

Novartis in Society

Integrated Report 2021



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Welcome to the first Novartis in Society Integrated Report. This report highlights progress against our strategy and describes how we create value for our stakeholders. It is intended for all Novartis stakeholders, particularly shareholders, investors, and environmental, social and governance (ESG) professionals.

This report combines our Novartis in Society ESG Report and Annual Review. It is published in conjunction with our regulatory disclosure documents: our [Annual Report](#) filed with the SIX Swiss Exchange, and our [Form 20-F](#) filed with the US Securities and Exchange Commission (SEC). Details of our annual reports can be found at www.reporting.novartis.com.

Our Novartis in Society Integrated Report contains three main sections:

- Our approach, including details of our business environment, stakeholders, strategy and risk management
- Our performance, including financial performance and performance against our five strategic priorities: deliver transformative innovation, embrace operational excellence, go big on data and digital, unleash the power of our people, and build trust with society
- Corporate governance and our approach to executive compensation

Content of this report is subject to approval by the Governance, Nomination and Corporate Responsibilities Committee of the Novartis Board of Directors prior to publication. PricewaterhouseCoopers AG (PwC) has provided limited independent assurance on specific data and on our materiality assessment in this report (see [pages 114-115](#)).

All financial data is taken from our Annual Report, prepared in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB). This report has been prepared in accordance with the GRI Standards: Core option. We used other frameworks as references, including the Integrated Reporting Framework and SASB Standards provided by the Value Reporting Foundation. Further details of our compliance with the GRI and SASB Standards can be found on [pages 102-107](#).

In addition, Novartis supports the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). Our TCFD disclosure can be found on [pages 108-111](#).

All information reflects the continuing operations of the Novartis Group, including the various changes in the Group's portfolio of activities in prior years. Unless otherwise stated, data in this report relates to our financial year, which runs from January 1 to December 31. Environmental data is based on nine-month actual data (January to September 2021) plus three-month estimates. This data will be restated with actual figures on our [website](#) during the second half of 2022.

Please note that all product names printed in italics in this report are trademarks owned by, or licensed to, the Novartis Group.

Cover photo Silvia Bally, a Novartis employee
at a production facility in Stein, Switzerland

2021 at a glance

766 m
Patients reached
with Novartis medicines

21
Major approvals (US, EU, Japan, China)
including two new molecular entity approvals from the US Food and Drug Administration (FDA)

3
Breakthrough therapy designations
from the FDA

51.6 bn
Net sales
growing 4% in constant currencies from 2020 (USD)

16.6 bn
Core operating income
growing 6% in constant currencies from 2020 (USD)

7.4 bn
Total dividends paid
to shareholders (USD)

71 bn
Treatments supplied
through Novartis facilities

300 000
Patients using AI Nurse
our cardiovascular disease app in China

78
Employee engagement
score in Q4 (out of 100), 5 points higher than the industry benchmark

1 bn
Antimalarial treatments
delivered in the past two decades in endemic countries, more than 90% of which were supplied without profit

40 m
Doses produced
of the Pfizer-BioNTech vaccine for COVID-19

-34%
Greenhouse gas emissions
reduced vs. 2016 baseline (Scope 1 and Scope 2)

Ratings and recognition

Access to Medicine Index
Novartis ranked second in 2021, retaining our 2018 position

Dow Jones Sustainability World Index
Novartis was included in both the DJSI World and Europe indices

Sustainalytics
Novartis leads in the pharmaceutical subindustry group

World's 25 Best Workplaces™
Novartis was included in Fortune's World's 25 Best Workplaces™ list

Bloomberg Gender-Equality Index
Novartis was included for the third year in a row



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Photo Jian Zhang cooks in his kitchen in Shenyang, China. Mr. Zhang, who has heart failure, is one of approximately 300 000 people in China using AI Nurse, a digital health app that makes it easier for patients to manage cardiovascular disease progression.

Chairman's letter

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Looking ahead, we are confident we can maintain our momentum as we remain focused on operational excellence and science-based innovation

Joerg Reinhardt

Novartis delivered a solid performance in 2021. Strong demand for heart failure medicine *Entresto*, psoriasis and autoimmune disease treatment *Cosentyx*, and recently launched therapies such as multiple sclerosis drug *Kesimpta* helped us increase sales and net profit as we maintained cost discipline. Looking ahead, we are confident we can maintain our momentum as we remain focused on operational excellence and science-based innovation.

With more than 12 new drug approvals by the US Food and Drug Administration in the past five years, we are committed to our long-term research and development (R&D) strategy, which is aimed at creating breakthrough therapies for patients with high unmet medical needs. We strive to build leading market positions in fast-growing areas of medicine and broaden patient reach to deliver on our purpose to improve and extend people's lives around the world.

Last year we continued to make significant investments in R&D, including in cutting-edge medical technologies such as radioligand therapy and small-interfering RNA. Our clinical pipeline covers a diverse area of noncommunicable diseases such as cancer and heart disease. This is positioning us well for the

future amid the rising global need for innovative chronic therapies as we continue to strengthen patient engagement.

We started a strategic review of our Sandoz generics division with the goal of strengthening its operational performance and maximizing shareholder return. Also, we divested our investment in Roche Holding AG, reflecting our strategy to create a focused medicines company.

Acute pressure on societies and healthcare systems due to the COVID-19 pandemic remains high. In this challenging environment, our focus on operational excellence and shift to flexible working by our employees continued to help us navigate the crisis. In a post-pandemic world, these lessons will enable us to maintain high levels of resilience and operational efficiency while continuing to position us as an employer of choice in a changing work environment.

We also made further progress in our environmental, social and governance (ESG) activities, which are an essential part of our strategy and an important reputation driver. Besides our progress in reducing our environmental footprint, we broadened patient access to our strategic medicines and launched a new program in the United

States to address health disparities – all with the intention to create more equitable and sustainable healthcare systems and support the United Nations' efforts to achieve the Sustainable Development Goals.

The Board of Directors took further action to strengthen governance. We paved the way for comprehensive ESG oversight and changed the leadership of the Compensation Committee and the Governance, Nomination and Corporate Responsibilities Committee. We also nominated a new Board member. Together with the Executive Committee, the Board of Directors will continue the intensive dialogue with all stakeholder groups with a view to further strengthen trust in society and to maximize shareholder return.

I thank you for the confidence you have placed in our company and am pleased to be able to propose a dividend increase of 3.3% to CHF 3.10 at the next Annual General Meeting.

Sincerely,

Joerg Reinhardt
Chairman of the Board of Directors

Our impact on the world remains extraordinary, with 766 million patients reached in 2021

Vas Narasimhan



CEO's letter

2021 was another year of rapid change for the biopharmaceutical industry and the world. The pandemic continues to disrupt care for patients across the spectrum of disease, creating a syndemic, or confluence of epidemics, that requires healthcare systems to cope with COVID-19 while caring for patients with chronic diseases.

Through the challenges ahead, there are reasons to be optimistic a healthier future is within our grasp – including the ways our industry has brought to this crisis the power of technology and shown once again the extraordinary ability of science to overcome humanity's greatest tests.

As we reimagine medicine at Novartis, our unwavering focus on our strategy and purpose enabled us to continue creating value for patients, healthcare professionals, healthcare systems, employees, shareholders and society.

The adaptability and commitment of our employees, together with the resilience of our operations and capabilities in data science and technology, minimized disruptions to our business. Many changes, such as hybrid working, are now business as usual.

Our impact on the world remains extraordinary, with 766 million patients reached in 2021. We received 21 approvals in the US, the EU, Japan and China, including two new molecular entities. Our siRNA therapy *Leqvio* is now approved in more than 50 countries, including the US. We also demonstrated the strength of our in-market portfolio, with medicines like *Cosentyx*, *Entresto*, *Zolgensma*, *Kesimpta* and *Kisqali* driving growth.

We continued to go big on data science and digital technologies,

integrating our data and digital teams within Customer & Technology Solutions to maximize efficiency as we scale value-driving projects. For example, AI Nurse, developed in collaboration with Tencent, helps patients with heart failure and other cardiovascular diseases manage disease progression. It is used by 300 000 patients in China.

Novartis also continued doing our part to end the pandemic, quickly scaling up production of COVID-19 vaccines. We're proud to have helped develop a potential new treatment option with Molecular Partners.

Our financial performance highlights the progress we've made and drives confidence for the future – with 4% growth in net sales and 6% growth in core operating income from the previous year. We're confident we'll drive consistent growth to 2030 and beyond. We've also initiated a strategic review of Sandoz to enable Sandoz to be positioned as a long-term leader in the generics industry.

Emerging from the COVID-19 pandemic, I remain optimistic about a new era in medicine. Stakeholders like you play an important role in that. On behalf of all of us at Novartis, we're grateful for your contributions on the journey of reimagining medicine.

Sincerely,

Vas Narasimhan
Chief Executive Officer

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Novartis reimagines medicine to improve and extend people's lives. Our medicines, which reached 766 million patients around the world in 2021, address most major disease areas, from cancer to heart disease to rare genetic disorders.

Our purpose

Our purpose is to 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.

Our company

We have two global operating divisions: Innovative Medicines, which specializes in patent-protected medicines, and Sandoz, which sells generics and biosimilars. These divisions are supported by our research and development teams, our manufacturing operations, our business services and technology organization, and our corporate functions.

Innovative Medicines

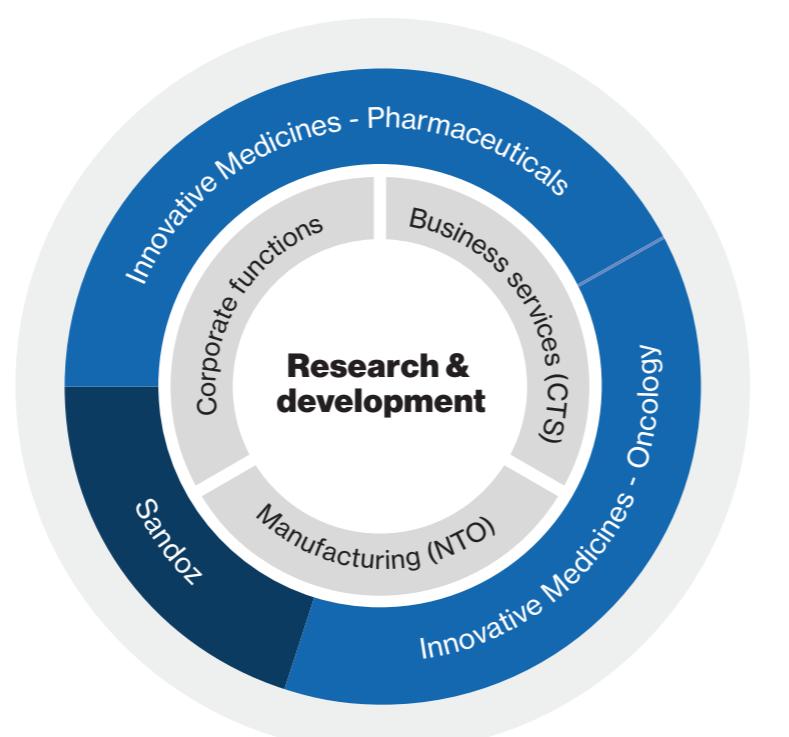
The Innovative Medicines Division has two business units:

Novartis Pharmaceuticals

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

Novartis Oncology

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



Sandoz

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

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.

Novartis Technical Operations (NTO)

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

Customer & Technology Solutions (CTS)

consolidates digital and other 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, global health, and ethics, risk and compliance.

Our global footprint

Novartis headquarters are located in Basel, Switzerland. We have more than 380 sites – including research and development locations, offices and production facilities – around the world.

Major Novartis facilities

(by area of site and/or number of employees)



Europe



North America



Asia

Switzerland

Basel

Global headquarters of Novartis

Stein

Production of a range of medicines, including cell and gene therapies; production of active pharmaceutical ingredients

Austria

Kundl and Schafenau

Production of biotechnological products, drug products and finished products, anti-infectives, active drug substances and nucleic acids; product development

Germany

Barleben

Production of a range of generics finished dosage forms

Holzkirchen

Sandoz Division production of transdermal delivery systems, biosimilars development, and certain international and global service functions

Slovenia

Menges

Production of drug substances and drug intermediates

France

Huningue

Production of drug substances for clinical and commercial supply

USA

East Hanover, NJ

Innovative Medicines Division US headquarters; research and development

Cambridge, MA

Research and development

China

Shanghai

Research and development

India

Hyderabad

The largest of our five global service centers supporting all Novartis business units

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How our business works

Research & development

Finding and developing new treatments for patients is at the core of our business. More than three-quarters of our sales come from innovative patent medicines. Our pipeline of investigational treatments, which spans around 50 diseases, has the potential to transform the standard of care for millions of patients worldwide.

Procurement & manufacturing

We have 53 manufacturing sites worldwide. These sites produce our patent medicines, devices, generics and biosimilars, as well as some raw materials we need for manufacture. Across our sites, we maintain high quality standards to ensure patient health and safety, and we require our suppliers to do the same.

Marketing & distribution

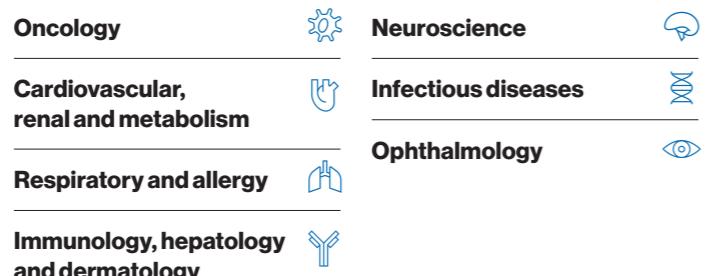
We aim to deliver our treatments to as many people as possible. We work with customers and payers, such as hospitals, physicians, insurance groups and governments, to understand their needs and improve outcomes for patients. We use a range of access approaches to ensure our medicines reach underserved patient populations.

Our medicines

Our medicines address most major disease areas and are sold in approximately 155 countries around the world.

Our manufacturing facilities supplied 71 billion treatments in 2021.

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.



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.



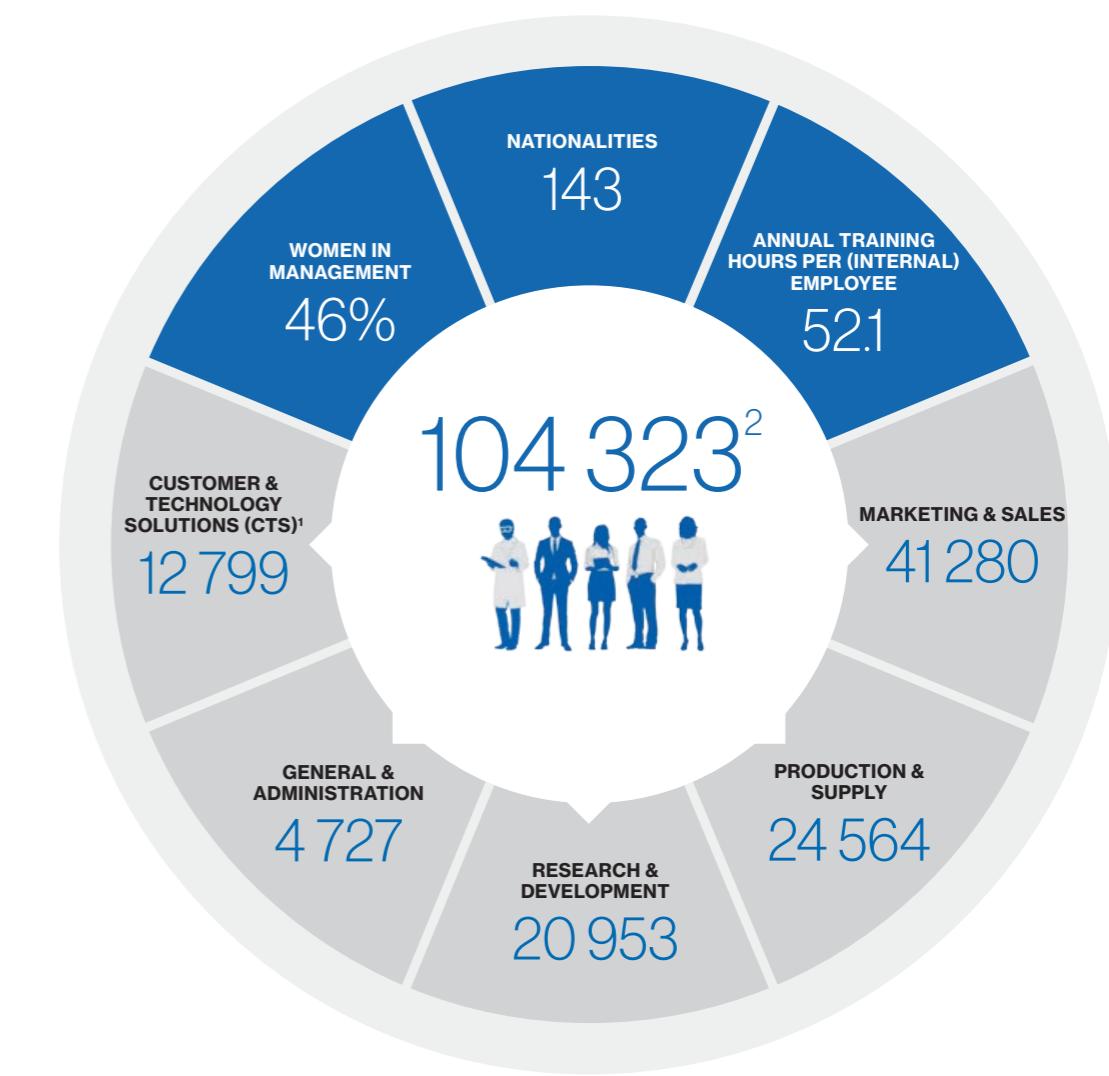
Novartis top 10 innovative medicines

Brand / 2021 net sales (USD, millions)

Cosentyx	4 718
Entresto	3 548
Gilenya	2 787
Lucentis	2 160
Tasigna	2 060
Promacta/Revolade	2 016
Tafinlar + Mekinist	1 693
Jakavi	1 595
Xolair	1 428
Sandostatin	1 413

Our people

The greatest strength of Novartis is our people, whose diversity, energy and creativity are crucial to our success. Around the world, we employ 108 514 people (104 323 full-time equivalent positions), with around one-fifth of our employees working in research and development.



¹ Formerly named Novartis Business Services

² Refers to full-time equivalent positions. Total headcount is 108 514.

Our culture and values

Our Values and Behaviors underpin our culture and enable us to deliver on our purpose. We encourage all Novartis employees to be inspired, curious and unbossed while acting with integrity.

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 is right

Our business environment

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Healthcare demand is expected to rise post-COVID-19

Global demand for healthcare and associated spending is expected to grow over the next five years, supported by renewed economic growth and increased investment in healthcare in many countries after the COVID-19 pandemic. We see growth for our business in many markets, including in the US and – over the longer term – in China. At the same time, pressure on pharmaceutical pricing is expected to continue as payers step up initiatives to reduce the cost of healthcare.

3–6%

The global medicines market is expected to grow at between 3–6% CAGR through 2025, according to IQVIA, a research firm. Growth in non-COVID-19 spending is expected to return to its pre-pandemic outlook by 2023. In China, spending on medicines is predicted to exceed USD 170 billion by 2025.

Innovation continues to accelerate

Medical innovation is accelerating, as technologies such as gene therapy and ribonucleic acid (RNA) therapies open new paths to scientific discovery. Increased cooperation within the industry could lead to a new era of open science. At the same time, innovation is getting harder, with new discoveries requiring significant long-term investment.

123 bn

In 2020, spending on research and development by the world's 15 leading pharmaceutical companies reached USD 123 billion, an increase of 43% since 2015, according to research published in 2021 by IQVIA.

Use of data and technology is expanding across our industry

The use of data science and technologies such as artificial intelligence is increasing rapidly across our industry – in everything from clinical trials and manufacturing to patient diagnostics and treatment. COVID-19 has accelerated this trend. Meanwhile, customers want more efficient and personalized ways to connect with pharmaceutical companies. Against this backdrop, data privacy and cybersecurity are growing in importance.

65%

According to a 2021 survey by Deloitte, nearly two-thirds of doctors, nurses and other healthcare professionals in the EU have increased their use of digital technology to support clinicians' new ways of working.

Access to healthcare remains a global challenge

Almost a third of the world's population does not have access to the medicines they need. For the past five years, access rates in the poorest countries have been declining. Meanwhile, the COVID-19 pandemic has highlighted deep health inequities in both developed and developing countries.

2 bn

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

Aging and other factors are changing the disease burden

As the complexity of the world's healthcare challenges grows, the nature of the global disease burden is also changing. Aging populations and lifestyle changes are fueling a rise in noncommunicable conditions such as cardiovascular disease and cancer, driving an increase in disability and early death, and putting additional pressure on healthcare systems.

71%

Noncommunicable diseases (NCDs) are responsible for 71% of global deaths, according to the WHO. Cardiovascular diseases account for most NCD deaths, followed by cancer, respiratory diseases, and diabetes.

Climate crisis threatens to undermine global health gains

Climate change is already causing extreme heat and poor air quality in some areas, which threaten to exacerbate pre-existing health conditions such as respiratory diseases. In addition, an increase in temperature and humidity may cause a proliferation of insects that carry vector-borne diseases, including dengue fever and malaria. Ultimately, climate change could undermine decades of progress in improving human health at a time when antimicrobial resistance is also rising.

250 000

Between 2030 and 2050, the WHO expects climate change will cause approximately 250 000 additional deaths each year – from malnutrition, malaria, diarrhea and heat stress alone.

New ways of working are here to stay after COVID-19

COVID-19 changed our work habits. Post-pandemic, many employees continue to want more flexibility in how they work. Within our own workforce, there is more emphasis on digital skills. At the same time, workplace diversity is more important than ever to attract and retain talented employees, and support innovation.

74%

Nearly three-quarters of workers want a mix of office-based and remote working, according to a 2021 survey by Accenture. Research also shows more flexible working can bring cost benefits for employers and can help companies widen their talent pool.

Opportunity to build public trust in the wake of the pandemic

COVID-19 has brought an opportunity to reset public trust in our industry, with companies working together to end the pandemic. Trust matters for our industry: Our success depends on patents and trademarks that are granted by society and protect the long-term investments required for our business. Trust also matters for patient engagement, for working with regulators and policymakers, and for attracting talented employees.

57%

Worldwide, trust in pharmaceutical companies stood at 57% in 2021, according to the Edelman Trust Barometer. Trust improved in the US, Germany, the UK and Italy, from 2020, though from relatively low levels.

Our stakeholders

We can deliver on our purpose only by working with a diverse range of individuals and groups who are important to our business. Engaging these stakeholders helps us to better understand their needs and expectations, and work together toward common goals.

The table below shows a summary of why and how we engage with our main stakeholder groups.

Patients and caregivers	Customers	Employees
We work with patients and caregivers to understand the effects of our medicines and to ensure our treatments address unmet medical needs.	We build relationships with customers – including healthcare professionals and payers – to understand their needs and constraints, and to explain the benefits and risks of our medicines.	We engage employees to develop skills, improve working conditions, and promote an inspired, curious and unbossed culture.
How we engage		
<ul style="list-style-type: none"> Engage with patients and patient representative groups to ensure they have a voice in the research and development of our medicines Talk with patients to better understand and integrate their perspectives before we launch our medicines Work with patient organizations worldwide to address common goals, such as improving cardiovascular health 	<ul style="list-style-type: none"> Expand the use of digital technologies to make interactions with healthcare professionals more personalized and convenient Participate in scientific and medical congresses to highlight our progress across therapeutic areas and platforms Talk to payers to understand their needs and improve patient outcomes through sustainable access for our medicines 	<ul style="list-style-type: none"> Hold regular employee events (mainly online during the COVID-19 pandemic) Conduct quarterly surveys that measure employee engagement and other aspects of corporate culture Offer health and well-being programs, and conduct regular evaluation, training and feedback sessions
Shareholders and investors		
We communicate with shareholders and other investors to explain our strategy, performance and governance.	We work closely with external researchers, suppliers and a variety of other organizations to help discover new medicines, improve access to our medicines, and support business growth.	We maintain a constructive dialogue with policymakers and regulators so that our views are represented on issues affecting our industry.
How we engage		
<ul style="list-style-type: none"> Hold face-to-face and online meetings with asset managers; financial and environmental, social and governance (ESG) analysts; and stewardship teams Hold conferences, seminars and quarterly earnings presentations Focus on our 100 largest shareholders, who together own 60% of our shares 	<ul style="list-style-type: none"> Conduct risk assessments of suppliers, and work to improve areas such as environmental sustainability Foster a network of academic and industry research alliances Work alongside global health organizations to improve access to medicines Establish co-marketing, licensing and distribution agreements with other companies 	<ul style="list-style-type: none"> Work with trade associations and participate in leading industry initiatives alongside peer companies Provide policymakers with regular data and insights to enable informed decision-making and improved patient outcomes

Our 2021 materiality assessment

Every four years we conduct a detailed materiality assessment to identify issues that matter most to our stakeholders, and where we have the most potential to create value aligned with our purpose. The assessment informs our strategy and our reporting on ESG topics, and guides our impact performance measurement.

Our latest materiality assessment, conducted in 2021, was based on a survey of more than 500 external stakeholders and 12 000 internal stakeholders, and 140 follow-up interviews.

External stakeholders were drawn from our main stakeholder groups, including patients, customers, partners and shareholders. Internal stakeholders – including senior management – were drawn from across our business

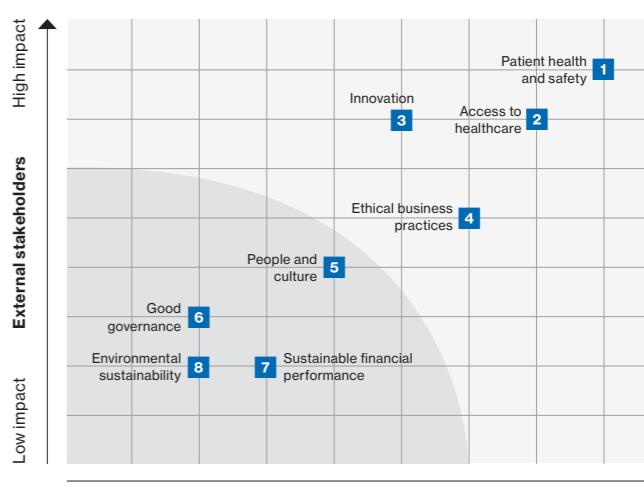
divisions. Participants were asked to rank the impact of Novartis across eight impact clusters. Results can be seen in the chart below.

Overall, results were in line with our previous materiality assessment conducted in 2017 and were consistent across stakeholder groups: patient safety, access to healthcare, innovation and ethical business practices were again ranked highly. Although environmental sustainability was ranked lower than other impact clusters, it remains an essential component of our strategy and operating model.

For full details of our materiality assessment, please see www.novartis.com/materiality

Ranking of impact clusters

External / internal stakeholders



□ Material impact clusters □ Relevant impact clusters

1 Patient health and safety → p.48

This is about the safety of our medicines and is therefore part of our core responsibilities.

2 Access to healthcare → p.70

We have an important role to play in making our medicines available and affordable to as many people as possible.

3 Innovation → p.35

Innovation is about helping to address the global burden of disease by researching and developing new medicines for unmet patient needs.

4 Ethical business practices → p.80

Acting responsibly and holding ourselves to high ethical standards are closely tied to trust in Novartis.

5 People and culture → p.61

A strong corporate culture helps us attract and retain talent. This topic is also about the health and safety of our employees, and fair working conditions.

6 Good governance → p.89

This relates to our corporate governance: how we manage our company, take decisions and allocate resources.

7 Sustainable financial performance → p.28

This is about sustainable financial returns and allocation of capital to areas we believe have the most impact.

8 Environmental sustainability → p.83

This relates to our management of emissions, waste and other effluents, and our consumption of natural resources.

Our strategy

Our strategy is to build a focused medicines company powered by technology leadership in research and development, world-class commercialization, global access and data science. As we implement this strategy, we have five priorities to help shape our decision-making and ensure we continue to deliver on our purpose.

Our strategic priorities

Deliver transformative innovation

We seek to find new ways to cure disease, intervene earlier in chronic illnesses, and improve patients' quality of life.

Our research and development (R&D) programs stand to help millions of people living with cancer, heart disease, neurological conditions and immune system disorders, as well as a variety of other diseases.

We prioritize projects with the potential to transform the standard of care for patients, and we are investing in new technology platforms – including cell and gene therapies, RNA therapies, and radioligand therapies – that offer more targeted approaches to fighting and, in some cases, potentially curing serious diseases.

Our focus on transformative innovation is expected to drive above-sector sales growth. By 2026, we anticipate approval of more than 20 pipeline assets with the potential to become blockbuster medicines with annual sales of more than USD 1 billion.

Embrace operational excellence

We strive to improve the efficiency and effectiveness of our operations while maintaining high standards of patient safety, product quality and environmental sustainability. These activities underpin our investments in innovation and support our financial performance, while helping to build trust with society.

In our commercial operations, we aim to consistently deliver successful launches enabling broad and rapid access to our medicines.

Our manufacturing operations are evolving as we invest in new technologies to improve productivity and respond to the changing business environment.

We continue to transform our business services and technology functions to enable the execution of our strategy and drive profitable growth.

Go big on data and digital

Our aim is to transform Novartis into a medicines company powered by data science and digital technologies.

Using data, we believe, can improve efficiency, drive sales and spur innovation to enhance our pipeline of new medicines and improve outcomes for patients.

To do this, we are embracing data analytics and technologies such as artificial intelligence while partnering with technology companies both large and small.

We also work to ensure the ethical and responsible use of new technologies and prioritize effective data privacy and cybersecurity.

Unleash the power of our people

We continue to transform our corporate culture to support our long-term performance.

We want every employee to feel inspired by our purpose, be curious about new ideas, and work in an unbossed environment that encourages initiative and teamwork.

We are exploring new ways of working, post-pandemic, to give employees greater flexibility and ensure we continue to attract and retain world-class talent.

At the same time, we are making progress in diversity and inclusion to increase employee engagement and support innovation.

Build trust with society

Building trust with patients, customers, partners, our employees and society is critical to delivering on our purpose.

It defines our approach to managing our key environmental, social and governance (ESG) topics: being part of the solution on pricing and access, addressing global health challenges, being a responsible citizen, and holding ourselves to high ethical standards.

We strive to make our medicines accessible to as many people as possible, while embedding ethics across our business, reducing our environmental footprint, and helping to address global issues such as antimicrobial resistance.

We take a systematic approach, integrating our ESG priorities across our strategy with clear targets and reporting. Please see [page 16](#) for more information on our ESG management targets.

We have made significant progress since we launched our strategy in 2018.

We have improved the productivity of our R&D pipeline, delivered cost savings, and ramped up our investments in data and digital. We have also made important progress in providing access to our medicines, and further strengthened our approach to ethics and compliance.

For more information on our performance against our strategy, see [pages 28-86](#).

ESG management targets

Our management targets covering environmental, social and governance (ESG) topics are integrated throughout our strategy. Topics covered include access to medicines, global health challenges, environmental sustainability and ethical business practices. Relevant information is disclosed in this report within the strategic priority sections as outlined below.

Deliver transformative innovation

Innovation for global health → p. 41

- Advance clinical development programs for our next-generation antimalarials and for patients with Chagas-related heart failure

Diverse clinical trials → p. 42

- Evaluate diversity and inclusion principles for 100% of Phase III studies with US country participation (with a longer-term goal to increase and embed this evaluation throughout our global trials)

Embrace operational excellence

Third-party risk management → p. 52

- Conduct risk assessments for all new eligible suppliers

Unleash the power of our people

Diversity and inclusion → p. 64

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

Learning and development → p. 63

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

Build trust with society

Access and global health → p. 70

- Implement an access strategy for all new medicines launched
- Implement tiered pricing for launches in our Pharmaceuticals and Oncology business units based on national income levels and value-based pricing
- Increase by at least 200% patients reached with strategic innovative medicines in low- and middle-income countries (LMICs) by 2025 (compared with 2019)
- Increase by at least 50% the number of patients reached with Novartis flagship programs in LMICs by 2025 (compared with 2019)

Ethical business practices → p. 80

- Post all clinical trial results on www.clinicaltrials.gov or www.novartisclinicaltrials.com within one year of completion
- Integrate human rights into third-party risk assessments in scope
- Enhance external reporting on anti-bribery

Environmental sustainability¹ → p. 83

Emissions:

- Be carbon neutral in our own operations (Scope 1 and 2) by 2025 and across the value chain (Scope 1, 2 and 3) by 2030
- Achieve net zero carbon emissions across our value chain by 2040
- Include environmental criteria in all supplier contracts by 2025

Water:

- Reduce water consumption in our own operations by half by 2025 (compared with 2016), with no water quality impacts from the manufacturing of our products
- Become water neutral in all areas of our operations by 2030 while enhancing water quality wherever we operate

Waste:

- Eliminate polyvinyl chloride in packaging by 2025 (secondary and tertiary packaging; primary packaging when feasible)
- Reduce the amount of waste sent for disposal by half by 2025 (compared with 2016)
- Become plastic neutral by 2030, with all new products meeting sustainable design principles

¹ Additional information on environmental sustainability in our manufacturing operations and supply chain can be found on page 48 and page 53, respectively. Information relevant to the Task Force on Climate-related Financial Disclosures (TCFD) is on page 108.



How we create value

By executing on our strategy and delivering on our purpose, we create value for our business and improve the lives of millions of people around the world.

Our strategy

Deliver transformative innovation

9.5 bn	160+	20 000+
Investment in research and development (USD)	Pipeline projects in clinical development	Employees in research and development

Embrace operational excellence

53	12 064	9.8 m
Novartis manufacturing facilities	Suppliers risk-assessed	Energy use in gigajoules (on site and purchased)

Go big on data and digital

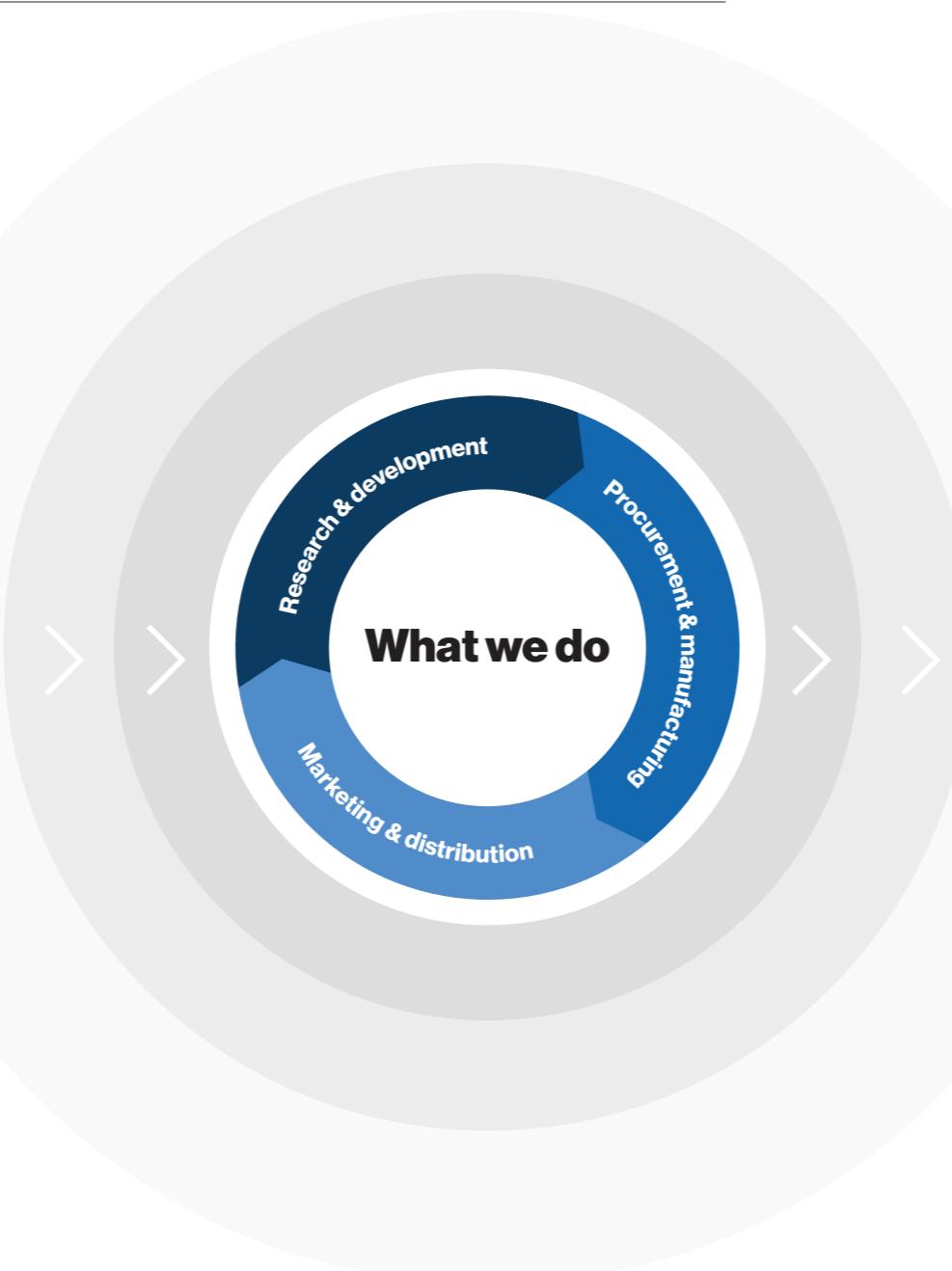
2 700+	3 000+	16 000
Clinical trials spanning two decades available on our data analytics platform	Clinical trial participants referred via an online enrollment portal in the US	Employees using a learning platform to enhance their digital skills

Unleash the power of our people

108 514	52.1	5 000
Headcount	Annual training hours per (internal) employee	Leaders taking "unbossed" training

Build trust with society

98%	31	122
Employees trained on Code of Ethics	Emerging market brands launched in 2021	Countries with Novartis Global Health ¹ medicines on the ground



Value created

For patients and healthcare professionals

766 m	21
Patients reached with Novartis medicines	Major approvals (US, EU, Japan, China)

For shareholders

51.6 bn	24.0 bn
Net sales (USD)	Net income (USD)

For employees

46%	78
Women in management	Engagement score in Q4 (out of 100), 5 points higher than the industry benchmark

For society

1 bn	56.2 m
Antimalarial treatments delivered since 1999, most supplied without profit	Patients reached through access-to-medicine approaches

-34%	-40%
Reduction in greenhouse gas emissions vs. 2016 baseline (Scope 1 and Scope 2)	Reduction in water consumption vs. 2016 baseline

Social, environmental and economic impact

Our medicines positively impact society by improving and extending the lives of hundreds of millions of people around the world. Through our business, we also create jobs and contribute to employee development – both in our own operations and across our supply chain. At the same time, our business impacts the environment through carbon emissions, water use and waste. For more information on how we assess the impact of our business on society, please see the section "[Measuring and valuing our impact](#)."

Contributing to the UN SDGs

We are committed to supporting the United Nations' Sustainable Development Goals (SDGs). An analysis by Trucost, a third-party sustainability data provider, showed that our most significant positive impact is on **goal 3** (good health and well-being), which aligns closely with our purpose.

We also positively impact **goal 8** (decent work and economic growth), **goal 9** (industry, innovation and infrastructure) and **goal 10** (reduced inequalities) through our business and operations, including our efforts to expand access to our medicines. Through our environmental targets, we contribute to **goal 6** (clean water and sanitation), **goal 7** (affordable and clean energy) and **goal 13** (climate action).

The [GRI Content Index](#) of this report contains a mapping of our activities against the SDGs.

¹ The Novartis Global Health unit focuses on transforming health in low- and middle-income countries.

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Measuring and valuing our impact

Impact valuation is an emerging discipline that seeks to measure the positive and negative effects of companies on society. Novartis is pioneering an approach called social, environmental and economic (SEE) impact valuation that aims to show the positive impact we bring to countries, health systems and individuals, balanced by the negative impact of our operations on the environment and other areas. Expressing these impacts in monetary terms makes them transparent and comparable for stakeholders.

Our latest SEE impact valuation figures for 2020 take into account the social impact of our Innovative Medicines and Sandoz product portfolio in 131 countries. We also assessed our impact on living wages and employee development in our own operations and in our supply chain, as well as our contributions to gross domestic product and employment in the countries in which we operate.

At the same time, we measured the negative impact of our business on occupational safety – both in our own operations and across our supply chain – as well as the negative impact of carbon and other greenhouse gas emissions, land use, water use and waste. Minimizing risks associated with third parties in our supply chain and improving environmental sustainability are key parts of our strategy and operating model. For more information, please see the section “[Embrace operational excellence](#).”

While impact valuation methodology is still evolving, our efforts are based on current leading approaches. For example, we engage with WfOR, an independent economic research institute, to calculate the social impact of our medicines, our direct GDP contribution, and our indirect and induced environmental and economic impacts. We are also a founding member of the [Value Balancing Alliance](#) (VBA), a nonprofit organization that aims to create a standard for measuring and disclosing the value companies provide to society. With the exception of the social impact of

our medicines, which is specific to our industry, all other reported impact indicators are subject to standardization through the VBA.

We first applied our impact valuation methodology in 2016. Since then, we have further developed the approach and expanded its scope. SEE impact valuation results have been used by Novartis teams for stakeholder engagement and business decision-making.

We also engage with stakeholders to raise awareness of impact valuation and promote standardization. In 2021, we hosted our fourth annual Co-Creating Impact Summit with more than 1 800 participants from academia, industry, the investment community and other areas.

For more information on the Co-Creating Impact Summit and impact valuation methodology, please see

www.cci-summit.com

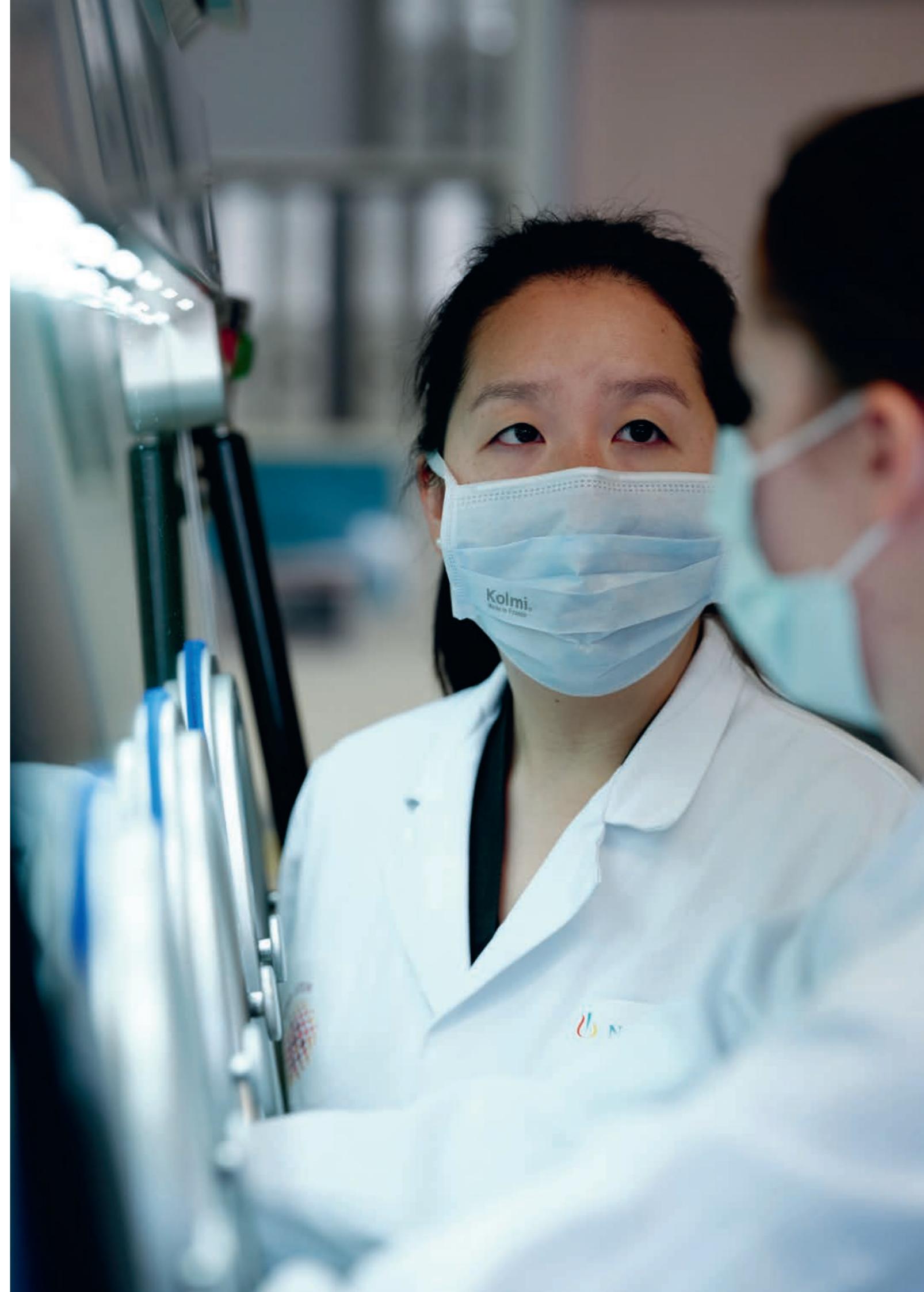
Novartis social, environmental and economic impact in 2020¹

Indicator	Results ²	Remarks
Social		
Living wages	USD 1.8 bn	Own operations USD 1.1 bn, indirect USD 0.7 bn
Employee development	USD 1.5 bn	Own operations USD 76 m, indirect USD 0.7 bn, induced USD 0.8 bn
Occupational safety ³	-USD 3.8 bn	Own operations -USD 2 m, indirect -USD 1.8 bn, induced -USD 2.0 bn
Other human capital impacts		Employee well-being, voluntary turnover, human rights beyond living wages not valued in 2020
Medicines	USD 242 bn	Based on 68 Innovative Medicines brands and 71 Sandoz products in 131 countries
Environmental		
Climate, energy and air pollution	-USD 4.7 bn	Own operations USD 138 m, indirect USD 1.7 bn, induced USD 2.8 bn
Water and waste	-USD 1.0 bn	Own operations USD 69 m, indirect USD 305 m, induced USD 433 m, downstream USD 153 m
Land use	-USD 2.0 bn	Own operations USD 43 000, indirect USD 308 m, induced USD 1.7 bn
Other environmental impacts		Biodiversity not valued in 2020
Economic		
GDP contribution	USD 87.4 bn	Own operations USD 49.7 bn, indirect USD 17.0 bn, induced USD 20.6 bn
Employment	957 433 FTEs	Own operations 105 794 FTEs, indirect 342 000 FTEs, induced 510 000 FTEs
Economic inefficiencies		Not valued in 2020 – no methodology available
Total taxes		Not valued globally in 2020

¹ 2021 figures will become available in May 2022 and will be published in our 2022 report.

² Our methodology is based on leading approaches, including WfOR (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).

³ Higher than in 2019, primarily due to a change in the third-party database used for occupational diseases in the supply chain



How we manage risk

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Our approach to risk

The Novartis Enterprise Risk Management (ERM) framework is designed to generate a holistic view of risks for the company and drive a culture of smart risk-taking. While our [Code of Ethics](#) sets the ethical framework for all employees to manage risk across our business, risk management is a fundamental leadership responsibility that involves active engagement by leaders at each stage of the process.

The overall ERM process is the responsibility of the Chief Ethics, Risk & Compliance Officer, with oversight from the Executive Committee of Novartis and the Board of Directors. For further details on governance of

risk at Novartis, please see the section [“Our corporate governance approach.”](#)

Our ERM framework is aligned with our strategic planning and helps us better understand our overall level of risk exposure. The Risk & Resilience team conducts risk workshops and collaborates with all risk assurance functions to identify key risks across the company. Each Novartis unit organizes a focused risk workshop at the leadership level. In parallel, risk workshops are held in our largest markets by revenue and in certain focus markets.

The outcomes of these workshops are consolidated into the Novartis Risk

Compass, which groups risks into three categories: strategic, operational and emerging. Risks are rated based on likelihood and potential impact over the next five years, using the “most-probable worst-case” scenario for each risk as a reference point. Once key risks are identified, mitigation plans are created. In addition to the three categories described above, we identify separate “awareness topics” that we believe may become new risks over time.

The Risk Compass helps senior management and our Board of Directors focus discussions on key risks and align strategy with risk exposure. We regularly monitor risks and revise our assessments, if necessary.

Novartis Risk Compass

Strategic risks

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

Emerging risks

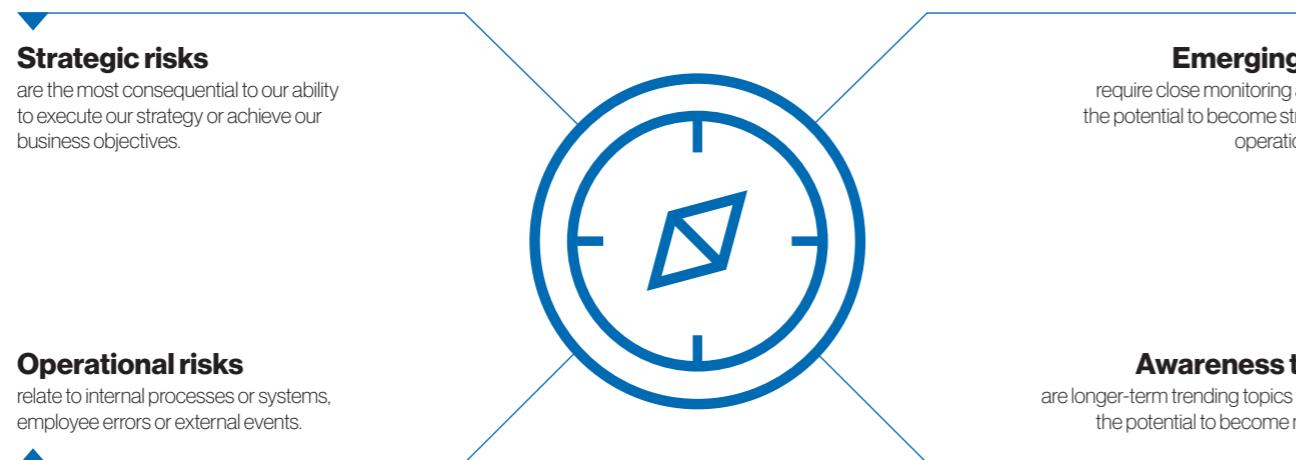
require close monitoring and have the potential to become strategic or operational risks.

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.



Risks in 2021

Our risk portfolio covers 20 risks. Of these, seven are categorized as strategic, nine as operational, and the remaining four as emerging. In addition, we have identified four awareness topics.

Overall, our 2021 risk portfolio is broadly consistent with the previous year. “Sandoz business transformation” was added as a new strategic risk in 2021, reflecting the increasingly competitive environment for generic medicines. Additionally, “facility and

workplace safety” was renamed “occupational health and workplace safety” in 2021 to incorporate aspects of the post-pandemic working environment – such as employee well-being – that were identified as an emerging risk in 2020.

Risk rating: ● Very high ● High ● Medium ○ Low

Strategic risks

● Key products and commercial priorities

Failure to deliver key commercial priorities and successfully launch new products

● Pricing, reimbursement and access

Pricing and reimbursement pressure, including access to healthcare

● Alliances, acquisitions and divestments

Failure to identify external business opportunities or realize the expected benefits from our strategic acquisitions or divestments

● Research and development

Failure or delay in the research and development of new products or new indications for existing products

● Sandoz business transformation

Inability to drive sustainable growth mid-term by pursuing biosimilars and inorganic growth opportunities

● Occupational health and workplace safety

Failure to ensure the safety of Novartis facilities and operations, and that of our employees and contractors

● Legal, ethics and compliance

Challenges in keeping up with legal and regulatory requirements, and evolving societal expectations regarding ethical behavior

● Manufacturing and product quality

Inability to ensure proper controls in product development and product manufacturing, and failure to comply with applicable regulations and standards

● Data privacy

Noncompliance with personal data protection laws and regulations

● Supply chain

Inability to maintain continuity of product supply

Operational risks

● Cybersecurity and IT systems

Cybersecurity breaches and catastrophic loss of IT systems

● Fragmented IT landscape and ERP/EDM implementation

Fragmented business processes and unclear data ownership may impact future digital opportunities, including the implementation of the new Enterprise Resource Planning (ERP) system and Enterprise Data Management (EDM) governance

● Tax laws and developments

Changes in tax laws or their application

● Intellectual property

Expiry, assertion or loss of intellectual property protection

● Antitrust

Potential increased antitrust scrutiny of transactions, together with continued close examination of conduct by pharmaceutical companies

Awareness topics

● Climate change

Climate change and increased risk of major natural disasters

● Changes in disease patterns, antimicrobial resistance and pandemics

Antimicrobial resistance is a growing threat to public health, closely related to changes in disease patterns including possible future pandemics

● Falsified medicines

Impact on patient safety, and reputational and financial harm to Novartis and our products

● Governance and ethical use of artificial intelligence

Lack of artificial intelligence governance or ethical lapses in its use may expose Novartis to operational, reputational and regulatory risks

Risks in focus

The table below provides an overview of our seven strategic risks. For more information on our full risk portfolio, please see [Item 3.D](#) ("Risk factors") in the Novartis Annual Report.

Risk	Context	Actions	Risk	Context	Actions
Deliver transformative innovation					Go big on data and digital
Research and development	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.	<ul style="list-style-type: none"> Enter into agreements with other pharmaceutical and biotechnology companies and with academic and other institutions to develop new products Accelerate the use of data science and digital technology to make the drug discovery and development process more efficient and effective 	Emerging business models	Missed opportunities in digitalization and emerging business models	<ul style="list-style-type: none"> Develop a digital operating model to enable faster innovation, simplify our operations and improve productivity Accelerate the implementation of a new customer engagement model, which combines traditional face-to-face visits with virtual engagements with healthcare professionals. We are similarly changing our approach to partnering with healthcare systems, payers and other healthcare providers.
Embrace operational excellence					Build trust with society
Key products and commercial priorities	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.	<ul style="list-style-type: none"> Pursue a "launch excellence" strategy in commercial execution, including investing earlier in pre-launch activities and using data science to test and learn from new commercial models Accelerate the implementation of a new customer engagement model, which combines traditional face-to-face visits with virtual engagements with healthcare professionals. We are similarly changing our approach to partnering with healthcare systems, payers and other healthcare providers. 	Pricing, reimbursement and access	Pricing and reimbursement pressure, including access to healthcare	<ul style="list-style-type: none"> Establish dedicated teams that actively seek to optimize patient access, including formulary positions, for our products Increase efforts to enable patient access through innovative pricing and access initiatives in the US, Europe and other markets, including contract structures such as pay-over-time and outcome-based agreements Continue to execute against access-to-medicine and global health targets. These targets are backed by a sustainability-linked bond, which embeds them into the core of our business operations.
Alliances, acquisitions and divestments	As part of our strategy, we acquire and divest products or entire businesses, and enter into strategic alliances and collaborations. This strategy depends in part on our ability to identify and move forward with strategic opportunities. Efforts to develop and market acquired products, to integrate acquired businesses or to achieve expected synergies may fail or may not fully meet expectations. Also, our strategic alliances and collaborations with third parties may not achieve their intended goals and objectives.	<ul style="list-style-type: none"> Establish an enterprise-wide business development strategy to identify external opportunities that align with and advance our corporate strategy Enhance our risk-based due diligence approach through end-to-end risk management 	Environmental, social and governance matters	Failure to meet increasingly challenging environmental, social and governance expectations	<ul style="list-style-type: none"> Further develop the Novartis ESG strategy based on the results of the 2021 global materiality assessment Revisit and further strengthen our environmental target for full carbon neutrality by 2030 by committing to achieve net zero across the Novartis value chain by 2040
Sandoz business transformation	Our Sandoz Division faces competition and pricing pressures as it seeks to increase its market share and achieve sustainable and profitable growth mid-term. Our strategy for Sandoz focuses on accelerating biosimilars growth in the long term; rebuilding the Sandoz US business; and achieving inorganic growth by identifying and successfully executing on merger and acquisition and strategic in-licensing partnership opportunities. Failure to achieve these goals may have a material adverse effect on the success of the Sandoz Division and the Group as a whole, as well as potentially on our results of operations and financial condition.	<ul style="list-style-type: none"> Accelerate biosimilars growth Rebuild the US business by increasing loss-of-exclusivity coverage and enhancing our pipeline with first-to-file launches Pursue inorganic growth opportunities, for example through bolt-on acquisitions and in-licensing 			

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Photo Romanus Oyibe, a medicine vendor in Ebonyi State, Nigeria, attends to a patient in his store. Together with local partners, Novartis is helping to train vendors like Mr. Oyibe to test patients for common childhood illnesses such as malaria. Severe cases are referred to the closest health center.

Financial performance

Novartis delivered a solid financial performance in 2021, supported by sales growth in key products and increased margins. These factors helped counter the impact of the COVID-19 pandemic in some therapeutic areas and a challenging environment for our generics business.

51.6 bn
Net sales (USD)

11.7 bn
Operating income (USD)

24.0 bn
Net income (USD)

16.6 bn
Core operating income (USD)

13.3 bn
Free cash flow (USD)

Strong sales of key products continued to underpin our financial performance in 2021. Novartis full-year net sales were USD 51.6 billion, up 4% from the prior year when measured in constant currencies (cc) to remove the impact of exchange rate movements, and up 6% when measured in US dollar terms. The COVID-19 pandemic continued to impact some therapeutic areas – most notably oncology and our generics business.

Sales of our heart failure medicine *Entresto* grew 40% (cc) to USD 3.5 billion, driven by increased patient share across major markets. In 2021, *Entresto* received approval in the US for an expanded indication in chronic heart failure.

Cosentyx, our treatment for psoriasis and other autoimmune diseases, also continued to grow strongly. Sales rose 17% (cc) from the prior year to USD 4.7 billion, driven by demand in the US and Europe as well as strong volume growth in China. Meanwhile, *Zolgensma*, our gene therapy for children with spinal muscular atrophy, delivered sales of USD 1.4 billion, up 46% (cc), reaching blockbuster status for the first time.

Recently launched products also progressed well. *Kesimpta*, a treatment for relapsing multiple sclerosis that was approved in Europe in 2021, had sales of USD 372 million, driven by launch uptake, strong access and increased demand.

Our oncology products also contributed to the solid performance. *Promacta*, a treatment for blood disorders that is known as *Revolade* outside the US, grew 15% (cc) to USD 2.0 billion. *Kisqali*, a breast cancer treatment, had sales of USD 937 million, up 36% (cc). *Jakavi*, a treatment for blood disorders and

cancers, grew 16% (cc) to USD 1.6 billion, showing double-digit growth across all regions.

Sales of Sandoz biopharmaceuticals continued to be a bright spot, with a 7% (cc) increase to USD 2.1 billion. However, that was countered by price competition and softer retail demand, including the impact of a weak cough and cold season, leading to an overall decline (-2%⁴ cc; 0% in US dollar terms) in Sandoz Division net sales.

Novartis Group sales in Europe, our largest market, grew 5% (cc). Sales in the US rose 2%. Sales in emerging growth markets grew 11% (cc), led by a double-digit increase in China.

Operating income was USD 11.7 billion, up 13% (cc) from the prior year, mainly driven by higher sales and lower legal expenses, partly offset by increased investments in marketing and sales and in research and development, and higher amortization. Net income was USD 24.0 billion, benefiting from the USD 14.6 billion gain from the divestment of our investment in Roche. Earnings per share were USD 10.71.

To help people understand our underlying performance, we also present our core results, which exclude the impact of amortization, restructurings, acquisitions and other significant items. Core operating income of USD 16.6 billion rose 6% (cc). Core net income of USD 14.1 billion rose 5% (cc). Core earnings per share were USD 6.29, up 7% (cc). Free cash flow of USD 13.3 billion was up 14%, driven by higher operating income adjusted for non-cash items and lower payments for legal provisions, partly offset by a USD 650 million upfront payment to in-license tislelizumab from an affiliate of BeiGene, Ltd.

Key figures¹

(in USD millions, unless indicated otherwise)

	2021	2020	USD	Constant currencies
Net sales to third parties	51 626	48 659	6	4
Operating income	11 689	10 152	15	13
% of net sales to third parties	22.6	20.9		
Net income	24 018	8 071	198	195
Basic earnings per share ² (USD)	10.71	3.55	202	200
Core operating income	16 588	15 416	8	6
% of net sales to third parties	32.1	31.7		
Core net income	14 094	13 158	7	5
Core earnings per share ² (USD)	6.29	5.78	9	7
Free cash flow	13 282	11 691	14	

Share information

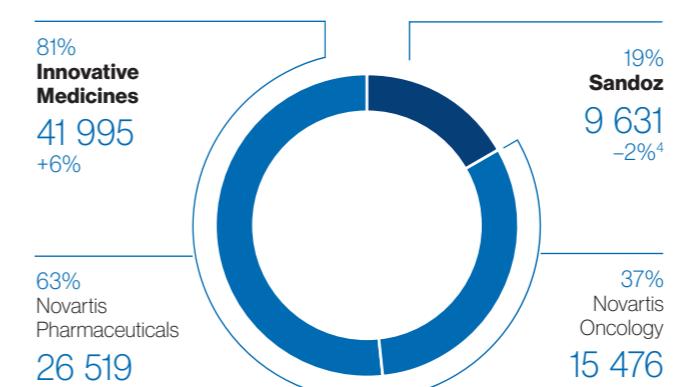
	2021	2020	% Change
Share price at year-end (CHF)	80.28	83.65	- 4
ADR price at year-end (USD)	87.47	94.43	- 7
Dividend ³ (CHF)	3.10	3.00	3

¹ This Novartis in Society Integrated Report 2021 includes non-IFRS financial measures such as core results, constant currencies and free cash flow. Novartis believes that investor understanding of the Group's performance is enhanced by disclosing these non-IFRS measures. A definition of non-IFRS measures used by Novartis, and further details, including reconciliation tables, can be found in "Item 5. Operating and Financial Review and Prospects" of the Novartis Annual Report 2021.

² 2021 weighted average number of shares outstanding: 2 243 million (2020: 2 277 million)
³ Dividend 2021: proposal to shareholders for approval at the Annual General Meeting on March 4, 2022

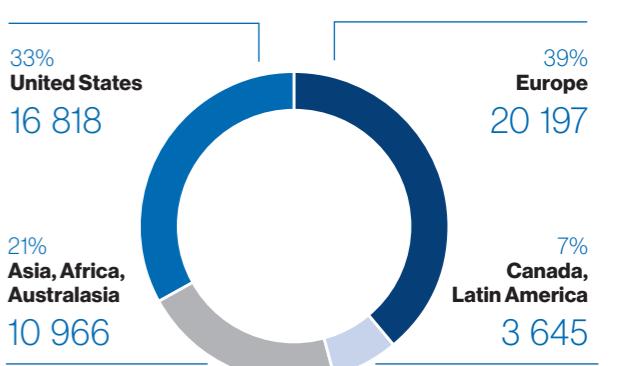
2021 net sales by division

(in USD millions, % growth in constant currencies, and divisional or business unit share of net sales)



2021 net sales by geographical region

(% of net sales and in USD millions)



⁴ FY sales growth for Sandoz includes +1% impact from a reclassification of contract manufacturing from other revenue to sales

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42.0 bn

Innovative Medicines net sales (USD), up 6% (cc)

Innovative Medicines

The Innovative Medicines (IM) Division includes the Novartis Oncology and Novartis Pharmaceuticals business units. Novartis Pharmaceuticals focuses on the franchises of Immunology, Hepatology and Dermatology; Neuroscience; Ophthalmology; Cardiovascular, Renal and Metabolism; Respiratory and Allergy; and Established Medicines. Novartis Oncology, which provides treatments for a variety of cancers and rare diseases, consists of the Hematology and Solid Tumor franchises.

The IM Division delivered net sales of USD 42.0 billion in 2021, an increase of 6% (cc) from the prior year. Overall, products that we consider our key growth drivers contributed 52% of IM net sales in 2021, compared with 44% in 2020, demonstrating our ability to renew our product portfolio and offset the impact of patent expirations. Core operating income for the IM Division was USD 15.2 billion, up 10% (cc).

Innovative Medicines 2021 net sales by business unit and franchise (in USD millions, % growth in constant currencies, and business unit share of net sales)

63% Novartis Pharmaceuticals	26 519 +7%
Immunology, Hepatology and Dermatology	5 777 +18%
Neuroscience	5 052 +15%
Ophthalmology	4 330 -4%
Cardiovascular, Renal and Metabolism	3 560 +40%
Respiratory and Allergy	2 065 +6%
Established Medicines	5 735 -10%
37% Novartis Oncology	15 476 +4%
Hematology	8 363 +6%
Solid Tumor	7 113 +2%

Novartis Pharmaceuticals

The Novartis Pharmaceuticals business unit had net sales of USD 26.5 billion in 2021, an increase of 7% (cc) from the prior year, supported by continued growth in key products across multiple franchises.

Immunology, Hepatology and Dermatology

Sales reached USD 5.8 billion, an increase of 18% (cc) from the previous year. Cosentyx saw strong growth with sales of USD 4.7 billion, up 17% (cc). This was driven by sustained demand across indications in the US and Europe, as well as strong volume growth in China after the product was included in the country's National Reimbursement Drug List. Sales of Ilaris reached USD 1.1 billion, up 22% (cc), with double-digit growth across all regions.

Neuroscience

Sales were USD 5.1 billion, increasing by 15% (cc), mainly due to expanded access in Europe and other markets

for Zolgensma, as well as Kesimpta launch uptake. Zolgensma reached blockbuster status with sales of USD 1.4 billion, up 46% (cc). Sales of Kesimpta reached USD 372 million.

Meanwhile, sales of Gilenya decreased 9% (cc) to USD 2.8 billion due to increased competition.

Ophthalmology

Sales were USD 4.3 billion, declining by 4% (cc) from the previous year due to generic competition for our mature ophthalmology portfolio. Lucentis sales grew 8% (cc) to USD 2.2 billion. Xiidra sales grew 24% (cc) to USD 468 million. Beovu sales declined 3% (cc) to USD 186 million.

Cardiovascular, Renal and Metabolism

Sales were USD 3.6 billion, up 40% (cc), driven by sustained growth for Entresto, which registered sales of USD 3.5 billion, up 40% (cc). Entresto was approved in the US in 2021 for an expanded indication in patients with left ventricular ejection fraction (LVEF) below normal. It was also approved for the treatment of hypertension (high blood pressure) in Japan and China. Meanwhile, Leqvi, our treatment for high cholesterol, registered sales of USD 12 million. Leqvi is approved in more than 45 countries, with most awaiting reimbursement.

Respiratory and Allergy

Sales were USD 2.1 billion, up 6% (cc). Xolair delivered 12% (cc) on-year growth with sales of USD 1.4 billion, mainly driven by the chronic spontaneous urticaria and severe allergic asthma indications. In 2021, Xolair was approved for self-injection in the US.

Established Medicines

Sales were USD 5.7 billion, down 10% (cc) from the previous year, as sales of established medicines such as Diovan and Galvus continued to decline as a result of generic competition.

Novartis Oncology

The Novartis Oncology business unit delivered net sales of USD 15.5 billion, an increase of 4% (cc) from the prior year. The performance underscores the strength of our oncology portfolio, with solid growth in sales of key products.

Hematology

Sales were USD 8.4 billion, up 6% (cc) from the prior year. Promacta, which is known as Revolade outside the US, grew 15% (cc) to USD 2.0 billion, with double-digit growth across all regions, driven by increased use in chronic immune thrombocytopenia and as first-line treatment for severe aplastic anemia. Sales of Tasigna grew 4% (cc) to USD 2.1 billion, mainly driven by growth in emerging markets.

Jakavi showed double-digit growth across all regions to register sales of USD 1.6 billion, up 16% (cc) from the previous year, driven by strong demand in the myelofibrosis and polycythemia vera indications. Kymriah saw growth across all markets as coverage for the chimeric antigen receptor T-cell (CAR-T) therapy continued to expand, with sales of USD 587 million representing a 22% (cc) increase from the previous year.

Solid Tumor

Sales were USD 7.1 billion, up 2% (cc) from the previous year. The performance was led by Kisqali, which continued to see growth across all regions with sales of USD 937 million, up 36% (cc). Tafinlar + Mekinist, a combination therapy, registered an 8% (cc) increase in sales to USD 1.7 billion as demand increased in the BRAF+ adjuvant melanoma and non-small cell lung cancer indications. Tabrecta registered USD 90 million in sales in its first full year after launch, as the lung cancer treatment continued to gain traction in the US. Meanwhile, sales of three products – Sandostatin, Afinitor/Votubia, and Votrient – declined due to increased competition in major markets.

2021 news highlights

In February we were granted an expanded indication for Entresto by the US FDA, allowing for the treatment of most chronic heart failure patients, including all those with an ejection fraction below normal.

In March we received EU approval for Kesimpta for treatment of relapsing forms of multiple sclerosis in adults with active disease defined by clinical or imaging features. Kesimpta is the first B-cell therapy that can be self-administered once-monthly at home.

In June we announced US approval for Cosentyx for treatment of children and adolescents with moderate to severe plaque psoriasis – a chronic inflammatory disease that may impact up to 350 000 children worldwide, with onset most common during adolescence.

In October we received US approval for Scemblix for treatment of chronic myeloid leukemia (CML) in two distinct indications. It offers a new treatment option for CML patients who are resistant or intolerant to prior treatments.

In December we received US approval for our cholesterol-lowering medicine Leqvi. Separately, we announced in September a world-first agreement between Novartis and the National Health Service in England to enable broad and rapid access to Leqvi via a population health management approach.

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In February we signed an agreement to acquire GlaxoSmithKline's cephalosporin antibiotics business, reinforcing Sandoz's leading global position in antibiotics.

In May we announced plans to further expand Sandoz antibiotics production capabilities in Kundl, Austria, and in Palafolls, Spain. By modernizing and simplifying its manufacturing setup, Sandoz will improve its ability to consistently deliver high-quality medicines to patients while remaining cost-competitive in the global market.

In June we announced the launch of generic oncology treatment pemetrexed in 11 countries across Europe, including Germany, Switzerland, and Spain.

Sandoz

The Sandoz Division is a global leader in generic pharmaceuticals and biosimilars, and sells products in more than 100 countries. The division has three global franchises: Retail Generics, Biopharmaceuticals and Anti-Infectives.

Sandoz net sales were USD 9.6 billion in 2021, decreasing by 2%¹ (cc) from the previous year, as volume growth in our Biopharmaceuticals and contract manufacturing businesses was offset by the effects of price competition and continued headwinds for our Retail Generics business in the US. We continued to see an impact from COVID-19, particularly in the Retail Generics and Anti-Infectives businesses. However, the effects have been more moderate in recent months and the Sandoz business is continuing to normalize.

Sandoz sales in Europe declined 2% (cc) due to the impact of COVID-19 on the Retail Generics business. Sales in the US were down 15%. Core operating income was USD 2.1 billion, declining 14% (cc) from the previous year due to unfavorable gross margin and lower sales.

Sales in the Retail Generics business declined 4% (cc) to USD 7.1 billion, impacted primarily by continued sales volume decline in the US for oral solids as a result of partnership terminations.

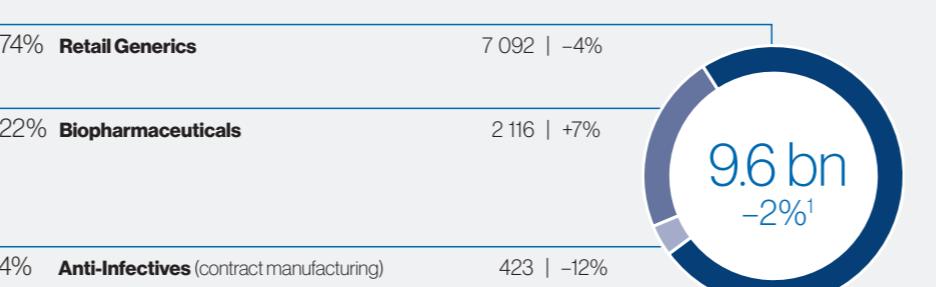
Sales in the Biopharmaceuticals franchise grew 7% (cc) to USD 2.1 billion, driven by continued growth outside the US. Sandoz develops, manufactures and markets protein- and other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

In Anti-Infectives, Sandoz manufactures and supplies active pharmaceutical ingredients and intermediates, mainly antibiotics, for use by the Retail Generics franchise and for sale to third-party customers. Total franchise sales were USD 1.1 billion, a decrease of 5% (cc) from the prior year.

In 2021, Novartis announced that it will commence a strategic review of the Sandoz Division. The review will explore all options, ranging from retaining the business to separation, to determine how to best maximize value for our shareholders.

Sandoz 2021 net sales by franchise

(in USD millions, % growth in constant currencies, and franchise share of net sales)



¹ FY sales growth for Sandoz includes +1% impact from a reclassification of contract manufacturing from other revenue to sales



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Deliver transformative innovation

Every day, Novartis is working to reduce the burden of disease for patients and societies around the world. More than 20 000 Novartis employees in research and development deploy cutting-edge technologies to find new ways to cure disease, intervene earlier in chronic illnesses and improve patients' quality of life.

2021 highlights

9.5 bn

Invested in R&D
comprising approximately
18.5% of our net sales (USD)

3

**Breakthrough therapy
designations**
from the US Food and Drug
Administration (FDA)

54

**Ongoing Phase III
programs**
in our development pipeline

21

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

In this section

Our approach to R&D

We tackle the toughest scientific challenges and prioritize projects with the potential to transform the standard of care for patients.

→ p. 36

Advancing a strong and diverse pipeline

We have one of the strongest clinical development programs in the industry, spanning around 50 diseases. We focus on areas where unmet need remains high.

→ p. 37

Advanced technology platforms

We are investing in technologies that offer precise new approaches to fighting otherwise intractable diseases.

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Innovation for global health

We work to reduce the burden of neglected diseases that affect hundreds of millions of patients worldwide.

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Putting patients at the center of our clinical trials

We integrate the views of patients and caregivers into how we research and develop new medicines, and we strive to include diverse patient populations in our clinical trials.

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Related links and disclosures:

- Novartis pipeline
- Position on Responsible Clinical Trials
- Commitment to Patients and Caregivers
- Commitment to Diversity in Clinical Trials
- Clinical Study Transparency

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Diseases

within the scope of our research and development programs

Our approach to R&D

The COVID-19 pandemic is only one example of the enormous burden that disease puts on society. From leading causes of death such as heart disease and cancer, to rare but debilitating genetic disorders, the disability and mortality associated with serious illness harms economic growth and exacerbates social inequality.

Finding solutions to these problems is why Novartis exists. Our more than 20 000 employees in research and development (R&D) work to discover and develop medicines for diseases with high unmet need. Our R&D teams have built depth in core disease areas including cardiovascular and renal, oncology, hematology, immunology and neuroscience, while we maintain innovative investigational and in-market programs in ophthalmology and respiratory-allergy. We are also advancing our pipeline of investigational medicines for malaria and other neglected diseases.

With our strong capabilities across five platforms – chemical biology, biotherapeutics (biologics), radioligand therapy, cell therapy and gene therapy – we have a unique foundation to address disease burdens faced by people around the world today and for decades to come.

Novartis continued to deliver transformative innovation to patients in 2021. We received 21 major approvals, including new treatments for high cholesterol and chronic myeloid leukemia, and made 34 major submissions. We advanced our diverse pipeline of investigational therapies, with three breakthrough therapy designations from the US Food and Drug Administration (FDA) and around 20 clinical data readouts paving the way for further launches in 2022 and beyond.

Our R&D efforts span two units. The Novartis Institutes for BioMedical Research (NIBR) leads drug discovery and development from concept to early clinical evaluation, and also partners with an external network of around 300 academic collaborators

and 100 industry collaborators focused on areas of mutual scientific interest. Global Drug Development (GDD) leads the advanced clinical development of potential new medicines, running large clinical trials and steering the way to regulatory approval and access for patients.

These efforts have given Novartis one of the strongest discovery and development programs in the industry, with more than 275 research programs as well as 98 assets in development, spanning around 50 diseases and 71 new molecular entities. We invested USD 9.5 billion in R&D in 2021, or approximately 18.5% of our net sales, compared with USD 9.0 billion in 2020.

We prioritize projects with the potential to transform the standard of care for patients. Approximately 85% of our treatments in development have the potential to be first in class or first in a specific indication, while about 80% target areas of high unmet patient need.

We systematically integrate access into our discovery and development work. For example, we regularly review all drug development submissions and hold our clinical research teams accountable for acting on access opportunities. We also engage patients in how we research and develop our medicines, and we strive to include diverse patient populations in our studies to ensure we understand how patients everywhere might respond to a medicine.

Data science and digital technology

We use data and digital strategies across our R&D operations to open new paths to scientific discovery, improve patient outcomes and streamline the development process. Our investments in digital technology also helped to keep our clinical trials on track during the COVID-19 pandemic. For more information, please see the section "[Go big on data and digital](#)".

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Clinical data readouts

in 2021, paving the way for further launches in 2022 and beyond

Advancing a strong and diverse pipeline

We are advancing more than 160 projects in full clinical development, with 54 ongoing Phase III programs. By 2026, we anticipate approval of 20 pipeline assets with the potential to become blockbuster medicines with annual sales of more than USD 1 billion. Building on our success in small-molecule therapies and biologics, we are also investing in advanced technologies that offer new treatment paradigms for patients, such as radioligand therapies and gene therapies.

Cardiovascular, renal and metabolism

Cardiovascular disease (CVD) is the leading cause of death worldwide. It is one of several complex and often interrelated chronic disorders – along with renal and metabolic diseases – that together affect billions of people around the globe. Novartis is pioneering treatments that address the spectrum of these diseases.

Entresto is approved in more than 100 countries for the treatment of adult symptomatic heart failure with reduced ejection fraction, a condition in which the heart fails to pump blood as well as it should. In 2021, *Entresto* was granted an expanded indication in the US and other countries, allowing for the treatment of most chronic heart failure patients, including all those with an ejection fraction below normal.

Also in 2021, *Entresto* received approval in China and Japan for treatment of patients with essential hypertension, the most common form of high blood pressure. This new indication makes *Entresto* the first new therapy for hypertension in China in over 10 years.

Leqvio is a novel treatment that reduces low-density lipoprotein (LDL) cholesterol, a highly important modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD),

which accounts for over 85% of all CVD deaths. Clinical studies showed that this first and only small-interfering RNA therapy for ASCVD can reduce LDL cholesterol by up to 52%, on top of maximally tolerated statins, through two injections per year, after an initial dose and one at three months. *Leqvio* has been approved in more than 50 countries, including the US and the EU, as well as in the UK as part of a population health management agreement that is expected to reach up to 300 000 patients in three years.

TQJ230 (pelacarsen), another nucleic acid-based therapy, is currently in Phase III development for the secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a), an independent inherited ASCVD risk factor that cannot be effectively addressed by diet and other lifestyle changes. Phase II trial data showed that TQJ230 can reduce lipoprotein(a) in high-risk patients below recognized risk thresholds.

LNP023 (iptacopan) is an investigational treatment for several severe, life-limiting kidney conditions, including C3 glomerulopathy (C3G) and IgA nephropathy (IgAN) – two diseases that mainly affect younger patients – as well as paroxysmal nocturnal hemoglobinuria, a life-threatening blood disorder. In 2021, we announced that LNP023 met its primary endpoints for C3G and its primary endpoint for IgAN in Phase II clinical trials. Phase III studies are ongoing.

In our mid-stage pipeline, we are exploring the potential of two compounds discovered at NIBR – JDQ443 and TNO155 – to target the previously “undruggable” proteins KRAS and SHP2, respectively. If proven effective, the combination therapy could open up new treatment options for patients with lung cancer as well as other hard-to-treat tumors.

Our oncology pipeline also includes LXH254 (nafoparib), a targeted cancer therapy currently being studied in multiple combinations in defined populations of melanoma and lung cancer patients, and NIS793, for which the FDA has granted orphan drug designation for the treatment of pancreatic cancer in combination with chemotherapy.

Novartis is a leader in finding new treatments for cancer, with approximately 45 compounds in development

Lung cancer

More people die of lung cancer than any other type of cancer, with death rates increasing in many parts of the world.

ACZ885 (canakinumab) is an antibody treatment currently in Phase III development for non-small cell lung cancer. It was accelerated into lung cancer studies after results in a large-scale cardiovascular study demonstrated a significantly lower than expected lung cancer mortality. In 2021, we reported that two Phase III trials in non-small cell lung cancer for second- and first-line patients did not meet their primary endpoints. In the first-line study, however Novartis researchers observed potentially meaningful improvements among certain groups of patients. These results support continued study of ACZ885 in earlier stages of lung cancer and further evaluation of Pro-Tumor Inflammation in all lung cancer settings. Studies of ACZ885 in both the adjuvant and neoadjuvant setting are ongoing.

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Photo Novartis scientists during the early days of research into targeted cancer therapies

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Major submissions
in the US, the EU, Japan and China during 2021

Prostate cancer

Prostate cancer is the second most diagnosed cancer in people with a prostate gland, with poor survival prognosis in metastatic disease.

Novartis is exploring a new, targeted way to treat metastatic castration-resistant prostate cancer (mCRPC) with ¹⁷⁷Lu-PSMA-617 (lutetium Lu 177 vipivotide tetraxetan/lutetium (¹⁷⁷Lu) vipivotide tetraxetan), an investigational radioligand therapy. In 2021, the FDA granted ¹⁷⁷Lu-PSMA-617 breakthrough therapy designation after a Phase III study showed that the treatment plus existing care options significantly improved overall survival and radiographic progression-free survival for patients with mCRPC compared to existing care options alone. Regulatory submissions for ¹⁷⁷Lu-PSMA-617 have been accepted by the FDA and European Medicines Agency.

Breast cancer

Breast cancer, the most common cancer in women, is responsible for more than 685 000 deaths per year.

We continue to see results from our clinical program for *Kisqali*. The results of a Phase III study announced in 2021 showed that *Kisqali* in combination with an aromatase inhibitor achieved an overall survival benefit of more than five years for postmenopausal women with hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer, which is the most common subtype of the disease. The data represent the longest reported median survival from a randomized trial in HR+/HER2- advanced breast cancer. Novartis is also conducting a Phase III study of *Kisqali* with endocrine therapy in the adjuvant treatment of HR+/HER2- early breast cancer. The trial completed enrollment in 2021.

Piqray is approved in the US and the EU for breast cancer patients whose disease harbors a PIK3CA mutation. Results from an ongoing Phase II study presented in 2021, as well as recent guideline updates, highlight the efficacy of *Piqray* with fulvestrant for postmenopausal HR+/HER2-,

Two decades of pioneering innovation in chronic myeloid leukemia (CML)

With a breakthrough approval 20 years ago, Novartis opened the door to reimagine CML and other cancers. Despite these advancements, we're not standing still.

In May 2001, Novartis received approval in the US for the first targeted therapy for cancer, known as a tyrosine kinase inhibitor. This was a watershed moment in drug discovery, transforming the treatment landscape for CML and opening the door to treatment possibilities for other forms of cancer and blood disorders. Today the estimated five-year survival rate for CML is above 70%; in the 1970s, it was only 22%.

Yet despite CML being transformed into a chronic disease for many patients, significant unmet needs still remain – particularly for patients who have experienced resistance or intolerance to available treatments. Our research continues, and in 2021 we received US approval of a new treatment for CML in two distinct indications, offering a new treatment option for patients who are resistant or intolerant to existing therapies, and marking another milestone in our long-standing scientific commitment to patients living with CML.

Deliver transformative innovation – key figures¹

	2021	2020	2019
Projects entering development pipeline ²	7	6	8
Ongoing Phase III programs ³	54	44	38
US FDA breakthrough therapy designations ⁴	3	2	3
Major submissions (US, EU, JP, China) ⁵	34	13	33
Major approvals (US, EU, JP, China) ⁶	21	26	24
New molecular entity (NME) approvals ⁶	2	4	5

¹ Includes Innovative Medicines and Sandoz biosimilars only

² Includes projects entering confirmatory development from internal R&D activities. First patient, first visit (PPFV) has occurred in post-proof-of-concept stage after NIBR

³ Includes projects with PPFV in a Phase III study but not yet filed in the US, the EU, Japan or China

⁴ Number of breakthrough therapy designations granted by the US Food and Drug Administration for therapies under development by Novartis

⁵ Includes small molecules, biologics; new fixed-dose combinations of existing APIs; and new target indications, defined as new disease or new line of treatment (e.g., first line vs. second line)

⁶ Includes NMEs such as small molecules, biologics; in the EU, new fixed-dose combinations of existing APIs

demonstrated superiority compared with placebo in the treatment of CSU, but not versus *Xolair*. Novartis is continuing to evaluate the trial data. We also continue to evaluate the potential for QGE031 to bring benefit to patients in the areas of chronic inducible urticaria and food allergy, where there is significant unmet need.

Cosentyx, our treatment for several systemic inflammatory conditions, continues to show strength in addressing a variety of debilitating dermatological and rheumatological conditions. In 2021, we announced approvals of *Cosentyx* in the US and China for the treatment of moderate-to-severe plaque psoriasis in pediatric patients aged 6 years and older who are candidates for systemic therapy or phototherapy, as well as in the US to treat active juvenile psoriatic arthritis (JPsA) in patients aged 2 years and older, and active enthesitis-related arthritis (ERA) in patients aged 4 years and older. *Cosentyx* is the only biologic treatment approved for children and adolescents for both ERA and JPsA in the US.

Cosentyx is also being studied for other inflammatory conditions, including hidradenitis suppurativa, giant cell arteritis and lichen planus, highlighting our commitment to expand *Cosentyx* to more indications and provide new treatment options for patients.

In 2021, we announced the discontinuation of a Phase IIb study of CFZ533 (iscalimab) in kidney transplant patients. The study of CFZ533 in liver transplant continues, as do studies exploring CFZ533 as a potential treatment in other conditions, such as hidradenitis suppurativa and Sjögren's syndrome.

Neuroscience

Neurological diseases are a leading cause of death and disability worldwide. Our work in neurological disorders includes investigational treatments for multiple sclerosis (MS), spinal muscular atrophy (SMA) and other diseases.

PIK3CA-mutated advanced breast cancer patients immediately after failure on prior CDK4/6i treatment (a type of targeted treatment). Development is underway for five new indications, including PIK3CA-relative overgrowth syndrome, a group of rare disorders that cause overgrowth of parts of the body.

Hematology

Scemblix, a new treatment for chronic myeloid leukemia (CML), was approved by the FDA in 2021 for use in patients who are resistant or intolerant to prior treatments, and also for patients with a specific mutation. Discovered by researchers at NIBR, the treatment highlights our ongoing commitment to patients with the disease (see "Two decades of pioneering innovation in chronic myeloid leukemia" on the previous page).

MBG453 (sabatolimab) is an anti-TIM-3 monoclonal antibody being studied for the treatment of higher-risk myelodysplastic syndromes and acute myeloid leukemia, both rare blood cancers. In 2021, MBG453 received a fast track designation from the FDA and an orphan drug designation from the European Commission. In 2021, we reported that a Phase III clinical study of *Kymriah* as a second-line treatment in aggressive B-cell non-Hodgkin lymphoma did not meet its primary endpoint. We continue to study *Kymriah* in other forms of lymphoma and leukemia.

In 2021, we reported that a Phase III clinical study of our chimeric antigen receptor T-cell (CAR-T) therapy *Kymriah* as a second-line treatment in aggressive B-cell non-Hodgkin lymphoma did not meet its primary endpoint. We continue to study *Kymriah* in other forms of lymphoma and leukemia.

Immunology, hepatology and dermatology

Our R&D teams are pioneering the development of therapies for immune system disorders, skin conditions and other diseases with high unmet needs.

We are committed to developing medicines that will advance the treatment of chronic spontaneous urticaria (CSU), so patients are able to live their lives without the distressing and unpredictable symptoms of this skin disease. Any new therapies will add to our portfolio of medicines that already includes *Xolair*, our existing approved therapy for CSU.

Enrollment began in 2021 for Phase III studies in CSU of LOU064 (remibrutinib), an oral BTK inhibitor that we are investigating for a number of immune-mediated conditions.

Also in 2021, Phase III clinical trials for QGE031 (ligelizumab), a next-generation monoclonal anti-immunoglobulin E (IgE) antibody, showed that QGE031

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Research and clinical programs
underway to identify and accelerate the next generation of radioligand therapies for cancer

Our gene therapy Zolgensma is a treatment for both presymptomatic and symptomatic children with SMA, a devastating neurodevelopmental disease. It is approved in 42 countries. Building on our success with Zolgensma, in 2021 we started a new Phase III study of an intrathecal formulation in treatment-naïve patients with SMA type 2. Early patient identification through newborn screening is critical for SMA patients since the disease causes irreplaceable motor neuron loss. For more on how we work with payers and healthcare systems to highlight the importance of early screening for SMA patients, please see the section "Embrace operational excellence."

Our comprehensive portfolio for MS – a debilitating chronic disease that affects 2.8 million people worldwide – emphasizes our commitment to improving the quality of life for people living with MS at all stages of the disease. *Kesimpta*, one of our therapies for MS, received approval in the EU in 2021 for the treatment of relapsing forms of MS in adults with active disease. It is already approved in the US and other key markets. *Kesimpta* is the first B-cell therapy that can be self-administered at home. In 2021, we also started Phase III trials to investigate LOU064 in patients with relapsing forms of MS.

Our portfolio shows our commitment to improving the quality of life for people living with multiple sclerosis

We are exploring other neurological conditions where the need for new treatments is pressing. One example is Huntington's disease, a rare, inherited neurodegenerative condition that leads to progressive disability and death. There currently are no approved therapies that delay onset of the disease or slow its progression. LMI070 (branaplam), our investigational, oral small-molecule RNA splicing modulator, could potentially treat Huntington's disease by targeting RNA to reduce levels of a mutant protein. Phase II trials were initiated in 2021.

In 2021, Novartis and UCB announced a global co-development and co-commercialization agreement to bring potentially disease-modifying therapies to people living with Parkinson's disease, which affects more than 10 million people worldwide. These investigational therapies include UCB0599, a small-molecule, alpha-synuclein misfolding inhibitor currently in Phase II development, which is being studied to understand if it can slow or stop the progression of Parkinson's disease. In addition, upon completion of an ongoing Phase I program, there is an opt-in to co-develop UCB7853, an anti-alpha-synuclein antibody.

Ophthalmology

We are working to find innovative treatments for diseases of the eye, with the goal of reducing or eliminating the huge burden on patients and society caused by visual impairment and blindness.

One of our novel treatments is UNR844, a topical ophthalmic solution currently in Phase II development for presbyopia – a common, gradual, age-related loss of the ability to focus actively on nearby objects, caused by loss of elasticity of the lens of the eye.

In 2021, Novartis announced an agreement to acquire the UK-based ocular gene therapy company Gyroscope Therapeutics, adding to our pipeline a one-time gene therapy that could transform care for geographic atrophy (GA), an advanced form of dry age-related macular degeneration (AMD) that leads to progressive and irreversible vision loss. There are no approved treatments for GA, making it one of the most significant unmet needs remaining in retinal diseases.

GT005, the lead asset from Gyroscope Therapeutics, is designed as an AAV2-based, one-time investigational gene therapy for GA secondary to AMD that is delivered under the retina. Completion of the acquisition is subject to customary closing conditions. Novartis and Gyroscope Therapeutics will continue to operate as separate and independent companies until closing.

Respiratory and allergy

Novartis is developing novel therapies to treat respiratory conditions such as asthma, chronic obstructive pulmonary disease and fibrotic lung diseases. These illnesses affect the lives of millions of people worldwide, and evidence suggests the burden is increasing due to climate change.

Building on our success with Xolair, the first biologic brought to market for asthma, we are pursuing Phase II studies for CSJ117, an inhaled biologic adjuvant therapy for severe uncontrolled asthma. We also initiated Phase III studies of QGE031 for patients with IgE-mediated peanut allergy.

Advanced technology platforms

Novartis is investing in new technologies and platforms that offer more targeted approaches to fighting – and, in some cases, potentially curing – serious diseases. We have the depth and scale to discover, develop and commercialize therapies using these advanced platforms.

Radioligand therapy delivers precision-targeted radiation to cancer cells widely disseminated in the body, with the goal of limiting damage to surrounding tissue. It has the potential to address a wide range of cancers and become a major pillar of cancer care.

Novartis has built a strong foundation in this area with *Lutathera*, our first approved radioligand therapy, and with ¹⁷⁷Lu-PSMA-617, our investigational therapy for prostate cancer (see "Oncology" above). In 2021, we acquired fibroblast associated protein (FAP) targeted assets from iTherapeutics. We launched a collaboration with Artios to explore novel combinations of radioligand therapy and DNA damage pathway inhibitors and with PeptiDream to work on macrocyclic and constrained peptides. We also established a partnership with Molecular Partners to work on DARPin protein-based binding domains. We have more than 15 research and clinical programs underway to identify

and accelerate the next generation of radioligand therapies for cancer.

In gene therapy, one of our technologies uses benign viruses called adeno-associated viruses (AAVs) to deliver genes to cells inside the body. The goal is to repair the cells with a one-time treatment. Our first approved AAV-based therapy was *Zolgensma* for SMA, and we are now exploring experimental forms of gene therapy for other diseases, from brain disease to blood disorders. Altogether we have more than 20 research programs in gene therapy.

The Novartis early-stage pipeline features a growing arsenal of optogenetic gene therapies, based on genetically engineered light-sensitive proteins that can rewire cells in the eye, allowing them to act as replacement photoreceptors. In 2020 and 2021, we obtained two key optogenetic technologies through the acquisitions of Vedere Bio and Arctos Medical. The resulting therapies could potentially treat blinding diseases such as inherited retinal dystrophies and age-related macular degeneration, which affect millions of patients worldwide.

With cell therapy, a patient has key cell types extracted and genetically modified in a clinical lab before being injected back into the body. An example of this is CAR-T therapy, a treatment generated from a patient's own T-cells. Novartis was the first pharmaceutical company to significantly invest in pioneering CAR-T research and initiate global CAR-T trials. Our flagship CAR-T therapy, *Kymriah*, was the first cell therapy approved in the US for certain kinds of leukemia and lymphoma, and is now available to patients in 30 countries. We aim to broaden the impact of CAR-T technology to help patients with a variety of difficult-to-treat hematological cancers and solid tumors.

Novartis has a resilient global CAR-T manufacturing footprint, spanning seven facilities across four continents. In 2021, we announced the development of a novel manufacturing plat-

form – created at NIBR – called T-Charge, which is expected to improve the therapeutic potency of the T-cell product while halving the time needed to take cells from the patient, manufacture the product, and return it to a healthcare professional for administration.

Innovation for global health

Our R&D efforts include discovering and developing novel medicines for our company's flagship global health priorities, as well as other diseases that predominantly affect underserved patients in lower-income countries, while exploring new ways to treat COVID-19, the most urgent public health issue in the world today.

COVID-19

We are collaborating with **Molecular Partners** to develop ensovibep, a potential new treatment option for COVID-19 that targets the virus using proprietary DARPin technology to neutralize SARS-CoV-2.

The topline results of a Phase II study reported in early 2022 showed that a single intravenous dose of ensovibep reduced viral load through Day Eight, shortened symptom duration, reduced emergency room visits and/or hospitalizations related to COVID-19, and reduced deaths, compared to placebo. In separate studies, it maintained potent in-vitro pan-variant activity against all variants of concern identified so far, including Omicron. Novartis in-licensed ensovibep from Molecular Partners. We will accelerate manufacturing scale-up and plan to seek expedited regulatory authorizations globally.

Separately, we are working to discover a novel therapy targeting the main protease – an enzyme essential to viral replication across coronaviruses, including SARS-CoV-2. The goal is to develop a therapy that could treat many or all other forms of coronaviruses, potentially addressing future pandemics.

OUR PERFORMANCE IN 2021

Malaria

Malaria continues to burden societies across the globe, particularly in Africa, and evidence suggests that cases may rise as a result of climate change. Novartis has taken a multipronged approach to fighting the disease, working with partners such as [Medicines for Malaria Venture](#) to research, develop and manufacture a portfolio of essential antimalarial drugs.

In 1999, we introduced our first malaria drug, a highly effective fixed dose of artemisinin-based combination therapy. In 2021, we crossed the 1 billion mark in antimalarial treatments delivered to patients worldwide (please see "[Build trust with society](#)" for more information).

For more than 20 years, the [Novartis Institute for Tropical Diseases](#) (NITD), part of NIBR, has been at the forefront in the search for novel medicines for malaria and other neglected diseases. Two Novartis compounds for uncomplicated and severe malaria, KAF156 (ganaplacid) and KAE609 (cipargamin), respectively, are in clinical trials in Africa and Asia. These compounds could potentially address resistance to current therapies as well as provide simplified therapeutic regimens. In 2021, a Phase IIb study of KAF156 and its partner medicine, lumefantrine, in adults and children with malaria reported positive results, supporting continued development of the combination treatment.

Neglected tropical diseases

NITD, with funding from the Wellcome Trust, is in the early stages of a discovery program aimed at finding first-in-class curative anti-parasitic therapies for Chagas disease, a serious condition affecting more than 6 million people mainly in Latin America. We are also conducting a Phase IV trial of our heart failure medicine *Entresto* in patients with chronic Chagas cardiomyopathy. Chagas disease is a tropical parasitic infection but can manifest in the long term as chronic heart failure or other complications, causing disability and even death.

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 2020, 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 Phase I studies, technical research and development activities, and regulatory interactions. 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 activities, with the first Phase II study scheduled to start in 2022 in India. Additional trials are planned in East Africa, which has the highest burden of visceral leishmaniasis.

Sickle cell disease

Sickle cell disease (SCD) is a hereditary blood condition that afflicts millions around the globe, particularly people of African descent, with sub-Saharan Africa bearing roughly 80% of the disease burden. Our commitment to addressing SCD includes a therapeutic pipeline as well as a holistic approach to diagnose, treat and manage the disease in sub-Saharan Africa.

While the genetic cause of SCD has been known for decades, only recently has medical science gained the tools to potentially mitigate the biological effects of the errant gene that causes the disease. We also are pursuing an ex vivo hematopoietic stem cell program for SCD, using CRISPR gene editing technology licensed from Intellia Therapeutics, and in 2021 we initiated patient dosing. Also in 2021, Novartis announced a pioneering collaboration with the [Bill & Melinda Gates Foundation](#) to support the discovery of a single-administration in vivo gene therapy to cure SCD, designed from the start to be practical for use in lower-resourced settings.

Putting patients at the center of our clinical trials

Engaging with patients and caregivers across the life cycle of our medicines is critically important to ensure we develop treatments that not only are safe and effective, but also truly address unmet medical needs.

The [Novartis Commitment to Patients and Caregivers](#), launched in 2018, guides our teams across functions and divisions in ensuring patients have a voice in the research, development and commercialization of our medicines. We continue to roll out a systematic approach to patient engagement that covers the full development life cycle – from early research to post-launch.

We continue to roll out a systematic approach to patient engagement that covers the full development life cycle – from early research to post-launch

In 2021, 57, or around 30%, of our clinical development programs had a patient engagement component, up from 44 in 2020. Patients provided input on key aspects such as clinical study endpoints that matter to their disease, how to facilitate easier access to clinical trial sites, and how to enable remote trial participation. We also integrated patient insights into early-stage research: In 2021, 46 NIBR programs had a patient engagement component.

Patient engagement also enables us to streamline our clinical trials and bring our medicines to market more quickly. For example, early input from patients in trial design can help us reduce the need for costly and time-consuming protocol changes later in the development process while ensuring that the trial design is aligned with study participants' needs

and preferences. In addition, we continue to help patients access medicines through our patient support and managed access programs. Please see the section "[Build trust with society](#)" for more details.

In 2021, we engaged with 162 patient organizations across 48 disease areas to inform our decision-making.

During the COVID-19 pandemic, the need for patient support grew while the income of patient organizations dropped, primarily due to the cancellation of educational events and fundraising activities. We provided funding to the community that was – among other purposes – used to strengthen digital communications tools and channels to help bridge these gaps. In 2020, the latest year for which data is available, Novartis supported 1 248 patient organizations in 79 countries. Please see the [Novartis corporate website](#) for more information.

Diversity in clinical trials

We strive to include diverse patient populations in our clinical trials – both to understand how patients who are most likely to be treated for a disease will respond to a medicine, and because it is the right thing to do.

We are working to address barriers to clinical trial participation, such as identifying sites where patients with a particular disease or condition may be located, identifying healthcare providers that treat underserved or underrepresented populations, and collaborating with researchers to enroll diverse populations in clinical trials.

In 2021, we published a [Commitment to Diversity in Clinical Trials](#). In the short term, we committed to evaluate diversity and inclusion principles for all our Phase III studies with US country participation. In the longer term, we aim to expand this to all our global trials while leveraging data science and digital technology to track diversity data across our drug development programs.

In the US, health disparities affecting minority groups are endemic – an issue that was highlighted and exacerbated by the COVID-19 pandemic. Compared with non-Hispanic whites, the Black and African American community has a lower life expectancy, a higher mortality rate from cancer, a greater likelihood of diseases such as asthma, and significantly increased rates of maternal and infant mortality. Health inequity is also a particular challenge for the Black and African American community in medical schools and among physicians and clinical trial investigators; in all three groups, Black and African Americans are proportionally underrepresented.

In 2021, Novartis and the [Novartis US Foundation](#) announced plans to invest approximately USD 13.7 million to establish three research centers at Morehouse School of Medicine in Georgia, including a clinical trial center of excellence that could be a model for possible expansion to other historically Black colleges, universities and medical schools.

The investment is part of a 10-year commitment with Morehouse; 26 historically Black colleges, universities and medical schools; and other organizations. The objective is to co-create programs that address the root causes of systemic disparities in health outcomes and foster greater diversity, equity and inclusion across the R&D ecosystem.

In addition, we are collaborating with [GlaxoSmithKline \(GSK\)](#) to support research investigating the link between genetic diversity across different regions in Africa and its potential impact on response to drug therapeutics. With a combined funding commitment of GBP 2.8 million (USD 3.6 million) over five years, the project calls on African researchers to submit research proposals on the relevance of African genetic diversity to the treatment of malaria and tuberculosis. Proposals selected for funding are expected to be announced in the first half of 2022.

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Clinical programs
with a patient engagement component, up from 44 in 2020

For more information on the Novartis R&D pipeline, please see
www.novartis.com/research-development/novartis-pipeline



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Embrace operational excellence

From discovery to delivery, we work to improve the efficiency and effectiveness of our operations. These activities support our profitable growth and free up resources to invest in innovation for patients. In everything we do, patient safety and product quality remain paramount.

2021 highlights

52%

Launch brands and growth-driver products
contribution to Innovative Medicines Division net sales

71 bn

Treatments supplied
through Novartis manufacturing sites

99.2%

Regulatory inspections
of our facilities deemed acceptable without major findings

12 064

Suppliers risk-assessed
through our third-party risk management framework

In this section

Strengthening product launches

We aim to consistently deliver successful launches to support our financial performance and enable broad and rapid access to our medicines.

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Transforming manufacturing

We are transforming our manufacturing operations to support our strategy while reducing the environmental footprint of our facilities.

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Ensuring patient health and safety

Patient health and safety is fundamental to our purpose. Our activities are focused on three areas: product quality, pharmacovigilance and combating falsified medicines.

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Managing our supply chain responsibly

We promote ethical behavior and foster environmental sustainability across our supply chain.

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Delivering effective business services

Our business services and digital teams improve productivity while enabling our people to execute on our strategy and deliver on our purpose.

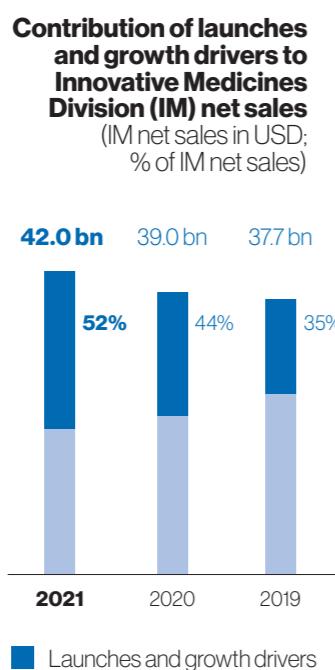
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Related links and disclosures:

- Novartis Third-Party Code
- Quality Commitment
- Green Expectations from Suppliers
- Our Ethical and Sustainability Standards for Third Parties
- Position on Falsified and Counterfeit Medical Products

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Strengthening product launches

In our commercial operations, we aim to consistently deliver successful launches to support our financial performance and enable broad and rapid access to our medicines.

In 2021, launch brands and medicines we consider our key growth drivers¹ contributed 52% of net sales in our Innovative Medicines Division, compared with 44% in 2020. By 2026, we expect approval of more than 20 pipeline assets with the potential to become blockbuster medicines with sales of more than USD 1 billion.

By 2026, we expect approval of more than 20 pipeline assets with the potential to become blockbuster medicines

We have developed a launch roadmap to codify best practices. For example, we start to prepare early – more than three years before the anticipated launch date in many cases – including talking with patients, physicians and payers to better understand their perspectives and needs. In our Novartis Pharmaceuticals business unit, for example, around 80% of investment in medical affairs is now focused on the pre-launch stage.

For *Kesimpta*, our treatment for multiple sclerosis (MS), we focused pre-launch investment on three key markets: the US, Germany and China. We deployed an unbranded digital information platform that reached up to 2 000 physicians in the US. We also worked with patient advocacy groups to ensure their views were integrated into our launch preparations, and we talked to payers to understand their needs.

The preparations paid off: In the six months after launch in the US, we had reached 85% of our target customer base, most of them virtually, while around 20% of patients received *Kesimpta* as their first-ever treatment for MS and more than 50% of patients received it as their first-line treatment. *Kesimpta* is approved in more than 60 countries worldwide.

Another example is *Zolgensma*, our gene therapy for spinal muscular atrophy (SMA) that reached USD 1.4 billion in sales in 2021. Early patient identification through newborn screening programs and treatment awareness are critical for SMA patients. We work closely with stakeholders such as payers to highlight the importance of early treatment, and provide disease awareness programs for parents, physicians and other health professionals to spot the signs and symptoms of SMA. In 2021, around 85% of new births in the US underwent screening for SMA, and we anticipate that the EU will have SMA screening in place for all new births by 2025.

Our pre-launch preparations also found that achieving sustainable access to a one-time gene therapy like *Zolgensma* in diverse markets such as Argentina and Egypt requires a menu of options to address the needs of stakeholders. For example, our early access and "Day One" access agreements offer customizable options for payers – including retroactive rebates, deferred payments, installment options and outcome-based rebates – and are designed to ensure that access is available to patients even before regulatory approval and formal national reimbursement agreements are in place. In 2021, we had early access agreements in place in six markets, and pay-for-performance agreements in place in 16 markets.

The therapy was commercially available in over 40 countries.

Meanwhile, in our Oncology business unit we leveraged more than 20 years of experience in chronic myeloid leukemia (CML) to launch *Scemblix*, a new treatment option for patients that was approved in the US in 2021 for treatment of CML in two distinct indications.

Despite tremendous advances in CML treatment over the past decades, some patients struggle to meet treatment goals due to intolerance or inadequate response. Before launch, we took steps to raise awareness of remaining unmet needs for CML patients. Additionally, at the time of launch we estimate that more than 80% of US healthcare providers who treat CML were aware of the compound and/or its unique mechanism of action – known in scientific literature as a STAMP inhibitor. We anticipate approval in Japan and Europe during 2022.

We are also preparing for other launches in our oncology pipeline. For example, we plan to enter the growing checkpoint inhibitor field with VDT482 (tislelizumab), an anti-PD-1 monoclonal antibody that we in-licensed in 2021 as part of an agreement with an affiliate of BeiGene, Ltd. We anticipate launch of VDT482 in second-line esophageal squamous cell carcinoma – the most common type of esophageal cancer globally – in the US in mid-2022. Looking further ahead, the need to extend survival for more patients with different tumor types still exists. We believe VDT482 has the potential for synergistic combinations with other Novartis medicines to help address these unmet needs, and we have initiated three combinations in clinical trials and aim to advance several more within the next years.

Transforming manufacturing

The Novartis Technical Operations (NTO) organization, which manufactures innovative medicines and Sandoz products, helps us to optimize resource allocation while ensuring quality across our 53 production sites worldwide. NTO is split into different technology platforms with responsibility for large molecules, small molecules, Sandoz products, cell and gene therapies, and ophthalmology and local market production.

In 2021, we continued to ensure a reliable supply of medicines to patients worldwide. Our NTO employees supplied 71 billion treatments in 2021, broadly in line with the previous two years, while also supplying tens of millions of vaccine doses for COVID-19.

Supporting demand for COVID-19 vaccines

Novartis is helping produce COVID-19 vaccines at our facilities in Switzerland and Austria as part of our efforts to help end the pandemic and support the stability of global health systems.

Although Novartis no longer has a vaccines business, our many biologics products give us the capabilities to perform mRNA manufacturing and the final step of aseptically filling the vaccine into vials. We prepared our facilities to do this task in only a few months – a process that usually takes more than a year. We produced 40 million doses of the Pfizer-BioNTech vaccine in 2021.

We also signed an agreement with Roche for the production at our Singapore site of the active pharmaceutical ingredient for Roche's Actemra®/RoActemra®, a treatment for rheumatoid arthritis that received emergency use authorization by the US FDA for the treatment of COVID-19 in hospitalized adults and children.



40 m
Doses produced

of the Pfizer-BioNTech vaccine in 2021

¹ Launch brands include *Zolgensma*, *Kesimpta*, *Mayzent*, *Beovu*, *Luxturna*, *Legvio*, *Enerzair*, *Aetectura*, *Piqray*, *Adakveo*, *Tabrecta* and *Scemblix*. Growth drivers include *Cosentyx*, *Entresto*, *Xolair*, *Ilaris*, *Xiidra*, *Aimovig*, *Promacta/Revolade*, *Tafinlar + Mekinist*, *Kisqali*, *Lutathera*, *Kymriah* and *Jakavi* (marketed by Novartis outside the US).

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Our manufacturing operations also continue to evolve as we invest in new technologies and respond to the changing business environment. In 2021, we started manufacturing our cholesterol-lowering drug *Leqvio* at our Schafteinau drug production site in Austria. *Leqvio* is a small-interfering RNA (siRNA) therapy that is approved in more than 50 countries. We are also installing our first siRNA oligonucleotide manufacturing facility at our Schweizerhalle site in Switzerland, which will produce the active ingredient of *Leqvio*.

In 2021, our production sites responded to sharply increased demand for some Novartis products in China after their inclusion on the country's National Reimbursement Drug List made them available to more patients. For example, we responded to a significant increase in demand for *Cosentyx* and *Tafinlar* versus the previous year.

We are also pursuing a digital transformation of our manufacturing operations with the aim of improved quality and greater efficiency. For more details on how we are using digital technology and data analytics across the company, please see the section "[Go big on data and digital](#)."

We continue to optimize our network of manufacturing sites worldwide, adjusting our production capacity to match our changing product mix. In 2021, we announced plans to transform 11 sites, including three that we plan to sell or close and one that we already sold. We are working with employees affected by the changes to help them manage through the transition.

Sustainability in manufacturing

Our manufacturing facilities are central to our efforts to minimize our environmental footprint. The majority of Novartis carbon emissions, water usage and waste in our own operations come from our production sites. In 2021, efforts to reduce the environmental footprint of our manufacturing sites contributed more than 10% of our overall reduction in carbon emissions (Scope 1 and 2) and more than 7% reduction in water consumption, as well as more than 34% of waste reduction in our own operations.

We are investing in new technologies to make our manufacturing processes more resource efficient. For example, an upgrade to the solvent process at our Kundl site in Austria led to a reduction of 8 500 tons of carbon dioxide (CO₂) annually. Our site in Huningue, France, reduced 19% of its annual energy consumption – equivalent to 1600 tons of CO₂ – through a more energy-efficient system. A site in Turkey used a filtration system to cut water consumption by 14%.

All manufacturing sites are required to treat process water according to local legal requirements before it is returned to the environment. Novartis facilities and priority suppliers are included in our PiE (Pharmaceuticals in the Environment) program to assess their effluent load of active pharmaceutical ingredients (APIs) in water streams against internal standards and requirements from the AMR Industry Alliance framework – a private sector coalition providing sustainable solutions to curb antimicrobial resistance. Potential impacts on water quality from the use of our products downstream in the value chain are considered part of the marketing authorization approval process.

Novartis sites are on track to eliminate polyvinyl chloride in secondary and tertiary packaging by the end of 2022

In addition, Novartis sites are on track to eliminate polyvinyl chloride (PVC) in secondary and tertiary packaging by the end of 2022. For example, we now use a carton-based packaging design for *Aimovig*, a migraine treatment.

For more on this topic, please see the section "[Build trust with society](#)" and our [TCFD disclosure](#).

Ensuring patient health and safety

Patient safety is fundamental to our purpose: We cannot improve and extend people's lives if we do not deliver safe, high-quality medicines. The importance of patient safety was highlighted in our [2021 materiality assessment](#), with both internal and external stakeholders identifying it as the most material topic.

Patient safety cuts across several strategic priorities for Novartis, including operational excellence and building trust with society. Our activities are focused on three areas that span the life cycle of our medicines and cover both our own operations and activities outside our walls: product quality, pharmacovigilance and combating falsified medicines.

Product quality

We maintain a robust quality management system for the production of marketed products and investigational medicines, in full compliance with requirements from health authorities and other regulators around the world.

We hold relevant manufacturing licenses and Good Manufacturing Practice (GMP) certificates for 100% of our manufacturing, supply and distribution operations. These are issued after inspections by external health authorities such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the World Health Organization (WHO) and Swissmedic. We hold relevant ISO certifications for the manufacture of medical devices.

Patient health and safety performance indicators

	2021	2020	2019
GxP audits			
Total audits executed	1 419	903	1 607
Internal ¹	125	111	162
External ²	1 294	792	1 445
Regulatory authorities			
Total inspections	126	126	187
Inspections found to be acceptable (%)	99.2	99.2	96.8
US FDA			
FDA inspections	10	6	19
FDA warning letters	0	0	0
FDA Form 483	5	1	11
US FDA sponsor inspections			
Inspections related to clinical trial management and pharmacovigilance	3	1	2
Number of FDA VAI (voluntary action indicated) classifications	0	0	1
Number of FDA OAI (official action indicated) classifications	0	0	0
Recalls			
Total recalls	27	27	29
Class I recalls	3	1	3
Class II recalls	20	21	21
US FDA			
FDA recalls	1	0	2

¹ Total number of audits that are performed on facilities owned by Novartis

² Total number of audits that are performed on GxP suppliers to Novartis

99.2%

Regulatory inspections
of our facilities worldwide found to be acceptable

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10 days

Our policy

to report all confirmed incidents of falsified medicines to the WHO within 10 days was recognized as a best practice by the Access to Medicine Foundation

audits conducted remotely. All but six audits were found to be acceptable (99.1%). One of the audits that required further improvement was at our own site due to unretrievable source data from a legacy system that is set to be decommissioned and replaced by the end of 2021. The other audits with opportunities for improvement were at external suppliers with corrective actions in progress.

We conduct thorough investigations when any deviations from current GMPs or other relevant regulations occur, or when we detect out-of-specification results or any other failures in our manufacturing processes. Incidents are assessed by subject matter experts and conclusions are provided to the appropriate health authorities with relevant documentation. Actions such as recalls are executed in agreement with the relevant authorities. Novartis initiated 27 recalls in 2021.

We also monitor our medicines for the possible presence of nitrosamines and completed all necessary nitrosamine assessments in 2021, closely following the recently agreed EMA/FDA implementation plan for the pharmaceutical industry.

We have a robust quality and safety training process for employees and third parties. We require all employees involved in manufacturing, supply and distribution to undergo at least two annual training sessions on quality standards. Employees can take additional training relevant to their role or worksite. We are regularly audited on our training procedures.

All third parties providing services or products manufactured to good practice standards are required 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 ongoing disruptions created by the COVID-19 pandemic, we maintained our quality and safety training process in 2021.

We look for ways to strengthen and streamline our quality processes to improve efficiency and bring our medicines to patients faster. This includes the use of digital technology and remote work across our quality operations, a trend that has been accelerated by the COVID-19 pandemic. For example, in 2021 we rolled out paperless quality control at three sites, including in Torre Annunziata, Italy, and in Ljubljana, Slovenia.

For more on this topic, please see the [Novartis quality management system](#) section of our corporate website.

Pharmacovigilance

Novartis continues its efforts to boost pharmacovigilance capabilities to support patient safety worldwide.

While clinical trials provide important information on a medicine's safety during development, it is only after its use in greater numbers of patients in real-world settings that some adverse events become known. Effective pharmacovigilance requires activities to educate patients, providers and pharmacists, and strengthen reporting of adverse events to the company. Our pharmacovigilance and falsified medicines teams also work closely together, for example in cases where a disproportionate number of adverse events may indicate the presence of suspected falsified medicines.

We maintain a high level of compliance to regulatory requirements for both individual case safety reports and periodic benefit-risk assessments. In addition, in 2021 an internal audit confirmed the strength of the Novartis integrated pharmacovigilance governance model after it obtained ISO 9001 certification in the previous year.

With a growing number of medical devices in the Novartis portfolio, we have also built a robust system to monitor adverse events associated with medical devices worldwide. Novartis was the first company certified for compliance with the [European Medical Devices Regulation](#), which came into force in 2021.

As a complement to traditional pharmacovigilance methods, we increasingly use technologies such as process automation, machine learning and natural language processing to analyze multiple data sources for adverse events.

Novartis collaborates with pharmacovigilance associations and authorities in multiple countries, including Italy, the Scandinavian countries, Switzerland, China and India, to support the implementation of local and international guidelines as well as the implementation of new adverse event reporting submission methods.

Further examples of our capacity-building initiatives in 2021 included training for clinical trial investigators in Mexico and China, as well as support for the creation of a local organization for pharmacovigilance professionals in the Philippines. In Asia, Novartis participated in regional forums where we presented our pharmacovigilance approach for advanced technology platforms, such as cell and gene therapies, while in Latin America we worked with partners to support them in reporting adverse events under different scenarios of the COVID-19 pandemic.

Examples of our capacity-building initiatives in 2021 included training for clinical trial investigators in Mexico and China

In response to the COVID-19 pandemic, we set up a task force to ensure the continuity of our pharmacovigilance system while providing support to healthcare professionals. We applied a pragmatic approach that created efficiencies across some of our processes such as the Individual Case Safety Report (ICSR) follow-up. We estimate that the ICSR efficiency gain translated into 2 500 saved hours for healthcare professionals at a critical time.

Worldwide patient safety offices contributed with safety data collection on COVID-19 investigator-initiated trials to support assessments about the impact of the new virus.

Falsified medicines

Falsified medicines are a growing global problem. The Pharmaceutical Security Institute reported a 38% increase in incidents of falsified medicines from 2016 to 2020, a trend that has been exacerbated by increased demand for medicines amid the COVID-19 pandemic.

At Novartis, our priority is to protect patient health and safety through quick authentication and reporting of falsified medicines to health authorities and the WHO. Since 2017, our efforts have been recognized as a best practice by the [Access to Medicine Foundation](#). In 2021, Novartis was among the first pharmaceutical companies to join the WHO's new online reporting platform for falsified medicines incidents.

In 2021, close collaboration with local law enforcement led to the investigation of 318 incidents in 41 countries, 66 successful enforcement actions, and the seizure of 1 million units of falsified medicines as well as the removal of more than 10 100 illicit advertisements from online platforms.

Digital technology is a critical part of our efforts to quickly authenticate falsified medicines. In 2021, we made significant progress on three interconnected digital solutions.

Authentifield by Novartis is a cost-effective mobile spectrometric sensor that can reduce the time needed to authenticate suspect medicines from several weeks to a maximum of five days. By early 2023, we aim to train 1000 end users and deploy 500 sensors in 96 countries across 100 high-risk products in our portfolio.

Another project is MoVe, a mobile platform that enables Novartis employees to quickly verify the authenticity of secondary packaging for any product. The solution was in use in 24 countries by the end of 2021.

Finally, Novartis continued to lead an initiative with the Innovative Medicines Initiative and 12 major pharmaceutical companies to develop a use case for blockchain technology in the pharmaceutical supply chain. The aim is to empower patients to check their own medicines for authenticity while generating data – backed by robust privacy controls – on trends in falsified medicines.

Fast authentication needs to be supported by timely reporting. Novartis has a policy to report all confirmed incidents of falsified medicines to the WHO within 10 days. Our efforts have been recognized as a best practice by the [Access to Medicine Foundation](#). In 2021, Novartis was among the first pharmaceutical companies to join the WHO's new online reporting platform for falsified medicines incidents.

We also engage with public and private stakeholders, such as the WHO and the Organization for Economic Co-operation and Development, to encourage coordinated action and promote effective policy-making on falsified medicines. In 2021, we delivered over 150 engagements and reached over 7 200 stakeholders in 14 countries.

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Suppliers assessed

through our Third-Party Risk Management framework

Managing our supply chain responsibly

We are committed to working with third parties who operate in a manner that is consistent with our values and ethical principles. While interactions with third parties at Novartis are broadly defined by our [Third-Party Code](#), we identify, assess, monitor and mitigate risk associated with suppliers through our [Third-Party Risk Management \(TPRM\) framework](#).

Implemented globally across Novartis in 2019, our TPRM process promotes ethical behavior and fosters sustainability across our supply chain by addressing risk areas such as anti-bribery; animal welfare; health, safety and environment (HSE); labor rights; information security; and data privacy. We conduct risk assessments for all new eligible suppliers and new products, services or sites from existing suppliers. Not all suppliers trigger a detailed risk assessment.

In 2021, we assessed 12 064 suppliers through our TPRM process, up from 8 448 in 2020. We agreed on remediation actions with 912 suppliers, and we stopped engagements

with 37 suppliers due to the risk assessment results. We audited 85 suppliers, a significant increase from the previous year as the impact of the COVID-19 pandemic eased in several countries.

We took steps to increase the efficiency of our TPRM process and align it more closely to our overall view of risk at Novartis

In 2021, we took steps to increase the efficiency of our TPRM process and align it more closely to our overall view of risk at Novartis, while maintaining a high level of assurance.

For example, we started to prioritize all third parties in scope by risk severity. As part of this process, we de-scoped two risk areas – financial due diligence and business continuity – since the former is already embedded in other process steps while the latter is covered by default within other risk areas.

We also completed the integration of human rights into four relevant risk

Supply chain performance indicators

	2021	2020	2019
Suppliers risk-assessed by Third-Party Risk Management (TPRM)^{1,2,3}			
Number of suppliers risk-assessed by TPRM	12 064	8 448	2 839
Suppliers assessed by risk area⁴			
Anti-bribery	2 303	2 014	479
Animal welfare	9	10	3
Health, safety and environment	477	315	226
Information security and data privacy	5 668	3 174	1 142
Labor rights	6 755	4 635	1 423
Quality GmP	848	561	162
Actions taken			
Suppliers audited ^{2,5}	85	35	135
Suppliers with remediation action agreed	912	521	122
Supplier engagements stopped due to risk assessment outcomes	37	120	15

¹ Assessment is done on new suppliers and new products, services or sites from existing suppliers. Not all suppliers trigger risk assessments.

² Figures do not include GxP audits (see [Ensuring patient health and safety](#) for more details).

³ Data from 2019 reflect April–December 2019, managed under the TPRM umbrella, based on the TPRM program geographical rollout.

⁴ Reflects risk assessments conducted on the suppliers. One supplier can trigger more than one assessment depending on the risk areas involved.

⁵ Anti-bribery audits included from 2021 onward

areas (labor rights, HSE, data privacy, and anti-bribery and corruption) in our TPRM process. (For more on human rights at Novartis, please see the section [“Build trust with society.”](#)) In addition, we moved responsibility for screening new vendors for Good Manufacturing Practice under the scope of Quality teams in NTO, which have specialized expertise in this area.

We also evaluated ways to automate our processes. For example, current manual risk assessments for distributors and wholesalers will be gradually incorporated into an automated TPRM process, ensuring a standardized and auditable practice around the world.

Sustainability in our supply chain

To reach our emissions reduction targets, we are working with our suppliers to help them apply, where possible, the same high standards of environmental sustainability as we do. By 2025, we aim to include environmental sustainability criteria as part of all supplier contracts.

We are working with key suppliers to set baselines and targets for CO₂ emissions, water consumption and waste management

In our manufacturing operations, we are working with key suppliers to set baselines and targets for CO₂ emissions, water consumption and waste management, as well as confirm the API content of manufacturing effluents. We are jointly developing sustainability roadmaps by focusing on product-specific technology action plans. Suppliers are also expected to report annually on progress and implement remediation plans where needed.

We are also engaging our commercial suppliers, with a focus on those with the largest contribution to our carbon

footprint. In 2021, we published the [Novartis Green Expectations from Suppliers](#) engagement framework. Our top 100 suppliers are expected to commit to emissions reduction targets approved by the Science Based Targets initiative (SBTi) and regularly report on their environmental impact management and achievements through CDP. Meanwhile, we organized a Green Supplier Summit to discuss environmental sustainability challenges and potential solutions with our commercial suppliers.

Also in 2021, we worked with Schneider Electric and nine major pharmaceutical companies through an initiative called Energize to accelerate the adoption of renewable electricity in our shared supply chains in the US and Europe. We also provide guidance and tools to our manufacturing suppliers on water quality topics, including a tailored mass balance calculator to identify and quantify APIs in wastewater.

For more on this topic, please see the section [“Build trust with society”](#) and our [TCFD disclosure](#).

Delivering effective business services

Since 2018, we have transformed business services at Novartis to better enable our people to execute on our strategy and deliver on our purpose. Through these efforts, we have improved productivity and user satisfaction while reducing our cost base and expanding our service offerings.

In 2021, we made further progress by creating a new organization called Customer & Technology Solutions (CTS), which combines the global scale of our business services functions with the transformative nature of our enterprise digital teams. The aim is to deliver services and solutions that drive value across Novartis and enable the transformation of our enterprise. Over the next several years, CTS is expected to continue

to improve productivity to drive profitable growth

CTS has around 12 000 employees located in over 40 countries and across five global service centers, with offerings spanning technology, facilities, finance, human resources, procurement, consulting, data science and artificial intelligence (AI).

Key focus areas include upgrading and simplifying our global enterprise resource planning systems. This multiyear project, which started in 2020, will help Novartis leverage digital technology at an even greater scale. The goal is to significantly simplify our core processes, capabilities and systems to provide greater flexibility and support to our business operations.

CTS teams are also helping to simplify the employee experience at Novartis. For example, we have introduced an AI-based virtual assistant to support employees with technology- and human resource-related queries. The tool will be expanded in the coming years to include all other functions.

We are also accelerating the use of technologies such as cognitive robotic process automation to improve productivity, enhance remote assistance, and enable employees to focus their time on high-impact tasks. For example, more than 1 million transactions that account for 75 000 hours of manual, repetitive work in functions such as human resources, finance and drug development are now done in a fraction of the time through AI-enabled automation.



Photo Dr. Yang Gao at a hospital in Shenyang, China.
Dr. Gao is one of 5 000 healthcare professionals in China using AI Nurse, our cardiovascular disease app, to help patients manage disease progression.

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GO BIG ON DATA AND DIGITAL

OUR PERFORMANCE IN 2021

Go big on data and digital

We are reimagining medicine using the power of data science and digital technology. With tools like artificial intelligence (AI), we're opening new paths to treat disease while finding new ways to engage customers, support patients and streamline our operations.

2021 highlights

300 000

Patients

using AI Nurse, our cardiovascular disease app in China

16

Clinical trials

incorporating digital endpoints, with plans to add more in the coming years

900+

Employees using data

42
our advanced data analytics platform

3 000+

Clinical trial participants

referred through an online enrollment portal in the US

In this section

Accelerating innovation

Novartis aspires to be an industry leader in applying data science and digital technologies to the challenge of discovering new medicines.

→ p.56

Digital health solutions

We are deploying digital health solutions to support patients across the world.

→ p.57

Engaging customers

We continue to invest in digital tools to provide personalization and better experiences for customers.

→ p.57

Embedding data and digital in our operations

We use technology to increase efficiency, while promoting digital skills and following robust standards on data management, ethics and cybersecurity.

→ p.59

Related links and disclosures:

- Privacy Policy
- Position on Nanotechnology-Based Medicine
- Novartis Biome
- Position on Regulatory Data Protection
- Our Commitment to Ethical and Responsible Use of AI

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2 700+
Clinical trials
over two decades
available through our
data42 analytics platform

Accelerating innovation

Novartis aspires to be an industry leader in applying data science and digital technologies to the challenge of discovering new medicines. By enhancing assets in our pipeline through data and digital, we aim to improve patient outcomes, streamline the development process, and support diverse, inclusive trials.

One example is the use of digital devices, such as wearable sensors, to capture continuous data on physical activity, sleep quality or fatigue, which could be used as endpoints in trials for diseases including chronic obstructive pulmonary disease (COPD) and Sjögren's syndrome. Such "digital endpoints" can improve the relevance and objectivity of clinical trial data, as well as offer new insights. In our chimeric antigen receptor T-cell (CAR-T) programs, for example, we are using a wearable digital sensor as an exploratory endpoint to pilot the early detection of serious side effects like cytokine release syndrome in outpatient settings. In 2021, digital endpoints were used in 16 Novartis trials, with plans to add more in the coming years.

Digital technology can also make clinical trials more convenient for patients and caregivers by reducing the need for repeated in-person clinic visits. For example, in a Phase III study of our gene therapy Zolgensma in older children with spinal muscular atrophy, parents can upload videos of their child's progress remotely from home.

Leveraging our data

We are taking advantage of a key resource – vast amounts of data that once existed in silos at Novartis – to improve productivity and spur innovation. In 2021, Novartis received a healthcare "Eye on Innovation" award from Gartner for our success in bringing this data together on a

foundational, enterprise-wide data and analytics platform that includes more than 100 solutions and covers the life cycle of our business.

One example is data42, which makes data from more than 2 700 clinical trials over two decades, as well as data from real-world settings, available to data scientists and researchers across Novartis. This advanced analytics platform makes it possible to discover connections in our data, identify relevant patient populations, and test hypotheses on a previously unimaginable scale – all with the aim of finding more treatments and getting them to patients faster.

Data42 makes it possible to discover connections in our data, identify relevant patient populations, and test hypotheses on a previously unimaginable scale

Patient data in data42 is anonymized and protected by a robust clinical data access policy, and users are granted access only after receiving training. We are currently expanding data42 by adding more preclinical data.

In 2021, data42 was used by more than 900 employees working on around 300 projects. These include efforts to better understand disease progression, optimize treatments and improve clinical trial design. For example, for an analysis in COPD, researchers can include data from patients in a heart failure trial who have COPD in their medical history or as an adverse event. For the first time, data scientists and researchers can also view the gender balance across all Novartis trials, sorted by disease area, indication and country. These insights help us design future trials with more emphasis on diversity and inclusion.

Resilient clinical trials

Our investments in technology also helped keep our clinical trials on track during the COVID-19 pandemic. For example, more than 3 000 participants across nine clinical trials were referred through an online enrollment portal, after more than 15 000 potential participants completed an online trial qualification questionnaire. In one Phase II trial, digital recruitment contributed over 25% of the cohort of randomized patients.

We used another digital tool to forecast COVID-19 case progression and anticipate disruptions to clinical trials. In one trial, for instance, we identified potential delays of up to several months in patient enrollment and first visits related to specific locations. By redirecting resources to compensate, we reduced this gap to a few weeks. In other trials, we switched to remote solutions such as home nursing and home delivery of the investigational medicine.

Streamlining R&D

The **Novartis AI Innovation Center (AI Lab)**, a collaboration with **Microsoft**, continues to scale a range of solutions to improve productivity in early research through to product launch. For example, the AI Lab developed a platform that assists medicinal chemists in optimizing molecular structures of promising molecules, enabling faster compound design and selection.

Also in partnership with Microsoft, we rolled out a new AI platform to help simplify and streamline some of our processes. In 2021, it was used by employees responsible for formulation development and early manufacturing of investigational medicines. The platform is improving efficiency by connecting data sets and leveraging information from thousands of past formulations, and is expected to yield cost savings of several million dollars per year. We plan to expand the platform to other areas in our R&D operations.

Novartis saved over USD 14 million from 2018 to 2021 by deploying BenchSci, an AI platform that derives actionable knowledge from scientific publications. Scientists at the Novartis Institutes for BioMedical Research (NIBR) use BenchSci to select the best antibody and other key reagents for their work, avoiding costly and unproductive experimental dead ends. BenchSci has helped accelerate projects by months, while also delivering novel scientific insights.

BenchSci has helped accelerate projects by months, while also delivering novel scientific insights

We also work with academic organizations in areas of mutual scientific interest. For example, a collaboration with the Oxford Big Data Institute uses AI to generate insights from a multiple sclerosis (MS) clinical data set containing brain MRI scans and other data from approximately 35 000 patients. The data set includes up to 15 years of follow-up for some patients. The project has already yielded peer-reviewed publications and will generate further insights on long-term disease progression and prognosis of MS patients.

Engaging customers

We continue to invest in digital tools to provide personalization and better experiences for customers. These include AI-powered digital assistants to optimize the content, timing and method of communications with physicians based on their preferences. For example, a tool used by our Medical Affairs function provides data insights to 685 field-based medical science liaisons in 28 countries, helping to personalize their engagements with healthcare professionals.

Such tools are part of a broader initiative to tailor information to the

needs of healthcare professionals. This enterprise-wide, multiyear effort uses data insights to provide relevant information to physicians at the right time, through preferred channels, and at a frequency that best meets their needs – helping to improve the quality of our commercial and medical affairs interactions.

In the US, commercial teams working on *Cosentyx*, *Promacta* and our portfolio of breast cancer medicines are using predictive analytics and machine learning to determine the most effective mix of face-to-face and digital communications to healthcare professionals – a personalized approach that has led to increased customer engagement. We aim to scale it to additional countries, including Germany and China.

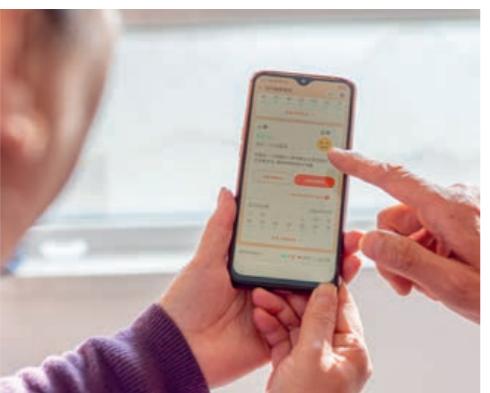
Digital health solutions

We are expanding patient-focused digital health solutions in key markets. This includes the cardiovascular disease app AI Nurse in China, which was developed in collaboration with Tencent. For more information, please see "Improving heart health in China" on the following page.

Another patient-focused solution is our clinically validated, AI-powered symptom checker for difficult-to-diagnose conditions such as psoriatic arthritis and axial spondyloarthritis, a chronic inflammatory disease that can take up to five years to diagnose. Patients enter their symptoms through a website that provides a detailed report that can be shared with their doctor. The site also gives links to disease information, details about local specialists and, in some cases, a telemedicine consultation. At the end of 2021, users had completed more than 53 000 assessments. Over 12 100 had symptoms consistent with psoriatic arthritis or axial spondyloarthritis, and approximately 2 300 took follow-up actions. The tool was developed with Ada Health, and the

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300 000

Patients using AI Nurse
compared with around 20 000
in the prior year

Improving heart health in China

Cardiovascular disease is a leading cause of death in China. AI Nurse is a digital health app, developed in collaboration with Tencent, that leverages the WeChat social media platform to make it easier for patients with heart failure and other cardiovascular diseases to manage disease progression.

Hospitals enroll patients with the AI Nurse app after treatment for a cardiac event. Upon discharge, patients send regular updates to their doctor via an AI-enabled chatbot, which provides medication reminders and recommendations for diet and exercise. The app alerts the doctor to signs of deterioration, helping to determine if follow-up care is needed.

At the end of 2021, usage of AI Nurse had grown to more than 300 000 patients, from around 20 000 in the prior year. More than 5 000 healthcare professionals and over 1 000 hospitals in at least 200 cities across China are using AI Nurse. We are in the process of expanding AI Nurse to hypertension (high blood pressure).

scope of the partnership has been expanded to include psoriasis, familial Mediterranean fever and Still's disease across 13 markets.

We are also scaling projects through the [Novartis Biome](#), a global network of innovation hubs that works with external partners on digital solutions across all aspects of our strategy. [OdySight](#), for example, is a smartphone game that encourages patients with chronic eye diseases such as age-related macular degeneration to monitor any deterioration in their vision. OdySight provides insights to doctors, enabling them to make earlier interventions and improve patient outcomes. Developed in France in collaboration with a startup called Tilak Healthcare, OdySight is now helping patients in six countries.

In 2021, we added five Novartis Biome hubs in Germany, Spain, Brazil, Singapore and sub-Saharan Africa, expanding the total network to 11 locations.

Digital solutions for global health

One of the first companies to partner with the Novartis Biome was Hemex Health, which developed a small, automated testing device – already approved for use in Ghana – to quickly detect genetic blood disorders such as sickle cell disease. The Novartis Biome is now working with Hemex Health on an extensive research implementation study to support expanded use of the device in primary care settings in sub-Saharan Africa, which carries 80% of the global disease burden.

We continued to work on an initiative co-founded by Novartis that aims to strengthen the foundations of digital healthcare systems in low- and middle-income countries (LMICs). Partners include the University of Oslo in Norway, which has developed the world's largest open-source health and disease information management system for LMICs,

known as DHIS2. It is currently in use in more than 73 countries. Together with our partners, we are adding disease metadata packages for our global health flagship programs to DHIS2, along with other enhancements, to enable countries to further reduce supply chain bottlenecks and improve access to medicine. Novartis teams are using the system to support our malaria programs as well.

In addition, we launched a partnership with Hewlett Packard Enterprise to accelerate the use of data and digital technologies for global health solutions. The first use case is a disease surveillance platform for dengue fever, which the World Health Organization has listed as a top 10 global health threat. For more information about how we address global health challenges, please see the section "[Build trust with society](#)".

Embedding data and digital in our operations

We use technology to drive greater efficiency and cost savings across our operations. For example, a platform in our manufacturing operations called SpotOn Insights Center provides multiple digital solutions to help maximize economy of scale, reduce throughput times and optimize inventories. One of these solutions already helps 18 production sites to optimize finished goods supply chains for more than 400 of our products.

In addition, we are automating core operational processes at scale by deploying robot cognitive automation – also known as “bots” – across our Customer & Technology Solutions organization. One example is an intelligent assistant that automates large parts of the writing of medical reports. Bots are also helping to resolve (either partially or fully) approximately 80% of user requests to our enterprise-wide IT helpdesk.

We promote training opportunities to develop digital skills among our employees. We have expanded our data science training and mentoring programs, which we launched in 2020. We have also invested in a learning platform for data science coding skills, which has been used by over 850 employees who spent a total of over 11 000 hours on the platform in 2021. For more examples of our progress in building digital skills across Novartis, please see the section "[Unleash the power of our people](#)".

Using data and AI responsibly and securely

In 2021, we completed the rollout of a new data management process – covering the entire data life cycle – to accelerate our digital transformation while ensuring data privacy. The new process spans nearly 5 million data sets, covering functions including R&D, finance, operations and procurement. Each domain has a data owner who is responsible for making their data available to the enterprise with the right quality and traceability, while also ensuring correct usage. These leaders are working together to unify data governance and processes across the organization and ensure that data is a strategic reusable asset for the company.

In 2021, we published our commitment to the ethical and responsible use of artificial intelligence

The use of new technologies such as AI creates new ethical questions, including how to avoid biases in data. In 2021, we published our commitment to the ethical and responsible use of AI to show the steps we are taking to be transparent, responsible

and respectful of human rights in our use of AI. We created these guidelines in collaboration with leading ethicists from the International Bioethics Advisory Committee, and specialists in AI and data privacy. The position outlines our commitment to data privacy, security, accountability and environmental sustainability. We are taking steps to integrate these principles across the organization.

Effective cybersecurity

We have robust governance, policies and systems in place to ensure the security of our data and IT systems, including Board-level oversight of cybersecurity through the Risk Committee, and management-level responsibility through our Chief Information Security Officer. Novartis did not experience any material cybersecurity incidents in 2021.

To prevent system interruptions, we have business continuity plans that we test at least every six months. We conduct internal vulnerability analyses as well as external testing via a third party to ensure the effectiveness of our controls.

The Novartis Global Information Management Policy is available to all employees via the Novartis intranet. We include cybersecurity in our [Code of Ethics](#) commitments and require suppliers to implement organizational security policies and standards.



Photo Skye Towers, a Novartis employee based in our Dublin office. Ms. Towers, a transgender woman who transitioned while working for Novartis, helped create our guide for managers to support employees who are gender transitioning.

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UNLEASH THE POWER OF OUR PEOPLE

OUR PERFORMANCE IN 2021

Unleash the power of our people

Our people bring our purpose to life. We are transforming our culture to empower each employee to be inspired by our purpose and drive innovation. We are creating an environment that supports diversity and the freedom to be our authentic selves, while providing the flexibility to deliver our best work.

2021 highlights

78	16 000	80%	5 000
Employee engagement score (out of 100) in Q4, 5 points higher than the industry benchmark	Employees using a digital awareness hub to enhance their skills in data science, AI and other areas	Of global hiring with no historical salary data to reduce the risk of gender bias	Leaders taking part in the Unbossed Leadership Development program

In this section

- Evolving ways of working**
In a changing working environment, we are giving employees and teams the flexibility to optimize their performance.
→ p. 62
- Learning and development**
We promote a culture of curiosity and unbossed leadership to help drive innovation and performance.
→ p. 63
- Diversity and inclusion**
We continue to build an environment that provides equal opportunities for all employees and where everyone is treated with dignity and respect.
→ p. 64

- Supporting and protecting our employees**
Novartis provides a range of benefits, including paid parental leave. We also continue to protect our employees amid the ongoing COVID-19 pandemic.
→ p. 65
- Engagement and volunteering**
Thousands of Novartis employees participated in volunteering programs in 2021, ranging from on-the-ground projects to virtual volunteering.
→ p. 65

Related links and disclosures:

- Our Equal Pay International Coalition (EPIC) commitments
- Global Guideline on P&O Principles and Labor Rights Practices
- Health, Safety and Environment Policy
- Global Non-Discrimination, Non-Harassment, Civility and Non-Retaliation Guideline
- Global Parental Leave Guideline

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Our employees are critical to fulfilling our purpose of reimagining medicine to improve and extend people's lives. We depend on the skills and creativity of our people to develop and produce new medicines, and deliver them to patients. Our aspiration is for every employee to feel inspired by our purpose, be curious about new ideas, and work in an unbossed environment that encourages teamwork, initiative and innovation.

In 2021, we made progress in transforming our culture to attract and retain the best talent to support our strategy. Amid the COVID-19 pandemic, we explored new working models that allow employees to maximize their performance. We continued to promote digital skills across the organization and reached more leaders with our flagship leadership development program, while becoming a more diverse, equitable and inclusive organization.

The score for engagement in our quarterly employee survey stood at 78 in Q4 2021, compared to 80 in Q4 2020. The latest score was 5 points higher than the industry benchmark and was broadly consistent across genders, with scores of 78 for men and 79 for women. Engagement favorability, which measures the percentage of "agree" or "strongly agree" survey responses, was 86% in the fourth quarter, compared with 87% a year earlier.

In 2021, we continued to score highly in environmental, social and governance (ESG) ratings on human capital. For example, Novartis improved its performance in the [S&P Global Corporate Sustainability Assessment](#), with strong ESG scores achieved in the areas of human capital development, labor practices, and talent attraction and retention.

Evolving ways of working

COVID-19 has reshaped the global working environment. In an internal survey, more than three-quarters of Novartis employees said they wanted to continue with a mix of office-based and remote working post-pandemic – consistent with external trends.

In this environment, we embarked on a multiyear program called Choice with Responsibility to explore new working models. The aim is to give employees greater flexibility in how they work to optimize their well-being and performance while maintaining a focus on productivity and innovation. As part of this program, we continued a policy introduced in 2020 for employees to choose how, when and where they work within their country (and in the US, within their state) of employment, in alignment with their teams to ensure a continued focus on collaboration and innovation.

Choice with Responsibility applies to all employees, but we recognize there is a wide diversity of roles within the organization. Some production work and laboratory research, for example, may not allow as much flexibility as other roles. The choices about how, when and where people work will therefore be different based on their role; the nature of the team; and health, safety and legal/regulatory requirements.

During 2021, we conducted around 70 local and global experiments involving a total of 25 000 employees, which are giving clarity on the path forward. The results will provide the basis for our ways of working in the future.

For example, 500 employees in 15 countries took part in a three-month

experiment to understand and address the challenges of moving to a virtual environment. The results showed 70% of participants prefer a hybrid arrangement in which their time is divided between their home and workplace. Meanwhile, teams that determined their own solutions on how to work together felt more able to collaborate and manage their workload compared with teams that had not, leading to an overall feeling of Novartis having improved as a place to work.

In 2021, we continued expanding our global program to help employees manage their physical, mental and social well-being. All 20 000 Novartis leaders and 2 189 other employees took part in an e-learning program to enhance their well-being, while 57 001 people visited a "How are you feeling?" webpage with resources to help them manage stress and other topics. In addition, 14 257 employees attended workshops during a well-being month, with 96% of attendees saying they would apply learnings in their daily work. Meanwhile, two third-party smartphone apps provided by Novartis were used by 32 709 employees to increase self-awareness and develop positive habits in areas including movement, nutrition, recovery and mindset, which are important for holistic well-being.

In another important change, we transformed our approach to performance management and development by replacing annual performance ratings with a flexible, continuous system of coaching, feedback and recognition by managers and colleagues. Teams and individuals create objectives that include a focus on longer-term impact over several years. In addition, managers and employees have regular discussions on topics including progress toward goals, development, feedback and well-being.

Learning and development

In 2021, we continued to focus on promoting a culture of curiosity and learning. This was the third year of our Go Big on Learning initiative, which involves a USD 100 million investment in addition to the normal annual training budget of USD 200 million.

Our aspiration is for every internal employee to spend 100 hours a year on learning. We achieved an average of 52.1 training hours per internal employee in 2021, broadly in line with the previous year.

Our focus on learning and development is being recognized by current and prospective employees. The score for learning engagement and growth in the OurVoice survey remained at an all-time high of 75 in 2021, compared to an industry benchmark of 71. In addition, opportunities for learning and career growth were cited by successful applicants as a leading reason for wanting to join Novartis.

Furthermore, we launched a new learning platform for 10 000 employees, primarily in our commercial operations, that uses AI to customize learning on digital skills based on an individual's role and daily activities.

Learning requirements reflected the change to more flexible working practices as well as greater demand for digital skills to support our strategy. Across both LinkedIn Learning and Coursera, we registered a total of more than 47 000 active users and more than 105 000 courses completed in 2021. We also maintained access to the Coursera friends and family program for 15 000 users.

16 000

Employees used a digital awareness hub

to enhance their knowledge and skills in data science, artificial intelligence and related areas

Unbossed: learning to lead differently

The idea behind "unbossed" is that people are most creative and productive when they are empowered to pursue their ideas. We want Novartis leaders to provide clarity and accountability for their teams, remove obstacles, and empower others to reach their potential.

In 2021, more than 5 000 leaders took part in a development program called the Unbossed Leadership Experience (ULE), which provides them with the skills needed to drive our cultural transformation in an environment conducive to personal growth. We are now nearly halfway to meeting our ambition of bringing ULE to all 20 000 leaders at Novartis.

In an employee survey, teams reporting to senior leaders who completed the program showed higher results for engagement (3.8 percentage points), empowerment (2.9 percentage points), and feeling safe to speak up (3.6 percentage points) compared with the company benchmark. Teams working closely with ULE leaders were also more comfortable with experimentation and potential failure, according to a separate feedback process, suggesting they are becoming more open to innovation.



+3.8

Higher employee engagement

for teams reporting to senior leaders who completed the ULE program (percentage points vs. company benchmark)

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97%
Employees
completed D&I training

The platform, which will be rolled out to the full Novartis organization in 2022, is intended to build new skills and capabilities to support our enterprise data and digital strategy.

In addition, we launched pilots involving around 15 000 people for two AI-powered platforms that give employees access to resources for career planning, learning and mentoring, as well as opportunities to join short-term projects to develop new skills. The aim is to help employees navigate their careers and build the skills they need to succeed at Novartis. Global rollout is planned for 2022.

Diversity and inclusion

We seek to create a diverse, equitable and inclusive environment that provides equal opportunities for all employees and where everyone is treated with dignity and respect. We do this not only because it is right, but also because it helps to generate new ideas and brings us closer to the diverse perspectives of patients and other stakeholders. We recognize that everyone plays a part in building an inclusive environment, and in 2021, 97% of our employees completed the first global e-training on diversity and inclusion (D&I).

A key element of our D&I strategy is gender equity, and we made progress in 2021 toward our [Equal Pay International Coalition](#) (EPIC) pledge to achieve gender balance in management and improve pay equity and transparency processes by 2023. The percentage of women in management increased to 46% in 2021 from 45% in 2020.

Based on the latest data available as of December 31, 2020, Novartis has a global median pay gap of -2.3% and a global mean pay gap of +3.3%, compared with -3.1% and +3.6%, respectively, in the prior year. While we acknowledge this percentage is influenced by worldwide workforce demographics, this is significantly

ahead of the Bloomberg benchmarks of +19% median and +21% mean for the same period.

In 2021, we achieved external pay transparency in a further 10 countries, including Switzerland and the US, bringing the total to 16 countries. We continue to extend this initiative, through which employees can compare their pay to external benchmarks, and by February 2022 we expect pay transparency to cover more than 50 000 employees across 33 countries.

We have eliminated historical salary data from 80% of global hiring to reduce the risk of gender bias when making job offers. We are taking steps to apply this to every job offer worldwide by 2023.

Novartis was the first global pharmaceutical company to support the [United Nations Standards of Conduct for Business](#) to tackle discrimination against lesbian, gay, bisexual, transgender, queer and intersex (LGBTQI) employees. In 2021, we distributed an updated guide for employees and managers to support employees in gender transitioning. We are working to include coverage for gender dysphoria, the condition in which someone feels a strong desire to change gender, in Novartis company healthcare plans, where possible. We continued our senior sponsorship program for LGBTQI employees with reverse mentoring for participants, including two members of the Executive Committee of Novartis.

We recognize the need to provide an environment where people with disabilities can perform at their best. In 2021, we developed a strategy and solutions to involve them fully in the workplace and ensure they have the same opportunities as everyone at Novartis. This was done in conjunction with external partners, including the International Labor Organization's Global Business and Disability Network; the Center for Disability and Integration at the University of St.

Gallen; and The Valuable 500, a group of global organizations putting disability on their leadership agenda.

Novartis is committed to promoting racial equity both inside and outside the company. In 2021, we announced a 10-year collaboration with 26 historically Black colleges, universities and medical schools in the US to address the causes of disparity in healthcare. For more information, see the section "[Deliver transformative innovation](#)".

We encourage employees with shared interests, experiences and backgrounds to form voluntary communities called Employee Resource Groups (ERGs), which give them a forum to network with peers and ensure their perspectives are recognized. There are more than 80 such ERGs at Novartis, including for LGBTQI employees, working parents, employees with disabilities, and other groups.

Our progress in building a diverse and inclusive environment was recognized externally: Novartis was included in the [Bloomberg Gender Equality Index](#) for the third year in a row.

Supporting and protecting our employees

Where possible, Novartis provides benefits to all full- and part-time employees. These vary between countries but generally include comprehensive health, well-being and retirement benefits; generous vacation policies; and a global recognition program. Our enterprise and digital training programs are generally available to all employees regardless of contract type.

All Novartis employees worldwide are eligible for a minimum 14 weeks of paid parental leave on the birth or adoption of a child, effective from their first day of employment. A total of 4 632 people took advantage of this benefit during the year, based on

data that was available for 33 countries covering 63% of our employee population. Of the total employees taking parental leave, 59% were female and 41% were male.

In 2021, Novartis launched an Employee Share Purchase Plan, which enables employees to voluntarily purchase Novartis shares at a discounted price. The plan is global in scope: The first phase of its four-year rollout, starting in 2021, covers North America (the US, Puerto Rico and Canada), with subsequent waves in other countries and regions starting in 2022, 2023 and 2024. All permanent employees are eligible for the plan (with certain exceptions).

Keeping employees safe

In 2021, we took further steps to protect the health and safety of employees as the impact of COVID-19 continued to be felt worldwide.

In countries where sufficient vaccines were available – and where the guidance was in line with local laws and regulations – we asked employees to only come on site if they were either fully vaccinated or fully recovered from COVID-19 within the previous six months. Local management could decide to adjust these principles based on the local regulations and in-country situation. COVID-19 test results could also be accepted as a means to access sites if deemed appropriate by the local management team. When on site, employees were asked to continue to adhere to safety and hygiene measures, with an emphasis on closely following the rules introduced in 2020.

Meanwhile, we made the Everbridge global emergency communications tool available to 160 000 Novartis employees as well as chosen partners and suppliers in 2021. This provided advance warning of any security, health or environmental risks that could affect employees, whether working on site, at home, or in other remote locations.

Engagement and volunteering

In 2021, we continued to strengthen our engagement and volunteering program, building on 25 years of Novartis employees giving back to the communities in which we operate. We have shifted our focus from a single day of community activity each year to long-term partnerships that are aligned with our strategy and where our support can have a sustainable impact.

Since 2015, the program's virtual platform has been used by a total of 23 346 employees in more than 60 countries, with activities ranging from on-the-ground projects to virtual volunteering from home. Employees are empowered to share their skills and experience in a way that best suits their interests and availability – with no specific time limits on activities.

Volunteering programs during 2021 included the US President's Malaria Initiative, the International Committee of the Red Cross, Save the Children, Last Mile Health, The Max Foundation, and the Tropical Health and Education Trust.

We began a partnership with the International Rescue Committee in which Novartis volunteers supported 22 refugees, migrants and asylum-seekers to sustain small businesses in the US. We also engaged with the Tent Partnership for Refugees and committed to provide 50 mentoring opportunities for LGBTQI refugees in the US, Germany and the UK over the next three years.

In addition, we are preparing to launch in early 2022 a new digital tool that matches the needs of our partners with the skills and interests of our employees. Going forward, this will enable us to better measure the impact of our volunteering activities.

OUR PERFORMANCE IN 2021

People performance indicators

	2021	2020	2019
Headcount ¹	108 514	110 738	108 776
Full-time equivalent positions ¹	104 323	105 794	103 914
Annual training hours per employee (full population / internal only) ²	44.6 / 52.1	45.7 / 53.2	35.8 / n/a
Representation of nationalities: overall / management ³	143 / 115	142 / 113	149 / 110
Employees represented by an employee representative body or covered by a collective bargaining agreement (%) ⁴	47	46	45
Percentage turnover: voluntary / overall	7.5 / 13.2	5.2 / 10.1	7.0 / 14.0
Percentage of hires: internal / external	62 / 38	58 / 42	55 / 45
Health and safety⁵			
Lost-time injury and illness rate (per 200 000 hours worked)	0.13	0.13	0.18
Total recordable case rate (per 200 000 hours worked) ⁶	0.25	0.23	0.36
Fatalities	0	1	1
Gender indicators⁷			
Median tenure in years: female / male	4.8 / 5.5	4.7 / 5.5	5.5 / 6.5
Gender representation (% female / % male)			
Overall headcount	51 / 49	50 / 49	50 / 50
Hires ⁸	52 / 47	52 / 48	53 / 47
Promotions	55 / 45	52 / 48	51 / 49
Overall turnover	50 / 50	49 / 51	48 / 52
Entry-level positions (job levels 6, 7, 8)	52 / 48	52 / 48	52 / 48
Revenue-producing roles ⁹	51 / 49	50 / 50	49 / 51
IT roles (IT job family)	23 / 77	22 / 78	22 / 78
Engineering roles (R&D + TechOps job families) ¹⁰	48 / 52	47 / 53	46 / 54
Overall management ³	46 / 54	45 / 55	44 / 56
Novartis Top Leaders ¹¹	38 / 62	33 / 67	31 / 69
Senior management	39 / 61	39 / 61	38 / 62
Middle management	47 / 53	46 / 54	45 / 55
Board of Directors	31 / 69	29 / 71	25 / 75
Gender representation by contract type (female / male)			
Full time	48 618 / 51 904	48 472 / 53 507	46 907 / 53 164
Part-time	6 755 / 1 133	7 204 / 1 219	7 338 / 1 246
Permanent	53 509 / 51 497	53 729 / 53 096	51 906 / 52 691
Temporary	1 854 / 1 539	1 935 / 1 629	2 327 / 1 718
Number of employees by region, by contract type (permanent / temporary)			
Asia-Pacific	28 229 / 420	27 711 / 300	26 559 / 666
Europe / Middle East / Africa	55 362 / 2 752	56 852 / 3 016	56 855 / 3 063
Latin America	5 101 / 127	5 092 / 157	5 311 / 194
North America	16 314 / 94	17 170 / 91	15 872 / 122

¹ Headcount reflects the total number of employees in our payroll systems. Full-time equivalent adjusts headcount for employees working less than 100%.

² From 2021, Novartis has begun reporting training hours for internal employees only, in addition to data for the full population.

³ Management defined by Global Job Level Architecture and Novartis Top Leaders

⁴ Non-management employees

⁵ Data include Novartis employees and third-party personnel managed by Novartis employees.

⁶ Data include all work-related injury and illness, whether leading to lost time or not.

⁷ Fewer than 0.5% of employees have unknown classification, apart from hires, which have a 1.2% unknown classification.

⁸ 1.2% of hires have unknown classification

⁹ Revenue-producing roles are defined as the sum of BD&L and strategy plan, commercial and general, market access, and marketing and sales job families.

¹⁰ Engineering roles are defined as the sum of research and development and Technical Operations job families.

¹¹ Novartis Top Leaders comprise the approximately 300 most senior managers at Novartis, including the Executive Committee of Novartis.



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BUILD TRUST WITH SOCIETY

OUR PERFORMANCE IN 2021

Build trust with society

Our long-term success depends on building and maintaining trust with society. We strive to meet the expectations of our stakeholders by making our medicines available to as many people as possible, by acting ethically, and by making a positive difference for society while minimizing our environmental impact.

2021 highlights

56.2 m

Patients reached
through access approaches

1 bn

Antimalarial treatments
delivered to patients since 1999,
with more than 90% supplied
without profit

31%

Increase in patients reached
through emerging market brands

-34%

Greenhouse gas emissions
reduced vs. 2016 baseline
(Scope 1 and Scope 2)

In this section

Leading the way on access and global health

Improving access to medicines remains one of the world's greatest healthcare needs. We seek to expand access to underserved patient populations while addressing major global health challenges.

→ p. 70

Being a responsible citizen

Novartis is committed to playing a positive and constructive role in society by addressing issues such as environmental sustainability and antimicrobial resistance.

→ p. 83

Holding ourselves to high ethical standards

Our stakeholders expect us to act with high ethical standards wherever we operate. We are making progress in embedding ethics and human rights across our company.

→ p. 80

Related links and disclosures:

- Position on Access to Medicines
- Position on Value-Based Healthcare
- Anti-Bribery Report
- Environmental Sustainability Strategy
- Human Rights Commitment Statement

Photo Charlotte Curtis lives with sickle cell disease (SCD) in the US. Ms. Curtis hosts a podcast to improve understanding of SCD, the most common genetic disease in the US, where it affects approximately 100 000 children and adults.

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56.2 m
Patients reached
through access approaches

Leading the way on access and global health

Improving access to medicines remains one of the world's greatest healthcare challenges. At Novartis, we know that building trust with society depends not only on finding new treatments but also on making them available to as many people as possible. Our [2021 materiality assessment](#) identified access as one of our most material topics.

We seek to expand access to our medicines to underserved patient populations in both developed and developing countries, while addressing major global health challenges. We reached 56.2 million patients in 2021 through access approaches, and we have set ambitious targets to reinforce our commitments. Relevant

members of the Executive Committee of Novartis have access metrics in their annual performance objectives.

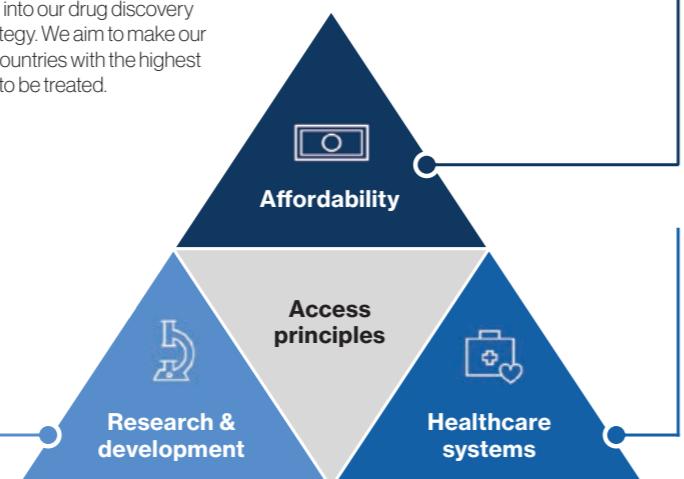
The Access to Medicine Foundation has recognized our efforts in this area, ranking us second in the [2021 Access to Medicine Index](#) among 20 of the world's largest healthcare companies.

Novartis access principles

We aim to implement an access strategy for all new medicines launched. These strategies include innovative pricing and access models, earlier launches in low- and middle-income countries (LMICs), and approaches to strengthen healthcare systems. Information in this chapter on access and global health is organized according to the three pillars of the [Novartis access principles](#) (see infographic below).

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. We aim to make our products available in countries with the highest burden of the disease to be treated.



Affordability: We aim to price our medicines based on the value they deliver to patients, healthcare systems and society. We work to make our medicines available by adopting innovative access and pricing models, taking into account local income levels, affordability barriers and economic realities.

System strengthening: We work with governments and other partners to lower barriers to healthcare delivery and support quality patient care in areas where we can have the greatest impact.

Our targets for access and global health

In 2020, Novartis committed to increase patient reach with our strategic innovative therapies in LMICs by at least 200% by 2025 (vs. 2019). In addition, we aim to increase patient reach of our four global health flagship programs in LMICs by at least 50% over the same period. To reinforce our commitment to these targets, we issued a EUR 1.85 billion sustainability-linked bond¹ in 2020. Bondholders are entitled to receive a higher amount of interest if Novartis does not meet its access targets.

We are on track to meet our targets. In 2021, we achieved a 36% increase in patient reach with our strategic innovative therapies compared with the previous year (up 73% from 2019). Patients reached through our global

flagship programs declined by 26% from the prior year, when we saw a sharp increase due to our ability to maintain delivery despite wider COVID-19 related supply disruptions. However, the latest figure was still more than double our 2019 baseline (please see the table on page 72 for more details).

Access principle 1: research and development

We systematically assess our research and development portfolio against the unmet needs of underserved populations. We select countries and sites to implement clinical trials based on medical needs, and we only initiate clinical trials in countries where we intend to make the medicine available to patients. We also work with governments and nongovernmental organizations to increase clinical trial capabilities in LMICs, with the goal of bringing more innovation to patients.

¹ For more information on our SLB, including measurement criteria, please see the bond prospectus at www.novartis.com/slbprospectus.

Our global health priorities

Our work on global health is aligned with our overall efforts to expand access to our medicines. We follow an integrated approach for the control or elimination of four diseases where there has been market failure and little investment in research and development:

Sickle cell disease (SCD) is a genetic blood disorder that affects more than 6 million people worldwide. While around 80% of the global disease burden is in Africa, SCD also affects approximately 100 000 children and adults in the US. Novartis is exploring new therapeutics and working to improve care for SCD patients in both developed and developing countries.

Chagas disease affects approximately 6 million people, mainly in Latin America. Starting as a parasitic disease, it can lead to chronic cardiac disorders in up to 30% of patients. Novartis is active in drug discovery for new antiparasitic compounds and clinical research on Chagas cardiomyopathy, as well as health system strengthening initiatives.

For more information on our research and development activities for malaria, sickle cell disease and other neglected diseases, please see the section ["Deliver transformative innovation."](#)

Adaptive development

Beyond our investigational therapies, we also adapt existing medicines for different patient groups or for diverse environments. In 2021, for example, our Sandoz teams worked on a pediatric-friendly formulation of hydroxyurea to treat SCD that received conditional approval in Ghana less than six months after submission.

Our adaptive development work supports our global health flagship programs, as well as a range of other therapeutic areas. For more information, please see the ["Selected adaptive development projects"](#) table in the appendix of this report.

Malaria is preventable and curable, yet it remains one of the most deadly infectious diseases in the world. Novartis has been at the forefront of the fight against malaria for more than two decades, launching the first fixed-dose artemisinin-based combination therapy (ACT) and working with partners to deliver more than 1 billion antimalarials, the majority without profit.

Leprosy causes physical disability and stigma for approximately 1.5 million people worldwide. Multidrug therapy donated by Novartis has been a cornerstone of global elimination efforts, leading to the treatment of more than 7 million people since 2000.

In addition, through the Novartis Institute for Tropical Diseases (NITD), we continue to research and develop a promising portfolio of drug candidates for the treatment of neglected tropical diseases that affect around 1.6 billion people worldwide, including dengue fever, diarrheal disease and visceral leishmaniasis.

For more information on our global health priorities, please see www.novartis.com/esg/global-health

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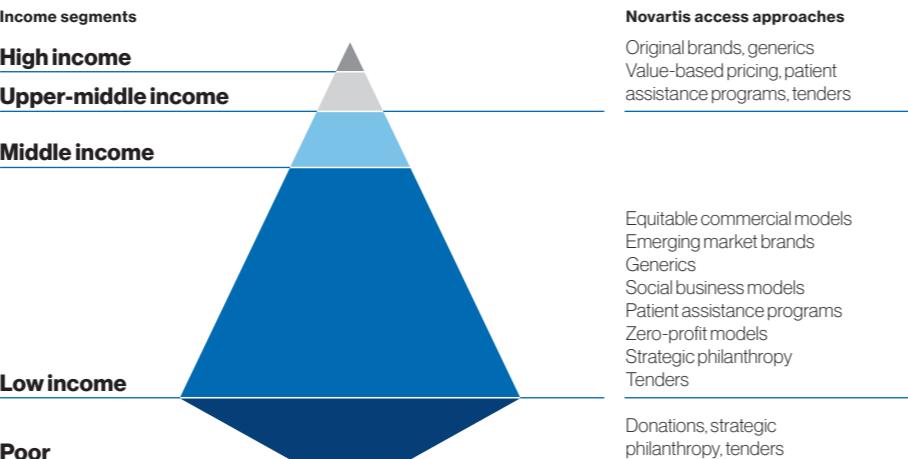
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Build trust with society

**Access principle 2:
affordability**

We use a combination of approaches to help patients across the income pyramid access our medicines. We seek to price our medicines based on the value they deliver to patients, healthcare systems and society. We aim to implement tiered pricing for launches in our Pharmaceuticals and Oncology business units, taking into account income levels, local affordability barriers and economic realities, while maintaining the sustainability of our business. We also make our medicines available through patient support programs, as well as managed access and post-trial access programs.

Novartis access strategies

Our access strategies are adapted to the needs of people across income segments

**Access to healthcare performance indicators**

	2021	2020	2019
Overall patients reached (millions)			
Patients reached with medicines – total	766	769	799
Patients reached through access approaches ¹	56.2	66.4	15.6
Sustainability-linked bond (September 23, 2020 – September 23, 2028)			
Patients reached with strategic innovative therapies	947 699	695 669	547 664
Patients reached through flagship programs	32 695 224	43 912 152	15 069 483
Novartis Global Health^{2,3}			
Countries with medicines on the ground	122	115	33
FTEs ^{4,5}	1 330	1 334	786
Patients reached with medicines through Novartis Global Health (millions) ⁶	55.5	65.8	15.1
Health educators trained	2 827	671	1 536
Healthcare providers trained	10 719	12 648	1 516
Policymakers trained	176	90	145
Points of service provision ⁷	4 365	5 902	13 635
People reached at points of service provision	360 356	486 642	986 701
Awareness events held	412 872	424 878	250 432
People reached at awareness events	9 678 360	8 048 360	10 211 704

¹ Includes patients reached with medicines through Novartis Global Health, as well as patients reached with support programs, emerging market brands and 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.

³ Novartis Global Health focuses on transforming health in low- and middle-income countries through various approaches, which include the flagship programs (targeting malaria, sickle cell disease, leprosy and Chagas disease) as well as a core portfolio of medicines for non-communicable diseases.

⁴ Full-time equivalent positions and contractors

⁵ Significant number of headcounts integrated from different units as a result of the establishment of the new SSA organization

⁶ 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. Includes patients reached through flagship programs (malaria, sickle cell disease, leprosy, Chagas disease), patients reached with donations (leprosy and fascioliasis), and patients reached with other Sandoz medicines

⁷ Points of service provision include facilities and health camps where healthcare services are provided.

Value-based pricing

We aim to price our medicines according to the value they deliver to patients, healthcare systems and society. We believe this approach incentivizes healthcare systems to focus on interventions that deliver the most effective, efficient and sustainable outcomes.

In 2021, for example, we announced a world-first agreement with the UK's public healthcare system to make *Leqvio*, our cholesterol-lowering medicine, available to patients in England through an innovative population health management approach. The agreement followed a positive recommendation by the UK's National Institute for Health and Care Excellence, which determines whether medicines represent value-for-money to the country's healthcare system.

Novartis was also one of the first pharmaceutical companies to enter into value-based contracting for medicines, linking pricing and reimbursement rates to specific outcomes – including for *Zolgensma*, our breakthrough gene therapy for patients with spinal muscular atrophy.

We consider the following elements in proposing the price of our innovative medicines:

Patient value: Do our medicines help increase patient quality of life and/or patient safety?

Healthcare system value: Do our medicines help increase efficiency and/or reduce costs elsewhere in the system, for example by preventing hospitalizations?

Societal value: Do our medicines have an impact beyond the immediate healthcare benefit, such as by helping to improve economic productivity?

A variety of approaches exist on how to measure the value of our medicines. We aim to generate transpar-

ent, real-world evidence to support the most accurate possible value assessment for our medicines.

While we take all of these factors into account in proposing the price of our medicines, in the majority of cases the final price is the result of a negotiation with payers. We stand ready to support and strengthen healthcare systems in the journey toward value-based healthcare, so the price of medicines overall can more closely and consistently align with our principles without limiting patient access to care.

For more information on our position on value-based pricing, please see www.novartis.com/affordability

Equitable commercial models

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 our business and supports governments in responding to unmet medical needs.

In 2021, we launched 26 EMBs in our Novartis Pharmaceuticals portfolio and five in Oncology. These launches helped Novartis reach 483 459 patients through EMBs, a 31% increase from 2020.

Entresto, our heart failure medicine, is a key contributor to our target to increase patient reach for our strategic innovative therapies. EMBs for *Entresto*, which number 42 overall, achieved a 39% increase in patient reach and 43% growth in sales compared with 2020.

We continue to narrow or eliminate the time lag between launches in Europe and in LMICs. For instance,

we launched the EMB of our lung cancer treatment *Tabrecta* in India in November, at least six months ahead of expected first launch in Europe.

We launched the EMB of our lung cancer treatment *Tabrecta* in India in November, at least six months ahead of expected first launch in Europe

Novartis Access is our portfolio of medicines to address public health needs – in particular noncommunicable diseases – in lower-income countries. The program offers 15 on-and off-patent medicines, which in 2021 were provided to governments and public sector customers in 11 countries across Africa, Asia and Latin America. Since 2015, *Novartis Access* medicines have reached more than 5.4 million patients.

We also use social business models to reach patients in countries where Novartis has limited or no presence. In 2021, through a program called Global Health Markets, we reached patients in Cuba, Cambodia and Laos.

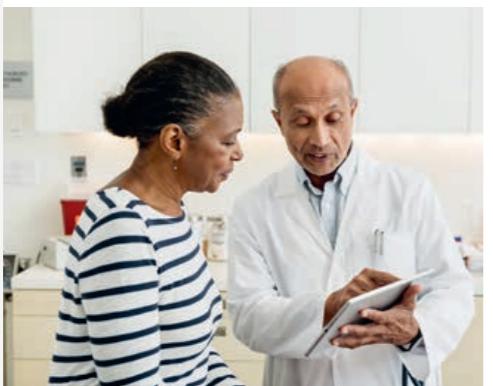
Our community solutions, known as **Healthy Family** programs, provide health education and strengthen healthcare infrastructure for populations living at the base of the income pyramid in India, Kenya, Uganda and Vietnam. In 2021, we expanded our geographical coverage in India and Vietnam, and we aim to launch the program in additional underserved markets. Since 2007, Healthy Family programs have delivered health education to more than 75 million people.

Patients reached with emerging market brands

	2021	2020	2019
Novartis Pharmaceuticals	464.6	355.1	302.6
Novartis Oncology	18.9	13.9	11.3

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~300 000
Patients in the UK

at high risk of a second cardiovascular event are expected to be treated with Leqvo in the community setting over three years

31%
Increase in patients reached through emerging market brands (vs. 2020)

To drive access in sub-Saharan Africa (SSA), we established a dedicated Novartis SSA unit of about 700 employees that aims to expand the availability of our full portfolio of medicines, taking a high-volume, lower-price approach – with an aspiration to double patient reach in the region by 2022.

For example, we aim to bring affordable cancer treatments to 22 countries in SSA through our [Cancer Access Partnership](#) (CAP) with the [Clinton Health Access Initiative](#). In 2021, we implemented the program in more than six countries, reaching patients with breast, prostate and cervical cancer through our CAP product line, which includes patented medicines and Sandoz generics. Medicines are offered at a competitive yet sustainable price, and we are working with partners to minimize markups on CAP products for patients purchasing their treatments out of pocket. Together with our partners, we aim to optimize the continuum of care across the patient journey, including through health system strengthening activities.

Zero-profit models
In 2021, we reached the milestone of 1 billion treatments of our antimalarial medicine *Coartem* delivered since 1999, with more than 90% supplied without profit. For more information, please see "[One billion antimalarials delivered to patients](#)" on page 76.

Donations
Through our donation programs, 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.

One of our key programs is [CMLPath to Care™](#), which 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 67 countries that are most urgently in need of medicines, as identified by the Access to Medicine Index. In 2021, the program reached more than 29 300 patients.

Leqvo: integrated access in action

Our cholesterol-lowering medicine *Leqvo* is a prime example of how we integrate innovative access strategies into the launch of our medicines.

Leqvo is approved in more than 50 countries to treat atherosclerotic cardiovascular disease, which accounts for over 85% of all cardiovascular disease (CVD) deaths. As part of our access strategy, we aim to introduce emerging market brands for *Leqvo* with tiered pricing in LMICs and upper-middle-income countries to address affordability challenges, based on local feasibility assessments. We also intend to minimize time lags between first launch in Europe and launches in LMICs.

We also partner with health systems to improve patient outcomes. In the UK, for instance, *Leqvo* is provided under a first-of-its-kind population health management approach through the National Health Service in England; it is expected to treat up to 300 000 patients at high risk of a second cardiovascular event in the community setting over three years. We are also exploring population health approaches in other markets. In Colombia, for example, we formed an alliance with the innovation chamber of the government and civil society stakeholders to help remove treatment barriers for more than 50 000 high-risk CVD patients.

Donations

	2021	2020	2019
Patients reached with donations (thousands)			
Leprosy (WHO) ¹	75.3	245.4	168.6
Fascioliasis/Egaten ²	159.0	132.8	154.7
CMLPath to Care™	29.3	30.3	14.4
Donations value (USD millions)^{3,4}			
Emergency relief	1.4	2.5	2.8

¹ In 2020, the leprosy program fully transitioned to the Global Health organization as one of the flagship programs. It is also included in data reported in the Novartis Global Health table.
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

For over 30 years, Novartis has been working with partners around the world to eliminate leprosy

For over 30 years, Novartis has 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 119 million through the WHO, helping to treat more than 7.3 million leprosy patients worldwide. In 2021, we extended our donation agreement with the WHO, and reached more than 75 000 patients. This was lower than the number of patients reached in 2020, primarily due to countries reducing their screening activities amid the COVID-19 pandemic.

The new five-year agreement with the WHO also covers the continuing donation of triclabendazole for the treatment of fascioliasis, a disease caused by parasites known as liver fluke. Novartis has been donating the drug to the WHO since 2005, helping to treat around 2 million fascioliasis patients in more than 30 countries.

Our Sandoz Division works with organizations including Amicares,

for individuals who are experiencing financial hardship and have limited or no prescription drug coverage in the US. In 2021, NPAF made medicines available to more than 127 000 patients.

Another program is [Novartis Oncology Access](#), which shares the cost of medicines with government healthcare systems, charities and other payers, or directly with patients without healthcare coverage who are unable to pay the full cost. In 2021, more than 29 400 patients in seven countries benefited from the Novartis Oncology portfolio in multiple disease areas.

Other examples include the [Vale Mais Saúde™](#) program in Brazil, which reached more than 1.7 million patients in 2021. The program provides discounts on Novartis therapies for chronic conditions and promotes disease awareness and treatment adherence. In China, meanwhile, we reached 31 000 *Cosentyx* patients through a program designed to support patients and healthcare professionals with medication adherence and disease awareness. Overall, our patient support programs helped more than 3.8 million patients in 2021.

Managed access programs

Physicians sometimes seek access to medicines 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.

Patients reached through support programs

(in thousands)	2021	2020	2019
Novartis Patient Assistance Foundation Inc. (US) ¹	127.4	107.2	87.2
Novartis Oncology Access	29.4	33.9	60.7

¹ 2020 figure corrected and restated

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7.6 m
Lives saved since 2000
due to adopting ACTs as a first-line treatment for malaria, along with disease prevention efforts and better diagnostics, according to the WHO

13 000 Patients

receiving treatment through managed access programs

In 2021, we reviewed 8 559 MAP requests from physicians. We approved 95% of those requests from 95 countries and across 62 compounds. At the end of 2021, more than 13 000 patients were receiving treatment through MAPs.

We fulfilled our 2021 commitment to make *Zolgensma*, our one-time gene therapy to treat pediatric patients with spinal muscular atrophy, available to up to 100 patients via a global MAP. Further, *Tabrecta* was provided to 838 patients suffering from lung cancer.

Since 2017, Novartis has collaborated with an external Independent Bioethics Advisory Committee (IBAC), which provides analysis and recommendations on Novartis 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 is made up of bioethicists, clinicians, healthcare practitioners, patient advocates and other experts appropriate to the problem at hand.

Post-trial access programs

Novartis has a comprehensive post-trial access (PTA) policy to ensure continuity of treatment for patients who have participated in a confirmatory, Novartis-sponsored clinical trial designed to demonstrate superiority versus a placebo or another drug. Patients who have derived clinical benefit from an investigational treatment can continue to receive it, free of charge, until it is commercially available and accessible locally.

Our PTA commitment applies regardless of the severity of the disease, the availability of alternative therapies, or the geographical location of the clinical trial. PTA commitments were incorporated in all in-scope trials approved in 2021.

We also convene a cross-functional consultation board to provide guidance on PTA activities and ensure a consistent approach across the company in accordance with our [Commitment to Patients and Caregivers](#) and the [Novartis Position on Post-Trial Access](#).

One billion antimalarials delivered to patients

For decades, Novartis has been involved in the fight against malaria, a disease that causes hundreds of thousands of deaths worldwide despite it being treatable and curable.

In 1999, Novartis launched the first fixed-dose artemisinin-based combination therapy (ACT). In 2001, in a landmark agreement with the WHO, we were the first healthcare company to commit to supply antimalarial treatments to the public sector of endemic countries without profit.

In 2021, we reached the milestone of 1 billion treatments of our ACT delivered since 1999, with more than 90% supplied without profit. More than 450 million were a pediatric formulation developed jointly with Medicines for Malaria Venture. The WHO estimates that adopting ACTs as a first-line treatment for malaria, together with prevention efforts and better diagnostics, have saved 7.6 million lives since 2000.

Malaria is still endemic in many countries. Moreover, increased temperatures and humidity due to climate change threaten to increase the number of insects that carry vector-borne diseases like malaria. We remain committed to finding solutions for patients. Alongside our access programs, Novartis is advancing the next generation of antimalarials, with several promising candidates in our development pipeline.

Access principle 3: strengthening healthcare systems

A medicine is only as good as the system that delivers it. Improving access to healthcare requires long-term investments in healthcare infrastructure. We work with governments and partners to strengthen healthcare systems and lower barriers to healthcare delivery. Several examples are provided below. For more information on our health system strengthening framework, please see the [Novartis corporate website](#).

Tackling SCD in Africa

Launched in Ghana in 2019, our Africa sickle cell disease (SCD) program is a public-private partnership that encompasses newborn screening, diagnosis, treatment, education, research and advocacy. In 2021, the program was active in Ghana and Uganda. Novartis continues to work with our partners, including the ministries of health in both countries, to strengthen healthcare systems for the safe and sustainable delivery of SCD treatments for patients. In 2022, we aim to launch the program in Tanzania and Kenya, where the government recently launched national guidelines for the management of SCD. As part of our efforts to support treatment for SCD in Africa, we received conditional approval for our SCD treatment crizanlizumab in Ghana in December 2021, only six months after submission. Also in 2021, we received approval in Ghana for a pediatric-friendly formulation of hydroxyurea to treat SCD (see "Adaptive development").

Addressing malaria and SCD in India

India has the world's highest burden of malaria and SCD outside of Africa. Novartis is running a malaria screening campaign under the umbrella of the Novartis Healthy Family program (*Arogya Parivar*) in seven districts in Odisha state, a highly endemic area that bears almost a quarter of the country's malaria burden. Since the

start of the campaign in September 2020, more than 121 000 people have been screened for malaria and potential co-morbidities at around 2 200 health camps. Separately, Novartis and local authorities in India established the National SCD council, which aims to address policy-related gaps in delivering healthcare services to SCD patients. This resulted in dedicated or increased funding for SCD diagnosis and treatment across 11 states in the country. We also collaborated with partners to conduct education and awareness programs on SCD in the states of Maharashtra, Madhya Pradesh and Gujarat, covering a total of 80 districts, 250 healthcare professionals and 1 150 healthcare workers. We plan to expand this project in 2022.

Since the start of the campaign, more than 121 000 people have been screened for malaria and potential co-morbidities

Eliminating avoidable blindness

One billion people worldwide live with preventable visual impairment due to a lack of access to basic eye care. Of these, an estimated 90% live in LMICs. In 2021, we implemented a program built upon an ecosystem of key partners, including Aravind Eye Care System, a network of hospitals in India that is one of the largest providers of eye care in the world, to tackle avoidable blindness in underserved communities in India. In addition, our [eXcellence in Ophthalmology Vision Awards \(XOVA\)](#) have funded 44 projects across 27 LMICs

to

elevate community health education activities, capability-building and training for healthcare professionals, and access to affordable eye care services. Moving forward, together with Aravind, XOVA and other global and local partners, we plan to expand the program to improve outcomes in underserved communities in SSA, Vietnam, the US and Bolivia.

The Novartis Foundation

The Novartis Foundation focuses on advancing digital and data-led approaches to population health, with a particular emphasis on cardiovascular disease (CVD), the leading cause of death globally.

Better Hearts Better Cities

Rapid urbanization in LMICs, and associated lifestyle changes, present increasing challenges to address CVD and its prime risk factor, hypertension (high blood pressure). Although therapeutic options exist, blood pressure control rates remain poor. In November, the [Novartis Foundation](#) published its strategy for addressing cardiovascular population health, known as the CARDIO approach, in the journal *Cities & Health*.

This approach has been applied across different continents together with local city authorities and partners in the [Better Hearts Better Cities](#) initiative, which addresses hypertension and its underlying determinants by increasing early access to quality care, promoting partnerships, and maximizing the application of technology to strengthen health systems.

First results show that between 2018 and 2019, blood pressure control rates in patients treated with medication improved in São Paulo (Brazil), Dakar (Senegal) and Ulaanbaatar (Mongolia). Full results will be published in 2022.

Reducing inequity in cardiovascular health

Our health is influenced by where we are born, grow, live, work and age; these factors are referred to as social determinants of health (SDoH). During the COVID-19 pandemic, SDoH put a spotlight on health inequities worldwide, yet the differences in health outcomes between population groups reach far beyond the pandemic, especially when it comes to cardiovascular (CV) population health.

The Novartis Foundation and Microsoft are applying artificial intelligence and advanced analytics to a combina-

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13.7 m
Committed (USD)

to address racial disparities in healthcare as part of our 10-year commitment with Historically Black Colleges in the US

tion of clinical, SDoH and environmental data to deliver insights on how to identify communities at risk and improve CV health equity at a population level. Leveraging the foundation's CARDIO approach and Microsoft's data storage and data analytics tools, partners will work with city health authorities to better understand the factors that drive unequal CV health outcomes. Ultimately, the aim is to create roadmaps that translate these insights into action and prioritize the most impactful interventions.

For more information on the Novartis Foundation, please see www.novartisfoundation.org.

The Novartis US Foundation

The Novartis US Foundation seeks 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 the US, health disparities affecting minority groups are endemic – an issue that was highlighted and exacerbated by the COVID-19 pandemic. In 2021, Novartis and the Novartis US Foundation announced plans to invest approximately USD 13.7 million to establish three research centers at Morehouse School of Medicine in Georgia, including a clinical trial center of excellence that could be a model for possible expansion to other historically Black colleges, universities and medical schools.

Please see the section "[Deliver transformative innovation](#)" for more details on how we work to address diversity in clinical trials.

For more information on the activities of the Novartis US Foundation, please see the Novartis in Society US Report

Photo Romanus Oyibe, a medicine vendor in Ebonyi State, Nigeria, examines a patient in his store. Together with local partners, Novartis is helping to train vendors like Mr. Oyibe to test for common childhood illnesses such as malaria. Severe cases are referred to the closest health center.

Expanding access through generics and biosimilars

Our Sandoz Division, a leading global generics company, plays an important role in Novartis efforts to increase access to affordable, high-quality medicines for patients worldwide. In 2021, Sandoz reached approximately 490 million patients with its portfolio of around 1 000 molecules across a wide range of disease areas.

Generics and biosimilars enable healthcare systems to improve access while containing spending growth. In the US, for example, generics accounted for 90% of the volume but only 18% of the cost of prescription medicines in 2020, according to research firm IQVIA.

Sandoz teams consider access in pricing strategies for all medicines, for example by typically entering the market well below the list price of the reference product, as well as taking local economic realities into account and acting to keep prices stable at times of market disruption – such as during the COVID-19 pandemic.

Our portfolio of generics and biosimilars increases the supply of affordable medicines across the income pyramid. They also provide the majority of products to our global health markets.

As one of the world's largest suppliers of antibiotics, Sandoz also plays a central role in our efforts to tackle antimicrobial resistance. For more information, please see the section "[Advancing our program to combat antimicrobial resistance](#)".



OUR PERFORMANCE IN 2021

Holding ourselves to high ethical standards

Acting in an ethical manner is essential to building trust with society. Our stakeholders not only expect us to do what is legally required, but also to follow high standards of ethical behavior wherever we operate.

Supporting ethical decision-making

We are making progress in embedding our [Code of Ethics](#) across the organization and supporting employees to do what's right when faced with ethical dilemmas.

In 2021, around 98% of employees completed e-training on the Code of Ethics. In addition, around 84 000 employees visited an internal Code of Ethics information platform and around 65 000 accessed an online tool called Decision Explorer that provides guidance to help resolve ethical dilemmas. We also launched a toolkit to support leaders in discussing ethical dilemmas with their teams.

We improved the way we manage conflicts of interest with the release of a revised framework, including a new guideline, disclosure process and supporting tool. Around 97% of employees completed a declaration on potential conflicts of interest.

Further, we took steps to integrate an ethics dialogue into the process for recruiting potential new employees. In 2021, we launched a guide for interviewers to assess the ethical profile of potential hires and their fit with the Novartis Values and Behaviors and our Code of Ethics. By signaling that ethics and integrity matter to Novartis during the first interaction with a candidate, we improve our chances of hiring high-integrity individuals who are a good fit for our ethical culture.

In our Code of Ethics, we commit to use artificial intelligence in a transpar-

ent and responsible way. In 2021, we were one of the first companies to issue a position statement on the topic. For more information, please see the section "[Go big on data and digital](#)".

Advances in digital technology have led to new, more personalized ways of engaging with our customers across multiple channels. To ensure we navigate these changes in the external environment ethically, we are adjusting our [Professional Practices Policy](#) and processes to create consistency in how we manage new relevant types of compliance risks. We have rolled out a global system architecture to ensure our processes are implemented consistently across markets.

Measuring our ethical climate

We launched our first annual global ethics survey in 2021 to measure our progress in embedding our Code of Ethics across the organization. Translated into 15 languages, the survey was sent out to 150 000 Novartis employees and external contractors.

The results from more than 50 000 responses to the survey provide us with robust data across different parts of the company to evaluate the effectiveness of our policies, programs and controls. Importantly, they also help us identify areas where we may need to reinforce our ethical culture and climate. We are working to turn these insights into processes and tools to further encourage ethical behavior, and we plan to repeat the survey in 2022 to gain further insights.

Anti-bribery policies and practices

Our [Anti-Bribery Policy](#) states expectations for all employees, and we also clearly state our standards in our Code of Ethics. Specific principles are set out in our Professional Practices Policy, while third-party risk is governed by our [Anti-Bribery Third-Party Guideline](#). Our SpeakUp Office investigates allegations of misconduct.

Novartis participated in a collective action initiated by Norges Bank Investment Management (NBIM) to jointly develop a reporting standard on anti-bribery. In early 2022, we published our first [anti-bribery report](#) based on the guidance issued by NBIM and aligned with principles such as the United Nations (UN) Global Compact and the OECD Guidelines for Multinational Enterprises.

Upholding our commitment to human rights

We continue to make progress in expanding our efforts to respect human rights within our operations and throughout our supply chain. In 2021, we published a holistic [Human Rights Commitment Statement](#) that builds on our previous commitments and reflects the increasing importance of integrating human rights across the organization.

New measurement framework

In 2021, we took another key step in implementing the [UN Guiding Principles on Business and Human Rights](#) by developing a measurement framework to track our performance across three pillars: due diligence, empowerment and external engagement.

We continued our engagement in five priority areas: third-party labor rights, diversity and inclusion, clinical trials, grievance mechanisms, and anti-bribery and corruption. We also updated our list of 12 salient human rights issues based on human rights assessments conducted since 2017.

Human rights assessment of clinical trials

Clinical trials play a critical role in medicine development, but they also raise significant human rights considerations. In 2021, we completed a human rights assessment of the global policy framework governing our clinical trials. Results showed that we are aligned with external expectations

on human rights, including on informed consent, transparency, post-trial access to medicine, financial compensation, and potential conflicts of interest, among other areas. Please see [here](#) for a list of relevant policies and [here](#) for clinical trial results.

Empowering employees to understand and assess human rights

Through our internal Human Rights Ambassador Network, we worked with our pharmaceutical export business to develop a human rights assessment toolkit. We are piloting two remote human rights assessments in countries with heightened human rights risk.

Purchasing raw materials from certified sources

Internally, we continued to address risks from raw material inputs into our medicines, and we are rolling out guides to support our procurement team in purchasing ingredients from certified sources. Externally, through the [Pharmaceutical Supply Chain Initiative's Human Rights and Labor Subcommittee](#), which Novartis co-chairs, we continued to investigate human rights risks associated with raw material inputs in pharmaceutical products and to develop approaches for collective action in our supply chains.

Integrating human rights into our third-party risk process

In 2021, we completed the integration of human rights into the four relevant risk areas (labor rights; health, safety and environment; data privacy; and anti-bribery and corruption) in our Third-Party Risk Management process. This included updating our [Third-Party Code](#) and self-assessment questionnaires, as well as ongoing training with our third-party labor rights risk experts.

Further, we launched a pilot to support suppliers with higher-risk profiles in implementing our Third-Party Code. We are working with suppliers in

Ethical business practices performance indicators

	2021	2020	2019
Code of Ethics			
Employees trained and certified (%) ¹	98	98	98
Grievance indicators: SpeakUp Office – central matters ^{2,3,4,5}			
Misconduct cases reported	174	157	209
Total allegations ⁶	296	284	427
Total allegations per category (%): SpeakUp Office – central matters			
Fraud/asset misappropriation	13	7	7
Expense fraud	4	2	5
Books and records, accounting irregularities	0	1	1
Improper professional practices	20	14	17
Bribery, kickbacks	2	1	2
Discrimination and sexual harassment	8	11	8
Retaliation	5	3	6
Other employee relations issues	14	18	18
Conflict of interest	12	13	11
IT security breach	4	4	4
Quality assurance/data integrity	3	8	6
Data privacy	3	2	3
Antitrust, fair competition	1	1	0
Company confidential/trade secret information	2	4	0
Other	9	11	12
Allegations substantiated⁷			
Dismissals and resignations related to misconduct	137	118	252
	62	101	186

¹ Active Novartis employees with email addresses, trained via e-learning or via One Deck for Novartis Technical Operations. Training rolled out from July 2021 to January 2022, with a preliminary completion rate as of December 31, 2021.

² The SpeakUp Office provides a safe place for employees to raise concerns (including anonymously) about potential misconduct while being protected against retaliation.

³ A central matter applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and significant financial impact.

⁴ The number of misconduct cases, allegations reported and substantiated, and dismissals and resignations may change year-on-year as matters may be reassessed in the course of the case life cycle. As a result, we may restate the previous two years of reported data.

⁵ The remainder of the complaints were addressed or investigated locally, as they were of lower and local risk.

⁶ The number of allegations is higher than the actual number of cases as a case can have more than one allegation.

⁷ "Allegations substantiated" may include allegations from previous years while "misconduct cases reported," "total allegations" and "total allegations per category" refer to allegations reported within each calendar year.

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98%
Employees trained
and certified
on our Code of Ethics

Singapore and Malaysia to develop guidance and key performance indicators to help them manage risks linked to migrant workers.

We publish a [statement](#) explaining how we address modern slavery risks or impacts each year.

Encouraging employees to speak up

The Novartis SpeakUp Office, which from 2021 has been integrated into the Ethics, Risk & Compliance (ERC) function, enables employees and external parties to raise concerns about potential misconduct while being protected against retaliation.

In 2021, a total of 2 099 complaints of alleged misconduct resulting in 1 932 cases, with 2 385 allegations, were received and handled. Of the complaints, 84% came via the SpeakUp channel and the remainder were self-identified via existing internal controls. Anonymous complaints were 33% of the total. We saw a 5% increase in SpeakUp complaints in 2021 compared with 2020, primarily due to employees returning to worksites as the pandemic situation eased in some countries, and due to increased training and awareness of the program.

Of the total cases, 174 (9%) were classified as central matters (higher-risk cases) warranting further investigation, while 1 758 lower-risk matters were addressed or investigated locally. The investigated central matter allegations resulted in 62 dismissals or resignations, and in 27 written warnings. Other remedial actions such as training, coaching and implementing new controls were also used when deemed appropriate.

The shift to new ways of working amid the COVID-19 pandemic led to certain SpeakUp topics arising more frequently. For instance, we observed an increase in complaints regarding leadership behaviors amid flexible working arrangements, as well as

those related to company guidelines on vaccinations or testing. Such complaints typically did not require investigation and could be addressed through local management or human resources teams. Allegations related to improper professional practices continued to decrease in 2021 due to the strengthening of our ERC policy, training and monitoring program.

In 2021, we took steps to increase awareness about the SpeakUp program in certain markets and regions through targeted training and awareness sessions. We saw, for instance, a 6% increase in misconduct reporting in the Europe, Middle East and Africa region.

Commitment to transparency and disclosure

Transparent reporting and disclosure play a key role in building trust with society. Novartis applies and supports laws and regulations that promote transparency around relationships between healthcare companies and healthcare professionals, healthcare organizations and patient organizations, and related transfers of value. Novartis is keeping pace with these developments and is committed to meeting new transparency requirements. Please see [here](#) for further details.

For patient organizations, Novartis goes beyond the reporting requirements set by the EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice. We [publish](#) a global report covering transfers of value made to patient organizations in all countries where we operate.

Novartis has supported transparency in clinical trials for more than 20 years and was one of the first companies to commit to publishing trial results of innovative medicines within one year of study completion, regardless of outcome. For more information, please see www.novartisclinicaltrials.com.

Being a responsible citizen

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 such as climate change and antimicrobial resistance. We can help drive positive change by harnessing the assets that make us successful in the first place: people, ideas and capital. For information on how we help combat the global problem of falsified medicines, please see the section "[Embrace operational excellence](#)".

Enhancing environmental sustainability

Our commitment to environmental sustainability is an important part of how we build trust with society and is aligned with our purpose. Unless we can operate sustainably, our efforts to improve and extend people's lives may be compromised by our environmental impact.

In 2021, we further strengthened our environmental targets by committing to become net zero in terms of climate emissions across our value chain by 2040, building on our mid- and long-term goals to become carbon neutral, plastic neutral and water sustainable. More details on our performance in 2021 can be found in our climate-related financial disclosures ([TCFD](#)). Please see our corporate website for full details of our [environmental sustainability strategy](#).

Environmental targets

Our targets to be carbon neutral, plastic neutral and water sustainable are the central focus of our environmental sustainability strategy. In 2021, we reduced greenhouse gas emissions by 34% (Scope 1 and Scope 2) versus our 2016 baseline, making further progress after a 26% reduction in the previous year. We reduced water consumption by 40%, compared with 35% in 2020, and reduced waste

Novartis environmental targets

	2025	2030	2040	Progress
Climate 	Become carbon neutral in own operations (Scope 1 and 2)	Achieve total carbon footprint neutrality (Scope 1, 2 and 3)	Achieve net zero carbon emissions across our value chain	Greenhouse gas emissions (Scope 1 and 2) excluding offsets –34% vs. 2016 baseline
	Include environmental criteria in all supplier contracts			Green Expectations published; being acknowledged by suppliers
Waste 	Eliminate PVC in packaging (secondary and tertiary packaging; primary packaging when feasible)	Become plastic neutral		One Novartis site still using PVC for secondary and tertiary packaging but has plans in place to eliminate its use during 2022
	Reduce waste disposal by half	Ensure all new products meet sustainable design principles		Waste disposal –56% vs. 2016 baseline Eliminated 17 types of single-use plastics at 132 Novartis sites
Water 	Reduce water consumption by half in our operations	Become water neutral in all areas		Water consumption –40% vs. 2016 baseline
	Prevent any water quality impacts from manufacturing effluents	Enhance water quality wherever we operate		85%+ of Novartis manufacturing sites meet internal quality standards. Suppliers being trained on Novartis water quality standards
	disposal by 56%, compared with 38% in 2020 (all versus 2016 baseline figures).			megawatts of green power generation capacity to the Spanish grid by 2023.
	In addition, we achieved our goal of eliminating 17 types of single-use plastics at 132 Novartis workplaces in scope (remaining stocks are being used at some locations). For example, in the US, all single-use plastic bottles in vending machines were replaced by recyclable aluminum, glass or biodegradable containers.			In 2020, our own operations (Scope 1 and Scope 2) represented 9% of our overall carbon footprint (Scope 1, Scope 2 and Scope 3). To achieve net zero carbon emissions across our value chain will therefore require a coordinated approach with our suppliers. In 2021, we launched Novartis Green Expectations from Suppliers , which requires suppliers to map out their emissions, water consumption and waste footprint baselines; understand water quality thoroughly; set targets; and report their progress. For more on how we approach environmental sustainability in our manufacturing operations and our supply chain, please see the section " Embrace operational excellence ".

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In 2021, Novartis laboratories were certified by [My Green Lab](#), a third-party framework that aims to improve environmental sustainability in laboratory settings. More than 800 Novartis researchers across 24 laboratory sites in 11 countries took part in the certification process.

Novartis sites use water for cleaning and cooling purposes, and as a solvent. To ensure the effective management of water quality, we go beyond regulatory requirements and ensure that our active pharmaceutical ingredients (APIs) are discharged at levels that are predicted to not cause harm to the environment.

By 2030, we will expand our current water quality scope to include all effluents from API and finished dosage form production within Novartis and relevant suppliers, and become water neutral. This means ensuring the amount of water Novartis withdraws from the local environment does not contribute to the depletion of local water reserves. It entails valuing the water needs of stakeholders and the ecosystem in an equitable way.

Further details of our progress in the area of water quality and quantity are included in the [CDP Water Security Report](#), the [AMR Industry Alliance report](#) and the [Access to Medicine Foundation AMR Benchmark report](#).

Sustainable medicines

Novartis is committed to embedding environmental sustainability into the design of new products, devices and packaging. We assess the environmental impact associated with all stages of a product's life, from raw material extraction to processing, manufacturing, distribution, use and disposal. In 2020 and 2021, we conducted pilot life-cycle assessment studies for one of our respiratory dry powder inhaler devices, which showed that on average our product has a low carbon footprint compared to other products with similar published studies.

We also aim to create a culture where sustainability is embedded in the

decision-making process. To this end, in 2021 we established a Green Ambassadors Network to communicate, sponsor and share sustainability initiatives between local and global teams. We also established a global network of colleagues collaborating on sustainability projects, and we offered new training modules to all employees on our environmental sustainability strategy.

Advancing our program to combat antimicrobial resistance

The WHO has declared antimicrobial resistance (AMR) – when antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat – as one of the major public health threats facing humanity.

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.

Responsible manufacturing is a central part of our efforts. This includes minimizing antibiotic residues – especially into water bodies – and reducing waste. Please see the section "[Enhancing environmental sustainability](#)" for more information.

We also continue to invest in new antibiotic manufacturing facilities. In 2021, our Sandoz Division – which is the world's largest volume provider of generic antibiotics – confirmed it would invest more than EUR 100 million in new manufacturing technology at its Kundl site in Austria, the hub of the only remaining end-to-end antibiotic manufacturing network in Europe. Sandoz also announced a EUR 50 million investment in new production technology and increased manufacturing capacity at its Palafolls site in Spain.

We support innovation and adaptive development in antibiotics. For example, Novartis is an investor in the AMR Action Fund together with other pharmaceutical companies, philanthropic organizations and development banks. The initiative aims to bring two to four new antibiotics to patients by 2030.

Education on responsible use is key to tackling AMR. We embarked on a program with MedShr to train healthcare professionals on antimicrobial resistance, reaching 250 000 individuals through 33 000 engagements. AMR education is a key feature of our partnerships with Save the Children in Kenya and with the Commonwealth Pharmacists Association across SSA. We also engage with communities directly in rural areas of Africa and India as part of our Healthy Family program, including on water rehabilitation projects in Kenya and India.

Our AMR approach

We take a balanced, cross-sectorial approach to combating AMR.

Prevention

- Responsible manufacturing to help reduce the environmental impact of the production of antibiotics
- Manufacturing site in Austria is hub of last vertically integrated antibiotic production chain in Europe

Access

- Strengthening high-quality, affordable antibiotics portfolio
- Adaptable portfolio for tailored AMR response
- Pediatric-specific formulations
- Stable formulations for LMICs

Responsible use

- Balancing access efforts with global and local initiatives to ensure prescription of the right drug at the right dose for the right duration
- New tools and technological solutions for advocacy, surveillance, diagnostics and education
- Healthcare professional/patient education, user-friendly packs, awareness campaigns, safe drug disposal

Innovation and adaptive development

- Focusing on areas where we can really make a difference
- AMR Action Fund

Environment performance indicators¹

	2021	2020	2019
Energy use – on site and purchased (million GJ)	9.77	10.85	12.75
Emissions (1 000 tCO₂e)			
GHG emissions, Scope 1, combustion and process	248.1	286.9	356.6
GHG emissions, Scope 1, vehicles	88.5	91.3	128.4
GHG emissions, Scope 2, purchased energy (market based)	310.4	338.9	404.0
GHG emissions, Scope 3, business travel ²	35.5	22.0	191.3
Total GHG emissions, Scope 1 and Scope 2 (excluding offsets) ³	647.0	717.1	888.9
GHG emissions offsets ⁴	-34.7	33.6	29.8
Emissions intensity (1 000 tCO₂e)			
GHG emissions (Scope 1 and Scope 2) per million USD sales	12.5	14.7	18.7
GHG emissions (Scope 1 and Scope 2) per FTE	6.2	6.8	8.6
VOCs (t)			
Halogenated volatile organic compounds	4.5	11.6	26.6
Non-halogenated volatile organic compounds	310.0	443.0	406.8
Water (million m³)			
Water withdrawal ⁵	47.9	54.7	66.8
Water discharged directly to aquatic environment (cooling water)	39.5	46.1	55.5
Water consumption ⁶	7.8	8.4	11.2
Waste (1 000 t)			
Non-hazardous waste recycled	83.9	59.9	57.7
Hazardous waste recycled	15.9	28.7	58.8
Non-hazardous waste not recycled	10.1	8.8	12.9
Hazardous waste not recycled	19.2	33.2	41.2

¹ Other than where indicated, environmental data for the current year are based on actuals for January–September and estimates for October–December (to be updated with actuals in H2 2022 in our annual Novartis Environmental Sustainability and Occupational Health and Safety Data Supplement). Any significant deviations are restated the following year in the Novartis in Society Integrated Report. Previous years' data reflect only actuals.
² 2021 data includes indirect emissions from air travel, train travel, car rentals and hotel stays. The methodology changed in 2021, with previous years' data covering emissions from air travel only. This is part of a calculation effort to expand the Scope 3 category 6 emission activities reported and part of a wider Scope 3 calculation review that aims to increase the coverage to more than 90% of the overall Scope 3. New to 2021, air travel emissions now also cover radiative forcing, which multiplies the indirect emissions by 1.9. The published metric represents actual data from January 1, 2021 through December 31, 2021, which was made available on January 5, 2022. This data may be updated after the reporting date as emissions are calculated based on bookings, which may be adjusted after the reporting period. For further Scope 3 disclosures, please see our [latest HSE supplement](#).

³ Scope 1: combustion and process; and vehicles; Scope 2: purchased energy

⁴ GHG offsets are based on data provided by third parties. The Santo Domingo forest carbon offset project in Argentina is due to reach maturity; as projects near this phase, routine operations involve thinning and harvesting. These operations have generated the negative GHG emissions offset value for 2021. The Santo Domingo offsets are based on January–June actual data and July–December estimates, while offsets from our Hacienda El Manatí project in Colombia are based on January–September actual data and October–December estimates (to be revised with actuals in Q1 2022). The methodology we use to measure offsets will be reviewed in 2022.

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

⁶ Water discharged via treatment and water lost

OUR PERFORMANCE IN 2021

No. 4

Antimicrobial Resistance Benchmark

improving our ranking by one place since 2020

Responding to the call from UNICEF to combat childhood pneumonia, Sandoz developed pediatric amoxicillin, today recommended by the WHO as first-line treatment for childhood pneumonia.

Novartis was ranked fourth in the [2021 Antimicrobial Resistance Benchmark](#) (from fifth in 2020), which evaluates the performance of the world's 17 largest pharmaceutical companies in the fight against AMR. We are recognized for performing strongly in the areas of responsible manufacturing, appropriate access and stewardship.

Conducting animal research responsibly

Novartis is committed to using alternatives to animal research wherever feasible. Our global policy and standards define key principles, responsibilities and requirements governing animal research. All studies sponsored by Novartis, whether conducted internally or externally, must adhere to our policy and standards.

In 2021, all Novartis Institutes for BioMedical Research in-vivo research sites received accreditation from the [Association for Assessment and Accreditation of Laboratory Animal Care International](#), underscoring our progress in conducting responsible animal research.

We adhere to the 3R principles: reduce the number of animals in studies, refine study methods to improve the animal's experience, and replace animal studies with alternative options. In 2021, for example, researchers across three disease areas joined forces to profile neuroinflammation pathways in a model for amyotrophic lateral sclerosis (ALS), reducing the number of animals needed for study by 86%.

Similarly, researchers reduced the number of animals needed for a chimeric antigen receptor T-cell (CAR-T) study by developing a non-invasive method for measuring anti-tumor activity in the same animals over time. We also replaced the use of animals in a training program on key principles of surgery by deploying a new digital training platform.

Animal testing indicators¹

	2021	2020	2019
Total	353 772	410 359	454 454
Rodents	265 111	312 332	355 451
% of total	74.94%	76.11%	78.21%
Zebrafish	88 229	97 596	97 551
% of total	24.94%	23.78%	21.47%
Other species	432	431	1 452
% of total	0.12%	0.11%	0.32%

¹ Data refer to animals needed for internally conducted animal studies for Novartis. For animals needed for both internally and externally conducted animal studies, please see [here](#).

Photo In 2007, Novartis purchased the Santo Domingo Estate in northern Corrientes, Argentina, for a carbon-sink project. Today, it is our most mature project, helping to offset our carbon emissions through carbon removals via native species.





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Our corporate governance approach

Strong corporate governance supports the effective management of our business and is the basis of trust in our company. Our corporate governance framework – along with our internal controls and policies – is intended to support sustainable financial performance and long-term value creation for shareholders, patients, employees and other stakeholders. For more detailed information on corporate governance at Novartis, please see our 2021 Annual Report.

In this section

▼ **Our corporate governance framework**

Our system of corporate governance is based on effective checks and balances. We have a three-tier structure: the Annual General Meeting of Shareholders, our Board of Directors, and our Executive Committee.

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▼ **Ethics, risk and compliance**

We have an extensive ethics, risk and compliance approach that ensures clear alignment between risk management, policies and controls.

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▼ **Internal Audit**

Our Internal Audit function assists the Board and Executive Committee by providing independent assurance and advice on key topics.

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Topic

Share capital

Information

Articles of Incorporation of Novartis AG
www.novartis.com/investors/company-overview/corporate-governance
Novartis key share data
www.novartis.com/investors/share-data-analysis

Shareholder rights

Articles of Incorporation of Novartis AG
www.novartis.com/investors/company-overview/corporate-governance

Annual General Meeting of Shareholders

Annual General Meeting of Shareholders
www.novartis.com/investors/shareholder-information/annual-general-meeting

Board Regulations

Board Regulations
www.novartis.com/investors/company-overview/corporate-governance

Novartis code for senior financial officers

Novartis Code of Ethical Conduct for CEO and Senior Financial Officers
www.novartis.com/investors/company-overview/corporate-governance

Novartis Annual Report and Form 20-F

Novartis Annual Report and Form 20-F
www.novartis.com/reportingsuite

Novartis financial data

Novartis financial data
www.novartis.com/investors/financial-data

Press releases

Press releases
www.novartis.com/news/news-archive?type=media_release
Free email service
www.novartis.com/news/stay-up-to-date

Additional information
(including Novartis investor event calendar, registered office, contact and email addresses, phone numbers, etc.)

Novartis Investor Relations
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Our corporate governance framework

Our system of corporate governance is based on effective checks and balances. We have a three-tier structure: the Annual General Meeting of Shareholders (AGM), our Board of Directors, and the Executive Committee of Novartis (ECN):

- Shareholders approve the company's financial statements and other disclosures, as well as compensation for members of our Board and ECN. They also approve the dividend and elect the company's Chairman, Board members, Compensation Committee members, Independent Proxy and external auditor.
- Our Board of Directors holds the company's ultimate decision-making authority, with the exception of decisions reserved for shareholders. The Board represents the interests of all stakeholders. The Board operates through five committees: Audit and Compliance; Compensation; Governance, Nomination and Corporate Responsibilities; Risk; and Science & Technology.
- The ECN, which reports to the Board and is led by the CEO, is responsible for operational management, including achieving the company's financial and strategic objectives.

The external auditor provides their opinion on the compliance of Novartis Group consolidated statements and other financial information, the Compensation Report, internal controls over financial reporting, and sustainability reporting with applicable standards and laws.

Board of Novartis

All members of the Board, including the Chairman, are independent and non-executive, as defined by our corporate governance rules. When choosing Board members, we aim for a balance of skills, expertise and experience. We believe a diverse Board,

including in gender, age, nationality and ethnicity, supports long-term value creation. Most of our Board members have experience in leadership or management positions; half have direct experience in the healthcare or pharmaceutical industry.

Members of the Board are elected for one-year terms and may serve a maximum of 12 years; this term limit was approved by shareholders in 2021. The Board is subject to an annual assessment, which is carried out by an external consultant in every third year.

Board members also have regular training sessions. In 2021, these mostly virtual sessions included training on diversity and inclusion, our ethical commitments and our [Professional Practices Policy](#), as well as insider trading, data privacy, and digital engagement for personal use. Please see [page 91](#) for Board highlights in 2021.

Executive Committee of Novartis

The Board appoints the ECN members and delegates to them the overall responsibility for and oversight of the operational management of Novartis. The ECN currently has 12 members and is led by the CEO (see next page for details).

Novartis AG and Novartis shares

Novartis AG, the Group's holding company, is a corporation organized under Swiss law with its registered office in Basel, Switzerland. Novartis shares are listed on the SIX Swiss Exchange (symbol: NOVN) and the New York Stock Exchange (symbol: NVS). The latter are in the form of American depositary receipts representing Novartis American depositary shares.

Shareholder rights

Shareholders have the right to vote and to execute all other rights as granted under Swiss law and the Articles of Incorporation. All shares have equal voting rights and carry

equal entitlements to dividends. The AGM usually takes place in late February or early March. Normally, shareholders can vote their shares by themselves or appoint another shareholder or the Independent Proxy to vote on their behalf. However, in accordance with Swiss legislation passed in response to the COVID-19 pandemic, it was not possible to physically attend our 2021 AGM, and shareholders could exercise their voting rights only through the Independent Proxy.

ESG governance

The Governance, Nomination and Corporate Responsibilities Committee (GNCRC) regularly reviews corporate governance principles and key governance documents against evolving best practice standards and new developments.

The ECN-level Trust & Reputation Committee, chaired by the CEO, meets every two months to oversee the company's environmental, social and governance (ESG) performance. In addition, we have an ESG Management Office to further embed ESG priorities across our business.

Stakeholder engagement is key to our ESG approach. We engage with our stakeholders through regular meetings, conferences and seminars; this engagement is a key part of building trust with society. For shareholders, we organize ESG investor days and issue a quarterly progress update. For more information, please see [page 12](#).

In addition, we work through external initiatives on important health, industry and social issues. Please see ["External initiatives and memberships of associations"](#) in the appendix of this report.

Board diversity profile



30%	American	12%	German
30%	Swiss	8%	British
12%	Dutch	4%	Irish



23%	55-60	23%	>65
54%	61-65		
		23%	



69%	Male
31%	Female



23%	<3y	23%	7-9y
31%	3-6y		
23%	7-9y		
	23% >9y		

ECN diversity profile



42%	American	8%	Dutch
25%	German	8%	British
17%	Swiss		



25%	45-50	75%	>50
		25%	



75%	Male
25%	Female



17%	<2y	66%	2-4y
66%	2-4y	17%	>4y
		17%	

Board highlights for 2021

During 2021, the Board of Directors met nine times, including both regular and ad hoc meetings. In response to the COVID-19 pandemic, the Board held virtual, hybrid and physical meetings, with participants joining in person when possible. In their discussions, the Board and committees covered a number of issues, including:

- ▶ Progress with the company's strategy, including therapeutic areas and technology platforms, key geographic areas and the generics business
- ▶ Review of larger strategic considerations to drive sustainable growth, such as mergers and acquisitions
- ▶ Review of the Novartis ESG strategy
- ▶ A key strategy review for the US and China markets
- ▶ Longer-term Board succession planning and required profiles, including proposing one new Board member candidate to be elected at the 2022 AGM
- ▶ How Novartis is prepared to respond to cybersecurity incidents
- ▶ The annual Board self-evaluation
- ▶ Discussion and approved the divestment of the Company's investment in Roche Holding AG
- ▶ Initiation of a strategic review of Sandoz to maximize shareholder value

¹ Please note that five Board members and two Executive Committee members have dual nationalities. Each of these nationalities is counted as a half in the above charts.

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Joerg Reinhardt, Ph.D.
Chairman
German

Enrico Vanni, Ph.D.
Vice Chairman, Lead
Independent Director since
January 1, 2021
Swiss

**Nancy C. Andrews,
M.D., Ph.D.**
American/Swiss

Ton Buechner
Dutch/Swiss

Patrice Bula
Swiss



Elizabeth (Liz) Doherty
British/Irish

Ann Fudge
American

Bridgette Heller
American

Frans van Houten
Dutch

Simon Moroney, D.Phil.
German/New Zealander



**Andreas von Planta,
Ph.D.**
Swiss

**Charles L. Sawyers,
M.D.**
American

William T. Winters
British/American

For CVs of our Board members
www.novartis.com/about/board-directors

Our Executive Committee



**Vasant (Vas)
Narasimhan, M.D.**
Chief Executive Officer
American

**James (Jay) Bradner,
M.D.**
President of the Novartis
Institutes for BioMedical
Research (NIBR)
American

Karen L. Hale
Chief Legal Officer
American

Harry Kirsch
Chief Financial Officer
German/Swiss

Robert (Rob) Kowalski
Chief People & Organization
Officer
American



Steffen Lang, Ph.D.
Global Head of Novartis
Technical Operations (NTO)
German/Swiss

Klaus Moosmayer, Ph.D.
Chief Ethics, Risk &
Compliance Officer
German

Richard Saynor
Chief Executive Officer of
Sandoz
British

Susanne Schaffert, Ph.D.
President of Novartis Oncology
German

John Tsai, M.D.
Head of Global Drug
Development
and Chief Medical Officer
American



Marie-France Tschudin
President of Novartis
Pharmaceuticals
Swiss

Robert Weltevreden
Head of Customer & Technology
Solutions (CTS)
Dutch

For CVs of our ECN members and other members of senior management
www.novartis.com/ecn

Audit and Compliance Committee	Compensation Committee	Risk Committee	Science & Technology Committee	Governance, Nomination and Corporate Responsibilities Committee
E. Doherty (Chair)	S. Moroney (Chair)	T. Buechner (Chair)	J. Reinhardt (Chair) ¹	A. von Planta (Chair) ¹
T. Buechner	P. Bula	N. Andrews	A. Fudge	A. Fudge
B. Heller	B. Heller	E. Doherty	F. van Houten	C. Sawyers
F. van Houten	E. Vanni	A. von Planta ¹	S. Moroney	E. Vanni
E. Vanni	W. Winters	C. Sawyers	C. Sawyers	W. Winters

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We have an extensive ethics, risk and compliance approach, comprising:

Ethics	Risk	Compliance
<ul style="list-style-type: none"> • Ethics (including our Code of Ethics) • Human rights • Ethical culture and impact 	<ul style="list-style-type: none"> • Enterprise risk and crisis management • Enterprise policy and control management • Third-party risk management • Health, safety and environment (HSE) governance 	<ul style="list-style-type: none"> • Compliance management system • SpeakUp Office (our whistleblower program) • Centralized team for monitoring and remediation

This approach is overseen by our Ethics, Risk & Compliance (ERC) function; it ensures clear alignment between risk management, policies and controls. We have specific internal policies in place in areas such as data privacy, non-discrimination, anti-bribery, human rights and HSE, which help us maintain high standards of ethics and integrity across our business.

Central to our approach is the [Novartis Code of Ethics](#), which comprises 23 commitments on topics such as human rights, drug safety, data use, and access to medicines. The code guides employees in daily decision-making and provides an ethical framework to our risk management approach. For more information on how we embed our Code of Ethics across the organization, see [page 80](#).

Many of our policies and controls are based on international norms and standards, including the United Nations Global Compact, the OECD Guidelines for Multinational Enterprises, and standards published by the International Labor Organization. We regard ethics, compliance and good risk management as crucial to maintaining public trust.

Risk management

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. Our objective is to prevent or minimize risks that may affect our business, while ensuring that we can still capture opportunities for growth.

Our objective is to prevent or minimize risks that may affect our business, while ensuring that we can still capture opportunities for growth

Regular workshops are held across the company to identify risks and possible mitigation measures. These are consolidated into the Novartis Risk Compass, which provides an overview of strategic, operational and emerging risks for use by senior management (see [page 22](#)).

The Chief Ethics, Risk & Compliance Officer is responsible for the overall risk management process at Novartis.

Compliance

As part of our ERC approach, we have a comprehensive compliance management system to detect and prevent systemic misconduct. This system covers five principal risk areas: ethical dilemmas, bribery and corruption, third-party misconduct, professional practices, and conflicts of interest. Within our ERC function, we have a team responsible for monitoring compliance and taking action to address any misconduct with internal units and third parties.

The 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 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 142](#) of our 2021 Annual Report.

In 2021, we integrated global governance of our HSE activities within ERC, merging it with our Business Continuity Management and Novartis Emergency Management teams to create a new function called Global HSE & Resilience. The goal is to reduce risks, increase resilience and generate further positive impact on our people, patients and planet.

Compliance

As part of our ERC approach, we have a comprehensive compliance management system to detect and prevent systemic misconduct. This system covers five principal risk areas: ethical dilemmas, bribery and corruption, third-party misconduct, professional practices, and conflicts of interest. Within our ERC function, we have a team responsible for monitoring compliance and taking action to address any misconduct with internal units and third parties.

In 2021, the Novartis SpeakUp Office, which enables employees and external parties to raise concerns about potential misconduct while being protected against retaliation, was integrated into the ERC function to further align our efforts and embed our Code of Ethics across the organization (see [page 82](#)).

Internal Audit

Internal Audit assists the Board of Directors and the ECN in discharging their governance responsibilities by providing independent assurance and advice on the effectiveness, efficiency and adequacy of processes and controls that support Novartis in achieving its objectives, managing its major risks, and ensuring compliance with applicable policies, laws and regulations. The Internal Audit function executes the risk-based annual audit plan approved by the Board-level Audit and Compliance Committee (ACC) and reports the results to the audited units, the ECN and the ACC.

2021 Internal Audit activities and observations**AUDITS**

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Recurring observations relate to:

- ▶ Data governance and management; oversight of digital initiatives
- ▶ Third-party management, including subcontracting oversight
- ▶ Design of certain commercial and R&D processes, and cross-functional collaboration over complex programs, such as Enterprise Resource Planning (ERP) implementation
- ▶ Patient support program, including monitoring of external service providers

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In 2021, we continued our transformation into a leading, focused medicines company powered by technology, leadership in research and development, world-class commercialization, global access and data science. Feedback from shareholder engagement prior to our last Annual General Meeting (AGM) suggested that shareholders were in agreement that our current compensation system is aligned with the company's purpose, strategy and culture. No major changes are therefore proposed for 2022.

2021 changes to compensation system and disclosures

The year completes the first three-year performance cycle of the new Long-Term Performance Plan (LTPP), following the combination of the previous LTPP and the Long-Term Relative Performance Plan (LTRPP), as communicated in our 2018 Compensation Report. The combined plan focuses on four equally weighted performance metrics: net sales compound annual growth rate (CAGR), core operating income CAGR, innovation, and relative total shareholder return (TSR).

In 2021, we reviewed our [Compensation Report](#) format with a view to increase its accessibility while maintaining its depth of disclosure. We chose to develop our "compensation at a glance" section to incorporate a more graphical illustration of the 2021 CEO pay outcomes and a summary of our executive compensation framework for 2022. In addition, we provide further visibility into the 2019-2021 LTPP targets, showing the threshold, target and maximum opportunity for each performance metric.

2021 performance highlights

2021 was a year of solid performance, with growth across sales, profits, margins and cash flow. Sales growth drivers were Entresto (USD 3.5 billion), Cosentyx (USD 4.7 billion), and Zolgensma (USD 1.4 billion), along with therapies like Kesimpta, Promacta/

Revolade, Kisqali and Jakavi. While overall sales performance was on target, COVID-19 continued to impact parts of our business, specifically Oncology and Sandoz.

We continued to deliver innovation to patients in 2021 with 21 approvals, including Leqvio (US, EU) and Semplicit (US), and 34 submissions made across our top four markets. However, the year was not without setbacks, as some clinical trials of experimental compounds – including Kymriah for blood cancer, ACZ885 (canakinumab) for lung cancer, and CFZ533 (iscalimab) in kidney transplant patients – did not meet their primary goals.

We progressed our efforts to deliver next-generation medicines while driving our environmental, social and governance (ESG) agenda. Pursuing new health equity initiatives in clinical trial diversity, advancing access to medicines, and using data and digital technologies in underserved regions in Africa, South America and Asia are examples of our long-term commitment to transform global health. More details on our ESG efforts are provided earlier in this report.

Performance against the incentive targets, combined with base salary and other benefits, pension, Alcon Keep Whole awards and dividend equivalents, resulted in 2021 total realized compensation for the CEO of CHF 11 224 727. This is a reduction of 11.8% compared to 2020. Overall, while the financial and operational targets were met or surpassed, some of the innovation targets were missed, which

led to a reduction in long-term growth potential. This is reflected in a TSR performance below the peer group median. The reduced contribution of innovation and relative TSR to the 2019-2021 LTPP cycle were the main drivers of the lower total realized compensation in 2021 versus 2020. Full details of the 2019-2021 LTPP performance can be found in the [Compensation Report of our 2021 Annual Report](#).

Alignment with company strategy

Our strategy is to build a focused medicines company powered by technology, leadership in research and development, world-class commercialization, global access and data science. We foster a company culture that is inspired, curious and unbossed. We believe these elements drive continued innovation and will support the creation of value over the long term for our company, society and shareholders. To continue to align the compensation system with this strategy and to ensure that Novartis is a high-performing organization, the company operates both a short-term Annual Incentive plan and a Long-Term Incentive (LTI) plan with a balanced set of measures and targets. The Board of Directors determines specific, measurable and time-bound performance measures for the Annual Incentive and LTI plans.

The Compensation Committee has reviewed the existing compensation system and determined that it continues to support our strategy.

2021 Executive Committee compensation system

	2021 fixed pay and benefits		Performance-related variable pay	
	Annual base salary	Pension and other benefits	2021 Annual Incentive	Long-Term Incentive awards cycle 2021-2023 LTPP ¹
Purpose	Reflects responsibilities, experience and skill sets	Provide retirement and risk insurances (tailored to local market practices/regulations)	Rewards for performance against short-term financial and strategic objectives, and Values and Behaviors	Rewards long-term shareholder value creation and innovation in line with our strategy
Form of payment	Cash	Country/individual-specific and aligned with other employees	50% cash 50% equity ² deferred for three years ³	Equity, vesting following a three-year performance period
Performance measures	-	-	Balanced scorecard comprising: • Financial measures (60%) • Strategic objectives ⁴ (40%)	• Net sales growth CAGR (25%) • Core operating income CAGR (25%) • Innovation (25%) • Relative TSR (25%)

¹ LTPP = Long-Term Performance Plan

² Executive Committee members may elect to receive more of their Annual Incentive in equity instead of cash.

³ The Annual Incentive deferred in equity is granted under the Deferred Share Bonus Plan (DSBP).

⁴ Strategic objectives are aligned with the five strategic pillars: innovation, operational excellence, data and digital, people and culture, and building trust with society.

The 2019-2021 cycle is the first vesting of the new LTPP plan, when the metrics were transformed into four equally weighted measures: net sales CAGR, core operating income CAGR, innovation and relative TSR.

Executive Committee compensation governance

A summary of the compensation decision authorization levels within the parameters set by the AGM is shown below, along with an overview of the risk management principles.

Decision on	Decision-making authority
Compensation of CEO	Board of Directors
Compensation of other Executive Committee members	Compensation Committee

Executive Committee compensation risk management principles

- Rigorous performance management process, with approval of targets and evaluation of performance for the CEO by the Board of Directors
- Balanced mix of short-term and long-term variable compensation elements
- Values and Behaviors are a key component of the Annual Incentive and are embedded in our culture
- Performance-based Long-Term Incentives, with three-year cycles
- All variable compensation is capped at 200% of target
- Contractual notice period of 12 months
- Post-contractual non-compete period is limited to a maximum of 12 months from the end of employment. Resulting compensation is limited to the annual base salary plus the prior-year Annual Incentive as per contract, if applicable
- Good and bad leaver provisions apply to the variable compensation of leavers
- No severance payments or change-of-control clauses
- Clawback and malus principles apply to all elements of variable compensation
- Share ownership requirements; no hedging or pledging of Novartis share ownership position

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2021 CEO pay for performance – outcomes

Measure	Target	Achievement versus target
2021 Annual Incentive		
Financial measures – 60% of total Annual Incentive, comprising:		
Group net sales (cc) (30%)	USD 50 010 million	Met
Group operating income (cc) (30%)	USD 10 805 million	Above
Group free cash flow as a % of sales (cc) (20%)	24.9%	Above
Share of peers for Novartis Group (USD) (20%)	8.1%	Below
Overall assessment of Group financial targets in constant currencies		Met
Strategic objectives – 40% of total Annual Incentive, comprising:		
Innovation (20%)		Below
Operational excellence (20%)		Above
Data and digital (20%)		Met
People and culture (including Values and Behaviors) (20%)		Met
Building trust with society (including access to healthcare, reputation and other ESG topics) (20%)		Met
Overall assessment of strategic objectives		Met
Overall assessment of CEO balanced scorecard		Met
TOTAL Annual Incentive:		100% of target (payout range 0% – 200%)
2019-2021 Long-Term Incentives		
Long-Term Performance Plan (LTPP)		
Net sales CAGR (25%)	4.3%	Above
Core operating income CAGR (25%)	7.0%	Above
Innovation (25%)		Above
Relative TSR (25%)		Below threshold
TOTAL LTPP:		107% of target (payout range 0% – 200%)

2021 total realized compensation for the CEO

The 2021 total realized compensation for the CEO was CHF 11 224 727. It includes payouts of the Annual Incentive and LTPP based on actual performance assessed for cycles concluding in 2021.

CHF	Fixed pay and benefits		Variable pay: performance-related		
	Annual base salary	Pension and other benefits	2021 Annual Incentive	LTPP 2019-2021 ¹	Total realized compensation
Vasant Narasimhan	1 769 200	442 132	2 657 267	6 356 128	11 224 727

¹ The shown amount represents the underlying share value of the total number of shares vested (including dividend equivalents of CHF 581 198 and Alcon Keep Whole awards of 612 696) to the CEO for the 2019-2021 LTPP performance cycle.

2021 Board of Directors compensation

All fees to Board members are delivered at least 50% in equity and the remainder in cash. Board members receive no variable or performance-based compensation, no share options, and no additional fees for attending meetings. Board members do not receive any company pension or insurance benefits.

CHF 000	2021-2022 AGM, annual fee ¹
Compensation of Chairman	3 800
Board membership	280
Vice Chairman	50
Chair of the Audit and Compliance Committee	130
Chair of the Compensation Committee	90
Chair of the following committees:	
• Governance, Nomination and Corporate Responsibilities Committee	
• Science & Technology Committee	
• Risk Committee	70
Membership of the Audit and Compliance Committee	70
Membership of the following committees:	
• Compensation Committee	
• Governance, Nomination and Corporate Responsibilities Committee	
• Science & Technology Committee	
• Risk Committee	40

¹ No additional compensation was paid for the Lead Independent Director role.

Total actual compensation earned by Board members in the 2021 financial year was CHF 3 804 560 for the Chairman of the Board and CHF 4 764 354 for the other members of the Board.

Shareholder votes on compensation at the 2022 AGM

In line with our Articles of Incorporation, at the 2022 AGM, shareholders will be asked to approve the maximum aggregate amount of compensation for the members of the Executive Committee of CHF 91 million. This is the same as the amount requested last year. For the Board of Directors, the maximum aggregate amount proposed to shareholders is CHF 8.6 million, which is in line with the prior term. This

amount includes an annual fixed fee of CHF 20 000 for the Lead Independent Director role. Full details on compensation for the CEO, other Executive Committee members and Board members can be found in the [Compensation Report](#) of our 2021 Annual Report, and in the compensation votes at the 2022 AGM.

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Photo In Ivrea, Italy, production technician Paolo Ballurio takes a sample of *Lutathera*, a targeted radioligand therapy for certain rare tumors found in the digestive tract, for quality analysis. *Lutathera* vials are contained inside the green lead flasks.



Novartis GRI Content Index

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102-51 Date of most recent report						02.02.21
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103-1 Explanation of the material topic and its boundary	3 8 9 10 13					p. 13, Global Materiality Assessment 2021
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207-1 Approach to tax						Annual Report 2021 p. 168
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300 – ENVIRONMENT					
301-2	Recycled input materials used	8	8		p. 83-85, HSE Supplement ¹ , HSE Data 2021
301-3	Reclaimed products and their packaging materials	8	8		Waste HSE Supplement ¹ ,
302-1	Energy consumption within the organization	7, 8, 9	7 8 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
302-2	Energy consumption outside of the organization	8	7 8 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
302-3	Energy intensity	8	7 8 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
302-4	Reduction of energy consumption	7, 8, 9	7 8 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
302-5	Reductions in energy requirements of products and services	8, 9	7 8 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
303-1	Interactions with water as a shared resource	7, 8	6 8	We recognize the gap on the revised GRI 303 standards for Water and Effluents 2018, and are developing a plan to align with the GRI in the future.	p. 83-85, HSE Supplement ¹ , HSE Data 2021
303-2	Management of water discharge-related impacts	7, 8, 9	6 8		p. 83-85, HSE Supplement ¹ , HSE Data 2021
303-3	Water withdrawal	7, 8, 19	6 8		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-1	Direct (Scope 1) GHG emissions	7, 8	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-2	Energy indirect (Scope 2) GHG emissions	7, 8	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-3	Other indirect (Scope 3) GHG emissions	7, 8	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-4	GHG emissions intensity	8	13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-5	Reduction of GHG emissions	7, 8, 9	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-6	Emissions of ozone-depleting substances (ODS)	7, 8, 9	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
305-7	Nitrogen oxides (NO _x), sulfur oxides (SO _x), and other significant air emissions	7, 8, 9	3 13		p. 83-85, HSE Supplement ¹ , HSE Data 2021
306-1	Waste generation and significant waste-related impacts	7, 8, 9	3 6		p. 83-85, HSE Supplement ¹ , HSE Data 2021
306-2	Management of significant waste-related impacts	7, 8	3 6		p. 83-85, HSE Supplement ¹ , HSE Data 2021
308-1	New suppliers that were screened using environmental criteria	8			p. 48
308-2	Negative environmental impacts in the supply chain and actions taken				p. 48

¹ Please note that the "HSE Supplement" refers to the Novartis Environmental Sustainability and Occupational Health and Safety Data Supplement published on [Novartis.com](#). This document will be updated with actuals and published in the second half of 2022.

DISCLOSURE NUMBER	DISCLOSURE TITLE	UNGCR PRINCIPLE	UN SDG	COMMENTS	REFERENCE
400 – SOCIAL					
401-1	New employee hires and employee turnover	6	8		p. 66
403-1	Occupational health and safety management system	3 8		We recognize the gap on the revised GRI 403 standards for Occupational Health and Safety 2018, and are developing a plan to align with the GRI in the future.	HSE Supplement ¹ , HSE Policy
403-2	Hazard identification, risk assessment, and incident investigation	3 8			HSE Supplement ¹
403-3	Occupational health services	3 8			
403-5	Worker training on occupational health and safety	3 8			p. 50, p. 65
403-6	Promotion of worker health	3 8			HSE Supplement ¹ A Safe Workplace, HSE Policy
403-9	Work-related injuries	3 8			HSE Supplement ¹ A Safe Workplace, HSE Policy
404-1	Average hours of training per year, per employee	6	8		p. 66
404-2	Programs for upgrading employee skills and transition assistance programs				p. 63
405-1	Diversity of governance bodies and employees	6	8 10		Annual Report 2021 p. 130
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	4	8		p. 52
412-1	Operations that have been subject to human rights reviews or impact assessments	1			p. 80
414-1	New suppliers that were screened using social criteria				p. 52
414-2	Negative social impacts in the supply chain and actions taken				Novartis Green Expectations from Suppliers
415-1	Political contributions				Novartis Responsible Lobbying Disclosures Public Policy & Advocacy
416-2	Incidents of noncompliance concerning the health and safety indicators impacts of products and services				p. 49
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
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data				p. 49-51
419-1	Noncompliance with laws and regulations in the social and economic area				Annual Report 2021 F 48-51

¹ Please note that the "HSE Supplement" refers to the Novartis Environmental Sustainability and Occupational Health and Safety Data Supplement published on [Novartis.com](#). This document will be updated with actuals and published in the second half of 2022.

Sustainability Accounting Standards Board (SASB) Index

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Healthcare sector

Biotechnology and pharmaceutical 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 2021 corporate reporting suite (Novartis in Society Integrated Report and Annual Report/Form 20-F), our corporate website, 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	
HC-BP-210a.1	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 Human Rights Commitment Statement (p. 7)
HC-BP-210a.2 Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	
HC-BP-210a.2	Ensuring patient Health and Safety (p. 48-50)
HC-BP-210a.3 Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	
HC-BP-210a.3	All material legal proceedings are disclosed within the Annual Report and accounts (p. F-48).
ACCESS TO MEDICINES	
HC-BP-240a.1 Description of actions and initiatives to promote access to healthcare products for priority diseases and in priority countries as defined by the Access to Medicine Index	
HC-BP-240a.1	Leading the way on access and global health (p. 70-78) 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)	
HC-BP-240a.2	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	
HC-BP-240b.1	Not reported
HC-BP-240b.2 Percentage change in: (1) average list price and (2) average net price across US product portfolio compared to previous year	
HC-BP-240b.2	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	
HC-BP-240b.3	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	
HC-BP-250a.1	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	
HC-BP-250a.2	Available via FDA Adverse Event Reporting website
HC-BP-250a.3 Number of recalls issued, total units recalled	
HC-BP-250a.3	Ensuring patient Health and Safety (p. 48-50)

SASB indicator	Novartis references
COUNTERFEIT DRUGS	
HC-BP-250a.4 Total amount of product accepted for takeback, reuse, or disposal	
HC-BP-250a.4	Ensuring patient Health and Safety (p. 48-50)
HC-BP-250a.5 Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	
ETHICAL MARKETING	
HC-BP-260a.1 Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	
HC-BP-260a.1	Falsified medicines (p. 51) Novartis Position on Falsified and Counterfeit Medical Products
HC-BP-260a.2 Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	
HC-BP-260a.2	Falsified medicines (p. 51)
HC-BP-260a.3 Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	
HC-BP-260a.3	Falsified medicines (p. 51)
EMPLOYEE RECRUITMENT, DEVELOPMENT & RETENTION	
HC-BP-270a.1 Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	
HC-BP-270a.1	All material legal proceedings are disclosed within the Annual Report and accounts (p. F-48).
HC-BP-270a.2 Description of code of ethics governing promotion of off-label use of products	
HC-BP-270a.2	Procedures for off-label requests outlined; further information on ethical marketing contained in Professional Practices Policy (p. 6) on Promotional and Non-Promotional Materials
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	
HC-BP-430a.1	Ensuring patient Health and Safety (p. 48-50) Novartis Quality Management System (QMS)
BUSINESS ETHICS	
HC-BP-510a.1 Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	
HC-BP-510a.1	All material legal proceedings are disclosed within the Annual Report and accounts (p. F-48).
HC-BP-510a.2 Description of code of ethics governing interactions with healthcare professionals	
HC-BP-510a.2	Professional Practices Policy Payments to Healthcare Professionals
ACTIVITY METRICS	
HC-BP-000.A Number of patients treated	
HC-BP-000.A	Access to healthcare performance indicators table (p. 72)
HC-BP-000.B Number of drugs (1) in portfolio and (2) in research and development (Phases I-III)	
HC-BP-000.B	(1) Novartis Global Product Portfolio (Novartis Innovative Medicines) Sandoz Advanced Accelerator Applications (2) 160+ Our approach to R&D (p. 36-37)

Task Force on Climate-related Financial Disclosures (TCFD)

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Novartis committed in 2020 to fully support the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) and included a qualitative disclosure in the Novartis in Society Report that year. This is our first quantitative TCFD disclosure, building on our qualitative disclosure and responses to the CDP climate questionnaire in previous years. We aim to provide iterative qualitative and quantitative disclosures on climate-related topics on a recurring basis as we incorporate the TCFD recommendations into our business, enterprise risk management and strategy development and become more mature in how we create actionable information on climate risks and opportunities.

Governance

Board oversight

The Governance, Nomination and Corporate Responsibilities Committee of the Novartis Board of Directors receives regular updates on climate risks 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) is responsible for approving the environmental sustainability strategy of Novartis, including climate, water, and waste targets. The Chief Sustainability Officer provides an annually updated climate scenario analysis, and information on physical 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.

Novartis launched a new environmental sustainability strategy in 2021. Per the revised governance, under the leadership of the Chief Sustainability Officer, the Environmental Sustainability Office will provide the leadership, subject matter expertise and portfolio management support that will support the implementation of our strategy. The primary steering committee for this strategy is the Environmental Sustainability Strategy Implementation Steering Committee (ESSI), while the Trust & Reputation Committee will continue to oversee its delivery.

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 threatens 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. In 2020 and 2021, climate change met 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 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 as the first-generation climate risk analysis. The analysis was based on a scenario that aligns to the Representative Concentration Pathway (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. The scenario analysis was a multiphase project which included a detailed climate risk analysis of a key site, as well as an initial

global assessment of 70 sites that are critical for the production and research parts of the company. The scenarios used 2030, 2050 and 2070 as timelines.

During 2021, Novartis initiated a second round of climate scenario analysis to define physical and transition risks across its operations and supply chain. The physical risk analysis was based on a comparison of outcomes aligned to RCP 4.5 and RCP 8.5 over two timeframes (2030 and 2050). Physical risk was assessed at 21 sites to include business-critical operations sites, major research and development locations, and other major support sites. The transition risk analysis related to the transition to a low-carbon economy was based on a 1.5-degree outcome and a 3.0-degree outcome, and was run over four timeframes (2025, 2030, 2040 and 2050). Initial risks and opportunities were assessed at the enterprise level.

The ongoing climate scenario analysis is being coordinated with Novartis employees 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, physical adaptation, and potential future changes in therapeutic research and development.

In 2020 and into 2021, 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 and to achieve our water neutrality target.

Progress

The following Novartis accomplishments in 2021 are relevant to the TCFD recommendations:

- Novartis conducted environmental life cycle analysis (LCA) pilot studies for its respiratory dry powder inhaler (DPI) devices across six environmental categories in accordance with the Greenhouse Gas (GHG) Protocol's sector guidance for pharmaceuticals and medical devices. The study suggested that the Novartis DPIs have, on average, a carbon footprint of less than half compared to other published DPI LCAs – with classical pressurized metered dose inhalers (pMDIs) using HFC-134a as propellant gas displaying an average carbon footprint of up to 50 times higher than the Novartis DPI. Including carbon impact and pricing into early-stage development of drugs can drive investment optimization and reduce carbon emissions during the scale-up of new products.
- Following the success of DPI devices, we launched a new sustainability study on Coartem to make it our next and our first large-scale carbon-neutral project.
- We reached the milestone of 1 billion treatments of our artemisinin-based combination therapy (ACT) delivered since 1999, with more than 90% supplied without profit. More than 450 million were a pediatric formulation developed jointly with Medicines for Malaria Venture. The World Health Organization estimates that adopting ACTs as a first-line treatment for malaria, together with prevention efforts and better diagnostics, have saved 7.6 million lives since 2000.
- Construction started for new generation capacity as part of our pan-European virtual power purchase agreement. It 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.
- Novartis partnered with One Young World to organize and sponsor Operation Planetary Health to raise awareness about environmental sustainability and to create a movement to accelerate change within the organization. The theme of "planetary health" aligned with and built on Novartis environmental sustainability targets and strategy. The event aimed to inspire employees to address specific environmental challenges with actionable and sustainable solutions. Our focus was on carbon neutrality (Scope 3 emissions; emissions in our value/supply chain) and the circular economy. We also sought to gain insights and solutions for emerging issues that do not yet form part of our company targets.
- We developed the Novartis Green Expectations from Suppliers document to outline what is needed from our suppliers and support them on that journey. Using the ACCA model, we track and measure suppliers' journey toward carbon neutrality. The four-stage ACCA framework involves:
 - 1. Awareness building
 - 2. Comprehension of the requirements of the carbon emission targets
 - 3. Commitment to achieve carbon neutrality
 - 4. Definition of action plans to meet environmental sustainability targets
- The Green Expectations framework was issued to 43 suppliers in 2021. Our Green Supplier Summit complemented the Green Expectations initiative, with 88% of participating suppliers acknowledging receipt. We are engaging our suppliers in dialogue, and this will be underpinned with concrete tools and mechanisms to facilitate their journey as much as possible. The breadth of this engagement – approximately 36 000 suppliers – means the process needs time to yield significant results, particularly among suppliers with whom we do not have direct interaction.
- In 2021, Novartis joined the 100-plus company EV100 initiative, demonstrating our commitment to transition our fleet to electric vehicles (EVs). Novartis plans to reduce vehicle fleet emissions by over 63% by 2025, and 94% by 2030. In 2021, implementation began in 30 countries, impacting 18,000 of 26,000 vehicles in the Novartis fleet.

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- We also joined RE100 in 2021, a global initiative bringing together the world's most influential businesses committed to 100% renewable electricity. Our power purchase agreements with renewable power developers, both existing and in the commissioning phase, are a key vehicle to us achieving our target 100% renewable energy in the US, Canadian and European markets by 2023.
- We made further progress in reducing our emissions: Scope 1 and 2 emissions decreased by 34% in 2021 versus the 2016 baseline.
- In 2021, business travel was 85% less when compared to 2019. While this was largely due to COVID-19 restrictions, internal processes have been adapted to maximize virtual meeting technology and dramatically reduce future travel even as pandemic restrictions are relaxed in the future.
- Scope 3 data accuracy has been enhanced in terms of extent and method of calculation. This has resulted in higher 2019 emissions and a revision of the 2016 baseline. A more robust tracking system is in place to enable comparability of calculations and data across years. Currently, we can account for over 90% of our Scope 3 emissions.
- New manufacturing technologies have been implemented and utility equipment has been upgraded to improve process efficiencies. These updates include continuous manufacturing, biocatalysts and high-intensity perfusion batches.
- In 2021, Novartis identified 59 locations as being situated in regions that are either currently water-stressed or will be classified as such in the coming years. Seven of these locations are currently deemed high-risk. We will work with these locations to minimize their water consumption, and we aim to achieve neutrality by ensuring that an equivalent of water that cannot be avoided is returned to the same watershed.
- In 2021, Novartis supported the development of a watershed project in the Telangana, India, region that will address the long-term challenge of water availability in water-stressed areas. The goal is to help local communities in the long run by increasing water availability, providing additional and safe drinking water, supporting agricultural best practice, building personal hygiene structures for schoolchildren, and contributing to the local ecosystems. This will serve as a pilot to also examine how Novartis can most successfully contribute to water security in water-stressed regions of the world where we may have water-intense production operations.

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 C2.1b, C2.2, C2.3a, C2.4a, C3.1.
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 C3.2, C3.2a and C3.4.

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 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 pages 22-25.

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 at a progressively higher risk of substantial flooding. Other facilities that depend on the availability of water for manufacturing processes may be impacted by water scarcity.

During 2021, Novartis initiated a second round of climate scenario analysis to define physical and transition risks across its operations and supply chain. All of the detailed calculations were provided by an expert third party, Environmental Resources Management, using initial data collection. Knowing that this is an iterative process and that both data granularity and understanding of company-specific risks will increase over time, Environmental Resources Management and Novartis have estimated risk exposure and management costs associated with these limited initial risks as:

Risk A

Novartis operates globally, and we have significant financial exposure to carbon pricing due to the carbon footprint of our production facilities. Our sites in Kundl (Austria), Lendava (Slovenia), Menges (Slovenia) and Ringaskiddy (Ireland) are all subject to the EU's carbon pricing mechanism (EU ETS), while our site in Grimsby (UK) is subject, as of 2021, to the UK ETS, which closely tracks the EU ETS. The benchmark price for EU carbon allowances has been on an upward trajectory for the most part of the past few years, rising from EUR 5 a ton in 2017 to over EUR 80 a ton in 2021. We estimate potential exposure in a possible range of USD 19 million to USD 150.9 million related to the carbon price in 2030, according to our best current knowledge. Please note that the quantification of our exposure was realized by Environmental Resources Management and that these numbers might change significantly in the future.

Risk B

Novartis is exposed to physical risks from climate change, both chronic and acute. The most common types of global risk events are heat events, wildfires, water stress/scarcity, cyclones and flooding from sea level rise or severe weather events. Our exposure to physical risk due to flooding and cyclones was estimated using scenario analysis based on Representative Concentration Pathways (RCP) 4.5 and 8.5, which represent a best case and a worst case scenario of potential disruption to Novartis operations. Reasonable best and worst risk exposures in 2030 range from USD 80 million to USD 112 million, and in 2050 range from USD 151 million to USD 163 million. Please note that the quantification of our exposure was realized by Environmental Resources Management and that these numbers might change significantly in the future.

Risk C

Forty-nine nations have announced that they will decarbonize their healthcare systems, requiring Novartis to also reduce its carbon footprint to align with national healthcare sector decarbonization targets, and maintain its competitive position in order to have continued opportunities to sell medicines in these markets. The current revenue generated in these markets is USD 27.5 billion. This is also an opportunity, as success in decarbonizing ahead of our competitors may open up more opportunities for revenue in these markets. Potential exposure is USD 27.5 billion if Novartis products are not net zero by country-specific deadlines leading up to 2050. Please note that the quantification of our exposure was realized by Environmental Resources Management and that these numbers might change significantly in the future.

Further work is already underway and will be completed in 2022 to provide greater clarity on physical and transition risks upstream and downstream in our supply chain, and on risks to our core business related to loss of biodiversity and the burgeoning impact of climate change on human health.

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.
- Novartis has a goal to be net zero carbon across the entire value chain (Scopes 1, 2 and 3) by 2040.
- In 2021, Novartis reduced greenhouse gas emissions by 34% compared to our 2016 baseline.
- Additional details on our year-on-year 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 on 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 C4.1, C4.1a, C4.1b.
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, C4.2, and C4.2a.

Appendix: external initiatives and membership of associations

GRI 102-12: External initiatives

- Member of 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
- 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 (WEF)
- Joined the WEF Alliance of CEO Climate Leaders

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, SwissHoldings, Swiss Employers' Association, and Avenir Suisse in Switzerland
- Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO), Association for Accessible Medicines (AAM) 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: Selected adaptive development projects

Category	Product	Objectives	Progress to date
Expansion of clinical use of existing medicines into new indications and populations	Femara	Extend label to treatment of epithelial ovarian cancer	Phase III clinical trial started recruitment in January 2021.
	Entresto	Conduct a Phase IV clinical trial to assess the efficacy and safety of Entresto in people with heart failure due to chronic Chagas cardiomyopathy	The study is still recruiting in Argentina, Brazil, Colombia and Mexico, due to the COVID-19 situation.
	Hydroxyurea	Develop pediatric formulation for treatment of sickle cell disease	The drug was approved in Ghana in September and the launch is expected in February 2022; a dossier was submitted for registration in Uganda, Tanzania, and Kenya in July.
Development of new formulations for greater incremental benefit to vulnerable patients	Coartem	Develop pediatric formulation for infants < 5 kg body weight	Enrollment for the first cohort is complete and the trial started 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	Conduct a 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	Enrollment is complete and the study is on track. The final study report is planned for release in Q1 2022.

Appendix: supplier spend 2021

Supplier spend

Country	Total %	Spend Direct spend % ²	Supplier ¹ Indirect spend % ³	Total ⁴	%
Switzerland	33.91	34.66	33.61	4 430	13.97
USA	25.23	9.81	31.22	2 649	8.35
Austria	6.87	11.88	4.93	1 747	5.51
Germany	5.26	8.32	4.08	2 610	8.23
Japan	2.17	2.50	2.04	1 578	4.98
Ireland	2.05	4.73	1.01	459	1.45
France	2.03	2.28	1.93	1 233	3.89
China	1.75	0.44	2.26	1 569	4.95
Spain	1.56	2.34	1.26	791	2.49
Canada	1.44	1.46	1.43	670	2.11
India	1.31	1.78	1.12	1 059	3.34
Belgium	1.04	1.58	0.83	692	2.18
United Kingdom	0.98	0.80	1.05	449	1.42
Italy	0.94	0.71	1.04	626	1.97
Singapore	0.72	0.91	0.64	441	1.39
Rest of the world	12.75	15.80	11.56	13 422	42.33
Total	100	100	100	31 706	100

¹ Suppliers with whom we have a direct contractual relationship pertaining to the delivery of goods and services. The decrease is due to reporting system enhancements and supplier consolidation.

² Purchase of goods and services directly incorporated into a product being manufactured. Example: raw material, subcontracted manufacturing services, packaging

³ All suppliers necessary to run an organization, such as utilities, IT hardware/software, furniture, capital expenditure, marketing supplies, etc.

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

Independent Assurance Report on the 2021 Novartis in Society Integrated Report

To the Board of Directors of Novartis AG, Basel

We have been engaged by the Board of Directors of Novartis AG to perform assurance procedures to provide limited assurance on the ESG performance indicators included within the 2021 Novartis in Society Integrated Report of Novartis AG and its consolidated subsidiaries (Novartis Group) for the period ended December 31, 2021.

SCOPE AND SUBJECT MATTER

Our limited assurance engagement focused on the following 2021 ESG performance indicators, data and information disclosed in the Novartis in Society Integrated Report 2021 of the Novartis Group for the year ended December 31, 2021:

- The “Supply chain performance indicators” on page 52, the “People performance indicators” on page 66 (excluding those metrics listed below), the “Access to healthcare performance indicators” on page 72, the “Patients reached with emerging market brands” on page 73, the “Donations” on page 75, the “Patients reached through support programs” on page 75, the “Ethical business practices performance indicators” on page 81, and the “Environmental performance indicators” on page 84.
- 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 in the “Global Materiality Assessment 2021 Results Report” linked on page 13 and as applied to the Novartis in Society Integrated Report 2021.
- Reporting processes and related controls in relation to data aggregation of the select ESG indicators.

The following ESG “People performance indicators” on page 66 are not subject to this Assurance Report. Consequently, we do not express any conclusion on these ESG performance indicators.

- The following indicators within the subheading “Health and safety”:
 - The “Fatalities”
- The following indicators within the subheading “Gender indicators”:
 - The “Median tenure in years: female/male”
- The following indicators within the subheading “Gender representation (% female / % male)”:
 - The “Overall headcount”
 - The “Promotions”
 - The “Overall turnover”
 - The “Entry-level positions (job levels 6,7,8)”
 - The “Revenue-producing roles”
 - The “IT roles (IT job family)”
 - The “Engineering roles (R&D + TechOps job families)”
- All indicators within the subheading “Gender representation by contract type (female/male)”
- All indicators within the subheading “Number of employees by region, by contract type (permanent/temporary)”

CRITERIA

The ESG performance indicators disclosed within the Novartis in Society Integrated Report 2021 were prepared by the Board of Directors of Novartis AG (the ‘company’) based on the following criteria:

- GRI Standards
- Novartis Corporate Responsibility Guideline
- Novartis Code of Ethics
- Novartis procedures for gathering, collecting, and aggregating data for the ESG performance indicators
- The terms and conditions as outlined within the “Final Listing Prospectus dated 21 September 2020” for the “Patients reached with strategic innovative therapies” and “Patients reached through flagship programs” ESG performance indicators

BOARD OF DIRECTORS' RESPONSIBILITY

The Board of Directors of the company is responsible for preparing the Novartis in Society Integrated Report in accordance with the applicable criteria. This responsibility includes the design, implementation and maintenance of the internal control system related to the preparation of the Novartis in Society Integrated Report that are free from material misstatement, whether due to fraud or error. Furthermore, the Board of Directors is responsible for the selection and application of the criteria and adequate record keeping.

INDEPENDENCE AND QUALITY CONTROL

We have complied with the independence guidance 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 behaviour.

PricewaterhouseCoopers AG applies Swiss 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.

ASSURANCE PRACTITIONER'S RESPONSIBILITY

Our responsibility is to perform an assurance engagement and to express an opinion on the ESG performance indicators outlined within the “Scope and subject matter” section above. We conducted our engagement 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 procedures to obtain limited assurance about whether the ESG performance indicators outlined within the “Scope and subject matter” section above was prepared, in all material aspects, in accordance with the criteria as outline within the “Criteria” section above.

Based on risk and materiality considerations, we performed our procedures to obtain sufficient and appropriate assurance evidence. The procedures selected depend on the assurance practitioner’s judgement. The evidence gathering procedures were more limited than they would be on a reasonable assurance engagement and, therefore, less assurance was obtained than would be on a reasonable assurance engagement.

We performed the following procedures, among others:

- Review of application of the Novartis Corporate Responsibility Guideline
- Interviewing personnel responsible for internal reporting and data collection
- Performing tests on a sample basis of evidence supporting selected ESG data concerning completeness, accuracy, adequacy, and consistency
- Inspecting relevant documentation on a sample basis, including Novartis ESG policies, management reporting structures and documentation
- Review of the management reporting processes for ESG reporting and assessing the consolidation process of data at Novartis Group level and the related controls
- 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 conclusion.

CONCLUSION

Based on the work we performed, nothing has come to our attention that would cause us to believe that the ESG performance indicators outlined within the “Scope and subject matter” section above of Novartis AG for the period ended December 31, 2021 are not prepared, in all material respects, in accordance with the criteria as outline within the “Criteria” section above.

INHERENT LIMITATIONS

The accuracy and completeness of the ESG performance indicators outlined within the “Scope and subject matter” section above 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 the criteria as outline within the “Criteria” section above.

PricewaterhouseCoopers AG 


KRIS MULLER


CLAUDIA BENZ

Basel, February 1, 2022

The maintenance and integrity of Novartis AG's website is the responsibility of the Board of Directors and Management; the work carried out by PricewaterhouseCoopers AG does not involve consideration of these matters and, accordingly, PricewaterhouseCoopers AG accepts no responsibility for any changes that may have occurred to the figures or criteria as published on Novartis AG's website.

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 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 Integrated Report



The Novartis in Society Integrated Report covers our business, strategy and performance. It highlights progress against our five strategic priorities and describes how we create value for diverse stakeholders. A digital and interactive version can be accessed through the link below.

www.reporting.novartis.com

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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; 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 Integrated 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.

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The use of a ™ or the registered trademark symbol ® in combination with a brand name in a normal script indicates a third-party brand.

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

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Photo Ukamaka Obilie (left), a medicine vendor in Ebonyi State, Nigeria, talks to a mother and her child about preventing and treating common childhood illnesses such as malaria.

Back cover photo Jian Zhang (left), a patient with heart failure, and his wife leave a hospital in Shenyang, China.

