Novartis in Society

ESG Report 2019

NOVARTIS

Contents

Photo A worker at Zipline's distribution center in Omenako, Ghana, prepares a medical order for drone delivery. Novartis has partnered with Zipline, a US-based automated logistics company, to help deliver vital medicines to remote areas.

Cover photo Patients at Kumasi General Hospital in Ghana, where newborns are screened for sickle cell disease. Only about 4% of babies in Ghana are tested for this debilitating genetic blood disorder.

2019 highlights

ETHICAL STANDARDS

99/100
SCORE
achieved by Novartis for clinical trial transparency in a recent analysis published by BMJ

500+
ASSOCIATES
volunteered to be part of the networkthat will create the NovartisCode of Ethics

135
HIGH-LEVEL AUDITS
performed on 100% of suppliers with active follow-up

ACCESS TO HEALTHCARE

16 m
PATIENTS
reached through access programs

10 m+
PEOPLE
reached through training and health education programs

300 000+
PATIENTS
reached with over 90 local brands for some of our most advanced medicines

GLOBAL HEALTH

900 m+
TREATMENT COURSES
of *Coartem* delivered to date in malaria-endemic countries

20 000+
TREATMENTS
of hydroxyurea delivered to Ghana for the treatment of people withsickle cell disease

7 m+
PATIENTS
reached with free multidrug therapy for leprosy since 2000

CORPORATE CITIZENSHIP

80 000
TONNES REDUCTION
of carbon emissions (Scope 1 and 2) vs. 2016

44%
WOMEN
in management

100 000
HOURS
devoted to learning during Novartis Learning Month

Who we are

Our purpose

We reimagine medicine to improve and extend people's lives. We use innovative science and technology to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. We also aim to reward those who invest their money, time and ideas in our company.

Our company

INNOVATIVE MEDICINES

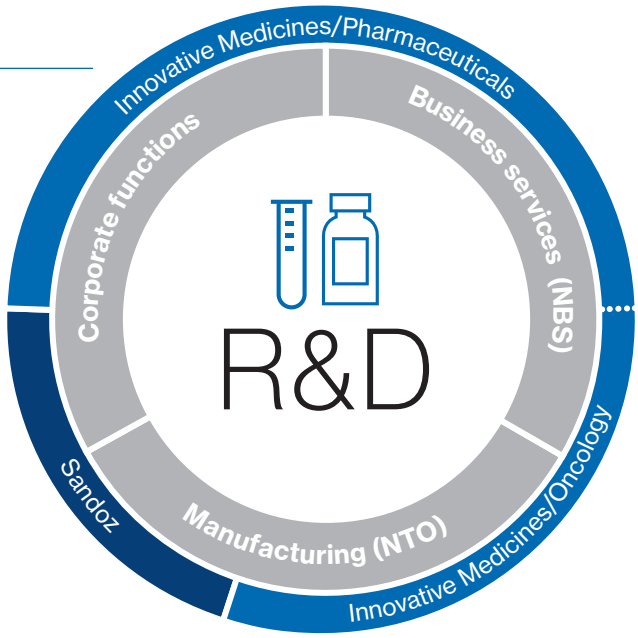
The Innovative Medicines Division has two business units:

Novartis Oncology
Novartis Oncology focuses on patented treatments for a variety of cancers and rare diseases.

Novartis Pharmaceuticals
Novartis Pharmaceuticals focuses on patented treatments in multiple disease areas to enhance health outcomes for patients and offer solutions to healthcare providers.

SANDOZ

Sandoz offers patients and healthcare professionals high-quality, affordable generics and biosimilars.



NOVARTIS TECHNICAL OPERATIONS (NTO)

is responsible for making our innovative medicines, devices and Sandoz products and delivering them to our customers across the world.

NOVARTIS BUSINESS SERVICES (NBS)

consolidates support services across our organization, helping drive efficiency, simplification, standardization and quality.

CORPORATE FUNCTIONS

support the enterprise in specific areas of expertise, including finance, human resources, legal and communications.

RESEARCH AND DEVELOPMENT (R&D)

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis. NIBR focuses on discovering new drugs that can change the practice of medicine.

The Global Drug Development (GDD) organization oversees the development of new medicines discovered by our researchers and partners.

Our culture

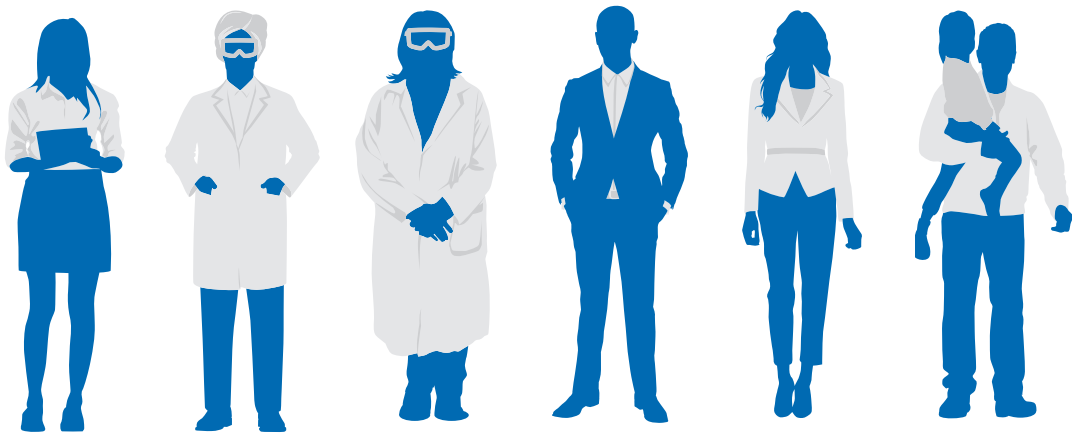
Curious
Inspired
Unbossed

Our values

Innovation
Quality
Collaboration
Performance
Courage
Integrity

Our people

The greatest strength of Novartis is our people, whose diversity, energy and creativity are crucial to our success.



HEADCOUNT	NATIONALITIES	ANNUAL TRAINING HOURS PER EMPLOYEE	WOMEN IN MANAGEMENT
108 775	149	35.8	44%

What we do

Our business model

RESOURCES WE USE

TALENTED PEOPLE
We depend on the skills and creativity of our employees to discover, develop and produce new medicines, and deliver them to patients.

FINANCIAL CAPITAL
We use cash, equity and debt to meet our financial commitments, make investments and pay dividends.

INTELLECTUAL CAPITAL
We use expertise and data to develop and market our products. We hold patents and trademarks that protect the long-term investments required for our business.

NATURAL CAPITAL
We consume energy, water and other resources to manufacture our products and operate our business.

TECHNOLOGY
We use artificial intelligence, gene editing and other cutting-edge technologies to spur innovation and increase efficiency.

INFRASTRUCTURE AND FACILITIES
We own or lease research laboratories, manufacturing sites, offices and distribution facilities around the world.

RELATIONSHIPS
We work with doctors to get effective treatments to patients. We partner with external organizations to accelerate drug discovery, develop business opportunities and expand patient access.

THE VALUE WE CREATE

JOBS
1.3 m
Indirect, induced (2018)

108 775
Own operations

SHAREHOLDER RETURNS
22.3 %
2019 total shareholder return (USD), including Alcon spin-off

6.6 bn
Total dividends paid (USD)

TAXES PAID
1.9 bn
(USD)

IMPROVED HEALTH AND WELL-BEING
67 bn
Social impact (USD, 2018), based on estimated value of health benefits to patients

ACCESS TO MEDICINE AND HEALTHCARE
799 m
Patients reached with Novartis medicines

10 m
People reached through training and health education programs

Our products

Our products address most major disease areas and are sold in approximately 155 countries around the world. Our manufacturing facilities produced 72 billion treatments in 2019.

We develop and produce innovative medicines to address patient needs in disease areas where our experience and knowledge have the potential to produce transformative treatments.

- ONCOLOGY
- RESPIRATORY
- NEUROSCIENCE
- CARDIOVASCULAR, RENAL AND METABOLISM
- IMMUNOLOGY, HEPATOLOGY AND DERMATOLOGY
- INFECTIOUS DISEASES
- OPHTHALMOLOGY

We also offer about 1 000 generic and biosimilar medicines covering a broad range of therapeutic areas. They can bring substantial savings to patients and healthcare systems, and help improve access to healthcare.

- PILLS
- INJECTIONS
- INHALERS

Our environment

We live in an era of amazing medical innovation, driven by better understanding of the genetic and biological roots of disease, and surging use of data analytics and digital technology in science and healthcare. At the same time, the world's population continues to grow and people are living longer, fueling a rise in chronic diseases. Together, these factors are increasing demand for high-quality care worldwide and pressuring healthcare systems to restrain spending growth.

ACCELERATING INNOVATION

39%

The rise in the average yearly number of new drugs approved by the US FDA's Center for Drug Evaluation and Research from 2015-2019, compared to 2010-2014

235bn

The projected value of the global digital health market by 2023 (USD), a 60% increase from 2019, according to the Frost & Sullivan Global Digital Health Outlook 2020

AGING POPULATION

997m

The projected number of people in the world aged 65 or older by 2030, a 64% increase from 2015, according to the United Nations World Population Prospects

HEALTHCARE SPENDING

5%

The expected annual average growth in healthcare spending between 2019 and 2023, according to the Economist Intelligence Unit

Our strategy

Our strategy is to build a leading, focused medicines company powered by advanced therapy platforms and data science.

As we implement our strategy, we have five priorities to shape our future and help us continue to create value for our company, our shareholders and society.

STRATEGIC PRIORITIES

Unleash the power of our people

We are transforming our culture to ensure people can fully apply their talent and energy. We're creating an organization where people are inspired, curious and unbossed.

Deliver transformative innovation

In our pursuit of transformative treatments, we challenge medical paradigms and explore possibilities to cure disease, intervene earlier in chronic illnesses, and find ways to dramatically improve quality of life.

Embrace operational excellence

We are rethinking how we work, embracing agile teams and building better productivity into our company to free resources that we can invest in innovation and help boost returns.

Go big on data and digital

We aim to spark a digital revolution at Novartis, embracing digital technologies, advanced analytics and artificial intelligence to help drive innovation and improve efficiency.

Build trust with society

We strive to build trust with society through our efforts to operate with integrity, and to find new ways to expand patients' access to our treatments.

- **Holding ourselves to the highest ethical standards**
- **Being part of the solution on pricing and access**
- **Addressing global health challenges**
- **Being a responsible citizen**

We aspire to be a leader on environmental, social and governance topics and to build trust with society. In the long run, that's what will enable us to continue reimagining medicine

Vas Narasimhan

Message from the CEO

Dear reader,

Thank you for taking the time to learn more about how Novartis continues to make meaningful progress on environmental, social and governance (ESG) topics. We've long been on this journey, including as a founding signatory of the United Nations (UN) Global Compact, and as our world changes and grows increasingly complex, we continue to evolve and advance our perspective and approach to building trust with society.

Our ESG-related commitments are not add-ons to our business – they permeate Novartis to the core – and we are owning this journey at the most senior levels of the company. In 2019, we established a Trust & Reputation Committee, which I personally chair, to review our ESG performance. Building trust with society has been elevated as one of our top strategic priorities, and within that priority we are focused on four key areas, which I believe are critical for our strategy and our contributions to the world: access to medicines, global health, ethical standards and responsible citizenship.

Within that framework, I wanted to share some of our ESG highlights from 2019:

To widen access to medicines, we continued to implement our pioneering Access Principles to enable populations around the world to access the latest medical innovations, and we continued to ensure responsible, value-based pricing, including global tiered pricing based on national income. We also announced plans to shift from maximizing profit to maximizing access in sub-Saharan Africa, which has the world's most underserved patient population.

We made significant progress in global health, including on our efforts to eliminate leprosy and malaria. Additionally, with the Ghanaian government and the Sickle Cell Foundation of Ghana, we launched a first-of-its-kind partnership to improve care for people with sickle cell disease.

Focusing on ethical behavior, we rolled out an integrated approach to enterprise risk management (known as the Novartis Risk Compass) and further embedded principles-based decision-making frameworks throughout our business, including through country-specific workshops.

Related to responsible citizenship, we made significant progress toward making good on the promises we made in signing the UN Equal Pay International Coalition (EPIC) pledge for pay equity. Our teams also took important steps to help ensure we meet our commitment to become carbon neutral in our own operations by 2025.

There's much more to share, and our 2019 report provides an update on our commitments but more importantly on our actions. We understand our contributions must be part of a larger social movement, as the challenges society faces are too great for any group or government to solve alone. I hope the following pages will inspire you to join us on our journey to forge a healthier, more sustainable future.

Sincerely,

Vas Narasimhan
Chief Executive Officer

Global Health & Corporate Responsibility at Novartis

Our Global Health & Corporate Responsibility journey

The Novartis purpose is inherently a social one: We reimagine medicine to improve and extend people's lives. We develop breakthrough therapies and aim to deliver them to as many people as possible. Over the past 20 years, our company has evolved its approach to corporate responsibility, moving beyond philanthropic initiatives to strategically integrate access in our core business operations. In 2018, we changed the name of the function to Global Health & Corporate Responsibility (GH&CR), and in 2019, we took important steps to create a new GH&CR organization and launched a three-year strategy.

Our strategy rests on five pillars and is rooted in one of the five corporate priorities: building trust with society.

1 Guide the implementation of the Novartis Access Principles in the areas of research and development (R&D), affordability and pricing, and health system strengthening

2 Drive end-to-end strategies for the elimination or control of four diseases where there has been market failure and little investment in R&D: malaria, leprosy, sickle cell disease and Chagas disease

3 Implement a new strategy for sub-Saharan Africa focused on reaching more patients and expanding the availability of our full portfolio of medicines

4 Deepen our company's role as a responsible citizen with a greater focus on social impact valuation, CR materiality assessment, corporate volunteering and environmental stewardship

5 Expand our engagement with key stakeholders, with robust reporting to support transparency and accountability

As we strive to build a leading, focused medicines company powered by advanced therapy platforms and data science, we're confident that our new GH&CR strategy will accelerate our journey to build trust and maximize our positive social impact everywhere Novartis does business.

Our annual progress and aspirations for the future are reflected in this report, which is organized around our four key GH&CR focus areas:

- Holding ourselves to the highest ethical standards
- Being part of the solution on pricing and access to medicines
- Helping tackle global health challenges
- Being a responsible citizen

We are committed to taking real, measurable and reportable action in these key areas, and making sure that we communicate about them clearly and transparently. We are also determined to learn from and share our experience. In 2019, we introduced new management targets covering environmental, social and governance (ESG) topics such as the environment, access to medicines, global health, human rights and third-party risk.

Identifying our key issues

As a global innovator, we strive to expand our focus beyond financial results to create long-term value along our entire value chain. One way we approach this is through our corporate responsibility materiality assessment to understand what matters to our stakeholders and how they perceive our impact. It allows us to capture non-financial issues, such as social and environmental impacts, and prioritize issues to focus on. We conducted our third global materiality assessment in 2017. The results identified four material CR issue clusters: access to healthcare, innovation, patient health and safety, and ethical business practices. Within these clusters, priority topics were identified. These topics are at the core of the four GH&CR focus areas outlined above, and are covered in the following sections of this report.

Our organization

NOVARTIS SOCIAL BUSINESS

brings together our flagship global health priorities, our work in noncommunicable diseases and our social business commercial operations

NOVARTIS FOUNDATION

focuses on how data, digital and artificial intelligence can transform global health

SUB-SAHARAN AFRICA UNIT

a ims to maximize patient reach across income levels by focusing on affordability strategies and social business models

HEALTH SYSTEM STRENGTHENING AND INNOVATION

serves as a center of excellence for capacity-building, partnerships, digital solutions and innovation in global health

CORPORATE RESPONSIBILITY INITIATIVES

encompass employee engagement and volunteering, as well as measurement and evaluation efforts, including impact valuation

Streamlining our governance

In March, Novartis established an internal Trust & Reputation Committee as a sub-committee of the Executive Committee of Novartis. Chaired by our CEO, it oversees progress and aims to accelerate decision-making in key GH&CR areas. This was followed in May by the launch of our new GH&CR organization, which is now responsible for end-to-end execution of the company's global health priorities, from discovery through development to implementation. The new setup will help achieve a stronger focus on the areas where Novartis can have the greatest impact.

Novartis Social Business and the Novartis Foundation were integrated into the GH&CR organization, and a new team was created to focus on health system strengthening and innovation. Most recently, we announced a new unit in sub-Saharan Africa, bringing together the expertise and portfolio across divisions and business units.

The Governance, Nomination and Corporate Responsibilities Committee (GNCRC) of the Board of Directors continues to oversee the company's strategy and governance on GH&CR topics. Our approach to patient access in sub-Saharan Africa and ESG targets were among the topics discussed by the GNCRC in 2019 (see page 180 of the Annual Report 2019).

The Group Head of Global Health & Corporate Responsibility continues to report to the CEO of Novartis. The GH&CR leadership team includes representatives from the business divisions and relevant functions.

Engaging with stakeholders

Novartis continues to engage with a wide range of stakeholders, including patients and caregivers, associates, healthcare providers, governmental organizations, nongovernmental organizations (NGOs), shareholders and other financial market participants, local communities, and partners from the pharmaceutical and other industries.

In March, Novartis Social Business convened its first pan-African stakeholder dialogue in Kampala, Uganda. The event brought together more than 160 attendees from 12 African countries spanning faith-based organizations, NGOs, government agencies, private sector firms, patient organizations, the media and health technology companies to discuss strategies to achieve universal health coverage in Africa.

In May, our CEO addressed the annual Shared Value Leadership Summit in Boston, Massachusetts, in the US. He presented the company's approach to embracing shared value as a driver of both business strategy and cultural transformation.

In September, we held our sixth ESG investor event, including a physical event for the first time, in addition to a webcast. The event was hosted by our CEO and included our Chief Ethics, Risk & Compliance Officer, as well as the Group Head of Global Health & Corporate Responsibility and the Chief Operating Officer for Global Health. Senior management attendance highlighted our company's commitment to trust and reputation priorities.

Also in September, Novartis and the Novartis Foundation were headline sponsors of Intelligent Health's AI in Medicine Summit in Basel, Switzerland, which was attended by 2 000 clinicians, technologists, business executives and entrepreneurs. Delegates discussed the future of artificial intelligence (AI) and its potential to revolutionize healthcare.

In addition, we conducted three materiality assessment webinars on evaluating social materiality by measuring outcomes, capturing intangible risks of global trends, and focusing on the United Nations (UN) Sustainable Development Goals. Approximately 60 participants, including representatives from industry, NGOs, and access-related and sustainability groups, as well as investors, dialed into each webinar, which featured both internal and external speakers.

Novartis also engages in dialogue with policymakers and other external stakeholders. Providing policymakers with data and insights enables informed decision-making conducive to improving patient outcomes. We also work closely with trade associations and participate in industry initiatives, which create opportunities to raise industry standards and exchange best practices. A list of our memberships can be found in the appendix on page 63.

Novartis makes financial contributions to support political dialogue on issues of relevance to the company or to certain government projects (e.g., for capacity building). Such contributions need to be fully compliant with applicable regulations, and we only make political contributions in countries where such contributions by corporations are both legal and generally considered appropriate. We publish the amounts of these contributions on our website and, for the US and Switzerland, in the Novartis in Society US and Novartis in Society Switzerland reports, respectively.

Measuring and valuing our total impact

We work with partners to establish methodologies to measure the total impact of our business activities. For example, we are currently working on valuing the social return on investments at the intersection of community health and the local environment. We are also exploring ways to better assess social risks in our supply chain beyond those associated with living wages.

In February, Boston University (BU) published the midline measurement and evaluation results on Novartis Access, our program that offers a portfolio of medicines for noncommunicable diseases at the price of USD 1 per treatment, per month, in low- and middle-income countries. BU evaluated the program in Kenya, the first country to receive the program. More details on the results and how we are adjusting our business model based on the learnings can be found on page 25.

We are a founding member of the Value Balancing Alliance, an association developing a standard model for measuring and disclosing the environmental, human, social and financial value companies provide to society. We are also a member of the Impact Valuation Roundtable, an informal group of more than a dozen international companies that wish to develop and operationalize the emerging field of impact valuation. In December, we hosted an event on co-creating social impact, held on the Novartis campus in Basel. It featured Robert Eccles, from Saïd Business School at the University of Oxford, and was moderated by John Elkington, from Volans, who chairs our Impact Valuation Advisory Council.

Novartis financial, environmental and social impact 2018

Indicator	Results [1]	Remarks
Financial		
GDP contribution	USD 102 bn	Own operations USD 58 bn, indirect impacts USD 20 bn, induced impacts USD 24 bn
Employment [2]	1.3 m	Own operations 125 000, indirect 360 000, induced 940 000
Economic inefficiencies		Not valued in 2018 – no methodology available
Total taxes		Not valued globally in 2018
Environmental		
Climate, energy and air pollution	(USD 4.4 bn)	Own operations USD 210 m, indirect USD 1.5 bn, induced USD 2.7 bn
Water and waste	(USD 1.0 bn)	Own operations USD 32 m, indirect USD 282 m, induced USD 530 m, downstream USD 150 m
Other environmental impacts		Land use, biodiversity not valued in 2018
Social		
Living wages	USD 4.5 bn	Own operations USD 600 m, indirect USD 3.9 bn
Employee development	USD 375 m	Own operations
Occupational safety	(USD 3.7 m)	Own operations, including third-party personnel
Other human capital impacts		Employee well-being, voluntary turnover, human rights beyond living wages not valued in 2018
Products	USD 67 bn	Large part of the Innovative Medicines portfolio in 117 countries

[1] Data represent continuing and discontinued operations.
[2] Total excludes own operations.

In parallel, we further developed the Novartis financial, environmental and social (FES) impact valuation approach. We now have FES impact data available for all countries where Novartis operates. In addition to gaining insights on the impact they create, several countries are using impact valuation to engage with stakeholders and communicate results through different channels, including brochures, fact sheets and stakeholder events.

In 2018, this approach showed that our activities contributed USD 102 billion to the global gross domestic product (GDP), as well as an estimated 1.3 million jobs beyond those held by our own employees. In addition, our human capital impact – including employee development, occupational safety and living wages – was valued at USD 4.8 billion, with USD 4.5 billion coming from the social impact of living wages in our own operations and the entire supply chain, and USD 0.3 billion coming from employee development and occupational safety. At the same time, we are taking steps to minimize our negative environmental impact, as measured by the carbon, other air emissions, water and waste impacts of our own operations and supply chain, which were valued at USD 5.3 billion. We also calculated the social impact of a large part of our Innovative Medicines portfolio in 117 countries, amounting to USD 67 billion in 2018.

Indirect impacts in Switzerland

In Switzerland (Basel), where we are headquartered, Novartis offers jobs not only directly but also indirectly as a buyer of goods and services from suppliers, including many small- and medium-sized enterprises. In 2019, the company placed orders worth about CHF 2.7 billion with companies in the 26 Swiss cantons. Major areas of procurement include laboratory equipment, information technology products and services, raw materials, building costs, fixtures and fittings, and chemical products. More information on our impacts is available in the Novartis in Society Switzerland report to be published in February 2020.

Contributing to the UN goals

We have a long-term commitment to support the UN in achieving its development goals, starting with the Millennium Development Goals and, since their adoption in 2015, the Sustainable Development Goals (SDGs). As a leading healthcare company, ensuring good health and well-being (goal 3) is at the core of our business and is aligned with our purpose of reimagining medicine to improve and extend people's lives. Through our business operations and ongoing activities, we make essential contributions to goal 8 (decent work and economic growth), goal 9 (innovation and infrastructure), and goal 13 (climate action). We harness the power of partnerships (goal 17) to discover and develop breakthrough treatments and deliver them to as many people as possible. In 2019, we made further progress to help increase our contributions to goal 5 (gender equality), and our ambitious environmental sustainability strategy and targets align with goal 6 (clean water and sanitation), goal 7 (affordable and clean energy), and goal 12 (responsible consumption).

As an original signatory of the UN Global Compact (UNGC), we are committed to sharing our progress in implementing the 10 principles of the compact. This report serves as our UNGC Communication on Progress. We published a Communication on Progress in the first quarter of 2019, and will do so again in 2020.

A mapping of our activities against the SDGs and the UNGC principles can be found in the GRI Content Index on page 55 of this report.

Expanding access to as many people as possible

Patrice Matchaba, M.D., heads Global Health & Corporate Responsibility (GH&CR) at Novartis. He is driving the implementation of the new GH&CR strategy, including embedding the Novartis Access Principles in the way we operate.

Why did Novartis transform its GH&CR organization?

The new GH&CR organization is now responsible for end-to-end execution of our global health priorities, from discovery through development to implementation. I believe the new setup will help achieve a stronger focus on the areas where Novartis can have the greatest impact.

Why did Novartis launch a sub-Saharan Africa unit in 2019?

Traditionally, the pharmaceutical industry has targeted patients and healthcare systems that could incur the costs associated with innovation. Donations took care of the poorest. In the past two years, through Novartis Social Business, we tested a new business approach in certain African countries to reach patients across the full income pyramid in a way that was financially sustainable for our company. We have seen this approach works and have decided to scale it up massively through a dedicated sub-Saharan Africa unit that will help broaden patient reach and availability of our entire portfolio of medicines in the region. Importantly, moving forward, we will prioritize driving access to medicines, in addition to pure financial metrics.

What is Novartis doing to bring innovative drugs faster to patients in the developing world?

We are working hard to ensure that the drugs we launch in Europe and the US reach developing markets faster. In the past, on average, it took around 10 years before a drug approved in these regions reached the developing world. We are aiming to bring this down to 12 months or less. In some instances, we have even been able to reduce this timeframe to five months. We clearly need to include the developing world in the innovation cycle.

How can Novartis expand access to healthcare in areas of market failures?

One important part of our access strategy is to focus on so-called areas of market failure, when economic and social framework conditions are too weak for companies to set up sustainable business strategies. Two fields in which Novartis has been working for years are malaria and leprosy. In the case of malaria, we are not only providing access to our therapies, but we are also actively discovering and developing new treatments to support the global effort to eliminate malaria. Likewise, in leprosy, we are working to eliminate this disease together with our partners, including Microsoft, which will support us with best-in-class digital technologies. In addition, we launched two new projects to tackle sickle cell disease and Chagas disease, where there has been little innovation for the past 100 years.

Social inequalities are growing around the world. How is Novartis helping to close equality gaps?

Simply put, healthier lives offer more equal opportunity. Social inequalities and health inequalities go hand in hand. Every child who is relieved of the burden of leprosy, malaria or sickle cell disease has the chance to go to school and get an education. Every successfully treated child relieves families and communities from the burden that disproportionately hits underprivileged populations.

How does impact valuation contribute to value creation?

The central question we need to ask ourselves is which metrics can best valuate what matters to all stakeholders beyond shareholders – from customers to vendors through to employees and society. The scope for impact valuation is broad, so we need a standardized approach that will enable us to compare results. With this in mind, Novartis became a founding member of the Value Balancing Alliance in 2019. For any company that cares about long-term value creation, it is meaningful to be part of this journey.

Photo Matteo Almeida, 4, with his mother, Nicole. Matteo was born with spinal muscular atrophy, a rare genetic disease that leads to progressive muscle weakness.

STRATEGIC AREAS

Holding ourselves to the highest ethical standards

Why is it important?

Research consistently shows that public trust in the pharmaceutical industry remains low. As society's expectations continue to grow, building trust with patients, physicians and other stakeholders is critical to delivering on our purpose, as well as long-term financial performance. Addressing allegations with respect to legacy conduct related to business practices and relationships to healthcare professionals is an important part of this journey. At the same time, Novartis engages with an extensive network of suppliers worldwide. It is of paramount importance that our goods and services are ethically sourced, and that we help ensure that companies we do business with also meet the standards for ethics and business integrity that are expected.

In this section

Read about our journey to strengthen ethics, risk, compliance and assurance at Novartis:

Risk management

Completed the global rollout of the Third-Party Risk Management program and introduced the Novartis Risk Compass, providing a holistic view of risk across the company

→ p. 15

Human rights

Introduced a five-year human rights strategy while integrating the function with Third-Party Risk Management

→ p. 16

SpeakUp

Transformed our SpeakUp Office to decentralize the way we manage whistleblowing and enable further focus on higher-risk cases

→ p. 17

Code of Ethics

Announced the co-creation by associates of a Code of Ethics to be launched in 2020

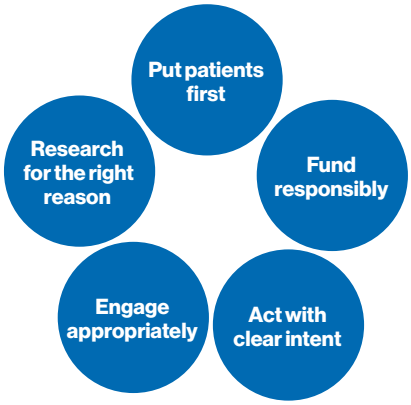
→ p. 18

Klaus Moosmayer Chief Ethics, Risk & Compliance Officer

When it comes to ethics in society, we win together or we lose together. Whether we are a private company, the public sector or an NGO, we all are society and have to overcome silo thinking and work together for the same goals. If we talk and listen to each other, understand and respect each other`s perspective, and form integrity alliances, we can make a difference in the fight against unethical behavior – for the benefit of all of us and especially the ones who need it most, our patients.

P3 PRINCIPLES

Novartis has adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis associates



Our approach and performance

We aspire to be a trusted leader in changing the practice of medicine. We are committed to meeting the highest ethical standards in what we do, and we are taking steps to earn and maintain the trust of patients, associates, partners, shareholders and society. As part of the company's cultural transformation, we continue to strengthen the tone from leaders, support constructive principles-based discussions, and guide the decision-making of our associates. Our aim is to prevent issues from occurring, drive personal accountability for behaviors, and generate learnings that can be applied across the organization. In addition, we maintain a strong commitment to upholding human rights and managing risk in our supply chain. We began this journey some years ago, and we continue to make progress.

We believe that our efforts, detailed in the following section of this report, continue to show positive results. In 2016, we adjusted the ratio of fixed to variable total compensation for our sales force to help ensure that the target variable component is a maximum of 35% of total compensation, on average across all countries. In addition, 20% of target variable pay for the sales force is based on demonstration of our Values and Behaviors. These standards have now been implemented across countries and divisions.

Although even the best system may not be able to entirely prevent individual misconduct, we have seen an 11% reduction, across divisions, in the number of reported complaints of fraud (fraud/asset misappropriation; expense fraud; books and records, accounting irregularities) and improper professional practices in the sales force in 2019 compared to 2018. We will continue to rigorously investigate all plausible complaints, take appropriate action if they are substantiated, and be transparent in our disclosures.

Our efforts are also recognized externally. Our Chief Ethics, Risk & Compliance Officer continues to chair the Anti-Corruption Committee of the Business and Industry Advisory Committee to the Organization for Economic Co-operation and Development (OECD), and was nominated in 2019 as co-chair of the B20 Integrity & Compliance Task Force.

Strengthening our governance

In 2018, we combined our risk management and compliance functions into a single organization called Ethics, Risk & Compliance (ERC) to help enable more effective risk management and mitigation efforts. We continue to increase the number of country and monitoring visits as part of our risk and compliance management efforts, reaching about 250 in 2019 compared to 220 in 2018.

In addition, we continued strengthening the function by integrating human rights and Third-Party Risk Management (TPRM). With this move, the collaboration between the TPRM team and the ERC function helps provide greater transparency around one of our key risks: third parties. The ERC function is responsible for the governance of the TPRM program, while Novartis Business Services has operational responsibility. Because of the elevated human rights risks when dealing with third parties, we merged our human rights and TPRM program into one function named Human Rights & Third-Party Risk Management. This will help ensure more effective human rights due diligence in our supply chain and ingrain human rights further into our core business practices and strategies across our markets. Our human rights management team now includes a Head of Human Rights and a Manager of External Assessments and Engagement.

We also created a new function for risk and resilience that brings together the former Risk Office, Risk Assessment and Monitoring, Business Continuity Management and Novartis Emergency Management, in order to establish a comprehensive and integrated risk management framework that is coordinated among risk functions and business units. The Risk Committee of the Board of Directors is responsible for overseeing the risk management system and processes (see page 182 of the Annual Report 2019).

In January 2019, we created Novartis Business Assurance & Advisory (NBAA). This independent corporate function brings together Global Security, the SpeakUp Office and Internal Audit, enabling us to leverage our resources and data, providing insights and protection, and acting as cultural change agents. NBAA offers insight, assurance and advice to the business, senior management and the Board of Directors.

By sharing insights from speak-up cases, audits and advisory engagements more broadly across the company, NBAA plays a key role in helping Novartis identify both best practices and important lessons learned that can be applied to every market in which we operate. Additionally, with continued learning and certification activities, we are further developing the professional standards of our teams. We plan to expand these efforts in 2020.

Improving risk management

The Risk & Resilience team introduced an innovative, integrated enterprise risk management (ERM) approach. The process is a series of coordinated activities designed to detect and control risks. It is based on risk discussions conducted by the leadership teams of business units at the global level in alignment with their own strategic planning processes, and in close collaboration with all risk functions within units and countries.

In 2019, we held a focused cross-divisional risk workshop linked to the strategic planning process. We also launched risk workshop pilots with our local businesses and the relevant risk functions in 10 countries across Africa, Asia, Europe and the Americas. Ultimately, business leaders and function representatives came together to discuss and consolidate the Novartis business risk portfolios; insights and advice from NBAA, including Internal Audit; and insights from the external business environment.

This process resulted in a single holistic view of risks across the company, known as the Novartis Risk Compass, which summarizes the key risks across four important dimensions: strategic, operational, emerging and awareness risks. The compass will help enable senior management and the Novartis Board of Directors to focus discussions on key strategic risks and more closely align the company strategy, our risk exposure and our ways of working.

Managing risk in our supply chain

One of our key risk areas is within our supply chain and our interactions with third parties. Our approach has evolved over time, and a few years ago, we identified the need for an integrated model, applicable across Novartis divisions and geographies. This realization led to the launch of the TPRM program in 2016.

TPRM assesses whether companies we do business with meet the standards for ethics, business integrity and environmental sustainability that we expect. It uses one end-to-end assessment process, one technology solution and a centralized operating model to deliver consistency and rigor, embed compliance and increase transparency. It covers seven risk areas: anti-bribery; animal welfare; health, safety and environment (HSE); labor rights; information security; data privacy; and quality for good manufacturing practices.

TPRM was introduced in the first country, Mexico, in late 2018. A key learning for the subsequent global rollout was the importance of local language materials and support. Since launch, we have conducted more than 100 training sessions for our people in the US, Latin America and Canada. In April 2019, the program went live in those regions, followed by 32 countries in Asia-Pacific, the Middle East and Africa. In July, we implemented the final wave in Europe, including Turkey and Russia. The completion of the global program rollout

The Novartis Risk Compass

STRATEGIC RISKS

Risks that are most consequential to the company's ability to execute its strategy or achieve its business objectives

EMERGING RISKS

Identified risks with the potential to become operational or strategic risks. Require close monitoring

OPERATIONAL RISKS

Risks resulting from inadequate or failed internal processes and/or systems, employee errors or external events

AWARENESS TOPICS

Trending topics that are not yet accounted for by Novartis risk management but that have the potential to become new risks

Supply chain performance indicators[1,2]

	2019	2018	2017
Suppliers posing an elevated risk under responsible procurement (RP)/Third-Party Risk Management (TPRM)[3]	**734**	347	436
Suppliers with active follow-up[3,4]	**122**	89	265
Suppliers audited[3,5]	**135**	48	49

[1] Data represent continuing operations.
[2] Data reflect responsible procurement (RP) and Third-Party Risk Management (TPRM) programs from January to July 2019, and the TPRM program only from August to December 2019. As of August 2019, after completion of the global TPRM program rollout, the RP program was officially retired.
[3] Includes new suppliers and new products, services or sites from existing suppliers. Figures include data on labor rights; health, safety and environment; and animal welfare.
[4] Follow-up includes more information requested, audits or on-site assessments.
[5] High-level audits

marked the official retirement of our former responsible procurement (RP) program, as of August 2019.

Under this new operating model, we believe we will be able to continuously scan for new risks, proactively take corrective measures where needed, and deliver continuous improvement in our supply chain. We expect to incorporate our entire supplier base into the program in the next three years. In addition, by integrating human rights into our daily procurement activities, we will be in a better position to assess human rights risks and the impact of breaches where third parties operate. We believe this will enable us to improve human rights management in the supply chain overall.

In parallel, we already kicked off the next level of improvement for TPRM. We are working to further strengthen compliance and facilitate integration with business operations. In particular, we held workshops to analyze the new system and identify opportunities to shorten turnaround time, and improve risk targeting and risk triggering to further optimize supplier prioritization. Based on these recommendations, we aim to expand the program's scope in 2020 to include distributors and wholesalers, as well as additional new risk areas covering third-party business continuity management and financial risk.

In 2019, through the TPRM rollout, we expanded the scope and enhanced the assessment of certain risk areas, such as labor rights and environment. As a result, we were better able to identify risk in our supply chain: 734 suppliers were identified as posing an elevated risk, compared to 347 in 2018. Of these, 122 have active follow-up actions, including more information requested, audits or on-site assessments. Additionally, 135 high-level audits of suppliers were conducted in 2019; these represented 100% of those identified as requiring follow-up actions, as well as some additional audits related to animal welfare. These data reflect both the RP and TPRM programs from January to July 2019, and the TPRM program only from August to December 2019.

The Novartis Third-Party Code (formerly the Supplier Code) sets out our expectations for our third parties. It is aligned with the Novartis Code of Conduct and is based on the UN Global Compact, the UN Guiding Principles on Business and Human Rights, and other international standards and accepted good practices, such as those of the International Labor Organization. Novartis is also a member of the Pharmaceutical Supply Chain Initiative (PSCI) and supports its principles for responsible supply chain management for ethics, labor, health and safety, environment and related management systems. Since 2018, we have played a leading role on the board, and we chaired the PSCI in 2019.

Further integrating human rights into our business

We are implementing a five-year human rights strategy, which is based on the following elements:

- Ongoing due diligence by integrating human rights into existing processes, or creating customized risk and impact management processes
- Site-level impact assessments in high-risk markets
- Promotion of rights relevant to Novartis business objectives and leadership ambitions (aligned with our corporate responsibility materiality priorities)
- Development of business and human rights training at Group-wide and function-specific levels
- Ongoing stakeholder engagement for the continuous improvement of human rights strategy development and implementation

We have already taken concrete steps to address the risk areas identified in our 2017 and 2018 human rights assessments. Overall, we have expanded our focus on human rights risks and impacts in our supply chain and in the communities where we work. In some of the markets piloted in 2017 and 2018, we found a need to address risks associated with our outsourced workforce, which again demonstrates the importance of combining our human rights efforts with Third-Party Risk Management.

Similarly, we found in our 2018 human rights assessment that more regular and broader consultation with external stakeholders was needed at the local level (from patient groups, local communities and health authorities to supply chain partners). Therefore, in 2019, we redesigned our human rights assessment program to include direct engagement with suppliers, communities and civil society actors. For instance, our assessments in India, Singapore, Brazil and China included supplier site visits as well as interviews with communities surrounding our or our suppliers' operations, and relevant nongovernmental organizations.

Our 2018 assessment also revealed the need to help put formal grievance mechanisms and processes in place for communities living close to our manufacturing operations. With this in mind, we started a gap analysis of our Group-wide grievance system against the effectiveness criteria of the UN Guiding

Principles on Business and Human Rights. In particular, we are working with our SpeakUp Office to develop a mechanism for communities surrounding our operations and those of our suppliers to raise concerns about risks or impacts linked to our or our suppliers' operations.

To demonstrate our commitment to addressing broader issues that affect people's rights and livelihoods, we continue to take steps to prevent modern slavery – as defined in the UK and Australia modern slavery acts – in our operations and supply chains. We publish a statement explaining how we address modern slavery risks or impacts each year on our website, and have developed an e-learning module on modern slavery that will be released globally in 2020.

As we expand our resources and strengthen our efforts to protect human rights, we plan to conduct broader and more frequent consultations with patient groups, local communities, health authorities and supply chain partners throughout our operations. This will help us benchmark our efforts, measure our progress, and fulfill our ambition to become a leader in the healthcare sector for respecting and protecting the rights of people affected by our or our suppliers' operations.

Providing independent insights and advice on risks and opportunities

The Internal Audit team is an independent sounding board that provides assurance and advice to the business, senior management, and the Audit and Compliance Committee of the Novartis Board of Directors on risks and opportunities related to key initiatives and activities. The team helps Novartis reach its objectives through audits and advisory engagements that focus on strengthening governance, risk management, processes and our culture.

In 2019, audit scopes were broadened to look at processes and activities from an end-to-end perspective rather than to focus on individual themes, especially in audits of commercial units but also across research and development (R&D) and other functions. All engagements were linked to the strategic objectives of the respective units to focus on what matters and support the organization in achieving its objectives.

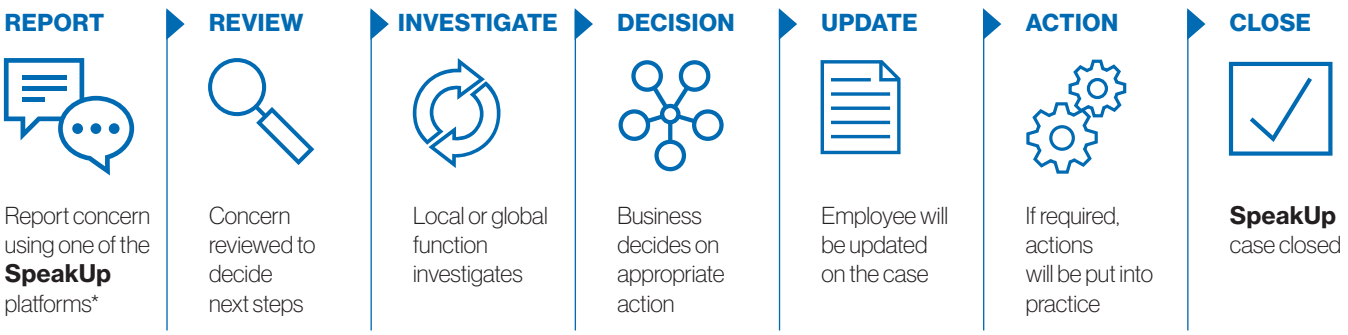
In 2019, the Internal Audit team completed 44 audits, 20 advisory engagements and 14 site visits. Complementing our assurance provision with advisory engagements enables us to bring our expertise around governance, risk management and processes to new areas and help units increase their chances of success. While also providing assurance on the activities under review, advisories are used to support units developing new approaches or deal with known challenges by strengthening their processes to manage potential risks. Advisories in 2019 included reviews in the following areas: newly acquired entities, Novartis Social Business, Group Patient Advocacy and Launch Excellence. In addition, we conducted an audit of the Innovative Medicines Division on the implementation of the Novartis Access Principles (see page 21 of this report).

Encouraging a speak-up culture

Our SpeakUp Office (formerly the Business Practices Office) underwent a transformation in 2019. The new name was chosen to better reflect the purpose of the program and the culture change at Novartis. It provides a safe place for everyone to raise concerns about potential misconduct. Complaints can be made directly to the SpeakUp Office through an externally hosted web-based platform, which offers the possibility to report anonymously. Complaints can also be raised through local channels, such as the ERC, People & Organization (P&O), and legal functions or senior management.

A revised process decentralizes the way we manage whistleblowing, enabling the SpeakUp Office to concentrate on central matters (higher-risk cases), and empowering local organizations to efficiently manage local matters (lower-risk cases). A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and financial significance. The aim is to reduce bureaucracy in local investigations and resolution processes, leading to faster handling of cases. A new web-based case management system was launched, giving more than 600 associates from the ERC and P&O functions the ability to enter, manage and track local speak-up cases on their own.

Our SpeakUp process



* Externally hosted web-based platform (web form or hotline) or via local channels, such as the ERC, People & Organization, and legal functions or senior management

Ethical business practices performance indicators[1]

	2019	2018	2017
Novartis associates trained and certified on the Code of Conduct (%)[2]	**98**	98	98
Misconduct cases (central matters) reported/allegations substantiated[3, 4]	**205 / 113**	289 / 356	525 / 519
SpeakUp Office allegations per category (% of all central matters)[5]			
Fraud/asset misappropriation	**12**	57	32
Expense fraud	**9**	11	10
Books and records, accounting irregularities	**2**	1	2
Improper professional practices	**29**	58	42
Gifts, bribery, kickbacks	**4**	6	10
Discrimination and sexual harassment	**16**	11	11
Retaliation	**13**	6	4
Other employee relation issues	**38**	21	23
Conflict of interest	**20**	13	11
IT security breach	**8**	5	6
Quality assurance/data integrity	**13**	8	12
Data privacy	**4**	1	2
Antitrust, fair competition	**0**	1	0
Other	**22**	13	18
Dismissals and resignations related to misconduct (central matters)[3, 6]	**45**	124	192

[1] Data represent continuing operations.
[2] Active Novartis associates with email addresses, trained via e-learning or via One Deck for Novartis Technical Operations
[3] Decrease in number of misconduct cases reported is due to change in methodology: As of January 1, 2019, we only report on central matters (higher-risk cases). A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and financial significance.
[4] The number of misconduct cases reported may change as matters may be reassessed in the course of the case lifecycle. The number of substantiated allegations may change due to the fact that investigation reports with assessments are received on an ongoing basis, which potentially leads to a difference in numbers at a later stage. A case can have more than one allegation and therefore the number of allegations is higher than the actual number of cases.
[5] One case can fall under several categories, so the total is greater than 100% and category figures total more than the stated number of cases. Investigation reports are received on an ongoing basis, which potentially leads to a reassessment of the allegation category and related figures.
[6] The number of dismissals and resignations related to misconduct may change due to the fact that investigation reports are received and then reviewed for remedial actions on an ongoing basis, which potentially leads to a difference in numbers at a later stage.

The revised process, which includes a SpeakUp mobile app available to all Novartis associates, will drive faster resolution by enabling leadership to respond to day-to-day concerns at the local level. Cases determined to be of higher risk are referred to the SpeakUp Office for further investigation at Group level. These changes aim to continue to drive fair, timely and thorough investigations of both local and higher-risk cases to protect Novartis associates, patients, customers, assets, brands and reputation.

In 2019, 2 309 complaints of alleged misconduct, with a total of 2 820 allegations, were made. 26% were self-identified (monitoring) and 74% came from SpeakUp. These fall under 14 categories:

- Fraud/asset misappropriation
- Expense fraud
- Books and records, accounting irregularities
- Improper professional practices
- Gifts, bribery, kickbacks
- Discrimination and sexual harassment
- Retaliation
- Other employee relations issue
- Conflict of interest
- IT security breach
- Quality assurance/data integrity
- Data privacy
- Antitrust, fair competition
- Other

Overall, the investigated central matter allegations resulted in 45 dismissals (for serious matters) or resignations, and in 51 written warnings. Other remedial actions such as training, coaching and implementing new controls are also widely used when deemed appropriate.

Creating a Code of Ethics

To further reinforce principles-based thinking and ethical decision-making in our organization and interactions with external stakeholders, we are developing a Novartis Code of Ethics. It is being co-created by Novartis associates and is planned for launch in 2020. More than 2 500 associates shared ideas and insights during early-stage crowdsourcing. A further 1 500 participated in EthicsLive, a global engagement event to encourage open conversations around ethical dilemmas at Novartis. Most recently, more than 500 associates volunteered to be part of the Voice of the Associate network that will create the code.

Addressing the *Zolgensma* data integrity issue

Novartis recognizes society's increasing expectations of our industry and our company. We are constantly learning and remain committed to not only meeting but exceeding these expectations as we endeavor to increase our positive impact everywhere we work. It is with this mindset that we approached the situation when, in August, the US Food and Drug Administration (FDA) released a statement addressing data integrity issues with the regulatory submission for *Zolgensma*, our gene therapy for spinal muscular atrophy. The statement followed the voluntary disclosure by AveXis, a Novartis company, to the FDA and to other health authorities that some data previously submitted to the agency as

part of our submission were inaccurate. The assays in question were used for initial product testing and are not currently used for commercial product release.

We immediately initiated an investigation to understand any implications and address the situation. At no time during the investigation did the findings indicate issues with product safety, efficacy or quality. As noted by the FDA, the data in question were a small portion of our overall submission and limited to an older process no longer in use.

We have a firm commitment to data integrity and transparency in our engagements with regulators, and we are confident that the actions we are taking will prevent data integrity issues from occurring in the future. We swiftly proceeded to implement leadership changes in the AveXis research and development organization, while also taking steps to integrate the AveXis quality organization more formally in the Novartis quality organization. Going forward, and taking the important learnings from this experience, we have voluntarily committed to notify the FDA within five business days of receipt by our quality organization of any credible allegation related to data integrity issues impacting any pending application in the Novartis Group. We will take a similar approach with other regulatory bodies in the absence of specific local regulations.

Working to address legacy issues

We are continuing our work to address certain legacy matters arising from past conduct. We are committed to cooperating with health authorities and relevant stakeholders in any ongoing investigations and, where appropriate, finding resolutions that will allow us to focus our efforts on reimagining medicine to improve and extend people's lives. Should wrongdoing be found, we will take fast and decisive action, and do everything possible to prevent its recurrence.

In Greece, Novartis is the subject of investigations both locally and in the US related to allegations going back to 2006 concerning potentially inappropriate economic benefits to government officials and healthcare professionals. While these matters remain ongoing, it is important to note that with respect to the allegations frequently repeated in the Greek media, Novartis has to date been unable to identify inappropriate payments made to government officials.

Novartis is also working to resolve a civil suit pending in the US District Court for the Southern District of New York challenging speaker programs and other promotional events conducted from 2002 through 2011 by Novartis Pharmaceuticals Corporation (NPC), a US subsidiary of Novartis AG. The company provisioned USD 700 million in the second quarter of 2019 for a potential settlement, and discussions remain ongoing.

Finally, Novartis continues to investigate allegations made against Sandoz, Fougera and other generic pharmaceutical companies in the context of federal and state government antitrust investigations and civil antitrust lawsuits in the US concerning the pricing of generic drugs going back at least to 2011. Novartis is cooperating with these investigations, which it believes to be part of a broader inquiry into industry practice. While prices of pharmaceuticals are subject to a broad range of factors, market data show that average prices in the generics industry have been going down year after year. The company takes its obligations under the antitrust laws seriously and is committed to conducting business with customers and the government with integrity. Our Fair Competition Policy applies to all Novartis associates, who are responsible for attending relevant training sessions and adhering to the principles and rules set out in the policy. Our last global e-training was held in 2018 with a 95% completion rate. Breaches of competition law are not tolerated and can lead to disciplinary and other actions, including termination of employment.

Commitment to transparency and disclosure

For many years, transparent reporting and disclosure has been a central part of our commitment to doing business responsibly. As the transparency landscape rapidly evolves, Novartis is keeping pace with developments and is committed to meeting new transparency requirements. We publish the Novartis in Society report and the Novartis in Society US report annually, and introduced the Novartis in Society Switzerland report in 2019. We aim to have more of our affiliates produce localized reports over the coming years.

We disclose payments and other transfers of value made to healthcare professionals and organizations in Europe, in line with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code. We also encourage healthcare professionals to consent to individual disclosure as part of their commitment to medical integrity. Additionally, we disclose spend within the scope of transparency codes in Australia, Brazil, Canada (voluntary disclosure), Israel, Japan, Saudi Arabia and the US. In Indonesia, spend is reported to the Ministry of Health, and in South Korea, spend is gathered and shared with the Ministry of Health upon request. These approximately 40 local reports are available on our website. We have prepared to report in line with requirements in Bosnia-Herzegovina, Colombia and North Macedonia, and are continuously working to prepare for disclosure of our spend as regulations and the industry evolve.

Novartis also discloses monetary and non-monetary support to patient organizations around the globe by June 30 every year, in compliance with the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations set by the EFPIA. These payments are also available on our website.

We fully support the publication of clinical study results. Our policy is to not withhold, veto or suppress data. We make every effort to comply with national and international standards for disclosure of clinical trial information, and we are committed to the timely disclosure of the design and results of all interventional clinical studies for innovative treatments in patients. Results are made publicly available, regardless of their outcome. In a recent BMJ publication, based upon an analysis of novel drugs approved in 2015, Novartis achieved an overall score of 99 out of 100 for clinical trial transparency.

Photo Kwaku Ohene-Frempong (left), a physician, speaks with a mother at Kumasi General Hospital in Ghana. Dr. Ohene-Frempong is head of the Sickle Cell Foundation of Ghana.

STRATEGIC AREAS

Being part of the solution on pricing and access

Why is it important?

Our medicines reach nearly 800 million people worldwide each year, and yet the need is far greater. The World Health Organization (WHO) estimates that 2 billion people lack access to quality medicine and healthcare. And the problem extends beyond developing countries. Affordability is a key challenge, with around 100 million people impoverished by medical expenses each year. About 28% of Americans under age 65 have no health insurance, and nearly 1 in 10 forego care or medicine because of cost. We can and must do more to make our medical innovations available to as many people as possible. We must challenge ourselves to go beyond global pricing strategies that are sometimes limited in impact due to local taxes, markups and distribution costs, and drive innovative financing solutions and distribution mechanisms for our portfolio of therapies, including emerging medical breakthroughs, such as cell and gene therapies.

In this section

Read about our approach to pricing and access, and our progress in implementing the Novartis Access Principles:

Innovative brands

Introduced outcome-based agreements for *Kymriah*, a managed access program for *Zolgensma*, and more than 10 new local brands for our innovative therapies

→ p. 23

Social business

Reached more than 15 million patients with medicines, and more than 10 million people with health education in 2019

→ p. 25

Sub-Saharan Africa

Announced a new strategy to reach more patients in sub-Saharan Africa with our portfolio of medicines

→ p. 26

Healthcare workers

Co-led an industry effort to expand the training of frontline health workers in developing countries

→ p. 29

Patrice Matchaba Group Head, Global Health & Corporate Responsibility

Access to healthcare has for a long time been defined by donations. But as I know from my own experience both growing up in Africa and as a practicing physician, this can often lead to dependence, and worse, to corruption. If we really want to change something, we need to include the developing world in the innovation cycle. This is what will open new possibilities.

Our approach and performance

As a global medicines company, we embrace our responsibility to society to help ensure our innovative treatments benefit more people who need them, no matter where they live. This is an important measure of our success, and we strive to create long-term value for healthcare systems, society and our company.

No. 2

In the 2018 Access to Medicine Index, up from third position in 2016

Novartis has a long legacy in delivering novel access-to-medicine programs. Our approach has evolved over several decades and has helped us understand the intricacies of health systems. In 2017, we made a fundamental shift in the way we do business and embarked on a journey to reimagine access to medicine. We established the Novartis Access Principles to systematically integrate access strategies into how we research, develop and deliver our new medicines globally. The Access to Medicine Foundation recognized our efforts in this area by ranking us second in the 2018 Access to Medicine Index, up from third in 2016.

In 2019, we conducted an audit of the Innovative Medicines Division on the implementation of the Access Principles. It showed good progress in addressing the affordability of innovative medicines and funding challenges in emerging markets. Better alignment of the currently fragmented activities aimed at strengthening healthcare systems in the countries was identified as an improvement opportunity to further increase patient reach.

To help ensure we are thinking holistically about access opportunities, we have introduced specific requirements in our drug development processes to challenge our teams to explore how we can increase health impact in low- and middle-income countries (LMICs) in terms of affordability, health system strengthening, and adaptive research and development (R&D). The Research & Development Committee of Novartis reviews all drug development submissions and holds our clinical research teams accountable for exploring these access opportunities.

This accountability rises to the highest ranks in our organization. Members of the Executive Committee of Novartis (ECN) and other senior leaders have access indicators in their annual objectives to keep our company focused on increasing our positive social impact.

In 2019, we introduced a set of targets to track our progress against the Novartis Access Principles in reaching patients in LMICs. For example, in 2020, we aim to increase the number of patients reached with our innovative medicines in LMICs by 20% versus 2019.

This journey will take time, and it will not be easy. We continue to challenge ourselves to try new approaches, and we remain committed to measuring our progress and sharing our successes and our learnings.

Developing medicines that address unmet needs

As we research and develop new drugs, we systematically assess our product portfolio against the unmet needs of underserved populations and integrate these needs, wherever possible, into our drug discovery and development strategies. We aim to evaluate and execute adaptive development initiatives that deliver incremental benefits to vulnerable patient populations, considering three main areas:

- Development of new formulations
- Expansion of the clinical use of existing medicines into new indications and populations (e.g., pediatric populations)
- Research to better understand issues of relevance for adaptive development (e.g., genetic polymorphisms)

NOVARTIS ACCESS PRINCIPLES

R&D

We systematically assess our product portfolio against the unmet needs of underserved populations and integrate these needs, as appropriate, into our drug discovery and development strategy

Affordability

We work to make our medicines available by considering both effective affordability strategies and innovative solutions to disease management

System strengthening

We seek opportunities to lower local barriers to healthcare delivery, working in collaboration with governments and other partners to support quality patient care in areas where we can have the greatest impact

We are progressing the development of a child-friendly formulation of hydroxyurea for the indication of sickle cell disease. Additionally, we have identified two sites in Ghana and two in Kenya to participate in clinical trials for SEG101 (crizanlizumab), a monoclonal antibody recently approved by the US Food and Drug Administration (FDA) as *Adakveo* to help prevent the painful and potentially life-threatening complications of the disease.

We are initiating a clinical study in Latin America to evaluate the safety and efficacy of *Entresto* (sacubitril/valsartan) to treat heart failure in people with chronic Chagas cardiomyopathy, which causes the majority of deaths and disability from the disease. This morbidity and mortality study will assess *Entresto* as a potential therapy for Chagas-related cardiac disease, an unmet medical need.

Together with Medicines for Malaria Venture (MMV), we are developing a new formulation of our antimalarial treatment *Coartem* (arthemeter/lumefantrine) to address the needs of infants weighing less than 5 kilograms, one of the most vulnerable groups affected by malaria. The clinical trial is scheduled to start in 2020.

In Pakistan, we received approval in August for a new indication for *Myfortic*, an immunosuppressive medication. It was approved for the treatment of lupus nephritis, an immune system disorder that can cause kidney failure. We are in the process of exploring registration of this indication in additional countries, including Argentina, Bangladesh and India.

In August, we submitted a study protocol to the Zimbabwean government to understand the impact of Africa-specific CYP2D6 polymorphism, a key enzyme to metabolize neuroleptics and other psychoactive drugs, on drug disposition. We aim to enroll the first patient in the clinic in early 2020. Genetic diversity is greater in Africa than in other continents, and African populations are heterogeneous with respect to these polymorphisms. This study would therefore help evaluate how certain medicines behave given genetic variations among African populations, and provide valuable insight into potential new applications for our medicines to address regional health challenges. As this is a poorly understood area of clinical research, it would also contribute to increasing the broader health community's knowledge of genetic polymorphisms, opening the door to potentially new discoveries that could help address unmet medical needs in underserved populations in sub-Saharan Africa.

In addition, we signed a five-year collaboration between Novartis and GlaxoSmithKline (GSK) to fund research into genetic diversity in different African regions, and its potential effect on therapeutics. The project, called GRADIENT (Genomic Research Approach for Diversity and Optimizing Therapeutics), aims to prioritize research to collect data from currently under-represented regions. The primary focus will be to evaluate the potential implications that genetic diversity may have on the dosing and efficacy of drugs used to treat malaria and tuberculosis in Africa.

Developing effective affordability strategies

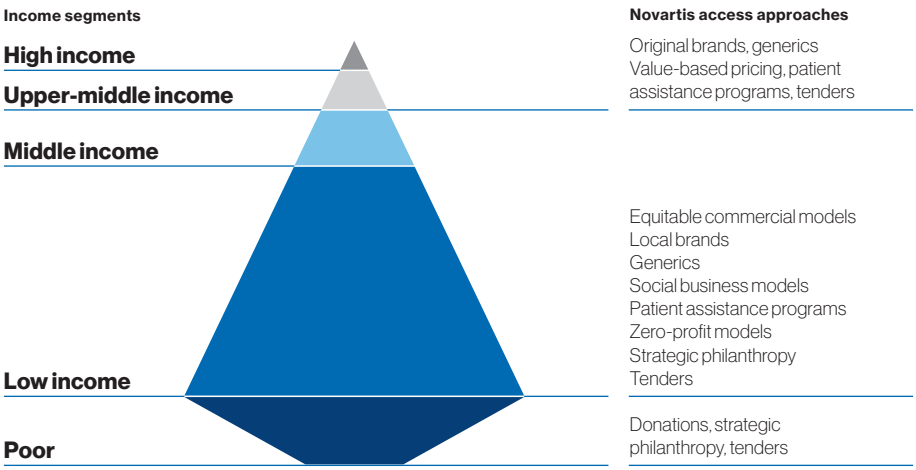
Novartis is committed to making our medicines available to the patients who need them, and pricing our new medicines responsibly based on the value they deliver to patients, healthcare systems and society.

We believe it is important to accelerate society's shift to value-based healthcare. We think medicines should be priced and paid for based on four key outcomes that they can deliver: clinical benefit, additional patient benefit (e.g., in terms of quality of life), and the benefits they offer to the healthcare system and society as a whole. We believe this approach could help focus all stakeholders on delivering the best possible outcomes while also helping systems become efficient and sustainable.

Novartis was among the first pharmaceutical companies to enter into value-

NOVARTIS ACCESS FRAMEWORK

Our access framework can be adapted to the needs of people across income segments



Measuring the value of our medicines

In 2019, we developed a new modeling tool, the Novartis Health Footprint, to capture the impact of some of our medicines on patient-relevant outcomes. We intend to share this information with insurance companies, local governments and decision-makers in the healthcare system to inform them about the impact of our innovations.

The tool draws on randomized clinical trials (RCTs) or real-world evidence studies to quantify how our medicines have helped improve and extend life for patients, compared with the standard of care at the time our products were launched. For example, the following calculations are estimates for some of our treatments, based on RCT input.

- From 2006 to 2018, *Lucentis*, our drug to treat neovascular (wet) age-related macular degeneration and other forms of visual impairment, prevented 355 124 years of legal blindness and led to 1 425 403 more years with driving ability.
- From 2015 to 2018, *Entresto*, our treatment for chronic heart failure, avoided 12 172 deaths and 69 556 hospitalizations.

A German study published in 2019 in Expert Review of Pharmacoeconomics & Outcomes Research demonstrated that in psoriatic arthritis patients not responding adequately to disease-modifying antirheumatic drugs, the use of *Cosentyx* was estimated to increase their productivity. This would translate into 32 million productive hours gained between 2016 and 2030. Productive time was valued according to gross value added, and this resulted in an estimated direct productivity gain of EUR 829 million. Taking together direct and indirect effects up to 2030, a gain of EUR 2.7 billion benefit to German society is estimated.

based contracting for medicines, which links pricing and reimbursement rates to specific patient outcomes. We have made progress with several agreements and continue to learn from our experience.

For example, value-based contracts are integral to expanding access to emerging medical breakthroughs like cell and gene therapies that can treat devastating or fatal diseases with a single administration. We offer outcome-based agreements for *Kymriah*, our cell therapy for acute lymphoblastic leukemia and large B-cell lymphoma, in approximately one-third of the countries where the treatment is already approved, such as the US, Spain, Germany and Italy. These typically involve a full upfront payment of the product with a partial refund in case of failed outcomes, or installment payments based on successful patient outcomes at agreed milestones for one or both of the approved indications of *Kymriah*.

Our access strategy for *Zolgensma*, a one-time gene therapy approved by the FDA in May for the treatment of pediatric patients less than 2 years old with spinal muscular atrophy (SMA), includes working closely with payers to create five-year outcome-based agreements and novel pay-over-time options. In December, we announced a global Managed Access Program (MAP) to provide *Zolgensma* free of charge to eligible patients with SMA who are under the age of 2 and are citizens or legal residents of countries where the therapy is not yet approved by regulatory authorities. Recognizing that the program will not be a solution for all families in all countries, we are working to increase supply and to design sustainable solutions to further expand access.

In addition, to help improve the affordability of our medicines, we take local affordability and economic realities into account. We consider a range of approaches to expand access, including tiered pricing models, innovative business models and solutions to disease management, local brand strategies and off-patent solutions.

In 2019, our teams developed access strategies for all medicines preparing for launch, including *Mayzent* for multiple sclerosis, *Beovu* for neovascular (wet) age-related macular degeneration, and *Piqray* for advanced breast cancer.

For *Beovu*, for example, our access strategy for lower-income countries was developed across teams representing more than 100 countries and with input from hundreds of patients, physicians and payers around the world. It is focused on achieving rapid access to patients across geographies and includes a local brand strategy, reinforcing our commitment to responsible pricing and lowering the out-of-pocket burden for patients. Affordable local brands offer the potential to accelerate the introduction and availability of *Beovu* to treat patients in several developing countries in 2020, shortly after the anticipated European approval. In addition, we are leveraging other tools such as managed entry agreements and novel distribution models to better serve these populations. Together with local partners, we are working to strengthen health systems through scalable digital solutions. For example, in countries where diagnostic capacity is limited, we are exploring the introduction of digital screening using smartphones. We believe that co-creating these solutions with other stakeholders in the healthcare ecosystem will go a long way toward removing infrastructure barriers in these countries.

Our Sandoz Division drives access through the provision of quality generic medicines. It focuses increasingly on segments where it can make a real difference, either by making available the most competitive generic alternative or by offering a novel and more affordable alternative to existing therapies (e.g., leading biologic medicines through its global biosimilar business).

5 MONTHS

Our lowest ever launch time lag between developed and developing markets achieved with breast cancer drug *Kisqali*

LOCAL BRANDS

Globally, innovative drugs reach less than 10% of patients[1] five years after launch, and less than 1% of patients[1] in emerging markets. We strive to close these gaps by implementing a differential pricing approach, including tiered pricing that considers socioeconomic factors such as gross domestic product/national income per capita, human development index, income disparity and local affordability.

In LMICs, we have introduced more affordable local brands of many of our innovative therapies, such as *Entresto* (which has benefited more than 186 000 patients to date in LMICs) and *Kisqali* (which has benefited more than 2 500 patients). We now have over 90 local brands launched for some of our most advanced medicines, including 17 for oncology medicines, across more than 50 LMICs, reaching more than 300 000 patients. In 2019, we launched more than 10 new local brands, including four for oncology medicines. These improve affordability by lowering the out-of-pocket burden for patients in these countries.

Further, by systematically integrating access considerations into our launch process, we have reduced the launch time lag between developed and developing markets to our lowest ever. This is demonstrated by the launch of the first local brand for breast cancer drug *Kisqali* five months after the launch in Europe, and the launch of the first local brand for migraine treatment *Aimovig* around six months after the launch in Europe.

In 2017, we initiated a review of access to *Lucentis* in Central American countries. As this medicine had been available since 2013 with limited patient uptake, we decided to launch a local brand to help improve affordability and access. We worked with an array of partners in our distribution network, including wholesalers and pharmacies, to lower markup impacts on the final price paid, enabling us to reach significantly more patients.

LOWERING DISTRIBUTION COSTS

Even when medicines are available in LMICs, many patients may not have access due to a lack of funding for public healthcare delivery and the strong dependence on out-of-pocket expenditure. Markups in the distribution chain can inflate prices paid at the pharmacy by as much as 400%. We are leveraging technology to better understand and address these challenges.

We have developed proprietary methodologies and tools using curated data from publicly available sources such as the World Bank and Euromonitor (e.g., household disposable income, and the percent of household income allocated to healthcare), and inputs such as product price, intermediary markups and taxes. We use one of these tools, called Potential Affordability by Decile, to simulate the impact of pricing decisions in a given country based on income deciles, which helps us better understand affordability gaps at the household level.

Based on these data, we are exploring innovative distribution models that incorporate e-commerce and online pharmacies to lower distribution costs. These models leverage existing partners with e-pharmacy capabilities to help enable direct distribution to patients and apply market pressure to lower markups. In 2019, we rolled out pilot programs, for instance, in Argentina, Chile and Venezuela, which are showing early signs of success.

In Chile, Novartis is working with multiple pharmacies to sell the local brand

[1] World Bank, World Cancer Research Fund, Globocan, Centers for Disease Control and Prevention, IQVIA

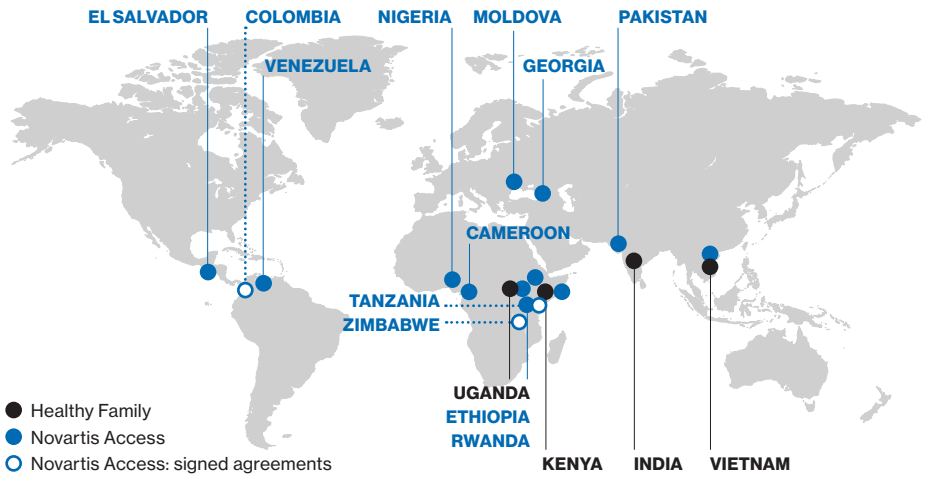
Local brands performance indicators

	Patients reached (thousands)		
	2019	2018	2017
Local brands			
Novartis Pharmaceuticals	**301.7**	213.3	99.1
Novartis Oncology	**11.3**	8.0	6.5

of *Aimovig* directly to patients through an e-commerce platform connected with patient support programs to provide a single point of sale. This enables patients to compare prices online and select the pharmacy with the lowest price. After the platform was launched, several participating pharmacies with higher initial list prices quickly reduced their prices to be more competitive with our preferred pharmacy.

We are also investing in research to understand how markups contribute to higher drug prices in LMICs. In November, we published an online report with Management Sciences for Health that investigated factors affecting the final prices of medicines for noncommunicable diseases (NCDs) in LMICs. We found that ex-factory prices, taxes, markups, distribution costs, market access policies addressing generics, and generic substitution were the main drivers of prices. Although various global pricing policies are implemented in these countries, the countries often lack the capacity to enforce them or adapt them to the local context, hence limiting the impact on affordability. Further, some countries like Colombia and Russia have introduced pricing policy reforms, but markups for wholesalers, distributors and retailers continue to be unregulated. Limited pharmaceutical competition in LMICs also often means that single suppliers can charge higher markups.

Novartis Social Business initiatives around the world



NOVARTIS SOCIAL BUSINESS

Novartis Social Business (NSB) works to develop novel sustainable business models that aim to enable access to high-quality medicines against infectious and chronic diseases in lower-income countries. In 2019, NSB reached more than 15 million patients with medicines, and more than 10 million people with health education.

NSB was integrated into the Global Health & Corporate Responsibility (GH&CR) organization in 2019. It manages our four flagship programs (leprosy, malaria, sickle cell disease and Chagas disease) and drives implementation of novel social business models, such as Novartis Access and Healthy Family, in lower-income countries. Since 2018, NSB has also assumed full responsibility for the entire Novartis product range in seven countries in Africa and Asia (Malawi, Rwanda, Tanzania, Uganda, Laos, Cambodia and Nepal). Further, it also leads the Sandoz business in Burundi, Kenya, Nigeria and Sudan. These countries were selected because they are large enough for social business models to scale up and be sustainable over time.

In countries under NSB responsibility, in collaboration with health authorities, we are aligning our product portfolio with healthcare needs. In 2019, we launched a tiered pricing strategy based on household wealth, and specific distribution channels to reach different income segments with our branded and generic medicines. We also began exploring synergies and integrated approaches between our different disease areas and programs. For instance, we are taking this approach with Healthy Family and are looking at including malaria and leprosy in its health education activities starting in 2020.

Our goal is to contribute to universal health coverage and help ensure that patients in these countries have access to affordable treatment options.

One way we measure the effectiveness and outcomes of our interventions is by looking at the change in availability of our medicines at both facility and household level over time. Through our health programs, we aim to raise disease awareness, provide screening and enable care for patients, and strengthen health systems through capacity building.

Novartis Access

We continue to expand and evolve Novartis Access. The program offers on- and off-patent medicines addressing key NCDs (cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer) as well as childhood pneumonia, and includes capacity-building activities to strengthen health systems.

In 2019, based on learnings on the ground and the results from the independent evaluation conducted in Kenya by Boston University and published in The Lancet, we took several steps to enhance the program. First, the portfolio approach, while commercially attractive, poses a set of implementation hurdles for procurement agencies, nongovernmental organizations (NGOs) and government clinics. We have therefore continued to increase the flexibility of our offering to better respond to country requirements.

Another important evolution was to expand distribution of Novartis Access into the private sector. Supply was originally restricted to the public, faith-based and NGO sector. However, results from the Boston University study further confirmed that in lower-income countries, although the majority of NCDs are diagnosed in the public sector, patients buy their medicines in the private, for-profit sector. To address this key learning, in 2018, we launched Novartis Access in the private sector in Kenya, Nigeria, Tanzania and Uganda.

Novartis Social Business performance indicators

	2019	2018	2017
Countries with products on the ground	**33**	26	35
FTEs working for NSB [1]	**786**	651	555
Patients reached with products (thousands) [2, 3]	**15 058.5**	24 832.6	35 202.3
Health educators trained	**1 536**	1 028	1 037
Healthcare providers trained	**1 516**	697	311
Policymakers trained	**145**	131	25
Points of service provision [4]	**13 635**	15 190	12 680
People reached at points of service provision	**986 701**	765 055	585 821
Awareness events held	**250 432**	185 756	157 846
People reached at awareness events	**10 211 704**	7 982 078	7 709 652

[1] Full-time equivalent positions and contractors
[2] The patient number was calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as NCD patients often take several drugs). The treatment adherence and treatment overlap factors are based on assumptions from developed markets.
[3] Our patient reach has steadily declined over the past five years, due to the increasing availability of WHO prequalified generic ACTs, eligible for international donor-funded procurement. In addition, to harmonize the patient reach calculation methodology across Novartis, the malaria patient reach calculation was revised.
[4] Points of service provision include facilities and health camps where healthcare services are provided.

Overall, the program has delivered more than 4.5 million monthly treatments to 12 countries (Cameroon, El Salvador, Ethiopia, Georgia, Kenya, Moldova, Nigeria, Pakistan, Rwanda, Uganda, Venezuela and Vietnam) since launch. We have agreements for implementation in three additional countries (Colombia, Tanzania and Zimbabwe). Our objective remains to roll out the program in 30 countries in the coming years.

Novartis Healthy Family

The Novartis Healthy Family programs are innovative business models that are expanding access to community education, improved infrastructure and affordable healthcare products for people living at the base of the income pyramid – in a way that is sustainable. Programs are active in India (Arogya Parivar), Kenya (Familia Nawiri), and Vietnam (Cùng Sông Khòe). In 2019, we expanded Healthy Family to more states in India, now covering 15 000 villages in 15 states. We also grew our presence in Vietnam to 19 provinces in the North, Central and Mekong regions. In addition, we rolled out new activities in Uganda. Overall, in 2019, the Novartis Healthy Family programs reached more than 9.4 million people through education in India, Kenya, Vietnam and Uganda.

The National Health Authority of India and NSB signed a memorandum of understanding in November 2019. Our mutual intent is to strengthen the awareness about Ayushman Bharat PM-JAY, a national scheme fully financed by the government of India that aims to provide health insurance for secondary and tertiary care hospitalization to poor and vulnerable families. The agreement will combine the knowledge and expertise of both the public and private sector. Our Arogya Parivar health educators will help provide detailed information about Ayushman Bharat PM-JAY benefits to help improve health-seeking behavior in the villages.

SUB-SAHARAN AFRICA STRATEGY

In November, we announced a new strategy to reach more patients in sub-Saharan Africa (SSA) with our portfolio of medicines. As part of this strategy, the regional organization will prioritize driving access to medicines and helping reach more patients across income levels, in addition to traditional business metrics, such as profits and margins. Starting in the second quarter of 2020, we plan to establish a new organizational unit, bringing together the expertise and portfolio of our Sandoz Division, Innovative Medicines Division (Novartis Pharmaceuticals and Novartis Oncology), and NSB. The unit will work to implement strategies to improve the affordability and availability of our medicines across our portfolio, including tiered pricing models, tender business and social business models. We plan to continue working hand in hand with governments and NGOs to build stronger healthcare systems and increase clinical trial capabilities, with the ultimate goal of bringing more innovation to the region. SSA is home to the largest underserved patient population in the world, with a quarter of the global disease burden but only 3% of the world's health workers.

Patient assistance programs performance indicators

	Patients reached (thousands)		
	2019	2018	2017
Patient assistance programs			
Novartis Patient Assistance Foundation Inc. (US) [1]	**87.2**	68.1	55.5
Novartis Oncology Access	**60.7**	71.1	82.9

[1] Data represent continuing operations.

PATIENT ASSISTANCE PROGRAMS

Patient assistance programs play a crucial role in helping individuals gain access to healthcare when they are unable to afford it, including in high-income countries when people are uninsured or underinsured. For example, having prescription drug coverage does not always guarantee that people can access the medicine they need or that they can afford to pay for it.

The Novartis Patient Assistance Foundation Inc. (NPAF) provides medicines at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage. In 2019, NPAF provided free medicines to more than 87 000 patients in the US, covering more than 75 medicines from our portfolio. Over the past five years, medication has been provided at no charge to close to 300 000 patients.

Building on 2018 innovation efforts, NPAF continues to leverage new technologies to improve the patient experience. A streamlined, patient-friendly application has been developed to highlight important consents and reduce processing and fulfillment time. Further, to enable patients to get the medicines they need on a timely basis, an automated texting platform was launched in 2019, enhancing the refill process and reducing the time to communicate with patients. An electronic benefit verification program is planned in 2020 to screen patient insurance information and to aid with insurance reverification.

NPAF has expanded access to new Novartis medicines launched in 2019, including *Beovu*, *Mayzent* and *Piqray*. In addition, NPAF's Institutional Patient Assistance Program (IPAP) now includes ophthalmology and cardiovascular products, and has increased alliances with safety net clinics, which provide healthcare services to indigent populations. IPAP clinics receive Novartis medications directly and handle patient enrollment and processing. This allows patients to walk in and receive the medicines they need almost immediately, filling a critical gap in the healthcare system.

In developing countries, Novartis Oncology Access makes medicines in its portfolio available through equitable pricing models. As governments of LMICs increasingly invest in health systems and the infrastructure needed to address NCDs, they are actively funding a greater share of cancer care and transitioning patients into new and growing national programs. In 2019, approximately 61 000 patients in 17 countries benefited from the Novartis Oncology portfolio in multiple disease areas.

DONATIONS

Through our medicine donation program, we continue to support low-income countries in their efforts to treat patients for neglected diseases and to provide medicines in areas impacted by natural disasters and extreme poverty.

For over 30 years, Novartis and the Novartis Foundation have been working with partners around the world to eliminate leprosy. Since 2000, Novartis has donated more than 65 million blister packs of multidrug therapy valued at approximately USD 108 million through the WHO, helping to treat more than 7 million leprosy patients worldwide.

In 2015, Novartis renewed its pledge with the WHO to end leprosy by extending its multidrug therapy donation through the year 2020. This five-year agreement includes treatments worth more than USD 40 million, and up to USD 2.5 million to support the WHO in handling the donation supply chain. The program is expected to reach an estimated 1.3 million patients by 2020. Overall, multidrug therapy has made it possible to treat patients, interrupt the transmission of leprosy, and prevent disabilities.

In 2018, the WHO issued revised guidelines for diagnosing, treating and preventing leprosy, which recommend treating both paucibacillary and multibacillary forms of the disease with the same three-medicine regimen made up of rifampicin, dapsone and clofazimine.

The same year, Novartis began working with the WHO to revise planning methods and introduce a robust replenishment process, significantly improving stock availability for leprosy medicines globally. A monthly review process was implemented to enable immediate visibility of demand fluctuation. By improving these processes, we have strengthened the overall supply chain capability and reduced the likelihood of needing to fulfill rush orders of medicines.

Novartis has also been donating *Egaten* (triclabendazole) to the WHO for the treatment of fascioliasis, or liver fluke, since 2005, helping to treat around 2 million patients in more than 30 countries. Fascioliasis infects more than 2.4 million people globally. *Egaten* is currently the only medicine for fascioliasis recommended by the WHO and is on the WHO Model List of Essential Medicines.

Donations performance indicators

	Patients reached (thousands)		
	2019	2018	2017
Donations			
Leprosy (WHO)	**168.6**	176.2	227
Fascioliasis/*Egaten* [1]	**154.7**	154.7	147.9
CMLPath to Care™	**14.4**	13.4	7.8

	Value USD (millions) [2]		
	2019	2018	2017
World Child Cancer	**<0.1**	0.1	0.1
Medicine donations (emergency relief)	**2.8**	4.7	10.9

[1] Numbers of patients reached have been updated to reflect the new methodology used by WHO and based on real-world evidence.

[2] Wholesale acquisition cost (WAC) plus logistics costs for some programs

CMLPath to Care™ is a unique global initiative that connects people living with chronic myeloid leukemia (CML) with effective and free treatments, professional medical capabilities, trained physicians and hands-on support. The initiative is directed by The Max Foundation, with support from Novartis through drug donations and funding. The geographic scope is aligned with the Access to Medicine Index geographic scope. CMLPath to Care™ is an evolution of the agreement between The Max Foundation and Novartis Oncology for the original *Glivec* International Patient Assistance Program (GIPAP), which began in 2002.

100m

Daily doses of our CML treatments donated to The Max Foundation since the beginning of our collaboration

The transition of GIPAP to CMLPath to Care™, which started in 2017, continued in 2019 with 62 countries formally transferred to The Max Foundation. We plan to transfer the final six countries in the first half of 2020. Novartis has committed USD 29 million from 2017 to 2021 in the form of financial support and 150 million tablets to cover treatment for approximately 36 000 patients. The donation program is expected to make *Glivec* and *Tasigna* (both life-saving treatments) available to patients and help expand access. In fact, in 2019, in collaboration with Novartis, The Max Foundation was able to make *Glivec* and *Tasigna* available to an additional 16 countries, bringing the total tally to 84 countries. Since the beginning of our collaboration with The Max Foundation 17 years ago, we have donated more than 100 million daily doses of our CML treatments and have reached more than 80 000 patients in 80 countries. Our work together has contributed to bringing overall survival of CML in LMICs to levels similar to those in developed countries.

Our generics division, Sandoz, continued its partnership with World Child Cancer, a global charity that aims to improve diagnosis and access to treatment for children suffering from cancer in LMICs. The collaboration focuses on four countries: the Philippines, Ghana, Mexico and Myanmar. By 2023, the charity aims to reach 10 000 children a year. Sandoz began its partnership with World Child Cancer in 2016, and to date, 5 643 children have been diagnosed in the four countries Sandoz has supported. In addition, 4 095 healthcare professionals have received training as a result, enabling them to provide the best possible treatment and care for children with cancer and their families.

Sandoz also works with Americares, a leading health-focused relief and development organization that aids people affected by poverty and disaster. It provides long-term assistance in five healthcare areas: maternal, newborn and child health; infectious diseases; health system strengthening; mental health; and hypertension and diabetes. Americares notifies Sandoz of products required, based on the healthcare needs of countries and partners.

In June, Novartis and Sandoz received the Power of Partnership Award from Americares, in partnership with the Healthcare Distribution Alliance, in recognition of our outstanding commitment to increasing access to healthcare around the world. Since 1986, Novartis and Sandoz have donated nearly USD 300 million worth of medicine to support health programs in 113 countries.

Strengthening health systems

Strengthening health systems is a key pillar of our Access Principles, and we actively seek opportunities to lower local barriers to healthcare delivery, working in collaboration with governments and other partners to support quality patient care in areas where we can have the greatest impact. We believe in delivering sustainable solutions through effective collaboration among public and private partners with diverse capabilities. In 2019, we established a Health Systems Strengthening and Innovation team within our GH&CR group to further integrate this priority into our core business.

The new team has accountability for driving global health partnerships, implementing adaptive R&D programs, enhancing local healthcare delivery capabilities, and driving innovation in global health financing. We plan to leverage the expertise of NSB, notably through the Healthy Family programs and their capability-building activities, as well as the Novartis Foundation, in expanding our role in health system strengthening.

Vietnam provides one example of how we are leveraging multi-stakeholder partnerships to help countries strengthen primary healthcare delivery. In May, the government established a new working group for primary healthcare transformation, founded by the World Economic Forum, Harvard Medical School and Novartis, and led by the country's Min-

istry of Health. The new group will oversee pilot projects in 26 community health stations across Vietnamese provinces, using the lessons learned to develop solutions that can be replicated and scaled up throughout the country. In December, we signed a memorandum of understanding with the Vietnam Ministry of Health, a significant step in strengthening community-based healthcare using a public-private partnership approach and in working on primary healthcare to help achieve universal healthcare.

Furthermore, the Novartis Foundation partnered with PATH and the Ho Chi Minh City health department to examine and test novel models of service delivery that strengthen primary healthcare, bring services closer to people at risk or affected by hypertension, and engage multiple sectors to increase access and affordability. As part of this program, an electronic patient tracker, the eHTN.Tracker, was developed to monitor patients screened, diagnosed and treated for hypertension. The online database empowers health authorities to centrally manage information for this disease, significantly strengthening health systems in one of the country's most populous cities.

The Novartis Global Health Alliance (previously called the Novartis Africa Health Alliance) focuses on health system strengthening programs in areas of long-term business interest. In 2019, the initiative supported programs involved in training health authorities on the review of biologic medicines, improving detection of counterfeit medicines, and strengthening primary health systems in Vietnam and Ethiopia.

The Global Health Alliance has also helped strengthen access to evidence-based clinical research tools in sub-Saharan Africa in collaboration with Better Evidence at Ariadne Labs, a joint health system innovation center of Brigham and Women's Hospital and Harvard T.H. Chan School of Public Health in the US. Medical students and faculty at eight institutions in sub-Saharan Africa, and healthcare workers serving vulnerable populations around the world will have expanded access to a regularly updated, peer-reviewed, evidence-based platform focused on the diagnosis and management of a wide range of diseases.

BUILDING SCIENTIFIC CAPABILITY AROUND THE WORLD

Well-equipped, aptly trained scientists are a key component of clinical research that ultimately translates to improved patient care. We invest in the training and support of researchers and scientists around the world, as well as healthcare workers, to help expand their knowledge and improve their ability to help patients. In addition, we facilitate programs and collaborations that can build local research and clinical trial capabilities.

Novartis and the University of Basel in Switzerland run a fellowship training program called Next Generation Scientist (NGS), designed to enhance professional development for scientists in LMICs. In 2019, we welcomed a new group of 21 top students from 19 institutions in 14 developing countries. NGS improves our company's understanding of global healthcare challenges while providing young scientists in LMICs with skills, knowledge, tools and inspiration to improve healthcare in their communities. Overall, more than 180 scientists and clinicians from 30 countries have participated in the program over the past nine years. A complementary scientific exchange program takes place at the Novartis Institutes for BioMedical Research in the US. In 2019, eight junior scientists from various parts of Africa, South America and Thailand participated in research programs focused on malaria, sickle cell disease, Chagas and other diseases. Overall, more than 60 fellows have completed the program since it started 10 years ago.

Additionally, the European & Developing Countries Clinical Trials Partnership (EDCTP) granted EUR 10 million over five years to a unique collaboration between antimalarial drug researchers in Africa and Europe from 10 academic institutions, Novartis and MMV. The grant aims to support African trials of a novel antimalarial combination comprising KAF156 and lumefantrine in a new once-daily formulation. In July, this joint project – called WANECAM-2 (West African Network for Clinical Trials of Antimalarial Drugs) – conducted a good clinical practice training workshop in Bamako, Mali, with 36 participants from Mali and Niger to strengthen their capacity to conduct these trials.

Also in 2019, Novartis and EDCTP launched a career development fellowship in the field of poverty-related diseases. To facilitate opportunities for early- and mid-career scientists in sub-Saharan Africa, we are co-funding at least five fellowships over three years, to a maximum value of EUR 750 000, for research proposals in the area of maternal and child health, and specifically on the interaction between poverty-related diseases and NCDs.

Through EDCTP, Novartis also hosted two research fellows from Tanzania and Nigeria. These mentorship opportunities help strengthen the competencies of scientists who could later assume leading roles in clinical research at their host institutions.

TRAINING COMMUNITY HEALTHCARE WORKERS

Recognizing the important role of community health workers (CHWs) in building stronger healthcare systems in developing countries, Novartis continues its commitment as a founding partner of Last Mile Health's Community Health Academy through our USD 1 million contribution over three years. To date, the academy has enrolled over 10 800 health system leaders from 175 countries, and over 3 500 CHWs and their clinical supervisors in the digital training platform. The course emphasizes the importance of government-led primary healthcare systems that enable CHW programs, with a focus on the systems that support CHWs and on the quality of the healthcare services they deliver.

Through the Bill & Melinda Gates Foundation CEO Roundtable, Novartis co-led an industry effort to expand the training of frontline health workers in developing countries. Two NGOs – Last Mile Health and Living Goods – were selected through a competitive process to deploy 2 550 health workers, develop content for the Community Health Academy, and launch digital solutions to improve community health. We catalyzed a total of USD 18 million for these two NGOs over three years. Novartis, the Bill & Melinda Gates Foundation, Eli Lilly, GSK, Johnson & Johnson, and Pfizer are each now contributing USD 1.5 million, with matching funds from the Audacious Project, an innovative funding body.

TACKLING CARDIOVASCULAR HEALTH IN LOW-INCOME SETTINGS

While urbanization increases the risk of NCDs, cities also offer huge opportunities to become drivers of public health. Recognizing this, the Novartis Foundation launched Better Hearts Better Cities (BHBC) in 2017 to help improve cardiovascular health in three low-income urban populations: Ulaanbaatar, Mongolia; Dakar, Senegal; and São Paulo, Brazil. The innovative model applied a multisector approach to address hypertension and its underlying determinants. In each city, we leveraged partnerships with local and national government agencies, along with an array of civil society organizations, achieving significant results in under two years. The initiatives strengthened early disease detection and health awareness in the community, combined with a consistent referral of patients into care. Additionally, BHBC improved patient treatment and control through actions such as translating national hypertension guidelines into a standardized algorithm and protocols. This was complemented by progress and outcome measurement systems to enhance data-driven decision-making.

In São Paulo, for example, most people are unaware that they have high blood pressure, and only 20% of those who know their condition are taking regular medication. Moreover, less than a third of the population is physically active. We developed a drug adherence kit and care optimization tool for pharmacists, now used by public pharmacists across São Paulo, as well as the first online training for hypertension in Brazil. Further, we brought health and care closer to people by partnering with community leaders such as the Corinthians football club and samba schools to increase hypertension and heart health awareness, and encourage care-seeking behavior in high-risk groups through a direct referral from the community into primary care. Local public and private sector partners co-financed these initiatives, reinforcing local ownership. Interventions were rolled out across 11% of the population, covering 1.5 million people. Health system integration and translation into policy is ongoing.

In total across the three cities, BHBC interventions reached more than 4 million people, leading to significant increases in hypertension diagnosis, treatment and control rates in under two years.

In Ethiopia, NSB is working with the Tropical Health and Education Trust as well as Health Limited to deliver training and capacity building to bring hypertension, diabetes and chronic respiratory disease services closer to communities. Based on population sizes, the Ministry of Health selected 15 hospitals and 45 health centers. Since May, more than 26 000 patients have been screened for NCDs in 34 health centers. Of the 2 702 diagnosed with an NCD, 62% were found to have hypertension, 28% have diabetes, 6% have chronic respiratory diseases, and 3% have epilepsy.

LEVERAGING DIGITAL HEALTH SOLUTIONS

The Novartis strategy is to build a leading, focused medicines company powered by advanced therapy platforms and data science. We have adopted a companywide focus on digital technologies, advanced analytics and artificial intelligence (AI) to help drive innovation and improve efficiency.

Through the Novartis Foundation, we are exploring ways in which data, digital and AI can help transform global health and re-engineer health systems from being reactive to becoming proactive and even predictive. One way to achieve this is through partnerships with governments to co-define national health priorities that data, digital and AI can address, and jointly build roadmaps for the digital transformation of health systems.

Another way is through partnerships with leading data science innovators. Since 2016, the foundation has chaired the Broadband Commission for Sustainable Development Working Group on Digital Health. In 2019, Microsoft joined as co-chair, and together we are exploring opportunities to leverage our capabilities in data science and data architecture to transform the response to healthcare challenges in LMICs.

In addition to the work done by the Novartis Foundation, NSB is pursuing digital solutions in lower-income countries to scale up its social and commercial operations and help improve healthcare systems.

In the Philippines, we continued working with reach52 (formerly Allied World Healthcare), a social business startup, to help improve access to care for underserved populations. People register on Curis, a digital platform managed by reach52, during health camps and other health education events. Based on their self-reported data, an algorithm flags potential health issues, so they can be referred to healthcare practitioners for further care. In addition, aggregated data provide local authorities with information on disease prevalence in difficult-to-reach regions, and give them a tool to detect and respond to healthcare trends. The platform has continued to expand, with over 50 000 patients now enrolled in the Philippines. Additionally, 9 000 patients are enrolled in Cambodia. At the same time, we worked with reach52 on a delivery model for medicines to help ensure remote communities in these countries have access to the medicines they need.

A partnership between NSB, Medtronic Labs and Management Sciences for Health in Kenya is yet another example of how investing in digital technologies can create new opportunities. The project aims to expand access to quality care, educate and empower healthcare providers, and collect data to tailor solutions to local needs. With our partners, we are working on an end-to-end system for NCD management, linking patients to community health workers, pharmacists and clinicians.

We started the program in three counties in 2019, and we expect to reach 50 000 patients through 2020. Once registered on the platform, patients are able to access blood pressure checks at community-based locations. Clinicians can view patient data, provide feedback via text message, and write electronic prescriptions that are accessible through participating pharmacies. The program also provides training to community health workers and facility health providers on NCD treatment guidelines to help ensure they can provide quality care.

In 2019, Sandoz held its second Healthcare Access Challenge, inviting entrepreneurs and innovators in the field of digital technology to submit ideas with the potential to complement – or even positively disrupt – established approaches to driving access to healthcare. More than 400 ideas were submitted across 80 countries, and three winners (from Uganda, the US and the Netherlands) were selected. Each received EUR 20 000 to help bring their idea to life with ongoing support from Sandoz experts. The winning ideas

were a prescription-only digital therapeutic for patients with irritable bowel syndrome, a smart social network with a matchmaker tool to connect patients across the world who suffer from rare and undiagnosed diseases, and a mobile clinic using an app and a mobile van to provide door-to-door maternal healthcare services in Uganda.

SUPPORTING FRAGILE POPULATIONS

There are more than 70 million refugees and displaced people around the world. Everyone, including business, has a role to play in helping refugees rebuild their lives and livelihoods.

In September, Novartis joined philanthropic organizations, government officials, and prominent business leaders from across industries to demand action on a major issue threatening the success of the Sustainable Development Goals (SDGs): the lack of refugee inclusion.

In an event convened by the International Rescue Committee on behalf of the Business Refugee Action Network, business leaders came together to show their ongoing commitment to improving the lives of refugees. All noted the critical role business plays in creating opportunity for refugees, and called on governments to take stronger action to improve the lives of refugees and to promote refugee inclusion in the SDGs.

Humanitarian aid in Bangladesh

Rural communities in Bangladesh are suffering from a massive shortage of skilled healthcare providers. In 2011, Novartis and Swisscontact, an organization that promotes economic, social and environmental development, established ASTHA (Achieve Sustainability Through Healthcare Access) to help address this gap. The project aims to improve access to healthcare services for rural communities in Bangladesh by training community paramedics, with a focus on maternal and child health, family planning and basic primary healthcare services. These paramedics can later return to their villages and deliver care in hard-to-reach areas. The program creates a positive health impact in communities and helps lift individuals out of poverty by providing a steady income.

ASTHA is now in its final implementation phase. Since 2015, 363 young adults, including 178 women, have completed the two-year training, and 70% work as community paramedics. More than 180 000 people in rural communities now have access to skilled health providers.

Additionally, since 2018, Novartis has supported the Swiss Red Cross in building five primary healthcare centers in the world's largest refugee camp in Cox's Bazar. Here, approximately 1 million people live in tattered tents on an area of 6 000 square meters, and around 60 000 babies are born every year. There is no infrastructure and very little clean drinking water. As the area is under constant threat of violence, humanitarian workers must leave the camp in the afternoon to help ensure their safety. Three primary healthcare centers were built in less than two years, providing basic medical care to more than 118 000 camp residents, and two are under construction.

PROTECTING INVENTORS IN DEVELOPING COUNTRIES

We continued to lead the industry in our level of participation in the Patent Information Initiative for Medicines (PatINFORMED), a public online resource for accessing patent information, which launched in 2018. After listing the patent information for all of our small-molecule medicines – which far exceeds the standard commitment to list information only for certain diseases – we are now driving the industry effort to explore the inclusion of patent information for biologics medicines, as biologics are at the forefront of medical research and hold great promise for patient health.

Furthermore, in 2019, we continued our strong commitment to pro bono efforts in the intellectual property (IP) space through the WIPO-World Economic Forum Inventor Assistance Program (IAP), of which Novartis is a founding member. The IAP provides free IP-related legal services to under-resourced inventors in developing countries, helping them access the patent system, which in turn leads to local innovation across a spectrum of technological fields that contribute to economic growth and prosperity. We aim to expand this program and develop a framework to publicly recognize these inventors, their innovations, and the attorneys who, through the patent system, helped bring the innovations to fruition.

Photo In Accra, Ghana, John Dzido feeds his son Caleb, 11, who has experienced a series of strokes due to sickle cell disease. The inherited blood disorder can be life-threatening.

STRATEGIC AREAS

Addressing global health challenges

Why is it important?

While the impact of noncommunicable diseases is growing globally, infectious diseases continue to devastate developing countries and hinder economic growth, especially in sub-Saharan Africa. Drug-resistant malaria threatens to undo decades of progress. Altogether, neglected tropical diseases affect more than 1 billion people and cause tremendous suffering. Many are preventable and treatable conditions; however, weak healthcare systems in low-income countries prevent timely diagnosis and treatment. Children under 5 are among the most affected by infectious diseases such as malaria, and by preventable complications from genetic diseases such as sickle cell disease, the single most important genetic cause of childhood mortality globally.

In this section

Read about the progress we have made on our four flagship programs:

Sickle cell disease

Launched the Novartis Africa sickle cell disease program in Ghana, a first-of-its-kind effort to manage the disease holistically on the continent

→ p. 33

Chagas disease

Started a first-ever clinical trial to expand treatment options for people with Chagas-related heart disease

→ p. 34

Malaria

Initiated the development of a new formulation of *Coartem* for infants weighing less than 5 kilograms

→ p. 35

Leprosy

Announced a strategic alliance with Microsoft and the Oswaldo Cruz Foundation to use artificial intelligence to improve leprosy detection

→ p. 36

H.E. Alhaji Dr. Mahamudu Bawumia Vice president of the Republic of Ghana

Our collective goal is to reimagine what the future could look like for people with sickle cell disease. Where children do not need to miss out on school or be singled out. Where young adults can have equal opportunity for employment. And where families can flourish and continue to be the bedrock of our civil society.

Our approach and performance

Novartis has a long heritage in tackling infectious and neglected tropical diseases, and we continue to play a significant role in global movements to end leprosy and malaria. With the transformation of our new Global Health & Corporate Responsibility (GH&CR) organization in 2019, we have consolidated our decades-long work against leprosy and malaria, together with our newly initiated efforts in sickle cell disease (SCD) and Chagas disease, into four flagship program areas. Across these programs, we are aligning our work with the Novartis Access Principles to adopt an integrated end-to-end approach to disease management, leveraging research and development (R&D) to address unmet needs, improving affordability through novel pricing and business models, and strengthening health systems.

32 m

Invested in R&D to discover new and better treatments for infectious and neglected diseases (USD)

We continue to maintain a strong commitment to research for various infectious and neglected diseases through the Novartis Institute for Tropical Diseases (NITD). In 2019, the Novartis investment in R&D to discover new and better treatments, including through NITD, was approximately USD 32 million. These efforts have produced three potential new medicines currently in clinical testing for malaria and leishmaniasis.

Building a holistic approach for sickle cell disease: the Novartis Africa sickle cell disease program

Novartis has been committed to understanding SCD and working toward treatment for more than 40 years. At the World Economic Forum in January 2019, we announced a five-year agreement with the Ministry of Health of Ghana, Ghana Health Service and the Sickle Cell Foundation of Ghana to adopt a holistic approach to tackling the diagnosis and treatment of SCD. This public-private partnership builds on three years of consultations with health authorities and local stakeholders, and represents a major step forward in putting the Novartis Access Principles into action to treat SCD at scale. This also makes Ghana, where an estimated 15 000 babies are born with SCD every year, the first African country to commit to offering the global standard of care for people with SCD.

The partnership aims to improve and extend the lives of people with SCD by taking a comprehensive approach to screening and diagnosis, treatment and disease management, and training and education, and by elevating basic and clinical research capabilities. Specifically, the partners aim to collaborate on field testing and implementation of SCD treatment guidelines, the establishment of centers of excellence across regions, and the implementation of newborn screening at these centers. Partners also plan to make accessible treatment options available in line with the global standards of care, and use digital technologies to monitor and evaluate patient registration, report real-time data, and help ensure the safe large-scale rollout of treatment.

The partnership was officially launched in November when the government of Ghana announced the availability of hydroxyurea for the treatment of people with SCD. Hydroxyurea is a commonly used medicine for patients with SCD in developed countries, and is approved for use in both adults and children. In October 2018, the Ghana Food and Drugs Authority granted marketing authorization to hydroxyurea, and Novartis has delivered more than 20 000 treatments to date. The therapy is expected to cover the needs of patients for up to 12 months and is currently available through 11 trained treatment centers as well as through private distribution channels. Discussions are already underway to include the medicine and associated laboratory testing in the National Health Insurance Scheme, and to prioritize SCD as a national program.

At the same time, Novartis has committed to develop a child-friendly formulation of hydroxyurea and has announced plans to conduct two clinical trials in Ghana and Kenya for its next-generation treatment for SCD, crizanlizumab. Crizanlizumab is a novel targeted biologic therapy that is approved in the US, under the name *Adakveo*, to reduce the frequency of pain crises in adults and pediatric patients 16 years and older with SCD. The trials are expected to start in 2020; this will be the first time that a biologic therapy that is not a vaccine enters multicenter clinical trials in sub-Saharan Africa (excluding South Africa).

In parallel, Novartis is working with Zipline, a US-based automated logistics company, to make hydroxyurea treatments widely available, especially in rural areas. Zipline is already operating two distribution centers in Ghana, with plans to open two more in the near future. On World Sickle Cell Disease Day in June, we completed a pilot flight with Zipline to provide access to hydroxyurea.

Our goal is to establish a comprehensive model in Ghana that can be used to expand access to SCD medicines and improve patient outcomes in other countries in sub-Saharan Africa, aiming to reach 10 countries by 2022. Approximately 80% of individuals with SCD globally are born in sub-Saharan Africa, and there is evidence to suggest that more than half of affected children may die before the age of 5 due to preventable complications.

Partnering to address Chagas disease

900

Patients to be recruited for a first-of-its-kind clinical trial in patients with Chagas-related heart failure

Chagas disease affects approximately 6 million people, mainly in Latin America. Less than 1% of affected individuals receive proper treatment, and current tools to fight the disease are outdated and inadequate. We have been working with the World Heart Federation since 2018 to develop an end-to-end roadmap to help address this global health challenge. The roadmap, to be launched in 2020, explores the patient journey from diagnosis to treatment, with the aim to provide actionable recommendations for policymakers and healthcare professionals toward an end-to-end approach to patient care.

In March, we marked our commitment to help fight the disease by joining the Global Chagas Disease Coalition, an alliance that aims to increase awareness of Chagas disease and foster synergies in controlling the disease and promoting access to diagnosis and treatment.

We also announced a new clinical study, PARACHUTE-HF, with the goal of expanding options to treat Chagas-related heart disease. A first of its kind in this population, this study will assess the efficacy and safety of *Entresto* (sacubitril/valsartan) in people with chronic Chagas cardiomyopathy – which accounts for the majority of death and disability among individuals affected by the disease – and further explore potential disease biomarkers. The trial was launched in December and is expected to recruit approximately 900 patients with confirmed Chagas disease in Argentina, Brazil, Colombia and Mexico. This study is another example of our commitment to apply the Novartis Access Principles in our global health work, incorporating unmet medical needs into our R&D strategy.

In 2019, we also increased our focus on drug discovery for new antiparasitic medicines to address Chagas disease. The proteasome inhibitor LXE408 was advanced to the clinic as a promising drug candidate for the treatment of visceral leishmaniasis. This novel mechanism of action is now being investigated, along with other drug candidate series, as a potential therapy for Chagas disease. In parallel, NITD and colleagues at the Novartis Institutes for BioMedical Research (NIBR) are advancing collaborations focused on identifying urgently needed new biomarkers for Chagas disease that would facilitate clinical development and possibly patient management.

A cross-divisional delegation from our company, including team members from NIBR, Global Drug Development and the country-level organizations, traveled to Argentina, Brazil and Colombia in 2019 to lay the groundwork for the trial and learn firsthand how Novartis can best contribute to local efforts through R&D and access-to-medicine programs.

The teams visited 15 clinics and research institutes in eight cities, and held extensive consultations with health authorities and local stakeholders to better understand the environments where our medicines would be tested. They identified strategically important centers with solid clinical trial capabilities in endemic rural and urban areas, enabling us to design rigorous study protocols. The exchange of ideas also helped us identify opportunities where Novartis could help strengthen health systems to better control and manage Chagas disease in Latin America.

In October, we signed a memorandum of understanding with the Oswaldo Cruz Foundation (Fiocruz) in Brazil to collaborate on research and education for neglected diseases, including Chagas disease, leprosy, malaria and sickle cell disease.

In addition, Novartis is already working with stakeholders in endemic countries to co-develop tailored access-to-medicine programs and health system strengthening strategies. We believe our end-to-end approach will help improve disease diagnosis and management, and the delivery of care, helping ensure lower-income patients suffering from chronic Chagas-related heart disease can benefit from the best available treatment and care.

Tackling drug resistance to help eliminate malaria

According to the World Malaria Report, published in December, the decline in malaria cases and deaths has slowed significantly. Though an increasing number of countries are progressing toward elimination, there is still a long road ahead. Unfortunately, malaria still takes a heavy toll on pregnant women and children under 5, primarily in sub-Saharan Africa. More needs to be done.

Collaborating to fuel drug discovery for Chagas disease

Novartis supports drug discovery for neglected diseases and helps foster research capabilities in low- and middle-income countries. Our research collaboration with Artur Cordeiro at Laboratório Nacional de Biociências (LNBio) – the first WIPO Re:Search collaboration for the Brazilian institute – merged those interests to conduct research on Chagas disease. Dr. Cordeiro previously discovered compounds that inhibit two key Trypanosoma cruzi enzymes and are active against the parasite. After securing a grant to cover his expenses, Dr. Cordeiro traveled to NIBR headquarters in the US, where he screened thousands of proprietary Novartis compounds to identify additional active compounds to move his drug discovery work forward. He also benefited from technical support and mentorship from NIBR scientists. Dr. Cordeiro returned to LNBio with data for both drug targets and new chemical structures with good activity.

Novartis has a long-standing commitment to malaria. Overall, we have delivered more than 900 million treatment courses of our antimalarial, *Coartem*. In 2019, we celebrated the 10th anniversary of the first dispersible artemisinin-based combination therapy (ACT) developed by Novartis and Medicines for Malaria Venture (MMV) to treat malaria in children and infants. Since its launch in 2009, we have distributed more than 390 million pediatric courses in 50 countries, contributing to a significant reduction in malaria deaths. In addition, in collaboration with MMV, we are working to develop a new formulation of *Coartem* for infants weighing less than 5 kilograms, one of the most vulnerable groups affected by the disease and for whom there is currently no approved treatment.

Drug discovery efforts at NITD have delivered an industry-leading pipeline of drug candidates to address the emerging threat of resistance and support malaria elimination. Novartis leads two of the most advanced malaria development programs worldwide, featuring compounds that employ new mechanisms of action and activity against resistant strains of the disease.

With scientific and financial support from MMV in collaboration with the Bill & Melinda Gates Foundation, we are conducting a Phase II efficacy and safety study of KAF156 (ganaplacide) in combination with a new once-daily formulation of lumefantrine. The trial is assessing adults and children with uncomplicated *Plasmodium falciparum* malaria to determine the most effective and tolerable dose at the shortest dosing regimen. During 2019, we experienced difficulties with clinical supplies of KAF156, and as a result, had to pause clinical trial activities. We anticipate being able to restart them in 2020.

Novartis is also running a Phase II dose-escalation study of KAE609 (cipargamin) in collaboration with MMV and with financial and technical support from the Wellcome Trust to better understand its safety and efficacy profile.

If successfully developed, these compounds would represent the cutting edge of next-generation antimalarials beyond ACTs and provide new options to treat the disease. Novartis is underwriting these trials with a commitment of more than USD 100 million through 2023. This investment will also help expand access to pediatric antimalarials, and strengthen clinical trial sites in Africa where malaria takes the greatest toll.

To complement these efforts, we created an insectary at our research site in Emeryville, California, in the US, to study mosquitoes that transmit *Plasmodium vivax* malaria, the most widespread form of the disease. Scientists can extract the microbe and inject it into human cells or animals to generate disease models, which aid research teams. Novartis is one of a few pharmaceutical companies to have such a facility in-house.

In April, Novartis commemorated World Malaria Day – together with the Asia Pacific Leaders Malaria Alliance, RBM Partnership to End Malaria, Malaria Consortium, Malaria No More UK and

Malaria No More US – with the launch of the Malaria Futures for Asia report. Building on our initial report focused on Africa in 2018, this study featured insights from local malaria experts in government, the research community, and nongovernmental organizations (NGOs) in Asia to discuss progress and challenges in achieving the 2030 malaria elimination goals. In 2019, we also completed our Africa work by surveying an additional four highly endemic central African countries. Based on this data, we released an expanded version of the Malaria Futures for Africa report at an RBM meeting in Abuja, Nigeria, in October.

Also in October, the kENUP Foundation, together with the European Commission and with support from Novartis, launched a first-of-its-kind EUR 300 million fund to advance malaria R&D at the World Health Summit in Berlin, Germany. The funds will be extended as venture loans to nine companies with 17 antimalarial projects, spanning treatment, vaccines and a field diagnostic. Backed by the European Union, loan repayment will be contingent on success. Only companies that produce commercially viable products will have to repay the loans with interest. This new fund is part of a broader trend of using innovative financing to support large-scale improvements to health services, infrastructure, regulatory capacity and public-private partnerships that advance global health.

Using artificial intelligence (AI) to help accelerate leprosy elimination

For over 30 years, Novartis and the Novartis Foundation have been working with partners around the world to help eliminate leprosy. The global disease burden has been reduced by 99% since the introduction of multidrug therapy in 1981. We have contributed to this effort by donating multidrug therapy through the World Health Organization (WHO) since 2000, helping treat more than 7 million patients worldwide. The Novartis Foundation is a founding member of the Global Partnership for Zero Leprosy, established in 2018 to help interrupt transmission and achieve zero new leprosy cases.

In March, the Novartis Foundation and Microsoft announced a strategic alliance to develop an AI-enabled digital health tool to aid in the early detection of leprosy. The initiative's vision is to accelerate leprosy detection, thus enabling earlier care and preventing patients from developing nerve damage or transmitting the infection to others. Microsoft and the Novartis Foundation are collaborating with local investigators from the Oswaldo Cruz Foundation (Fiocruz) in Brazil, with support from Novartis in India. The group developed a protocol to collect, examine and process anonymized leprosy skin lesion images. This data is currently training an AI algorithm with the aspiration to give an accurate indication if the disease is present or not. The imagery and AI code are planned to be made publicly accessible at a later stage to empower leprosy scientists to accelerate research in this field and improve patient outcomes.

This initiative builds on the five-year Leprosy Post-Exposure Prophylaxis (LPEP) program, which tested the real-world effectiveness of preventative treatment for reducing the risk of leprosy in close contacts of newly diagnosed patients. Country-level results are exemplary. In Nepal, for example, LPEP successfully traced 55 715 contacts, identifying a risk of leprosy in 94% and providing preventative treatment. The evidence generated by LPEP has led to this strategy being included in the WHO Guidelines for the Diagnosis, Treatment and Prevention of Leprosy. In November, we presented results, to be published in 2020, showing through epidemiological modeling that large-scale implementation of this strategy could reduce the number of new leprosy cases globally by 75% by 2030 and 90% by 2040.

Expanding our impact on infectious and neglected tropical diseases

Novartis is a signatory to the London Declaration on Neglected Tropical Diseases, which aims to control, eliminate or eradicate 10 diseases by 2020. In line with our reaffirmed commitment, NITD and the Genomics Institute of the Novartis Research Foundation (GNF) have developed, in partnership with the Wellcome Trust, a promising portfolio of novel drug candidates for the treatment of three kinetoplastid diseases: human African trypanosomiasis (sleeping sickness), leishmaniasis and Chagas disease. Together with our leprosy elimination effort, this strategic focus on kinetoplastid parasitic diseases would address four out of 10 diseases in scope of the London Declaration.

GNF and NITD advanced LXE408 for the treatment of visceral leishmaniasis. LXE408 is a first-in-class inhibitor of the kinetoplastid proteasome, discovered by Novartis (with financial support from the Wellcome Trust). The candidate is in a Phase I clinical trial to establish the pharmacokinetics, safety and tolerability of single doses and multiple doses in healthy volunteers, and we enrolled our first patient in January 2019.

After a decade of research, NITD identified an antiviral compound with potential activity on dengue, an infectious disease that causes illness in 100 million people a year and can lead to death in severe cases. We are currently conducting safety studies for this compound, with the aim of initiating a clinical trial by the end of 2020.

We also continue to make progress against under-resourced infectious diseases. In February, Novartis received approval from the US Food and Drug Administration (FDA) for *Egaten* (triclabendazole) for the treatment of fascioliasis. This neglected disease, commonly known as liver fluke infestation, affects an estimated 2.4 million people globally. *Egaten* is the only drug approved in the US for the treatment of people with fascioliasis and is currently the only treatment recommended by the WHO. This approval is expected to facilitate drug licensing and import to endemic countries, helping ensure sufficient and prompt availability of the drug when needed. Novartis has been donating *Egaten* to the WHO since 2005, helping to treat around 2 million patients in more than 30 countries.

Diarrheal diseases are a leading cause of mortality, and cryptosporidium infection is a major pathogen responsible for diarrhea-associated death in young children in developing countries. Through an exploratory effort leveraging the results of our malaria research program, we identified the apicomplexan lipid kinase PI4K as a potential molecular target for new medicines to treat diarrhea caused by cryptosporidium. The Bill & Melinda Gates Foundation supported the preclinical development of the initial candidate KDU731. In 2019, through intensive medicinal chemistry efforts at NITD, we were able to develop an analog of KDU731 into a soft drug candidate that has a promising in vivo efficacy with little systemic exposure following oral administration, thereby improving its safety profile. Soft drug design represents a new approach that integrates metabolism considerations early into the drug design process. This new drug candidate is currently advancing through preclinical studies.

In 2016, the WHO updated its treatment guidelines for multidrug-resistant tuberculosis (MDR-TB) to include our medicine clofazimine. In 2019, the WHO revised its guidelines and now recommends clofazimine for both the longer and the shorter treatment regimens. Further, Novartis applied for WHO prequalification of clofazimine for the treatment of MDR-TB. Prequalification would facilitate patient access in countries where the drug is most needed. We continue to work with regulatory agencies around the world to expand the clofazimine label to include this indication. In November, the health authorities in South Africa approved *Lamprene* (clofazimine) 100 mg for the treatment of MDR-TB; we expect a decision on *Lamprene* 50 mg in 2020.

Novartis is also providing clofazimine to independent researchers who are investigating its use in non-tuberculous mycobacterial infections (NTM). In view of the high unmet need, especially in the US, Novartis is working closely with the FDA to help ensure patient access to clofazimine for compassionate use via its Managed Access Program. Since 2017, approximately 2 200 patients have received clofazimine through this process. A similar program is also available to NTM patients in Canada.

Unleashing the power of Ghanaian plants against leishmaniasis

Leishmaniasis is a growing public health problem with high rates of morbidity and mortality. Migration, climate change, deforestation and urbanization are all contributing to the spread of leishmaniasis. Newer treatments are superior to older medicines but can still be highly toxic.

Edmund Ekuadzi, a former Novartis Next Generation Scientist program fellow who works at the Kwame Nkrumah University of Science and Technology Central Laboratory in Ghana, is exploring the anti-leishmanial properties of Ghanaian plants used in traditional medicines. Dr. Ekuadzi is a fellow at the Wellcome Centre for Anti-Infectives Research at the University of Dundee in Scotland. There, he is being trained in bioassay-guided fractionation, a technique that will enable him to isolate anti-leishmanial compounds from his plant extracts. Through this experience, Dr. Ekuadzi will acquire the expertise necessary to continue his drug discovery program.

Addressing the needs of children

We have a long-standing commitment to research and develop pediatric medicines. We have pioneered many first-in-class pediatric treatments, and we continue to lead the industry in sponsoring Phase I-III pediatric clinical trials in the US, as well as in Europe, where we sponsor more than twice as many trials as any other biotech or pharmaceutical company. We were the first company to manufacture oral therapy for asthma in children, and we led the first industry-sponsored global interventional trial with *Lucentis* (ranibizumab injection) for retinopathy in extremely premature infants in Europe. Further, more than half (51%) of all Novartis medicines approved by the FDA contain a pediatric indication listed in the prescribing information.

In 2019, we received FDA approval for *Zolgensma* (onasemnogene abeparvovec-xioi), a one-time gene therapy for the treatment of pediatric patients less than 2 years old with spinal muscular atrophy. And *Lucentis* received European approval for preterm infants with retinopathy of prematurity, making it the first and only licensed pharmacological treatment for this indication.

Sickle cell disease is a global health problem, with the highest disease burden concentrated in sub-Saharan Africa. It is estimated that approximately 1 000 children in Africa are born with SCD every day, and more than half die before their fifth birthday. Novartis is currently developing a child-friendly formulation of hydroxyurea that would

SANDOZ STATEMENT OF INTENT FOR ADDRESSING AMR: AREAS OF FOCUS

Prevention: initiatives to drive responsible manufacturing standards that help reduce the environmental impact of the production of antibiotics

Access: global and local collaborations with a range of partners to help improve access to anti-infectives

Stewardship: global and local initiatives to ensure prescription of the right drug at the right dose for the right duration

Innovation: non-traditional research and development to explore innovative solutions to prolong the life of existing antibiotics and improve patient adherence to therapy

7m

Courses of pediatric amoxicillin supplied to treat more than 280 000 patients with childhood pneumonia

facilitate administration of the medicine for children unable to swallow capsules.

Despite a reduction in child mortality by more than half since 1990, infectious diseases continue to take a significant toll on children. There is an urgent need for new medicines and therapeutic approaches to solve acute public health challenges in low- to middle-income countries (LMICs).

In addition to our work with MMV on the development of an infant formulation of our antimalarial, *Coartem* (see page 22), we are exploring a pediatric formulation of *Lamprene* (clofazimine) to treat leprosy and drug-resistant tuberculosis. We are also meeting with health authorities and local clinics in India, a country with a high burden of these two diseases, to better understand how we can strengthen our capacity to conduct pediatric clinical trials in the country.

Responding to the call from UNICEF to combat childhood pneumonia, Sandoz developed pediatric amoxicillin, today recommended by the WHO as first-line treatment for childhood pneumonia. To date, Novartis has supplied almost 7 million pediatric amoxicillin courses to UNICEF and Médecins Sans Frontières, helping treat more than 280 000 young patients with childhood pneumonia. Novartis continues to be active in the fight against childhood pneumonia through the Every Breath Counts Coalition, a global network of partners, representing more than 30 organizations, that are working to help target and increase investments for pneumonia prevention, diagnosis and treatment to help end preventable child pneumonia deaths by 2030. The partners will work to expand pneumococcal vaccine coverage and increase access to better diagnosis and treatment tools, including pulse oximetry and child-friendly amoxicillin.

Through the Global Antibiotic Research & Development Partnership (GARDP), we are working to accelerate the development and availability of generic antibiotics to help reduce child deaths from drug-resistant infections. In 2019, we started the country registration process for a heat-stable form of a pediatric antibiotic to increase access for children in LMICs. In addition, we are developing an antibiotic to treat neonatal sepsis.

Addressing antimicrobial resistance

Antimicrobial resistance (AMR) is recognized by the WHO as one of the major threats to global public health and requires action across all government sectors and society. While antibiotics are the cornerstone of modern medicine and have saved countless lives, their misuse and overuse is accelerating AMR.

The Global Action Plan on AMR states that, without harmonized and immediate action on a global scale, the world is heading toward a post-antibiotic era in which common infections could once again become leading killers and also undermine many other advances in health and medicine. AMR could lead to 10 million more deaths annually by 2050.

Sandoz, our generics division, is the world's largest provider of high-quality, affordable antibiotics. We therefore recognize the need to find the right balance between improving access to existing antibiotics and helping ensure that they are used in a responsible and sustainable way. We are committed to playing a leading role in efforts to combat the growing threat of AMR and are actively involved in global and local partnerships to help ensure the responsible and appropriate use of antibiotics in line with the WHO guidelines. Across countries, we work with health authorities and healthcare professionals to foster stewardship and education. We also work with NGOs and not-for-profit organizations to expand access to antibiotics regardless of patient affordability. Further, we are partnering with stakeholders to bring innovation to existing antibiotics.

Sandoz is an active participant as a board member of the AMR Industry Alliance, the premier life sciences industry organization working to address AMR through multisectoral approaches. With other stakeholders, we are working to combat AMR while helping ensure patient access to life-saving antibiotics. In March, a spokesperson from Sandoz was invited to speak at The Economist's AMR 2019 event in the UK about how to address the increasing threat of AMR.

Photo Finn Song, an associate clinical scientist at Novartis in Shanghai, China, enjoys free time on the weekend.

STRATEGIC AREAS

Being a responsible citizen

Why is it important?

Multinational companies have a great responsibility and an even greater opportunity to lead the world in creating positive social change. As more companies embrace social impact as a core business objective, society's trust in the private sector will grow. Strong leadership is needed now more than ever to move beyond business as usual and catalyze a global response to complex societal challenges like climate change.

In this section

Read about our efforts to protect the safety of those using our medicines, care for our people and minimize our impact on the environment:

Patient safety

Launched Authentifield by Novartis to empower low- and middle-income countries with mobile and affordable sensor technology that can detect falsified and counterfeit medicines

→ p. 42

Our people

Committed to invest USD100 million over the next five years in expanding learning opportunities for our employees

→ p. 44

Diversity and inclusion

Introduced a global guideline providing for at least 14 weeks' paid leave for all parents, regardless of gender, after the birth or adoption of a child

→ p. 45

Environmental sustainability

Launched the Novartis Plastic-Free Workplace to phase out single-use plastics at all Novartis sites by 2021

→ p. 48

Klaus Schwab Head of the World Economic Forum; adapted from an interview to FT Moral Money on Jan. 14, 2020

When a company engages in something which is addressing the general public, the company does not serve its stakeholders, but is itself a stakeholder of our global future. A corporation, particularly a multinational, has a responsibility to work together with governments and civil society to address the big global challenges. The underlying assumption is that those big challenges cannot be solved by governments alone or by business alone or by civil society. You need cooperation.

Our approach and performance

Novartis is committed to playing a positive and constructive role in society. We are focused on building a company that our customers, associates, shareholders and partners can all be proud of. Above all, we aim to discover and develop breakthrough treatments that improve and extend people's lives, and to deliver them to as many people as possible. Our primary concern is to protect the safety and well-being of everyone who uses our medicines. And we strive to engage with patients and caregivers worldwide to help ensure their needs and concerns are reflected in our clinical research and business operations. We want to be a responsible citizen wherever we do business, and we aim to minimize our environmental impact around the world.

Helping ensure patient health and safety

Our patient health and safety activities are focused on three key areas: patient safety and product quality, combating counterfeit medicines, and health education and prevention. We maintain an array of systems and processes, backed by cutting-edge technology, to continuously monitor and systematically review the data collected for all products in our portfolio, both on the market and in development. It is also our responsibility to balance the risks and benefits of our treatments, and clearly reflect these in the product labeling, so that patients together with their physicians can make informed treatment decisions.

MAINTAINING PATIENT SAFETY AND PRODUCT QUALITY

Patient safety and product quality are our top priorities. We maintain a robust quality system with harmonized processes and procedures. These include providing integrated medical safety evaluations and benefit-risk assessments as well as monitoring the quality and safety of in-market and investigational products. This quality system is compliant with regulatory requirements and standards.

Further, we regularly participate in health authority inspections to help ensure the highest quality in our manufacturing facilities. A total of 177 inspections were completed in 2019, and all but seven were deemed good or acceptable (96%). The slight increase from last year is due to new acquisitions and increased inspection focus on our clinical activities. In each of these cases, corrective and preventative actions were taken to improve our systems in product quality, patient safety, clinical trial monitoring and manufacturing compliance; the actions were accepted by the local health authority.

Patient health and safety performance indicators

Pharmacovigilance, safety profile and quality of drugs performance indicators

	2019	2018	2017
Novartis Group health authority regulatory reporting (ICSRs)[1] (%)[2]	**98.6**	99.1	NA
Regulatory inspections without major findings (%)[3]	**96.0**	98.5	99.1

[1] ICSRs: individual case safety reports

[2] % represents on-time regulatory submissions. Pharmacovigilance activities between the Innovative Medicines, Sandoz and Alcon Divisions were integrated in 2017 under one single pharmacovigilance system, leading to one single health authority regulatory reporting metric as of January 1, 2018. Prior to that time, individual divisional metrics were tracked. Alcon became a separate company in 2019. Its data is no longer included in the Novartis Group health authority regulatory reporting (ICSRs) % as of July 2019. Data reflect January to November 2019.

[3] Data represent continuing operations.

For the manufacturing of medical devices, we hold the relevant certifications from independent bodies. In September, we received the world's first medical device certification under the new EU Medical Devices Regulation by the British Standards Institution notified body for the Novartis Concept1 inhaler device used to administer inhaled medication. For the manufacturing, supply and distribution of our pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate health authorities – the US Food and Drug Administration (FDA), the European Medicines Agency, the World Health Organization (WHO) and SwissMedic – that confirm after inspection that our duties, including our quality management systems, comply with their regulatory requirements.

BOOSTING PHARMACOVIGILANCE EFFORTS

We continue our efforts to strengthen pharmacovigilance capabilities in low- and middle-income countries (LMICs). For example, in Jordan, together with local health authorities, we organized lectures and education campaigns for healthcare practitioners (HCPs) to raise awareness of best practices in pharmacovigilance and adverse event reporting. Similar activities were conducted in Egypt, also involving patient organizations.

In Turkey, we surveyed HCPs to gauge understanding of pharmacovigilance and solicit input on improving and streamlining the process for reporting adverse events. The survey outcome will be shared with the local health authority along with recommendations to improve patient safety.

In Senegal, through a partnership with Dakar University, we continued to train pharmacy students and pharmacists on pharmacovigilance standards and practices.

In Morocco, we conducted a meeting with internal and external stakeholders, including representatives from the Ministry of Health, to promote the importance of quality and safety of medicines for multiple sclerosis.

The overall number of adverse events reported to Novartis is growing, thanks in part to our education programs on pharmacovigilance, the widespread use of digital technology, and increasing reporting requirements. To manage this surge of data, we are exploring the development of advanced algorithms to screen and analyze data sources for adverse events. Novartis is leading and supporting various projects that employ robotic process automation, machine learning and natural language processing as a complement to traditional pharmacovigilance methods.

In 2019, we initiated activities to obtain an ISO certification of our pharmacovigilance governance. We also started a risk-based analysis of safety reports to trigger investigation into suspected falsified medicines when adverse events seem disproportionate.

COMBATING FALSIFIED AND COUNTERFEIT MEDICINES

Novartis is actively combating falsified and counterfeit medicines, and scaling up efforts to protect patients taking our medicines. Through our actions, we estimate that we have helped prevent falsified and counterfeit medicines from reaching and harming more than 1.2 million patients since 2017.

While we made significant progress in 2019, stronger collective action is required to protect patient safety and effectively tackle this emerging global health crisis. Pharmaceutical crimes are at an all-time high, with new incidents growing by 35% from 2017 to 2018. Against this background, Novartis expects to increase its anti-counterfeiting operational budget by 20% in 2020, and add six full-time employees, expanding our forensics, data analytics, governance and regional operational capabilities in Southeast Asia, Africa and the Americas.

Governance

Our Anti-Counterfeiting Steering Committee now includes two members of the Executive Committee of Novartis (ECN), and is chaired by the Global Head of Novartis Business Assurance & Advisory (NBAA). Our Anti-Counterfeiting Working Group added representatives from our business operations within the Novartis Pharmaceuticals

2m+

Falsified medicines seized by law enforcement and health authorities as a result of more than 260 investigations of suspected incidents

business unit and two additional functions – Ethics, Risk & Compliance (ERC) and Pharmacovigilance – raising the number of functions supporting the program to 15. We also launched a China Anti-Counterfeiting Working Group to accelerate efforts in this strategically important country.

Intelligence
We designed a software-based risk map to analyze and visualize global counterfeiting activities, and integrated it into the ERC-NBAA dashboard, giving us a sharper view of problems as they arise and a better understanding of emerging trends.

We enhanced our in-house forensic capabilities by acquiring a third mobile laboratory covering the Asia-Pacific region. Together with similar capabilities in the Americas and in Europe, the Middle East and Africa, these technologies help us detect suspected counterfeit medicines and enable timely support of local health authorities and law enforcement.

A key milestone in 2019 was the launch of Authentifield by Novartis to empower LMICs with mobile and affordable spectrometric sensor technology that can detect falsified medicines by performing noninvasive testing of a suspect sample to compare it to the library of genuine Novartis products. We deployed 50 smart sensors, primarily in Africa, focusing on medicines in the Novartis Access portfolio as well as treatments for malaria, heart failure and sickle cell disease. Based on the outcome of these activities, in 2020, we aim to deploy at least 200 more sensors worldwide, covering the most at-risk products in our portfolio, to strengthen capacity both within our company and among local partners.

To help ensure product package integrity, we maintained a global network of 248 secondary packaging security verifiers in 77 countries, who performed 528 secondary packaging inspections of suspected falsified medicines in 2019.

Prevention
Finding and eliminating the sources of falsification early on can help save lives. We continue to monitor the 25 most targeted Novartis products on online pharmacies, social media and commercial platforms to detect suspected cases of falsification. This led to 102 online investigations and the removal of 13 891 illegal listings in 2019.

In collaboration with local authorities, we also performed market surveys of highly targeted products in countries such as Mexico, Brazil, Egypt, Vietnam and Ghana, leading to investigations and subsequent enforcement measures.

Enforcement
We investigated 268 incidents of suspected falsified medicines (i.e., a 23% increase compared to 2018), which led to 61 successful enforcement actions and the seizure of over 2 million falsified medicines (unit dosage forms) by law enforcement and health authorities.

Our work helped dismantle 11 illegal pharmaceutical manufacturing facilities, including one large-scale assembly workshop in China that was producing and distributing counterfeit cardiovascular drugs. In Colombia, we partnered with law enforcement and health authorities to identify and dismantle criminal networks engaging in widespread social security fraud with falsified medicines. Our partnership with Europol through Operation Viribus led to 234 arrests, 3.8 million seized illicit medicine packs, and the dismantling of 17 organized criminal groups.

For the third consecutive year, we joined with 12 other pharmaceutical companies and various law enforcement and health authorities (Interpol, FDA-OCI, the Indian Directorate of Revenue, and others) under the umbrella of the Pharmaceutical Security Institute to help disrupt international clusters of rogue online pharmacies.

Stakeholder engagement
Our strategy to engage stakeholders begins with raising public awareness on the impact of falsified medicines on patients' safety. We actively supported two awareness campaigns: Fight the Fakes, a global campaign led by the International Federation of Pharmaceutical Manufacturers & Associations, and Unreal, a cross-industry effort to inform young consumers about the dangers of purchasing medicines online.

We further bolstered our capacity-building efforts by delivering 164 training sessions in 21 countries, and notably reached out to more than 2 300 law enforcement and health authority representatives, giving them the tools to detect suspected falsified medicines. In addition, we built a systematic escalation mechanism to report incidents of confirmed falsified medicines to the WHO within seven business days, as recommended by the Access to Medicine Index 2018 report.

The work we do to detect and stop falsified and counterfeit medicines contributes to the larger global effort to root out fraud, corruption and illicit trade. For example, in July, we participated in the presentation to the United Nations (UN) Conference on Trade and Development of a landmark report measuring the impact of illicit trade on the UN Sustainable Development Goals. At the invitation of the OECD Task Force on Countering Illicit Trade, we also contributed to a study measuring the societal impacts of counterfeit medicines, to be published in 2020.

WORKING WITH PATIENTS AND CAREGIVERS

In 2019, we celebrated the first anniversary of the Novartis Commitment to Patients and Caregivers. To help ensure patient insights continue to inform critical decision-making processes along our medicine lifecycle, we held dialogue sessions with patient communities and senior leaders, including the ECN.

More than 100 patient organizations from approximately 20 countries engaged with Novartis leadership teams and projects in more than 18 disease areas in 2018.

We use digitally enabled technology to engage patient communities where they live, so they don't need to travel. In 2019, we connected 400 patient advocates from 20 countries across Europe at the European Patient Innovation Summit. This platform was established in 2016 for patient advocates from across Europe to discuss all aspects of digital health, including how digital technologies can help them engage in medicine development, and the latest technology innovations that could improve their lives.

We continued to include patient insights in early research across seven therapeutic areas and in our early development programs, engaging 25 patient organizations. Twenty-one clinical development programs in 2018 (i.e., twice the number as in 2017) had a patient engagement component to help ensure our development programs reflect the endpoints that matter to patients.

We affirmed our commitment to transparency and reporting, with more than 30 posters and abstracts, as well as more than 10 published manuscripts in which we shared the insights collected on patient preferences regarding clinical outcomes. Further, we disclosed and reported all interactions with patient organizations globally.

Partnerships are critical to advancing our thinking and improving patient engagement. We continue to gain key insights through our contributions to and collaborations with IMI (Innovative Medicines Initiative) projects, including PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines), PREFER (Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle) and HARMONY (Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in hematology), as well as the EFPIA (European Federation of Pharmaceutical Industry) Patient Think Tank, CTTI (Clinical Trials Transformation Initiative), TransCelerate and PFMD (Patient Focused Medicines Development). To date, we have completed 28 IMI projects and are currently engaged in 41 IMI projects supporting the progression of healthcare and science. By working together, we believe we can help build a systematic and consistent approach to patient engagement across the healthcare system.

Patient support programs

In addition to the awareness and education activities run by Novartis Social Business and the Novartis Foundation (see pages 25 and 29), Novartis engages in patient support programs (PSPs).

For example, since 2004 in Brazil, we have been offering Vale Mais Saúde, an adherence program for patients who pay out-of-pocket for their medicines. The program provides information to patients on treatment compliance as well as educational materials on their condition and tips for healthy lifestyles, including diet and exercise. Conditions covered are diabetes, hypertension, glaucoma, epilepsy, asthma and chronic obstructive pulmonary disease. This is one of the largest programs in Latin America among pharmaceutical companies, with more than 5 million patients enrolled.

Despite the seriousness of a cancer diagnosis, adherence rates to oral cancer therapy can be as low as 40%. This is due to many factors, including a lack of treatment understanding, high treatment and emotional burden, and side effects. PSPs can help address the root causes that influence treatment adherence by educating patients about their condition and treatment, reducing perceived and real barriers to treatment, and improving their emotional and physical well-being. Channels for reaching out and providing information and support to patients include nurse calls, face-to-face counseling, emails, text message, print and direct mail, websites, apps and more. Novartis supports more than 240 oncology adherence-focused PSPs in 43 countries.

For more on how we work to expand access to medicines for underserved patient populations, see the Pricing & Access (pages 20–31) and Global Health (pages 32–38) sections of this report.

NOVARTIS COMMITMENT TO PATIENTS AND CAREGIVERS

Respecting and understanding the patient community perspective

Expanding access to our medicines

Conducting responsible clinical trials

Recognizing the importance of transparency and reporting

Caring for our people

Our company's culture is central to stimulating innovation, driving long-term value and maintaining our reputation. Our goal is to help employees feel inspired, curious and unbossed. This starts with developing strong and self-aware leaders who set clear priorities, empower their teams, and encourage employees to speak their mind and take smart risks.

More than 120 top leaders completed a yearlong leadership development program to build the capabilities they need to help transform our culture. We plan to cascade key aspects of this program to 10 000 leaders over the next three years, helping embed the new leadership approach in our organization. We believe effective leadership is grounded in self-awareness, and in 2019, we rolled

out a new online assessment tool that allows leaders to get feedback from colleagues and team members on how well they are encouraging an inspired, curious and unbossed culture. In addition, a range of tools monitor progress within the organization and provide regular feedback. In an annual survey, employees gave their managers an approval score of 82, 5 points higher than the global benchmark. A new quarterly survey to assess employee engagement in November 2019 showed a score of 74, 4 points above the pharmaceutical industry benchmark, with a score of 78 for sense of purpose, 2 points above the benchmark.

We are building a culture that simulates curiosity and provides multiple opportunities for employees to learn from colleagues and external experts. A popular employee-crowdsourced idea to support culture change prompted us to announce a new investment of USD 100 million over five years, in addition to our existing training budget of approximately USD 200 million per year. And we are encouraging all employees to devote 100 hours per year to learning activities, compared to the current average of nearly 36 hours.

Specifically, we aim to provide in-depth learning content and offer flexible ways for people to access that content whenever and wherever they want. In 2019, through a collaboration with Coursera, we began giving employees free access to 3 500 virtual courses provided in conjunction with 200 leading global universities. During the first year, more than 7 000 users took part in over 1 800 courses, many relating to leadership and digital skills, amounting to nearly 85 000 hours of training. In addition, 11 000 employees completed more than 370 000 shorter courses and training videos available from LinkedIn Learning. We also launched virtual language training and around 14 000 people took part, supporting effective communication among colleagues from more than 120 countries.

All this activity culminated in our second Novartis Learning Month in September, when over 15 000 employees devoted 100 000 hours to learning and participated in 130 webinars and 250 local learning events. This increased prioritization of learning resulted in Novartis being recognized as a leader across sectors by the Association of Talent Development (Excellence in Practice Award), Chief Learning Officer Magazine (Chief Learning Officer Award) and Cornerstone (Learning Strategy Innovation Award).

Curious and self-aware leaders also support inclusive environments. As part of our focus on learning and culture transformation, we have developed modules on inclusive leadership, active listening and psychological safety, to mention a few. These modules contain resources, ranging from small nudges to deep-dive exercises, to help leaders and teams discuss their inclusive behaviors and areas for improvement. In 2019, more than 1 500 employees took part in these culture activation modules.

In September, the Novartis Learning Institute was launched to further support curiosity and promote a consistent learning offering across seven regions, with full global coverage expected to be in place by the end of 2020.

To provide fresh insight into ways of transforming our leadership and culture, we also invited external thought leaders such as Dan Pink, Adam Grant and Margaret Heffernan to speak at global town halls.

To strengthen our digital learning capabilities, we further enhanced the Digital Awareness Hub (launched in 2018) to help demystify digital technology. The hub was used by 33 000 people, representing about a third of all employees.

A digital immersion course was also developed for leadership teams, including hands-on simulation with opportunities to experience and use the latest technologies. This was completed by approximately 2 000 leaders in 2019. In collaboration with Coursera, Novartis is also enabling selected employees to earn a master's degree (MSc) in data science.

Our purpose provides a major source of inspiration for employees, and we constantly seek ways to show them how their work contributes to its fulfillment. In addition, we aim to inspire our employees by providing them with a working environment and practices that encourage them to do their best work. For example, we are transforming our approach to performance management in line with the unbossed philosophy. The new process was launched with a pilot involving more than 16 000 employees in eight countries, and made several important changes, eliminating individual performance ratings while stressing the importance of teamwork and collaboration.

Goals can be set or changed at any point, instead of being fixed at the beginning of the year. Peers and colleagues as well as managers provide regular feedback, ensuring this is more constructive and comprehensive. Rewards are decided by fellow employees using a mutual recognition platform called SPARK. The experience we gained will inform how we extend the process across the company over the next two years.

Diversity and inclusion performance indicators

	2019[1]	2018[2]	2017[2]
Management representation by gender (% female / % male)[3]			
Overall	**44 / 56**	42 / 58	41 / 59
Novartis Top Leaders[4]	**31 / 69**	28 / 72	27 / 73
Senior management	**38 / 62**	36 / 64	34 / 66
Middle management	**45 / 55**	43 / 57	42 / 58
Gender representation of Board of Directors (% female / % male)	**25 / 75**	25 / 75	23 / 77

[1] Data represent continuing operations.
[2] Data represent continuing and discontinued operations.
[3] Management defined by Global Job Level Architecture and Novartis Top Leaders
[4] Novartis Top Leaders comprise the approximately 350 most senior managers at Novartis, including the Executive Committee of Novartis.

VALUING THE DIVERSITY OF OUR PEOPLE AND NURTURING AN INCLUSIVE ENVIRONMENT

In 2019, we made progress toward creating a diverse and inclusive workforce, implementing a number of major initiatives.

The Novartis diversity and inclusion (D&I) strategy focuses on six goals:

1 Reach balanced gender in management: balance gender representation in management by 2023 to fuel innovation, business value and positive impact on society

2 Attract and retain diverse talent: develop a sustainably diverse talent pipeline that meets present and future business needs at the global and local level, generates ideas and value, and attracts new talent

3 Foster inclusive behaviors: enable employees to experience an inclusive environment where they feel heard, respected and valued, resulting in increased engagement and innovation

4 Build internal communities: build global D&I communities to connect and energize employees, foster belonging, and allow them to make a positive impact on our culture

5 Promote LGBTI equity: uphold LGBTI human rights, accept and respect LGBTI employees, and create an inclusive workplace by supporting the UN LGBTI Standards of Conduct for Business

6 Improve pay equity and transparency: deliver on the UN Equal Pay International Coalition (EPIC) pledge to achieve gender balance and further improve our pay equity/transparency processes by 2023

We remain committed to achieving gender balance in management by 2023, with the percentage of women managers at 44%. The number of women on the ECN rose to three, up from two in 2018, and women now head both the Novartis Pharmaceuticals and Novartis Oncology business units within our Innovative Medicines Division.

We made progress toward the EPIC pledge to close the gender pay gap by 2023. One important step is to remove bias by eliminating historical salary data when making job offers. This was achieved in 2019 in seven countries covering 40% of global hiring, including the US and India. Further, following France in 2018, we plan to introduce pay transparency in seven additional countries in 2020, including the US and Switzerland.

We also began implementing a new global guideline providing for at least 14 weeks' paid leave for all new parents, regardless of gender, to support the well-being of their families after the birth or adoption of a child. Currently 82% of employees in more than 40 countries can benefit from the guideline. By January 2021, we expect it to cover all Novartis employees, helping them feel more fulfilled and inspired in their work and home lives.

Flexible working is a key component of our balanced gender strategy and can help employees sustain their energy and impact at work. As such, our Energized for Life initiative supports flexible working practices across all our countries. For example, open positions in Switzerland are increasingly advertised as 80–100%, and other flexibility options (e.g., home office, compressed work week, work-life balance contract, job sharing) are included in the hiring discussions for these positions.

We continued to roll out the Energized for Life initiative, including programs to improve employees' health and well-being. We aim to provide our associates with strategies and tools to be their best selves, every day and everywhere. Increased impact on yourself (energy, resilience and mental agility) can lead to an increased impact on others (e.g., energy giver, helping and inspiring others). Our alliance with an external company that gives advice and support in areas like nutrition, movement, mindset and recovery now extends to all employees worldwide and has reached about 50 000 associates in the top countries. In addition, we expanded our program that supports people affected by a range of medical conditions, including cancer and neurological and cardiometabolic disorders, to cover 80 000 employees and their families in more than 70 countries.

As the first major pharmaceutical company to support the UN LGBTI Standards of Conduct for Business, we also maintained our focus on fighting discrimination against lesbian, gay, bisexual, transgender and intersex (LGBTI) people. Novartis celebrated LGBTI inclusion through global events such as Pride Month in June.

As part of our talent strategy to attract and retain diverse talent, we provide employees with opportunities to engage in employee resource groups (ERGs), which are voluntary networks linking employees around specific topics of interest (e.g., women and parents, people with disabilities, ethnic and cultural affiliation, environmental sustainability, mindfulness, etc.). We have over 50 ERGs around the world, connecting thousands of employees around topics that matter to them. These ERGs make the unique aspects of D&I more tangible to everyone and contribute to a culture of curiosity and empowerment.

For the second year in a row, we attended One Young World, a global summit that brings together approximately 2 000 young leaders aged 18-30 from around the world to discuss the world's pressing global issues. We started with a small group of delegates in 2018, and we are committed to sending 40-45 delegates annually. In 2019, our delegation included 45 young and curious leaders from 23 different countries, and five returning ambassadors. Our aim is to support our talented employees in becoming leaders of the future and having a positive impact on the world.

Our progress in D&I was recognized in a number of external indexes in 2019. We were pharmaceutical industry leaders in the Refinitiv (formerly Thomson Reuters) D&I Index, ranking seventh out of more than 7 000 companies worldwide. We were also ranked No. 7 in the Dow Jones Sustainability Index, which compares the environmental, social and governance performance of the world's leading companies. We were industry leaders in labor practice indicators covering D&I, equal remuneration, and freedom of association. In a further sign of our commitment, Novartis has been included in the 2020 Bloomberg Gender-Equality Index, which tracks a range of measures including female leadership and talent pipeline, gender pay parity, and inclusive culture.

CORPORATE VOLUNTEERING

The Novartis corporate volunteering program operates a virtual platform that matches volunteers with volunteering opportunities. Co-sponsored by the Global Health & Corporate Responsibility and People & Organization teams, this online matching tool enables every Novartis associate to register a potential global health or corporate responsibility project idea, or sign up to become a corporate volunteer. Since its creation in 2015, over 14 200 associates from 40 countries have used the platform, with more than 1 990 new users in 2019. In 2019, nearly 790 associates were registered to donate pro bono skills and time, and around 40 new projects were initiated in addition to those started in previous years.

For example, we started a project on quality and supply chain awareness and capability building in Cameroon in 2017, and expanded it to Ethiopia in 2018 and Uganda in 2019. Through the project, Novartis associates train local partners (distributors, nongovernmental organizations and government representatives) on topics including supply chain and stock management, quality assurance and performance tracking criteria. This training is meant to support last-mile delivery to patients in rural areas by addressing bottlenecks in the supply chain.

Further, Novartis associates delivered training on business acumen skills in strategy, business development, social media, finance and human resources to the leadership of the Tanzanian Training Center for International Health, supported by the Tanzanian Ministry of Health and Social Welfare, the Novartis Foundation and the Swiss Tropical and Public Health Institute.

Our largest global volunteering activity was our annual Community Partnership Day. In 2019, 13 789 associates from six continents and 56 countries participated, dedicating 110 312 hours to causes in their communities.

TRAVEL SECURITY

Protecting our associates and those who travel on behalf of Novartis is a core part of our Global Security mission. Approximately 30 000 Novartis employees are frequent international travelers, and 1 300 are international assignees. This equates to over 250 000 journeys annually to all areas of the globe. The Novartis Travel Security program provides all associates with tools and advice to help de-risk their travel, specifically relating to security, medical/health, and environmental issues. This includes 24/7 access to online/on-call services, as well as pretravel advice, proactive alerts during travel, and post-trip information where relevant. We use a combination of third-party vendors and in-house experts to provide this service, and all information can also be used to inform leisure/personal travel.

In case of a security, health or environmental incident, automated up-to-date alerts are sent to travelers' mobile devices, informing them about the situation and providing advice. A simple process enables travelers to confirm via their mobile device that they are well, and Global Security follows up with those requesting assistance.

In 2019, 1 361 Novartis travelers were alerted about 62 incidents in 36 countries relating to explosions, shootings, natural disasters, epidemics, police operations or airport closures. Of these incidents, 47 were considered potentially life threatening and, without the alerts, may have had severe consequences for the travelers; 48 related to security; and 14 related to environmental events.

Global Security works with Real Estate and Facility Services security experts in assessing risks relating to Novartis congresses, meetings and events, and also assesses risks relating to Novartis business activities in complex environments. For instance, to help ensure the safety of associates working in clinical trial sites in Africa, we mapped the security risk, including risks relating to civil unrest, crime and terrorism, to enable the company to determine the location of our clinical trial sites for malaria. The group also provides security and intelligence analysis to the business (for example, to support a decision to enter a market or maintain our company's presence in high-risk environments).

Expanding our environmental stewardship

Our ambition is to be a leader in environmental sustainability, driving change both through our own operations and across our supply chain. We want to grow our business without consuming more natural resources, and our actions demonstrate it: While Novartis Group sales have increased in the past 10 years, our consumption of energy and water, as well as our greenhouse gas emissions, have declined. For example, we have reduced our carbon emissions (scope 1 and 2) by nearly 80 000 tonnes vs. 2016.

In 2018, the ECN approved a new environmental sustainability strategy. Our strategy sets ambitious targets to become carbon neutral in our own operations by 2025, reduce the carbon footprint of our supply chain by at least half by 2030, and achieve plastic and water neutrality by 2030. Our climate strategy was approved in 2019 by the Science Based Targets initiative, an organization that mobilizes companies to set science-based targets toward a low-carbon economy.

Although Novartis has not currently signed a statement of support to the voluntary recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), we are developing our reporting in line with its recommendations and have started to estimate the financial impact of climate change risks. Additionally, climate change has been included as part of our Enterprise Risk Management process and consolidated into the Novartis Risk Compass.

We made our environmental performance more visible in the organization in 2019. We have developed an environmental sustainability dashboard to track quarterly progress, which is presented to the Environmental Sustainability (ES) Steering Committee and the Trust & Reputation Committee, chaired by the Novartis CEO. In addition, starting in 2020, ES targets will be included in senior leaders' personal objectives.

Throughout the year, we continued to take steps to further reduce our environmental impact. In particular, we identified four key drivers to meet our 2025 energy target, summarized below.

Reduce our demand for energy by improving energy efficiency: We conducted 24 ES workshops globally to identify opportunities that can support our key sites in developing ES roadmaps. These have generated several energy efficiency projects that we are currently implementing, such as the optimization of boilers and chillers for heating, ventilation and air conditioning.

Switch to renewable energy: We are actively investing in renewable energy sources. Our Santa Rita East wind farm developed with Invenergy went online in Texas in the US in 2019. The climate emissions from all the electricity we use at Novartis offices and R&D facilities in the US are now compensated thanks to the renewable energy credits generated by this wind farm through the virtual power purchase agreement. We are actively exploring establishing a similar arrangement in Europe that would decarbonize our electricity sources.

Update our manufacturing technology: We have begun to shift away from traditional chemistry manufacturing toward more sustainable, environmentally friendly approaches like continuous manufacturing, biotechnology and surfactant technology.

Invest in greener infrastructure: Following our decision to include carbon pricing in our investment decisions, we started a one-year pilot in February to factor in a price of USD 100 per ton of carbon for new and upgraded facilities above USD 20 million. We will review pilot results in 2020 and determine if we should lower the USD 20 million threshold to encompass a broader range of projects.

In addition, we plan to use credible, transparent carbon sequestration projects (offsets) – for example, natural climate solutions such as Novartis-owned forestry projects – to further reduce our carbon footprint.

To have a positive environmental impact, we cannot limit our efforts to activities that take place within Novartis, since our supply chain makes up 80% of our overall environmental footprint. With this in mind, in June, in collaboration with the World Business Council for Sustainable Development, Novartis

ENVIRONMENTAL TARGETS

Carbon neutral in own operations by 2025

Water neutral in all areas by 2030

Plastic neutral by 2030

organized a workshop with our suppliers in India to develop an integrated energy strategy that considers all energy uses across our value chain, and help remove barriers to renewable energy.

We continue to reduce waste and increase material efficiency even as we provide more medicines to a growing number of patients. We currently recycle approximately 80% of all non-hazardous waste and continue to maximize opportunities for reuse and recycling. In late 2019, the ES Steering Committee approved a pilot take-back scheme in Switzerland for our *Breezhaler*, the inhaler used for the delivery of different medications for chronic obstructive pulmonary disease.

With plastics accumulating across the globe, harming oceans and other ecosystems, we are focusing on phasing out non-business-critical single-use plastics at all Novartis sites by 2021. In 2019, we launched Novartis Plastic-Free Workplace and, as a first symbolic move, we asked all associates to adopt refillable bottles and all sites to provide drinking water from refillable sources. We are taking a phased approach to banning single-use plastic bottles globally by 2021. Many Novartis sites around the world have already replaced plastic straws and stirrers, cups, garbage bags and styrofoam with biodegradable and compostable alternatives. Some sites have also launched reusable shopping bag-sharing initiatives to reduce plastic consumption.

These efforts are part of our ambition to eliminate polyvinyl chloride (PVC) in all packaging and reduce waste disposal by 50% compared to 2016 levels. We are currently assessing our global plastic footprint, and estimate that our factories generate around 2.5 tons of plastic annually, which is not recycled.

So far, 90% of our manufacturing sites globally have eliminated PVC in secondary and tertiary packaging, including three sites in 2019. We plan to eliminate PVC from two additional sites in 2020 and from the last three remaining sites in 2021.

Environmental performance indicators[1,2]

	2019	2018	2017
Energy use (million gigajoules), on site and purchased	**12.71**	13.06	13.35
Greenhouse gas (GHG) emissions, Scope 1, combustion and process (1 000 tCO_2e)	**347.8**	334.5	330.5
GHG emissions, Scope 1, vehicles (1 000 tCO_2e)	**135.5**	146.3	140.8
GHG emissions, Scope 2, purchased energy (1 000 tCO_2e)	**411.9**	450.4	461.8
GHG emissions, Scope 3, business travel (1 000 tCO_2e)	**205.8**	211.7	200.0
Total GHG emissions, Scope 1 and Scope 2 (1 000 tCO_2e)[3]	**895.1**	931.2	933.1
GHG offsets (1 000 tCO_2)	**29.8**	54.9	71.8
GHG emissions (Scope 1 and Scope 2) per sales (tCO_2e per million USD)	**18.86**	20.80	22.03
GHG emissions (Scope 1 and Scope 2) per associate (tCO_2e)	**8.22**	8.58	8.74
Halogenated volatile organic compounds (VOCs) (t)	**27.37**	78.98	75.58
Non-halogenated VOCs (t)	**502.44**	503.27	457.22
Non-hazardous waste recycled (%)	**80.6**	82.0	81.3
Hazardous waste recycled (%)	**58.7**	54.9	53.2
Non-hazardous waste not recycled (1 000 t)	**12.9**	12.5	12.7
Hazardous waste not recycled (1 000 t)	**42.5**	47.3	48.1
Water use (million m^3)[4]	**67.2**	69.2	72.3
Water consumption (million m^3)[5]	**10.9**	11.9	12.2

[1] Data represent continuing operations.
[2] The 2019 environmental sustainability data published in this report are actual data for the period from January through September, and best estimates for the period from October through December, which will be updated with actual data in the first quarter of 2020. Significant deviations will be reported on our website and restated in next year's end-of-year reports.
[3] Scope 1: combustion and process, and vehicles; Scope 2: purchased energy
[4] Sum of contact water and non-contact (cooling) water use
[5] Water discharged via treatment and water lost

We are also working to improve the sustainability of our sites across the globe more broadly. In 2019, we launched the One Novartis Environmental Sustainability Team (ONEST), a network of more than 200 people across 32 countries focused on environmental sustainability at Novartis. ONEST aims to offer a work structure for employees wishing to contribute to the achievement of our environmental targets through business-related, globally scalable ideas. For example, we currently have global teams working on designing eco-friendly events, reducing plastics and food waste, and developing carpooling solutions.

We are also making progress toward achieving water sustainability. Our 2025 goal to reduce water consumption in our operations by half versus 2016 is on track, as well as our water quality target. The water quality target has been adapted in the course of the environmental sustainability target setting for 2025, and requests our own and our key suppliers to meet risk-based discharge targets for manufacturing effluents. In 2019, 79% of our manufacturing sites could demonstrate that they do not have any water quality impacts from manufacturing by meeting the specific discharge targets for the produced drug substances. The remaining sites, as well as our key suppliers, are performing the assessment and working on plans to meet the target by 2025.

We are actively exploring ways to recycle water. For example, we developed a technology at our site in Kurtköy, Turkey, which enables us to treat and reuse wastewater in cooling towers. This technology was implemented at a second site in 2019 and is being considered for a further five.

For the past five years, Novartis has contributed to the Innovative Medicines Initiative's Intelligence-led Assessment of Pharmaceuticals in the Environment project to support the prioritization of medicinal compounds for environmental risk assessments. A conference in June marked the completion of the project with the release of an online tool that summarizes the properties, environmental toxicity and characteristics of active product ingredients.

Novartis is also a member of the Antimicrobial Resistance Industry Alliance, which aims to eliminate or significantly reduce antibiotic residues from manufacturing. For the first time in 2019, the alliance published a list of discharge targets, which will be regularly updated.

Together with the United States Congress and Massachusetts legislators, Novartis participated in education sessions for lawmakers. The objective was to provide a business perspective to policymakers in order to validate the need to monetize carbon, encourage adoption of technologies that decarbonize energy, and raise understanding of the physical risks climate change poses to business.

Conducting animal research responsibly

Novartis fully supports the use of alternatives to animal research wherever feasible. We adhere to the 3R principles (reducing the number of animals in studies, refining study methods to improve the animal's experience, and replacing animal studies with alternative options).

Each year, we recognize exceptional contributions to the 3Rs through global and local 3R awards. In 2019, award-winning projects:

- Reduced the number of animals needed for a study subtype by 99% using a 3-D tissue culture organoid model for liver regeneration
- Refined studies using digital technologies to observe and study mice in their home environment, preventing animal stress and improving the scientific quality of the data
- Replaced animals with human-derived cell cultures to screen for potential seizure side effects when assessing the safety of new medicines

About this report

This is our **Communication on Progress** in implementing the principles of the **United Nations Global Compact** and supporting broader UN goals.

We welcome feedback on its contents.

The UNGC has 10 guiding principles. The above icons reflect these relevant sections throughout the report.

For the seventh consecutive year, Novartis is publishing an annual Novartis in Society report (formerly our Corporate Responsibility Report). This report has been prepared in accordance with the GRI Standards: Core option. The report supplements the "Build trust with society" chapter in the 2019 Novartis Annual Review (pages 36-39) and the 2019 Novartis Annual Report. The previous report was published on January 30, 2019.

As an original signatory of the UN Global Compact (UNGC), we are committed to sharing our progress in implementing the 10 principles of the compact. This report serves as our UNGC Communication on Progress. We published a Communication on Progress in the first quarter of 2019, and will do so again in 2020. On page 11, we discuss our contribution to the UN Sustainable Development Goals (SDGs). In addition, both the UNGC principles and the SDGs are clearly mapped versus the GRI indicators (pages 55-58).

The report is divided into four chapters based on our CR material clusters and GH&CR priorities: holding ourselves to the highest ethical standards, being part of the solution on pricing and access, addressing global health challenges and being a responsible citizen. In each chapter, readers will find more focused and contextual information about the priority topics arising from our materiality assessment. Our materiality assessment is a key part of our CR strategy and provides much more than a list of priority CR topics to report against. It is part of a regular four-year cycle we have established to help us better understand the issues that matter most to our internal and external stakeholders, the impact these issues have on our current and future business, and the associated risks and opportunities for our company. Download the 2017 Corporate Responsibility Materiality Assessment Results Report.

As in previous years, the Governance, Nomination and Corporate Responsibilities Committee of the Board of Directors, which is the highest CR body in Novartis, has reviewed this report.

This report covers all regions and divisions from January 1, 2019, to December 31, 2019. All information reflects the continuing operations of the Novartis Group (except for 'Diversity and inclusion performance indicators' on page 44 and 'People performance indicators' on page 53 where 2018 and 2017 data represent continuing and discontinued operations), including the various changes in the Group's portfolio of activities in prior years. Environmental data is based on nine-month actual data (January to September 2019) plus three-month estimates. This data will be restated with actual figures on our website during the first half of 2020. Where data has been restated from previous reports, it is noted in an appropriate footnote in this report. GRI Topic Boundaries show where we as a company have impact and create value.

This report aims to meet the needs and expectations of CR professional audiences by offering easy access to our performance on key topics raised by our CR materiality analysis. The GRI Content Index on page 55 provides links to content within this report, the 2019 Annual Review, the 2019 Annual Report and novartis.com. In addition, in order to provide ESG analysts with easier access to our information, we will be publishing a Novartis ESG index to signpost where our key disclosures – content and KPIs – can be found across our publications and channels. The index will be available on our website in the first quarter of 2020.

PricewaterhouseCoopers AG has provided independent assurance on specific CR data and on our materiality assessment outlined in this report. For more detail, see the Independent Assurance Report on page 66.

Learn more about our GH&CR activities.
See all our GH&CR publications.
Receive the Novartis GH&CR e-newsletter via email.

For feedback and suggestions, contact Jill Gregson, Head, Global Health & Corporate Responsibility Reporting: jill.gregson@novartis.com.

Ratings and recognition
A full list of our ratings and rankings is available on our website.

Performance indicators 2019

Holding ourselves to the highest ethical standards

ETHICAL BUSINESS PRACTICES PERFORMANCE INDICATORS[1]

	2019	2018	2017
Novartis associates trained and certified on the Code of Conduct (%)[2]	**98**	98	98
Misconduct cases (central matters) reported/allegations substantiated[3,4]	**205 / 113**	289 / 356	525 / 519
SpeakUp Office allegations per category (% of all central matters)[5]			
Fraud/asset misappropriation	**12**	57	32
Expense fraud	**9**	11	10
Books and records, accounting irregularities	**2**	1	2
Improper professional practices	**29**	58	42
Gifts, bribery, kickbacks	**4**	6	10
Discrimination and sexual harassment	**16**	11	11
Retaliation	**13**	6	4
Other employee relation issues	**38**	21	23
Conflict of interest	**20**	13	11
IT security breach	**8**	5	6
Quality assurance/data integrity	**13**	8	12
Data privacy	**4**	1	2
Antitrust, fair competition	**0**	1	0
Other	**22**	13	18
Dismissals and resignations related to misconduct (central matters)[3,6]	**45**	124	192

Animal testing indicators

Rodents	**78.2% (355 451)**	70.4% (360 417)	70.8% (415 333)
Zebrafish	**21.5% (97 551)**	29.2% (149 474)	28.7% (168 201)
Other species	**0.3% (1 452)**	0.4% (2 246)	0.5% (3 114)

[1] Data represent continuing operations.
[2] Active Novartis associates with email addresses, trained via e-learning or via One Deck for Novartis Technical Operations
[3] Decrease in number of misconduct cases reported is due to change in methodology: As of January 1, 2019, we only report on central matters (higher-risk cases). A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and financial significance.
[4] The number of misconduct cases reported may change as matters may be reassessed in the course of the case lifecycle. The number of substantiated allegations may change due to the fact that investigation reports with assessments are received on an ongoing basis, which potentially leads to a difference in numbers at a later stage. A case can have more than one allegation and therefore the number of allegations is higher than the actual number of cases.
[5] One case can fall under several categories, so the total is greater than 100% and category figures total more than the stated number of cases. Investigation reports are received on an ongoing basis, which potentially leads to a reassessment of the allegation category and related figures.
[6] The number of dismissals and resignations related to misconduct may change due to the fact that investigation reports are received and then reviewed for remedial actions on an ongoing basis, which potentially leads to a difference in numbers at a later stage.

Being part of the solution on pricing and access; addressing global health challenges

ACCESS TO HEALTHCARE PERFORMANCE INDICATORS[1]

	2019	2018	2017
Total patients reached (millions)	**799**	765	816
Patients reached through access-to-healthcare programs (millions)[2]	**16**[3]	25	35

	2019	2018	2017
Novartis Social Business			
Countries with products on the ground	**33**	26	35
FTEs working for NSB[4]	**786**	651	555
Patients reached with products (thousands)[3, 5]	**15 058.5**	24 832.6	35 202.3
Health educators trained	**1 536**	1 028	1 037
Healthcare providers trained	**1 516**	697	311
Policymakers trained	**145**	131	25
Points of service provision[6]	**13 635**	15 190	12 680
People reached at points of service provision	**986 701**	765 055	585 821
Awareness events held	**250 432**	185 756	157 846
People reached at awareness events	**10 211 704**	7 982 078	7 709 652

	Patients reached (thousands)		
	2019	2018	2017
Local brands			
Novartis Pharmaceuticals	**301.7**	213.3	99.1
Novartis Oncology	**11.3**	8.0	6.5
Patient assistance programs			
Novartis Patient Assistance Foundation Inc. (US)	**87.2**	68.1	55.5
Novartis Oncology Access	**60.7**	71.1	82.9
Donations			
Leprosy (WHO)	**168.6**	176.2	227.0
Fascioliasis/*Egaten*[7]	**154.7**	154.7	147.9
CMLPath to Care™	**14.4**	13.4	7.8

	Value USD (millions)[8]		
	2019	2018	2017
World Child Cancer	**<0.1**	0.1	0.1
Medicine donations (emergency relief)	**2.8**	4.7	10.9

[1] Data represent continuing operations.
[2] Novartis Social Business, local brands, patient assistance programs, donations
[3] Our patient reach has steadily declined over the past five years, due to the increasing availability of WHO prequalified generic ACTs, eligible for international donor-funded procurement. In addition, to harmonize the patient reach calculation methodology across Novartis, the malaria patient reach calculation was revised.
[4] Full-time equivalent positions and contractors
[5] The patient number was calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as NCD patients often take several drugs). The treatment adherence and treatment overlap factors are based on assumptions from developed markets.
[6] Points of service provision include facilities and health camps where healthcare services are provided.
[7] Numbers of patients reached have been updated to reflect the new methodology used by WHO and based on real-world evidence.
[8] Wholesale acquisition cost (WAC) plus logistics costs for some programs

Being a responsible citizen

PEOPLE PERFORMANCE INDICATORS

	2019[1]	2018[2]	2017[2]
Full-time equivalent positions / headcount[3]	**103 914 / 108 775**	125 161 / 129 924	121 597 / 126 457
Turnover: % voluntary / % overall	**7.0 / 14.0**	7.1 / 11.5	7.0 / 11.3
Voluntary turnover of high performers (%)	**5.4**	5.5	5.2
Internal hires / external hires (%)	**55 / 45**	57 / 43	55 / 45
External hires by gender (% female / % male)	**53 / 47**	52 / 48	53 / 47
Management representation by gender (% female / % male)[4]			
Overall	**44 / 56**	42 / 58	41 / 59
Novartis Top Leaders[5]	**31 / 69**	28 / 72	27 / 73
Senior management	**38 / 62**	36 / 64	34 / 66
Middle management	**45 / 55**	43 / 57	42 / 58
Gender representation of Board of Directors (% female / % male)	**25 / 75**	25 / 75	23 / 77
Associate nationalities / associate nationalities in management[4]	**149 / 110**	147 / 115	145 / 112
Annual training hours per employee	**35.8**	22.6	24.5
Associates represented by a trade union/internal work council or covered by a collective bargaining agreement (%)[6]	**45**	39	39
Gender split of leavers (% female / % male)	**48 / 52**	51 / 49	49 / 51
Median tenure in years by gender (female / male)	**5.0 / 6.0**	4.5 / 5.5	NA
Internal promotion by gender (% female / % male)	**51 / 49**	48 / 52	49 / 51
Revenue-producing roles by gender (% female / % male)	**49 / 51**	47 / 53	47 / 53
Novartis IT and engineering workforce by gender (% female / % male)	**31 / 69**	36 / 64	36 / 64
Number of employees by employment contract (permanent and temporary), by gender[7]			
Women employed on a permanent contract	**51 905**	60 303	58 154
Women employed on a temporary contract	**2 327**	3 437	3 606
Men employed on a permanent contract	**52 691**	64 171	62 806
Men employed on a temporary contract	**1 718**	1 967	1 884
Number of employees by employment contract (permanent and temporary), by region[7]			
Employees on a permanent contract in Asia-Pacific region	**27 226**	30 663	29 546
Employees on a temporary contract in Asia-Pacific region	**668**	1 665	1 844
Employees on a permanent contract in Europe/Middle East/Africa region	**59 956**	63 137	60 870
Employees on a temporary contract in Europe/Middle East/Africa region	**3 063**	3 370	3 240
Employees on a permanent contract in Latin America region	**5 515**	6 205	5 954
Employees on a temporary contract in Latin America region	**195**	224	241
Employees on a permanent contract in North America region	**16 078**	24 509	24 596
Employees on a temporary contract in North America region	**128**	148	166
Number of employees by employment type (full time and part time), by gender[7]			
Women employed on a full-time contract	**66 167**	55 918	54 476
Women employed on a part-time contract	**7 338**	7 822	7 284
Men employed on a full-time contract	**82 105**	65 047	63 609
Men employed on a part-time contract	**1 246**	1 091	1 081

[1] Data represent continuing operations.
[2] Data represent continuing and discontinued operations.
[3] Headcount reflects the total number of associates in our payroll systems. Full-time equivalent adjusts headcount for associates working less than 100%. All data as of December 31
[4] Management defined by Global Job Level Architecture and Novartis Top Leaders
[5] Novartis Top Leaders comprise the approximately 350 most senior managers at Novartis, including the Executive Committee of Novartis.
[6] Non-management associates
[7] Less than 0.5% of associates have unknown classification.

PATIENT HEALTH AND SAFETY PERFORMANCE INDICATORS

Pharmacovigilance, safety profile and quality of drugs performance indicators

	2019	2018	2017
Novartis Group health authority regulatory reporting (ICSRs)[1] (%)[2]	**98.6**	99.1	NA
Regulatory inspections without major findings (%)[3]	**96.0**	98.5	99.1

SUPPLY CHAIN PERFORMANCE INDICATORS[3, 4]

	2019	2018	2017
Suppliers posing an elevated risk under responsible procurement (RP)/Third-Party Risk Management (TPRM)[5]	**734**	347	436
Suppliers with active follow-up[5, 6]	**122**	89	265
Suppliers audited[5, 7]	**135**	48	49

HEALTH, SAFETY AND ENVIRONMENT PERFORMANCE INDICATORS[3, 8]

	2019	2018	2017
Lost-time injury and illness rate (per 200 000 hours worked)[9]	**0.18**	0.16	0.12
Total recordable case rate (per 200 000 hours worked)[9, 10]	**0.36**	0.39	0.37
Energy use (million gigajoules), on site and purchased	**12.71**	13.06	13.35
Greenhouse gas (GHG) emissions, Scope 1, combustion and process (1 000 tCO_2e)	**347.8**	334.5	330.5
GHG emissions, Scope 1, vehicles (1 000 tCO_2e)	**135.5**	146.3	140.8
GHG emissions, Scope 2, purchased energy (1 000 tCO_2e)	**411.9**	450.4	461.8
GHG emissions, Scope 3, business travel (1 000 tCO_2e)	**205.8**	211.7	200.0
Total GHG emissions, Scope 1 and Scope 2 (1 000 tCO_2e)[11]	**895.1**	931.2	933.1
GHG offsets (1 000 tCO_2)	**29.8**	54.9	71.8
GHG emissions (Scope 1 and Scope 2) per sales (tCO_2e per million USD)	**18.86**	20.80	22.03
GHG emissions (Scope 1 and Scope 2) per associate (tCO_2e)	**8.22**	8.58	8.74
Halogenated volatile organic compounds (VOCs) (t)	**27.37**	78.98	75.58
Non-halogenated VOCs (t)	**502.44**	503.27	457.22
Non-hazardous waste recycled (%)	**80.6**	82.0	81.3
Hazardous waste recycled (%)	**58.7**	54.9	53.2
Non-hazardous waste not recycled (1 000 t)	**12.9**	12.5	12.7
Hazardous waste not recycled (1 000 t)	**42.5**	47.3	48.1
Water use (million m^3)[12]	**67.2**	69.2	72.3
Water consumption (million m^3)[13]	**10.9**	11.9	12.2

[1] ICSRs: individual case safety reports
[2] % represents on-time regulatory submissions. Pharmacovigilance activities between the Innovative Medicines, Sandoz and Alcon Divisions were integrated in 2017 under one single pharmacovigilance system, leading to one single health authority regulatory reporting metric as of January 1, 2018. Prior to that time, individual divisional metrics were tracked. Alcon became a separate company in 2019. Its data is no longer included in the Novartis Group health authority regulatory reporting (ICSRs) % as of July 2019. Data reflect January to November 2019.
[3] Data represent continuing operations.
[4] Data reflect responsible procurement (RP) and Third-Party Risk Management (TPRM) programs from January to July 2019, and the TPRM program only from August to December 2019. As of August 2019, after completion of the global TPRM program rollout, the RP program was officially retired.
[5] Includes new suppliers and new products, services or sites from existing suppliers. Figures include data on labor rights; health, safety and environment; and animal welfare.
[6] Follow-up includes more information requested, audits or on-site assessments.
[7] High-level audits
[8] The 2019 environmental sustainability data published in this report are actual data for the period from January through September, and best estimates for the period from October through December, which will be updated with actual data in the first quarter of 2020. Significant deviations will be reported on our website and restated in next year's end-of-year reports.
[9] Data include Novartis associates and third-party personnel managed by Novartis associates.
[10] Includes all work-related injury and illness, whether leading to lost time or not
[11] Scope 1: combustion and process, and vehicles; Scope 2: purchased energy
[12] Sum of contact water and non-contact (cooling) water use
[13] Water discharged via treatment and water lost

Novartis GRI Content Index

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGC PRINCIPLE	UN SDG	COMMENTS	REFERENCE
101 – FOUNDATION					
102 – GENERAL DISCLOSURES					
102-1	Name of the organization				Novartis in Society report 2019
102-2	Activities, brands, products and services				6
102-3	Location of headquarters				11
102-4	Location of operations				Annual Report 2019 F-89
102-5	Ownership and legal form				Annual Report 2019 A-9
102-6	Markets served				Annual Review 2019 p.14
102-7	Scale of the organization				4
102-8	Information on employees and other workers	**6**	8 12		53, 54
102-9	Supply chain	**3, 4, 5, 6, 8, 10**			15
102-10	Significant changes to the organization and its supply chain				Annual Report 2019 F-17
102-11	Precautionary principle or approach	**7**			Annual Report 2019 p.11
102-12	External initiatives				63
102-13	Membership of associations	**1, 8**			63
102-14	Statement from senior decision-maker				8
102-16	Values, principles, standards, and norms of behavior	**1, 2, 3, 4, 5, 6, 8, 10**	16		Ethics, Risk and Compliance
102-17	Mechanisms for advice and concerns about ethics	**10**	16		Establishing Standards of Integrity
102-18	Governance structure				Annual Review 2019 p.42
102-19	Delegating authority				9
102-20	Executive-level responsibility for economic, environmental and social topics				9
102-21	Consulting stakeholders on economic, environmental and social topics		16		9
102-22	Composition of the highest governance body and its committees		5 16		Annual Report 2019 p.170
102-23	Chair of the highest governance body		16		Annual Report 2019 p.172
102-24	Nominating and selecting the highest governance body		5 16		Annual Report 2019 p.170
102-25	Conflicts of interest		16		Annual Report 2019 p.180
102-26	Role of highest governance body in setting purpose, values and strategy				Annual Report 2019 p.177
102-27	Collective knowledge of highest governance body		4		9
102-28	Evaluating the highest governance body's performance				Annual Report 2019 p.176
102-29	Identifying and managing economic, environmental and social impacts		16		Annual Report 2019 p.180
102-30	Effectiveness of risk management processes				Annual Report 2019 p.182
102-31	Review of economic, environmental and social topics				Annual Report 2019 p.180
102-32	Highest governance body's role in sustainability reporting				9
102-33	Communicating critical concerns				9
102-34	Nature and total number of critical concerns			Number and nature of concerns are not disclosed	

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGC PRINCIPLE	UN SDG	COMMENTS	REFERENCE
102-35	Remuneration policies				Annual Report 2019 p.127
102-36	Process for determining remuneration				Annual Report 2019 p.130
102-37	Stakeholders' involvement in remuneration		16		Annual Report 2019 p.130
102-38	Annual total compensation ratio			Information is confidential and not disclosed	
102-39	Percentage increase in annual total compensation ratio			Information is confidential and not disclosed	
102-40	List of stakeholder groups				10
102-41	Collective bargaining agreements	**3**	8		53
102-42	Identifying and selecting stakeholders				10
102-43	Approach to stakeholder engagement				10
102-44	Key topics and concerns raised				9
102-45	Entities included in the consolidated financial statements				Annual Report 2019 F-89
102-46	Defining report content and topic boundaries				59
102-47	List of material topics				61
102-48	Restatements of information				50
102-49	Changes in reporting				50
102-50	Reporting period				50
102-51	Date of most recent report				50
102-52	Reporting cycle				50
102-53	Contact point for questions regarding the report				50
102-54	Claims of reporting in accordance with the GRI Standards				50
102-55	GRI Content Index				55
102-56	External assurance				66
103 – MANAGEMENT APPROACH					
103-1	Explanation of the material topic and its boundary				Corporate Responsibility Materiality Assessment Results Report
103-2	The management approach and its components				Corporate Responsibility Materiality Assessment Results Report
103-3	Evaluation of the management approach				Novartis in Society report 2019
200 – ECONOMIC					
201-1	Direct economic value generated and distributed				Annual Review 2019 p.8, 13
201-2	Financial implications and other risks and opportunities due to climate change	**7, 8, 9**	13		Annual Report 2019 p.22
203-2	Significant indirect economic impacts		1 2 8 10 17		10, 65
204-1	Proportion of spending on local suppliers				64
205-1	Operations assessed for risks related to corruption	**10**	16		14
206-1	Legal actions for anti-competitive behavior, anti-trust and monopoly practices				Annual Report 2019 F-55

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGC PRINCIPLE	UN SDG	COMMENTS	REFERENCE
300 – ENVIRONMENT					
301-2	Recycled input materials used	**8**	8 12		Novartis Health, Safety and Environment (HSE) Data 2019
301-3	Reclaimed products and their packaging materials	**8**	8 12		Waste
302-1	Energy consumption within the organization	**7, 8, 9**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2019
302-2	Energy consumption outside of the organization	**8**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2019
302-3	Energy intensity	**8**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2019
302-4	Reduction of energy consumption	**7, 8, 9**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2019
302-5	Reductions in energy requirements of products and services	**8, 9**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2019
303-1	Water withdrawal by source	**7, 8**	6 12		Novartis Health, Safety and Environment (HSE) Data 2019
303-2	Water sources significantly affected by withdrawal of water	**7, 8, 9**	6 12		Novartis Health, Safety and Environment (HSE) Data 2019
303-3	Water recycled and reused	**7, 8, 19**	6 12		Novartis Health, Safety and Environment (HSE) Data 2019
305-1	Direct (Scope 1) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
305-2	Energy indirect (Scope 2) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
305-3	Other indirect (Scope 3) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
305-4	GHG emissions intensity	**8**	13 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
305-5	Reduction of GHG emissions	**7, 8, 9**	13 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
305-6	Emissions of ozone-depleting substances (ODS)	**7, 8, 9**	3 12		Novartis Health, Safety and Environment (HSE) Data 2019
305-7	Nitrogen oxides (NOX), sulfur oxides (SOX), and other significant air emissions	**7, 8, 9**	3 12 14 15		Novartis Health, Safety and Environment (HSE) Data 2019
306-1	Water discharge by quality and destination	**7, 8, 9**	3 6 12 14		Novartis Health, Safety and Environment (HSE) Data 2019
306-2	Waste by type and disposal method	**7, 8**	3 6 12		Novartis Health, Safety and Environment (HSE) Data 2019
308-1	New suppliers that were screened using environmental criteria	**8**			Responsible Supply Chain Management
308-2	Negative environmental impacts in the supply chain and actions taken				Responsible Supply Chain Management

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGC PRINCIPLE	UN SDG	COMMENTS	REFERENCE
400 – SOCIAL					
401-1	New employee hires and employee turnover	**6**	5 8		53
403-2	Types of injury and rates of injury, occupational diseases, lost days and absenteeism, and number of work-related fatalities		3 8	Data not split by gender; data on non-occupational absenteeism, and on injury rate and occupational disease for contractors not available	54
403-3	Workers with high incidence or high risk of diseases related to their occupation		3 8		A Safe Workplace
403-4	Health and safety topics covered in formal agreements with trade unions		8		A Safe Workplace
404-1	Average hours of training per year, per employee	**6**	4 5 8		53
404-2	Programs for upgrading employee skills and transition assistance programs				Annual Review 2019 p.18
405-1	Diversity of governance bodies and employees	**6**	5 8		53
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	**4**	8		15 Responsible Supply Chain Management
412-1	Operations that have been subject to human rights reviews or impact assessments	**1**	16		16
414-1	New suppliers that were screened using social criteria				15 Responsible Supply Chain Management
414-2	Negative social impacts in the supply chain and actions taken				Novartis Third Party Code Responsible Supply Chain Management
415-1	Political contributions				Public Policy & Advocacy
416-2	Incidents of noncompliance concerning the health and safety indicators impacts of products and services				40
417-1	Requirements for product and service information and labeling			We operate in a strictly regulated industry; this information is obligatory for us to have a license to operate	41 Annual Report 2019 p.46
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data				51
419-1	Noncompliance with laws and regulations in the social and economic area				Annual Report 2019 F-55

Appendix: corporate responsibility material topic boundaries

CR MATERIAL TOPIC BOUNDARIES

As a company, the impacts we have and the value we create extend well beyond our own operations. Using Novartis Global Health & Corporate Responsibility strategic priorities, we have analyzed topics identified as material by the 2017 corporate responsibility materiality assessment (CRMA) and presented in this report in the context of our value chain. The resulting diagram displays the boundaries of our impacts (indicated in blue), and helps us better leverage opportunities and manage risks.

	Novartis simplified value chain		
Topic	**Supply chain**	**R&D, operations, distribution**	**Patients**
Holding ourselves to the highest ethical standards			
Ethical and compliant behavior	■	■	■
Transparency	■	■	■
Being part of the solution on pricing and access			
R&D for unmet needs	■	■	■
Affordability		■	■
Strengthening healthcare systems		■	■
Intellectual property	■	■	■
Addressing global health challenges			
Neglected and tropical diseases		■	■
Drug resistance	■	■	■
Being a responsible citizen			
Pharmacovigilance, safety profile and quality of drugs	■	■	■
Combating counterfeit medicines	■	■	■
Health education and prevention		■	■
Our people	■	■	■
Respect for human rights	■	■	■
Responsible supply chain	■	■	■
Environmental sustainability	■	■	■

The 2019 Novartis in Society (NiS) report aligns with the strategic priorities of Novartis and the four pillars of the GH&CR strategy, while retaining the materiality assessment as set out in the 2017 CRMA. To align the 2019 NiS report with this materiality assessment, we mapped each priority topic within one or more of the relevant sections of the 2019 NiS report. When a priority topic was adequately covered in the 2019 Novartis Annual Report and the 2019 Novartis Annual Review, we provided cross-references in the 2019 NiS report.

The mapping exercise is detailed in the table on the following page. This shows the priority topic and relevant page number(s) within the NiS report, the GH&CR strategic pillar the topic sits within, and the mapping rationale.

#	Priority topic (pages in 2019 NiS report)	GH&CR strategy pillar(s)	Rationale
1	Ethical and compliant behavior (pages 13-19)	Holding ourselves to the highest ethical standards	This is the cornerstone of the pillar of our GH&CR strategy (holding ourselves to the highest ethical standards).
2	Transparency (page 19)	Holding ourselves to the highest ethical standards	Transparency is part of our commitment to do business responsibly and is strongly linked to compliance.
3	Pricing (pages 20-31)	Being part of the solution on pricing and access	The Novartis Access Principles (see page 21 of the 2019 NiS report) are the cornerstone of this pillar, and affordability strategies tailored to different parts of the income pyramid is one of these principles.
4	Health system strengthening (HSS) (pages 28-31)	Being part of the solution on pricing and access	The Novartis Access Principles are the cornerstone of this pillar, with HSS being one of these principles.
5	Intellectual property (IP) (page 31)	Being part of the solution on pricing and access	Important developments in our approach to IP will help facilitate access to Novartis medicines in low- and middle-income countries.
6	Business model innovation (pages 25-26)	Being part of the solution on pricing and access	Established in 2016, Novartis Social Business (NSB) enables access to healthcare through innovative social business models that have received external thought leader recognition.
7	Innovative technologies (pages 17; 34; 35; 41-42; 44)	Being part of the solution on pricing and access Addressing global health challenges	We are collaborating across a number of digital solutions to help deliver healthcare to underserved populations. We are using artificial intelligence to help eliminate leprosy, and are using drone technology to deliver sickle cell treatment to rural Ghana. We also report on the use of technology to enhance our SpeakUp whistleblower process; help in our fight against counterfeit and falsified medicines; and engage with patient communities where they live, reducing the need to travel. Additionally, we strengthened our digital learning capabilities.
8	Drug resistance (page 36)	Addressing global health challenges	The Sandoz Statement of Intent explains our strategy on addressing drug resistance.
9	Financial health and performance (pages 20-31; 32-38; 39-49)	Being part of the solution on pricing and access Addressing global health challenges Being a responsible citizen	This is embedded across a number of pillars: In the context of total impact, pages 10-11 of the 2019 NiS report explain the Novartis financial, social and environmental impact. The 2019 Annual Report and 2019 Annual Review, referenced on page 50 of the 2018 NiS report, also provide information on financial health and performance. We reference company-wide economic sustainability in the 2019 Annual Review pages 8-9. Further, with transformative innovation as a cornerstone of our strategy and foundation for our future, we consider the GH&CR expression of this to be embodied in our R&D for unmet needs and in R&D for neglected and tropical diseases. Additionally, our people are the key to stimulating innovation and securing long-term value creation.
10	Pharmacovigilance, safety and quality (pages 40-42; performance indicators on page 40)	Being a responsible citizen	Patient health and safety was identified as a material cluster in the materiality assessment as set out in the 2017 CRMA, and we highlight our efforts across the three areas of pharmacovigilance, safety, and health education and prevention. To this end, we report on pharmacovigilance and chose to highlight our progress in combating counterfeit and falsified medicines, a key element in helping ensure patient safety in low- and middle-income countries. Similarly, we report on our work with patients and caregivers in health education and prevention.
11	Recruitment and retention of employees (pages 43-46; people performance indicators on page 53)	Being a responsible citizen	Our culture is central to our sustainability, and we have outlined the steps taken in 2019 to continue to change the Novartis culture, to provide a diverse and inclusive environment, and to promote the health and well-being of associates.
12	Pharmaceuticals in the environment (page 47)	Being a responsible citizen	In the section "expanding our environmental stewardship," we address the three priority topics "pharmaceuticals in the environment," "pollution waste and effluents" and "sustainable use of resources." This section includes our work in the Antimicrobial Resistance (AMR) Industry Alliance and in the Innovative Medicines Initiative for the Intelligent Assessment of Pharmaceuticals in the Environment (IMI-iPiE). We further include our commitments and targets, approach and performance (our environmental performance indicators) in managing waste, and our efforts in the sustainable use of resources.
13	Pollution waste and effluents (pages 48)		
14	Sustainable use of resources (pages 47-49)		

Respect for human rights, while not identified as a priority topic through statistical analysis, was ranked 13/30 in terms of impact in the materiality assessment as set out in the 2017 CRMA. In addition, with the increasing focus on the UK Modern Slavery Act (which is also gaining traction in other countries, such as Australia) and the Responsible Business Initiative in Switzerland, we have defined human rights as a key focus area of our GH&CR strategy. To this end, we have included our work in further integrating human rights in our business within this report under the pillar "holding ourselves to the highest ethical standards."

Appendix: corporate responsibility materiality assessment issue cluster and topic definitions

1. Access to healthcare

1.1. Availability of medicines

Efforts to manage barriers that may prevent, restrict or delay medicine availability for patients in need. Examples may include the registration process requirements, inefficient distribution and supply chain management, etc.

1.2. Pricing

Responsible pricing for innovative and generic medicines that takes into consideration affordable access, positive cost-benefit ratio, and overall healthcare costs. Examples may include pricing models such as tiered pricing, managed entry agreements, outcomes-based pricing and non-exclusive voluntary licensing.

1.3. Healthcare system strengthening

Efforts to improve healthcare infrastructure and deliver healthcare-related services "beyond the pill." Examples may include capacity building, training and education, partnerships involving public and private actors to improve healthcare access in underserved areas, and contribution to reducing healthcare costs for payers, insurance companies and consumers.

1.4. Intellectual property

Responsible patent exclusivity management that balances intellectual property (IP) protection with the provision of affordable drugs. Examples may include participation in IP-sharing arrangements and avoidance of compulsory licensing.

1.5. Patient assistance programs

Programs that support financially needy patients to either purchase their necessary medication at an affordable price or receive it for free.

2. Economic sustainability

2.1. Recruitment and retention of employees

Human resources management that aligns recruiting efforts with strategy and that provides talent management programs to engage and retain associates with relevant skill sets and ensure continuity through reduced associate turnover.

2.2. Fair contribution to society

Ensuring good relations and appropriate economic contribution in the areas in which the company operates. Examples may include payment of appropriate amount of tax and efforts to support the economy in countries of operation (e.g., local employment, local suppliers, active engagement in local initiatives).

2.3. Financial health and performance

Ensuring the company's continued viability, financial health and performance. Examples may include mergers and acquisitions (M&A), divesture activities, risk/crisis management and financial liquidity.

3. Environmental protection

3.1. Sustainable use of resources

Measures to ensure efficient consumption of energy, water and other resources. This includes efforts to responsibly source, recycle and/or reuse natural resources; manage the company's impact on plant and animal life; and preserve biodiversity.

3.2. Pollution, waste and effluents

Reduction and management of emissions, pollution, waste (including use of hazardous chemicals and ozone-depleting substances) and effluents. This includes activities to mitigate climate change and its impacts on human health.

3.3. Pharmaceuticals in the environment

Efforts to minimize the environmental impact of our activities and products over their lifecycle and to ensure proper and legal disposal of waste containing active pharmaceutical ingredients.

4. Ethical business practices

4.1. Ethical and compliant behavior

Processes and systems to ensure Novartis operates in line with high ethical standards, especially in regard to our interactions with healthcare professionals. Examples may include adherence to laws and regulations, anti-bribery, anti-corruption and anti-trust; responsible advocacy, lobbying and political contributions; and responsible incentive structures and compensation.

4.2. Animal testing

Measures to keep animal testing at a minimum and ensure tests are conducted according to the highest animal welfare standards.

4.3. Respect for human rights

Positions, policies and management systems to respect human rights across the business and direct supply chain. Examples may include implementation of responsible clinical trials in developed and developing countries, protection of personal data, and the right to health/healthcare.

4.4. Responsible supply chain management

Processes and systems to ensure a responsible supply chain and that our direct suppliers uphold appropriate standards on financial, social and environmental issues. Examples may include outsourcing, third-party manufacturing, the use of clinical research organizations, supplier audits and transparent reporting practices.

4.5. Responsible use of new technologies

Ensuring appropriate handling of and response to controversial ethical questions related to technological advancements. Examples may include cloning, human genetic engineering (e.g., genome editing through CRISPR), nanotechnology, wearables and life extension.

5. Good governance

5.1. Corporate governance

Ensuring the company management structure balances the interests of its relevant stakeholders, and the company is transparent and discloses critical information to stakeholders. Examples may include rules and regulations to ensure Board independence, shareholder rights and engagement, and levels of executive compensation and golden parachutes.

5.2. Transparency

Ensuring appropriate scope and quality of information disclosure and reporting, and engaging in dialogue with our stakeholders. Examples may include disclosing information that is critical to stakeholders such as the risk/safety profiles of products, misconduct cases, support of patient groups and political parties, and trial data.

5.3. Data privacy and security

Systems to ensure that the personally identifiable information of patients, employees, consumers and others is responsibly and securely collected, transferred and stored.

6. Innovation

6.1. R&D for unmet medical needs

Maintaining high investments in creating innovative medicines that address unmet medical needs, with a focus on maximizing patients' outcomes before considering market potential. This includes the research of new compounds but also the modification of existing medicines (i.e., to improve access or efficacy for poor and specifically vulnerable patient groups).

6.2. R&D for neglected diseases

R&D for diseases that disproportionately affect people in low-income settings, for which little or no treatment options are available and where market failure limits research activities. This may include infectious and tropical diseases.

6.3. Business model innovation

Efforts to respond to emerging health needs and trends by changing the existing business model and/or developing new business models. Examples may include responding to the needs of low-income patients and to the growing healthcare burden of noncommunicable diseases (NCDs).

6.4. Innovative technologies

Making the most of advances in IT and digital connectivity to advance R&D for products and outcomes, and to revolutionize the delivery of healthcare services. Examples may include using big data analysis or developing personalized healthcare solutions (e.g., products with companion diagnostic tests), and improving health solutions based on data collected by wearables.

6.5. Drug resistance

Contributing to the global response to drug resistance that is caused, for example, by inappropriate use and environmental pollution through antimicrobials.

7. Our people

7.1. Diversity and inclusion

Ensuring equal opportunities and fostering a diverse and inclusive workplace where each associate can contribute and be recognized. This applies in terms of age, ethnicity, gender, nationality, language, sexual orientation, physical ability, and religious and personal beliefs.

7.2. Health and safety

Ensuring the health and safety of associates. This includes efforts to reduce fatalities, injuries and sick leave, and to promote well-being through health programs.

7.3. Fair working conditions

Ensuring fair employment practices, including upholding labor rights to freedom of association and collective bargaining, labor relations and union practices, and fair compensation and benefits. This may also include work-life balance considerations.

8. Patient health and safety

8.1. Health education and prevention

Efforts to promote health literacy, disease prevention awareness, and the effective use of medicines. Examples may include treatment adherence, contributing to solutions to the rising burden of NCDs and chronic illnesses, and substance abuse prevention.

8.2. Counterfeit medicines

Using the company's influence to fight counterfeit drugs around the world.

8.3. Pharmacovigilance, safety profile and quality of drugs

Ensuring healthcare products (patented pharmaceuticals and generics) are manufactured at the highest quality level and that the efficacy and safety features of a medicine outweigh its risks (e.g., side effects), as well as collecting and recording adverse event reports. This includes transparent and timely communication in the case of product safety or quality issues (e.g., prompt product recalls).

Materiality assessment (MA)

2017 Corporate Responsibility Materiality Assessment Results Report: Identifying what matters most

MA webinars

Aug 2018: "What strategic value can materiality assessments deliver in the future?"
Nov 2018: "Monetizing impact dimensions of material issue areas"
Mar 2019: "Evaluating social materiality by measuring outcomes"
Sep 2019: "Capturing intangible risks of global trends"
Dec 2019: "Materiality and SDG: What will shape the business agenda for the next decade?"

Appendix: external initiatives and membership of associations

GRI 102-12: External initiatives

- Joined Access Accelerated, a global initiative to advance access to treatment and care for chronic diseases in lower-income countries
- Joined Global Chagas Disease Coalition
- Signatory to the London Declaration on Neglected Tropical Diseases
- Member of the Swiss Alliance against Neglected Tropical Diseases
- Signatory to the Davos Declaration on Combating Antimicrobial Resistance (AMR)
- Committed to the Industry Roadmap for Progress on Combating AMR
- Joined the AMR Industry Alliance
- Joined Business Refugee Action Network
- Founding member of the Value Balancing Alliance, which aims to develop a standard model for measuring and disclosing the environmental, human, social and financial value a company provides
- Member of the Impact Valuation Roundtable
- Joined the United Nations Equal Pay International Coalition (EPIC)
- Signatory to the Women's Empowerment Principles launched by the UNGC and the UN Development Fund for Women (UNIFEM)
- As a signatory to the UNGC, Novartis supports the Universal Declaration of Human Rights, the ILO's Declaration on Fundamental Principles and Rights at Work, the Rio Declaration on Environment and Development, the UN Convention Against Corruption, the Organization for Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises, the OECD Convention on Combating Bribery of Foreign Public Officials, and the UN Guiding Principles on Business and Human Rights
- Support for the United Nations' workplace standards protecting the rights of lesbian, gay, bisexual, transgender and intersex people
- Signatory to the International Chamber of Commerce's Business Charter for Sustainable Development
- Signatory to the ILO Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy
- Signatory to the CEO Letter on the UN Convention Against Corruption
- Support for the Pharmaceutical Industry Principles for Responsible Supply Chain Management set by the Pharmaceutical Supply Chain Initiative (PSCI)
- Voluntarily agreed to reduce greenhouse gas (GHG) emissions in line with the Paris Agreement and subsequent international target commitments, such as those of the European Union (GHG emissions are reported according to the GHG Protocol)
- Signatory to the UNGC/UNEP/World Business Council for Sustainable Development (WBCSD) initiative Caring for Climate: The Business Leadership Platform, also fulfilling the Business Leadership Criteria on Carbon Pricing
- Classify and dispose of waste according to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal
- Member of the Carbon Disclosure Project, Water Disclosure Project and Supply Chain Disclosure Project
- Signatory to WBCSD's Manifesto for Energy Efficiency in Buildings
- Signatory to the Guiding Principles on Access to Healthcare (GPAH), which frame the pharmaceutical industry's approach to expanding access to quality healthcare globally
- Strategic partner of the World Economic Forum

GRI 102-13: Membership of associations

Novartis Group companies are members of various chambers of commerce, sustainability industry associations and pharmaceutical industry associations.

We work closely with trade associations, which create opportunities to raise industry standards and exchange best practices.
Novartis is a member of:

- The European Federation of Pharmaceutical Industries and Associations (EFPIA)
- The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Interpharma, economiesuisse and scienceindustries in Switzerland
- Pharmaceutical Research and Manufacturers of America (PhRMA), Association for Accessible Medicines (AAM) and the Biotechnology Innovation Organization (BIO) in the US
- vfa – Die forschenden Pharma-Unternehmen in Germany
- Association of British Pharmaceutical Industry (ABPI) in the UK
- Farmindustria in Italy
- Innovative Medicines Canada in Canada
- Farmaindustria in Spain
- Interfarma in Brazil
- National associations in most markets where Novartis has a legal subsidiary

Appendix: supplier spend 2019

Supplier spend

	Spend			Supplier[3]	
Country	Total %	Direct spend %[1]	Indirect spend %[2]	Total	%
Switzerland	29.78	25.09	31.38	5 762	11.78
United States	24.43	11.19	28.94	3 857	7.89
Germany	6.53	9.79	5.42	5 107	10.44
Austria	5.78	10.46	4.18	3 054	6.25
Ireland	2.58	7.50	0.90	758	1.55
Japan	2.29	2.04	2.38	3 157	6.46
France	2.14	1.97	2.20	1 960	4.01
Spain	2.12	3.03	1.81	1 214	2.48
China	2.02	0.93	2.39	2 587	5.29
Italy	1.60	1.59	1.61	1 312	2.68
Canada	1.50	1.94	1.34	882	1.80
United Kingdom	1.31	1.40	1.29	978	2.00
Belgium	1.21	2.02	0.93	1 129	2.31
India	1.09	1.98	0.79	1 826	3.73
Singapore	0.74	0.94	0.67	761	1.56
Rest of the world	14.88	18.13	13.77	14 556	29.77
Total	**100**	**100**	**100**	**48 900**[4]	**100**[4]

[1] Purchase of goods and services directly incorporated into a product being manufactured. Example: raw material, subcontracted manufacturing services, packaging

[2] All suppliers necessary to run an organization, such as utilities, IT hardware/software, furniture, capital expenditure, marketing supplies, etc.

[3] Suppliers with whom we have a direct contractual relationship pertaining to the delivery of goods and services. The decrease (compared to 2018) is due to reporting system enhancements and supplier consolidation.

[4] The sum of individual country totals is larger than the grand total because one supplier can serve multiple countries. Suppliers are counted for each country they serve, but they are counted only once for the grand total.

Appendix: the responsible procurement (RP) risk indicator tool

The RP risk indicator tool uses the category risk, country risk and contract value in combination to indicate a potential risk around the five areas of elevated ethical risk in the supply chain: labor rights, HSE general, HSE specific, animal welfare and anti-bribery. As of August 2019, after completion of the global rollout of the Third-Party Risk Management program, the RP program was officially retired.

THE RP RISK INDICATOR TOOL

	Labor rights	HSE general	HSE specific	Animal welfare	Anti-bribery
Policy or guidelines	Novartis Supplier Code	Novartis Supplier Code	HSE management system manual HSE guidance note 7.2 HSE guideline 8	Novartis Animal Welfare Policy	Novartis Anti-Bribery Policy and Third-Party Guideline
Applies to	All third-party suppliers	All third-party suppliers	Contract manufacturers, waste contractors, chemical producers, facilities or construction contractors working on our own sites	Third-party suppliers handling animals	Third-party suppliers acting on behalf of Novartis
Risk indication trigger	Category risk Country risk Contract value	Category risk Country risk Contract value	Category only (independent of country or contract value)	Category only (independent of country or contract value)	Category only (independent of country or contract value)
Assessment and due diligence	Depending on the risk type, policies and/or guidelines and related standards set forth the due diligence process for suppliers using a variety of tools, including desktop reviews, supplier questionnaires, assessment visits and audits.				
Collaboration/ engagement	Focuses on implementing improvement plans (developed after audits or other assessments) and other targeted initiatives to help suppliers improve their standards and ethical business practices				
Case review	If noncompliance is found through assessment and due diligence, the matter is escalated to a case review.				

Appendix: measuring and valuing our impact

White paper: operationalizing impact valuation
The global economic impact of Novartis: case study
The social impact of Novartis medicines: two case studies from South Africa and Kenya
The environmental impact of Novartis along global supply chains: case study
Valuing the impact of wages on human capital
Monetizing impact dimensions of material issue areas
Introductory video on Novartis materiality assessment and impact valuation

Independent Assurance Report on the 2019 Novartis in Society ESG reporting

To the Board of Directors of Novartis AG, Basel

We have been engaged to perform assurance procedures to provide limited assurance on the following aspects of the 2019 global health & corporate responsibility (GH&CR) reporting of Novartis AG and its consolidated subsidiaries (Novartis Group) included in the Novartis in Society ESG Report 2019

SCOPE AND SUBJECT MATTER

Our limited assurance engagement focused on the following 2019 data and information disclosed in the consolidated Novartis in Society ESG Report 2019 of the Novartis Group for the year ended December 31, 2019:

- The "ethical business practices performance indicators" on page 51, the "access to healthcare performance indicators" on page 52, the "people performance indicators" on page 53, the "supply chain performance indicators" on page 54, and the "health, safety and environmental performance indicators" on page 54 (GH&CR indicators)
- The materiality determination and stakeholder engagement process of Novartis at the Group level according to the requirements of the GRI Sustainability Reporting Standards (GRI Standards), published by the Global Reporting Initiative (GRI) and disclosed on pages 9, 10 and 50
- Reporting processes and related controls in relation to data aggregation of GH&CR indicators

The "pharmacovigilance, safety profile and quality of drugs performance indicators," the "animal testing indicators," the "gender split of leavers", the "median tenure in years by gender", the "internal promotion by gender", the "revenue producing roles by gender" the "Novartis IT and engineering workforce by gender", the "number of employees by employment contract (permanent and temporary), by gender," the "number of employees by employment contract (permanent and temporary), by region," and the "number of employees by employment type (full-time and part-time), by gender" are not subject to this Assurance Report. Consequently, we do not express any conclusion on this data.

CRITERIA

The management reporting processes with respect to the GH&CR reporting and GH&CR indicators were assessed against GRI Standards guidelines and Novartis Group internal policies and procedures, as set forth in the following:

- Guideline on Corporate Responsibility Management at Novartis and the Code of Conduct
- Procedures by which the data for the GH&CR indicators reporting is gathered, collected and aggregated internally

INHERENT LIMITATIONS

The accuracy and completeness of GH&CR indicators are subject to inherent limitations given their nature and methods for determining, calculating and estimating such data. Our Assurance Report should therefore be read in connection with Novartis Group guidelines, definitions and procedures on GH&CR reporting.

NOVARTIS RESPONSIBILITIES

The Board of Directors of Novartis AG is responsible for both the subject matter and the criteria as well as for the selection, preparation and presentation of the information in accordance with the criteria. This responsibility includes the design, implementation and maintenance of the internal control system related to this reporting process that is free from material misstatement, whether due to fraud or error.

OUR RESPONSIBILITIES

Our responsibility is to form an independent opinion, based on our limited assurance procedures, on whether anything has come to our attention to indicate that the GH&CR indicators are not stated, in all material respects, in accordance with the reporting criteria.

We planned and performed our procedures in accordance with the International Standard on Assurance Engagements (ISAE) 3000 (revised) 'Assurance engagements other than audits or reviews of historical financial information'. This standard requires that we plan and perform the assurance engagement to obtain limited assurance on the identified CR indicators prepared, in all material aspects, in accordance with the Novartis Group internal policies and procedures.

A limited assurance engagement under ISAE 3000 (revised) is substantially less in scope than a reasonable assurance engagement in relation to both the risk assessment procedures, including an understanding of internal control, and the procedures performed in response to the assessed risks. Consequently, the nature, timing and extent of procedures for gathering sufficient appropriate evidence are deliberately limited relative to a reasonable assurance engagement and, therefore, less assurance is obtained with a limited assurance engagement than for a reasonable assurance engagement.

OUR INDEPENDENCE AND QUALITY CONTROL

We have complied with the independence and other ethical requirements of the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

SUMMARY OF WORK PERFORMED

Our assurance procedures included, among others, the following:

- Evaluation of the application of Group guidelines Reviewing application of the Novartis Group internal GH&CR reporting guidelines
- Management inquiry Interviewing personnel responsible for internal reporting and data collection
- Assessment of key figures Performing tests on a sample basis of evidence supporting selected GH&CR data concerning completeness, accuracy, adequacy and consistency
- Inspection of documentation and analysis of relevant policies and principles Inspecting relevant documentation on a sample basis, including Group GH&CR policies, management reporting structures and documentation
- Assessment of the processes and data consolidation Reviewing the management reporting processes for GH&CR reporting and assessing the consolidation process of data at Group level and their related controls
- Evaluation of the materiality determination and stakeholder engagement process Inspecting the principles of the Novartis materiality assessment process providing the basis for the adherence to the GRI reporting requirements addressing the soundness of the methodology, the identification process, the determination of the impacted stakeholders as well as the prioritization based on the assessed impact of Novartis.

We have not carried out any work on data other than outlined in the scope and subject matter section as defined above. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our assurance conclusions.

LIMITED ASSURANCE CONCLUSION

Based on our work described in this report nothing has come to our attention causing us to believe that in all material respects that:

- The GH&CR indicators outlined in the scope and subject matter section and disclosed in the 2019 GH&CR reporting of Novartis Group are not stated in accordance with Novartis Group internal policies and procedures;
- The materiality determination and stakeholder engagement process of Novartis does not adhere to the principles and guiding factors defined with the GRI Standards; and
- The reporting processes and related controls in relation to data aggregation of GH&CR indicators are not functioning as designed.

PricewaterhouseCoopers AG

pwc

Kris Muller Jennifer L Kodat

KRIS MULLER **JENNIFER KODAT**

Basel, January 28, 2020

Novartis annual reporting suite

Annual Report and US Securities & Exchange Commission Form 20-F

These reports, filed with the SIX Swiss Exchange in Switzerland and the US Securities and Exchange Commission in the US, provide a comprehensive overview of Novartis, including our company structure, corporate governance and compensation practices. They also disclose our operating and financial results, accompanied by audited annual financial statements.

www.novartis.com/reportingsuite

Novartis in Society ESG Report

The Novartis in Society ESG Report details progress and demonstrates the company's commitment in global health and corporate responsibility.

www.novartis.com/nisreport2019

Annual Review

The Annual Review explains who we are and what we do, and highlights our progress against the company's five strategic priorities in 2019.

www.novartis.com/ar19english

www.novartis.com/ar19german

Digital Annual Review

A digital and interactive version of the Annual Review

www.annualreview.novartis.com

Follow us on

Disclaimer

These materials contain forward-looking statements that can generally be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," "may," "could," "would," "anticipate," "seek," or similar terms, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; or regarding the potential outcome, or financial or other impact on Novartis, of the acquisition of The Medicines Company or the proposed divestiture of certain portions of our Sandoz Division business in the US; or regarding the potential impact of share buybacks; or regarding potential future sales or earnings of the Group or any of its divisions or potential shareholder returns; or regarding potential future credit ratings of the Group; or by discussions of strategy, plans, expectations or intentions. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. In particular, our expectations could be affected by, among other things: global trends toward healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of information security or disruptions of our information technology systems; uncertainties regarding the success of key products and commercial priorities; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products that commenced in prior years and is expected to continue this year; uncertainties in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the proposed transactions or the development of the products described in this Novartis In Society ESG Report; uncertainties regarding actual or potential legal proceedings, including, among others, litigation or other legal disputes with respect to the proposed transactions, product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; our reliance on outsourcing key business functions to third parties; our ability to comply with data privacy laws and regulations, and uncertainties regarding potential significant breaches of data privacy; safety, quality, data integrity or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; the potential that the strategic benefits, synergies or opportunities expected from our recent and proposed future transactions may not be realized or may take longer to realize than expected; the uncertainties involved in predicting shareholder returns; our performance on environmental, social and governance measures; political, economic and trade conditions, including uncertainties regarding the effects of ongoing instability in various parts of the world; uncertainties regarding the effects of recent and anticipated future changes in tax laws and their application to us; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in these materials as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

The business policy of Novartis takes into account the OECD's Guidelines for Multinational Enterprises, with their recommendations on the disclosure of information.

Publisher: Novartis International AG, Basel, Switzerland
Design: phorbis communications, Basel, Switzerland
Reportage photographer: Brent Stirton, New York, US
Production: Management Digital Data AG, Lenzburg, Switzerland

Photo Giang Giua Cua (right) is treated by a doctor at his home in Vietnam. Mr. Cua, 77, has chronic obstructive pulmonary disease, which is on the rise in Vietnam.

Back cover photo A mother and child in a poor district of Dhaka, Bangladesh. Health workers there routinely screen for childhood pneumonia, which is the leading cause of death among young children worldwide.


NOVARTIS