



# Dialogue matters

Starting with health to build a sustainable future

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# Can businesses create sustainable value?

To move towards sustainable development, companies must rethink their business models to include social and environmental responsibilities and the creation of shared value for the entire community, while also remaining profitable.

Until recently, this vision was predominantly seen as being linked to ethical and environmental considerations, but in the last few years it has become an important factor in business' innovation and competitiveness too.

**Sustainability is now the only option if we want a positive future for our businesses.** While it is foolish to talk about 'happy degrow' or consider a return to a world of closed borders, it is equally wrong to think that a business must be focused purely on profit, without looking at its consumption of natural resources or the quality of life of its employees. With new technologies and materials to draw upon, sustainable development and the circular economy have become paradigms that allow businesses to reveal their true nature: prospering and creating value over time, while respecting our planet's limitations and sharing successes with all stakeholders.

Today's business, institutional and political leaders must have the courage to change the capitalist system's forty-year-old perspective and adapt it to the challenges of the twenty-first century. Finance is heading in the same direction, and the pandemic we are all dealing with has led to a dramatic acceleration in the pace of change. We therefore need a systemic vision at both a business and political level that brings together innovation, environmental sustainability and social inclusion.

**Novartis has decided to play its part, and is working out how to speed up its transition to full sustainability through a process based on dialogue with stakeholders. Identifying the priority topics both within and outside the company and talking to stakeholders is not only an innovative approach, it also shows a willingness to identify and rapidly implement tangible solutions.**

There can be no sustainable development without sustainable businesses. That said, it will be difficult to transform the social and economic system at the speed of the climate crisis, social tensions and now the pandemic demand without political commitment too. Economic and cultural leaders must therefore work openly to make sustainable development the baseline for all individual and collective decisions.

**Enrico Giovannini**

Full Professor of Economic Statistics  
at the University of Rome Tor Vergata,  
Lecturer in Sustainable Development at LUISS

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# The path taken by Novartis Italy

## A letter from the Country President

Two years ago, we carried out our first tangible measurement of the value that Novartis is capable of generating for Italian society. In doing so, we launched a new process, aiming to understand how our company performs in its role as Italy's leading healthcare company, and the principles and priorities on which its work is based. We then expanded our analysis, seeking to 'calculate' the value Novartis produces with specific financial, environmental and social parameters. The positive results of these assessments encouraged us to take things further.

**We therefore decided to launch an open and unfiltered dialogue with our stakeholders, to identify definitively the areas and topics where Novartis can maximise its impact on Italian society. For patients, the healthcare system, the environment and the public at large; for Italy's present, and especially for its future.**

This was no easy task. We took on the challenge because we are aware that Italy faces many challenges of its own related to the right to healthcare, sustainability and innovation governance, and that tackling these issues requires as unified a vision as possible of the priorities we face and the methods we adopt. This concept, complex yet also full of opportunities, must underpin the commitment at Novartis to creating value.

For almost a whole year, Novartis worked with The European House – Ambrosetti to study the areas, objectives and critical points of this commitment through the eyes of both the company and our stakeholders.

The most important consideration of all is innovation. This means directing resources and investment to the most cutting-edge research, from digital technology to highly personalised treatments, as well as identifying new and sustainable criteria to ensure patients can access the (often revolutionary) therapies resulting from the research. Linked to this is our strong commitment to supporting the

strengthening of the Italian National Health Service, to ensure everyone has the right to treatment, without any regional disparity or inefficiencies, a need highlighted in the most dramatic of ways by the Covid-19 crisis.

Patient services are another pressing topic Novartis is committed to, focused on disease prevention and providing accurate health information. The same goes for environmental sustainability and business transparency and ethics, which is of extraordinary strategic value because it plays a key role in defining how much we are trusted by the public.

'Trust' is the word that best summarises the work illustrated on the following pages. Trust in our listening and in the dialogue between us and our stakeholders; rebuilding trust in the pharmaceutical sector from the Italian people, patients and the healthcare world, in which pharma plays an integral role; and rebuilding society's trust in innovation and science.

The last of these is by far the most important, and Novartis is working extremely hard to achieve it, especially with the younger generations, as we know this is crucial if Italy is to have a constructive future. In the years to come, the healthcare sector may drive economic, social and civil development even more than it does today.

And this is the direction in which Novartis is heading, towards ever more sustainable, measurable and long-lasting goals.



**Pasquale Frega**  
 Country President  
 Novartis Italy

# Will capitalism post-Covid be stakeholder capitalism?

In 2019, the Business Roundtable, which brings together 200 CEOs from the largest US companies, issued a 'Statement on the Purpose of a Corporation', which commits the signatories not only to pursue profit, but also to **invest in employees, protect the environment, deal ethically with suppliers, focus on the quality of products and services offered and, finally, create long-term value for shareholders**. Many initiatives all over the world have focused attention on the role of stakeholders in creating long-term value, including the new Italian Corporate Governance Code, which introduces the concept of 'sustainable success'.

These signals, which were already visible pre-Covid, revealed the need to come up with a form of 'stakeholder capitalism'. This is nothing new: forty years ago, R. E. Freeman's Strategic Management: A Stakeholder Approach anticipated the strategic role of stakeholders in the success of a business.

Today, however, these signals are impossible to ignore. Pope Francis's phrase "*none of us is saved alone*" in his message to those attending The European House – Ambrosetti's 46th Scenario Forum should give us further encouragement to make changes in this area.

Leaving to one side the ethical and political considerations that link the rise of stakeholder capitalism with the failure of neoliberalism, are there other, more pragmatic reasons for a company to listen to the expectations of its stakeholders? The key consideration when answering this question is uncertainty.

We are living in times of rapidly escalating phenomena: the climate emergency, vast overuse of resources, growing inequality, economic crisis and geopolitical tensions are all being exacerbated by a more multipolar and less multilateral world. And then, as if that wasn't enough, Covid-19 showed up too. These changes, and the speed with which they are

occurring, require us to rapidly identify solutions and put them into practice, but this is hindered by the uncertainty in all the issues we face.

Because we cannot always provide definitive answers, it is important that we are transparent in the methodology used to take decisions, giving those affected the opportunity to ascertain that the choice was made with the utmost commitment and competence. This is why **it is vital that all social stakeholders take part in the decision-making process**. Basically, if we don't know exactly where we are going, we must at least decide together that we wish to move.

Participation therefore plays a crucial role in decisions concerning change, but this is impeded by people's declining trust in institutions and businesses.

Uncertainty and a lack of trust are complex elements to govern when it comes to managing change. Leaving aside ethical considerations, it is clear that stakeholder capitalism encourages increased dialogue between organisations and social stakeholders. The alternatives, which pursue simplification at all costs due to the emergency situation, risk us unnecessarily wasting even more time.

In conclusion, it is up to today's businesses to come up with processes built around dialogue that can reach joint decisions within defined timescales, leaving others to worry about new political, cultural and economic paradigms. There is no shortage of positive experiences to back this up: the materiality assessments carried out by Novartis, for example, can act as inspiration for other public and private organisations.

**Carlo Cici**

Head of Sustainability Practice  
The European House - Ambrosetti

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# The value (and values) of Novartis

## The identity of Novartis Italy and its commitment to ESG (Environmental, Social and Governance) goals

### Globally

799 m Patients helped in 155 countries. <sup>1</sup>	-\$ 5,3 bn Environmental impact (emissions, energy, water and waste). <sup>1</sup>	+\$ 67 bn Social impact of Novartis medicines in terms of contribution to global GDP through reduced healthcare costs. <sup>1</sup>
+\$ 4,8 bn Impact on human capital (pay, training and safety). <sup>1</sup>	\$ 9,4 bn Global investment in research & development (19.8% of 2019 turnover). <sup>1</sup>	

### In Italy

+ € 1.310 m Contribution to Italy's GDP derived from Novartis operations. <sup>2</sup>	-€ 56 m Environmental impact (emissions, energy, water and waste) expressed in euros. <sup>2</sup>	+ € 5,7 m Social impact of Novartis medicines in terms of their contribution to Italy's GDP through reduced healthcare costs. <sup>2</sup>
+ € 17 m Impact on human capital (pay, training, and safety). <sup>2</sup>	€ 80 m Investments in clinical trials in Italy in 2019 (+17% v 2018). <sup>3</sup>	

1. Novartis Global, 2019 | 2. WifOR Institute, 2019 | 3. Novartis Italy, 2019

Novartis Italy is part of a **global organisation committed to reimagining medicine** and providing innovative solutions that meet the constantly changing needs of people and patients across the world. To measure the impact of its activities, in each area and at all levels, Novartis developed an evaluation method based on **FES (Financial, Environmental and Social) indices**, which quantifies the economic, social and environmental impacts of the company's activities at a global level.

Applying the FES methodology to the work carried out by Novartis in Italy revealed the company's local impact, and the results of this analysis were published in the company brochure in August 2020. The FES indices are also useful for contextualising, quantifying and monitoring the contribution made by Novartis towards meeting the United Nations Sustainable Development Goals (SDGs)<sup>1</sup>.

Measuring corporate citizenship and ESG (environmental, social and governance) performance levels following international standards is particularly important for a business that aims to actively contribute to public wellbeing in a sector as vital as the healthcare industry. Novartis decided to reveal the extent of its impact by adopting a verifiable performance measurement model, which analyses the 'costs' of the business' activities and the benefits these produce for the economy, society and the environment across Italy. **The net value Novartis generates for Italy is €5,316 million**, a figure derived from the difference between its financial contribution to GDP and the benefits it gives to society and the burdens the business' activities place on the Italian public.

These results express in numerical terms the value that Novartis generates for the country, and confirm the active role the business plays in Italian society, especially during the current health, economic and social crisis. Early on in the pandemic, the Novartis Group launched the Novartis Covid-19 Response Fund, a tool created to provide financial support to public health initiatives across the world. These included strengthening local and national healthcare infrastructure and the recruitment of additional medical staff, supplying drugs and medical equipment, and creating digital platforms for collecting data on the pandemic and providing remote healthcare assistance. In Italy, Novartis decided to support the community through **donations** (with €1 million given to the Campania Region and €720,000 given to the Italian Red Cross in Lombardy), **home medicine deliveries and free supplies of Novartis drugs to Covid-19 patients**,

**as well as guaranteed access for all Italian doctors to the digital platform [www.professionistisalute.it](http://www.professionistisalute.it).**

Novartis intends to put just as much effort into the country's recovery, beginning with the areas that matter most to its stakeholders.

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1. In 2015 the United Nations General Assembly adopted the 2030 Agenda for Sustainable Development, with a list of 17 targets (Sustainable Development Goals – SDGs) to achieve by 2030, covering all aspects of human life and our planet.

# Executive summary

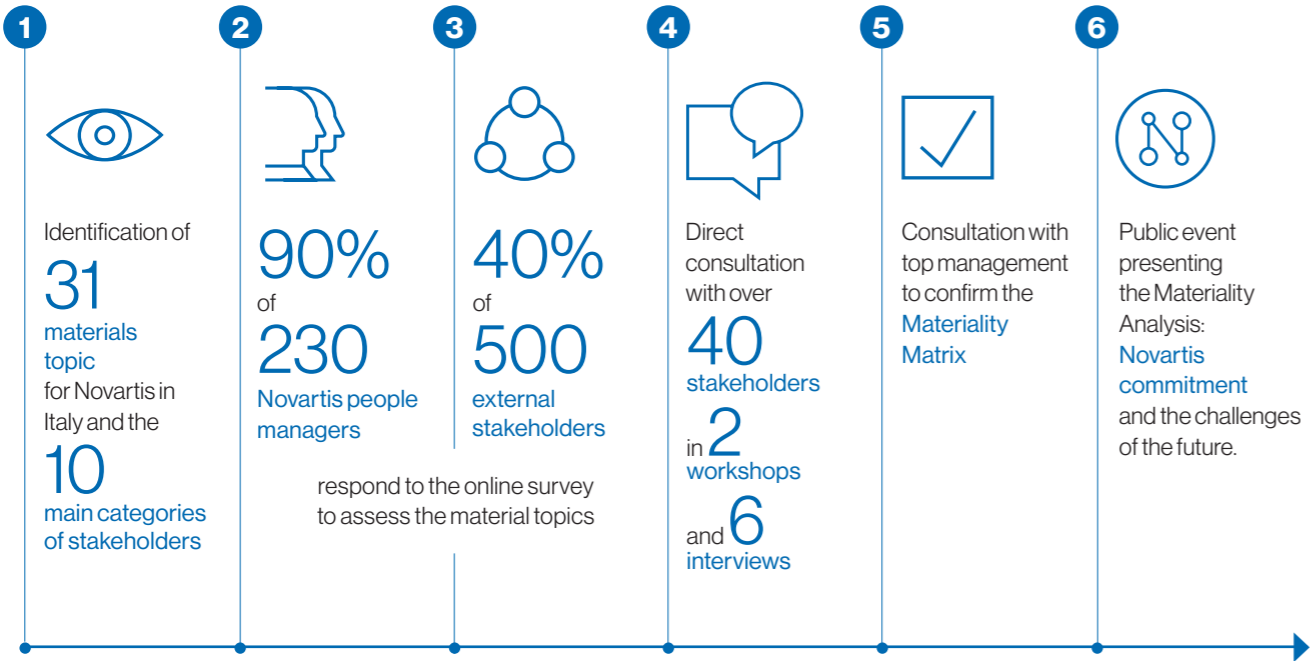
## The topics that matter most to Novartis Italy

### The process

In recent years, at a global level, **Novartis has developed a Materiality Assessment process that identifies the most important topics for the company to pursue in its goal to generate value for the company and its stakeholders.** When Novartis Italy followed this methodology in 2020, it was the first time it has been applied to a large Country subsidiary.

Novartis Italy combined the Group’s methodology with the finely tuned approach of The European House – Ambrosetti, listening to the viewpoints of various internal and external stakeholders and guiding a process based on dialogue, before identifying their interests and priorities together.

The process involved the following six stages:



The perspectives of stakeholders and Novartis top management were combined to identify

**9 strategic topics,**  
in  
**3 key areas**



### Reimagining medicine

- INNOVATIVE TECHNOLOGIES
- R&D FOR UNMET MEDICAL NEEDS
- AVAILABILITY OF MEDICINES & PRICING



### Putting health first

- HEALTH SYSTEM STRENGTHENING
- HEALTH EDUCATION AND PREVENTION
- PATIENT ASSISTANCE PROGRAMMES



### Doing the right thing

- SUSTAINABLE USE OF RESOURCES
- TRANSPARENCY
- ETHICAL & COMPLIANT BEHAVIOR

# Identifying key topics through dialogue

## Pre-selection of the topics that matter most

A Materiality Analysis summarises the points of view within an organisation and its stakeholders in order to **identify the topics that matter most**. The ultimate aim of the process is to compile a shortlist of the most strategically important environmental, social and business-related topics for the organisation, starting from a broader list that includes all potentially relevant themes.

A preliminary analysis was therefore conducted on thirty

important topics – divided into eight material clusters – derived from the Novartis global Materiality Analysis. A benchmark analysis involving sixteen peers and a scenario analysis were used to ensure the topics fitted the specific Italian context.

At the end of the preliminary analysis phase, an additional topic – digital skills – was added to the list of thirty already identified.

## Gathering internal and external points of view through surveys and interviews

The pre-selection stage covered a wide selection of internal and external stakeholders, and involved an online survey and a series of individual interviews. The interviewees included key figures from national and regional healthcare institutions, and added qualitative data to the quantitative results produced by the surveys, so the various topics could be **given an initial order of priority**.

All of the approximately 500 people in the panel were chosen for their experience, skills and abilities, so as to provide an authoritative view on the most important topics for Novartis Italy.

At the same time, around 230 managers were asked for their opinion on two parameters: the impact of each topic on Novartis and the company's ability to handle each one.



## Novartis Italy's ten categories of key stakeholders



31 important topics, grouped into 8 material clusters, with 18 chosen

Survey results

Innovations	<b>1. R&amp;D for unmet medical needs</b>
	2. R&D for neglected diseases
	3. Business model innovation
	<b>4. Innovative technologies</b>
	5. Drug resistance
Our people	<b>6. Digital skills</b>
	7. Diversity and inclusion
	8. Health and safety
	<b>9. Fair working conditions</b>
Patient health and safety	<b>10. Health education and prevention</b>
	11. Counterfeit medicines
	<b>12. Pharmacovigilance, safety profile and quality of drugs</b>
Economic Sustainability	<b>13. Recruitment &amp; retention of employees</b>
	14. Fair contribution to society
	<b>15. Financial health &amp; performance</b>
Environmental protection	<b>16. Sustainable use of resources</b>
	17. Pollution, waste and effluents
	18. Pharmaceuticals in the environment
Access to healthcare	<b>19. Availability of medicines</b>
	<b>20. Pricing</b>
	<b>21. Health system strengthening</b>
	<b>22. Patient assistance programmes</b>
Good governance	<b>23. Intellectual property</b>
	24. Corporate governance
	<b>25. Transparency</b>
	<b>26. Data privacy and security</b>
Ethical business practices	<b>27. Ethical &amp; compliant behavior</b>
	28. Animal testing
	<b>29. Respect for human rights</b>
	30. Responsible supply chain management
	31. Responsible use of new technologies

The results of the two surveys and the interviews led to eighteen topics being chosen, based on three criteria: the relationship between the impact of the topic and company performance, how frequently the topic came up and the discrepancy between internal and external views. These observations were used to identify the topics that:

- had a high/very high impact and low/very low performance;
- revealed significant differences between the viewpoints expressed in the internal and external surveys;
- were mentioned most often during interviews with institutional stakeholders.

Some comments from participants

” Innovative technologies and services are vital for companies that aim to cure patients rather than simply providing them with treatment. The key to their development is a combination of artificial intelligence and big data, which allows a reduction in the timescales and risks associated with testing.”

Innovative technologies, Digital skills

” Businesses are increasingly being asked to perform at the highest possible level, in this case creating effective medicines and ensuring they are available to patients. Creating added value is just one result of this. Novartis must continue to innovate and consider evidence-based pricing systems that combine the cutting-edge innovation for which it is renowned with all considerations relating to access to medicines.”

Pricing, Availability of medicines, R&D for unmet medical needs

” We need to increase the amount of dialogue in our relationship with patients: patients are ever more proactive in searching for information and increasingly exposed to inaccurate or incorrect sources. A proactive approach to informing patients would lead to better use of medicines and therefore increased effectiveness, reduced wastage and release into the environment and lower costs for the Italian health service.”

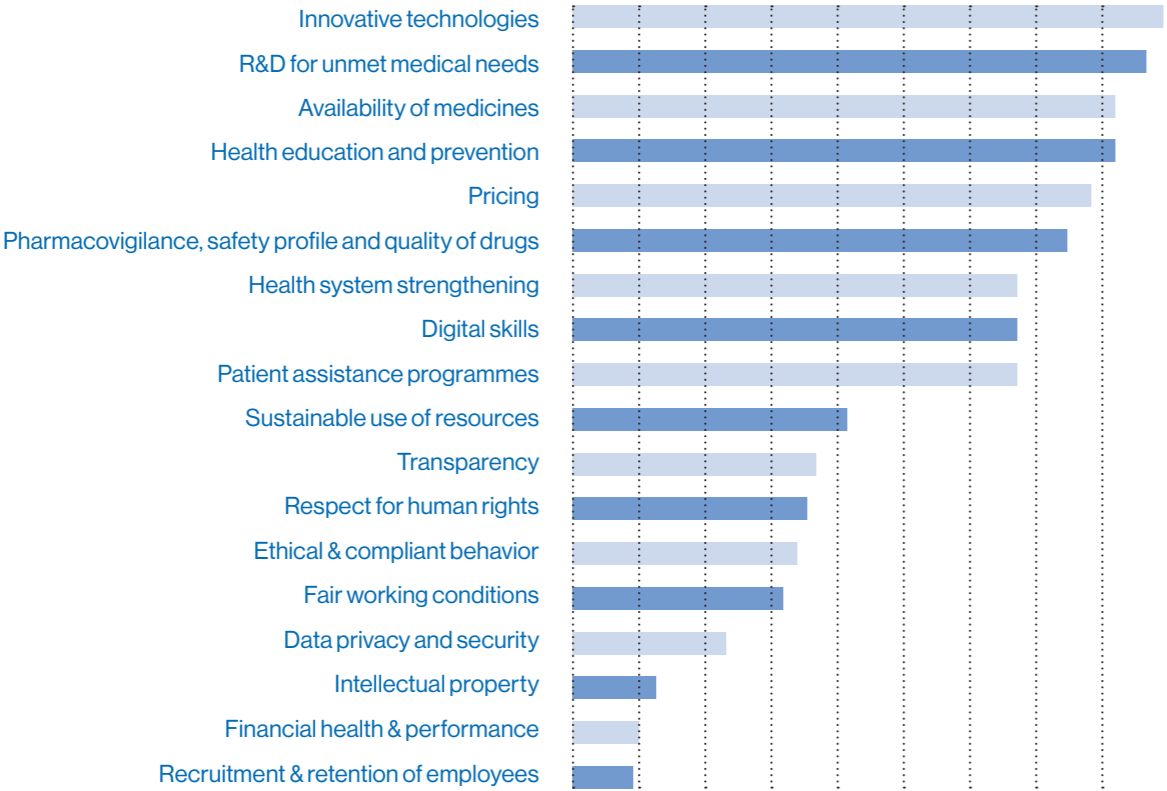
Health education and prevention, Sustainable use of resources

” The ability of Novartis to affect patients’ behaviour, with health education as its main objective, depends on its ability to present stakeholders (and foremost patients) with an image of itself that is not artificially positive. Education can only happen if those wanting to or obliged to educate do so in an educated manner!

Patient health and safety

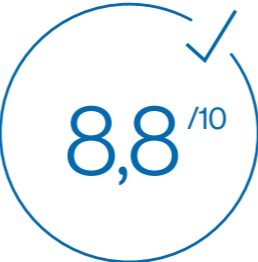
The topics that matter to stakeholders in order of priority

Results of the workshops



What matters most according to Novartis stakeholders

In late July 2020, Novartis Italy invited forty stakeholders from all categories to two interactive and participatory consultation meetings in Milan and Rome, where, in an environment of open dialogue, stakeholders were asked to put the eighteen strategic topics in order of priority. The stakeholders, moderated by a facilitator, assessed the topics; each one informed the other participants at the workshop about the importance of a particular topic, thereby increasing awareness of less familiar subjects, and giving stakeholders a greater level of knowledge of the topics when they voted on the order of priority. The meetings were very successful, with stakeholders giving them an average satisfaction rating of 8.8/10.



Average satisfaction rating given by stakeholders



What matters most according to Novartis top management

The meeting with Novartis' Country Leadership Team, conducted in the same way as the stakeholder meeting, allowed **Novartis Italy** to produce its first **Materiality Matrix**. At the end of the process, the Materiality threshold was drawn, a line beyond which a certain topic becomes a strategic priority, both in terms of stakeholders' requests and the company's objectives.

The matrix shows:

- on the vertical axis, the priority that stakeholders give to the various topics: those at the top of the matrix are the most important, for which one would reasonably expect greater commitment from Novartis Italy;

- on the horizontal axis, the priority that Novartis gives the various topics in terms of their impact, the investment required and the future challenges: the topics to the right of the matrix are therefore those on which the company intends to focus its efforts in the coming years.


Looking together at the two perspectives allowed three groups of key topics to be identified:



**Reimagining medicine**  
Innovative technologies, R&D for unmet medical needs, Availability of medicines and pricing.

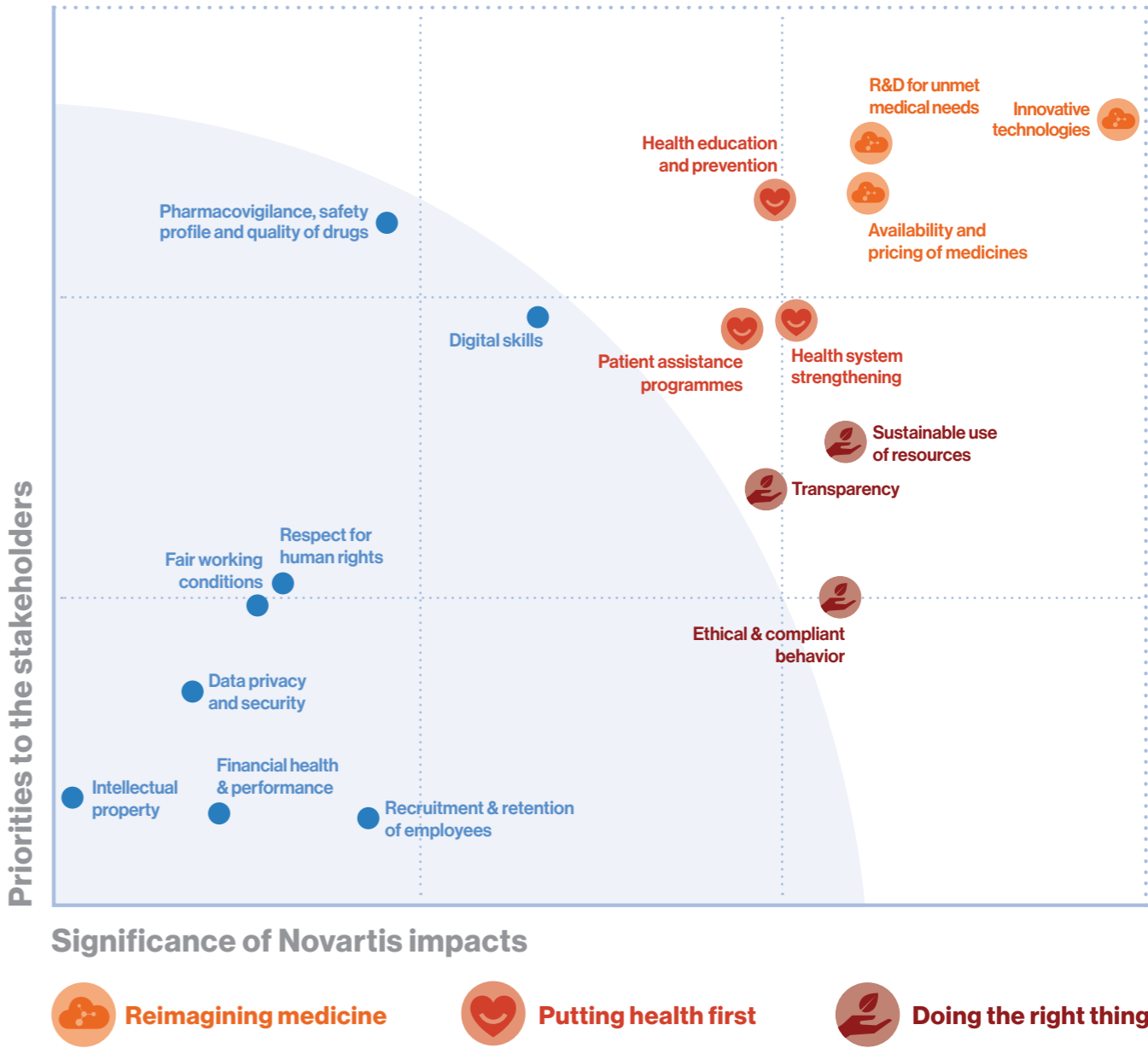


**Putting health first**  
Health system strengthening, Health education and prevention, Patient assistance programmes.



**Doing the right thing**  
Sustainable use of resources, Transparency, Ethical & compliant behavior.

The Materiality Matrix



Below the materiality threshold are the eight topics that underpin Novartis Italy's identity and the company's 'licence to operate'. These topics – no less important than the others – make up the company's DNA, the key values on which its business is founded, and which the organisation is already handling well.

NB: There are 17 topics shown in the Materiality Matrix because during the consultation with the top management it was decided to combine the topics "Availability of medicines" and "Pricing".

# Future challenges

## An analysis of Novartis Italy ‘material’ challenges in the medium term



### INNOVATIVE TECHNOLOGIES

#### Current scenario – Key statistics

<b>25th place</b> Italy’s position among the 28 EU member states in the Digital Economy and Society Index. <small>(DESI 2020)</small>	<b>29,7</b> difference in the DESI score between the most digital (Lombardy) and least digital (Calabria) regions. <small>(Digital Agenda Observatory at the Politecnico di Milano, DESI 2019)</small>	<b>14</b> the number of Italian regions that have implemented the Electronic Health Record (EHR), a key part of digital healthcare for almost ten years. <small>(2020 Meridiano Sanità report using 2020 AgID data)</small>	<b>350</b> telemedicine initiatives implemented in Italy in 2014-17; over 170 were registered in two months during the pandemic. <small>(2020 Meridiano Sanità report using 2020 ISS data)</small>	<b>38%</b> patients with a chronic condition who found health information or advice on healthy lifestyles online. <small>(2020 Meridiano Sanità report using 2020 ISS data)</small>
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#### Novartis vision and challenges

For Novartis Italy, the digital transformation of healthcare does not just involve digitalising existing services, but also **medical and clinical innovation in the management of patients’ clinical pathways** and a multisector transformation comprising **people, processes and technologies**, rooted in **widespread system connectivity**.

This will enable a shift from a silo-based model focused on hospital care to one based on a connected, integrated and systemic vision of healthcare, supporting the development of predictive, preventive, personalised and participative medicine. The goal is to create a value-based healthcare system with people’s needs at its heart. To achieve this aim, those responsible for the healthcare system must ensure that health data is collected, analysed and shared following common rules, procedures and guidelines, in compliance with privacy legislation.

The Covid-19 pandemic has led to unprecedented growth in demand for digital health solutions, which enable dialogue between professionals and allow doctors and patients to meet virtually. These solutions have removed barriers between people while allowing them to remain physically distant, protecting patients and workers alike from the risk of spreading the virus. They have also helped to optimise performance levels within the current organisational structures and have increased awareness of how to improve innovative healthcare pathways away from physical buildings, using services that do not require patients to move.

The pandemic has therefore sped up the integration of new technologies in the services provided to the general public and to patients, and we must continue to work on these to enact the digital transformation of the system that has been discussed for many years.

#### Novartis response

Novartis Italy wants to contribute to the digital transformation of healthcare by encouraging the development of bottom-up solutions channelled through open innovation processes. One such process is **BioUpper**, the first Italian training and acceleration platform, which promotes and finances innovative projects in the life sciences sector, creating synergies between start-ups, universities, industry, NGOs, public institutions and investors. Founded in 2015 from a partnership between Novartis and Fondazione Cariplo, with support from IBM, BioUpper promotes the best projects (with over 500 collected over the years) and turns them into tangible business initiatives, allowing Novartis to intercept digital projects with extraordinary innovation potential.

Some, like **Confirmo**, help to simplify processes and create paperless processes in the health and insurance sectors.

Others, like **PatchAI**, contribute to optimising the experience in clinical trials and testing through a cognitive platform fed by machine learning.

And others, like **Abzero**, are using drones to revolutionise sensitive activities such as the transportation of perishable medicines and biological materials.

Initiatives like BioUpper will be part of **Novartis Biome, a global network that acts as catalyst for innovative and digital solutions**, bringing together the best scientific and technological skills in support of the healthcare of tomorrow, working closely with the ecosystem of Italian and international start-ups, SMEs, universities and research centres.

**Biome will have two Italian hubs, one in Milan and one in Torre Annunziata, in the province of Naples.** The northern hub will be located within the Milano Innovation District (MIND), based in the former Expo area and set to become one of Italy’s main centres for innovation. The Biome hub in Torre Annunziata, meanwhile, is being built in an ‘innovation campus’ on the Novartis site, with spaces and services dedicated to start-ups and SMEs. The result will be a network that can develop projects and partnerships and interact with universities and public institutions.

One project in this area, still under discussion with the Lombardy Region, is **BioBank**, a database containing human genomic and health data compiled at a regional level that could reduce the failure rate in the development of new drugs and inform developers using real-world evidence. This will allow new pharmaceutical targets to be identified and help us to better understand the patient population, ensuring the

Novartis Italy wants to contribute to the digital transformation of healthcare by encouraging the development of bottom-up solutions channelled through open innovation processes.

development of new medicines is geared towards those who need them the most.

Novartis wants to work with these public and private organisations to contribute to an innovative life sciences ecosystem that can stimulate growth in Italy. To be successful, we must collaborate across disciplines and bring together a wide range of experiences.

R&D FOR UNMET MEDICAL NEEDS

Current scenario – Key statistics

<b>+73%</b> contribution to the increase in life expectancy from innovation in pharmaceuticals over ten years. <small>(The European House - Ambrosetti su dati Lichtenberg, "Health Policy Technology", 2020)</small>	<b>93,3% and 90,2%</b> deaths and DALYs <sup>1</sup> in Italy caused by non-transmissible illnesses, predominantly cardiovascular diseases, cancer and neurological conditions. <small>(2020 Meridiano Sanità Report using data from Global Burden of Disease, 2020of Disease, 2020)</small>	<b>325.000</b> people with rare illnesses on the Italian National Rare Diseases Registry, although the estimated total is over 1 million. <small>(2020 Meridiano Sanità Report, using 2020 data from UNIAMO)</small> <b>70% of cases begin in early childhood.</b> <small>(Italian Union for the Fight Against Muscular Dystrophy – UILDM, 2020)</small>	<b>56%</b> patients with rare conditions in Italy that have recorded continuity of treatment issues; 52% have declined treatment or interrupted their clinical pathway. <small>(Italian National Institute of Health and UNIAMO, 2020)</small>
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Novartis vision and challenges

Novartis continues to invest in a **strong research pipeline** developing over twenty-five potential blockbuster medicines, and focusing on diversifying its areas of treatment and creating cutting-edge platforms. There are currently around ninety new molecular entities (NMEs) emerging from the **Novartis Institutes for BioMedical Research (NIBR)**. Novartis is also a leader in three different advanced therapies: cell therapy, gene therapy and radioligands – radioactive biochemical substances used to treat cancer.

Italy is playing an active role in these developments, with significant efforts put into clinical research, an area in which around 290 Novartis associates are directly employed and which in 2019 involved over **7,650 patients and 2,130 centres, with a total investment of €80 million**, supporting **over 240 clinical trials** with a similar number (over 230) of **publications in scientific journals**.

Novartis research aims at **responding to unmet medical needs with highly innovative solutions**, ranging from common to rare diseases. The former include diseases that have a major social and economic as well as health impact (cardiovascular, respiratory, autoimmune, ophthalmological and neurological diseases, cancers, etc.), which still have very high levels of unmet needs despite significant progress in recent years. Rare diseases, meanwhile, which

are constantly growing in number thanks to our improved ability at identifying them, are often untreatable, and research in this area requires major investment.



Novartis response

The commitment from Novartis to non-transmissible diseases is particularly significant in Italy, given the country's ageing population and increased levels of chronic diseases. In various therapeutic areas, including **immunology, dermatology, respiratory, ophthalmology, cardiovascular, neuroscience and oncology, Novartis drugs** are often the standard of care treatments, improving the quality of life of patients and helping to reduce the economic impact in terms of direct cost (on the healthcare system) and indirect costs (linked to loss of productivity)..

This applies, for example, to the treatment of multiple sclerosis or psoriasis, and may also be seen in the treatment of high cholesterol with inclisiran, the **first and only siRNA** (small interfering RNA, a gene silencing treatment), a new class of medicines **developed to reduce the cholesterol circulating in the body**. High cholesterol is a serious pathological condition that significantly increases the risk of cardiovascular problems: considering its widespread nature, it has been proposed that a population health management model could be adopted for this drug at an international level, which could include making it available to a wide range of people who could potentially benefit from the treatment.

The solutions that Novartis has developed in the field of cell and gene therapy, meanwhile, could be even more disruptive.

*Tisagenlecleucel* (Kymriah®), **the first treatment from the CAR-T<sup>1</sup> family**, is a form of cell therapy that is tailored to the individual patient. T cells are taken from the patient's immune system, and then reprogrammed to recognise and attack specific types of tumour cells, taking advantage of their natural defence capacity. It is especially recommended for children with acute lymphoblastic leukaemia and patients with B-cell lymphoma who have become resistant to other treatments or for whom the disease has returned after the standard treatments. Italy is renowned for its excellence in haematology, and it played a major role in the clinical development of this therapy, which was introduced in the country back in mid-2019.

*Voretigene neparvovec* (Luxturna®), is the **first gene therapy to be authorised** both by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for a **form of hereditary retinal dystrophy** that severely affects sight and is the main cause of childhood blindness. The treatment will be available in Italy for all affected patients in early 2021.

Novartis drugs are often the standard of care treatments, improving the quality of life of patients and helping to reduce the economic impact in terms of direct and indirect costs.

*Onasemnogene abeparvovec-xioi* (Zolgensma®) is another gene therapy, designed to target **spinal muscular entropy (SMA), a rare genetic illness** that leads to gradual muscular decline, paralysis, and, in its most severe form (SMA 1) and in the absence of treatment, to the need for permanent ventilation or death before the age of two. *Onasemnogene abeparvovec-xioi* (Zolgensma®) finally provides a **treatment that tackles the genetic root cause of SMA**, and only needs to be administered once.

One way Novartis can develop the most innovative and promising treatments and provide them to the widest possible number of patients is carefully targeted acquisitions, which enable it to enhance its scientific and technological assets with resources from leading players in international research. One recent acquisition is **Advanced Accelerator Applications (AAA), a radiopharmaceutical company that works in the radioligands sector**. It has a major presence in Italy and designed the first pair of **theragnostic medicines** (therapeutic and diagnostic for the same condition) **in nuclear medicine and oncology**.

1. Disability-adjusted life year: the number of years lost due to disability or premature death.

1. Chimeric antigen receptor T cell

AVAILABILITY OF MEDICINES & PRICING

Current scenario – Key statistics

**436**  
the average number of days Italian citizens have to wait for access to a new drug following EMA approval (European average: 378 days).  
(Meridiano Sanità report using 2020 EFPIA data)

**72%**  
of the 172 products approved by EMA in 2015-2018 are available in Italy  
(Meridiano Sanità report using 2020 EFPIA data)

**52,2%**  
proportion of branded drugs with a lapsed patent sold in Italian pharmacies in 2019.  
(Assogenerici, 2019)

Novartis vision and challenges

The speed of researching and developing new treatment solutions is slowed down by approval procedures that are often long and complex, delaying patients' access to treatments even after they have been placed on the market.

These procedures are often closely connected to pricing and the need to balance patients' access to innovative treatments with the sustainability of pharmaceutical spending. Furthermore, the level of spending on medicines is determined by legislation, based on policies linked to balancing healthcare costs and outcomes and on the corresponding health benefits for patients and the wider population. This is all tied to drug and healthcare technology pricing and reimbursement policies, which must also take into account the economic sustainability of the system and keep spending under control.

The current health system is designed for actively managing chronic conditions, where treatment is given on a continual basis, for months or even many years. In contrast, 'disruptive' innovative techniques, like many of the cell and gene therapies, have the ability to block the progress of a disease or even reverse it, and, given the nature of these 'advanced' therapies, in the majority of cases the benefits deriving from a single dose last for a lifetime.

**'Disease-modifying' drugs** are another noteworthy branch of medicine: they do not affect the root cause of previously potentially fatal conditions, but instead slow down their progression, 'chronicising' them.

Novartis wants to continue its pioneering work in this type of treatments, and to do so it needs to adopt a holistic approach when defining drug prices, embracing the

principles of **value-based medicine**: the cost of a treatment should reflect the overall benefit it can generate, based on health needs and its personal, technical, allocative and social value.



Novartis response

Cell and gene therapies offer an excellent case study for value-based medicine: they can provide revolutionary clinical results yet at the same time present significant challenges in terms of sustainability and accessibility.

The treatments provided by Novartis – *tisagenlecleucel* (*Kymriah*®) for haematological conditions, *voritigene neparvovec* (*Luxturna*®) for hereditary retinal dystrophy and *onasemnogene abeparvovec-xioi* (*Zolgensma*®) for spinal muscular atrophy – mostly involve a single dose and potentially transformative results, but at the same time have a major impact on pharmaceutical spending.

To guarantee access to them for patients who could benefit, we need to **identify innovative solutions that balance the right to treatment with financial sustainability**. The need for the drug is often urgent: for spinal muscular atrophy, for example, the treatment must be provided as early as possible, to block the irreversible loss of motor neurons and the development of the disease. Novartis Italy is deeply committed to finding balanced solutions, and holds discussions with all stakeholders to forge the most suitable approach together.

This approach enabled us to design a reimbursement system for *tisagenlecleucel* (*Kymriah*®) using an innovative risk-sharing agreement, **payment at results**, through which payment for the therapy is postponed until a positive result is achieved, without requiring money in advance from the health service.

Overall, for gene and cell therapies, Novartis **determines the price of the treatment (or the cost of the therapy) responsibly**, in line with the value it gives patients, caregivers and society as a whole.

Novartis, through its Sandoz division, also has a fundamental role to play when it comes to sustainability. **Sandoz's wide range of generic drugs and biosimilars**, in various therapeutic areas,, ensures the availability of **alternative treatments at a more sustainable price** once their patent expires, thereby freeing up significant resources for the health system and supporting wider access to healthcare. As well as saving money for the health system, generic drugs, which are just as effective and safe as branded drugs, also save patients money every time they use them.

Looking to the future, ensuring access to innovative treatments is a key priority. We will achieve this by actually committing to documenting their value and helping to support the development of innovation-friendly organisational models, including using resources freed up by the availability of

generic and biosimilar medicines, to ensure the Italian health service can run sustainably. Sandoz has launched various regional projects that seek to promote resource-sharing and gainsharing among hospital pharmacists, clinics and patients' associations and payers: part of a long-term project to increase access to medicines.

To guarantee access to treatments for patients who could benefit, we need to identify innovative solutions that balance the right to treatment with financial sustainability



Putting health first

HELATH SYSTEM STRENGTHENING

The current scenario and the challenges facing Novartis

1,4% average rate of growth in public health spending in Italy in the last ten years, compared to 5.3% in Germany and 4.7% in France. <small>(Meridiano Sanità report 2020 using 2020 OECD data)</small>	35% regional variation in annual public health spending per capita between the Autonomous Province of Bolzano (€2,415) and Campania (€1,794) <small>(2020 Meridiano Sanità report using 2020 State General Accounting Department data)</small>	74% surgical procedures postponed in 2020 during the Covid-19 pandemic, equivalent to roughly 600,000 elective procedures. <small>(Meridiano Sanità report)</small>	Approx. 11 months the time needed to clear the appointment backlog. <small>(2020 Meridiano Sanità report)</small>
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Novartis vision and challenges

The current pandemic has highlighted the weak points of the Italian health system, revealing an urgent need to invest in strengthening the Italian National Health Service – building it around people’s needs, strengthening local care and reorganising and modernising hospital facilities, in order to increase the system’s resilience and ensure continued protection of public health.

The challenge for everyone involved in managing public healthcare is to increase investment in health and reduce inequalities. This requires a systemic vision, based on collaboration between multiple stakeholders and the public healthcare system and private companies.

Novartis believes that strengthening the Italian National Health Service requires investment in three main areas:

- Regional and local services, to ensure efficient management of chronic illnesses and the most delicate situations;
- Digitalisation and technological ambition, going beyond remote appointments and telemedicine;
- Simplifying bureaucracy and reshaping governance, both needed to channel the innovation of the private sector (including clinical testing) into responding to public needs.

Novartis believes that **the Italian National Health Service and the pharmaceutical world should work together on identifying needs and developing solutions**, particularly when chronic conditions are taking up growing amounts of resources and a substantial increase in residential and local services is needed.

The challenge for everyone involved in managing public healthcare is to increase investment in health and reduce inequalities. This requires a systemic vision, based on collaboration between multiple stakeholders.

Novartis response

The healthcare crisis caused by the rapid spread of Covid-19 has highlighted the inadequacy of the regional health system network and the lack of hospital facilities, caused by a reduction in the number of bed spaces and staff over time. One of our responses to the Covid-19 emergency was the **‘Torniamo a curarci’** campaign, launched by Cittadinanzattiva in partnership with the Italian Federation of General Practitioners (FIMMG), with the backing of the Italian Ministry of Health and various associations and scientific companies. This campaign, supported by Novartis, aims to promote continuity of care for patients, especially those with chronic conditions, to compensate for the delays and interruptions that have occurred.

These developments will lead to a major reshaping of the role and responsibilities of General Practitioners (GPs), including active monitoring of the patients for whom they are responsible, management of chronic patients and urgent cases, and the formation of an integrated network of GPs and specialists.

Even before the pandemic, Novartis had decided to strengthen its relationship with GPs, as they are in close contact with families and increasingly involved in proactive medicine, actively seeking out the patients at greatest risk.

In early 2019 we therefore launched the **Embrace project, a national network of young professionals specifically trained to deal with chronic conditions** who interact with GPs, helping them to improve early identification of patients at risk and the decisions made in their clinical pathways. **This relationship with GPs is also developing in response to the demands for scientific and technological training. A partnership with IBM and FIMMG-NetMedica Italia has led to the development of Open Health Platform**, an open-source portal that uses the power of artificial intelligence to support GPs in the local management of patients affected by chronic conditions and/or Covid-19. The platform has an open structure that can be integrated with numerous tools and management systems, and helps to improve the care received by patients, but most importantly it forges connections and introduces new channels of collaboration between the key figures involved in the treatment.

Another **major digital platform** that meets the needs of both patients and professionals is **WelCARE**, developed by Novartis with a start-up from Milan, which helps clinics to **manage innovative treatments like the CAR-T family of therapies**. The **platform combines telemedicine and artificial intelligence**, allowing doctors to exchange

Even before the pandemic, Novartis had decided to strengthen its relationship with GPs, as they are in close contact with families and increasingly involved in proactive medicine.

information on patients who could potentially be suited to the therapy, to follow their screening, and for follow-up after treatment. This has several benefits. Firstly, it makes communication and interaction between clinics more efficient, within a network of centres that can provide the treatment (known as ‘Hubs’) and small centres that refer patients (known as ‘Spokes’). Secondly, patients receive well-organised and timely access to this innovative therapy when it is ascertained that they need it. And finally the anonymised and aggregated data collected and stored in the platform’s database can help clinics to tackle the complexities linked to the treatment and to managing patients.

HEALTH EDUCATION AND PREVENTION

Current scenario – Key statistics

3	74,8%	36,8%	54,4%	24,6%
categories of determinants of health (WHO): socioeconomic context, environmental context, personal characteristics and individual behaviours.  (2020 Meridiano Sanità report using 2020 WHO data)	breast cancer screening coverage in Italy, with a large discrepancy between north and south (84% vs. 62%).  (2020 Meridiano Sanità report using 2020 ISS data)	young Italians who are overweight/obese (OECD average: 28.6%).  (2020 Meridiano Sanità report using 2020 OECD data)	proportion of the Italian population with poor health literacy.  (2020 Meridiano Sanità report)	graduates with a degree in STEM subjects (science, technology, engineering and mathematics), with a very wide gender gap: 37.3% of men, compared to 16.2% of women.  (Istat, 2019)

Novartis vision and challenges

Novartis believes strongly in building a network to promote health and disease prevention, including both communication activities and tangible actions, to inform and empower citizens regarding their behaviour and the importance of primary and secondary prevention.

The company has therefore decided to **invest in improving patient information and education, and to reinforce scientific culture and health literacy among the entire population – not just patients – and so move beyond communication focused on medicinal treatments**. The aim is to develop a cultural environment that highlights the value of science and the collective benefits that Novartis is helping to shape. This will increase the opportunities for public-private partnerships, which provide shared access not only to economic resources but also to intellectual capital and skills, and allow joint solutions to be developed.

Building trust in **scientific culture** is part of a wider vision of competitive growth in Italy: fostering an interest in science among young people means **helping to build the skills of the workers and scientists of tomorrow**. Novartis intends to play a major role in **reducing the skills gap in the sciences and the lack of familiarity with the natural sciences**, where young Italians are currently at a disadvantage compared to their peers in other countries.



Novartis’s response

In late September 2020, the launch of **a joint programme between Novartis Italy and the Italian Ministry of Cultural Heritage and Activities and Tourism (MiBACT)** was announced, aimed predominantly at young people, **to support scientific and technological literacy in Italy**, a crucial factor if we are to build a future-proof economy and set the economic and social recovery we need in motion. As part of this collaboration, Novartis and MiBACT will together identify inclusive engagement processes to encourage access to and the promotion of scientific culture, including significant use of digital resources. This partnership will form part of Novartis Italy’s wider programme **People in Science - Scienza da vivere**, which will develop into multiple projects and **initiatives in support of science literacy**. One such project is **La Salute in Movimento**, launched as a way of promoting sustainable, inclusive, and innovative healthcare, and as a unifying and participatory social project that encourages patients, citizens, healthcare professionals and institutions to design the healthcare of the future together. Stemming from **an initiative launched by Novartis in partnership with CittadinanzAttiva, Politecnico di Milano, Humanitas University, the University of Naples Federico II, the InnovaFiducia e Generativita Association and the Culture consultancy**, the project will look again at every aspect of the future of health, including digital medical science, personal wellbeing, artificial intelligence applied to surgery and care and new organisational and regional models.

Some of the more recent projects developed under the banner of **Alleati per la Salute**, a programme launched ten years ago by Novartis **to support patient advocacy in Italy in information and training**, are also directed towards increasing awareness of the value of science. In particular, a new digital platform will be launched in 2021 that will help to fight the growing phenomenon of fake news in the healthcare world, while also improving knowledge of the opportunities digital technologies can provide for healthcare protection.

**Alleati per la Salute** already makes widespread use of digital technology in its work with those it supports. A web portal of the same name, divided up into multiple sections and currently under development, allows interaction with citizens through areas dedicated to information and public services (for example help finding a treatment facility or webinars providing information); and interaction with healthcare professionals, thanks to a medical cloud section offering scientific updates on the clinical areas overseen by Novartis.

This work is backed up by a partnership with Adnkronos to develop the publishing schedule and the support of a permanent board of six patients’ associations.

People in Science – Scienza da vivere is a science literacy project that promotes sustainable, inclusive, and innovative healthcare, encouraging citizens, patients, healthcare professionals and institutions to design the healthcare of the future together.

PATIENT ASSISTANCE PROGRAMMES

Current scenario – Key statistics

7,7 per hundred hospital admissions – death rate at 30 days following a heart attack. <small>(2020 Meridiano Sanità report using 2020 AGENAS data)</small>	63% and 54% cancer survival rate, in women and men respectively, after five years. <small>(2020 Meridiano Sanità report using 2020 AIOM/AIRTUM data)</small>	2,8% proportion of over-65s receiving integrated homecare. <small>(Italian Ministry of Health, 2020)</small>	736,000 patients (approx. 9% of all those in hospital) treated in different regions from their home region. <small>(2020 Meridiano Sanità report using 2020 Italian Ministry of Health data)</small>
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Novartis vision and challenges

Even today, diagnosis, care and healthcare support are not distributed fairly around Italy in terms of either local access or quality, forcing many patients to move around the country and creating different life expectancy data in different regions.

This situation is of concern to Novartis, as it considers accompanying patients on their recommended treatment pathway, alleviating suffering and improving the quality of life of both them and their caregivers an integral part of its mission.

Novartis is well aware that **the needs of patients are not solely connected to their physical state, but also involve their physical wellbeing, quality of life and their right to health**, and it is committed to continually extending the work it carries out on these specific topics.

With this in mind, Novartis is prioritising listening, trying to intercept and respond to the needs of the people it talks to, patients and non-patients alike, while remaining transparent and faithful to its identity and its mission as a pharmaceutical company.

**Reaching ever larger numbers of people**, including through specific **remote and in-person support programmes**, provides a new way to build a system and strengthen partnerships with various categories of stakeholders, including patient and caregiver organisations. Novartis can make a strategic contribution in this area by helping to make the appointment and consultation system more efficient, reducing waiting times and increasing the capacity of individual centres.



Novartis response

In response to these challenges, Novartis is continuing its development of virtual appointment programmes, designed to optimise and improve patients’ clinical pathways, with **patient empowerment** at their centre.

The **VIVA** project, **developed by the Neuroscience area and dedicated to patients with multiple sclerosis**, is a virtual appointment system that enables doctors to provide remote neurological assessments and monitoring. This innovative approach is extremely important for patients who find it very challenging to physically visit a treatment centre, and its benefits were highlighted further during the Covid-19 crisis, showing its excellent potential to be scaled up in numerous different therapeutic areas, and so helping to increase treatment centres’ patient intake capacity.

The Covid-19 crisis further underlined the importance of regional support, especially in managing cancer patients and other people whose treatment and support needs are not limited to therapy, but also include psychological and emotional aspects.

Novartis and Sandoz intend to provide a tangible response to these needs through **the ‘local oncology pharmacist’, a new role dedicated to supporting cancer patients**. The **OncoCare - Networking in oncologia** project does not involve creating new services or infrastructure, **but instead seeks to enhance and promote the skills of local pharmacists in providing support to those with cancer**, and investing in collaboration between clinics and community- and hospital-based pharmacists, to assist discharged patients throughout their treatment.

Another project in the same vein in the field of **CAR-T cell therapy is the introduction of cultural mediators, who accompany patients and their families through the clinical pathway**, both providing clear and easily understandable information on the therapy and supporting them with practical aspects such as transport, staying in the family home and work permits, as well as psychological considerations. This form of mediation is proving vital in the drive to improve access to innovative and complex technologies like CAR-T – a revolutionary therapy that requires both staff at centres and patients to be suitably prepared.

Novartis is continuing its development of virtual appointment programmes, designed to optimise and improve patients’ clinical pathways, with patient empowerment at their centre.



## Doing the right thing

### SUSTAINABLE USE OF RESOURCES

#### Current scenario – Key statistics

<b>48.55 tonnes of CO<sub>2</sub></b> average emissions for a pharmaceutical company (per million dollars of profit), 55% more than the car sector. <small>(Journal of Cleaner Production, Volume 214, 20 March 2019)</small>	<b>-59%</b> emissions reduction target for 2025, with which the pharmaceutical sector must comply if it is to meet the commitments made in the Paris agreement. <small>(Journal of Cleaner Production, Volume 214, 20 March 2019)</small>	<b>44%</b> the proportion of investment in pollution prevention technology (reducing or eliminating pollution at source in the production process) in the pharmaceutical industry, compared to an average in the manufacturing sector of 37%. <small>(Farmindustria, 2020)</small>
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#### Novartis vision and challenges

Novartis considers **protecting natural resources and managing them sustainably** an essential part of its corporate responsibility, given the implications of the quality of the environment on protecting people's health and the role of biodiversity in furthering pharmaceutical research.

With this in mind, Novartis has set itself some medium- and long-term sustainability targets: **carbon neutrality by the end of 2025, and plastic neutrality and water neutrality by the end of 2030**. Novartis Italy is fully engaged in this ambitious global plan, which includes specific measures to reduce greenhouse gas emissions, ensure efficient use of energy and water, save money on operating costs and improve biodiversity.

By adopting this approach, Novartis is **repaying the environment and society for the resources it benefits from, with the aim of renewing its relationship with local communities and institutions and gaining their trust**. Investing in sustainability also makes business sense: sustainably optimising the use of resources brings with it a significant economic advantage, as it helps to reduce operating costs and so opens up access to sections of the market where Novartis products were generally too expensive.

Novartis has recently announced the signing of five virtual power purchase agreements (VPPAs) at a European

level – including one with Enel Green Power – which will, according to forecasts, add more than 275 MW of clean energy to the grid. This operation will make Novartis the first pharmaceutical company **to acquire 100% of its electricity from renewable sources in its European operations**.

Looking globally, Novartis has recently announced the launch of a €1.85 billion **Sustainability-Linked Bond (SLB), the first of its kind in the healthcare sector**. Those investing in these bonds will receive greater interest if Novartis fails to reach two targets on access to its innovative medicines and carbon neutrality. This financial initiative is a new and important step in Novartis process of integrating ESG (Environmental, Social and Governance) performance into the management of the business.

#### Novartis response

Novartis Italy is doubling down in its commitment to improve the quality of people's living, working and healthcare environment. Acting in this area can significantly improve people's health and wellbeing, for example reducing the impact of respiratory diseases, which is why, in late 2019, it signed an **agreement with Enel X and the National Association of Italian Municipalities (ANCI) that aims to jointly identify solutions to help municipalities better manage air quality and pollution issues**.

Following a multi-sectoral and interdisciplinary approach, Novartis and Enel X organised joint work groups that shared mutual knowledge on health, disease prevention, sustainability and transport, allowing them to plan a series of potential interventions to reduce air pollution and promote sustainability, which were presented in November 2020 at ANCI's 37th national assembly.

To meet its global carbon neutrality, plastic neutrality and water neutrality targets, Novartis is concentrating its efforts in Italy on its main facilities.

At the firm's headquarters in Origgio – which has already reached its goal of **eliminating the use of single-use plastic on food**, ahead of the Group's targets – a **move to a high-energy-efficiency building** with platinum LEED (Leadership in Energy and Environmental Design) certification is being planned. The new premises will be located in the centre of Milan, which will also have a positive impact on employees' ability to use public transport.

At the site in **Torre Annunziata** (Naples), meanwhile, one of Novartis most important international production centres and one of the largest pharmaceutical factories in the south of Italy, a detailed **Energy Management Plan** has been drawn up, **listing a series of investments in various areas: new machinery with a low environment impact** (trigeneration, heating, ventilation, and air conditioning and wastewater treatment); new projects and **digital systems that aim to reduce paper and plastic use in the production chain** (such as packaging); and creating a cultural programme for the site's entire population, managed by the Green Team.

Novartis Italy is doubling down in its commitment to improve the quality of people's living, working and healthcare environment.



TRANSPARENCY

Current scenario – Key statistics

**64%**  
consumers at a global level who base their purchasing decisions on trust, and who are willing to support or boycott a brand depending on its position on social or political issues, up from 51% in 2017.  
(Edelman Trust Barometer, 2020)

**85%**  
people willing to support a company during a time of crisis for the brand, if the organisation has a good reputation for transparency.  
(Sproutsocial, 2018)

**70,9**  
the reputation (on a scale of 1 to 100) of the pharmaceutical sector in 2020, an improvement on 2015.  
(Reputation Institute, 2020)

Novartis vision and challenges

Non-transparent or anticompetitive conduct, such as aggressive pricing policies and marketing initiatives that restrict consumers’ right to a free choice, damage patients, their families and public health, as well as healthcare professionals themselves, whose relationship with patients may be indirectly compromised. Initiatives that seek to increase transparency and fight anticompetitive practices can help to strengthen the health system, reduce costs for taxpayers and, most importantly, improve patients’ experience and health. Over the years, the pharmaceutical sector has developed rules and codes of conduct that respond to the need for transparency and ethical conduct.

Novartis believes that one of the challenges in terms of transparency is the context in which the pharmaceutical sector is currently operating. The current rules on transparency that govern the relationship between Novartis, public bodies, regulatory bodies and patients have the undesired effect of creating a distance between the various parties and their projects, so there is no opportunity for dialogue and collaboration between them and the immense scientific and social value this brings.

The vision of Novartis is to **invest in reinforcing a business culture rooted in transparency and integrity**, putting everybody who works for or on behalf of Novartis in a better position to make ethical decisions that take into account the interests of all the parties involved.

This business culture must be reflected in a new narrative that communicates financial and intangible value, and that

highlights the desire of Novartis to **reimagine medicine through new strategic assets such as transparency, ethics and brand reputation**.



Novartis response

**Transparency-related activities** at Novartis Italy are dedicated to looking in depth at these topics and explaining their impact both within and outside the organisation. Its strategy is to forge an alternative to the traditional top-down model by identifying a community that is willing to share content related to **ethics, risk and compliance, to improve trust within the organisation and therefore rebuild trust in the society in which it operates**. This will allow it to tackle the issues related to its past commercial dealings and relationships with healthcare workers.

Novartis aims to restore a mutually beneficial relationship with the country and with public institutions, primarily due to the importance of this for patients. It is therefore committed to meeting the highest possible standards of transparency in its work, so it can earn or win back the faith of its stakeholders, whether patients, commercial partners, associations or institutions.

Novartis aims to set in motion **a cultural revolution based on constructive dialogue and individual responsibility**, to consolidate the company’s leadership and the awareness of everyone who works with or for the firm, and to avoid potentially risky situations.

This transformation process will include developing the **Novartis Principle Supporters initiative: building a community that represents an organisation that takes wide-ranging ownership of regulatory compliance**, and completing a major shift from an episodic approach to a systemic vision of regulatory compliance.

The strategy is to forge an alternative to the traditional top-down model, to improve trust within the organisation.

ETHICAL & COMPLIANT BEHAVIOR

Current scenario – Key statistics

76%

people who put their trust in a company based on ethical factors like integrity, reliability and aspirations.  
(Edelman Trust Barometer 2020)

40%

Italian citizens who say they trust the pharmaceutical sector (2019).  
(Statista, 2020)

32%

proportion of the patient advocacy community that believes the pharmaceutical sector acts with integrity.  
(Patient View Italy 2019)

Novartis vision and challenges

Another issue the pharmaceutical industry and life sciences sector face in their aim to improve public opinion is the apparent contradiction between the need for businesses that support people’s health and wellbeing and the lack of trust in those who claim to meet that need. Working in the industry is often seen as a way of claiming power, generating profit and exploiting others.

The challenge Novartis faces is to create a new form of leadership based on ethics and social and environmental sustainability, which reflects an awareness of the importance of public attitudes, both for Novartis and for the pharmaceutical sector as a whole.

The provisions put in place to fight corruption and other phenomena must be accompanied by a parallel transformation of the business’ organisational, cultural and ethical standards.

To respond to the ethical challenges it faces, Novartis has developed a vision focused on the attitude of those who are helping to create an atmosphere of integrity at the company.

Novartis can achieve its vision by introducing a new leadership style that seeks to create shared value and that sees corporate ethics as a strategic asset and a way of attracting and retaining talent.

Transforming how ethics are perceived, both within and outside the company, is vital for achieving growth at Novartis, and is an ongoing challenge that requires the utmost skill, intellectual honesty and creativity from senior figures, managers and regional representatives alike.

Novartis can achieve its vision by introducing a new leadership style that seeks to create shared value.



Novartis response

The publication of the new **Code of Ethics is part of the cultural shift currently underway at Novartis**. The changes taking place have inspired numerous major activities in Italy, most notably the **Be Real** project, and the launch of **Ethics Day**. This comes under the umbrella of **Ethical Journey Events**, a series of events launched in 2020 that invite guests from outside the company to act as spokespeople and ambassadors for a culture based on integrity.

At the same time, Novartis is investing in implementing a **holacracy and sociocracy organisational model, a freer organisational structure** that aims to allow people to give their best and take independent ethical decisions. The focus is on ‘doing the right thing’, and on the principle that all decisions, at all levels, have a tangible impact on Novartis stakeholders, first and foremost patients. This organisational model embraces a more evenly distributed decision-making process, moving from a centralised model focused on maximising profit to a value-centred strategy guided by the business’ purpose.

A decision-making process that moves from a centralised model focused on maximising profit to a value-centred strategy guided by the business’ purpose.

# Conclusions

The priorities identified through dialogue with stakeholders during the Materiality Analysis clearly show the routes Novartis must take to meet their needs, and those of patients and the general public in particular. Taken together, they also provide a way of assessing the extent to which the company’s actions meet the expectations of stakeholders.

In this sense, **the Materiality Analysis marks an important moment in the efforts Novartis Italy makes to improve its ability to create value for the public and to integrate performance-related targets on environmental, social and governance issues into its strategies.** These goals and the business’ commitment to achieving them sit within a wider context of the increased prominence of sustainability-related issues on the global political agenda – as seen, for example, in the United Nations 2030 Sustainable Development Goals.

The information set out in this document provides a vital tool for the **Shared Values & Sustainability committee, which Novartis Italy founded this year to instigate an ESG governance model at the company.**

The interdivisional committee reports to the Country President and comprises the managers of the Country business units (Quality, Public Affairs, Ethics, Risk & Compliance, Communications & Patient Advocacy and People & Organisation) and business and Technical Operations representatives. It reflects a similar body launched at a global level, the Trust and Reputation Committee, and its mission is to encourage a more structured and consistent approach to sustainability, in its various forms, from all parts of the business.

**Ethical conduct, a focus on health and social responsibility** will be the committee’s priority areas, with the aim of promoting the numerous initiatives, programmes and projects launched at the company, shaping their contents and development and implementing ways to monitor and report on the progress made on ESG performance and the company’s contribution to achieving the SDGs that are directly relevant to Novartis¹.

But the commitment to **strengthen the business’ ESG culture** is even more crucial, as it will make every associate at Novartis an ambassador for sustainability, open to change and increasingly directed towards working with the outside world, in the society in which we work. **Essentially, Novartis aims to show through its actions that dialogue matters.**

The Materiality Analysis marks an important moment in the efforts Novartis Italy makes to improve its ability to create value for the public and to integrate ESG goals into its strategies.

	3 GOOD HEALTH AND WELL-BEING	8 DECENT WORK AND ECONOMIC GROWTH	9 INDUSTRY, INNOVATION AND INFRASTRUCTURE	13 CLIMATE ACTION	16 PEACE, JUSTICE AND STRONG INSTITUTIONS
Availability of medicines and pricing	•		•		
Innovative technologies		•	•		
R&D for unmet medical needs	•		•		
Health education and prevention	•	•			
Strengthening the Italian National Health Service			•		•
Patient assistance programmes	•	•			
Ethical & compliant behavior				•	•
Sustainable use of resources	•			•	
Transparency					•

1. **The 2030 United Nations goals on which Novartis can have the greatest impact:**

- SDG 3 – Ensure healthy lives and promote wellbeing for all at all ages.
- SDG 8 – Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all.
- SDG 9 – Resilient infrastructure, sustainable industrialisation and innovation.
- SDG 13 – Take urgent action to combat climate change and its impacts.
- SDG 16 – Peace, justice and effective institutions.

Appendix

The 31 topics

The thirty-one topics are listed below in alphabetical order, along with their definitions.

Animal testing

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

Availability of medicines

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

Business model innovation

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

Corporate governance

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

Counterfeit medicines

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

Data privacy and security

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

Digital skills

Ensuring that the new skills required for the business' digital evolution are acquired and developed. Examples may include data and information management skills and new relationship-building skills connected to the development of virtual healthcare environments.

Diversity and inclusion

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

Drug resistance

Contributing to the global response to drug resistance that is caused e.g. by inappropriate use and environmental pollution through antimicrobials.

Ethical & compliant behavior

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

Fair contribution to society

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

Fair working conditions

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

Financial health & performance

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

Health and safety

Ensuring the health and safety of associates. This includes efforts to avoid accidents on any scale and sick leave, and seeking to promote wellbeing through programmes dedicated to health.

Health education and prevention

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

Health system strengthening

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

Innovative technologies

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

Intellectual property

Responsible patent exclusivity management that balances IP protection with the provision of affordable drugs. Examples may include participation in IP sharing and licensing arrangements.

Patient assistance programmes

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

Pharmaceuticals in the environment

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

Pharmacovigilance, safety profile and quality of drugs

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

Pollution, waste and effluents

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

Pricing

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

R&D for neglected diseases

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

R&D for unmet medical needs

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

Recruitment & retention of employees

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

Respect for human rights

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

Responsible supply chain management

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

Responsible use of new technologies

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

Sustainable use of resources

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

Transparency

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

## The internal and external surveys

### What we asked

The aim of the surveys was to gather the points of view of internal and external stakeholders on the thirty-one topics, and to discover which topics they considered most important.

Two identical surveys were distributed: one was sent to recipients inside Novartis (all 230 people managers, the members of the Extended Leadership Teams in the various Business Units and the group's Italian divisions); the other was sent to external participants (approximately 500 individuals, chosen from the various categories of stakeholder identified by Novartis).

The survey took around 15-20 minutes to complete, and each participant was asked to give their opinion in three areas:

- A short description of their relevant business area at the time of their response and the category of stakeholder they belonged to (for external participants).
- An assessment of their own familiarity with the topics put forward and the Novartis Group's corporate responsibility activities and commitments.
- For each of the thirty-one topics, their appraisal of the impact that topic has on Novartis Italy and the business' performance regarding that subject.

### Survey results and response rate

Distribution of the internal survey began on 20 January 2020, with replies admitted until 10 February 2020. During this period, 202 completed surveys were received, making a response rate of 86%. Of these, seventy-seven came from the Novartis Pharmaceuticals business unit, forty-seven from the Novartis Oncology business unit, thirty-five from Sandoz, fifteen from Novartis Torre Annunziata, thirteen from Global Drug Development, nine from Novartis Business Services, four from Advanced Accelerator Applications and two from AveXis (now Novartis Gene Therapies).

The time period for completing the external survey was 20 May to 16 June 2020. 173 completed surveys were received, making a response rate of 39%. Of these responses, forty-seven came from the Healthcare Providers category of stakeholders, thirty-two from Suppliers, twenty-one from Patients' Organisations and NGOs, twenty from the Academy and Scientific Research category, fourteen from Regulatory Bodies and Legislators, eleven from the Pharmaceutical Market and Industrial Sector category, ten from the Media, six from Human Resources, six from Financial Market Operators and four from the Local Communities category.

