Novartis in Society

ESG Report 2020

NOVARTIS


10-12-14-K
NHY
+100
PVC
160/5 → PV
160/10 → stabilité
80/5 → stabilité
+0.5$/day

Contents

Inside cover photo Novartis employees at a production facility in Torre Annunziata, Italy.

Cover photo Dr. Ngo Viet Quynh Tram (right) watches as a student practices the correct way to use a mask at the Hue University of Medicine and Pharmacy in central Vietnam. Dr. Tram participated in a nationwide effort to train all final-year medical students how to screen, diagnose and treat COVID-19 patients. The program was supported by the Novartis COVID-19 Response Fund.

2020 highlights

ETHICAL STANDARDS

22
ETHICAL COMMITMENTS
included in our new Code of Ethics, co-created with more than 3 000 Novartis associates

98%
ASSOCIATES
completed global e-training on the new Code of Ethics (rollout to be completed by February 2021)

8 400+
SUPPLIERS
risk-assessed through our Third-Party Risk Management program, with 120 engagements stopped due to assessment outcomes

ACCESS TO HEALTHCARE

66m
PATIENTS
reached with products through our access activities

369 000
PATIENTS
reached with our emerging market brands in 2020

8m
PEOPLE
reached with health education at awareness events

GLOBAL HEALTH

980m
TREATMENT COURSES
of *Coartem* delivered in the past two decades in malaria-endemic countries

3 400+
PATIENTS
treated for sickle cell disease with hydroxyurea in 11 treatment centers in Ghana

7.3m
PATIENTS
reached with free multidrug therapy for leprosy since 2000

CORPORATE CITIZENSHIP

19%
REDUCTION
in greenhouse gas emissions vs. 2016 baseline

45%
WOMEN
in management

60 000
HOURS
of learning on topics such as innovation, digital skills, and access to medicines during Curiosity Month in September

Our response to COVID-19

In the face of a global crisis, Novartis quickly mobilized research and development capabilities, medicines, clinical trial expertise and philanthropic aid to address the COVID-19 pandemic.

Supporting our associates

We took steps to support our associates and their families as they adapted to new conditions and commitments such as working remotely, educating children at home, and caring for loved ones. We provided additional paid leave and enhanced childcare support for associates in critical roles who needed to be on site. We announced a new global policy to give office-based associates more flexibility to choose how, where and when they work.

Clinical investigations

We played our part in the scientific effort to find treatments for COVID-19. We quickly designed and launched three Phase III, placebo-controlled trials to determine if our products could help patients with certain COVID-19-related symptoms. We provided these and other medicines to investigator-initiated trials and managed access programs upon request. We are also collaborating with Molecular Partners to develop two potential antiviral treatments for COVID-19 based on a new class of protein therapeutics known as DARPin®.

Access and pricing commitments

Novartis is making 15 drugs that treat key symptoms of COVID-19 available to low-income and lower-middle-income countries at zero profit until a vaccine or curative treatment is available. Our Sandoz Division is maintaining prices on a basket of essential medicines that may help in the treatment of COVID-19.

Collaborating with partners

We are making efforts to leverage our capabilities in discovery, development and scale-up manufacturing. We are partnering with multi-stakeholder consortia, including the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, the Wellcome Trust and Mastercard, as well as a partnership supported by the Innovative Medicines Initiative. We are participating with the University of California, Berkeley, and other pharmaceutical companies to develop an antiviral molecule to potentially treat all coronaviruses, including the virus that causes COVID-19.

Community funds

Novartis committed to donating up to USD 40 million to support communities around the world impacted by the pandemic. This includes the Novartis COVID-19 Response Fund and a US COVID-19 Community Response Fund, established by Novartis and the Novartis US Foundation, that will provide cash and in-kind donations for immediate response and recovery efforts related to the pandemic in the US.

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

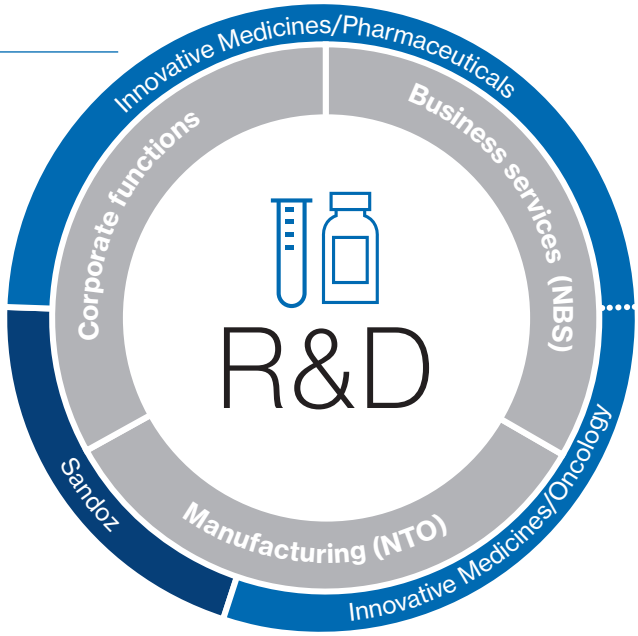
The Innovative Medicines Division has two business units:

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

The Sandoz Division 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, communications, and ethics, risk and compliance.

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 values and behaviors

INSPIRED

ENGAGE OUR PEOPLE
STRIVE FOR PATIENTS
LIVE OUR PURPOSE

CURIOUS

LEARN
BE OPEN
BE SELF-AWARE

UNBOSSED

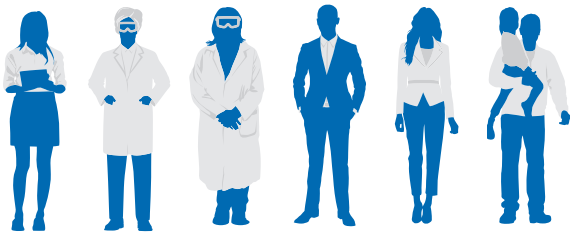
CREATE CLARITY
SERVE OTHERS
OWN YOUR ACTIONS

INTEGRITY

BE HONEST
HAVE COURAGE
DO WHAT'S RIGHT

Our people

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



HEADCOUNT
110 738

NATIONALITIES
142

ANNUAL TRAINING HOURS PER EMPLOYEE
45.7

WOMEN IN MANAGEMENT
45%

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 2020.

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

How we create value

In a rapidly changing business environment, our strategy and business model help us deliver on our purpose and create value for our company and society.

Our business environment

ACCELERATING INNOVATION

46

The average yearly number of new drugs approved by the US FDA's Center for Drug Evaluation and Research from 2016-2020, an increase of 25% compared with 2011-2015

SURGING USE OF DIGITAL TECHNOLOGY IN HEALTHCARE

235 bn

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 POPULATIONS FUELING A RISE IN CHRONIC DISEASES

77.1 years

The projected average global life expectancy in 2050, compared with 72.6 years in 2019, according to the United Nations World Population Prospects

RISING HEALTHCARE SPENDING

5%

The expected annual average growth in healthcare spending between 2020 and 2023, according to the Economist Intelligence Unit

ACCESS TO HEALTHCARE REMAINS A GLOBAL ISSUE

2 bn

The number of people who lack access to essential medicines, according to the World Health Organization

Our strategic priorities

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

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 finding new ways to expand patients' access to our treatments and operating with integrity.

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

Our business model

RESOURCES WE USE

HUMAN CAPITAL

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

110 738 Headcount

45.7 Annual training hours per employee

FINANCIAL CAPITAL

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

214.3 bn Year-end market capitalization (USD)

1.85 bn The value of our sustainability-linked bond issued in 2020 (EUR)

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.

9.0 bn Investment in research and development in 2020 (USD)

160+ Pipeline projects with ongoing clinical trials in Phases I to III

NATURAL CAPITAL

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

11.15 Energy use, on site and purchased (million gigajoules)

8.5 Water consumption (million m^3)

MANUFACTURED CAPITAL

We own or lease research laboratories, manufacturing sites and offices around the world. We use artificial intelligence, gene editing and other technologies.

60 Novartis manufacturing facilities

72 bn Treatments produced by our manufacturing facilities in 2020

RELATIONSHIP CAPITAL

We build trusted relationships with stakeholders to bring treatments to patients, advance drug discovery and expand patient access.

24 432 Field force representatives in our Innovative Medicines Division

98% Employees who completed e-training on new Code of Ethics (to be completed by February 2021)

VALUE WE CREATE

PATIENTS

769 m

Patients reached with Novartis medicines

26

Approvals granted to Novartis in 2020 in the US, the EU, Japan and China for new treatments as well as new indications for existing treatments

EMPLOYMENT

974 000

Estimated jobs created by Novartis (2019), including own employees, indirect and induced

80

Engagement score (out of 100) in Q4 survey of Novartis associates, an all-time high and 7 points ahead of the industry benchmark

SHAREHOLDERS

8.1 bn

Net income in 2020 (USD)

7.0 bn

Total dividends paid (USD)

ENVIRONMENT

19%

Reduction in greenhouse gas emissions vs. 2016 baseline (Scope 1 and Scope 2)

35%

Reduction in water consumption vs. 2016 baseline (million m^3)

This infographic is informed by the framework of the International Integrated Reporting Council (IIRC).

Message from the Chairman

Dear reader,

The outbreak of the COVID-19 pandemic, which has caused millions of deaths worldwide, highlighted the need for rapid and concerted global action to overcome an unprecedented crisis, and served as a litmus test for the ability of the international community to tackle emerging crises.

Novartis took fast and coordinated action in response to the pandemic. We quickly took steps to protect the safety and well-being of associates. We committed to donating up to USD 40 million to support communities around the world impacted by the pandemic. We also introduced a portfolio of 15 generic and over-the-counter medicines to treat patients in low-income and lower-middle-income countries suffering from COVID-19 symptoms. And we collaborated with academic researchers and industry peers in the effort to find effective treatments for COVID-19.

In parallel, we continued to advance our environmental, social and governance (ESG) agenda. In September, we issued a bond linked to targets for global health and access to medicine, including a target to increase access to our strategic innovative therapies by 200% in low- and middle-income countries by 2025. Furthermore, we strengthened our environmental ambitions with a new target to be carbon neutral across our entire value chain by 2030.

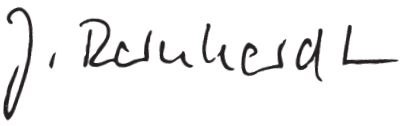
These measures demonstrate the growing importance of ESG for the Novartis Board of Directors and senior management. Ambitious targets are necessary to reduce pollution and support healthcare equity on an international scale. The measures are also designed to help the international community strengthen crisis preparedness and support the United Nations in its efforts to meet its Sustainable Development Goals, which we strongly endorse.

Increasing safety and sustainability also drove the transformation of our Third-Party Risk Management program, under which we are introducing stricter control of our supplier network to help protect the interests of patients, stakeholders and shareholders. We also launched our Code of Ethics in 2020 to strengthen integrity in decision-making and help Novartis achieve its ambition to be among the most trusted partners in healthcare.

We are proud that our ESG efforts are recognized by leading nongovernmental organizations and sustainability rating agencies, such as the Access to Medicine Foundation and Sustainalytics, and we are committed to making further progress. We will also continue our efforts to support nonprofit research, for example with the Friedrich Miescher Institute in Basel, Switzerland, and the recently founded Institute of Molecular and Clinical Ophthalmology Basel.

The COVID-19 pandemic continues to disrupt everyday lives, jeopardizing businesses and putting healthcare systems under increased stress. Novartis will remain a committed partner to support private and public ventures designed to help patients, protect the environment, promote business integrity, and support international efforts to address future challenges.

Sincerely,



Joerg Reinhardt
Chairman of the Board of Directors

Novartis will remain a committed partner to support private and public ventures designed to help patients, protect the environment, promote business integrity, and support international efforts to address future challenges

Joerg Reinhardt

We aspire to create a culture in which our ESG activities are deeply embedded in our daily work, reflecting both the responsibility we have to our patients around the world today as well as those who will come after us

Vas Narasimhan

Message from the CEO

Dear reader,

As a leading global medicines company that reaches more than 750 million patients every year, we know our work to build trust with society extends far beyond researching and developing innovative therapies. It entails the totality of human health and the promotion of health equity, including environmental protection, the delivery of medicines to as many people as possible, and living up to high ethical business standards. In 2020, we continued taking important steps to integrate our environmental, social and governance (ESG) agenda into the core of our business.

With our perspective on our company's role in society in mind, I am proud of the ways Novartis has helped lead as part of the global pandemic response. In addition to collaborating with governments, academia and other life sciences companies, we focused our research and development (R&D) engine on finding scientific solutions, set up emergency health programs, and were the first company to commit to keeping relevant and essential generic medicines cost-stable.

More broadly, as a founding signatory of the United Nations Global Compact, Novartis has worked to build a strong legacy over the past two decades as we've developed and refined our corporate sustainability principles. The sum of these efforts has prepared us to take further action and pave the way to reach our goal to be a trusted ESG leader by integrating our global efforts, enhancing executive accountability and measuring our performance against transparent targets.

An important step in our integrated approach was the initiation of our Trust & Reputation Committee, which I have chaired since its inception in 2019. In its first full year of existence, the committee, among others, reviewed potential gaps in our ESG performance and identified new commitments. As part of these efforts, I signed the CEO Water Mandate and the CEO Guide to Human Rights.

In 2020, Novartis made measurable progress in our existing ESG agenda while setting new targets. We were able to resolve our long-standing legal issues and launched a new Code of Ethics. We also worked to expand access to innovative and generic therapies in low- and middle-income countries, and we set ambitious targets in this realm going forward. In addition, we strengthened our environmental sustainability targets and now aim to be fully carbon, plastic and water neutral over the next decade.

Our ambitions will remain high. Along with the urgency of finding solutions to overcome the global pandemic, climate change is one of the most pressing challenges of our time given its deep interconnection with human health. This increasingly urgent problem requires fast and vigorous science-based action and the collective strengthening of a sustainability mindset to ensure a healthier planet for rising generations.

As we look ahead at the years to come, I remain optimistic about our ability to meet our company's ambitions to be an ESG leader and the most trusted healthcare company in the world. We aspire to create a culture in which our ESG activities are deeply embedded in our daily work, reflecting both the responsibility we have to our patients around the world today as well as those who will come after us.

Sincerely,

Vas Narasimhan
Chief Executive Officer

Our journey to build trust with society

As a global company, we have a great responsibility and an even greater opportunity to lead the world in creating positive social change. We can help catalyze a global response to complex challenges, such as the current pandemic or climate change, by embracing societal impact as a core business objective. At Novartis, we work to build trust with society and deliver long-term value to our stakeholders by embedding environmental, social and governance (ESG) topics into the core of our business strategy and operations.

Building trust with our stakeholders is critical to our ability to deliver on our purpose, as well as our long-term financial performance. Our purpose is inherently a social one: We reimagine medicine to improve and extend people's lives. We discover and develop breakthrough therapies and aim to deliver them to as many people as possible.

We have a clear strategic path that we believe will further accelerate our journey to build trust with key stakeholders and society, centered around four key focus areas:

- Holding ourselves to high ethical standards
- Being part of the solution on pricing and access to medicines
- Addressing 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.

Maintaining strong governance

In 2020, the Governance, Nomination and Corporate Responsibilities Committee (GNCRC) of the Board of Directors met four times and continued to oversee the company's strategy and governance on global health, corporate responsibility and other ESG topics at the Board level. Our new ESG targets and the issuance of a sustainability-linked bond were among the topics discussed by the GNCRC in 2020.

The Novartis Trust & Reputation Committee met six times in 2020. Chaired by our CEO, this sub-committee of the Executive Committee of Novartis (ECN) oversees progress and aims to accelerate decision-making in key ESG areas. Topics discussed in 2020 included potential gaps in our ESG performance, new ESG commitments, the environmental sustainability strategy, and diversity and inclusion.

In 2020, we created the position of Chief Sustainability Officer, who reports to a member of the ECN, to lead the strategy and execution of environmental sustainability across Novartis.

We also created the ESG Management Office in our Corporate Strategy group to further institutionalize ESG efforts across the organization. The new office will work with experts in divisions, functions and countries to develop a trust and ESG strategy framework and lead key ESG initiatives.

In addition, we are establishing an external advisory board to provide guidance to the Global Health & Corporate Responsibility (GH&CR) organization on strategy and related plans, policies and indicators.

Our journey toward more sustainable social impact

2000
Sole donor to the WHO of multidrug therapy for leprosy

2001
Antimalarial *Coartem* (not-for-profit strategy)

2007
Healthy Family[1]

2014
Local innovative brands in LMICs[2]

2015
Novartis Access[3]

2017
Novartis access principles

2019
New strategy for sub-Saharan Africa

2020
Sustainability bond linked to new access targets

1 Health education and access to medicines for rural populations at the bottom of the income pyramid
2 Low- and middle- income countries
3 Portfolio of 15 on- and off-patent medicines for noncommunicable diseases

Materiality and reporting

We strive to create long-term value along our entire value chain. Our materiality assessment helps us understand the issues that matter most to our internal and external stakeholders; how our economic, social and environmental impacts are perceived along our value chain; and how they translate today and in the future into associated risks and opportunities for our company. Our materiality assessment enables us to capture our impacts in a nonfinancial manner, helps us prioritize impacts on which to focus, and informs our strategic thinking.

We conduct global materiality assessments every four years, and are currently preparing for our fourth assessment in 2021. In our third global materiality assessment conducted in 2017, internal and external stakeholders ranked issue clusters based upon their impact on the performance and business of Novartis overall. Four issue clusters were identified as being most important: access to healthcare, patient health and safety, ethical business practices and innovation. Novartis applied statistical analysis to the results to further prioritize the issues and focus areas, identifying 14 priority topics. These topics are reflected in the four key focus areas of building trust with society and are covered in the following sections of this report. A list of the topics is on page 86. We have introduced new management targets across the four focus areas, as outlined below.

ESG management targets

HOLDING OURSELVES TO HIGH ETHICAL STANDARDS

- Conduct risk assessments for all new eligible suppliers
- Complete risk assessments of existing suppliers by 2022
- Fully integrate human rights into third-party risk assessments in scope
- Enhance external reporting on anti-bribery by 2022
- Post all clinical trial results on clinicaltrials.gov or novartisclinicaltrials.com within one year of completion

BEING PART OF THE SOLUTION ON PRICING AND ACCESS TO MEDICINES

- Implement an access strategy for all new products launched
- Increase by 200% patients reached with strategic innovative therapies in low- and middle-income countries by 2025
- Achieve a twofold increase in the number of patients reached in sub-Saharan Africa by 2022, and a fivefold increase by 2025
- Implement tiered pricing for launches in Pharmaceuticals and Oncology based on national income levels and value-based pricing

ADDRESSING GLOBAL HEALTH CHALLENGES

- Increase by 50% patients reached by the global health flagship programs by 2025
- Advance clinical development program for our next-generation antimalarials
- Expand Africa sickle cell disease program to 10 countries by 2022
- Advance clinical development program in patients with Chagas-related heart failure

BEING A RESPONSIBLE CITIZEN

- Be carbon neutral in own operations (Scope 1 and 2) by 2025 and across the value chain (Scope 1, 2 and 3) by 2030
- Include environmental criteria in all supplier contracts by 2025
- Reduce water consumption in our operations by half by 2025 (vs. 2016), with no water quality impacts from the manufacturing of our products
- Be water neutral in all areas of our operations by 2030 while enhancing water quality wherever we operate
- Eliminate polyvinyl chloride in packaging by 2025
- Reduce the amount of waste sent for disposal by half by 2025 (vs. 2016)
- Be plastic neutral by 2030, with all new products meeting sustainable design principles
- Achieve gender balance in management by 2023
- Close the gender pay gap by 2023
- Invest USD 100 million in learning over five years from 2019

Photo Dr. Juliet Akoth (left) walks with a patient in Kitui, Kenya. Dr. Akoth enrolled in Echo for Life, a Novartis-sponsored program in partnership with the University of Nairobi to train healthcare professionals in the diagnosis and treatment of cardiovascular disease.

Engaging with stakeholders

A cornerstone of our approach is consistent engagement with a wide range of stakeholders, including patients and caregivers, associates, healthcare providers, governmental organizations, non-governmental organizations (NGOs), shareholders and other financial market participants, local communities, and partners from the pharmaceutical and other industries.

Our CEO was invited to co-chair the Bill & Melinda Gates Foundation CEO Roundtable, a group comprising 15 CEOs of the top pharmaceutical companies globally. The roundtable focused on collective action related to the COVID-19 pandemic and established several workstreams. Additionally, Novartis and the roundtable are working with various governments and stakeholders on future pandemic preparedness, and Novartis will continue to co-chair the CEO Roundtable in 2021.

Novartis is also active in multi-stakeholder initiatives on business ethics and environmental issues. In October, Novartis became a signatory to the Partnering Against Corruption Initiative, the principal CEO-led platform in the global anti-corruption arena, building on the pillars of public-private cooperation, responsible leadership and technological advances. In September, we joined PREMIER, a new six-year project with the Innovative Medicines Initiative (IMI), focused on evaluating and mitigating the risk of medicines in the environment.

We believe we can help build a systematic and consistent approach to patient engagement across the healthcare system. To this end, we continue to participate in 41 IMI projects supporting the progression of healthcare and science, as well as other patient-focused initiatives and collaborations.

We regularly engage with our associates globally through physical and virtual events, which encourage open dialogue and communication. We run a global quarterly survey in which associate engagement is one of the main parameters we measure.

We also consistently engage with global health stakeholders on key topics. For example, the Novartis Foundation, the Massachusetts Institute of Technology and the Harvard Global Health Institute hosted a series of 14 webinars to explore the role of artificial intelligence (AI) in responding to the pandemic in low-resource settings. The webinars gathered over 3 000 participants. In 2021, the foundation plans to launch the HealthTech Dialogue Hub, an initiative to connect policymakers, tech innovators, NGOs and other key stakeholders and drive the implementation of AI for health in low- and middle-income countries.

The Novartis Foundation and Women in Global Health also co-hosted the #BuildBackBetter Digital Innovation and AI Challenge to support gender equity in digital health while advancing health security. Over 100 startups from all continents participated in the challenge. The winning startup, Clafiya, received USD 10 000 for its innovative digital platform that connects patients in semi-urban and rural parts of Nigeria to community health workers to provide home-based primary care services. As the runner-up, Wheels for Life received USD 5 000 for its innovation in providing prompt triage consultation and transferring pregnant mothers from homes to hospitals to prevent delays in accessing maternal healthcare and reduce maternal morbidity in Kenya.

Engaging the investor community on ESG topics

Novartis has more than doubled the number of investor engagements on ESG matters in recent years, and in 2020, our CEO led our ESG Investor Day for the second time (marking our seventh dedicated ESG event for investors since 2014). In 2020, with ECN members and the Group Head of Global Health & Corporate Responsibility, we held an ESG roadshow series in the Netherlands, France, the US and Switzerland. Further, as part of our comprehensive ESG engagement program, we increased the frequency of our communication, issuing a quarterly ESG newsletter to investors. Please see page 130 of the Annual Report 2020 for key topics discussed during our shareholder engagements.

We conducted five webinars in 2020 to share how Novartis is implementing the outcomes of our previous materiality assessments. Webinar topics included

access to healthcare, wealth and health, and measuring the social outcomes of access initiatives (see the appendix on page 87). Each webinar featured internal and external speakers and attracted approximately 80 participants from industry, NGOs, access-related and sustainability groups, and investors.

We also organized and participated in several events to promote the value of measuring business impact beyond traditional financial metrics, an important element in driving the ESG agenda with a broader stakeholder audience. For instance, as part of our impact valuation work, we participated in discussions at a Global Solutions Initiative summit about the true value contribution of business. We continue to drive impact valuation standardization through the Value Balancing Alliance, of which Novartis is a founding member. We are also a member of the Impact Valuation Roundtable, an informal group of more than a dozen international companies seeking to develop and operationalize the field of impact valuation.

Engaging with policymakers

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. Additionally, we 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 88.

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.

Contributing to the Sustainable Development Goals

We have a long-term commitment to support the UN in achieving its Sustainable Development Goals (SDGs). As a leading medicines 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. We contribute to goal 5 (gender equality), and our environmental sustainability targets align with goal 6 (clean water and sanitation), goal 7 (affordable and clean energy), and goal 12 (responsible consumption).

As a founding signatory of the UN Global Compact (UNGC), we are committed to sharing our progress in implementing the 10 principles of the compact. We published a Communication on Progress in the first quarter of 2020 and will do so again in 2021.

A mapping of our activities against the SDGs and the UNGC principles can be found in the GRI Content Index on page 78 of this report.

Valuing our impact

While the understanding of long-term value creation is still evolving, there is increasing interest in the topic among key stakeholders. Part of our work entails engagement and dialogue to foster a better understanding of the concept and contextualize impact valuation within broader health economic considerations.

In December, we hosted our annual Co-Creating Impact Summit with external and internal speakers. To make the experience engaging and interactive, we also held a virtual exhibition to enable participants to explore the building blocks of our impact valuation roadmap and discover and discuss inspiring best practices.

We continue to work with partners to publish studies that, for example, help measure the social impact of a disease burden or preventive interventions in averting negative health impacts and environmental damage (see the appendix on page 89). Our current research covers an array of topics, including social risk in the supply chain, the social impact of pediatric formulations, and environmental footprints of products.

For impact valuation to be transformational, standard setters and policies need to embrace it. To this end, we continue to drive impact valuation standardization through the Value Balancing Alliance (VBA), of which Novartis is a founding member. In 2020, we piloted the alliance's first impact valuation indicators meant to measure and disclose the environmental, human, social and economic value companies provide to society. Overall, we found the indicators consistent with our approach except for the environmental impact of land use and of waste in the supply chain, which we did not cover previously but have now added. The social dimension of the indicators in the VBA model could be strengthened by including the social impact of our medicines and particularly of living wages.

We continue to refine our approach, now called Novartis social, environmental and economic (SEE) impact valuation, to prioritize the social impact of our medicines. In 2020, more than 20 Novartis country organizations – including, for the first time, the UK and Spain – drew on local impact valuation results to derive insights and engage with stakeholders. In total, data is now available for 189 countries, including our own operations and supply chain. We also conducted pilots using forecasted impact valuation results for both Novartis operations and our supply chain.

Overall, in 2019, our activities contributed USD 90.4 billion to global gross domestic product (GDP), as well as an estimated 974 000 jobs, including those held by our own employees. In addition, our human capital impact – including employee development, occupational safety and living wages – was valued at USD 1.9 billion, with USD 2.2 billion coming from the social impact of living wages in our own operations and the entire supply chain, USD 1.5 billion coming from employee development, and a negative USD 1.8 billion coming from 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 6.5 billion. The overall social impact of our portfolio, including Innovative Medicines and Sandoz products in 132 countries, amounted to USD 219 billion in 2019. More information on our impacts in Switzerland is available in the Novartis in Society Switzerland report, which will be published in February 2021 on novartis.ch.

Novartis social, environmental and economic impact 2019

Indicator	Results [1, 2]	Remarks
Social		
Living wages	USD 2.2 bn	Own operations USD 1 bn, indirect USD 1.2 bn
Employee development	USD 1.5 bn	Own operations USD 80 m, indirect USD 697 m, induced USD 775 m
Occupational safety	-USD 1.8 bn	Own operations USD 461 m, indirect USD 767 m, induced USD 561 m
Other human capital impacts		Employee well-being, voluntary turnover, human rights beyond living wages not valued in 2019
Products	USD 219 bn	Based on 54 Innovative Medicines brands and 40 Sandoz products in 132 countries
Environmental		
Climate, energy and air pollution	-USD 3.80 bn	Own operations USD 164 m, indirect USD 1.4 bn, induced USD 2.2 bn
Water and waste	-USD 1.03 bn	Own operations USD 15 m, indirect USD 322 m, induced USD 542 m, downstream USD 152 m
Land use	-USD 1.71 bn	Own operations USD 43 000, indirect USD 266 m, induced USD 1.441 m
Other environmental impacts		Biodiversity not valued in 2019
Economic		
GDP contribution	USD 90.4 bn	Own operations USD 52.1 bn, indirect impacts USD 17.7 bn, induced impacts USD 20.6 bn
Employment	974 000 FTEs	Own operations 104 000 FTEs, indirect 351 000 FTEs, induced 519 000 FTEs
Economic inefficiencies		Not valued in 2019 – no methodology available
Total taxes		Not valued globally in 2019

[1] Our methodology is based on leading approaches including WifOR (social impact of medicines, direct GDP contribution, indirect and induced environmental and economic impacts), Valuing Nature (social impact of wages and salaries), VBA (employee development, occupational safety, waste, land use) and Impact Valuation Roundtable (general approach).
[2] Data represent continuing operations.

Photo Leo Vieira exercises in São Paulo, Brazil, after recovering from COVID-19. Mr. Vieira was treated at the Hospital das Clinicas of the University of São Paulo, where doctors used an artificial intelligence platform – developed with the support of the Novartis Foundation as well as government and civil society partners – to assess damage to his lungs.

Photo Novartis employees at a production facility in Torre Annunziata, Italy.

STRATEGIC AREAS

Holding ourselves to high ethical standards

Why is it important?

Building trust with customers, patients, associates and society is the foundation of our long-term success. Our stakeholders not only expect us to do what is legally required, but also to act with high ethical standards wherever we operate and to be accountable for the way our business impacts people and the environment. We recognize these expectations of our company and strive to do what's right both for Novartis and for society at large.

In this section

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

Code of Ethics

Launched a new Code of Ethics, encouraging associates to be bold, open-minded, honest and accountable when making decisions

→ p. 19

Risk management

Defined the Novartis risk portfolio, which comprises 21 risks categorized as strategic, operational or emerging, as well as awareness topics

→ p. 20

Third-party risk management

Revised our Novartis Third Party Code, outlining requirements for third parties on environmental sustainability, human rights, and diversity and inclusion

→ p. 25

Human rights

Signed the CEO Guide to Human Rights, calling on businesses to contribute to the realization of universal human rights

→ p. 26

Our targets

- **Conduct risk assessments** for all new eligible suppliers
- **Complete risk assessments** of existing suppliers by 2022
- **Fully integrate human rights** into third-party risk assessments in scope
- **Enhance external reporting** on anti-bribery by 2022
- **Post all clinical trial results** on clinicaltrials.gov or novartisclinicaltrials.com within one year of completion

"The experiences of the past 12 months have shown just how important it is to coordinate risk management locally, regionally and internationally – based on our ethical commitment to do what's right"

Klaus Moosmayer,
Chief Ethics, Risk & Compliance Officer

OUR ETHICAL PRINCIPLES

Be open-minded

Am I actively listening to ideas or concerns?
Am I questioning the impact of my decisions?
Am I valuing the perspective of others?

Be honest

Am I acting with clear intent?
Am I avoiding harm?
Am I speaking up?

Be bold

Am I standing up for what I believe?
Am I putting patients first?
Am I making a positive difference?

Be accountable

Am I taking responsibility for my decisions?
Am I treating others as I would like to be treated?
Am I putting the team before myself?

Our approach and performance

We work to build trust – with associates and partners, doctors and patients, and with society more broadly – by embedding environmental, social and governance (ESG) topics into the core of our business. We are governed by strong and consistent values and continue to implement policies and practices to hold our company, our associates, our suppliers, and stakeholders we work and interact with to high ethical standards. We endeavor to identify potential problems, prevent issues from occurring, promote personal accountability, and generate lessons that we can apply across the company.

This continues to be a journey, and we are making progress. We are embedding principle-based decision-making in our business interactions to help ensure our leaders and associates act appropriately when faced with ethical dilemmas. We are expanding our efforts to protect human rights within our operations and throughout our supply chain. This extends from creating a more inclusive company culture to protecting people and communities with uncompromising standards for ethical sourcing and practices. As a diverse company operating globally, we know this is a challenging endeavor and there will always be more we can do.

Creating a Code of Ethics

Over the past two years, we have been on a journey to strengthen principle-based decision-making by introducing P3, our Professional Practices Policy. We have learned about the importance of providing room for open dialogue and discussion, especially in grey areas, so associates understand what it means to behave and act ethically.

Our new Code of Ethics, launched in September, is a natural step on this journey. It is rooted in behavioral science, which is about what we do, why we do it, and how it is influenced. If we want to change behaviors, we need to change the context and environment in which we work and live.

Our new Code of Ethics elevates principle-based decision-making and reinforces our commitment to ethics across all business interactions, encouraging associates to be bold, open-minded, honest and accountable when making decisions. Co-created with more than 3 000 Novartis associates sharing feedback, ideas and insights into the areas that matter most, our Code of Ethics is a collection of 22 ethical commitments we make as an organization, reflecting the diverse voices of our associates. The code is accompanied by an online decision-making framework based on behavioral science that helps associates challenge their intuition and encourages reflection on the potential impacts of their decisions. In 2020, more than 45 750 associates used the interactive tool and resources.

To mark the launch of the code, we held a companywide Ethics Week, which included a series of global events hosted by internal and external experts, with almost 20 000 associates tuning into the live virtual sessions. Additionally, 160 local events were held across 78 countries, and more than 1 200 associates participated in virtual trainings on understanding why, and how, we make decisions. Global e-training on

the new Code of Ethics is being rolled out from September 2020 to February 2021, with a preliminary completion rate of 98% by December 31, 2020.

Safeguarding our company from risks
In a rapidly changing business environment, effective risk management is critical to our ability to build resilience and provide sustained, long-term value to patients, shareholders and other stakeholders. We strive to minimize or prevent negative issues from occurring while helping ensure we capture business opportunities as they arise.

The Enterprise Risk Management (ERM) process at Novartis is a series of coordinated activities designed to identify risks, promote accountability and support balanced decision-making for sustainable long-term growth. The process begins with leadership discussions about risk at the global level and in country organizations as part of annual strategic planning. In 2020, we held mostly virtual cross-divisional workshops in our top 11 markets and a number of additional countries in Africa, Asia, Europe and South America. At the global level, we also held risk workshops with business and organizational units. Additionally, we looked at reports by Novartis functions such as Internal Audit, as well as external data on industry and macro-economic trends, to help identify high-risk areas.

The Chief Ethics, Risk & Compliance Officer is responsible for the overall risk management process at Novartis. The Ethics, Risk & Compliance (ERC) function oversees the company's risk management and compliance functions, including risk-based companywide policy and internal control management, as well as crisis and business continuity management.

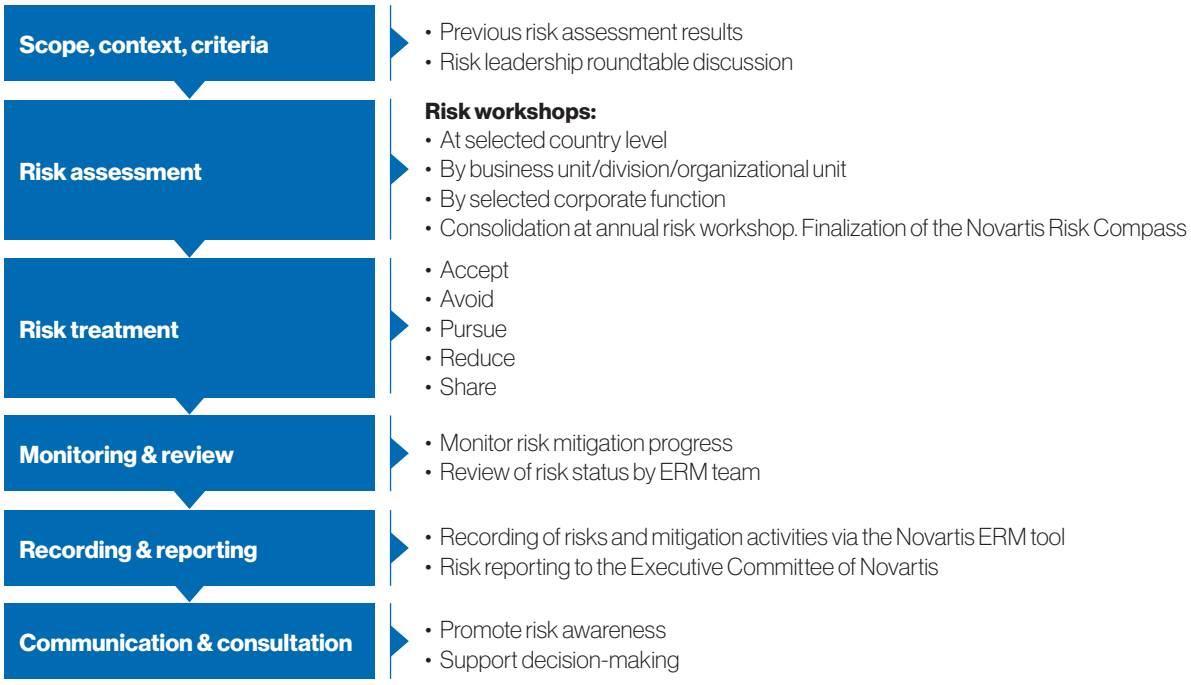
The Executive Committee of Novartis (ECN), led by the CEO, reviews and endorses the risk portfolio. The Board of Directors provides the highest layer of oversight. It focuses on the most significant risks, while the Board-level Risk Committee reviews the entire risk portfolio and actions implemented by management. For further details on the Risk Committee and its activities, please see page 146 of the Novartis Annual Report 2020.

While our purpose – reimagining medicine to improve and extend people's lives – drives our values and defines our culture, our ethical principles guide us in everyday decision-making and ensure we act with integrity. Our new Code of Ethics sets the ethical framework for risk management at Novartis. In addition, within the Novartis Risk & Resilience organization, Business Continuity Management (BCM) and Novartis Emergency Management (NEM) are important elements of our risk management strategy. During the COVID-19 pandemic, more than 100 NEM teams worldwide supported the business to help ensure the safety and well-being of associates as well as the uninterrupted supply of medicines to patients.

THE NOVARTIS RISK COMPASS

We use the outcomes of the ERM process to update the Novartis Risk Compass, which provides a single holistic view of risk across the company. We group risks into four categories and assign a risk rating based on likelihood, potential impact and other factors within a time horizon of up to five years. This approach helps senior manage-

Enterprise Risk Management process (ERM)



Novartis Risk Compass

STRATEGIC RISKS
are the most consequential to our ability to execute our strategy or achieve our business objectives.

EMERGING RISKS
require close monitoring and have the potential to become strategic or operational risks.

OPERATIONAL RISKS
relate to internal processes or systems, employee errors or external events.

AWARENESS TOPICS
are longer-term trending topics that have the potential to become new risks

ment and the Board of Directors align the company strategy and our risk exposure. Once a risk is identified, we decide how to treat it based on our risk appetite. We regularly monitor and reassess risks in case there are changes in the risk situation.

RISKS IN 2020

The Novartis risk portfolio comprises 21 risks, of which seven are categorized as strategic, 10 are categorized as operational, and four are categorized as emerging. In addition, we identified three awareness topics.

For ERM purposes, we assessed whether the COVID-19 pandemic amplified or accelerated known risks in our portfolio, rather than labeling it as a standalone risk. For example, we escalated "geo-political and socio-economic threats" from an awareness topic to an emerging risk in 2020, due in part to the widespread societal and economic impact of the COVID-19 pandemic. We also identified "new ways of working" as an emerging risk, partly due to the potential impact of a widespread shift to remote working amid the pandemic.

Novartis has for some time actively managed a range of ESG matters. These are now included within the risk portfolio as a strategic risk, taking into account their expected impact on the sustainability of our business over time, and the potential impact of our activities on society and the environment.

The below categories show the degree of risk exposure for Novartis, based on a combination of the risk's likelihood and potential impact on our business.

● Very high ◑ High ● Medium ● Low

STRATEGIC RISKS

- ● Key products and commercial priorities
- ● Pricing, reimbursement and access
- ◑ Research and development
- ◑ Alliances, acquisitions and divestments
- ◑ Environmental, social and governance matters
- ● Organizational, structural and cultural transformations
- ● Digitalization and emerging business models

OPERATIONAL RISKS

- ● Cybersecurity and IT systems
- ◑ Third-party management
- ◑ Manufacturing and product quality
- ◑ Fragmented core processes and IT landscape
- ◑ Talent management
- ◑ Facility and workplace safety
- ◑ Legal and compliance
- ◑ Inadequate oversight of medical programs
- ● Data privacy
- ● Supply chain

EMERGING RISKS

- ◑ Geo-political and socio-economic threats
- ● New ways of working
- ● Global enterprise resource planning (ERP) implementation
- ● Social media and digital engagement

AWARENESS TOPICS

Climate change

Antimicrobial resistance and changes in disease patterns, including pandemics

Deterioration of human rights protection

Risks in focus

The following provides further details on key risks for Novartis, including the top risks in each category as well as those that have been significantly upgraded in 2020.

Risk	Context	Actions
STRATEGIC RISKS		
Key products and commercial priorities Failure to deliver key commercial priorities and successfully launch new products	Our ability to grow our business depends on the commercial success of key products. Their success could be impacted by a number of factors, including pressure from new or existing competitive products; changes in the prescribing habits of healthcare professionals; unexpected side effects or safety signals; supply chain issues or other product shortages; pricing pressures; regulatory proceedings; changes in labeling; loss of intellectual property protection; and global pandemics.	• We are pursuing a "launch excellence" strategy in commercial execution, including investing in earlier prelaunch preparations and using data science to test and learn from new commercial models. • We are accelerating the planned implementation of a new customer engagement model, which combines traditional face-to-face visits with digital methods of engaging healthcare professionals. We are similarly changing our approach to engaging healthcare systems, payers and other healthcare providers. • We enter into business development agreements with other companies and with academic and other institutions to develop new products and access new markets.
Pricing, reimbursement and access Pricing and reimbursement pressure, including access to healthcare	We experience significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement from governments, insurers and other payers. These pressures have many sources, including rising healthcare costs (exacerbated in 2020 by the COVID-19 pandemic); funding restrictions and policy changes; and public controversies, debate, investigations and legal proceedings around pharmaceutical pricing. Such pressures may impact product pricing and market access. We also face price controls and other measures imposed by governments and other payers. In addition, our Sandoz Division has faced and may in the future face continued price erosion in the generics and biosimilars segment.	• We have dedicated teams that actively seek to optimize patient access, including formulary positions, for our products. • We are increasing our efforts to enable patient access through innovative pricing and access initiatives in the US, Europe and other markets. These include contract structures such as pay-over-time and outcome-based agreements. • We announced new access-to-medicine and global health targets in 2020. We also launched a sustainability-linked bond, embedding the targets into the core of Novartis business operations.
Research and development (R&D) Failure or delay in the research and development of new products or new indications for existing products	We engage in costly, lengthy and uncertain R&D activities, both independently and in collaboration with third parties, to identify and develop new products and new indications for existing products. Failure can occur at any point, including after substantial investment. New products must undergo intensive preclinical and clinical testing. Further, regulatory authorities continue to establish new and increasingly rigorous requirements for approval and reimbursement. The post-approval regulatory burden has also increased.	• We enter into agreements with other pharmaceutical and biotechnology companies and with academic and other institutions to develop new products. • We are accelerating the use of data science and digital technology to make the drug discovery and development process more efficient and effective.

Risk	Context	Actions
STRATEGIC RISKS (CONTINUED)		
Environmental, social and governance matters Unsuccessful management of environmental, social and governance matters	Increasingly, in addition to their financial performance, companies are being judged on their performance on a variety of ESG matters. Novartis actively manages a broad range of ESG topics that impact our business, including environmental sustainability, falsified medicines, patient access and human capital management. An inability to demonstrate performance on ESG matters can result in negative impacts to our reputation, operations, recruitment and retention of employees, financial results and/or our share price. Reflecting the growing importance of ESG for Novartis, this risk was upgraded to the strategic category in 2020, from an awareness topic in the previous year.	• We announced new access-to-medicine and global health targets in 2020. We also launched a sustainability-linked bond, embedding the targets into the core of Novartis business operations. • We strengthened our environmental targets in 2020, including aiming for full carbon neutrality across our entire supply chain (Scope 1, 2 and 3) by 2030. • We established an ESG Management Office under Corporate Strategy to track performance and drive strategic initiatives.
OPERATIONAL RISKS		
Cybersecurity and IT systems Cybersecurity breaches and catastrophic loss of IT systems	We rely on critical, complex and interdependent information technology (IT) systems to support our business processes. We are therefore vulnerable to cybersecurity attacks and incidents, both on our own networks and those of third parties to whom we outsource parts of our IT infrastructure. In the context of the COVID-19 pandemic, the risk of such threats and attacks has increased as virtual and remote working becomes more widely used and as employees access sensitive data in less secure, home-based environments. The disruption of our IT systems could negatively impact important business processes, including R&D, regulatory submissions to health authorities, and our manufacturing and distribution operations, among others.	• We established Security Operations Center and Cyber Security Center teams to proactively assess threats to Novartis, perform security monitoring, and respond to security incidents. Our Vulnerability Management team also monitors the environment for vulnerabilities and coordinates mitigation activities. • We continually validate and identify critical assets for enhanced protection.
Third-party management Failure to maintain adequate governance and oversight over third-party relationships, and failure of third parties to meet their contractual, regulatory or other obligations	We outsource certain key business functions to third parties. These include R&D collaborations, manufacturing and distribution, certain finance functions, sales and marketing activities, and data management, among others. We may fail to receive the expected benefits of these agreements if third parties fail to meet their obligations. In addition, we may be held responsible if third parties fail to comply with laws or our standards, or otherwise act inappropriately.	• We require third parties to comply with the Novartis Third Party Code. We also expect third parties to adopt standards that cover the same principles and content in the code with their own suppliers. • We merged our human rights and Third-Party Risk Management program into one function to help ensure more effective human rights due diligence.
Manufacturing and product quality Inability to ensure proper controls in product development and product manufacturing, and failure to comply with applicable regulations and standards	The development and manufacture of our products is complex and highly regulated by health authorities around the world. We must ensure that all relevant processes comply with regulatory requirements as well as our own quality standards. Failure to do so may result in warning letters, suspension of manufacturing, seizure of products, injunctions, product recalls, failure to secure product approvals, or debarment. Any of these could have a material adverse effect on our business, financial condition, and results of operations.	• We aligned the Novartis Quality organization to the business, while embedding Quality Management System requirements closer to the points of execution. • In 2020, we took steps to ensure the Novartis Quality audit program continued to cover internal and external sites across the product lifecycle despite COVID-19 challenges. • We took action to fulfill new regulatory requirements within specified timeframes with respect to acceptable impurity levels in our products.

Risk	Context	Actions
EMERGING RISKS		
Geo-political and socio-economic threats Negative impact of geo- and socio-political threats and economic instability	A range of geo-political and socio-economic issues may affect our business. These include trade restrictions, such as tariffs, and government policies on drug pricing and other issues. In addition, unpredictable economic conditions may adversely affect the financial position of payers, distributors, customers, suppliers and service providers. Financial market issues may also result in a lower return on our financial investments, and a lower value on some of our assets. This risk was upgraded to an emerging risk in 2020, from an awareness topic in the previous year, as the COVID-19 pandemic, trade frictions and other trends continue to create an unpredictable environment for global business.	• We consider assessments of the geo-political, macro-economic and socio-economic environment in our Enterprise Risk Management process to identify high-risk areas. • We work with trade associations, key stakeholders and multilateral organizations to anticipate policy/trade developments and related consequences for our business.
New ways of working Impact on productivity and well-being of associates of constant remote working due to the current pandemic crisis and in planned future setup	The COVID-19 pandemic has fundamentally changed the way we work. It has accelerated existing trends and triggered new ones. These include reduced business travel, increased dependence on virtual communications platforms, potential mental health concerns due to prolonged isolation, and blurred lines between working and non-working life. These trends pose several risks for our business, including decreased productivity, challenges around keeping associates engaged with our corporate culture, employee burnout, and data privacy/protection issues.	• We accelerated the launch of a new global working model for office-based functions, called Choice with Responsibility, which addresses associates' need for flexibility in working arrangements while seeking to maintain business performance. • We expanded mental health resources and tools available to associates.
Global enterprise resource planning (ERP) implementation Inability to implement and properly operate our new global ERP system	We are in the design and planning phase for the implementation of a new global ERP system that seeks to simplify, standardize and digitize processes across several business functions. The aim is to help ensure efficient and compliant business operations as well as to ensure the availability of high-quality data necessary to aid our decision-making. Any disruption or malfunction of our new ERP system could negatively affect our operations.	• We expect the planning, design and build phase to continue through 2021, with the first implementations of our new ERP system expected to begin in the second half of 2022.
AWARENESS TOPIC		
Climate change Climate change and increased risk of major natural disasters	Climate change and the potential failure of adaptation are key risks highlighted across most risk and trend reports. The transition to a low-carbon economy and the adjustment of energy production and consumption will continue to be critical for investors and society as a whole. Novartis is potentially exposed to physical risks from varying natural disaster or extreme weather events. In addition, we face increasing transition risks due to market and regulatory dynamics, including carbon taxes and carbon pricing. Novartis is committed to using resources efficiently and reducing greenhouse gas emissions. We aim to achieve carbon neutrality across our supply chain (Scope 1, 2 and 3) by 2030. However, in a rapidly changing world, there can be no certainty that we will manage such issues successfully to meet our targets.	• We formally signed on to the Task Force on Climate-related Financial Disclosures. • We provided long-term sensitivity and stress-testing analysis for climate and water to relevant business functions. • We started a process to assess climate-related risks for our development pipeline and existing medicines. For more information on our climate-related actions and disclosures, please see page 64 and page 75.

Strengthening internal assurance and advisory

Novartis Business Assurance & Advisory (NBAA) plays an important role in supporting the risk and compliance process. It is an independent corporate function comprising Internal Audit, the SpeakUp Office (our whistleblower program) and Global Security that provides protection, insight, advice and assurance to the business and the Audit & Compliance Committee of the Board of Directors. In 2020, we invested in upskilling 115 NBAA associates to become better at identifying emerging risks, and we accelerated data and digital awareness.

With our joint ambition for integrated assurance and data and digital, we are leveraging new digital capabilities to seamlessly connect and analyze data from NBAA, ERC and across Novartis divisions into a single dashboard to detect emerging risks, trends and developments more quickly and accurately.

These enhancements were crucial in helping us adapt to the COVID-19 pandemic. As lockdowns took effect, we quickly shifted to remote audits, advisories and investigations, and recalibrated our focus on evolving threats such as cybersecurity in coordination with Novartis Information Security and Risk Management. These efforts helped ensure NBAA provided senior management and the Board of Directors with timely advice on how to optimize business continuity in critical units such as Novartis Technical Operations, which oversees global manufacturing operations, the supply chain and quality assurance. Support included early intervention advice to review business continuity and emergency management plans so sites could continue to operate seamlessly until Novartis had established a global response plan.

We further strengthened our Internal Audit function by introducing data automation and laying the foundation for continuous risk assessment through data analytics. We also introduced automated analytics for commercial auditors, with an estimated 150 hours saved across commercial audits per year. We enhanced our understanding of key company risks as well as our coverage by using new approaches such as reviews covering smaller markets or emerging topics, and piloted culture pulse checks providing additional insight into the Novartis culture journey.

We performed 81% of planned activities (equating to 62 engagements) in 2020, most conducted remotely, despite the obstacles created by COVID-19. These engagements comprised 39 audits, 17 advisories and six internal reviews covering the entire value chain of Novartis and key risks.

We evolved our approach from a main focus on findings to truly understand the root causes, and started to share knowledge and learnings that our associates can apply. As an example, insights were shared from engagements exploring the unique challenges associated with *Kymriah*, our chimeric antigen receptor T-cell (CAR-T) therapy. Learnings regarding the need to strongly connect the supply chain and commercial functions, or how to implement innovative agreements with payers, helped us identify and mitigate risks linked to the new business model for this immunotherapy.

Expanding the third-party risk management process

Our Third-Party Risk Management (TPRM) team is responsible for identifying, assessing and managing risk, promoting ethical behavior and fostering sustainability in our supply chain. In 2020, we continued to integrate human rights into TPRM, most notably through labor rights; health, safety and environment (HSE); anti-bribery; and corruption. Further, we expanded our risk assessment methodologies to include additional human rights risks and strengthened our due diligence processes.

TPRM covers the following core risk areas: anti-bribery; animal welfare; HSE; labor rights; information security; data privacy; and good manufacturing practices. In 2020, we added financial due diligence and assessment of suppliers' business continuity plans. The latter has been especially relevant during COVID-19, with some suppliers requiring support in dealing with financial distress. We also included trade sanction checks in TPRM, further integrating our risk management processes.

We expanded our risk management practices to include wholesalers and distributors, who are important Novartis customers. In October, we launched a new global standard for assessing these groups, covering anti-bribery, credit risk and trade sanctions. We will first conduct assessments in 12 pilot countries in Asia, Africa, Europe, and North and South America before rolling out this centralized risk management process globally.

In November, we launched our revised Novartis Third Party Code to strengthen the environmental sustainability language and outline requirements for third parties around setting environmental targets and managing their environmental performance and that of their supply chain. Further, it specifies requirements for our suppliers with respect to human rights (e.g., minimum wages, working hours and child labor), and reinforces our ongoing commitment to diversity and inclusion, prohibiting supplier discrimination based on national or ethnic minority status, and gender identity or expression.

ADDRESSING ENVIRONMENTAL RISK IN OUR SUPPLY CHAIN

In 2020, we established a dedicated in-house team of global HSE risk experts within our HSE Supplier Assurance and Risk function to perform supplier audits and assessments, covering all regions. We assess third parties in terms of their compliance with the Novartis Third Party Code, the effectiveness of their management system, and if they meet legal and Novartis HSE standards. The HSE risk assessment team works closely with the Third-Party Labor Rights, Human Rights and Quality teams to help ensure a focus on human rights and community impact.

We continued to monitor the environmental performance of our suppliers against Novartis targets for carbon, energy, water and waste reduction. Every year, we measure and monitor the performance of key suppliers through a dedicated sustainability survey. In 2020, we distributed the survey to more than 80 suppliers, with an 86% response rate. Moving forward, we will also implement an environmental maturity ladder approach, outlining the milestones suppliers should reach within a certain timeframe to continuously enhance their environmental performance. This is important for progressing toward our 2030 sustainability targets, and in particular for achieving carbon neutrality in the supply chain (see page 64 of this

Supply chain performance indicators

	2020	2019	2018
Suppliers risk-assessed by TPRM [1, 2]	**8 448**	2 839[3]	NA[4]
Suppliers with remediation action agreed [2, 5]	**521**	122	89
Suppliers audited [2]	**35**	135	48
Suppliers assessed for anti-bribery risks	**2 014**	479[3]	NA[6]
Suppliers assessed for animal welfare	**10**	3[3]	NA[6]
Suppliers assessed for business continuity plans	**70**	NA[6]	NA[6]
Suppliers assessed for financial due diligence	**193**	NA[6]	NA[6]
Suppliers assessed for health, safety and environment	**315**	226[3]	NA[6]
Suppliers assessed for information security and data privacy	**3 174**	1 142[3]	NA[6]
Suppliers assessed for labor rights risks	**4 635**	1 423[3]	NA[6]
Suppliers assessed for Quality GmP	**561**	162[3]	NA[6]
Supplier engagements stopped due to risk assessment outcomes	**120**	15[3]	NA[6]

[1] TPRM: Third-Party Risk Management
[2] Includes new suppliers and new products, services or sites from existing suppliers. Figures do not include GxP audits (see page 57 for more details).
[3] Data reflect April to December 2019, based on the TPRM program geographical rollout.
[4] Data not available; the TPRM program was not launched.
[5] Follow-up includes more information requested, audits or on-site assessments.
[6] Not available; the specific risk domain was not yet included in TPRM

report). In addition, we now also embed environmental sustainability objectives in our supplier contracts.

Despite COVID-19, we performed a total of 382 comprehensive HSE assessments in 2020. These included 33 audits and led to 383 findings. Findings across Europe, the Americas, China and India highlighted process safety as an area for improvement. Specifically in China and India, industrial hygiene was also a concern. Together with our suppliers, we have developed mitigation plans with set timelines to address these findings.

In 2020, Novartis identified eight suppliers with unacceptable gaps in HSE compliance leading to either an exit or termination of the evaluation process. We also engaged in capability-building activities with suppliers, especially in India and China as part of our involvement in the Pharmaceutical Supply Chain Initiative (PSCI). In particular, we worked with the PSCI to develop HSE guidance documents based on industry best practices that were rolled out during webinars and published on the PSCI's supplier platform.

Upholding our commitment to human rights

In 2020, our CEO was the first from a pharmaceutical company to sign the World Business Council for Sustainable Development's CEO Guide to Human Rights, calling on businesses to contribute to the realization of universal human rights. He was also one of more than 1 000 CEOs to endorse the Statement from Business Leaders for Renewed Global Cooperation, reaffirming support for the United Nations (UN) and renewed global cooperation, with firm commitments to uphold human rights.

We continued to conduct due diligence to embed the UN Guiding Principles on Business and Human Rights throughout our operations. Although the pandemic limited our ability to perform due diligence on the ground, we conducted desk-based research in preparation for future field-based human rights assessments in Bangladesh, Indonesia, Mexico and Russia, and we completed virtual labor rights and HSE audits in India, Brazil and Mexico. We have initiated a process of human rights risk mapping and assessments regarding raw material inputs into our products, and clinical trial policies and processes, which we will report on once findings are available.

In April, based on the World Health Organization's technical information on COVID-19, we provided guidance to our suppliers to help ensure they met our expectations for the treatment of work-

Novartis human rights strategy

ONGOING DUE DILIGENCE

Augmenting existing due diligence processes by embedding human rights

HUMAN RIGHTS ASSESSMENTS

Investigating markets, products, and services for potential human rights risks and impacts

CAPACITY BUILDING

Building capacity in Novartis about human rights and due diligence processes

STRATEGIC RIGHTS PROMOTION

Supporting protection of human rights in areas that align with our business

STAKEHOLDER ENGAGEMENT

Reporting and engaging with key internal functions and external stakeholders

ers. Together with Human Rights, HSE, TPRM and other functions, the Labor Rights team in India also established a Novartis supplier extension program to share COVID-19-related good practices with suppliers virtually.

Our Novartis Third Party Code includes a specific requirement for suppliers to respect human rights and align to our requirements for minimum wages, paid overtime, maximum working hours, time off and breaks, and definitions of child labor and young workers, to comply with international standards. The code reinforces our commitment to diversity and inclusion in our supply chain by prohibiting supplier discrimination based on national or ethnic minority status, and gender identity or expression. In addition, we rolled out training for relevant internal functions to raise their awareness and provide them with due diligence guidance to help prevent modern slavery. To further build internal capacity, we plan to launch pilots in 2021 to enable our supply chain managers to better identify and manage human rights concerns among higher-risk third parties.

We publish a statement explaining how we address modern slavery risks or impacts each year on our website.

In 2020, to drive collective action at scale beyond our own company's operations, we spearheaded projects through the PSCI's Human Rights and Labor Subcommittee, which we co-chair. For example, in India, we mobilized a coalition of PSCI members to support the state of Telangana's initiative to restore the Musi River in Hyderabad by raising supplier awareness and capability to avoid discharging untreated wastewater effluents. In Brazil, we coordinated a PSCI working group to investigate human and labor rights practices among carnauba wax suppliers and encourage them to join sector-wide initiatives for addressing these issues, in particular the risk of forced labor. Further, we mobilized a group of pharmaceutical companies to look into the human rights risks associated with raw material inputs in pharmaceutical products. Novartis also led the development and delivery of human rights and modern slavery trainings for PSCI members, and for the annual pharmaceutical supplier conferences in China and India.

We continued to promote human rights through more inclusive policies at Novartis. Our Human Rights, Diversity & Inclusion, and People & Organization (P&O) teams partnered to support human rights leadership opportunities, including the promotion of lesbian, gay, bisexual, transgender and intersex (LGBTI) associates' rights and the development of the company's first global policy and strategy for ensuring respect for the right to equal opportunities of disabled associates.

Encouraging associates to speak up

The SpeakUp Office continues to provide a safe place for associates to raise concerns about potential misconduct while being protected against retaliation. Complaints can be made directly to the SpeakUp Office through an external web-based platform, which offers the possibility to report anonymously, or through our mobile app. Complaints can also be raised via a generic email address to the SpeakUp Office; through local channels such as the ERC, P&O and Legal functions; or to senior management. Our process helps ensure that complaints are swiftly received, risk-assessed, prioritized, investigated, and resolved at the appropriate level. We are committed to analyzing and understanding the root causes of misconduct to help prevent similar issues from occurring in the future.

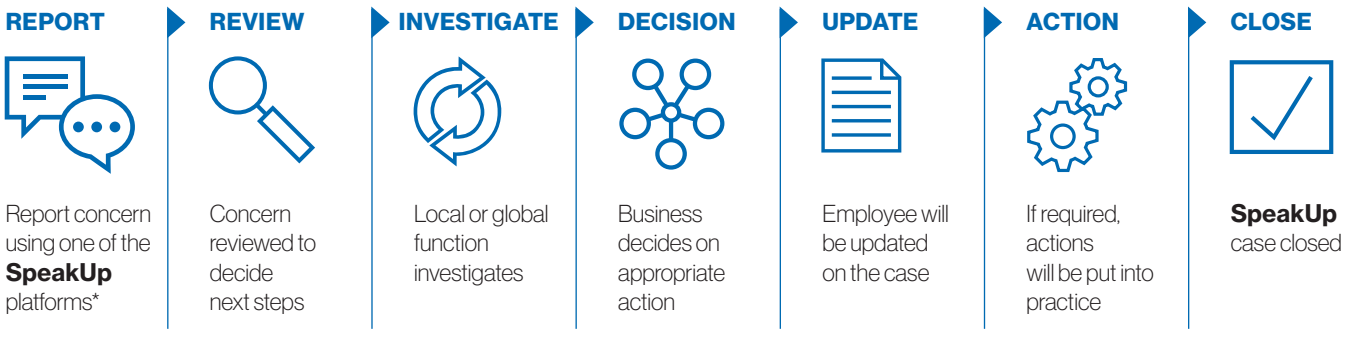
In total, 1 941 complaints of alleged misconduct, with a total of 2 186 allegations, were made. 22% were self-identified (monitoring), and 78% came from SpeakUp. 35% were made anonymously. There was a 17% decrease in overall complaints in comparison to last year (similar to peers) due to COVID-19 and the stricter risk assessment.

Complaints fell under 15 categories (see the prior table). In 2020, we factored human rights-related violations into our existing misconduct categories; within these categories, nine cases contained allegations of human rights violations.

Overall, the investigated central matter allegations (higher-risk cases) resulted in 102 dismissals or resignations, and in 68 written warnings. Other remedial actions such as training, coaching and implementing new controls were also widely used when deemed appropriate.

We continued to strengthen the SpeakUp Office with general awareness sessions about the program, and together with the Global Security team responsible for investigating most central matter allegations, we offered training on specific investigations to upskill local case

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

Photo Novartis employees at a production facility in Torre Annunziata, Italy.

Ethical business practices performance indicators

	2020	2019	2018
Novartis associates trained and certified on the Code of Ethics (%) [1]	**98**	98	98
Misconduct cases (central matters) reported to the SpeakUp Office [2, 3, 4]	**142**	209	441
Total SpeakUp Office allegations (central matters) [2, 4, 5]	**243**	427	768
SpeakUp Office allegations (central matters) per category (%) [2, 7]			
Fraud/asset misappropriation	**7.8**	6.8	21.6
Expense fraud	**2.9**	5.4	23.4 [8]
Books and records, accounting irregularities	**0.8**	1.2	0.4
Improper professional practices	**11.9**	16.9	22.3
Bribery, kickbacks	**0.8**	1.6	2.1
Discrimination and sexual harassment	**12.8**	8.2	4.0
Retaliation	**3.0**	6.3	2.1
Other employee relations issues	**19.0**	18.0	7.9
Conflict of interest	**10.7**	10.8	5.2
IT security breach	**3.7**	4.0	1.9
Quality assurance/data integrity	**8.6**	6.3	3.1
Data privacy	**1.6**	2.6	0.5
Antitrust, fair competition	**0.8**	0.2	0.3
Company confidential/trade secret information	**3.7**	0	0
Other	**11.9**	11.7	5.1
SpeakUp Office allegations (central matters) substantiated [2, 4, 6, 9]	**114**	254	558
Dismissals and resignations related to misconduct (central matters) [2, 4, 6, 9, 10]	**102**	186	350

[1] Active Novartis associates with email addresses, trained via e-learning or via One Deck for Novartis Technical Operations. Training rolled out from September 2020 to February 2021, with a preliminary completion rate as of December 31, 2020.
[2] A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and significant financial impact.
[3] The number of misconduct cases reported may change year-on-year as matters may be reassessed in the course of the case lifecycle.
[4] The decrease in the number of misconduct cases reported is due to a new risk assessment as of 2019.
[5] The number of allegations is higher than the actual number of cases as a case can have more than one allegation.
[6] May include allegations from previous years
[7] Percentages are based on total SpeakUp Office allegations number. Results for 2019 and 2018 have been revised to reflect the change in methodology from using the number of misconduct cases to the number of allegations.
[8] Until the end of 2018, these expense fraud allegations are assessed to be of higher risk in China. The risk assessment of these issues changed as of 2019.
[9] Data based on when investigation report was received. Results for 2019 and 2018 have been revised to reflect this change in methodology.
[10] Data based on year when case is closed. Results for 2019 and 2018 have been revised to reflect this change in methodology.

managers in ERC and P&O teams. A total of 755 associates were engaged, and more than 150 completed virtual training sessions.

Addressing legacy legal issues

Novartis resolved several legacy litigation matters in 2020. We reached settlements with the US Department of Justice and the US Securities and Exchange Commission, resolving all Foreign Corrupt Practices Act investigations into historical conduct by the company and its subsidiaries. Specifically, with respect to allegations pertaining to our subsidiary in Greece, the resolutions contained no allegations relating to any bribery of Greek politicians, which is consistent with what Novartis found in its own internal investigation. We also resolved 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 in the US. As part of this settlement, Novartis will continue to evolve its approach to peer-to-peer medical education in the US by transitioning predominantly to digital formats. Going forward, we aim to set the standard by embracing new, digitally enabled education programs that will help physicians keep pace with medical innovation and support better outcomes for patients.

Commitment to transparency and disclosure

Transparent reporting and disclosure play a key role in building trust with society. We aim to be open and clearly disclose what we do, how we work, where we are successful and where we face challenges. This applies across all aspects of our business around the world, including clinical trials, interactions with healthcare professionals, and patient group funding. For more disclosures, visit our website.


SOP

Photo Dr. Juliet Akoth (right) speaks with a patient and her family during a home visit in Kitui, Kenya. Dr. Akoth enrolled in Echo for Life, a training program sponsored by Novartis in partnership with the University of Nairobi.

STRATEGIC AREAS

Being part of the solution on pricing and access

Why is it important?

Improving access to medicines remains one of the greatest healthcare needs worldwide. According to the World Health Organization (WHO), one-quarter of the world's population – 2 billion people – have no access to basic medicines. Roughly 1 billion people faced catastrophic payments for healthcare in 2020, driven in large part by out-of-pocket spending on medicines. With COVID-19 putting nearly half of the global workforce at risk of losing their livelihoods, there has never been more urgency to make medicines affordable and secure equitable access to healthcare. Collectively, the global health community has a responsibility to help ensure that no one is left behind and that anyone who requires treatment receives it.

In this section

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

New targets

Launched new access targets and issued a sustainability bond linked to those targets

→ p. 31

Innovative brands

Introduced outcome-based agreements for *Luxturna*, and more than 20 new local brands for our innovative therapies

→ p. 33

Sub-Saharan Africa

Announced a collaboration with the Africa Medical Supplies Platform to help provide more efficient and rapid access to medicines in the Novartis COVID-19 Pandemic Response Portfolio for the member states

→ p. 37

Healthcare workers

Provided access to peer-reviewed information for diagnosis and management of a range of diseases to more than 20 000 healthcare professionals in 150 countries, through the Better Evidence program at Ariadne Labs

→ p. 42

Our targets

- **Implement an access strategy for all new products launched**
- **Increase patients reached** with strategic innovative therapies in low- and middle-income countries (LMICs) by at least 200% by 2025
- **Implement tiered pricing for launches in Pharmaceuticals and Oncology** based on national income levels and value-based pricing
- **Achieve a twofold increase in the number of patients reached** in sub-Saharan Africa by 2022, and a fivefold increase by 2025

Our approach and performance

Through our core business – the discovery, development and marketing of innovative treatments – we have helped prevent and treat diseases, ease suffering, and improve quality of life. But as the size and complexity of the world's healthcare challenges grow, we must widen our scope, extending our impact even further to help effectively address the needs of underserved populations in a way that is sustainable for our business.

We established the Novartis access principles in 2017 to systematically integrate access strategies into how we research, develop and deliver our new medicines globally. This is a key measure of success for our leaders and associates. Our emerging markets center of excellence in our Pharmaceuticals business unit supports the implementation of the principles by ingraining access into all new launches in LMICs. Strategies can include establishing innovative pricing and access models, driving early launches in these countries, and supporting approaches to strengthen healthcare systems. The Access to Medicine Foundation has repeatedly recognized our efforts in this area, ranking us second in the 2018 Access to Medicine Index among 20 of the world's largest healthcare companies.

Our drug development processes require our teams to explore how we can increase our impact in LMICs in terms of affordability, health system strengthening, and adaptive research and development (R&D). The Novartis Research & Development Committee reviews all drug development submissions and holds our clinical research teams accountable for acting on access opportunities.

The highest ranks of our organization are accountable for expanding access to our treatments. Members of the Executive Committee of Novartis (ECN) and other senior leaders have access indicators in their annual objectives. This keeps our entire company focused on increasing our positive impact on society.

In September, as part of the company's ambition to expand access to innovative medicines in LMICs, Novartis committed to increase patient reach with our strategic innovative therapies by at least 200% by 2025. In addition, we announced we would increase patient reach of our global health flagship programs in leprosy, malaria, sickle cell disease and Chagas disease by at least 50% over the same period. Achievement of these targets, which we will report on annually, should result in a potential reach of more than 24 million patients across therapy areas.

To reinforce our commitment to the patient access targets, we issued a EUR 1.85 billion sustainability-linked bond (SLB). The bond is the first of its kind in the healthcare industry and the first SLB incorporating social targets, with bondholders entitled to receive a higher amount of interest if Novartis fails to meet its access targets. Novartis obtained two separate second-party opinions that validate the robustness and relevance of the key performance indicators and targets, one from the Access to Medicine Foundation and one from Sustainalytics, a consultancy with recognized environmental, social and governance (ESG) expertise. Sus-

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

tainalytics also confirmed alignment of the bond with the Sustainability-Linked Bond Principles published by the International Capital Markets Association. We will report annually on our performance against these patient access targets, with limited assurance by an external verifier.

Adapting medicines to address unmet needs

In line with the Novartis access principles, we carry out research and development with an aim to help address the unmet needs of underserved patients, known as adaptive development. This means we continually assess our product portfolio to see where we can deliver new solutions for vulnerable populations by:

- Developing new formulations
- Expanding the clinical use of existing medicines into new indications and new populations (e.g., infants and children)
- Conducting research that enables us to better pursue adaptive development of new medicines (e.g., genetic diversity)

We focus our adaptive development efforts to support our global health flagship programs in sickle cell disease, Chagas disease, malaria and leprosy (see "Addressing global health challenges" on page 46). We also conduct adaptive development projects in a range of other therapeutic areas to address emerging needs. Selected projects are shown in the table below.

Early in the COVID-19 outbreak, we assessed whether our investigational or approved medicines could be repurposed beyond their present indications to treat the symptoms or complications of COVID-19. This included conducting multiple large clinical trials for *Jakavi* (blood malignancies), in collaboration with Incyte Corporation, and for *Ilaris* (rare inflammatory diseases), among others. In addition, Novartis medicines are being studied in more than 30 ongoing investigator-initiated trials around the world.

Developing effective affordability strategies

We live in an era of medical innovation, driven by a better understanding of the genetic and biological roots of disease, and a burgeoning 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 healthcare worldwide and pressuring healthcare systems to contain spending growth. The COVID-19 pandemic has exacerbated this pressure on healthcare budgets.

In 2020, the WHO published an updated policy guideline on country pharmaceu-

Adaptive development projects

Category	Product	Objectives	Progress to date
Expansion of clinical use of existing medicines into new indications and populations	***Entresto***	Phase IV clinical trial to assess the efficacy and safety of *Entresto* in people with heart failure due to chronic Chagas cardiomyopathy	Study approved by the health authorities and started recruitment in Argentina, Brazil, Colombia and Mexico
	Hydroxyurea	Develop pediatric formulation for treatment of sickle cell disease	Dossier submitted for registration in Ghana in October; submissions in Uganda, Tanzania and Kenya are planned for 2021
	Myfortic	Expansion of lupus nephritis indication	Following registration in 2019 of *Myfortic* for the treatment of lupus nephritis in Pakistan, we are continuing to register this indication in countries with high prevalence and unmet medical need, including Argentina, Bangladesh and Myanmar, to provide better treatment options.
Development of new formulations for greater incremental benefit to vulnerable patients	***Coartem***	Develop pediatric formulation for infants < 5 kg body weight	The trial is expected to start in 2021 in collaboration with the PAMAfrica consortium, funded by the European & Developing Countries Clinical Trials Partnership.
Conducting research that enables us to better pursue adaptive development of new medicines	**Tamoxifen**	Study to understand how Africa-specific CYP2D6 polymorphism – a key enzyme to metabolize a large number of clinically important drugs – potentially affects how the drug metabolizes in the body	In 2019, we submitted a study protocol to the government of Zimbabwe. All study approval requests were granted in 2020. However, patient enrollment in the study was placed on hold due to the COVID-19 pandemic.

tical pricing policies, making recommendations on 10 pricing policies commonly considered in countries to manage medicine prices, as well as pragmatic considerations for what is required to implement these policies according to the objectives and context of individual health systems.

Novartis welcomes the WHO's conditional recommendation on value-based pricing and is committed to pricing our medicines according to the value they deliver. Yet most healthcare systems base their payment models on volume of procedures – such as the number of visits to the doctor, days spent at the hospital, or the number of medicines delivered – which often results in a suboptimal allocation of resources.

We believe medicine prices should be based on four value pillars: clinical value, patient value, value to the healthcare system, and value to society as a whole. As an example, cost offsets from prevented hospitalizations have been considered in pricing our treatments for heart failure.

A value-based approach to healthcare incentivizes the healthcare sector to focus on the interventions that deliver the most effective, efficient and sustainable outcomes. Novartis was among the first pharmaceutical companies to enter into value-based contracting for medicines, linking pricing and reimbursement rates to specific outcomes.

For example, outcome-based agreements are in place for our breakthrough therapy *Luxturna*, which can be sight-saving by treating a gene mutation causing an inherited retinal dystrophy. To address payers' concern about the durability of the effect of this one-time treatment, payment is dependent on the accepted clinical threshold reached by patients at agreed time points based on a commonly used light sensitivity test. In addition, to help improve affordability and increase access, we have developed an overarching tiered pricing approach taking local economic considerations into account. We are also exploring other innovative payment models, such as installment payments and deferred payments. In markets where *Luxturna* is not yet approved, we implemented early access schemes, such as providing individual named patient funding and facilitating cross-border treatments whereby patients from smaller countries lacking the necessary infrastructure are treated in centers in larger countries. In addition, we are working with local partners to increase the low level of symptom awareness and genetic diagnoses in developed and emerging markets, establishing patient support programs and referral networks to address these hurdles.

To help improve the affordability of our medicines in countries around the world, we take local economic realities into account in considering a range of approaches to expand access across the income pyramid, including tiered pricing, innovative business models, emerging market brand strategies, patient access programs and off-patent solutions.

EMERGING MARKET BRANDS

The WHO estimates that up to 90% of the population in LMICs purchases medicines through out-of-pocket payments. In 2014, Novartis introduced an emerging market brand (EMB) strategy to expand access to innovative medicines to people in LMICs, in a way that is sustainable for the business and supports governments in responding to unmet medical needs. One of the key objectives of the EMB strategy (previously known as our local brand strategy) is to provide access to innovative drugs as early as possible at a price patients can afford. We continue to expand this strategy in LMICs to reduce the out-of-pocket burden for patients, improve access, and help shorten the time lag between the availability of our innovative medicines in higher-income countries and in LMICs.

In 2020, we launched EMBs for therapies in our Innovative Medicines portfolio, including *Piqray* (advanced breast cancer), *Kisqali* (metastatic breast cancer), *Tafinlar* + *Mekinist* (lung cancer and metastatic melanoma), *Rydapt* (acute myeloid leukemia), *Entresto* (heart failure), *Aimovig* (migraine) and *Beovu* (wet age-related macular degeneration). Novartis is systematically evaluating the feasibility of implementing EMBs for key launches. This has proven to be an effective tool to reach more patients. For instance, the EMB of *Entresto* is benefiting more than 230 000 heart failure patients, a 50% increase in patient reach in LMICs compared to the same period last year. In 2020, we reached more than 355 000 patients and launched 15 EMBs in Pharmaceuticals, and we reached more than 13 900 patients and launched seven EMBs in Oncology.

The Access to Medicine Foundation estimates that innovative drugs reach less than 1% of patients in emerging markets five years after launch. One of our priorities has been to reduce the time it takes us to bring new therapies to patients in LMICs compared to the original brand in higher-income countries. In 2019, we reduced this time lag to five months for the first EMB of *Kisqali*, six months for *Aimovig,* and seven months for *Beovu* by more effectively integrating access considerations into the launch process. In 2020, we launched the EMB of *Piqray* in India one month ahead of the first European country launch thanks to early planning and more formalized processes.

EXPANDING ACCESS TO HIGH-QUALITY GENERICS

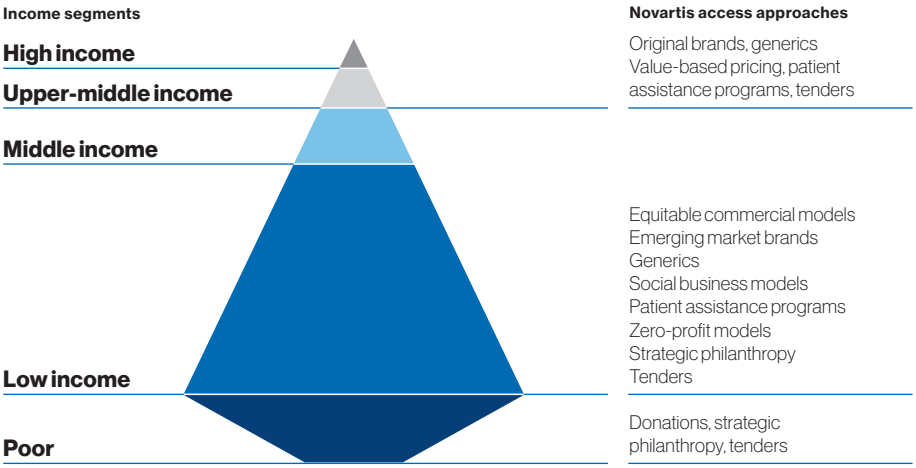
Our Sandoz Division drives access through the provision of affordable, quality generic medicines and biosimilars. It focuses increasingly on segments where it can make a difference, either by making available a competitive generic alternative or by offering a novel and more affordable alternative to existing therapies (such as leading biologic medicines through its global biosimilar business). In 2019 alone, the US generics industry contributed more than USD 313 billion in savings, with Sandoz medicines accounting for USD 12.1 billion.

In February, Sandoz was the first company to commit to maintaining stable prices for 23 essential medicines for the treatment of COVID-19-related symptoms and disease complications, including antivirals to reduce the impact of COVID-19, and antibiotics to combat pneumonia.

Further, the Novartis COVID-19 portfolio launched in July includes 15 Sandoz drugs that treat key symptoms of COVID-19, such as fever, coughing, respiratory problems and pneumonia. The medicines – including dexamethasone, which has been shown to reduce deaths in severe COVID-19 pneumonia – are made available to governments, non-governmental organizations (NGOs) and other institutional customers in up to 79 eligible LMICs at zero profit.

NOVARTIS ACCESS FRAMEWORK

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



"How do we make broader access possible? In addition to having more affordable prices, it is also about working with health systems and partnering with governments, payers and relevant organizations to accelerate access to transformative therapies"

Marie-France Tschudin, President of Novartis Pharmaceuticals

INTEGRATED ACCESS PROGRAMS & MARKETS

Novartis has been pioneering social business models for more than 10 years. Our experience in implementing social business activities and community health education has provided important lessons for expanding access to affordable medicines and delivering quality care in lower-income settings.

In particular, our experience with *Novartis Access*, our portfolio of medicines addressing key noncommunicable diseases (NCDs) and childhood pneumonia, revealed that we had to expand our offering to additional therapeutic areas in order to best meet healthcare needs. Further, although our pricing was attractive (USD 1 per treatment per month for the portfolio), our model should be more flexible. (See "Evaluating *Novartis Access*.")

We are also investigating ways to expand on our direct market approach in the three countries where we assume responsibility for the full Novartis portfolio (Laos, Cambodia and Nepal) to build a roadmap that will enable us to deliver better solutions for underserved patient populations. In these and other countries in Latin America, we are exploring how to best address unmet needs in complex environments through a cross-divisional approach and with the right partners.

Once more, our experience on the ground showed that delivering quality care along the patient journey – from diagnosis to treatment and disease management – requires strong healthcare systems. To support this, we will place even more emphasis on health system strengthening activities in the future.

In 2020, we created the Integrated Access Programs & Markets (IAPM) unit to help apply these learnings more consistently and support our shift to further integrate social business activities into our core business and operations. The new unit builds on the core capabilities of our former Novartis Social Business group and aims to better leverage synergies across our Global Health & Corporate Responsibility organization, our Innovative Medicines and Sandoz Divisions, functions and regions. IAPM includes *Novartis Access*, Healthy Family, direct markets (countries where IAPM has full responsibility for the entire Novartis product portfolio), and a new center of excel-

Emerging market brands performance indicators

	Patients reached (thousands)		
	2020	2019	2018
Emerging market brands			
Novartis Pharmaceuticals	**355.1**	302.6	213.3
Novartis Oncology	**13.9**	11.3	8.2

lence to facilitate the implementation of the Novartis access principles across the company, with a focus on health system strengthening.

While the structure has changed, our commitments remain the same. We continue to develop global health programs and social business models, with the ambition of advancing them into sustainable solutions that can be scaled in the market.

Novartis Access
Novartis Access provides on- and off-patent medicines addressing childhood pneumonia and key NCDs (cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer). Medicines are offered together with capacity-building activities to strengthen health systems in lower-income countries. Novartis Access currently operates in 14 countries across Africa, Asia and Latin America, and has reached 4.5 million patients since launch.

In 2020, as part of the transition of our social business activities into IAPM, we undertook an in-depth assessment of unmet medical needs in LMICs based on data from the Institute for Health Metrics and Evaluation, the WHO and medical reviews. When an unmet need was identified, we analyzed the feasibility of producing and registering medicines to effectively address this need in target countries. Based on this analysis, we are considering additional therapeutic areas for our future *Novartis Access* offering.

With nearly 30% of the population living below the poverty line, Latin America is home to some of the poorest populations in the world. People living in disadvantaged communities are disproportionally affected by NCDs and are particularly vulnerable to the health and socio-economic impacts of the COVID-19 pandemic. This situation adds to the unprecedented migration crisis facing the region. Despite operational challenges due to COVID-19, we achieved an estimated patient reach of 69 000 patients in Venezuela, El Salvador and Colombia in 2020. We aim to expand *Novartis Access* to more Latin American countries over the next years.

In Asia, we are continuing to operate *Novartis Access* in Pakistan and Vietnam. In Pakistan, we launched a new digital medicine dispensing service in partnership with the Health Promotion Foundation in Karachi. Data gathered through the platform enables the foundation to see if *Novartis Access* medicines are dispensed in accordance with guidelines, identify disease hotspots, gain insights into comorbidities, and monitor adherence. By having access to aggregated data, Novartis is able to track usage patterns and prevent product stockouts. Approximately 800 patients were registered in 2020, and we have signed an agreement with a second NGO to launch a similar solution in 2021.

Our social business initiatives around the world

Evaluating Novartis Access
We have invested in rigorous evaluation to measure the impact of *Novartis Access*. In 2019, we reported on interim results of an independent evaluation of *Novartis Access* in Kenya, conducted by Boston University in the US.

Final results were released in 2020. They demonstrated that *Novartis Access* did not have a major impact on NCD medicine access at the household level for various reasons, including the lengthy process in registering the portfolio, which made it difficult to get medicines into supply streams. Further, involving end users at the county and household levels (instead of stakeholders at the central level alone) prior to launching *Novartis Access* in Kenya would have informed refinements that may have increased impact. It was also widely acknowledged that the conclusion of the study came too soon, and ideally the evaluation should have continued for an additional one or two years.

Yet, overall, academic researchers commended Novartis for investing in a gold standard, transparent evaluation, which is the first randomized, controlled trial of its kind. Further, learnings will benefit companies in designing access interventions that are more likely to be successful, undertaking rigorous measurement and evaluation from the outset. Several papers linked to the study were published, for instance on equity in access to NCD medicines in Kenya.

We have started evolving *Novartis Access* based on the interim findings. We will further strengthen our efforts around NCD screening and local procurement processes, especially where molecule-based tendering is the norm, and work with local authorities to help ensure patients can benefit to the greatest extent possible from *Novartis Access* medicines. The final results will further guide our journey toward strengthening the program and our overall approach to expanding access to medicines. Moving forward, we aim to further empower Novartis country teams in the implementation of our access objectives, and focus more strongly on health system strengthening.

Novartis Global Health performance indicators

	2020[1]	2019	2018
Countries with products on the ground	**115**	33	26
FTEs[2,3]	**1 334**	786	651
Patients reached with products (thousands)[4]	**65 828**	15 069[5]	28 509[5]
Health educators trained	**671**	1 536	1 028
Healthcare providers trained[6]	**12 648**	1 516	697
Policymakers trained	**90**	145	131
Points of service provision[7]	**5 902**	13 635	15 190
People reached at points of service provision	**486 642**	986 701	765 055
Awareness events held[8]	**424 878**	250 432	185 756
People reached at awareness events	**8 048 360**	10 211 704	982 078

[1] Data reflect the full scope of access approaches managed by the Global Health organization, including the activities formerly managed by Novartis Social Business, as well as the newly formed sub-Saharan Africa (SSA) organization and the Integrated Access Programs & Markets unit. More details are on pages 33-38.
[2] Full-time equivalent positions and contractors
[3] Significant number of headcounts integrated from different units as a result of the establishment of the new SSA organization
[4] The patient number was calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (NCD patients often take several drugs). The treatment adherence and treatment overlap factors are based on assumptions from developed markets.
[5] Data restated to reflect the patients reached as defined by the sustainability-linked bond, which includes private sector sales in LMICs
[6] Shift to virtual events
[7] Points of service provision include facilities and health camps where healthcare services are provided.
[8] In India, we adjusted our approach from hosting large health education meetings with community groups to a door-to-door model, and also partnered with schools to deliver health education to classrooms virtually. This led to an increase in the number of events, but with a restricted reach.

Novartis Healthy Family

The Novartis Healthy Family programs are innovative social business models that build local, sustainable healthcare capabilities for populations at the base of the income pyramid. They address social issues that impact access to healthcare, such as education, infrastructure and distribution. The programs are operational in India (*Arogya Parivar*), Kenya (*Familia Nawiri*), Uganda (*Familia Nawiri*) and Vietnam (*Kung Kong Khoe*). Each program is unique and adapted to the country's healthcare priorities and local customs. To be included in the respective portfolios, products must be simple to use and tailored to meet the needs of underserved rural populations with a low disposable income.

Since 2007, the combined outreach for all projects across the four countries has delivered health education to more than 66 million people. Beyond delivering education and healthcare, the programs also provide people with jobs, income, and skills enhancement – opportunities that may not otherwise exist in rural communities.

In 2020, despite challenges posed by the COVID-19 pandemic, we continued to make progress in all four countries, adjusting to the situation as needed.

For example, in India, we were able to maintain activities in 285 out of 300 project cells thanks to a change in approach. Instead of hosting health education meetings with community groups, we switched to a door-to-door model and partnered with schools to deliver health education to classrooms virtually. We also partnered with state governments in educating communities about COVID-19. Additionally, in Bihar state, we engaged communities in 2 400 villages, educating families about the national health insurance scheme known as Ayushman Bharat. As a result of providing this education, the number of individuals enrolled in health insurance nearly doubled.

In the first quarter of 2020, in Kenya and Uganda, we organized 204 health camps offering NCD screening, which were attended by more than 30 000 people. In total, we reached nearly 130 000 community members with

Patient assistance programs performance indicators

	Patients reached (thousands)		
	2020	2019	2018
Patient assistance programs			
Novartis Patient Assistance Foundation Inc. (US)	**102.7**	87.2	68.1
Novartis Oncology Access	**33.9**	60.7	71.1

health education in both countries. Due to restrictions on mass gatherings, in April we halted all community-based education and outreach activities. Similarly, in Vietnam, restrictions led to a 50% reduction in program coverage compared to 2019.

Overall, in 2020, Healthy Family programs brought direct health benefits to over 180 000 patients through diagnosis and treatment. Moving forward, we are working to expand our Healthy Family programs to reach more underserved communities in Asia and other regions.

Direct markets

In Asia, our plans to expand direct market activities into Laos, Nepal and Cambodia were impacted by COVID-19. In Cambodia, we are also adapting our strategy following an EU ruling classifying the country as one of 12 high-risk countries for money laundering. Moving forward, we plan to support the healthcare system through scientific knowledge exchange rather than the marketing of Novartis products. For example, working with medical scientific liaisons, we are disseminating guidance to physicians on the effective prevention and treatment of ophthalmologic and cardiovascular diseases. In Laos, we continued to distribute products from our ophthalmology portfolio. We were unable to expand into Nepal due to COVID-19 restrictions.

In addition, in Latin America, we conducted an assessment of public health needs in our first two direct markets: Paraguay and Bolivia. Breast cancer and cardio-metabolic diseases stood out as areas where there is significant need in both countries. Further, in Bolivia, where Chagas disease has the highest prevalence in Latin America, we are exploring a cross-divisional approach to treat Chagas-related cardiomyopathy and associated cardiovascular diseases.

LEAVING NO PATIENT BEHIND IN SUB-SAHARAN AFRICA

In 2019, we established a dedicated organization to reach more patients in sub-Saharan Africa (SSA), which is home to the largest underserved population in the world. The SSA unit is supporting a One Novartis approach to doing business in Africa and is deploying innovative approaches to increase patient reach, taking a high-volume, lower-price approach.

In line with our mandate, we have set ambitious targets to increase patient reach twofold by 2022 and fivefold by 2025. To achieve these targets, we will focus on three strategic pillars:

- A customized therapeutic area strategy tailored to the regional burden of disease
- A strategic shift from the private sector to the public sector to gain market share and drive maximization of patient reach potential
- Geographical prioritization to countries where we can deliver higher impact at lower cost

The COVID-19 pandemic put our SSA unit to the test, with most African countries going into lockdown in March. We quickly adapted to maintain access to our medicines during the crisis.

In September, we announced a collaboration with the African Union (AU) through the Africa Medical Supplies Platform (AMSP). The AMSP portal is an online marketplace that enables the supply of COVID-19-related critical medicines and medical equipment in Africa. Our collaboration focused on helping ensure more efficient and rapid access to medicines in the Novartis COVID-19 Pandemic Response Portfolio for the 55 AU member states and 15 eligible countries from the Caribbean Community (CARICOM).

In addition, Novartis provided USD 2 million to relief organizations such as the International Federation of Red Cross and Red Crescent Societies to mobilize community-based efforts to prevent the spread of COVID-19 in more than a dozen African countries. This included purchases of soap, sanitizer and bleach, and essential caregiver equipment like personal protective equipment. We also provided educational materials on how to support vulnerable and impacted patients. Further, the funds included assistance for the International Rescue Committee's pandemic response for refugee camps in Kenya, Uganda and Somalia, providing humanitarian and psychosocial support for displaced people.

Beyond the pandemic response, the SSA unit made significant progress in improving patient access. In June, we joined a collaboration with the American Cancer Society, the Clinton Health Access Initiative and other pharmaceutical companies to expand access to 20 lifesaving cancer therapies in 26 countries across SSA and Asia. It is estimated that there were approximately 811 000

Increasing patient reach in sub-Saharan Africa (SSA)

OUR STRATEGIC MANDATE

Our strategic pillars

CUSTOMIZED THERAPEUTIC AREA STRATEGY tailored to the regional burden of disease

A STRATEGIC SHIFT FROM THE PRIVATE TO THE PUBLIC SECTOR to gain market share and drive maximization of patient reach potential

GEOGRAPHICAL PRIORITIZATION TO COUNTRIES where we can deliver higher impact at lower cost

new cancer cases and 534 000 cancer deaths in SSA in 2018. Novartis is contributing with a portfolio of chemo- and hormonal therapies for breast, cervical and prostate cancers, with plans to add more therapies in the future.

We are also expanding access to our portfolio of inhaled medicines for chronic obstructive pulmonary disease (COPD), including *Ultibro Breezhaler*, *Onbrez* and *Seebri*. Our teams in East Africa are developing access and launch plans for *Ultibro Breezhaler* in four countries where the treatment has been approved. COPD has a high prevalence in East Africa, affecting 44 million individuals in the region due to widespread high-risk factors such as biomass fuel and smoking.

Africa also has a high prevalence of glaucoma and front-of-the-eye diseases. If left untreated, glaucoma can lead to blindness. We are therefore working to expand access to our mature ophthalmology medicines to 20 countries across Africa. This expansion is part of an ongoing effort to improve patient access to medicines that treat ocular diseases such as glaucoma, allergy, inflammation and infection.

PATIENT ASSISTANCE PROGRAMS

Assistance programs are critical for helping patients access healthcare when it is unaffordable. This includes uninsured or underinsured patients in high-income countries. Even when patients have insurance coverage for drug prescriptions, they may be unable to afford to pay for certain medicines.

To help support such patients, the Novartis Patient Assistance Foundation Inc. (NPAF) provides medicines at no cost for individuals who are experiencing financial hardship and have limited or no prescription drug coverage in the US. In 2020, NPAF served more than 107 000 patients, making available more than 72 medicines from our portfolio. Over the past five years, NPAF has provided medicines at no charge to more than 363 500 patients.

In 2020, NPAF began providing access to new Novartis medicines launched the same year, including *Tabrecta* for metastatic non-small cell lung cancer, *Kesimpta* for multiple sclerosis, inclisiran for managing cholesterol, and *Ziextenzo* for use in patients who are receiving chemotherapy and are at risk of infection.

At the start of 2020, NPAF focused on improving the patient experience. For example, NPAF reduced the time it took to process enrollment applications, providing patients more timely access to medicines. NPAF then had to adapt to the impact of COVID-19 on employment, travel restrictions and medication access. Due to quarantine and travel restrictions, patients faced challenges in submitting documentation for NPAF eligibility. Additionally, healthcare professionals (HCPs), who collect patient NPAF enrollment documents, had restricted access to patients. Many patients lost their jobs as well as insurance coverage for drug prescriptions, and many expressed concerns about their ability to continue accessing Novartis medicines.

In response, NPAF took measures to reduce the additional burden on patients and HCPs, working to ensure continuity of treatment. We quickly modified our processes for gathering and reviewing documentation in order to account for circumstances created by COVID-19. We expanded timeframes for refills, shipped patients a greater supply of medicines, and provided additional flexibility in the renewal process.

We also expanded NPAF's Institutional Patient Assistance Program (IPAP) to include ophthalmology and cardiovascular products. Moreover, we widened the IPAP network of collaborating safety net clinics, which provide healthcare services to indigent populations. IPAP clinics receive Novartis medications directly, enroll patients in the program, and assist them with administrative processing. This support allows patients to walk in and receive medicines almost immediately, filling a critical gap in the healthcare system. We worked to ensure these clinics maintained continuity of care during the pandemic.

In LMICs, Novartis Oncology Access (NOA) makes medicines in its portfolio available through equitable pricing models. NOA pursues a partnership-based approach, sharing the cost of its medicines with government healthcare systems, charities and other payers, or directly with patients without healthcare coverage who are unable to pay for the full cost of their medication. In 2020, more than 33 000 patients in seven countries benefited from the Novartis Oncology portfolio in multiple disease areas.

MANAGED ACCESS PROGRAMS

Physicians sometimes seek access to medical products that are not yet approved or available in their country to treat patients with serious or life-threatening conditions. Novartis Managed Access Programs (MAPs) address this need by making certain investigational or unapproved treatments available to eligible patients. Novartis has been widely acknowledged as a leading company when it comes to providing patients with access to medicines though MAPs.

Since 2017, Novartis has collaborated with an external Independent Bioethics Advisory Committee (IBAC), which provides analysis and recommendations on our guidelines and policies for the ethical conduct of clinical research, and on selected ethical challenges that may arise in clinical trials, development programs, managed access programs and other areas across Novartis. The IBAC includes bioethicists, clinicians, healthcare practitioners, patient advocates and other domain knowledge experts as required. We are one of a few companies that consults with an independent bioethics committee.

Novartis monitors patient support via MAPs through the Novartis Managed Access Center of Excellence. In 2020, we received and reviewed 10 670 MAP requests from physicians and we approved 94% of those requests from 82 countries and across 64 compounds. An additional estimate of 4 500 patients were supported via requests from healthcare institutions and governments. More than 14 000 patients are currently on treatment via MAPs.

COVID-19 was the leading indication for which Novartis received managed access requests in 2020, followed by metastatic breast cancer. Novartis provided medicines for treating COVID-19-related conditions to more than 7 000 patients, responding to unsolicited requests from physicians, healthcare institutions and governments. The initial demand came from Italy, with approximately 900 requests for medicines received within the first few weeks of the outbreak in that country. In response to the demand and urgency

of the situation, we instituted an expedited review process that shortened MAP approval times from five working days to three or four hours, with medicines shipped within 24 hours. Novartis approved nearly 100% of requests for medicines to treat COVID-19 patients.

In 2019, the US Food and Drug Administration approved *Piqray* (alpelisib), a targeted treatment for advanced breast cancer. As part of our access strategy, through a global MAP we made the medicine available to patients with no alternative or comparable treatment options in countries where the product was yet to be approved or unavailable. In 2020, we received over 1 550 requests from 40 countries, and we approved 89%. To date, we have provided the medicine to more than 2 040 patients through managed access.

Despite supply constraints, in 2020 we fulfilled our commitment to make *Zolgensma* (onasemnogene abeparvovec), our one-time gene therapy approved to treat pediatric patients with spinal muscular atrophy, available to up to 100 patients via a global MAP. In 2020, 100 patients received *Zolgensma* in more than 20 countries where the therapy is not yet approved by regulatory authorities.

Further, through a MAP we continued to make *Lamprene* (clofazimine) available to more than 1 900 patients in 2020, mainly for nontuberculous mycobacterial infection.

DONATIONS

Through our medicine donation program, Novartis supports LMICs in their efforts to treat patients for neglected diseases or life-threatening conditions, and to provide medicines in areas impacted by the COVID-19 pandemic, natural disasters and extreme poverty.

In March, Novartis announced a USD 20 million COVID-19 Response Fund to support communities around the world impacted by the pandemic. In total, 172 local projects across 81 countries have received funding.

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 68 million blister packs of multidrug therapy (MDT) valued at approximately USD 108 million through the WHO, helping to treat more than 7.3 million leprosy patients worldwide. In 2020, we renewed our pledge with the WHO to extend our MDT donation to 2025.

Novartis has also been donating *Egaten* to the WHO for the treatment of fascioliasis, or liver fluke, since 2005, helping to treat approximately 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.

Our generics division, Sandoz, continued its collaboration with World Child Cancer, a global charity that aims to improve diagnosis and access to treatment for children with cancer in LMICs. Since our partnership began in 2016, 6 185 children have been diagnosed in Ghana, Mexico, Myanmar and the Philippines, and 7 116 healthcare profes-

20 m

COVID-19 Response Fund to support communities around the world impacted by the pandemic (USD)

Donations performance indicators

	Patients reached (thousands)		
	2020	2019	2018
Donations			
Leprosy (WHO) [1]	**245.4**	168.6	176.2
Fascioliasis/*Egaten* [2]	**132.8**	154.7	154.7
CMLPath to Care™	**30.2**	14.4	13.4

	Value USD (millions) [4]		
	2020	2019	2018
World Child Cancer	**<0.01**	<0.1	0.1
Emergency relief [3]	**2.5**	2.8	4.7

[1] In 2020, the leprosy program fully transitioned to the Global Health organization as one of the flagship programs and is also included in data reported in the Novartis Global Health table above.
[2] Numbers of patients reached have been updated to reflect the new methodology used by the WHO and based on real-world evidence.
[3] Monetary and product donations
[4] Wholesale acquisition cost (WAC) plus logistics costs for some programs

sionals have received training. In 2020, our efforts focused on the Philippines, where we helped 137 children receive a diagnosis. In addition, 2 795 healthcare professionals were trained in cancer treatment and care for children. By 2025, the charity aims to reach 16 000 children a year.

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. In 2020, Sandoz donated products worth approximately USD 35 million to the organization.

As the COVID-19 pandemic struck, we took rapid action to help ensure our donations reached patients in need. When hydroxychloroquine was considered as a potential treatment for COVID-19, Sandoz committed to donate 130 million doses of the medicine to public and private partners worldwide, based on government requests. To support the COVID-19 effort, Sandoz also partnered with Direct Relief to donate packages of critical medications and supplies to intensive care units throughout the US.

CMLPath to Care™ is a unique global initiative that connects people living with chronic myeloid leukemia (CML) with effective treatments made available at no cost, professional medical capabilities, trained physicians and hands-on support. The initiative is implemented in countries most urgently in need of medicines, as identified by the Access to Medicine Index. The Max Foundation directs the initiative, while Novartis donates medicines and provides financial resources.

CMLPath to Care™ evolved out of the *Glivec* International Assistance Program (GIPAP), also a collaboration between Novartis and the Max Foundation, that began in 2002. The transition of GIPAP to CMLPath to Care™ began in 2017 and encompassed 63 countries; the program is now expanding to an additional 17 lower-income countries. In 2020, we reached almost 32 000 patients through CMLPath to Care™. Novartis has committed to providing USD 29 million in financial assistance through 2021 and supplying 150 million *Glivec* and *Tasigna* tablets. Since the beginning of our partnership with the Max Foundation in 2002, we have donated more than 100 million daily doses of CML treatments.

This collaboration has helped significantly raise the CML survival rate in LMICs. Published in The Lancet's EClinicalMedicine journal in January 2020, a study by Boston University researchers showed that despite the challenges of delivering cancer care in LMICs, 89% of patients supported by GIPAP survived for at least five years – a rate comparable to patients in developed countries.

Strengthening health systems

The COVID-19 pandemic has demonstrated that fragile healthcare systems limit healthcare interventions and subsequently our ability to respond to public health challenges. This is why we need to continue to do more to strengthen healthcare systems across the globe.

To this end, we collaborate with governments and other partners to lower barriers to healthcare delivery, and we support quality patient care in areas where we can have the greatest impact. We work to empower patients to take ownership of their health and to better understand and manage disease. We also invest in the training and support of healthcare workers to expand their knowledge and improve their ability to help patients.

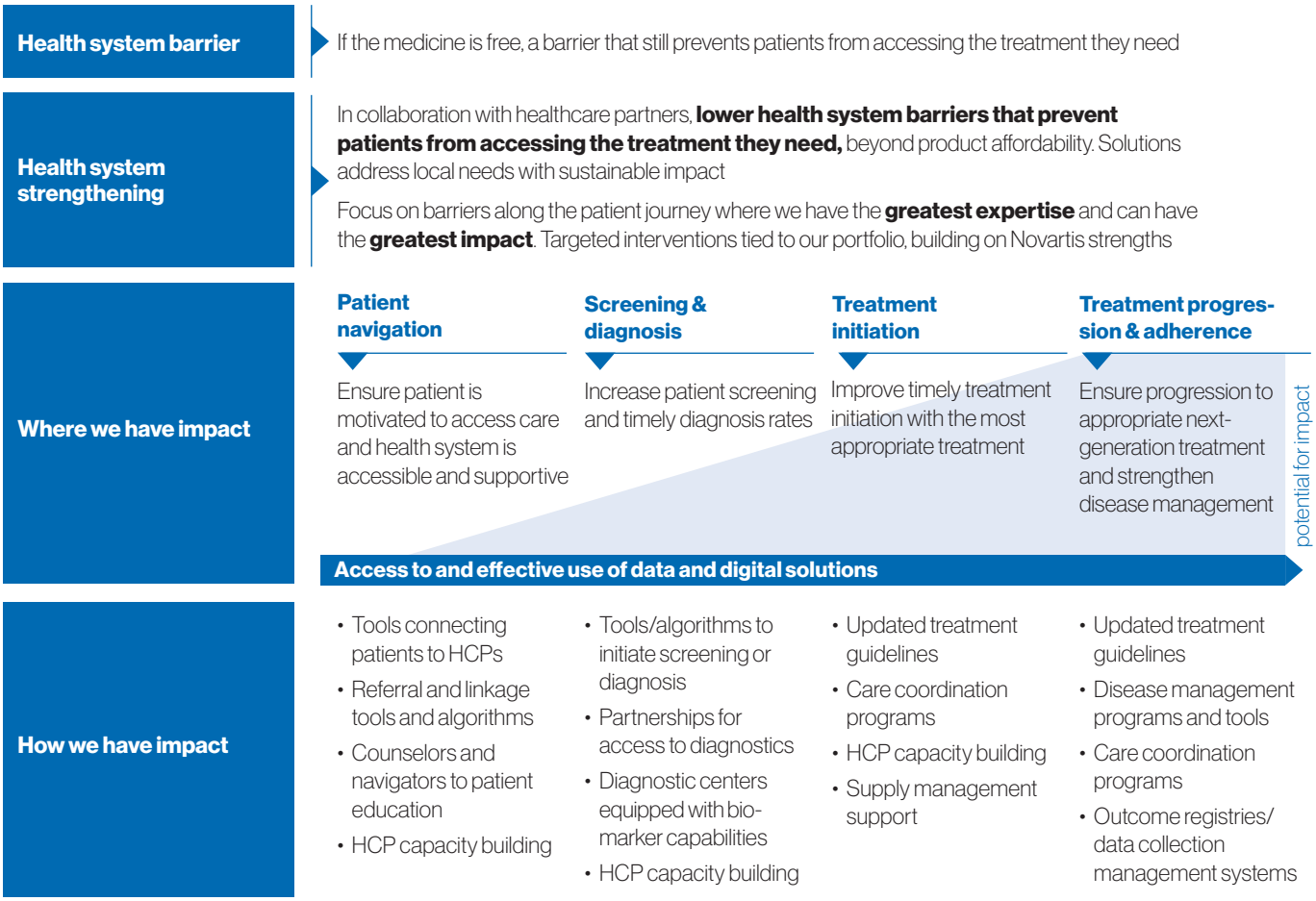
Humanitarian aid in Bangladesh

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 (Achieving Sustainability Towards 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 has a positive health impact in communities and helps lift individuals out of poverty by providing a steady income.

Since 2015, 464 young adults, including 244 women, have completed the two-year training, and 78% work as community paramedics. More than 135 000 people in rural communities have received healthcare services from project-supported community paramedics.

Additionally, since 2018, Novartis has assisted the Swiss Red Cross in building four primary healthcare centers in the world's largest refugee camp, located in Cox's Bazar in Bangladesh. Here, approximately 1 million refugees reside, and around 30 000 babies are born every year. In the Kutupalong expansion site, the largest cluster of camps, the population density is 40 000 persons per square kilometer, making it one of the world's most densely populated areas. There is only minimal infrastructure and very little clean drinking water. To date, four primary healthcare centers providing basic medical care to more than 100 000 camp residents have been built. A fifth center is currently under construction.

One Novartis health system strengthening framework



For example, in collaboration with the government of Vietnam, Harvard Medical School Center for Primary Care, and the World Economic Forum, we began implementing a new initiative that aims to strengthen the delivery of primary care at the community level by strengthening community-based healthcare services at 26 blueprint commune health centers. We initiated activities in the first two provinces (Hà Tĩnh and Khánh Hòa) during 2020, conducting education and outreach to encourage patients to seek care for treatable conditions at community-based primary care centers to alleviate pressure on district and central level hospitals. These activities led to 6 000 people receiving screening and health education in primary care centers.

In India, Novartis began its journey to help strengthen health systems for breast cancer care in 2018 with a national assessment that showed there was little knowledge of breast cancer detection and diagnosis, and limited access to early screening. Further, capabilities to screen and diagnose breast cancer were centralized at national and state teaching facilities and centers of excellence. Together with Jhpiego, a nonprofit health organization affiliated with Johns Hopkins University in the US, and the government of India, Novartis launched the PRARAMBH program to increase access to breast cancer care. Through capacity-building activities, the program is designed to enable early detection in primary care facilities and strengthen disease management at the secondary care level.

During the COVID-19 pandemic, the partners led India's first virtual stakeholder consultation on breast cancer with physicians, patient groups, patients, policymakers and researchers. We also virtually trained more than 60 healthcare professionals on delivering breast cancer care. Further, we developed screening algorithms for community-based healthcare providers, and mapped referral pathways to help women in rural and hard-to-reach areas access breast cancer diagnosis and treatment.

By 2021, PRARAMBH aims to reach 25 000 women between the ages of 30 and 65 with early breast cancer screening and diagnosis. The initiative is also working to expand access to treatment, and increase the number of facilities that can cover the full breast cancer continuum of care.

"For nearly two decades, we have been working with partners to improve access to our most innovative cancer therapies. We are committed to helping ensure that our medicines are accessible to as many patients as possible, and that everyone living with cancer gets the treatment they require"

Susanne Schaffert,
President of Novartis Oncology

385 000

Healthcare workers in LMICs received training on prevention, diagnosis and management of COVID-19

The Novartis US Foundation strives to improve health in underserved communities in the US by creating innovative and sustainable solutions to expand access to healthcare and build trust within the healthcare system. In September, the foundation announced an additional commitment of USD 15 million to develop partnerships and fund community organizations and programs that address health inequities, building on the more than USD 10 million committed to date. A key area of focus will be addressing the under-representation of minorities, including Black Americans, in clinical trials. Diversity in clinical trials is critical to understanding how medicines will work in all patient populations impacted by a disease.

THE NOVARTIS GLOBAL HEALTH ALLIANCE

The Novartis Global Health Alliance (GHA) helps support Novartis country organizations with targeted health system strengthening programs. In July, with GHA funding, the SSA unit successfully implemented the MedShr Heart Failure pilot project. This platform connects healthcare professionals via a smartphone app to share knowledge and experience on CV diagnosis, treatment and care, and also provides access to case studies on heart failure. In 2020, MedShr's heart failure education program reached more than 95 000 doctors and community health workers across the region. Approximately 85% of participating clinicians are general practitioners and community health workers, with cardiologists and internists comprising the rest.

Additionally, GHA helped expand the remit of MedShr's COVID-19 education program, delivering training to over 385 000 healthcare workers on the prevention, diagnosis and management of the disease in LMICs.

Over the past years, Novartis has supported an extensive capacity-building program to train doctors in Kenya on CV care. In 2020, with support from GHA, 30 handheld Butterfly iQ™ ultrasound devices used to diagnose CV diseases were provided to the University of Nairobi Enterprises and Services, and to The Heart Center, significantly enhancing their training and community outreach capabilities. Since February 2018, 115 doctors have completed the center's cardiac diagnosis and echocardiogram short-course training. More than half of them were fully sponsored by Novartis Kenya.

GHA continued its support to strengthen access to evidence-based clinical research tools in SSA, working with the Better Evidence program at Ariadne Labs – a joint health system innovation center of Brigham and Women's Hospital and the Harvard T.H. Chan School of Public Health in the US. The digital portal provides more than 20 000 healthcare professionals across 124 countries, including 36 in SSA, with online and offline access to regularly updated, peer-reviewed, evidence-based information for guiding the diagnosis and management of a wide range of diseases, including COVID-19. The program in SSA has partnered with 50 training facilities across 16 medical schools, filling a critical gap for clinicians in low-income settings who otherwise would face major challenges in accessing information needed to provide quality care.

INVESTING IN SCIENTIFIC EXCHANGE

Novartis trains and supports researchers, scientists and healthcare workers to help expand their knowledge and improve their ability to help patients. We offer mentorship opportunities for multidisciplinary partners to share expertise and build collaborations that advance the research and development of new therapies for major global health problems in ways that benefit both local research institutions and Novartis. More than 265 scientists and clinicians from 37 countries have participated in these programs over the past decade. These partnerships have also helped establish a global network of future leaders across academia, industry and government in LMICs.

In 2020, we brought our core scientific exchange programs under a common framework called Global Health Scholars. Going forward, this will help ensure we harness synergies and lessons learned across initiatives to maximize impact.

Many of these activities were affected by COVID-19 and related travel restrictions. However, we still made progress. We conducted our first virtual internship with six international students from Kenya,

Malawi, Mexico and India in the vaccinology and drug development master's program at the University of Siena in Italy. For five weeks, the interns trained in clinical trial management and patient safety, and received insights into key functions that support drug development.

Novartis continued to co-fund a European & Developing Countries Clinical Trials Partnership (EDCTP) career development fellowship call with at least five fellowship opportunities (to a maximum value of EUR 750 000) for proposals in the areas of maternal and child health, focusing on the interaction between poverty-related infectious diseases and NCDs. The scope of the fellowships was extended to include sickle cell disease in 2020.

Through EDCTP, Novartis also hosted two research fellows from Mali and Nigeria in 2020. These mentorship opportunities help strengthen the competencies of scientists who could later assume leading roles in clinical research at their host institutions. Further, the Novartis Institutes for BioMedical Research (NIBR) hosted a research fellow from Colombia through the WHO-TDR Clinical Research and Development Fellowship program to develop early-phase clinical trial management skills.

TRAINING COMMUNITY HEALTH WORKERS

Recognizing the important role of community health workers in building stronger healthcare systems in LMICs, Novartis continued its commitment as a founding partner of Last Mile Health's Community Health Academy through our USD 1 million contribution over three years. The academy provides university-quality courses delivered virtually and in person through coaching, mentorship and discussion. To date, more than 31 000 health workers from over 200 countries have accessed this content for health system leaders. The program helps community health workers deliver quality care within government-led primary healthcare systems.

The Community Health Academy has also helped ensure that community health workers are equipped to support the response to COVID-19. Alongside a consortium of partners, the academy launched the COVID-19 Digital Classroom, which provides medically reviewed training and education material for frontline health workers and communities. To date, more than 1 000 health workers across 79 countries have accessed these materials.

TACKLING CARDIOVASCULAR HEALTH IN LOW-INCOME SETTINGS

Cardiovascular diseases are the leading cause of death worldwide, with most of the disease burden concentrated in LMICs. By 2050, 70% of people will live in cities, increasing their exposure to unhealthy lifestyles and health risk factors. For instance, against this backdrop of rapid urbanization, health officials in LMICs are reporting new cases of heart disease at alarming rates. The Novartis Foundation is forging multisector partnerships to leverage data, digital and artificial intelligence (AI) solutions to strengthen population health in LMICs.

Partnering with local and national government agencies and an array of civil society organizations, in 2017 the Novartis Foundation launched Better Hearts Better Cities in three cities in LMICs: São Paulo, Brazil; Dakar, Senegal; and Ulaanbaatar, Mongolia. While activities were tailored to the unique conditions of each city, we applied a common strategy called CARDIO, based on six pillars: improve quality of care; ensure access; reform policies; leverage digital technology; create an intersectoral coalition; and ensure local ownership.

With this approach, the Novartis Foundation was able to achieve significant improvements in cardiovascular health outcomes. In São Paulo, preliminary data showed that the percentage of patients diagnosed with high blood pressure who had it controlled increased from 17% to 55.9% in just 18 months. Preliminary data from Dakar showed an eightfold increase in blood pressure control from 3.4% to 27% in two years, while in Ulaanbaatar, 90% of the target population with high blood pressure is now being treated.

LEVERAGING DIGITAL HEALTH SOLUTIONS

Embracing digital health technologies, advanced analytics and AI is a top priority for Novartis. These solutions have the power to radically change the way healthcare is delivered, especially in LMICs. Novartis is engaged in key partnerships to strengthen health systems and bring digital health solutions to patients.

To enable sustainable health system strengthening, Novartis co-founded the STELLA CoE (Strengthening of Translational Ecosystems for Lifesaving Local Access Center of Excellence) with the University of Basel Innovation Office and the Swiss Tropical and Public Health Institute. Launched in November, the STELLA CoE is a collaborative ecosystem that aims to address health system challenges in LMICs by bringing together the right partners to apply innovative digital solutions while supporting local entrepreneurship and ownership.

Several projects have already been initiated under the STELLA CoE umbrella, notably a collaboration with the Department of Informatics at the University of Oslo in Norway. The university developed the District Health Information Software 2 (DHIS2), the world's largest open source, web-based health management information system deployed in LMICs.

The STELLA CoE is also addressing supply chain inefficiencies, a major cause of drug stockouts. Through the SMS for Life program, Novartis pioneered a logistics management information system to tackle stockouts at the last mile. Novartis will transfer knowledge, experience and lessons learned from SMS for Life to DHIS2 to enable a robust, scalable and sustainable logistics solution for LMICs.

Through a partnership between Novartis, Medtronic Labs and Management Sciences for Health in Kenya, we are investing in digital technologies to create value for patients, providers and the healthcare system. We are supporting an integrated end-to-end solution for hypertension and diabetes care that links patients to community health workers, pharmacists and clinicians.

The core of the program is a dedicated screening app linked to an online platform. Once people have been screened and registered on the platform, they are able to access blood pressure checks at community-based locations. Clinicians can view patient data, provide

Photo Dr. Juliet Akoth (left) shows a Butterfly iQ™ portable ultrasound device to the mother of a patient in Kitui, Kenya. Dr. Akoth enrolled in Echo for Life, a program sponsored by Novartis in partnership with the University of Nairobi to train healthcare professionals in the diagnosis and treatment of cardiovascular disease. Although heart disease is a growing problem in Kenya, many people remain undiagnosed due to a lack of healthcare infrastructure and not enough doctors with relevant expertise.

feedback via text message, and write electronic prescriptions that are accessible through participating pharmacies. The program also provides training on NCD treatment guidelines to community health workers and facility health providers so that they can provide quality care. Since launch in 2019, the program has reached more than 200 000 community members with education on diabetes and hypertension, and has screened more than 20 000 people (with 6 500 screenings completed prior to launching the digital app).

AI has tremendous potential to make health systems proactive, predictive and preventive. To help drive the adoption of AI for health within countries, the Novartis Foundation and Microsoft – co-chairs of the Broadband Commission Working Group on Digital and AI in Health – led the development of a major new report in 2020 called "Reimagining Global Health through Artificial Intelligence: The Roadmap to AI Maturity." Based on a landscape review of more than 300 use cases of AI in health, the report presents a roadmap to help governments and their partners implement AI to transform their health systems.

The Novartis Foundation is also working with partners in countries to implement AI solutions. In Brazil, the Novartis Foundation together with Instituto Tellus supported the Hospital das Clinicas of the University of São Paulo AI nucleus to establish an AI-driven tool for detecting COVID-19 using CT scans and chest X-rays. The hospital adopted the solution and has used it to speed up COVID-19 diagnosis. Together with the hospital and Instituto Tellus, the Novartis Foundation also built an innovation platform that empowers local partners to apply data science and AI in other disease areas beyond COVID-19. Additionally, the Novartis Foundation and Instituto Tellus supported the São Paulo state government in developing a public policy roadmap to procure new technologies, and helped launch IdeiaGov, an initiative that sources innovative ideas to respond to government challenges such as COVID-19.

In 2020, together with Microsoft AI for Health and Apollo Hospitals (one of India's largest private healthcare providers), the Novartis Foundation initiated AI4BetterHearts, the first global data collaborative on cardiovascular population health. The collaboration aims to integrate heart patient data from the primary, secondary and tertiary healthcare levels, as well as from global partners, and use advanced analytics to change the way cardiovascular population health is managed, predicted and prevented. This knowledge can help empower policymakers, health system managers, health workers and patients to make more informed decisions. For example, it can help policymakers understand where they can best allocate resources for addressing cardiovascular disease at the population level.

Using a mobile clinic to provide healthcare services in Uganda

Through its Healthcare Access Challenge (HACk), Sandoz invites 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. Andrew Ddembe, founder and CEO of mobiklinik, a mobile clinic using an app and a mobile van to provide door-to-door maternal healthcare services in Uganda, was among the three 2019 winners.

In 2020, Mr. Ddembe continued his journey to provide access to basic health services to 42 million Ugandans living in last-mile villages (rural areas and peri-urban areas). His mobile application, which connects city doctors to community health partners providing health services to patients in rural areas, is now available in one of the largest districts of Uganda. The service is helping to expand the reach of medical services, improve medical information, scale knowledge transfer, and integrate patient referrals into the healthcare system. So far, mobiklinic has supported 80 expectant mothers, 350 patients with general healthcare needs, and more than 1 000 people who attended free medical camps.


KENYA COLLEGE OF COMMUNICATIONS TECHNOLOGY
(KOREMO CAMPUS)

Photo Dr. Fernanda Sardinha with a patient at a Chagas disease cardiac rehabilitation center in Rio de Janeiro, Brazil.

STRATEGIC AREAS

Addressing global health challenges

Why is it important?

Lower-income countries – fraught with a double burden of infectious and chronic diseases – now also face COVID-19 and are redeploying already stretched resources to fight the pandemic. Disruption to healthcare systems could reverse decades of hard-fought progress, in particular against neglected diseases. We must take action to control the spread of COVID-19 while maintaining a focus on other global health priorities that take a heavy toll on vulnerable populations.

In this section

Read about the progress we have made on addressing global health challenges and our flagship programs:

COVID-19

Announced a collaboration with Molecular Partners AG to develop, manufacture and commercialize two potential antiviral treatments

→ p. 48

Sickle cell disease

Expanded the Novartis Africa Sickle Cell Disease program to Kenya, Tanzania and Uganda

→ p. 48

Chagas disease

Initiated recruitment for PARACHUTE-HF, our Phase IV clinical trial in people with heart failure due to chronic Chagas cardiomyopathy

→ p. 49

Malaria

Discovered another novel malaria therapy with an entirely new mechanism of action, expected to begin clinical trials in 2021

→ p. 50

Our targets

- **Achieve a 50% increase in patients** reached through global health flagship programs in sickle cell disease, Chagas disease, malaria and leprosy by 2025
- **Advance our clinical development program** for our next-generation antimalarials KAE609 (cipargamin) and KAF156 (ganaplacide)
- **Expand our Africa sickle cell disease program** to 10 countries by 2022
- **Advance our clinical development program** for our heart failure medicine in patients with Chagas-related heart failure

67m

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

Our approach and performance

At Novartis, we apply our expertise, people and full organizational capability to address major, unresolved global health challenges with the aim of transforming health in lower-income populations.

We continue to align our global health work with the Novartis access principles, leveraging research and development (R&D) to address unmet needs, expanding affordable access through novel pricing and business models, and working with partners to strengthen health systems. We aim to adopt an integrated end-to-end approach to disease management for the elimination or control of four diseases where there has been market failure and little investment in R&D: sickle cell disease (SCD), Chagas disease, malaria and leprosy. In sub-Saharan Africa, we are implementing a targeted strategy focused on reaching more patients and expanding the availability of our full portfolio of medicines.

In 2020, Novartis quickly mobilized R&D capabilities, medicines, clinical trial expertise and philanthropic aid to help address the COVID-19 pandemic. Travel restrictions and lockdowns due to the pandemic caused unavoidable delays in our global health flagship programs. Despite these obstacles, we continued to make measurable progress, expanding our work on SCD and Chagas disease, and supporting global efforts to end malaria and leprosy.

We continue to maintain a strong commitment to research for various infectious and neglected diseases through the Novartis Institute for Tropical Diseases (NITD). In 2020, Novartis invested approximately USD 67 million in R&D to discover new and better treatments, including through NITD. These efforts have produced three potential new medicines currently in clinical testing – two for malaria and one for visceral leishmaniasis.

Joining forces to expand global access to COVID-19 solutions

COVID-19 threatens communities everywhere, and it can only be addressed through the collective actions of stakeholders across private, public and philanthropic sectors in partnership with civil society. With this in mind, in September, Novartis was one of 16 life sciences companies, together with the Bill & Melinda Gates Foundation, to commit to accelerating the discovery of COVID-19 diagnostics, therapeutics and vaccines. As a co-chair of the Gates Foundation CEO Roundtable, our CEO helped drive this commitment, which represents the most expansive and ambitious pandemic R&D response effort in history.

This is an unprecedented collaboration to tackle the biggest global health challenge of our lifetime, and this commitment is critical to helping ensure that people – no matter where they live or what they can pay – have access to the diagnostics, therapeutics and vaccines

"We take a holistic approach to addressing global health challenges. We work with partners and communities to help strengthen healthcare systems and create new opportunities for medical innovation to benefit lower-income populations"

Lutz Hegemann,
Chief Operating Officer, Global Health

that will help end this pandemic. To help ensure equitable global access to these innovations, we committed to conduct clinical trials in diverse settings and populations, and to rapidly scale up global manufacturing capacity. We aim to pursue a range of approaches to make the products we are developing or supporting affordable in lower-income countries, including through donations, not-for-profit supply, and tiered-pricing agreements based on country needs and capabilities.

In October, Novartis announced a collaboration with Molecular Partners AG to develop, manufacture and commercialize two potential antiviral treatments for COVID-19 based on a new class of protein therapeutics known as DARPin®.

Novartis is also collaborating in open science efforts to identify immediate solutions for patients and to anticipate pandemics of the future. For example, we're working with researchers from other pharmaceutical companies and the University of California, Berkeley, to target a protein that is essential for coronavirus survival. The goal is to find a molecule that blocks all coronaviruses, including the virus that causes COVID-19.

For more details on our COVID-19 response, see page 5 of this report, and visit our website.

10

The number of countries we plan to reach by 2022 through our Africa sickle cell disease program

Expanding the Novartis Africa Sickle Cell Disease program

SCD is a neglected health problem in sub-Saharan Africa, which carries 80% of the global disease burden. Approximately 1 000 children in Africa are born with SCD every day. More than half die before they reach age 5.

In 2020, we expanded our Africa SCD program with three new memoranda of understanding with the ministries of health of Uganda, Tanzania and Kenya. The program, first launched in Ghana in November 2019, aims to improve and extend the lives of people with SCD in sub-Saharan Africa. We plan to reach a total of 10 countries by 2022.

This expansion represents another ma jor step forward in putting the Novartis access principles into action to treat SCD at scale. Within the scope of the program, Novartis and its partners are collaborating to develop a comprehensive approach that makes screening, diagnosis and treatment available, accessible and affordable for patients, and that promotes scientific research, training and education. We have registered hydroxyurea, the global standard of care for the treatment of SCD, in Uganda, Tanzania and Kenya. Treatment guidelines are in place, and we are currently working with the ministries of health to conduct trainings for healthcare professionals, identify and set up centers of excellence, and further scope out the details of the respective partnership agreements. In October, we officially launched our partnership with the Ministry of Health in Uganda.

In Ghana, the program has been progressing well since launch. More than 3 400 patients have been treated with hydroxyurea in 11 treatment centers across the country. In total, Novartis has delivered more than 6 million capsules of hydroxyurea, providing SCD patients in Ghana with uninterrupted access to treatment during the global COVID-19 pandemic.

Together with our implementation partner, the Sickle Cell Foundation of Ghana (SCFG), we are working to increase awareness of the disease, encourage newborn screening, and address the stigma associated with the disease. In addition, we are employing digital technologies to help optimize diagnosis and disease management. In the past two years, we supported the SCFG in developing and rolling out a newborn screening mobile application, which has helped manage data from more than 17 000 babies in Ghana. Within the scope of our current memorandum of understanding, and taking into account the learnings from the screening app, we contributed to the development of a clinical management app to help ensure hydroxyurea is administered safely and that patients receive the maximum benefit from the treatment. In 2020, the app was rolled out to 11 treatment centers, with more than 2 200 patients already registered.

In June, Novartis signed a memorandum of understanding with the University of Ghana to collaborate on promoting education, research, advocacy and capacity building, with the goal of advancing Ghana's national health agenda to improve the health and well-being of people with SCD. This includes monitoring and evaluation activities to assess the impact of the Africa SCD program.

Moving forward, the priority will be to initiate field testing of treatment guidelines across more than 20 healthcare institutions in Ghana. We expect to start field testing in the first half of 2021. Together with the Ministry of Health and the SCFG, we are also working to identify and establish 12 centers of excellence for SCD in the country in early 2021.

We continued our efforts to develop a child-friendly formulation of hydroxyurea, which was submitted for registration in Ghana in October. Submissions in Uganda, Tanzania and Kenya are planned for 2021.

Due to COVID-19, the two clinical trials planned to start in 2020 in Ghana and Kenya for crizanlizumab, a novel targeted biologic therapy that reduces pain events in people with SCD, have been delayed. We have received health authority and ethics committee approval in both Ghana and Kenya for the STAND trial, a Phase III trial to assess the efficacy and safety of crizanlizumab in adolescents and adults with SCD, and site initiation visits have started in Ghana. These trials represent the first time that a non-vaccine biologic therapy will enter multicenter clinical trials in sub-Saharan Africa (excluding South Africa).

In February, Novartis joined the World Bank, the World Health Organization (WHO) and the US Department of Health and Human Services as a founding member of the Global Coalition on Sickle Cell Disease. The coalition aims to develop, organize and implement a global multisectoral initiative to combat SCD in Africa, with an initial focus on countries that have the ability to provide the basic primary care required to treat people with SCD.

In addition to our work to help improve the standard of care for people with SCD, we are committed to expanding the reach of cutting-edge innovations to patients everywhere who need them, including in SSA. We are starting a collaboration with the Bill & Melinda Gates Foundation to explore the discovery of in vivo gene therapies for SCD, whereby cells are modified inside the body, which has the potential to facilitate access to these advanced therapies in lower-resource settings.

Reimagining the fight against Chagas disease

Chagas disease affects approximately 6 million people, mainly in Latin America. Less than 1% of affected individuals receive proper antiparasitic treatment, and current drugs are inadequate to fight the entire spectrum of the disease. Against this background, Novartis is pursuing an end-to-end approach, with activity on three fronts: drug discovery, clinical research and health system strengthening.

In April, we joined the global community in marking the first World Chagas Day to raise awareness of this neglected disease and the resources needed for its prevention, control and elimination as a global health challenge. Further, we supported the World Heart Federation and the Inter-American Society of Cardiology in developing an end-to-end roadmap for Chagas disease. It outlines a vision for an ideal pathway of care, providing actionable recommendations for policymakers and healthcare professionals. Once health authorities can expand their focus beyond the immediate needs of the COVID-19 pandemic, we plan several roundtables with local stakeholders, using the roadmap as a tool to help overcome local barriers to comprehensive care for people with Chagas disease.

We took significant steps to advance the development of new treatments for Chagas disease. In early 2020, we launched a three-year drug discovery program for Chagas disease and cryptosporidiosis with support from the Wellcome Trust to pursue potential first-in-class treatments.

PARACHUTE-HF, our Phase IV clinical trial to assess the efficacy and safety of *Entresto* in people with heart failure due to chronic Chagas cardiomyopathy, was approved by the health authorities and started recruitment in Argentina, Brazil, Colombia and Mexico. Chagas cardiomyopathy accounts for the majority of deaths and disability among individuals affected by the disease. The study resumed recruitment after initial delays due to the COVID-19 pandemic and has managed to enroll 6 % of the total number of patients in 2020. Our goal is to recruit approximately 900 patients with heart failure with reduced ejection fraction and confirmed Chagas disease.

We also included sub-studies in PARACHUTE-HF to better understand the underlying pathophysiology of Chagas cardiomyopathy, coordinating activities across Global Drug Development, NITD, and our country organizations in Latin America together with our academic partner, the Brazilian Clinical Research Institute. This additional assessment will collect biological samples for biomarkers, estimate the arrhythmia burden, and use magnetic resonance imaging to evaluate cardiac structure, function and fibrosis. We are confident that these findings will help advance the global community's knowledge of Chagas disease and create new opportunities for partnerships to treat and control it.

Additionally, NITD and its academic partners have been conducting research into novel growth inhibitors for the treatment of Chagas disease and other kinetoplastid diseases. These efforts have identified a unique drug target for trypanosomatid parasitic protozoa and a new chemical tool for investigating the function of cell division. The parasites that cause Chagas disease, leishmaniasis and African sleeping sickness share a common cell cycle protein, which may be a promising new target for treatment. The study was published in Nature Microbiology in October.

We continue to work with local and international stakeholders to strengthen health systems. For example, we are collaborating with the Global Chagas Disease Coalition to develop an online medical platform for Chagas disease, which aims to build capability among healthcare professionals to adopt an integrated disease management approach. In Bolivia, we signed an agreement with the Barcelona Institute for Global Health (IS Global) to enhance awareness of Chagas disease and improve the well-being of Chagas disease patients. In Argentina, we continued to work with the Institute for Clinical Effectiveness and Health Policy to generate local evidence for healthcare system improvements at the first level of care. In Brazil and Mexico, we are exploring partnerships on community-based disease awareness and education activities to strengthen diagnosis and treatment.

Advancing a strong pipeline to help eliminate malaria

While an increasing number of countries are progressing toward malaria elimination, the threat of resistance to existing treatments demands urgent action to develop novel agents with activity against all malaria parasites. The disease continues to take a heavy toll on pregnant women and children under 5, primarily in sub-Saharan Africa, and there remains considerable work to be done.

980m

Treatment courses of our antimalarial *Coartem* have been delivered in the past two decades

Novartis has long been involved in the fight against malaria. In the past two decades, we have delivered more than 980 million treatment courses of our antimalarial medicine *Coartem*, the first fixed-dose, artemisinin-based combination therapy (ACT). Together with Medicines for Malaria Venture (MMV), we also developed the first dispersible pediatric ACT to treat malaria in children and infants. Since its launch in 2009, we have distributed 430 million pediatric courses in more than 50 countries, contributing to a significant reduction in malaria deaths. In 2020, despite the pandemic, we were able to help ensure a continuous supply of our antimalarial treatments through a comprehensive emergency plan implemented at our manufacturing site in Kurtköy, Turkey, which manufactures the majority of our malaria therapies.

430m

Pediatric courses of our antimalarial have been distributed in more than 50 countries since 2009

In March, we announced a new collaboration with the PAMAfrica consortium, funded by the European & Developing Countries Clinical Trials Partnership (EDCTP) to evaluate the first malaria treatment for neonates and infants weighing less than 5 kilograms in the CALINA trial. This is one of the most vulnerable groups affected by malaria, for whom there is currently no approved treatment. The trial is expected to start in 2021. The collaboration also includes the evaluation of our very fast-acting compound KAE609 for the treatment of severe malaria.

Drug discovery efforts at NITD have delivered an industry-leading pipeline of drug candidates to address the emerging threat of resistance and to support progress toward malaria elimination. While COVID-19 delayed some of our on-site research activities, we continued to conduct clinical trials for two antimalarials, KAF156 and KAE609. These candidates offer new mechanisms of action against the disease and have the potential for simplified therapeutic regimens that would offer an advantage over current treatments.

With scientific and financial support from MMV in collaboration with the Bill & Melinda Gates Foundation, we are conducting a Phase IIb efficacy study of KAF156 in combination with a new once-daily formulation of lumefantrine across a range of doses and regimens. Another Phase IIb trial of KAF156 and lumefantrine, KALUMI, is being initiated in collaboration with MMV and the WANECAM 2 consortium funded by EDCTP. The KALUMI trial will explore efficacy and safety in children as young as 6 months old with uncomplicated malaria.

Novartis completed a Phase II safety and efficacy study of KAE609 with financial and technical support from the Wellcome Trust. This confirmed the safety of KAE609 administered orally,

and its ability to rapidly clear parasites in patients with uncomplicated malaria. An intravenous formulation of KAE609 is also being developed with support from the Wellcome Trust.

In 2020, NITD discovered another novel malaria therapy, INE963, which has an entirely new mechanism of action and is expected to begin clinical trials in 2021. INE963 is a fast-acting, long-lasting antimalarial that could potentially be delivered as a single-dose cure. It was discovered with support from MMV and received the organization's "Project of the Year" award in July.

NITD also continued to explore early-stage discovery research for malaria, including a novel PI4K inhibitor and a program focused on a radical cure targeting the dormant liver stage of Plasmodium vivax malaria, which is the predominant form outside of Africa. We also pursued our Open Innovation program with the Bill & Melinda Gates Foundation, in which academic researchers work alongside Novartis scientists on global health problems. Open Innovation scholars contribute ideas to tackle scientific questions or technology gaps, while Novartis provides access to state-of-the-art research infrastructure and our network of scientists across disciplines. The current scholar is working in the field of Plasmodium vivax malaria research.

IMPROVING ACCESS TO ANTIMALARIAL TREATMENT

As a committed partner in the fight against malaria, we aim to extend our contribution to areas beyond treatment. Nearly 40% of children with fever do not have access to care, according to the WHO. Integrated community case management is a proven strategy for reaching underserved communities with life-saving treatments. The COVID-19 pandemic has only increased the need for properly equipped community health workers to lead outreach to the most vulnerable.

Novartis invested in two pilot projects to support these efforts in 2020. In Nigeria, we are working with partners to strengthen access to diagnosis and treatment at patent and proprietary medicine vendor (PPMV) shops for children under age 5 with pneumonia, malaria and diarrhea. This includes capacity building for 400 PPMVs in two states, with a focus on diagnosis and treatment of uncomplicated malaria. We expect to expand to additional countries in sub-Saharan Africa in the coming years.

In India, under the umbrella of the Novartis Healthy Family program (*Arogya Parivar*), we have started a massive malaria screening campaign in six districts in the Odisha state, a highly endemic area that bears almost a quarter of the country's malaria burden. In total, the plan is to screen 60 000 rural villagers by early 2021. If patients are diagnosed with malaria, they receive a prescription and are advised to visit the nearest government health clinic for treatment and follow-up. We also provided education at health camps on the higher risk of malaria transmission during monsoon periods.

Accelerating leprosy elimination

Novartis and the Novartis Foundation have been working with international partners for over three decades to help eliminate leprosy. Since 2000, we have donated more than 65 million blister packs of multidrug therapy (MDT) through the WHO, helping to treat more than 7.3 million patients worldwide.

Beyond treatment, we have pioneered innovative approaches to fight leprosy. One of these is the Leprosy Post-Exposure Prophylaxis (LPEP) program, which aims to decrease leprosy transmission by providing preventive treatment to close contacts of newly diagnosed patients. The evidence generated by LPEP in the seven countries where the program was operational from 2014-2018 led to the inclusion of this strategy in the WHO Guidelines for the Diagnosis, Treatment and Prevention of Leprosy. Since 2014, thanks to this approach, more than 170 000 contacts of patients have been traced, and more than 150 000 have received preventive treatment. Our epidemiological modeling showed that large-scale implementation of this strategy could massively reduce the global burden of leprosy. The results of the five-year LPEP program were published in The Lancet Global Health in October.

We continue to leverage artificial intelligence (AI), data and digital technologies to accelerate leprosy elimination efforts. In January 2020, Microsoft selected the Novartis Foundation as one of its four initial partners for its new AI for Health initiative, a five-year program to scale up global health initiatives using the power of AI. This will provide the Novartis Foundation with access to the latest technology, resources and technical expertise to help further embed AI in our leprosy work.

Microsoft and the Novartis Foundation are also collaborating with local investigators from the Oswaldo Cruz Foundation (Fiocruz) in Brazil. The group developed a protocol to collect, examine and process anonymized leprosy skin lesion images paired with information about the patients' leprosy symptoms. This data was used to train an AI model – called AI4Leprosy – to accelerate the diagnosis of leprosy through early screening. The protocol and the results of the first model will be published in 2021.

While the algorithm is currently being improved with additional skin images and data from India, a global protocol has been developed together with the University of Basel in Switzerland, and endorsed by international leprosy experts to help further improve the AI model. This should enable data collection to be extended to new geographies, minimizing bias and improving the accuracy of the prediction. AI4-Leprosy has the potential to be easily integrated at no cost in various tools supporting healthcare practitioners in the field or in clinics.

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

Developing treatments for infectious and neglected tropical diseases

Through NITD, we continue to research and develop a promising portfolio of novel drug candidates for the treatment of neglected tropical diseases that affect around 1.6 billion people worldwide.

We made progress on a potential first-in-class compound to treat dengue fever. Although this is the most common vector-borne viral disease in the world, there is currently no specific medicine to treat it. The WHO had listed dengue as a potential threat among 10 diseases, and recent outbreaks – with nearly twice as many dengue infections as in the past 20 years – confirm this. The compound identified by NITD has demonstrated activity against all four dengue serotypes. We completed initial preclinical safety studies and expect to begin clinical trials in 2021.

Cryptosporidium infection is the leading cause of parasitic diarrhea, a major cause of death among young children in developing countries. We reported in 2019 the discovery of the apicomplexan lipid kinase PI4K as a potential molecular target, and NITD has advanced a promising drug candidate, EDI408, through preclinical studies. EDI048 is active in the intestinal enterocytes, where the parasite resides, and is quickly metabolized by the body – a desirable feature in addition to the compound's safety profile. Although diarrhea is one of the top three killers of children globally, there are only a few novel medicines currently being developed to treat it. In 2020, NITD was awarded a three-year grant from the Wellcome Trust for drug discovery science in cryptosporidiosis and Chagas disease.

With an estimated 50 000 to 90 000 new cases per year, visceral leishmaniasis is the most serious form of leishmaniasis, causing fever, weight loss, spleen and liver enlargement, and death if left untreated. In February, we announced a collaboration with the Drugs for Neglected Diseases Initiative (DNDi) to jointly develop LXE408, a first-in-class inhibitor of the kinetoplastid proteasome, for the treatment of visceral leishmaniasis. Within the scope of the agreement, Novartis is responsible for completing Phase I clinical trials. Upon approval, we have committed to distributing the drug on an affordable basis worldwide to maximize access in endemic countries. DNDi will lead Phase II and III clinical development, with the first Phase II study scheduled to start in early 2021 in India. Additional trials are planned in East Africa, which has the highest burden of visceral leishmaniasis.

Taking a holistic approach to antimicrobial resistance

Antimicrobial resistance (AMR) is a growing threat to public health and could increase through the heavy use of antibiotics in the treatment of COVID-19 patients. While antibiotics have saved countless lives and treat numerous conditions, and are essential to many everyday procedures including surgery and chemotherapy, global health experts are increasingly concerned about a new "post-antibiotic" era in which common infections could once again kill. A UK government report estimates that without coordinated international action, AMR could lead to 10 million more deaths annually by 2050.

Novartis supports the global scientific consensus that overuse, underuse and misuse of antimicrobial medicines all contribute to the spread of AMR, and that a balanced approach encompassing prevention, stewardship, access and innovation is needed. Improvements in water sanitation and hygiene as well as wastewater management will help prevent infections and reduce the spread of AMR. The global healthcare community should make every effort to safeguard and maximize the efficacy of the medicines we have today through appropriate use. Lack of timely access to appropriate antimicrobial treatments (particularly antibiotics) and the inability to perform accurate point-of-care diagnostics also contribute to the spread of AMR.

Sandoz, our generics and biosimilars division, is the world's largest provider of high-quality, affordable generic antibiotics. We strive to ensure that our medicines are used in a responsible and sustainable way by engaging in global and local partnerships to support the use of antibiotics in line with WHO guidance. We work with health authorities and healthcare professionals throughout the world to foster stewardship and education, and with nongovernmental organizations and not-for-profit organizations to expand access to antibiotics regardless of patient affordability.

In July, we announced plans for a new public-private partnership with the Austrian federal government to strengthen the long-term future of antibiotic manufacturing in Europe. Sandoz plans to invest more than USD 175 million over the next five years in its integrated antibiotic manufacturing operations in Kundl, Austria, to implement innovative manufacturing technology for both active pharmaceutical ingredients (APIs) and finished dosage forms.

This is an important step toward stronger management of the production and supply of antibiotics in Europe. Sandoz produces enough penicillin products in Kundl to potentially meet all current Europe-wide demand. Under the agreement, we have committed to continue penicillin API production in Europe for the next 10 years. Further, as Kundl is the focal point of the Sandoz European antibiotic manufacturing network, making investments in this facility is vital to help ensure reliable, high-quality supply for European markets.

Novartis was one of 24 pharmaceutical companies that invested a total of USD 1 billion to launch a new AMR Action Fund in July. Developed with the European Investment Bank, the Wellcome Trust and the WHO, this groundbreaking initiative aims to bring two to four new antibiotics to patients by 2030.

Through the Global Antibiotic Research and Development Partnership, we are working to accelerate the development and availability of generic antibiotics to help reduce child deaths from drug-resistant infections. In 2020, we filed a heat-stable pediatric antibiotic for registration in eight African countries. This antibiotic treats a number of infections, including community-acquired pneumonia (pneumonia contracted in a community setting), acute otitis media (ear infection) and cellulitis (bacterial skin infection), especially in the case of penicillin resistance.

As a leading member of the AMR Industry Alliance since 2016, Novartis worked with other member companies to establish an industrywide framework for antibiotic manufacturing. While the contribution of pharmaceutical manufacturing to pharmaceuticals in the environment is relatively low, there is the potential for localized impacts when manufacturing effluents are inadequately managed. In addition, we recently joined the Responsible Antibiotics Manufacturing Platform, an alliance to combat AMR by producing antibiotics in a manner that is environmentally, socially and economically sustainable.

175m

Sandoz plans to invest over the next five years in its integrated antibiotic manufacturing operations in Kundl, Austria (USD)

Photo Dr. Ngo Viet Quynh Tram explains how to use personal protective equipment during a training session at the Hue University of Medicine and Pharmacy in central Vietnam.

STRATEGIC AREAS

Being a responsible citizen

Why is it important?

Society increasingly expects companies to take a stand on global challenges such as poverty, social justice, climate change and other complex issues, which the COVID-19 pandemic has brought into even sharper focus. Our purpose as a global medicines company is inherently social, and we have a responsibility, together with governments and civil society, to contribute solutions to big societal problems. We can help drive positive change by harnessing the assets that make us successful in the first place: people, ideas and capital.

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

Investigated 247 incidents of suspected falsified medicines, which led to 60 successful enforcement actions and the seizure of 1.7 million medicines (unit dosage forms)

→ p. 55

Our people

Announced a new global policy giving most office-based associates the right to choose how, when and where they work within their country of employment

→ p. 60

Our people

Introduced a new approach to performance management that involves team-created rolling objectives, the replacement of performance ratings, and regular feedback and coaching to improve performance

→ p. 62

Environmental sustainability

Created the position of Chief Sustainability Officer and announced a new target to achieve full carbon neutrality across our value chain by 2030

→ p. 64

Our targets

Environment targets

- **Become carbon neutral** in our own operations (Scope 1 and 2) and include environmental criteria in all supplier contracts by 2025.
- **Achieve full carbon neutrality** across the value chain (Scope 1, 2, and 3) by 2030
- **Reduce water consumption** in our operations by half by 2025 (vs. 2016), with no water quality impacts from the manufacturing of our products
- **Be water neutral** in all areas of our operations by 2030 while enhancing water quality wherever we operate
- **Eliminate polyvinyl chloride** in packaging (secondary and tertiary packaging; primary packaging when feasible) by 2025
- **Reduce the amount of waste** sent for disposal by half by 2025 (vs. 2016)
- **Be plastic neutral** by 2030, with all new products meeting sustainable design principles

Diversity and inclusion

- **Achieve gender balance** in management by 2023
- **Close the gender pay gap** by 2023

Training and development

- **Invest USD 100 million** in learning over five years from 2019

QUALITY FOCUS

Of 126 inspections of our facilities worldwide, 99.2% were without major findings

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 patients, 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. We engage with patients and caregivers worldwide to help ensure their needs and concerns are reflected in our clinical research and business operations. The health and safety of our associates are also key. As COVID-19 spread globally in 2020, we regularly assessed the situation and adapted accordingly to help ensure the well-being of those working remotely and those who needed to be on our premises. 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 falsified 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 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, clearly reflecting these in the product labeling, so that patients and 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, in compliance with external regulatory requirements and standards. We continually monitor and adhere to new regulations from health authorities and other regulators for both marketed products and investigational molecules. We conduct thorough investigations when deviations, out-of-specification and/or failure of our manufacturing processes to meet our quality standards, current Good Manufacturing Practices (cGMP) and other applicable regulations occur.

For 100% of manufacturing, supply and distribution of our pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate external health authorities – for example, the US Food and Drug Administration (FDA), the European Medicines Agency (EMA),

the World Health Organization (WHO) and Swissmedic – that confirm after inspection that our duties, including our quality management systems, comply with their strict regulatory requirements. For the manufacture of medical devices, we hold the relevant certifications from the International Organization for Standardization (ISO) and other notified bodies. Please see the Novartis Quality Management System section of our website.

To help ensure compliance with external regulatory quality and safety standards, and support the continuous improvement of our quality management system, Novartis has a robust and independent audit program that covers the product lifecycle.[1]

Travel restrictions introduced by the COVID-19 pandemic resulted in business disruptions across Novartis and our external partners globally. Auditor travel was temporarily paused, which impacted our ability to complete all the audits listed in our 2020 Unified Quality Audit Program (UQAP) plan.

The global audit team worked with all business partners to reprioritize good practice (GxP) audits planned in the UQAP to help ensure that as many high-risk audits as possible could be completed before the end of 2020. In parallel, the global audit team took several measures to conduct risk-based assessments either fully off site or through a combination of off-site assessment and short on-site audit when travel was possible. We will apply these measures until travel restrictions are lifted in all geographies in scope of the Novartis audit universe, and also in cases where remote audits are a more viable option. For those audits that were postponed, appropriate risk mitigation actions have been implemented.

Health authority inspection programs were also impacted, with inspections being postponed or conducted remotely. Novartis was subject to 19 remote inspections, all of which had acceptable outcomes. Postponed inspections will be performed as soon as possible, based upon a risk-benefit evaluation by the competent health authority. While pursuing our transformation, we maintained a focus on quality. Of 126 inspections of our facilities by health authorities around the world, all but one were found to be acceptable (99.2%). The one inspection that may require further improvement was due to increased inspection focus on our clinical activities. The final classification of this inspection is still to be determined.

Novartis has a companywide process to assess quality defects and safety issues, and determine whether an action such as a recall is required. Any such incident is investigated and assessed by subject matter experts, quality management, medical safety experts and regulatory teams. Conclusions are provided to the appropriate health authorities with all relevant documentation, including a safety assessment, and market actions such as recalls are executed as agreed with these authorities. Novartis initiated 27 recalls in 2020. There were no global recalls.

We work with health authorities around the world to continuously review all chemical and biological human medicines for the possible presence of nitrosamines. The EMA, the FDA and other health authorities have provided guidance to the pharmaceutical industry to prevent unacceptable levels of nitrosamines in medicines. The EMA review is due to conclude in March 2021 for chemical human medicines and in July 2021 for biological human medicines.

We have a very robust quality and safety training process (initial and continuous training) for our associates and third parties, and we are regularly audited on our training procedures. All third parties providing services or products manufactured to GxP standards are required by regulation to have their own quality assurance department and a formal training process. Novartis routinely assesses the capability and effectiveness of third-party training programs during audits to confirm suitability for the provided service or product. Despite the challenges created by COVID-19, we have maintained our quality and safety training process.

EXPANDING PHARMACOVIGILANCE EFFORTS

We continue our efforts to boost pharmacovigilance capabilities and support patient safety worldwide. This entails activities to educate patients, providers

[1] Third-party audits pertaining to standards for ethics, business integrity and environmental sustainability are conducted by TPRM (see the section regarding managing risk in our supply chain)

Patient health and safety performance indicators

Pharmacovigilance, safety profile and quality of drugs performance indicators

	2020	2019	2018
Novartis Group health authority regulatory reporting (ICSRs)[1] (%)[2]	**95.0**	98.6	99.1
All audits			
Total audits executed[3]	**903**	1 607	2 147
Internal	**111**	162	250
External	**792**	1 445	1 897
All regulatory authorities			
Inspections	**126**	187	202
Inspections considered acceptable (%)	**99.2**[4]	96.8	98.5
FDA inspections	**6**	19	18
FDA warning letters	**0**	0	0
FDA Form 483	**1**	11	8
FDA sponsor inspections			
Inspections related to clinical trial management and pharmacovigilance	**1**	2	3
Number of VAI (Voluntary Action Indicated)	**0**	1	1
Number of OAI (Official Action Indicated)	**0**	0	0
Recalls	**27**	29	42
FDA recalls[5]	**0**	2	2
Class I recalls[6]	**1**	3	5
Class II recalls[6]	**21**	21	18

[1] ICSRs: individual case safety reports
[2] % represents on-time regulatory submissions. Data reflect January to November 2020.
[3] The reduction in the number of audits is primarily due to the divestment of Novartis divisions, manufacturing network and supplier consolidation, and for 2020, the impact of COVID-19.
[4] One inspection may require further improvement; the final classification by the health authorities is still to be determined.
[5] As recorded on the FDA's "Recalls, Market Withdrawals, & Safety Alerts" webpage
[6] Definition of Class I/II recalls is given on the FDA webpage "Recalls Background and Definitions"

and pharmacists; increase the use of digital technology; and strengthen reporting for adverse events. While clinical trials provide important information on a medicine's safety, it is only after its use in greater numbers of patients in the real-world setting that some adverse events come to light. A robust, accurate and real-time adverse event reporting system is crucial for us to maintain the safety and well-being of our patients worldwide. We are further strengthening reporting through the development of advanced algorithms to screen and analyze multiple data sources for adverse events, including projects that employ robotic process automation, machine learning and natural language processing as a complement to traditional pharmacovigilance methods.

In addition to optimizing our global adverse event reporting system, countries conducted several patient safety initiatives in 2020.

In Austria, the Czech Republic and Ukraine, we organized workshops with healthcare professionals to raise awareness on pharmacovigilance and adverse event reporting, and to guide the development of risk management plans.

In Egypt, we supported efforts to bring attention to the importance of correct dispensing practices among pharmacists.

In Germany, we contributed to drug monitoring activities and logistical support for multiple sclerosis patients to assist with everyday challenges related to their therapy. We also helped breast cancer patients use virtual workshops and live chat to connect with specialist physicians in order to discuss how they respond to medication.

In Portugal, Novartis Patient Safety launched a series of web-based videos with content promoting the need for patients to read safety information in product leaflets and report adverse events.

In Sweden, we collaborated with universities to incorporate pharmacovigilance education into the curriculum of aspiring physicians.

Novartis Patient Safety teams worldwide are supporting the company's COVID-19 response, with two task forces. The first task force evaluates all Novartis products from a benefit-risk perspective and helps ensure patients continue to receive essential medications. The second monitors COVID-19 impacts on Novartis pharmacovigilance and medical device vigilance systems, helping ensure a rapid response when needed.

With a growing number of medical devices in the Novarti[s portfolio, we have additionally built a robust vigilance system to monitor adverse events associated with medical devices worldwide. Novartis became the first company certified for compliance with the new European Medical Devices regulations, which will come into force in May 2021.

In 2020, Novartis Patient Safety also obtained an ISO 9001 certification for its pharmacovigilance governance, confirming that Novartis has the appropriate processes in place to oversee patient safety.

1.7m

Falsified medicines (unit dosage forms) seized by law enforcement and health authorities as a result of 247 suspected incidents investigated

COMBATING FALSIFIED MEDICINES

Combating falsified medicines (as defined by the World Health Organization) is part of our commitment to expand access to quality medicines worldwide. Pandemic-related lockdowns introduced challenges that pushed us to deploy new efforts to help keep patients safe. In 2020, we focused on strengthening the capacity of our team, developing and using new anti-counterfeiting technological capabilities, and deepening our collaboration with law enforcement authorities. Since 2017, our efforts have helped prevent falsified medicines from reaching and harming more than 1.4 million patients.

Governance

We strengthened our governance structure with the executive-level Trust & Reputation Committee now overseeing our work to combat falsified medicines.

50

Devices to detect falsified medicines have been deployed in 15 countries through *Authentifield* by Novartis

The Combating Falsified Medicines team contributed to a new online dashboard, developed by the Ethics, Risk & Compliance (ERC) and Novartis Business Assurance & Advisory (NBAA) functions. This dashboard went live in October and links the various company risks across the world, including criminal activities related to medicines (enforcement cases and products seized, for example). We added six full-time employees to the team covering governance, forensics and regional operations, thereby doubling the company's workforce devoted to fighting falsified medicines.

67%

Of our general medicines programs obtained patient insights before starting human trials

Intelligence

We routinely monitor marketplaces, online pharmacies and social media platforms for evidence of falsified medicines. Our monitoring led to 68 online investigations and the removal of over 13 900 illegal product listings. Early in the pandemic, we doubled capacity in online monitoring and enforcement to mitigate the increased counterfeiting risks against medicines used to potentially treat COVID-19. We regularly briefed Interpol and Europol on new risks and supported their anti-counterfeiting efforts.

Further, we are leveraging data analytics and pharmacovigilance data of adverse events reported to Novartis to flag suspicious products for investigation.

Prevention

We take a holistic approach to preventing harm caused by falsified medicines using data analytics and the latest available technologies in spectrometry, anti-counterfeiting packaging features and mobile applications.

In cases where we identify falsified medicines, we are committed to complying with the WHO's recommendation to voluntarily report all confirmed incidents within 10 working days. To this end, we updated our internal standard operating procedures regarding incident reporting, and we trained associates in the countries.

In light of COVID-19, we took additional steps to secure our products and supply chains. For hydroxychloroquine, a malaria treatment that was investigated as a potential treatment for COVID-19, we enhanced warehouse security, organized secure transit, GPS-tracked all shipments, sought best-in-class advice on supply chain security, and deployed 24/7 supply chain monitoring. We also provided our teams in high-risk countries with updated spectrometric data used for product authentication in the field. To secure the authenticity of the products, we extended security features on secondary packaging for product verification and anti-tampering.

In January 2020, Novartis began co-leading with Universidad Politécnica de Madrid an industrywide public-private partnership under the Innovative Medicines Initiative (IMI) umbrella to use blockchain technology to enhance pharmaceutical supply chain security. Known as PharmaLedger, the project aims to develop a scalable blockchain-based platform for securing supply chains, clinical trials and health data. Twenty-nine public and private partners are participating in this two-year project, including 13 global pharmaceutical companies.

We continue to support local health authorities through *Authentifield* by Novartis, a pilot program launched in 2019 to supply LMICs with affordable spectrometric sensor technology to detect falsified medicines. To date, 50 devices have been deployed in 15 countries, mainly across Africa but also in South Asia and Latin America.

In October, we also launched a pilot called MOVE, which enables our in-country sales and regulatory teams to use a mobile application to verify Novartis secondary packaging equipped with security features. We plan a global rollout in 2021 and are also exploring ways to empower healthcare professionals and patients with this technology.

Enforcement
While pandemic lockdowns strained enforcement capabilities in 2020, we maintained operational excellence through close collaboration with international agencies, including Europol, Interpol, the World Customs Organization and the Pharmaceutical Security Institute. We investigated 247 incidents of suspected falsified medicines, which led to 60 successful enforcement actions and the seizure of 1.7 million medicines (unit dosage forms) by law enforcement and health authorities.

In Colombia, our work with law enforcement authorities led to the dismantlement of a criminal network and the seizure of 7.8 million units of falsified medicines impacting several companies – the largest seizure in the history of Colombia. In China, an enforcement action from 2018 led to the conviction and sentencing of several criminals in 2020 for their involvement in the manufacturing of falsified medicines.

Stakeholder engagement
We made significant progress on policy advocacy projects, notably with the United Nations (UN) Conference on Trade and Development addressing the impact of illicit trade on the UN Sustainable Development Goals. We contributed to an Organization for Economic Co-operation and Development report called "Trade in Counterfeit Pharmaceutical Products," joining the expert panel and sharing an industry perspective during the virtual launch event.

Through the International Pharmaceutical Federation, we conducted virtual events for more than 2 500 pharmacists that provided education about falsified medicines in the context of COVID-19. This led to a new collaboration with the Commonwealth Pharmacist Association focusing on online modules and webinars, and supported efforts to strengthen falsified medicines policy.

We also intensified public awareness efforts through participation in global campaigns such as Fight the Fakes. Additionally, we supported the Unreal Campaign in developing training materials about pharmaceutical crime. We increased associate awareness of the topic through various webinars and stories published on internal Novartis channels.

Supporting patients and caregivers during COVID-19

The Novartis Commitment to Patients and Caregivers continues to guide our associates and leaders to help ensure that patient insights inform our decisions. This is critical to fulfilling our commitment to address unmet needs of patients in our research and development (R&D) portfolio. The Executive Committee of Novartis (ECN) endorsed a new patient engagement strategy in 2020 that focuses on a disease area approach across the full medicine lifecycle – from early research to post-launch. This aims to increase our patient engagement activity across the company. For details on our access-to-medicine programs and commitments, see the pricing and access (pages 30-44) and global health (pages 46-53) sections of this report.

During the pandemic, the need for patient support grew exponentially while at the same time the revenue of patient organizations (POs) dropped dramatically primarily due to the cancellation of educational events and fundraising activities. We provided funding to strengthen digital communications tools and channels to help bridge these gaps. Our support helped ensure that patient needs were heard and that patients were able to access important information on topics such as the impact of COVID-19 on existing treatment and how to access medical help for diagnosis, screening and alternative treatment options. We did this by supporting technology that enabled remote access to healthcare professionals; strengthening call centers on routine and COVID-19-related services; and providing education on the pandemic to patients, caregivers and communities. In addition, Novartis promptly responded to unsolicited requests from physicians, healthcare institutions and governments, providing access to medicines for treating COVID-19-related conditions (see "Managed Access Programs" on pages 38-39 of this report).

In 2019, Novartis supported more than 1 481 POs in 69 countries. In 2020, we engaged with 119 organizations across 35 disease areas to inform our decision-making. Further, we supported 22 capacity- and capability-building programs. We also continued to support the European Patients' Academy on Therapeutic Innovation, which empowers patients to contribute meaningfully to R&D processes, as well as capacity-building projects of the National Health Council, the International Alliance of Patients' Organizations European Patients' Forum, and EURORDIS (the voice of rare disease patients in Europe).

We continue to include patient insights in early research, with 67% of our general medicines programs obtaining patient insights before beginning human trials. Further, 44 clinical development programs comprising 69 clinical studies had a patient engagement component in the study design or conduct. Patients provided valuable input on how study designs can be optimized to facilitate access to clinical trial sites and allow remote participation. We shared our learnings on patient engagement with the broader research community, publishing 11 manuscripts and 26 posters and abstracts on patient engagement practices and insights.

We expanded the geographical reach of our flagship program, the European Patient Innovation Summit (EPIS), to the Middle East and Africa, connecting up to 700 patient advocates from 40 countries to develop a common understanding of digital health and its importance for patients, and to agree on ways for patients to impact digital health. The response from the patient community has been so positive that we are now deploying the platform in Asia-Pacific and the US. Together with EPIS participants, we launched a position paper, calling on all stakeholders to prioritize patient involvement when developing digital health solutions.

80

The engagement score in our quarterly employee survey in Q4 2020, an all-time high

"Lasting success is built on our people and the culture that binds them together. Our strong purpose and commitment to environmental and social sustainability – and to diversity, inclusion and social equity – underpins our inspired, curious and unbossed culture and is a key factor in attracting, growing and retaining our unique talent"

Steven Baert,
Chief People & Organization Officer

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

In 2020, the FDA issued new guidance on patient-focused drug development to help ensure patient experiences and perspectives are incorporated into drug development and evaluation. We aim to implement this guidance in 2021. We have also begun adapting our processes and activities to reflect the outputs of the IMI PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines) initiative, for instance relating to the implementation of meaningful key performance indicators to measure the impact of patient engagement.

We believe we can help build a systematic and consistent approach to patient engagement across the healthcare system. To this end, we continue to participate in 39 IMI projects supporting the progression of healthcare and science. Additional collaborations include memberships in the EFPIA (European Federation of Pharmaceutical Industries and Associations) Patient Think Tank, the Clinical Trials Transformation Initiative, TransCelerate, the Council for International Organizations of Medical Sciences, and Patient Focused Medicines Development.

Unleashing the power of our people

We are transforming our culture to help fulfill our purpose of reimagining medicine to improve and extend people's lives, and to create an organization where people can fully apply their talent and energy at work. The aim of this transformation, which began two years ago, is to ensure that every employee feels inspired by our purpose, is curious about new ideas, and benefits from an unbossed environment in which leaders set clear objectives, remove obstacles, and empower people to attain their goals. The progress we have made helped us become more resilient and better able to overcome the challenges of COVID-19 in 2020. The pandemic also accelerated our culture transformation by connecting employees even more strongly to our purpose, creating new demands for learning, and demonstrating the benefits of empowered working.

PANDEMIC RESPONSE

Our priority in responding to COVID-19 was to ensure the safety of patients and employees. In March, Novartis announced a range of measures to protect and support our employees worldwide, and associates were instructed to work from home when possible. We provided childcare support for employees in critical on-site roles in laboratories or at manufacturing sites, as well as 12 days' extra paid leave in addition to existing vacation and personal time off. In countries where schools and childcare were closed, we offered support either in the form of access to special childcare facilities or reimbursement for employees' personal arrangements. Where feasible, similar benefits were provided for external contractors working for Novartis, subject to local laws and regulations.[1]

We stepped up our Energized for Life initiative, which provides a range of health and wellness resources to employees and their families, as they adapted to new working practices and commitments. These include the *TIGNUM* X smartphone app, which gives digital coaching in areas like nutrition, movement, mindset and recovery. We also expanded our resources to support the mental health of employees. To provide reassurance in uncertain times, we committed to no COVID-19-related job losses during the year and did not furlough our people.

The pandemic accelerated our ambition to explore new working models. In July, we announced a new global policy called Choice with Responsibility, giving most office-based associates the right to choose how, when and where they work within their country of employment.[2] Employees received a one-time payment to help purchase home office furniture and equipment. The program, supported by a total investment of USD 28 million, aims to keep employees safe during the pandemic and helps them maintain work-life balance while optimizing both personal and business performance.

[1] External contractors are individuals who are engaged under an agreement with a third-party employer (i.e., a staff leasing company) and assigned to work under the authority and directive of Novartis.
[2] Corporate tax, individual tax, employment law and social security regulations require special attention if the work is performed from outside the country/state in which the employer is located. Consequently, Choice with Responsibility is currently applicable in-country and in-state/local area only.

Diversity and inclusion performance indicators

	2020	2019	2018
Management representation by gender (% female / % male) [1]			
Overall	**45 / 55**	44 / 56	43 / 57
Novartis Top Leaders [2]	**33 / 67**	31 / 69	30 / 70
Senior management	**39 / 61**	38 / 62	36 / 64
Middle management	**46 / 54**	45 / 55	44 / 56
Gender representation of Board of Directors (% female / % male)	**29 / 71**	25 / 75	25 / 75

[1] Management defined by Global Job Level Architecture and Novartis Top Leaders

[2] Novartis Top Leaders comprise the approximately 300 most senior managers at Novartis, including the Executive Committee of Novartis.

Alongside the challenges posed by COVID-19, the pandemic also brought the importance and urgency of the Novartis purpose into sharper focus, and gave employees a clear sense of the impact of their work in improving and extending people's lives. The score for engagement in our quarterly employee survey reached an all-time high of 80 (out of 100) in the fourth quarter of 2020, compared to 74 a year earlier. This was 7 points higher than the industry benchmark, and was also ahead of the benchmark for the top 20% of global companies. Engagement favorability, which measures the percentage of "agree" or "strongly agree" survey responses, rose to 87% in the fourth quarter from 80% a year earlier.

FOCUS ON LEARNING

We continue our journey to build a culture that stimulates curiosity, for example by providing more learning opportunities and increasing skills in key areas such as data and digital. This was the second year of our pledge to "go big on learning," involving an investment of USD 100 million over five years in addition to the regular annual training budget of around USD 200 million. In 2020, the pandemic caused a significant shift in learning requirements, and we responded by expanding our offerings to meet the changing needs of employees and their families.

With so many people working from home, more than 14 000 employees visited a portal providing support for remote working. Usage of LinkedIn Learning increased from 1 000 hours a week in February to 7 000 in May, and more than 8 600 people from outside Novartis took part in the first-ever Coursera friends and family program. Every Novartis employee received two additional Coursera licenses, giving access to more than 5 700 courses in multiple languages. Novartis also donated USD 1 million to the Khan Academy, a not-for-profit organization providing free online education to millions of students worldwide.

In 2020, employees completed more than 175 000 courses from Coursera and LinkedIn Learning covering strategic skills such as data science, artificial intelligence (AI) and leadership resilience. In many of these areas, we were ahead of industry benchmarks. We also launched online master's degrees in data science, provided by Coursera in conjunction with the University of Michigan and the University of Illinois in the US. Novartis was the first company in the world to offer these courses free to employees.

Our aspiration is for all associates to devote 100 hours a year to learning. The average was 45.7 hours in 2020, up from 35.8 hours in 2019. This was supported by an ongoing campaign called #wearecurious to encourage learning, with more than 21 000 employees taking part in 215 webinars and other events during Curiosity Month in September. These totaled 60 000 hours of learning on topics such as innovation, digital skills, and patient access to medicines.

In the OurVoice survey, employees gave a score of 75 to opportunities for learning and growth, compared to 69 in 2019. The latest score was 5 points above the industry benchmark. We also conducted a separate study on the impact of learning on employee retention. The preliminary results indicated a significant correlation between voluntary learning and retention, and we aim to further study this topic in the future.

BUILDING SKILLS ACROSS THE ORGANIZATION

We are committed to developing talent at Novartis, and our comprehensive development and succession planning programs enable us to build capabilities across different levels of the organization. Dedicated divisional and functional training teams provide job-specific programs for all permanent and part-time employees, and we also offer engagement-specific training to contractors. We welcomed more than 14 500 new associates to Novartis during 2020, most of whom were onboarded virtually. Some of our training programs are outlined in the table on page 74.

Two years ago, Novartis began reimagining its approach to leadership by pursuing an unbossed approach in which self-aware leaders empower their teams and help unleash the power of our people. We have three development journeys to enable leadership excellence at different stages, and two talent development journeys to develop the succession pipeline with early and emerging talent.

In 2020, more than 5 000 senior leaders started a long-term development program called the Unbossed Leadership Experience (ULE) to enhance the capabilities they need to transform our culture. The ULE challenges leaders' assumptions and encourages them to learn about their impact on others. This ensures they are equipped to lead in an ever-changing and increasingly complex environment. The quarterly Leadership Perspectives survey showed a significant increase in self-awareness among leaders who completed the ULE, resulting in higher levels of openness and trust, and greater team effectiveness. In 2020, we converted the

2 700+

The number of employees who took advantage of the new Novartis parental leave guideline in 2020

21 000+

Associates participated in 215 webinars and other events during Curiosity Month

No.1

Our industry ranking in the Refinitiv D&I Index

ULE into a fully virtual program, and the goal is to make it available to 20 000 leaders by 2023.

The emphasis on learning is part of a five-year transformation of our talent strategy. This was launched in 2020 to support a proactive reskilling of the workforce, using data and analytical tools to predict the capabilities we will need in the future. We are also establishing a talent marketplace that helps employees navigate their own careers within Novartis, and provides guidance for hiring managers to help identify potential candidates across the organization. Our succession planning process covers all executive leadership and senior management roles, and evaluates possible successors at various levels of readiness, including middle management. There is a full annual review with the CEO, and summary succession plans and talent metrics are reported to the Board of Directors.

BENEFITS FOR ALL EMPLOYEES

Where possible, Novartis provides benefits to all full- and part-time employees. These vary from country to country but usually include comprehensive health, well-being and retirement benefits; generous vacation policies; and a global recognition program. In addition, during the year more than 2 700 employees took advantage of the company's new parental leave guideline. The guideline offers at least 14 weeks' paid leave to all new parents employed by Novartis, regardless of gender, to support the well-being of their families after the birth or adoption of a child. It covers all employees worldwide as of January 2021, and is effective from the first day of employment.

In 2021, we will begin full rollout of a new approach to performance management, following a successful pilot in 2020 involving 16 000 employees, 96% of whom were positive about the change. The new approach involves team-created rolling objectives, the replacement of performance rating with impact nominations, receiving regular feedback from colleagues as well as managers, and having more coaching to improve performance. Supporting this, in 2021 we are introducing a simpler set of behaviors against which performance is measured. These focus on the individual's contribution to creating an inspired, curious and unbossed culture, and also recognize personal integrity. Another important change to performance management was the rollout of Spark, an online platform that allows people to praise outstanding behavior by colleagues. This was used by 71% of employees in 2020.

In 2020, the Novartis Board of Directors approved a global Employee Share Purchase Plan covering all permanently employed Novartis associates. We aim to launch the plan in country waves over the next five years. It will give associates the option to use a percentage of their base salary to purchase Novartis shares at a discount.

DIVERSITY AND INCLUSION

Novartis strives to adhere to high standards of diversity and inclusion (D&I) in our culture and values, as embodied in the company's new Code of Ethics. We believe that creating a diverse, equitable and inclusive environment is a fundamental part of our aspiration to be inspired, curious and unbossed. Only by being themselves every day can people fully apply their talent and energy at work. Diverse perspectives and inclusive behaviors help us generate new ideas, drive innovation, and better understand patients and other stakeholders.

In 2020, the importance of D&I was demonstrated by heightened awareness of racial disparity across many societies. To promote understanding and support our ongoing efforts toward meaningful change, we created opportunities for open dialogue on racial equity and shared guidance and resources for additional learning. More than 4 800 people took part in an interactive global webcast to mark the African American Juneteenth celebration, followed by a Day of Reflection in September attended by 6 700 associates worldwide. We implemented new hiring guidelines to help increase racial/ethnic and gender diversity in leadership and across the organization, with a dedicated diversity hiring team in the US.

To make sure everyone feels heard, respected and valued as a member of our global community, we encourage Employee Resource Groups (ERGs) – voluntary networks linking employees who have shared backgrounds, interests, experiences and perspectives. There are now 60 such groups active across the company.

We made progress toward our UN Equal Pay International Coalition (EPIC) pledge to achieve gender balance in management and further improve pay equity and transparency processes by 2023. The percentage of women in overall management rose to 45% in 2020, from 44% a year earlier. Additionally, by February 2021 we aim to introduce pay transparency in 10 new countries (16 countries in total), including the US and Switzerland, so employees can compare their salary to external benchmarks.

We also made progress in removing possible gender bias from our recruiting system by eliminating historical salary data when making job offers across 75% of global hiring, up from 40% in 2019. Novartis has a global median pay gap of -3.1% and a global mean pay gap of +3.6%. While we acknowledge this percentage is influenced by worldwide workforce demographics, this is significantly ahead of the Bloomberg benchmarks of +19% median and +23% mean. Our parental leave and flexible working initiatives are also expected to positively influence the gender pay gap by enabling employees to further balance their work and family commitments. Recognizing this progress, Novartis was again included in the Bloomberg Gender-Equality Index, a listing of companies that achieve the highest standards in measures of inclusion such as female empowerment and gender pay parity.

Novartis was the first major pharmaceutical company to support the UN LGBTI Standards of Conduct, which seek to end discrimination against lesbian, gay, bisexual, transgender and intersex (LGBTI) people in the workplace. In June, more than 3 000 Novartis employees from 67 countries took part in a virtual Pride Month event celebrating LGBTI inclusion. In 2020, Novartis introduced sponsors to champion LGBTI awareness at senior levels. We also launched a learning program to promote wider understanding and support for LGBTI colleagues, and instituted an identity guide and health plan reviews to protect and care for our transgender community.

We recognize the need to provide an environment in which individuals with disabilities feel a sense of belonging and can perform at their best. Novartis is a member of the International Labour Organization (ILO) Global Business and Disability Network, which promotes the inclusion of people with disabilities in workplaces around the world. We also collaborate with the Center for Disability Integration at the University of St.Gallen in Switzerland to identify and develop solutions for disability inclusion.

To ensure this commitment to D&I is shared throughout our business network, we developed a US Diverse Supplier Protocol that empowers decision-makers to engage with approved suppliers owned by women, minorities, LGBTI people and veterans. Globally, we issued the first industrywide LGBTQI+ Supplier Good Practice Guidance. Novartis is also committed to avoiding the use of non-regular employment practices and contracts.

Novartis prepares an Inclusion Index to measure our progress toward creating an inclusive environment that treats all employees with dignity and respect. The composite score was 74 in November 2020, up from 69 a year earlier. Our achievements were also recognized externally. In the Refinitiv D&I Index, we were ranked No. 1 in our industry and No. 9 overall out of more than 9 000 companies worldwide, marking our third consecutive year in the top 10. We maintained our strong position in the Dow Jones Sustainability World Index, which compares the environmental, social and governance (ESG) performance of leading companies, with a percentile score of 91 compared with 87 in 2019. We achieved a maximum score on DJSI's labor practice indicators and human capital development criteria. In addition, Novartis achieved sector-leading performances on human capital from MSCI and Sustainalytics.

TRANSFORMING ENGAGEMENT AND VOLUNTEERING

Novartis empowers associates to engage and volunteer on their own terms; they can decide when, where and how. Our Novartis volunteering program does not set a limit on the number of volunteering or engagement hours. Every associate is encouraged to engage with responsibility.

Due to the COVID-19 pandemic, volunteering activities were conducted virtually in 2020. In the first few months of the pandemic, there was a fivefold increase in the donation of pro bono skills and time compared to the same period last year. Associates used the program's virtual marketplace, which enables them to register new project ideas and sign up as volunteers.

In April, the program launched a campaign to generate ideas among associates for virtual volunteering. More than 2 400 associates in 18 countries contributed, resulting in more than 60 new activities. One example is "Today Positive Thoughts," an open forum where associates can freely express their thoughts and feelings during COVID-19 to help overcome social and emotional isolation.

Since 2015, the program's virtual platform has been used by over 21 100 associates from 59 countries. In 2020, the team launched a new platform with advanced functionalities, powered by artificial intelligence, to increase the likelihood of finding the right match. Associates can now search for and recommend projects based on a range of criteria like skills, social causes or beneficiaries, UN Sustainable Development Goals, and geography. The new digital capabilities also enable impact measurement for volunteering activities and proactively forecasting trends. The platform launch is expected for the second quarter of 2021.

While the program continues to encompass a range of hands-on activities, the primary focus is to drive higher impact through skills-based volunteering. One example is the long-term engagement of Novartis volunteers in Hyderabad, India, who completed the launch of the Leprosy Patients Records Database

"You have to deliver every day in order to live up to your own standards and to meet the expectations of patients. This is the mindset that we also need to apply to our environmental sustainability efforts. We need to make these an essential element of how we run our business"

Montse Montaner,
Chief Sustainability Officer

(LEOPARD) in January 2020. The volunteers helped design and build a health management tool for the Sivananda Rehabilitation Home. This tool digitalizes patient data and helps run daily operations, enabling Sivananda to become a paperless hospital. Through the project, Novartis volunteers also plan to support other hospitals in the fight to eliminate leprosy.

In addition, for the first time, the platform gives access to external partners, who can directly post opportunities. This new feature is one example of how the program is transforming our approach to community partnership. In 2020, we took steps to shift the focus of volunteering beyond a single day of service toward a long-term, sustainable commitment with global health partners and local communities. To this end, we signed new agreements with the US President's Malaria Initiative, the International Rescue Committee and Save the Children to provide skills-based volunteering.

KEEPING ASSOCIATES SAFE

We made every effort to help ensure the safety of our associates during the COVID-19 pandemic. As travel restrictions were imposed early in the year, our travel security alerts helped Novartis associates mitigate their risk, either by avoiding travel to high-risk zones or by returning home.

We quickly adapted to address new threats as lockdowns led to a surge of criminal activity online. For example, we redirected our threat scanning to address potential risks during virtual product launches and meetings, congresses and events. In response to an upward trend of social engineering fraud (designed to harvest private personal and company information for criminal use), we also rolled out a "virtual kidnapping" awareness training to educate associates about online frauds and scams. These have become more sophisticated since the start of the pandemic as criminal tactics have adjusted to the situation. This training teaches associates how to identify the hallmarks of a scam, and outlines clear steps to help associates protect themselves and their families.

In 2020, we reached out to more than 8 000 associates regarding over 60 high-risk security and health matters, including COVID-19 responses, explosions, natural disasters and shootings. We continued to provide forward-looking risk insights to the business and conducted 31 enhanced due diligence inquiries relating to Novartis business activities in complex environments.

In collaboration with several functions, we launched the Everbridge global incident communications tool in September, enabling associates to receive alerts about security, environmental and health-related incidents that may affect them when working on site and remotely. A security guide for remote working was also issued to support associates.

Enhancing environmental sustainability

Planetary health has a direct impact on human health. Our commitment to environmental stewardship as a global healthcare company is directly aligned with our purpose to reimagine medicine to improve and extend people's lives. Our ambition is to be a leader in environmental sustainability, driving positive change through our operations and those of our suppliers.

In September, we announced a bold new target to achieve carbon neutrality across our value chain (Scope 1, 2 and 3) by 2030, replacing our existing target for a 50% reduction in emissions. Our supply chain makes up 89% of our overall carbon footprint. To achieve our new target, we plan to develop accurate assessments and benchmarks for the carbon footprints of our suppliers. This will be a challenging process, and it will require close collaboration with our suppliers to help them decarbonize the services they provide to Novartis.

In addition, we are pursuing carbon neutrality in our own operations (Scope 1 and 2) by 2025. In this respect, we have made significant progress since 2016, reducing our carbon emissions by 19%. At the same time, we achieved a 35% reduction in water consumption and a 36% reduction in waste sent for disposal (both versus a 2016 baseline). Our efforts and progress have been recognized; in 2020, Novartis was included in the CDP Water A-List and achieved an A- rating in CDP Climate.

Environmental sustainability targets are included in senior leaders' personal performance objectives. Additionally, the environmental sustainability dashboard, which tracks quarterly progress across the company, is regularly presented to the Environmental Sustainability Strategy Implementation Steering Committee and the Trust & Reputation Committee. For the first time in 2020, progress against our environmental sustainability targets was presented to the Novartis Board of Directors, which also endorsed our new 2030 carbon-neutrality target.

In 2020, we created the position of Chief Sustainability Officer to lead the strategy and execution of environmental sustainability across Novartis, and drive an effective stakeholder engagement strategy with our external stakeholders and across our value chain.

All these steps signal our commitment to further integrate environmental sustainability in our organization.

DECARBONIZING OUR OPERATIONS AND SUPPLY CHAIN

The COVID-19 pandemic created challenges but also opportunities with respect to carbon reduction and energy efficiency. Company travel emissions were reduced to near zero, and engineers were able to upgrade and optimize equipment in buildings that were unoccupied during lockdowns. However, we recognize that the shift to remote working simply displaced the consumption of energy from within our buildings to home offices. Further, changes to building ventilation systems have increased airflow rates and the use of fresh air, which has increased energy consumption.

To meet our 2025 carbon-neutrality target, we continued to work in line with our four key drivers:

Switch to renewable energy: All energy used in our US facilities is compensated with renewable energy credits generated through a virtual power purchase agreement (VPPA) with the Santa Rita East wind farm in Texas. In 2020, this project produced 417 000 megawatt hours of carbon-free electricity, which is the equivalent of powering 481 000 average American households for one year. We are on track to achieve the same ends in Europe. In 2020, we signed five VPPAs with three developers for wind and solar energy projects to address the company's carbon footprint across its European operations over a period of 10 years from the start of operations. This is equivalent to removing approximately 113 000 passenger vehicles from the road each year. This move makes Novartis the first pharmaceutical company set to achieve 100% renewable electricity in its European operations through VPPAs.

Environmental performance indicators[1]

	2020	2019	2018
Energy use (million gigajoules), on site and purchased	**11.15**	12.74	13.04
Greenhouse gas (GHG) emissions, Scope 1, combustion and process (1 000 tCO_2e)	**296.2**	356.6	334.5
GHG emissions, Scope 1, vehicles (1 000 tCO_2e)	**100.2**	128.4	146.3
GHG emissions, Scope 2, purchased energy (1 000 tCO_2e)	**392.2**	411.6	448.7
GHG emissions, Scope 3, business travel (1 000 tCO_2e)	**27.0**	191.3	211.7
Total GHG emissions, Scope 1 and Scope 2 (1 000 tCO_2e)[2]	**788.6**	896.6	929.5
GHG offsets (1 000 tCO_2)	**35.4**	29.8	54.9
GHG emissions (Scope 1 and Scope 2) per sales (tCO_2e per million USD)	**16.20**	18.86	20.8
GHG emissions (Scope 1 and Scope 2) per associate (tCO_2e)	**7.12**	8.22	8.58
Halogenated volatile organic compounds (VOCs) (t)	**13.18**	26.59	78.98
Non-halogenated VOCs (t)	**446.25**	406.82	480.10
Non-hazardous waste recycled (%)	**86.6**	81.7	82.0
Hazardous waste recycled (%)	**46.9**	58.8	54.9
Non-hazardous waste not recycled (1 000 t)	**8.8**	12.9	12.5
Hazardous waste not recycled (1 000 t)	**34.2**	41.2	47.3
Water withdrawal (million m^3)[3]	**54.7**	66.8	69.5
Water discharged directly to aquatic environment (cooling water) (million m^3)	**46.1**	55.5	57.9
Water consumption (million m^3)[4]	**8.5**	11.2	11.9

[1] The 2020 environmental and resource data published in the Annual Report and the Novartis in Society Report are actual data for the period from January through September, and best estimates for the period from October through December. This data will be updated with actual data in the first quarter of 2021. Significant deviations will be reported on our website and restated in next year's Annual Report.

[2] Scope 1: combustion and process, and vehicles; Scope 2: purchased energy

[3] Sum of contact water and non-contact (cooling) water use

[4] Water discharged via treatment and water lost

ENVIRONMENTAL TARGETS

Carbon neutral across entire supply chain by 2030

19% reduction in greenhouse gas emissions in 2020 vs. 2016 baseline

Water neutral in all areas by 2030

35% reduction in water consumption in 2020 vs. 2016 baseline

Plastic neutral by 2030

60% reduction in single-use plastics in the workplace in 2020 vs. 2016 baseline

Reduce our demand for energy by improving energy efficiency: The workshops Novartis held in 2019 to identify energy reduction opportunities across our sites have generated more than 300 projects, of which approximately 120 are currently being implemented across the organization. For instance, a steam condensate recovery project at one of our sites in Slovenia saved more than 5 000 gigajoules of energy and reduced the site's carbon footprint by more than 300 tonnes per year.

Update our manufacturing technology: We are continuing our long-term, strategic shift from traditional chemistry toward highly innovative, sustainable approaches that reduce our carbon footprint, resource consumption and waste. At our facility in Schaftenau, Austria, we are in the process of comparing the use of plastics with traditional stainless steel technology for manufacturing plants and equipment. Initial results suggest that while plastic has a lower overall carbon footprint, it generates more waste, and end-of-life management is more challenging. The information we gather from this experiment will inform how we balance our aim to reduce waste with our carbon neutrality target.

Invest in greener infrastructure: We continue to factor in a price of USD 100 per ton of carbon for investments greater than USD 20 million. Further, the Novartis ECN approved a new global fleet policy that mandates the switch to zero- and low-emission vehicles in at least 22 countries before the end of 2025.

We have identified a partner to diversify our portfolio of natural climate solutions. This entails moving beyond forestry to explore regenerative agriculture, blue carbon projects and mangrove restoration, with a focus on carbon removal that also benefits health, biodiversity and climate resilience.

We continued to assess the carbon footprints of select products to identify and address hot spots. For example, we completed lifecycle assessment studies of two *Breezhaler* inhaled products (*Atectura* and *Enerzair*), factoring in emissions from raw material production to consumer use and disposal. Carried out in accordance with the Greenhouse Gas Protocol Product Standard, the studies showed that the products had a much lower carbon footprint than metered dose inhalers on the market. We are evaluating if we can certify them as the first Novartis carbon-neutral products, which would likely make them the first pharmaceutical products certified as carbon neutral. That analysis is informing the development of a strategy for reducing product-associated emissions as much as possible, and then offsetting residual emissions that cannot be eliminated. We hope it will lead to a companywide approach to neutralizing carbon emissions across the Novartis product portfolio, which aligns with our new 2030 carbon neutrality target.

In addition, we continued to embed environmental sustainability objectives related to carbon, water, waste and plastics in our supplier contracts, and we work with suppliers to develop and refine their sustainability agendas. We updated the Novartis Third Party Code with specific requirements on environmental performance to reinforce these commitments. The revised code states that Novartis suppliers are expected to act beyond legal compliance to establish and track progress toward achieving their own environmental sustainability targets.

Managing water quality and consumption
We continued to make progress toward our 2025 targets to reduce water consumption in our operations by 50% versus 2016 levels and to ensure there are no water quality impacts from manufacturing effluents. This includes setting risk-based discharge limits for pharmaceuticals in effluent water from our own factories and those of our key suppliers.

In September, we joined PREMIER, a new six-year project with the IMI focused on evaluating and mitigating the risk of medicines in the environment. The IMI is a public-private partnership between pharmaceutical companies, the European Commission and the EFPIA. Following the success of the

five-year IMI project iPiE (Intelligent Assessment of Pharmaceuticals in the Environment), which concluded in 2019, PREMIER (Prioritization and Risk Evaluation of Medicines in the Environment) was launched as a collaboration among 10 pharmaceutical companies, 10 research institutes and four small- and medium-sized enterprises. The project aims to deliver an innovative framework for characterizing the environmental risks of active pharmaceutical ingredients (APIs), which can ultimately be used to explore and promote greener drug design and manufacturing.

REDUCING WASTE

We made significant progress toward reducing waste and increasing material efficiency in 2020. For example, by optimizing our in-house incinerators, we reduced the amount of waste sent for disposal by 300 tonnes and generated energy at the same time. We also implemented a new process called process mass intensification, which requires both Novartis associates and suppliers to report how much waste is generated during the production of APIs. We will use this information to identify and implement waste reduction opportunities.

We survey our sites quarterly to track progress toward eliminating single-use plastics in all workplaces by 2021. We were 60% toward achieving this goal before the outbreak of COVID-19. The pandemic has temporarily interrupted progress, as the use of single-use plastics has become necessary due to infection control protocols. Our efforts to eliminate polyvinyl chloride (PVC) in all secondary and tertiary packaging remain on track, with only four of our factories still using PVC. All plan to eliminate PVC before the end of 2021.

Further, we are evaluating more environmentally friendly alternatives to PVC. All our biologics development projects already use BioPET-A, a plant-derived polyethylene terephthalate made from 30% renewable raw material and 70% oil-based raw material. We also now use a fully carton-based packaging design instead of PVC for the packaging of *Aimovig* (a treatment to prevent migraine), and we plan to replace the PVC packaging of all our marketed biologics in 2021. Additionally, we are working to replace product leaflets with QR codes in medicine packs and have launched a pilot for *Kesimpta* (a treatment for relapsing forms of multiple sclerosis).

ADVOCATING FOR CHANGE

Novartis signed on to multiple environmental initiatives in 2020, including the UN Global Compact's CEO Water Mandate, which mobilizes business leaders to make progress on six elements of water sustainability, and Sustainability 30 (S30), a group of sustainability executives from 30 of the world's leading companies working to accelerate business action on sustainability.

At the height of the pandemic, we joined more than 150 global corporations in the largest ever UN-backed, CEO-led climate advocacy effort, urging world leaders for net-zero recovery from COVID-19. Our CEO reaffirmed the Novartis science-based commitment and signed the joint statement urging governments around the world to align their COVID-19 economic aid and recovery efforts with the latest climate science, calling for policies that build resilience and help drive the climate agenda.

In October, we expressed support for the Task Force on Climate-related Financial Disclosures (TCFD), which aims to develop voluntary climate-related financial risk disclosures across industries. We believe that having a consistent set of disclosures, which can be adopted by companies to inform investors and other stakeholders about the climate risks they face, will help both companies and financial markets better evaluate and price those risks. Please see further details in our first TCFD qualitative disclosure on pages 75-77.

Additionally, Novartis engaged with federal and state officials in the US, supporting legislative efforts related to carbon pricing, renewable portfolio standards, zero-emission vehicles, climate resilience and a just climate transition – all important components of responsible business.

Conducting animal research responsibly

Novartis fully supports the use of alternatives to animal research wherever feasible. We have a Global Animal Welfare Policy and a set of animal welfare standards that define key principles, responsibilities and explicit requirements governing animal research. All studies sponsored by Novartis, whether conducted internally or externally, must adhere to this policy and standards.

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 2020, award-winning projects:

- Replaced animals and reduced their number to monitor and maintain high standards of rodent health through exhaust air dust analysis
- Reduced the number of rodents in nerve regeneration studies through AI screening of rodent cells
- Replaced animals used in assessing tumorigenicity for new cell and gene therapies by a soft agar-based benchtop assay

In 2020, we established a Ph.D.-trained 3R scientist role to further strengthen our culture of ethical science at Novartis and to help advance the reduction, replacement and refinement of animal studies.

We also added a unique new role: a specialty-trained veterinarian to liaise between internal scientists and those conducting sponsored animal studies at external partner sites. This change has facilitated greater implementation of the 3R principles, and enhanced the level of ethical oversight before, during and after animal studies conducted by third parties. Further, our team of animal welfare experts prospectively and continually audits third parties.

About this report

For the eighth consecutive year, Novartis is publishing an annual Novartis in Society ESG 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 2020 Novartis Annual Review (pages 38-41) and the 2020 Novartis Annual Report. The previous report was published on January 28, 2020.

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. We published a Communication on Progress in the first quarter of 2020, and will do so again in 2021. On page 15, 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 78-81).

The report is divided into four chapters based on our corporate responsibility (CR) material clusters and our priorities for building trust with society: holding ourselves to high 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, 2020, to December 31, 2020. All information reflects the continuing operations of the Novartis Group, 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 2020) plus three-month estimates. This data will be restated with actual figures on our website during the first half of 2021. 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 78 and the SASB Index on page 82 provide links to content within this report, the 2020 Annual Review, the 2020 Annual Report and novartis.com. In 2020, we committed to fully support the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), and our first qualitative TCFD disclosure can be found on pages 75-77. We aim to provide quantitative disclosure on climate-related topics in the future as we incorporate the TCFD recommendations into our business. In addition, to provide ESG analysts with easier access to our information, we have published a Novartis ESG index, which signposts where our key disclosures – content and KPIs – can be found across our publications and channels.

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 90.

Learn more about our activities.
See our publications.

For feedback and suggestions, contact James Wallace, Head, Corporate Reporting and ESG Office: james.wallace@novartis.com.

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

access to medicine index

Dow Jones Sustainability Indices
In Collaboration with RobecoSAM

FTSE4Good

CDP
DRIVING SUSTAINABLE ECONOMIES

Performance indicators 2020

Holding ourselves to high ethical standards

ETHICAL BUSINESS PRACTICES PERFORMANCE INDICATORS

	2020	2019	2018
Novartis associates trained and certified on the Code of Ethics (%) [1]	**98**	98	98
Misconduct cases (central matters) reported to the SpeakUp Office [2, 3, 4]	**142**	209	441
Total SpeakUp Office allegations (central matters) [2, 4, 5]	**243**	427	768
SpeakUp Office allegations (central matters) per category (%) [2, 7]			
Fraud/asset misappropriation	**7.8**	6.8	21.6
Expense fraud	**2.9**	5.4	23.4 [8]
Books and records, accounting irregularities	**0.8**	1.2	0.4
Improper professional practices	**11.9**	16.9	22.3
Bribery, kickbacks	**0.8**	1.6	2.1
Discrimination and sexual harassment	**12.8**	8.2	4.0
Retaliation	**3.0**	6.3	2.1
Other employee relations issues	**19.0**	18.0	7.9
Conflict of interest	**10.7**	10.8	5.2
IT security breach	**3.7**	4.0	1.9
Quality assurance/data integrity	**8.6**	6.3	3.1
Data privacy	**1.6**	2.6	0.5
Antitrust, fair competition	**0.8**	0.2	0.3
Company confidential/trade secret information	**3.7**	0	0
Other	**11.9**	11.7	5.1
SpeakUp Office allegations (central matters) substantiated [2, 4, 6, 9]	**114**	254	558
Dismissals and resignations related to misconduct (central matters) [2, 4, 6, 9, 10]	**102**	186	350

Animal testing indicators

Rodents	**76.1% (312 332)**	78.2% (355 451)	70.4% (360 417)
Zebrafish	**23.8% (97 596)**	21.5% (97 551)	29.2% (149 474)
Other species	**0.1% (431)**	0.3% (1 452)	0.4% (2 246)

[1] Active Novartis associates with email addresses, trained via e-learning or via One Deck for Novartis Technical Operations. Training rolled out from September 2020 to February 2021, with a preliminary completion rate as of December 31, 2020.
[2] A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and significant financial impact.
[3] The number of misconduct cases reported may change year-on-year as matters may be reassessed in the course of the case lifecycle.
[4] The decrease in the number of misconduct cases reported is due to a new risk assessment as of 2019.
[5] The number of allegations is higher than the actual number of cases as a case can have more than one allegation.
[6] May include allegations from previous years
[7] Percentages are based on total SpeakUp Office allegations number. Results for 2019 and 2018 have been revised to reflect the change in methodology from using the number of misconduct cases to the number of allegations.
[8] Until the end of 2018, these expense fraud allegations are assessed to be of higher risk in China. The risk assessment of these issues changed as of 2019.
[9] Data based on when investigation report was received. Results for 2019 and 2018 have been revised to reflect this change in methodology.
[10] Data based on year when case is closed. Results for 2019 and 2018 have been revised to reflect this change in methodology.

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

ACCESS TO HEALTHCARE PERFORMANCE INDICATORS

	2020	2019	2018
Total patients reached (millions)	**769**	799	765
Patients reached through access-to-healthcare activities (millions) [1]	**66**	16	25

	2020	2019	2018
Sustainability-linked bond (September 23, 2020 – September 23, 2028)			
Strategic innovative therapies patient reach	**695 669**	547 664	382 714
Flagship programs patient reach	**43 912 152**	15 069 483	28 509 151

	2020[2]	2019	2018
Novartis Global Health			
Countries with products on the ground	**115**	33	26
FTEs [3, 4]	**1334**	786	651
Patients reached with products (thousands) [5]	**65 828**	15 069[6]	28 509[6]
Health educators trained	**671**	1 536	1 028
Healthcare providers trained [7]	**12 648**	1 516	697
Policymakers trained	**90**	145	131
Points of service provision [8]	**5 902**	13 635	15 190
People reached at points of service provision	**486 642**	986 701	765 055
Awareness events held [9]	**424 878**	250 432	185 756
People reached at awareness events	**8 048 360**	10 211 704	982 078

	Patients reached (thousands)		
	2020	2019	2018
Emerging market brands			
Novartis Pharmaceuticals	**355.1**	302.6	213.3
Novartis Oncology	**13.9**	11.3	8.2
Patient assistance programs			
Novartis Patient Assistance Foundation Inc. (US)	**102.7**	87.2	68.1
Novartis Oncology Access	**33.9**	60.7	71.1
Donations			
Leprosy (WHO) [10]	**245.4**	168.6	176.2
Fascioliasis/*Egaten* [11]	**132.8**	154.7	154.7
CMLPath to Care™	**30.2**	14.4	13.4

	Value USD (millions) [13]		
	2020	2019	2018
World Child Cancer	**<0.01**	<0.1	0.1
Emergency relief [12]	**2.5**	2.8	4.7

[1] Novartis Global Health, local brands, patient assistance programs, donations
[2] Data reflect the full scope of access approaches managed by the Global Health organization, including the activities formerly managed by Novartis Social Business, as well as the newly formed sub-Saharan Africa (SSA) organization and the Integrated Access Programs & Markets unit. More details are on pages 33-38.
[3] Full-time equivalent positions and contractors
[4] Significant number of headcounts integrated from different units as a result of the establishment of the new SSA organization
[5] The patient number is calculated based on treatments delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (NCD patients often take several drugs). The treatment adherence and treatment overlap factors are based on assumptions from developed markets.
[6] Data restated to reflect the patients reached as defined by the Sustainability Linked Bond, which includes private sector sales in LMICs.
[7] Shift to virtual events
[8] Points of service provision include facilities and health camps where healthcare services are provided.
[9] In India, we adjusted our approach from hosting large health education meeting with community groups to a door-to-door model and also partnered with schools to deliver health education to classrooms virtually. This led to an increase in the number of events, but with a restricted reach.
[10] In 2020, the leprosy program fully transitioned to the Global Health organization as one of the flagship programs and is also included in data reported in the Novartis Global Health table above.
[11] Numbers of patients reached have been updated to reflect the new methodology used by WHO and based on real-world evidence.
[12] Monetary and product donations
[13] Wholesale acquisition cost (WAC) plus logistics costs for some programs

Being a responsible citizen

PEOPLE PERFORMANCE INDICATORS

	2020	2019	2018
Full-time equivalent positions / headcount [1]	**105 794 / 110 738**	103 914 / 108 776	104 780 / 108 422
Turnover: % voluntary / % overall	**5.2 / 10.1**	7.0 / 14.0	7.4 / 12.0
Voluntary turnover of high performers (%)	**4.2**	5.4	5.8
Internal hires / external hires (%)	**58 / 42**	55 / 45	54 / 46
External hires by gender (% female / % male)	**52 / 48**	53 / 47	52 / 48
Management representation by gender (% female / % male) [2]			
Overall	**45 / 55**	44 / 56	43 / 57
Novartis Top Leaders [3]	**33 / 67**	31 / 69	30 / 70
Senior management	**39 / 61**	38 / 62	36 / 64
Middle management	**46 / 54**	45 / 55	44 / 56
Gender representation of Board of Directors (% female / % male)	**29 / 71**	25 / 75	25 / 75
Associate nationalities / associate nationalities in management [2]	**142 / 113**	149 / 110	142 / 113
Annual training hours per employee [4]	**45.7**	35.8	22.6
Associates represented by a trade union/internal work council or covered by a collective bargaining agreement (%) [5]	**46**	45	45
Gender split of leavers (% female / % male)	**49 / 51**	48 / 52	51 / 49
Median tenure in years by gender (female / male)	**4.7 / 5.5**	5.5 / 6.5	5.7 / 6.5
Internal promotion by gender (% female / % male)	**52 / 48**	51 / 49	50 / 50
Revenue-producing roles by gender (% female / % male)	**50 / 50**	49 / 51	48 / 52
Novartis IT and engineering workforce by gender (% female / % male)	**32 / 68**	31 / 69	30 / 70
Number of employees by employment contract (permanent and temporary), by gender [6]			
Women employed on a permanent contract	**53 729**	51 906	51 139
Women employed on a temporary contract	**1 935**	2 327	2 316
Men employed on a permanent contract	**53 096**	52 691	53 252
Men employed on a temporary contract	**1 629**	1 718	1 669
Number of employees by employment contract (permanent and temporary), by region [6]			
Employees on a permanent contract in Asia-Pacific region	**27 711**	26 559	26 581
Employees on a temporary contract in Asia-Pacific region	**300**	666	654
Employees on a permanent contract in Europe/Middle East/Africa region	**56 852**	56 855	57 178
Employees on a temporary contract in Europe/Middle East/Africa region	**3 016**	3 063	3 010
Employees on a permanent contract in Latin America region	**5 092**	5 311	5 395
Employees on a temporary contract in Latin America region	**157**	194	206
Employees on a permanent contract in North America region	**17 170**	15 872	15 237
Employees on a temporary contract in North America region	**91**	122	115
Number of employees by employment type (full time and part time), by gender [6]			
Women employed on a full-time contract	**48 472**	46 907	46 502
Women employed on a part-time contract	**7 204**	7 338	6 953
Men employed on a full-time contract	**53 507**	53 164	53 932
Men employed on a part-time contract	**1 219**	1 246	989

[1] 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
[2] Management defined by Global Job Level Architecture and Novartis Top Leaders
[3] Novartis Top Leaders comprise the approximately 300 most senior managers at Novartis, including the Executive Committee of Novartis.
[4] See page 74 for a list of selected training programs.
[5] Non-management associates
[6] Less than 0.5% of associates have unknown classification.

PATIENT HEALTH AND SAFETY PERFORMANCE INDICATORS

Pharmacovigilance, safety profile and quality of drugs performance indicators

	2020	2019	2018
Novartis Group health authority regulatory reporting (ICSRs)[1] (%)[2]	**95.0**	98.6	99.1
All audits			
Total audits executed[3]	**903**	1 607	2 147
Internal	**111**	162	250
External	**792**	1 445	1 897
All regulatory authorities			
Inspections	**126**	187	202
Inspections considered acceptable (%)	**99.2**[4]	96.8	98.5
FDA inspections	**6**	19	18
FDA warning letters	**0**	0	0
FDA Form 483	**1**	11	8
FDA sponsor inspections			
Inspections related to clinical trial management and pharmacovigilance	**1**	2	3
Number of VAI (Voluntary Action Indicated)	**0**	1	1
Number of OAI (Official Action Indicated)	**0**	0	0
Recalls	**27**	29	42
FDA recalls[5]	**0**	2	2
Class I recalls[6]	**1**	3	5
Class II recalls[6]	**21**	21	18

[1] ICSRs: individual case safety reports
[2] % represents on-time regulatory submissions. Data reflect January to November 2020.
[3] The reduction in the number of audits is primarily due to the divestment of Novartis divisions, manufacturing network and supplier consolidation, and for 2020, the impact of COVID-19.
[4] One inspection may require further improvement; the final classification by the health authorities is still to be determined.
[5] As recorded on the FDA's "Recalls, Market Withdrawals, & Safety Alerts" webpage
[6] Definition of Class I/II recalls is given on the FDA webpage "Recalls Background and Definitions"

SUPPLY CHAIN PERFORMANCE INDICATORS

	2020	2019	2018
Suppliers risk-assessed by TPRM[1, 2]	**8 448**	2 839[3]	NA[4]
Suppliers with remediation action agreed[2, 5]	**521**	122	89
Suppliers audited[2]	**35**	135	48
Suppliers assessed for anti-bribery risks	**2 014**	479[3]	NA[6]
Suppliers assessed for animal welfare	**10**	3[3]	NA[6]
Suppliers assessed for business continuity plans	**70**	NA[6]	NA[6]
Suppliers assessed for financial due diligence	**193**	NA[6]	NA[6]
Suppliers assessed for health, safety and environment	**315**	226[3]	NA[6]
Suppliers assessed for information security and data privacy	**3 174**	1 142[3]	NA[6]
Suppliers assessed for labor rights risks	**4 635**	1 423[3]	NA[6]
Suppliers assessed for Quality GmP	**561**	162[3]	NA[6]
Supplier engagements stopped due to risk assessment outcomes	**120**	15[3]	NA[6]

[1] TPRM: Third-Party Risk Management
[2] Includes new suppliers and new products, services or sites from existing suppliers. Figures do not include GxP audits (see page 57 for more details).
[3] Data reflect April to December 2019, based on the TPRM program geographical rollout.
[4] Data not available; the TPRM program was not launched.
[5] Follow-up includes more information requested, audits or on-site assessments.
[6] Not available; the specific risk domain was not yet included in TPRM

HEALTH, SAFETY AND ENVIRONMENT PERFORMANCE INDICATORS[1]

	2020	2019	2018
Lost-time injury and illness rate (per 200 000 hours worked)[2]	**0.13**	0.18	0.15
Total recordable case rate (per 200 000 hours worked)[2, 3]	**0.23**	0.35	0.33
Energy use (million gigajoules), on site and purchased	**11.15**	12.74	13.04
Greenhouse gas (GHG) emissions, Scope 1, combustion and process (1 000 tCO_2e)	**296.2**	356.6	334.5
GHG emissions, Scope 1, vehicles (1 000 tCO_2e)	**100.2**	128.4	146.3
GHG emissions, Scope 2, purchased energy (1 000 tCO_2e)	**392.2**	411.6	448.7
GHG emissions, Scope 3, business travel (1 000 tCO_2e)	**27.0**	191.3	211.7
Total GHG emissions, Scope 1 and Scope 2 (1 000 tCO_2e)[4]	**788.6**	896.6	929.5
GHG offsets (1 000 tCO_2)	**35.4**	29.8	54.9
GHG emissions (Scope 1 and Scope 2) per sales (tCO_2e per million USD)	**16.20**	18.86	20.8
GHG emissions (Scope 1 and Scope 2) per associate (tCO_2e)	**7.12**	8.22	8.58
Halogenated volatile organic compounds (VOCs) (t)	**13.18**	26.59	78.98
Non-halogenated VOCs (t)	**446.25**	406.82	480.10
Non-hazardous waste recycled (%)	**86.6**	81.7	82.0
Hazardous waste recycled (%)	**46.9**	58.8	54.9
Non-hazardous waste not recycled (1 000 t)	**8.8**	12.9	12.5
Hazardous waste not recycled (1 000 t)	**34.2**	41.2	47.3
Water withdrawal (million m^3)[5]	**54.7**	66.8	69.5
Water discharged directly to aquatic environment (cooling water) (million m^3)	**46.1**	55.5	57.9
Water consumption (million m^3)[6]	**8.5**	11.2	11.9

[1] The 2020 environmental and resource data published in the Annual Report and the Novartis in Society Report are actual data for the period from January through September, and best estimates for the period from October through December. This data will be updated with actual data in the first quarter of 2021. Significant deviations will be reported on our website and restated in next year's Annual Report.

[2] Data include Novartis associates and third-party personnel managed by Novartis associates.

[3] Data include all work-related injury and illness, whether leading to lost time or not.

[4] Scope 1: combustion and process, and vehicles; Scope 2: purchased energy

[5] Sum of contact water and non-contact (cooling) water use

[6] Water discharged via treatment and water lost

Selected training programs for associates

	All associates	Graduate / entry level	Leaders / talent development
General / cross-functional training programs	**Ethical standards:** E-trainings target all associates with a Novartis email address. All remaining associates are required to be trained face-to-face or through shared kiosks. Training and awareness programs for **health, safety and environment policy** **Quality and safety training:** Topics covered in initial training for all employees include product quality, reporting adverse events and information management. **Comprehensive virtual learning:** LinkedIn Learning provides over 16 000 video-based programs in seven languages. Coursera provides over 4 500 courses from over 200 global universities in 40 languages. In addition, associates can access 10 000 Skillsoft courses, videos and resources. **Novartis Learning Institute:** Offers personal effectiveness, digital capability and language programs, as well as talent acceleration and leadership programs	**Internships and apprenticeships:** At Novartis headquarters and other sites in Switzerland, we offer paid internships and apprenticeships to graduates from high school or commercial colleges, as well as students who are studying for a bachelor's degree. We also offer post-graduate internships.	We have **three leadership development journeys** to enable leadership excellence at different stages, and two talent development programs to develop the succession pipeline with early and emerging talent. In 2020, a total of 5 000 leaders took part in one of these programs to prepare for transition to a new career stage and build sustainable performance in their role. Unbossed Leadership Experience Reverse mentoring programs: • IGNITE: Accelerates leaders' ability to apply a global mindset through self-awareness, curiosity and experimentation in order to drive sustainable business impact • QUEST: Enables participants to become self-aware, authentic and purposeful leaders who accelerate positive change. QUEST leaders inspire others from their authentic selves, live their purpose, shape our culture and make a lasting difference to society. • EMBRACE (Female Leadership Program): Supports leaders to hone an inclusive mindset and behaviors, and help create a more diverse and inclusive workplace
R&D / Regulatory Affairs		**Innovation / discovery postdoctoral fellowships:** Enable aspiring drug hunters to join teams at the Novartis Institutes for BioMedical Research (NIBR) to gain experience in the design and development of breakthrough therapies **"AI for Life" residency program:** A one-year program in Switzerland that enables data-science graduates and researchers to apply their expertise to real-world healthcare challenges **Regulatory Affairs postgraduate program:** A two-year postgraduate training program in Switzerland	
Medical Affairs / Sales & Marketing	**Responsible marketing, promotion and interaction with healthcare professionals:** In-depth training covering promotional and non-promotional materials, events and professional meetings, external funding, engagement with healthcare professionals and healthcare organizations, interactions with patients and patient organizations, and market research	**Europe-based MBA program:** Novartis Oncology offers a two-year, multi-location rotational program across key markets in Europe for recent MBA graduates.	
Other corporate functions / organizations at Novartis	All Novartis associates in **Manufacturing and Quality Assurance** receive ongoing training in topics including quality management systems and third-party oversight.	**Finance postgraduate rotation program:** A three-year development program for recent postgraduates in finance, accounting or business administration	**Coach2Grow:** A program offered in Novartis Business Services to develop coaching skills and encourage unbossed leadership

Task Force on Climate-related Financial Disclosures (TCFD)

Novartis committed in 2020 to fully support the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). This is our first qualitative TCFD disclosure, building on our responses to the CDP climate questionnaire in previous years. We aim to provide quantitative disclosure on climate-related topics in the future as we incorporate the TCFD recommendations into our business.

Governance

BOARD OVERSIGHT

The Governance, Nomination and Corporate Responsibilities Committee of the Novartis Board of Directors receives regular updates on climate risk and opportunities as part of its oversight of environmental, social and governance (ESG) topics. These are scheduled as written updates semi-annually, with verbal updates in alternating quarters.

MANAGEMENT OVERSIGHT

Under the leadership of the CEO, the Executive Committee of Novartis (ECN) has responsibility for approving the company's environmental sustainability strategy, and climate and water targets and goals. The Chief Ethics, Risk & Compliance Officer, a member of the ECN, is responsible for fully integrating climate-related risks into the Enterprise Risk Management (ERM) process, including oversight of actions to reduce exposure to risks. The Chief Sustainability Officer provides an annually updated climate scenario analysis and information on physical risks and transition risks and opportunities to the ECN. The Trust & Reputation Committee, chaired by the CEO, meets every two months to assess progress as part of a quarterly ESG scorecard submission process. It also updates the ECN and the Board on progress and challenges.

RELEVANT DISCLOSURES:

TCFD recommendations (governance)	Novartis disclosures
a) Describe the board's oversight of climate-related risks and opportunities.	Refer to CDP question C1.1b.
b) Describe management's role in assessing and managing climate-related risks and opportunities.	Refer to CDP questions C1.2 and C1.2a.

Strategy

Climate change will have a major impact on our business, including our operations, strategy, financial planning and value chain, as well as on stakeholders such as patients. For example, climate change is already causing extreme heat and poor air quality in some areas, which threaten to exacerbate pre-existing health conditions such as heart failure, lung cancer and respiratory diseases. In addition, an increase in temperature and humidity may cause a proliferation of insects that carry vector-borne diseases, including dengue fever, malaria, Chagas disease and leishmaniasis. Novartis is working to understand and anticipate these risks to ensure we can continue to discover, develop and deliver life-saving medicines.

Novartis has been active in integrating climate and environmental considerations into our financial planning. For example, we apply a threshold of USD 20 million for capital expenditure projects requiring an environmental sustainability review. We also operate with a USD 100 per ton shadow carbon price to help inform our strategic decision-making and budget planning with respect to carbon impacts. This was underlined in 2020 by climate change meeting the financial materiality threshold for inclusion in our core annual report and in our ERM process as part of a broader strategic risk focused on ESG topics.

PROCESSES

Novartis has conducted a long-term sensitivity and stress-testing analysis for climate and water in collaboration with the Massachusetts Institute of Technology (MIT) Joint Program on the Science and Policy of Global Change. The analysis was based on a scenario that aligns to the RCP 6.0 model for temperature change, which assumes that climate policy remains constant in the wake of the Paris Accord after 2030, and that significant technology advancements in low-carbon emissions technologies take time to scale. This represents a conservative approach to risk (assuming greater exposure), and does not assume improvements that would require significant policy or technology changes. The scenario analysis was a multiphase project for detailed climate risk analysis of a key site, and an initial global assessment of 70 critical sites for the production and research portions of the company, examining scenarios in 2030, 2050 and 2070.

In 2020, we conducted a further analysis with MIT of water scarcity risks in three critical water basins in China, Europe and South Africa. The analysis is being used to plan for investments in water stewardship to achieve our water neutrality target.

We provided the outcome of the MIT analyses to Novartis associates in production, procurement, facilities, finance, risk and business continuity, with the aim of supporting the existing ERM process as well as business decisions in areas such as utilities procurement.

PROGRESS

The following Novartis accomplishments in 2020 are relevant to the TCFD recommendations:

- Awarded contracts for a Pan European Virtual Power Purchase Agreement that will deliver 100% renewable electricity and carbon neutrality for procured electricity in Novartis European operations by 2022 through newly built solar and wind projects in Spain
- Completed life cycle assessment (LCA) studies of two *Breezhaler* inhaled products that included the whole product lifecycle, including climate considerations covering the device, active pharmaceutical ingredients and the optional sensor
- Completed a long-term sensitivity and stress-testing analysis for climate and water, as well as a further analysis on water scarcity risks, and provided the results to associates in relevant business functions
- Held focused environmental sustainability risk and ESG risk workshops with a diverse group of internal stakeholders to further prioritize and incorporate climate risks and other ESG risks into the ERM process
- Started a process to assess climate-related risks for our development pipeline and existing medicines. Continued to make progress in research and development across our flagship global health programs, maintaining our focus on diseases that might be impacted by climate change:
  - Announced a new collaboration with Medicines for Malaria Venture and the PAMAfrica consortium to evaluate a new formulation of *Coartem* for infants weighing less than 5 kilograms, for whom there is no current treatment option
  - Launched a clinical study to evaluate the safety and efficacy of *Entresto* in 900 patients with Chagas-related heart failure
  - The Novartis Institute for Tropical Diseases (NITD) launched a Chagas disease drug discovery program pursuing potentially curative therapies
  - Continued development of a compound with the potential to be the first direct antiviral treatment for adults and children with dengue fever, and the first antiviral for prevention of dengue infection

RELEVANT DISCLOSURES:

TCFD recommendations (strategy)	Novartis disclosures
a) Describe the climate-related risks and opportunities the organization has identified over the short, medium, and long term.	Refer to CDP questions C2.1a, C2.3, C2.3a, C2.4 and C2.4a.
b) Describe the impact of climate-related risks and opportunities on the organization's businesses, strategy, and financial planning.	Refer to CDP questions C2.2, C2.3a, C2.4a, C3.1, C3.1d, C3.1e and C3.1f.
c) Describe the resilience of the organization's strategy, taking into consideration different climate-related scenarios, including a 2°C or lower scenario.	Refer to CDP questions C3.1a and C3.1b.

Risk management

Novartis integrates risk and strategy issues in a cross-functional ERM process. All risks are consolidated in a framework called the Novartis Risk Compass, which enables senior management, the ECN and the Novartis Board of Directors to focus on key strategic risks and to align the company strategy to our risk exposure. For more information on how we identify, assess and manage our risks, please see the section "Holding ourselves to high ethical standards."

In 2020, climate change was recognized as a financially material risk to Novartis, and was disclosed in our 2020 filing to the US Securities and Exchange Commission. Novartis is potentially exposed to physical risks from varying extreme weather events such as hurricanes, tornadoes, floods, or any other event that may result from the impact of climate change on the environment. For example, some of our production facilities are located in places that, because of increasingly violent weather events, sea level rise, or both, are increasingly at risk of substantial flooding. Other facilities that depend on the

availability of significant water supplies are located in areas where water is increasingly scarce. As a result, we could experience increased costs (production or other), business interruptions, and destruction of facilities, all of which would have a material adverse effect on our business, financial condition, or results of operations. Our distributed supply chains are also vulnerable to these effects.

Climate change may also trigger the adoption of new regulatory requirements across the globe. Such legislation could include increased requirements to invest in technology to reduce energy use, water use and greenhouse gas emissions, beyond what we expect to invest in our existing plans. In addition, legislation could include carbon pricing, climate risk disclosure mandates, and changes in zoning or building codes to increase climate resilience. The combined impact of these transition risks could increase our direct operating costs and result in the same impact across our supply chain.

In addition to the ERM process, our global materiality assessment evaluates our impact on society and the environment through a dialogue with internal and external stakeholders about value, risks and opportunity. Please see page 22 for more information.

RELEVANT DISCLOSURES:

TCFD recommendations (risk management)	Novartis disclosures
a) Describe the organization's processes for identifying and assessing climate-related risks.	Refer to CDP questions C2.1, C2.1a, C2.2 and C2.2a.
b) Describe the organization's processes for managing climate-related risks.	Refer to CDP questions C2.1, C2.1a and C2.2.
c) Describe how processes for identifying, assessing, and managing climate-related risks are integrated into the organization's overall risk management	Refer to CDP question C2.2.

Metrics and targets

- Novartis has a goal to be carbon neutral in our own operations by 2025.
- Novartis has a goal to be carbon neutral across the entire value chain (Scopes 1, 2 and 3) by 2030, and to be plastic and water neutral by 2030.
- Novartis has an approved 1.5°C Science Based Target for 35% absolute emissions reductions across Scopes 1, 2 and 3 by 2030.
- In 2020, Novartis reduced greenhouse gas emissions by 19% when compared to our 2016 baseline.
- Additional details on our emissions and other data can be found in the Novartis Environmental Sustainability and Occupational Health and Safety Data Supplement. Our most recent CDP climate questionnaire has details of methodologies, climate mitigation and climate adaptation efforts. Both are available on the Novartis website.

RELEVANT DISCLOSURES:

TCFD recommendations (metrics and targets)	Novartis disclosures
a) Disclose the metrics used by the organization to assess climate-related risks and opportunities in line with its strategy and risk management process.	Refer to CDP questions C4.2, C4.2a, C4.2b and C9.1.
b) Disclose Scope 1, Scope 2, and, if appropriate, Scope 3 greenhouse gas (GHG) emissions, and the related risks.	Refer to CDP questions C6.1, C6.3 and C6.5.
c) Describe the targets used by the organization to manage climate-related risks and opportunities and performance against targets.	Refer to CDP questions C4.1, C4.1a, C4.1b, C4.2, C4.2a and C4.2b.

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				Annual Review 2020 p.48
102-2	Activities, brands, products and services				p.7
102-3	Location of headquarters				Annual Review 2020 p.48
102-4	Location of operations				Annual Report 2020 F-83
102-5	Ownership and legal form				Annual Report 2020 A-9
102-6	Markets served				Annual Review 2020 p.14
102-7	Scale of the organization				p.4
102-8	Information on employees and other workers	**6**	8 12		p.71, p.73
102-9	Supply chain	**3, 4, 5, 6, 8, 10**			p.25-26
102-10	Significant changes to the organization and its supply chain				Annual Report 2020 F-15
102-11	Precautionary principle or approach	**7**			Annual Report 2020 p.11
102-12	External initiatives				p.88
102-13	Membership of associations	**1, 8**			p.88
102-14	Statement from senior decision-maker				p.10
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 2020 p.44
102-19	Delegating authority				p.12
102-20	Executive-level responsibility for economic, environmental and social topics				p.12
102-21	Consulting stakeholders on economic, environmental and social topics		16		p.14
102-22	Composition of the highest governance body and its committees		5 16		Annual Report 2020 p.133
102-23	Chair of the highest governance body		16		Annual Report 2020 p.134
102-24	Nominating and selecting the highest governance body		5 16		Annual Report 2020 p.133
102-25	Conflicts of interest		16		Annual Report 2020 p.145
102-26	Role of highest governance body in setting purpose, values and strategy				Annual Report 2020 p.142
102-27	Collective knowledge of highest governance body		4		p.12
102-28	Evaluating the highest governance body's performance				Annual Report 2020 p.141
102-29	Identifying and managing economic, environmental and social impacts		16		Annual Report 2020 p.145
102-30	Effectiveness of risk management processes				Annual Report 2020 p.146
102-31	Review of economic, environmental and social topics				Annual Report 2020 p.145
102-32	Highest governance body's role in sustainability reporting				p.12
102-33	Communicating critical concerns				p.12
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 2020 p.91
102-36	Process for determining remuneration				Annual Report 2020 p.94
102-37	Stakeholders' involvement in remuneration		16		Annual Report 2020 p.94
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				p.14
102-41	Collective bargaining agreements	**3**	8		p.71
102-42	Identifying and selecting stakeholders				p.14
102-43	Approach to stakeholder engagement				p.14
102-44	Key topics and concerns raised				p.12
102-45	Entities included in the consolidated financial statements				Annual Report 2020 F-83
102-46	Defining report content and topic boundaries				p.84
102-47	List of material topics				p.86
102-48	Restatements of information				p.68
102-49	Changes in reporting				p.68
102-50	Reporting period				p.68
102-51	Date of most recent report				p.68
102-52	Reporting cycle				p.68
102-53	Contact point for questions regarding the report				p.68
102-54	Claims of reporting in accordance with the GRI Standards				p.68
102-55	GRI Content Index				p.78
102-56	External assurance				p.90
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 ESG Report 2020
200 – ECONOMIC					
201-1	Direct economic value generated and distributed				Annual Review 2020 p.8, p.13
201-2	Financial implications and other risks and opportunities due to climate change	**7, 8, 9**	13		Annual Report 2020 p.22
203-2	Significant indirect economic impacts		1 2 8 10 17		p.16, p.89
204-1	Proportion of spending on local suppliers				Novartis ESG Index
205-1	Operations assessed for risks related to corruption	**10**	16		p.20
206-1	Legal actions for anti-competitive behavior, anti-trust and monopoly practices				Annual Report 2020 F-49
207-1	Approach to tax				Annual Report 2020 p. 171 Novartis Tax Policy Statement
207-2	Tax governance, control, and risk management				Annual Report 2020 p.171

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 2020
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 2020
302-2	Energy consumption outside of the organization	**8**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2020
302-3	Energy intensity	**8**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2020
302-4	Reduction of energy consumption	**7, 8, 9**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2020
302-5	Reductions in energy requirements of products and services	**8, 9**	7 8 12 13		Novartis Health, Safety and Environment (HSE) Data 2020
303-1	Water withdrawal by source	**7, 8**	6 12		Novartis Health, Safety and Environment (HSE) Data 2020
303-2	Water sources significantly affected by withdrawal of water	**7, 8, 9**	6 12		Novartis Health, Safety and Environment (HSE) Data 2020
303-3	Water recycled and reused	**7, 8, 19**	6 12		Novartis Health, Safety and Environment (HSE) Data 2020
305-1	Direct (Scope 1) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2020
305-2	Energy indirect (Scope 2) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2020
305-3	Other indirect (Scope 3) GHG emissions	**7, 8**	3 12 13 14 15		Novartis Health, Safety and Environment (HSE) Data 2020
305-4	GHG emissions intensity	**8**	13 14 15		Novartis Health, Safety and Environment (HSE) Data 2020
305-5	Reduction of GHG emissions	**7, 8, 9**	13 14 15		Novartis Health, Safety and Environment (HSE) Data 2020
305-6	Emissions of ozone-depleting substances (ODS)	**7, 8, 9**	3 12		Novartis Health, Safety and Environment (HSE) Data 2020
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 2020
306-1	Water discharge by quality and destination	**7, 8, 9**	3 6 12 14		Novartis Health, Safety and Environment (HSE) Data 2020
306-2	Waste by type and disposal method	**7, 8**	3 6 12		Novartis Health, Safety and Environment (HSE) Data 2020
308-1	New suppliers that were screened using environmental criteria	**8**			p.25
308-2	Negative environmental impacts in the supply chain and actions taken				p.25

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGC PRINCIPLE	UN SDG	COMMENTS	REFERENCE
400 – SOCIAL					
401-1	New employee hires and employee turnover	6	5 8		p.71
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	p.73
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		p.71
404-2	Programs for upgrading employee skills and transition assistance programs				Annual Review 2020 p.20
405-1	Diversity of governance bodies and employees	6	5 8		p.71
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	4	8		p.25, p.72
412-1	Operations that have been subject to human rights reviews or impact assessments	1	16		p.26
414-1	New suppliers that were screened using social criteria				p.25, p.72
414-2	Negative social impacts in the supply chain and actions taken				Novartis Third Party Code p.25
415-1	Political contributions				Public Policy & Advocacy
416-2	Incidents of noncompliance concerning the health and safety indicators impacts of products and services				p.55
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	p.56 Annual Report 2020 p.35
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data				p.69
419-1	Noncompliance with laws and regulations in the social and economic area				Annual Report 2020 F-49

Sustainability Accounting Standards Board (SASB) Index

Health Care Sector
Biotechnology and Pharmaceuticals Industry
The Novartis Sustainability Accounting Standards Board (SASB) Index aligns with the Biotechnology and Pharmaceutical Industry guidelines. Data and information disclosed are sourced from the Novartis 2020 Corporate Reporting suite (Annual Review; Annual Report/Form 20-F; Novartis in Society ESG Report), and Novartis public policies and positions.

SASB indicator		Novartis references
SAFETY OF CLINICAL TRIAL PARTICIPANTS		
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	We have mechanisms in place to protect all trial participants when consenting to the research, during the conduct of the trial, and after completion. We have additional processes in place to protect vulnerable patients. We ensure voluntary informed consent to the research, including the right to withdraw from the trial at any time and the right to withdraw consent for the collection and use of their personal data. Novartis Position on Responsible Clinical Trials Novartis Commitment to Patients and Caregivers Information for patients and caregivers Ethics in Clinical Trials Human Rights Guideline (p.6) – Procedure to obtain participants' free, prior and informed consent
HC-BP-210a.2	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	Novartis received six FDA inspections for which one resulted in a Form 483. In each case, corrective and preventative actions were taken. Novartis in Society ESG Report 2020 (p.57)
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	All material legal proceedings are disclosed within the Annual Report and accounts (p.F-49).
ACCESS TO MEDICINES		
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	Novartis in Society ESG Report 2020 (p.30-53) *Novartis Access*
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	Novartis has tuberculosis and malaria products on the WHO List of Prequalified Medicinal Products. Novartis products Sandoz products
AFFORDABILITY & PRICING		
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	Not reported
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	We report these changes annually within our Novartis in Society US Report.
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	Not reported
DRUG SAFETY		
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Available via FDA Adverse Event Reporting website
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Available via FDA Adverse Event Reporting website
HC-BP-250a.3	Number of recalls issued, total units recalled	In 2020, Novartis initiated 27 recalls (vs. 29 in 2019 and 42 in 2018). There were no global recalls. Novartis in Society ESG Report 2020 (p.56)

SASB indicator		Novartis references
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	Novartis in Society ESG Report 2020 (p.67)
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	Novartis in Society ESG Report 2020 (p.57)
COUNTERFEIT DRUGS		
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	Novartis in Society ESG Report 2020 (p.58-59)
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	Novartis in Society ESG Report 2020 (p.58-59)
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	We investigated 247 incidents of suspected falsified medicines, which led to 60 successful enforcement actions and the seizure of 1.7 million medicines (unit dosage forms) by law enforcement and health authorities. Novartis in Society ESG Report 2020 (p.59)
ETHICAL MARKETING		
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	All material legal proceedings are disclosed within the Annual Report and accounts (p.F-49).
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	Procedures for off-label requests outlined; further information on ethical marketing contained in Professional Practices Policy (p.5) on Promotional and Non-Promotional Materials
EMPLOYEE RECRUITMENT, DEVELOPMENT & RETENTION		
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	Novartis in Society ESG Report 2020 (p.42, p.61)
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	Voluntary/overall turnover rate: 5.2%/10.1%; high performers voluntary turnover rate: 4.2% Novartis in Society ESG Report 2020 (p.71)
SUPPLY CHAIN MANAGEMENT		
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	(1) For the manufacture of medical devices, we hold the relevant certifications from ISO and other notified bodies. For all manufacturing, supply and distribution of Novartis pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate health authorities (FDA, EMEA, WHO, SwissMedic), that confirm after inspection that our duties, including our quality management systems, comply with their regulatory requirements. All Novartis employees in Manufacturing and Quality Assurance are continuously trained to maintain the skills and knowledge needed to manufacture medicine safely, compliantly and effectively. These trainings include Aseptic Operator, Enhanced Third-party Oversight, Investigation Certification Program and Quality Management Systems. Novartis in Society ESG Report 2020 (p.55) Novartis Quality Management System (QMS) Product and patient safety training (2) Not reported
BUSINESS ETHICS		
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	All material legal proceedings are disclosed within the Annual Report and accounts (p.F-49).
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	Professional Practices Policy (p.5) Payments to Healthcare Professionals
ACTIVITY METRICS		
HC-BP-000.A	Number of patients treated	769 million Novartis in Society ESG Report 2020 (p.9)
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	(1) Novartis Global Product Portfolio (Novartis Innovative Medicines) Sandoz Advanced Accelerator Applications (2) 160+ Novartis Annual Review 2020 (p.29)

Appendix: corporate responsibility material topic boundaries

CR MATERIAL TOPIC BOUNDARIES

We have analyzed topics identified as material by the 2017 corporate responsibility materiality assessment 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 high 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 falsified medicines	■	■	■
Health education and prevention		■	■
Our people	■	■	■
Respect for human rights	■	■	■
Responsible supply chain	■	■	■
Environmental sustainability	■	■	■

To align the 2020 Novartis in Society (NiS) Report with the priority topics identified in the 2017 corporate responsibility materiality assessment, we mapped each of these topics within one or more of the relevant sections of the 2020 NiS Report. When a priority topic was adequately covered in the 2020 Novartis Annual Report and the 2020 Novartis Annual Review, we provided cross-references in the 2020 NiS Report.

The mapping exercise is detailed on the following page and shows the priority topic and relevant page number(s) within the NiS Report, the “building trust with society” focus area the topic sits within, and the mapping rationale.

#	Priority topic (pages in 2020 NiS Report or on novartis.com)	"Building trust with society" focus area(s)	Rationale
1	Ethical and compliant behavior (pages 18-28)	Holding ourselves to high ethical standards	This is the cornerstone of the pillar of our strategy to build trust with society (holding ourselves to high ethical standards).
2	Transparency (page 28)	Holding ourselves to high ethical standards	Transparency is part of our commitment to do business responsibly and is strongly linked to compliance.
3	Pricing (pages 30-40)	Being part of the solution on pricing and access	The Novartis access principles (see page 31) 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 40-45)	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) (Novartis ESG index, page 14 – intellectual property access)	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 34-36)	Being part of the solution on pricing and access	Novartis has been pioneering social business models for more than 10 years. Our experience in implementing social business activities and community health education has provided important lessons for expanding access to affordable medicines and delivering quality care in lower-income countries.
7	Innovative technologies (pages 32; 43; 44-45; 48; 51; 55-56; 58-59)	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 employing digital technologies to help optimize diagnosis and disease management in Ghana. We also report on the use of technology to help in our fight against falsified medicines, and engage with patient communities where they live, reducing the need to travel.
8	Drug resistance (pages 52-53)	Addressing global health challenges	The Sandoz Statement of Intent explains our strategy on addressing drug resistance.
9	Financial health and performance (pages 16; 30-45; 46-53; 54-67)	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: On page 16 of this report, we explain how we value our impact through our approach called Novartis social, environmental and economic (SEE) impact valuation. The 2020 Annual Report and 2020 Annual Review, referenced on page 92 of this report, also provide information on financial health and performance. We reference companywide economic sustainability on pages 6-7 and 8-9. Further, with transformative innovation as a cornerstone of our strategy and foundation for our future, we consider the "build trust with society" pillar 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 55-57; performance indicators on page 57)	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 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 60-64; people performance indicators on page 71)	Being a responsible citizen	Our culture is central to our sustainability, and we have outlined the steps taken in 2020 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 53)	Being a responsible citizen	In the section "Enhancing environmental sustainability," we address the three priority topics "pharmaceuticals in the environment," "pollution waste and effluents" and "sustainable use of resources." Our work in the Antimicrobial Resistance (AMR) Industry Alliance is included in the "Taking a holistic approach to antimicrobial resistance" section (page 52). 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 64-65)		
14	Sustainable use of resources (pages 64-67)		

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, and has been defined as a key focus area of our strategy to build trust with society. 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 high ethical standards" (pages 26-27).

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

2020 MA webinars

Measuring and Evaluating Social Outcomes of Access Initiatives (October; password: novartis2020)
Wealth and Health – Reframing Healthcare Costs as Economic Investments (July)
Embracing Double Materiality in Responding to the COVID-19 Pandemic (June)
Rethinking Healthcare System Strengthening (May)
Reimagine Access – Committing to the Access Principles (April)

For more webinars, visit our website.

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 the AMR Action Fund, an industry initiative
- Joined the Responsible Antibiotics Manufacturing Platform
- 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
- Signatory to the World Business Council for Sustainable Development's CEO Guide to 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
- Signatory to the Partnering Against Corruption Initiative (PACI), a World Economic Forum initiative
- Support for the Pharmaceutical Industry Principles for Responsible Supply Chain Management set by the Pharmaceutical Supply Chain Initiative (PSCI)
- Support for the Task Force on Climate-related Financial Disclosures (TCFD)
- Joined Sustainability 30 (S30), a group of sustainability executives from 30 of the world's leading companies working to accelerate business action on sustainability
- Signatory to the UN Global Compact's CEO Water Mandate
- Joined IMI-PREMIER (Prioritization and Risk Evaluation of Medicines in the Environment)
- 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:

- Interpharma, Intergenerika scienceindustries, economiesuisse, and SwissHoldings in Switzerland
- Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO), Association for Accessible Medicines (AAM), AdvaMed in the US
- Global and regional associations, including the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Alliance for Regenerative Medicines (ARM)
- European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio, Medicines for Europe, EUCOPE, MedTech in the EU
- National associations in most markets where Novartis has a legal subsidiary

Appendix: measuring and valuing our impact

Independent Assurance Report on the 2020 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 2020 global health & corporate responsibility (GH&CR) reporting of Novartis AG and its consolidated subsidiaries (Novartis Group) included in the Novartis in Society ESG Report 2020.

SCOPE AND SUBJECT MATTER

Our limited assurance engagement focused on the following 2020 data and information disclosed in the consolidated Novartis in Society ESG Report 2020 of the Novartis Group for the year ended December 31, 2020:

- The "ethical business practices performance indicators" on page 69, the "access to healthcare performance indicators" on page 70, the "people performance indicators" on page 71, the "supply chain performance indicators" on page 72, and the "health, safety and environment performance indicators" on page 73 (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 as "the 2017 Corporate Responsibility Materiality Assessment Results Report" on page 68 and as applied to the Novartis in Society ESG Report 2020 as indicated on pages 84 to 87
- Reporting processes and related controls in relation to data aggregation of GH&CR indicators

The following indicators are not subject to this Assurance Report. Consequently, we do not express any conclusion on this data.

- The "pharmacovigilance, safety profile and quality of drugs performance indicators" section (page 72)
- The indicators as noted within the "ethical business practices performance indicators" section (page 69), as follows:
  - The "animal testing indicators"
- The indicators as noted within the "people performance indicators" section (page 71), as follows:
  - 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"
  - The "number of employees by employment type (full-time and part-time), by gender"

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 Ethics
- Procedures by which the data for the GH&CR indicators reporting is gathered, collected and aggregated internally

The management reporting process with respect to the sustainability-linked bond "strategic innovative therapies patient reach" and "flagship programs patient reach" GH&CR indicators were assessed against the terms and conditions as outlined within the Final Listing Prospectus dated 21 September 2020.

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 GH&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 the 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 for the period ended December 31, 2020, in all material respects that:

- The GH&CR indicators outlined in the scope and subject matter section and disclosed in the 2020 GH&CR reporting of the Novartis Group are not stated in accordance with Novartis Group internal policies and procedures;
- The sustainability-linked bond "strategic innovative therapies patient reach" and "flagship programs patient reach" GH&CR indicators are not stated in accordance with the terms and conditions as outlined within the Final Listing Prospectus dated 21 September 2020;
- The materiality determination and stakeholder engagement process of Novartis does not adhere to the principles and guiding factors defined by 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 25, 2021

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.

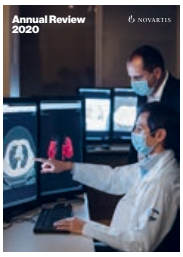
www.novartis.com/reportingsuite

Novartis in Society ESG Report

The Novartis in Society ESG Report details progress on environmental, social and governance topics and demonstrates the company's commitment in global health and corporate responsibility.

www.novartis.com/nisreport2020

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 2020.

www.novartis.com/ar20english

www.novartis.com/ar20german

Digital reporting homepage

We present digital and interactive versions of the Annual Review and Novartis in Society ESG Report.

www.reporting.novartis.com

Follow us on

Disclaimer

These materials contain forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding the impact of the COVID-19 pandemic on certain therapeutic areas including dermatology, ophthalmology and the Sandoz retail business, and on drug development operations; or regarding potential future, pending or announced transactions; regarding potential future sales or earnings of the Group or any of its divisions; 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: uncertainties regarding the success of key products and commercial priorities; global trends toward healthcare cost-containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; 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; the potential that the strategic benefits, operational efficiencies or opportunities expected from our recent transactions or our organizational, structural and cultural transformations may not be realized or may take longer to realize than expected; our performance on environmental, social and governance measures; uncertainties in the development or adoption of potentially transformational technologies and business models; uncertainties regarding potential significant breaches of information security or disruptions of our information technology systems; our reliance on outsourcing key business functions to third parties; our ability to attract, integrate and retain key personnel and qualified individuals; uncertainties regarding actual or potential legal proceedings, including, among others, litigation and other legal disputes with respect to our recent transactions, product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the development of the products described in this Novartis in Society ESG Report; 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; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; the impact of pandemic diseases such as COVID-19 on enrollment in, initiation and completion of our clinical trials in the future, and research and development timelines; uncertainties involved in predicting shareholder returns; 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
Production: Management Digital Data AG, Lenzburg, Switzerland
Photography: Getty Images for Novartis
Alexander Kumar

Photo Dr. Juliet Akoth (seated) calls a patient to a consultation room at Kitui Hospital, Kenya. Dr. Akoth enrolled in Echo for Life, a Novartis-sponsored training program in partnership with the University of Nairobi. Kitui Hospital has increased diagnosis of cardiovascular diseases and reduced the waiting time for cardiograms from over a month to less than a week.

Photo back cover Dr. Juliet Akoth poses with a Butterfly IQ™ ultrasound portable device during a home visit in Kitui, Kenya. Dr. Akoth enrolled in Echo for Life, a program sponsored by Novartis in partnership with the University of Nairobi to train healthcare professionals in the diagnosis and treatment of cardiovascular disease.


CONSULTATION
ROOM 4A

NOVARTIS