives to promote greater environmental responsibility.	Key measures in 2018 <ul style="list-style-type: none"> ■ Systematically examined potential energy savings at our production facilities ■ Labeled products to provide information on their use and disposal ■ Launched the online platform "Troc" at our site in Corsier-sur-Vevey (Switzerland) to raise employee awareness for waste minimization. ■ Commercialized greener products such as Cyrene™ ■ Offered employees sustainable mobility options such as Jobtickets and bike sharing 	Relevant GRI disclosures: 301 - 308	Reference: Climate action Water management Waste and recycling Plant and process safety Chemical product safety Patient safety Transport and warehouse safety Sustainable product design
Principle 9: Businesses should encourage the development and diffusion of environmentally friendly technologies.	Key measures in 2018 <ul style="list-style-type: none"> ■ Developed sustainable products such as liquid crystal technologies, raw materials for natural cosmetics and greener alternatives to chemicals ■ Implemented a new sustainable packaging strategy built on the following four goals: Reduce amount of packaging, achieve zero forestation, improve plastic sustainability, and optimize recycling ■ Expanded a recycling program for our Life Science customers 	Relevant GRI disclosures: 302-4, 302-5, 305-5	Reference: Sustainable product design Packaging and recycling Performance Materials

Anti-Corruption

Principle 10:	Key measures in 2018	Relevant GRI disclosures:	Reference:
Businesses should work against corruption in all its forms, including extortion and bribery.	<ul style="list-style-type: none"> ■ Performed internal corruption audits ■ Integrated our compliance program into our business sectors ■ 11,404 employees and external workers completed an online anti-corruption course ■ Rolled out business sector-specific e-learning programs centered on our Code of Conduct ■ Provided Group-wide SpeakUp Line for people to report corruption anonymously ■ Published annual EFPIA transparency reports 	102-16, 102-17, 205-1, 205-2, 205-3, 415-1	Compliance Interactions with health systems

glossary

3R principle

The international guiding principle for all animal testing. The number of laboratory animals used as well as the stress placed on them before, during and after testing are to be kept to an absolute minimum by using methods to replace animal experiments (replacement), reduce the required number of tests and animals (reduction), and improve the test methods (refinement).

Big Data

Extremely large data sets that may be analyzed computationally to reveal patterns, trends and associations, especially relating to human behavior and interactions.

Biodiversity

The diversity of ecosystems, habitats and landscapes on earth, the diversity of the species, and the genetic diversity within a biological species or population.

Biosimilars

Officially approved subsequent versions of innovator biopharmaceutical products made by a different company after the original product's patent or exclusivity expires. Based on guidance from the European Medicines Agency (EMA), biosimilars must demonstrate comparability, or biosimilarity, to an existing approved product.

Chatbot

A chatbot is a computer program or an artificial intelligence that conducts a conversation via auditory or textual methods.

Chromatography

A technique used to separate mixtures.

CLP

Short for "Classification, Labelling and Packaging of Substances and Mixtures", this is a European regulation based on the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

CO₂ equivalents

CO₂ equivalents (CO₂eq) indicate how much a specified quantity of a specific greenhouse gas has contributed to the greenhouse effect, using the global warming potential of carbon dioxide as a reference.

Compliance

Adherence to laws and regulations as well as to voluntary codices that are internal to a company. Compliance is a component of diligent corporate governance.

CRISPR/Cas

A biomolecular method for targeting, cutting and editing the DNA of an organism (gene editing). Experts think this technique has great potential for curing diseases or generating plants and animals with new traits.

Design thinking

An approach to developing new ideas. Design thinking uses the designer's sensibility and methods to match people's needs with what is technologically feasible and what a viable business strategy can convert into customer value and market opportunity.

Dual-use products

Goods that are normally used for civilian purposes, but that may also have military applications.

Due diligence

A risk analysis exercised with particular care.

EHS

Short for "Environment, Health and Safety", this refers to environmental management, health protection and occupational safety throughout a company.

End-user declaration

A binding customer statement regarding the intended use of a product.

Endemic countries

Countries in which a certain disease, in many cases an infectious disease, occurs.

EQ

EQ stands for our Group function "Environment, Health, Safety, Security, Quality".

ESG ratings

ESG ratings are used to assess a company's financial performance through factors that include aspects of environmental management, social issues and good governance.

Essential medicines

Defined by the World Health Organization as "those drugs that satisfy the health care needs of the majority of the population".

Exposure assessment

The U.S. Environmental Protection Agency defines exposure assessment as the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure between an agent and an organism. This analysis forms part of the chemical safety

assessment process.

FDA

The U.S. Food and Drug Administration is the U.S. government agency responsible for protecting and advancing public health, especially as concerns food and drugs.

First-line treatment

A therapy regimen that is generally accepted by the medical establishment for the initial treatment of a given disease. If the first-line treatment is not adequately successful, a second-line treatment may be administered.

Freshwater

Water containing 1,000 mg or less of dissolved solids per liter.

Gene drive technologies

Gene drive technologies refer to methods for accelerating the spread of genes in populations. In general, the technique can employ adding, deleting, disrupting, or modifying genes. These can be used, for example, on mosquitoes that transmit malaria, dengue, and Zika pathogens in order to stop their spread.

Global Grade

We use a market-oriented system to rate positions within the company. Until the end of 2016, all positions within the Merck KGaA, Darmstadt, Germany were assigned a Global Grade. In 2017, we replaced this system so that each position is now assigned a role.

Global Product Strategy

An initiative of the International Council of Chemical Associations (ICCA) through which participating companies of the chemical industry make a commitment to comprehensive product responsibility.

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

An international standard system to classify chemicals that covers labeling as well as safety data sheets.

Good clinical practice (GCP)

An international quality standard that enforces tight guidelines on ethical aspects of clinical studies.

Good distribution practice (GDP)

An EU guideline that regulates the proper distribution of medicinal products for human use.

Good manufacturing practice (GMP)

Good manufacturing practice (GMP) is a system for ensuring that products are consistently manufactured and controlled according to quality standards. These guidelines are used in the production of medicines, pharmaceutical active ingredients and cosmetics, as well as foodstuffs and feed.

Greenhouse gases

Gases in the atmosphere that contribute to global warming. They can be either naturally occurring or caused by humans (such as CO₂ emissions caused by burning fossil fuels).

GxP

The general term for good (anything ...) practice quality guidelines and regulations that are used in many fields, including the medical, pharmaceutical and pharmaceutical chemistry industries.

Hackathon

Portmanteau from the words hacking and marathon. A hackathon is an event attended by people from different professional backgrounds. Teams are given a few hours or days to develop innovative solutions and ideas for pre-defined issues or challenges.

HazCom 2012

A U.S. OSHA (Occupational Safety and Health Administration) standard pertaining to the safe handling of chemicals in the workplace, with an emphasis on occupational safety and environmental protection. This standard requires manufacturers and distributors to provide information on the hazards posed by a product as well as ways to minimize risks.

ICH

The aim of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is to promote uniform assessment criteria for product registration in Europe, the United States and Japan. The ICH develops guidelines for the evaluation of the quality, effectiveness and safety of medicinal products.

In vitro

Procedures involving components of an organism that have been isolated from their usual biological surroundings (e.g. test tube experiments).

In vivo

Latin for "within the living", this term describes processes that take place within a living organism.

Investigational drug

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including approved as well as unapproved products when used or assembled (formulated or packaged) in a way different from the approved form, when used for an unapproved indication, or when used to gain further information about an approved use.

ISO 14001

This international environmental management standard sets globally recognized requirements for an environmental management system.

ISO 50001

This international standard defines globally recognized requirements for energy management systems.

ISO 9001

This international standard defines globally recognized requirements for a quality management system.

Lead substances

Manufacturers/importers of a certain substance must submit a joint registration according to REACH. In this context, the company responsible for collecting the substance data and preparing the registration dossier uses the term "lead substance".

Least developed countries (LDC)

Countries that, according to the United Nations, exhibit the lowest indicators of socioeconomic development.

Liquid biopsy

Sampling and analysis of non-solid biological tissue such as blood.

Liquid Crystals (LC)

Liquid crystals are a hybrid of a crystalline and liquid state. In general, molecules are perfectly arranged only when in a solid crystal state, in contrast to the liquid state, when they move around chaotically. However, liquid crystals are a hybrid of the two states: Although they are liquid, they exhibit a certain crystalline arrangement. Their rod-shaped molecules align themselves like a shoal of fish. In addition, they respond to the electromagnetic waves of light like tiny antennae. Therefore, such swarms of molecules can either allow specially prepared "polarized" light to pass through, or they can block it. This takes place in the pixels of liquid crystal displays – as it does similarly in liquid crystal windows, which can provide shade against sunlight.

Liver-stage malaria

Certain forms of the malaria parasite (*P. vivax* and *P. ovale*) can remain dormant after they have infected the liver cells. In this stage, they persist for many weeks and even years until they relapse into a new disease cycle. Currently, it is not possible to treat this dormant form.

LTIR

The lost time injury rate measures the number of accidents resulting in missed days of work (one or more days) per one million man-hours.

Monoclonal antibodies

Monoclonal antibodies are made by identical immune cells that are all clones of a unique parent cell.

Mutagen

A substance that changes the DNA of an organism.

Neglected tropical disease (NTD)

Diseases that occur primarily in developing countries. NTDs

include schistosomiasis, intestinal worms, trachoma, lymphatic filariasis, and onchocerciasis. This group of diseases is called neglected because, despite the large number of people affected, they have historically received less attention and research funding than other diseases.

Nucleases

Nucleases are a group of enzymes whose primary function is to partially or fully degrade nucleic acids.

OHSAS

The Occupational Health and Safety Assessment Series (OHSAS) is an international occupational health and safety management system.

OLED

Organic light-emitting diodes are a new technology for displays and lighting.

Onchocerciasis

A chronic parasitic infection caused by nematodes that occurs in the tropical regions of Africa and South America. In approximately 10% of those infected, the disease leads to blindness, which is why onchocerciasis is also referred to as river blindness.

Organoid

An organoid is a miniaturized and simplified version of an organ produced in vitro in three dimensions by means of a cell culture. It shows realistic micro-anatomy similar to an organ. Organoids are derived from one or a few tissue cells, embryonic stem cells or induced pluripotent stem cells, which can self-organize in a three-dimensional culture, owing to their self-renewal and differentiation capacities. Organoids are, among others, used as model systems in the investigation of diseases and the development of drugs.

Orodispersible tablet

A tablet that dissolves in the mouth within 30 seconds and does not have to be taken with water. The active ingredient is absorbed through the mucous membrane in the mouth and also partly through the lining of the stomach.

Other water

Water containing more than 1,000 mg of dissolved solids per liter.

Patent pool

A consortium of at least two competing companies that allows partners to share the use of patents relating to a particular technology.

Patient access programs

Self-sustaining commercial programs with revenue-driven purpose which provide medication for underserved populations, either through free products or a reduced treatment fee.

Patient support programs

Any organized system providing services and direct patient or patient-caregiver interactions that are intended and designed to educate patients about certain diseases, and help patients with access to and/or the management of prescribed medication and/or disease outcomes and/or offer doctors support for their patients.

Pharmacovigilance

The continual, systematic monitoring of a drug's safety.

Phase I study

Phase I clinical trials test a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to evaluate safety (for instance to determine a safe dosage range and to identify side effects).

Source: <http://www.who.int/ictrp/glossary/en/>

Phase II study

Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Source: <http://www.who.int/ictrp/glossary/en/>

Phase III study

Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Source: <http://www.who.int/ictrp/glossary/en/>

Prediabetes

A condition regarded as indicative that a person is at risk of progressing to Type 2 diabetes.

Process-related emissions

Greenhouse gases released into the atmosphere during manufacturing operations.

Product safety summary

Intended to provide a general overview of the chemical substance and its use. It cannot take the place of a safety data sheet.

PS-VA

Abbreviation for polymer-stabilized vertical alignment: A polymer layer pre-aligns the molecules inside the display in a certain direction. In the black state, the liquid crystals are not exactly vertical, but slightly tilted, which allows the liquid crystals to switch more quickly. The light transmittance of the display is significantly higher, thus reducing the backlighting, one of the most costly components to produce.

Public-private partnership (PPP)

A collaboration between public sector (government) organizations, private companies and/or not-for-profit organizations.

Pyrogen

A foreign substance that causes a fever (temperature elevation) in the body.

REACH

A European Union chemical regulation (EC No. 1907/2006) that took effect on June 1, 2007. REACH stands for Registration, Evaluation, Authorization, and Restriction of Chemicals.

Reproductive health

The term covers various areas such as pregnancy, sexually transmitted diseases, contraception, and infertility.

Risk-sharing agreement

An agreement between the producer or manufacturer and the payer or provider that allows access to a health technology through coverage or reimbursement under certain conditions.

Role

We use a market-oriented system to rate positions within the company. To facilitate consistency across the organization, each position is assigned a specific role, with an overarching job architecture classifying each role as one of 11 levels, 15 functions and an array of career types (Core Operations, Services & Support Groups; Experts; Managers; Project Managers).

Schistosomiasis

A parasitic disease spread in warm lakes and ponds by snails that serve as intermediate hosts.

Scope 3

Scope 3 includes indirect greenhouse gas emissions, such as the extraction and production of purchased materials, transport-related activities, waste disposal, and employee travel.

Score card

A scorecard is an evaluation tool for measuring, documenting and controlling activities using metrics.

Scrum

Scrum is a framework for agile project management. It is a method that is simple, flexible and quick to deliver results.

Security

This term stands for all necessary measures and governance activities to detect, analyze, handle, and mitigate security- and crime-based threats to the company. This helps to protect employees as well as the tangible and intangible assets of the company.

Signal management

A set of activities performed to determine whether, based on an examination of individual case safety reports, aggregated data from active surveillance systems or studies, scientific literature information or other data sources, there are new risks associated with an active substance or a medicinal product or whether known risks have changed, as well as any related recommendations, decisions, communications and tracking.

Spontaneous reports on adverse effects

If a side effect has occurred while using a medicine and this is being reported, this is called a "spontaneous report", because the adverse reaction is reported spontaneously (for example by doctors or patients) and not in a study or an observational study.

Stakeholder

People or organizations that have a legitimate interest in a company, entitling them to make justified demands. Stakeholders include people such as employees, business partners, neighbors in the vicinity of our sites, and shareholders.

STEM

Science, technology, engineering, and mathematics.

Stem cell lines

Stem cell lines are groups of stem cells derived from animal or human tissue. They can be cultivated in vitro and multiply indefinitely.

Stem cells

Undifferentiated cells with the potential to develop into many different cell types that carry out different functions.

Sugar cane bagasse

A fibrous waste product of sugar refining that is left when sugarcane stalks are crushed to extract their juice.

Sunshine Act

The Sunshine Provisions of the U.S. Patient Protection and Affordable Care Act aim to create more transparent relationships between manufacturers of drugs, medical devices and medical aids on the one hand, and doctors and teaching hospitals on the other.

Traces

Substances dissolved in water that are present only in minute amounts. Also referred to as micropollutants, these are synthetic substances present in concentrations ranging from one nanogram to one microgram per liter of water.

Transfers of value

Direct and indirect transfers of value, whether in cash, in kind or otherwise (e.g. promotional purposes).

TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement between all the member nations of the World Trade Organization. TRIPS seeks to ensure that the measures and procedures for enforcing intellectual property rights do not become a barrier to lawful trade.

Working out loud

This technique is about deliberately sharing and providing knowledge as well as forming relevant working relationships. The goal is to discover new topics and ideas.

publication contributors

Published on April 15, 2019 by

Merck KGaA, Group Corporate Responsibility

Frankfurter Strasse 250, 64293 Darmstadt, Germany

Tel.: +49 (0) 6151-72 0

Fax: +49 (0) 6151-72 5577

Website: www.emdgroup.com

Contact for questions regarding this report:

Maria Schaad, Group Corporate Responsibility

Concept and implementation of HTML, PDF & Print:

[nexxar GmbH, Vienna](#) – Online annual reports and online sustainability reports

Text and consulting:

Stakeholder Reporting GmbH

www.stakeholder-reporting.com

Photos and graphics:

Merck KGaA, Darmstadt, Germany, Rüdiger Nehmzow

