NOVARTIS | Reimagining Medicine

Reporting Criteria for Novartis in Society Integrated Report (NiS) 2022

Basis for Reporting

This document provides definitions and methodologies for key environmental, social and governance (ESG) performance indicators in the Novartis in Society (NiS) Integrated Report 2022. Our ESG reporting covers the January 1 to December 31, 2022, reporting period.

The Novartis in Society Integrated Report is prepared in alignment with the Integrated Reporting Framework (published by the IFRS Foundation) and the Task Force on Climate-related Financial Disclosures (TCFD), the Sustainability Accounting Standards Board (SASB) and the latest non-financial standards published by the Global Reporting Initiative (GRI).

For disclosures relevant to our sustainability-linked bond, we follow the terms and conditions as outlined within the Final Listing Prospectus, dated September 21, 2020, for the “Patients reached with strategic innovative therapies” and “Patients reached through flagship programs” ESG performance metrics.

In addition, we take certain other internal principles and guidelines into account, including the Novartis Code of Ethics. We also have established procedures for gathering, collecting, and aggregating data for the ESG performance metrics.

We apply a financial control boundary and have detailed the scope of our reporting by metric in the sections below. All Novartis legal entities within the Novartis Group consolidated financial statements are in scope for the ESG performance metrics unless otherwise indicated.

We aim to fully integrate any acquired entities or businesses into our ESG performance metrics data collection.

Document updated on January 31, 2023

Reporting Frequency

We gather data internally on a monthly, quarterly, or annual basis, depending on the type of metric, and report publicly on an annual basis in the Novartis in Society Integrated Report.

Data sources and systems

Our objective is to gather and report reliable and robust data. Our data reporting systems are evolving, and we continue to work to align data recording and reporting methods across our business units. Data sources and systems for each ESG performance metric are outlined in the tables below.

Misstatements and Corrections

We make every effort to capture all information as accurately as possible. Any data that is subsequently found to be materially in error or where conversion factors may have changed, will be clearly indicated. Materiality is assessed based on judgment of what we believe would impact our readers. This data will then be restated for purposes of baselines and trend analysis. We continue to work and invest on enhancing our ESG data systems and governance to improve the quality of our data going forward.

Verification / Assurance

Independent limited assurance is provided by KPMG over data for the current reporting year 2022 on the performance indicators on pages 81-84 of the Novartis in Society Integrated Report. The limited assurance report is issued in accordance with International Standards of Assurance Engagements ISAE 3000 and ISAE 3410 and published as part of the Novartis in Society Integrated Report.

Patient health and safety

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
GxP Audits	Audits conducted by Novartis' quality auditors at GxP suppliers to Novartis (external audits) or at facilities owned by Novartis (internal audits). Unit of measure: number of completed audits	Data is collected via the internal database AQWA.	Includes Novartis quality audits completed during the reporting year, excludes any other type of audits such as financial or compliance audits.
Regulatory Authorities	Inspections performed by various health authorities. FDA inspections are a part of the total inspections and relate to inspections conducted by the US Federal Drug Administration. Unit of measure: number of completed inspections	Data is collected as soon as feasible via internal database AQWA.	Includes all inspections performed and completed by various authorities at facilities owned by Novartis during the reporting year.
Recalls	Recalls are counted each time Novartis completed a recall. A recall can be triggered by various stakeholders. FDA recalls are a part of the total recalls and relate to recalls performed in the US market. Unit of measure: number of recalls	Data is collected via the internal database AQWA.	Recalls include any type of Novartis' product recalls (mandatory, requested, voluntary) either commercial or in connection with a clinical trial. A recall can affect various countries.

Supply chain

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Suppliers risk-assessed by 3rd Party Risk Management (TPRM)	*Number of suppliers assessed*: As part of onboarding of suppliers or existing suppliers of new products, services, and sites are subject to a TPRM risk-assessment. The respective business owner fills out a questionnaire and based on the answers provided, a TPRM risk assessment is triggered according to an embedded risk matrix (type of spend and country) Unit of measure: number of risk assessments performed and closed on suppliers The assessments are done using these *risk areas*: anti- bribery, animal welfare, health/safety & environment, information security & data privacy, labour rights and quality GmP (up to November 2022). Unit of measure: number of risk assessments performed and closed on suppliers by risk area *Actions taken:* Depending on the outcome of the risk assessment an audit of the supplier might be triggered. In some cases, the risk assessment result requires remedial actions to be agreed and if not possible – the supplier engagement ceases. Unit of measure: number of actions taken by type of action	The total number of risk- assessed suppliers is aggregated in the supplier onboarding system whereby one supplier can trigger more than one assessment depending on the risk areas involved. The same applies for new sites or new products of an existing supplier.	Not all suppliers trigger a detailed risk assessment. The trigger is based on the outcome of the suppliers' onboarding questionnaire. TPRM assessments do not include the GxP audits.

People

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Headcount and FTE	Headcount reflects the total number of employees on Novartis payroll systems. Full-time equivalent adjusts headcount for employees working less than 100%. Management level is defined by the Global Job Family Architecture and Novartis Top Leaders. Unit of measure: number of headcount and FTE at the end of the reporting period	Data is collected via the various payroll systems and central HR system HR Core.	All employees on a payroll for a Novartis legal entity that is within the Group's consolidation scope. It does not include external employees, third party contractors working for external service providers or employees on unpaid leave.
Training and learning	Annual training hours completed by Novartis internal employees. Unit of measure: number of training hours completed during the reporting year	Data is collected via the internal learning / training platform HR Core and the training dashboard.	It includes all training hours that represent a completed course during the reporting year.
Nationalities representation	Number of nationalities employed by Novartis and nationalities represented in Novartis' management Unit of measure: number of nationalities employed	Management is defined by Global Job Level Architecture and Novartis Top Leaders. Nationalities are collected via the central HR System HR Core.	It represents the number of nationalities as registered in the internal payroll registries during employees' onboarding (primary nationality). Double nationalities are not counted.
Employee representative body re-presentation	Employees represented by an employee representative body or covered by a collective bargaining agreement in percent of total employees on non-management level. Unit of measure: percentage of non-management employees represented by an employee representative body or covered by a collective bargaining agreement	Data collected by means of a survey by the People & Organization function.	Generally, it includes only employees of non-management level.
Turnover	Number of employees leaving Novartis during the reporting period. We distinguish between voluntary turnover or non-voluntary turnover (including redundancies, divestments, retirements, and deaths).	The rate of turnover is measured as the number of employees who left Novartis during the reporting period divided by the average number of employees (13 months average).	The calculation includes permanent employees and excludes temporary employees.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Hiring by type	A hire is an employee having started a new position during the reporting year. We distinguish between internal and external hires. Unit of measure: percentage of internal and external hires over the total number of hires	Data is collected through the central HR System HR Core.	Internal hires include transfers of employees between or within Novartis legal entities without interruption of service. External hires include re-hires of previous Novartis employees.
Employee Health and Safety	An *Injury* is an instantaneous, unexpected bodily defect partly caused by external factors (e.g., cuts and burns, slips, trips, and falls). For our purposes, the term is synonymous with 'accidents'. An *Illness* is an abnormal health condition or disorder, other than those caused by injuries. Unit of measure 1: lost-time injury and illness rate (per 200 000 hours worked as per GRI standard) A *Recordable Case* includes any work-related injury and work-related illness (including work-related loss of consciousness) with or without lost time and work-related fatalities. Unit of measure 2: total recordable case rate (per 200 000 hours worked as per GRI standard) *Fatality* represents a work-related injury or illness leading to death. Unit of measure: number of fatalities during the reporting period split by contract type	Data is collected through our Health & Safety system and local HR for headcount and hours worked.	Data includes Novartis employees and third-party personnel managed by Novartis employees. Working hours include overtime and time worked from home. Aggravations of previously incurred or existing illnesses are considered as separate (new) cases, if work-related. Total recordable cases do not include near misses (i.e., an incident with the potential to have caused injury that did not).

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Gender Indicators	*Gender representation* Diversity is reported as the percentage split by gender between females and males. *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. *STEM roles* are defined as the sum of Research & Development, Technical Operations, and Information Technology & Technology Transformation job families. *Promotion* means an employee is promoted to a higher level within the Global Job Family Architecture. *Novartis Top Leaders* comprise the approximately 300 most senior managers at Novartis, including its Executive Committee. *Gender representation by contract type* We distinguish between full time (100% employment) and part time working contracts as well as permanent (working contract with no end date) and temporary (working contracts with an end date) positions. Unit of measure: total female / male percentage over total Headcount by each of the above indicated category at the end of the reporting period	Gender information is collected during the employee's onboarding process and maintained in the central HR System HR Core. Revenue producing roles, engineering roles, Novartis management and Top Leaders are defined via the Global Job Family Architecture. Management level is defined by the Global Job Family Architecture and Novartis Top Leaders.	The female / male gender representation percentage in the various categories do not include employees preferring not to disclose their gender ("unknown").
Employee representation by region	Employees are attributed to geographical regions according to their primary workplace as stated in their working contract. Unit of measure: total Headcount by geographical region and contract type at the end of the reporting period	Data is collected through the central HR System HR Core.	Each region also includes employees on global or corporate roles where work location is outside Switzerland.

Access to healthcare

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Overall Patients reached	Number of *Patients Reached* per calendar year receiving Novartis treatment. Unit of measure: total patients reached during the reporting year in million *Patients reached through access approaches* is a part of the total patients reached and includes patients reached with medicines through Novartis Global Health, support programs, emerging market brands and donations. Unit of measure: total patients reached through access approaches during the reporting year in million	The patient number is calculated based on treatments delivered (volumes sold) and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap. The treatment adherence and treatment overlap factors (Sandoz only) are based on assumptions defined by the Global Franchises team.	Includes patients reached through our Global Health Organization (including the Sub-Saharan Africa cluster, Emerging Market Brands (EMB)), donations, support programs and the Novartis access foundations.
Sustainability-linked bond	*Patients reached with strategic innovative therapies*. New therapies may be added to the list on a yearly basis but are subject to management's approval. Unit of measure: total patients reached through innovative therapies during the reporting year *Patients reached through flagship programs* (Malaria, Sickle Cell disease, Leprosy, Chagas disease). Unit of measure: total patients reached through flagship programs during the reporting year	Patients reached and Flagship program reports are computed via the agreed methodology (see also Patient Reached) without the treatment overlap correction factor. Quantity of Leprosy treatments delivered is provided by WHO.	In case of sale or out-licensing of one of the underlying therapies (brand-territory combination), the number of patients reached continues to be considered as long as Novartis keeps risks and rewards over the respective sales volume in relation to Novartis' partner (revenue shown at supply price).
Health systems strengthening	Novartis Global Health organization supports the strengthening of Health Systems with several initiatives: Training of *Health Educators* and *Healthcare Providers* where information on a particular disease, the prevention of it and the available treatment options are shared, mostly at physical events but also through virtual meetings (Teams and Zoom). Unit of measure: total Health Educators and Healthcare Providers trained during the reporting year	Data collected through the Global Health organization across the participating markets and supported by implementing partner's registers that are cross-checked by Novartis's employees; internally the data is shared through SharePoint. No assumptions are made as these are actual numbers.	Initiatives under the Global Health organization's scope.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
	Awareness events held on certain healthcare topics and the number of *people trained* attending such physical forums organized through partnerships with various associations, organizations, and religious bodies. Unit of measure: number of events during the reporting year. Unit of measure: total people trained at awareness events during the reporting year *Points of Service Provision include facilities and health camps* where healthcare services (e.g., training, drug administration, etc.) are provided and *number of people receiving services at such points of service provision* Unit of measure: number of service provision points during the reporting year Unit of measure: total people reached at such service points during the reporting year		In general, an awareness event is on non-communicable diseases (NCDs) e.g., Cardiovascular, Diabetes or Hypertension

Ethical business practises

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Code of Ethics	Active Novartis employees trained and certified on the Novartis Code of Ethics once per calendar year. This is a mandatory global training delivered through an e-learning module solution including a test and certification. Unit of measure: percentage of active Novartis employees who completed training on the Novartis Code of Ethics over total of active Novartis employees registered for the training	Data is collected via central Up4Growth system.	All active employees with a Novartis e-mail address are registered for the Code of Ethics e-learning except for approx. 1% of NVS employees (manufacturing employees without access to laptops) who are trained with the abbreviated OneDeck solution outside of Up4Growth. The OneDeck completions are not contributing to the Code of Ethics metric.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Grievance indicators: SpeakUp Office – central matters	Everyone (Novartis employees but also external parties) can raise a SpeakUp case through an externally hosted central internet page by either choosing to answer questions on a webform or by calling a phone number and talking to an external call agent. The person raising the case can choose to remain anonymous. *Central matter cases:* The number of central matter cases represent the number of central cases reported during the reporting period to the SpeakUp Office. Each misconduct case contains one or more allegations. Note: The number of misconduct cases, allegations reported and substantiated, and dismissals and resignations may change year-on-year as matters may be reassessed during the case life cycle. As a result, we may restate the previous two years of reported data. Unit of measure: total number of central cases and total number of allegations reported to the Speak-up office during the reporting period *Allegations substantiated categories:* We classify the allegations into the following categories: ▪ Fraud/ asset misappropriation ▪ Expense fraud ▪ Books and records, accounting irregularities ▪ Improper professional practices ▪ Bribery, kickbacks ▪ Discrimination and sexual harassment ▪ Retaliation ▪ Other employee related issues ▪ Conflict of interest ▪ IT security breach ▪ Quality, assurance, data integrity ▪ Data privacy ▪ Antitrust, fair competition ▪ Company confidential / trade secret information ▪ Other Unit of measure: percentage of each allegation category in relation to total allegations raised in central matters during the reporting period	Download from Global Case Management System (SpeakUp Office). Based on a fixed risk assessment questionnaire, each case is classified as either a local or central matter.	A central matter is a case with allegation character towards a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and/or significant financial impact.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Central matter results	*Number of central matter allegations substantiated.* Unit of measure: number of allegations substantiated during the reporting period	Download from Global Case Management System (SpeakUp Office).	Allegations substantiated may include allegations raised in previous years that are concluded during the reporting period.

Environment

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Energy use	Energy use is measured as the consumption of power, steam, heat and fuel (natural gas, wood, diesel oil) and includes energy generated on site as well as purchased. Unit of measure: Energy use - on site and purchased in million GJ	Energy use is based on meter readings and invoices, including stock counts (e.g. for diesel oil, wood etc.). The amount of energy used reported represents 9 months actual data plus the estimation for the 4th quarter. The estimation is done based on foreseen consumption and prior year's operating experiences.	De-minimis criteria have been established for sites and reporting units that do not contribute to more than 0.1% of the Novartis total. Sites in scope are reviewed annually. Energy for de-minimis sites is estimated based on the site's FTEs data (Novartis employees and third parties) multiplied by an average office use of electricity. Advanced Accelerator Applications (AAA) entities have not yet been onboarded for environmental metrics.
Green House Gas Emissions	*Scope 1* emissions comprise direct CO2 emissions from sources that are owned or controlled by Novartis and are presented as the sum of emissions from *vehicles* and *combustion & process.* Unit of measure: scope 1 GHG emissions by respective category and in total excluding offsets in 1000 tons of CO2 equivalents	The amount of emissions reported represents 9 months actuals plus the estimation for the 4th quarter based on foreseen activity and prior year's operating experiences. Novartis follows the Green House Gas protocol. Scope 1: data is collected from purchase and consumption logs, supplier invoices, mileage reports and fleet management systems multiplied by the respective emission factors obtained by EIA.	Scope 1 is the gross amount without considering any offsets.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
	Scope 2 comprise CO2 emissions from purchased or acquired electricity, cooling, heat, and steam and is presented as the emissions generated from energy purchased *market based* and *location based*. Unit of measure: scope 2 GHG emissions market or location based and in total excluding offsets in 1000 tons of CO2 equivalents	Scope 2 market-based: Total energy used is multiplied by supplier-specific emission factors for each market obtained from Accenture (based on data published by our electricity suppliers where such direct information is available). If this is not available – location-based emission factors are applied. Scope 2 location-based: total energy used is multiplied by location specific emission factors obtained from Accenture or the International Energy Agency (IEA).	Scope 2 is the gross amount without considering any offsets.
	Scope 3 comprise CO2 emissions across Novartis' value chain and is presented in these categories: *purchased goods & services, capital goods, business travel, use of sold products.* Unit of measure: scope 3 GHG emissions by respective categories and total excluding offsets in 1000 tons of CO2 equivalents	In general, Novartis follows the GHG Protocol, CDP (Climate Disclosure Project) definitions and PSC (Pharmaceutical Supply Chain) Initiative guidance for the calculation of the GHG emissions categories. A mix of different calculation methods is used based on either primary (information from the suppliers), secondary data (spend per Novartis Commodity Codes and countries) or a hybrid approach (primary data is transposed into a model to deliver specific emission factors). The methodology applied is determined based on data availability. Scope 3 purchased goods and services: purchase of non – capital goods and specific categories of services. Scope 3 capital goods: purchase of capital goods such as machinery /equipment, and specific groups of services.	Scope 3 is the gross amount without considering any offsets. Scope 3 categories as per GRI not mentioned specifically are not material to Novartis and therefore not disclosed separately, however included in the total scope 3 number.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
		Scope 3 business travel: includes air travel, rail, hotel and car expenses undertaken by employees as well as service providers on their trips for Novartis. It does not include employee commute. Scope 3 use of sold products: waste disposal and treatment of products sold by Novartis at the end of their life. Currently this is done for the respiratory inhalers only, assuming all hydrofluorocarbon (HFC) gas used in the production process is released upon use of the inhalers.	
	GHG emission offsets come from Novartis forestry projects and the balance of Carbon Dioxide (CO2) credits traded under Emission Trading Schemes (ETS). Unit of measure: GHG emissions offsets in 1000 tons of CO2 equivalents	GHG Emission offsets – the forestry projects are monitored by a third party (First Climate) who calculate the amount of sequestered carbon based on the UN CDM (Clean Development Mechanism) model and prepare the respective reports.	
Green House Gas Emissions intensity	Emission intensity is calculated as market based GHG emissions of Scope 1 plus Scope 2 in relation to sales and FTEs. Unit of measure: GHG emissions (Scope 1 and Scope 2) per million USD sales Unit of measure: GHG emissions (Scope 1 and Scope 2) per FTE (full time equivalents)	These are two calculated metrics based on metrics already described elsewhere: ▪ refer to Scope 1 and Scope 2 ▪ refer to Novartis Group Financial statements for sales data ▪ refer to People metrics for number of FTEs	Offsets are not deducted from Scope 1 and Scope to calculate the intensities.
VOCs (volatile organic compounds)	Amount of volatile organic compounds used in manufacturing and research facilities in tons segregated by *halogenated* (containing Fluorine, Chlorine, Bromine and/or Iodine) and *non-halogenated form* (not containing any of the former). Unit of measure: VOCs by category emitted to the air in tons.	Data is collected based on production and facility management logs (including stock counts, invoices, and consumption logs). The amount of VOC emissions reported represents 9 months actuals plus the estimation for the 4th quarter based on foreseen activity and prior year's operating experiences.	AAA entities have not yet been onboarded for environmental metrics. For de minimis sites, this information is not collected nor estimated.

Water	Water is defined as fresh water, which is salt free, such as drinking water, ground water, rainwater and water of natural water bodies (excluding sea water). *Water withdrawal* from all areas, including surface water, ground water and third-party water. It includes contact water and non-contact water (typically used for cooling). Unit of measure: water withdrawn from respective sources in million m3 *Water discharged* from all areas means water leaving the premises and includes water directly discharged to the aquatic environment (non-contact water), via treatment, or water lost. Unit of measure: water discharged in million m3 *Water consumed* includes surface water, ground water, third-party water. It's calculated as water discharged via on-site or off-site treatment plus water lost. Unit of measure: water consumed in million m3	Water withdrawal is measured based on meter readings and invoices. The amount of water reported represents 9 months actuals plus the estimation for the 4th quarter based on foreseen activity and prior year's operating experiences.	De-minimis criteria have been established for sites and reporting units that do not contribute to more than 0.1% of the Novartis total. Sites in scope are reviewed annually. Water for de-minimis sites is estimated based on the site's FTE data (Novartis employees and third parties) multiplied by an average office use of water. AAA entities have not yet been onboarded for environmental metrics.
Waste	Waste information is collected split into *hazardous waste* and *non-hazardous waste* – both *recycled* and *not recycled.* Total hazardous and non-hazardous waste represent the *total waste generated* and categorized into *directed to disposal (*treatment, incineration, or landfill) and *diverted from disposal* (re-use or recycle). Unit of measure: waste generated by respective category in 1000 tons	Waste is measured based on weight receipts e.g., waste transfer documentation, weighting logs, incineration memos, disposal documentation etc. The amount of waste reported represents 9 months actuals plus the estimation for the 4th quarter based on foreseen activity and prior year's operating experiences.	Includes both onsite and offsite waste. Excludes effluent (treated or untreated wastewater) - reported under "Water". De-minimis criteria have been established for sites and reporting units that do not contribute to more than 0.1% of the Novartis total. Sites in scope are reviewed annually. Waste for de-minimis sites is estimated based on the site's FTE data (Novartis employees and third parties) multiplied by an average office amount of non-hazardous waste. AAA entities have not yet been onboarded for environmental metrics.

Animals needed

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions
Animals needed	Number of animals needed to support internally conducted studies calculated as the sum of animals in our facilities at the beginning of the year plus animals internally bred and purchased throughout the reporting period. If a species exceeds 1% (one percent) of total animals needed, the species details will be reported (e.g., Rodents, Zebrafish). Unit of measure: number of animals Unit of measure: percentage of respective species over the total number of animals needed	Number of all living vertebrates engaged in any research setting are collected throughout the calendar year based on manual animal counts and data base queries such as animals bred or purchased.	Includes only animals in our facilities needed to support internally conducted Novartis studies. Animals needed to support studies conducted by 3rd parties on behalf of Novartis are not included.

Transformative innovation

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions*)
*) includes Innovative Medicine and Sandoz biosimilars projects only			
Projects entering development pipeline	Defined as projects with initial study start within confirmatory development being in phase Ph2b onwards or equivalent, having achieved first patient, first visit (FPFV) and have passed the Novartis IMB (Innovation Management Board) tollgate. Unit of measure: number of projects entering confirmatory development during the reporting year	FPFV information extracted from Horizon system and list of confirmatory projects from official IMB project list. IMB is an official NVS governance board with secretary, minuets and list of projects maintained.	Includes projects from internal R&D activities, acquired and in-licensed projects (excluding option-deals).
Projects in Phase III	Defines projects with FPFV in a Phase III study but not yet filed in the US, EU, Japan, or China. Unit of measure: number of projects entering confirmatory development during the reporting year	Data taken from annual/Q4 Investor Relations Reporting.	All ongoing Phase III projects, globally and across platforms.

ESG Category	Metric, Methodology, Definition	Assumptions, Calculation, Data collection	Scope and Exclusions*)
US FDA Breakthrough Therapy Designations	Number of breakthrough therapy designations within the reporting period granted by the US Food and Drug Administration for therapies under development by Novartis. Unit of measure: number of USD FDA breakthrough therapy designations during the reporting year	Data collected via regulatory affairs monthly dashboards and submission/approval tracker (based on HA letters).	Global scope across all platforms.
Major Submissions & Approvals	Major submissions (US, EU, Japan, China) Unit of measure: number of major submissions Major approvals (US, EU, Japan, China) Unit of measure: number of major approvals Includes submissions, respectively approvals, of small molecules or biologics which contain active moieties that were not previously approved, and which have new fixed-dose combinations of existing APIs, new target indications defined as a new disease, and a new line of treatment (e.g., first line vs. second line) or extended patient population (e.g., paediatric). Unit of measure: number of major submissions and approvals in the US, EU, Japan and China during the reporting year	Data collected via regulatory affairs monthly dashboards and submission/approval tracker (based on Health Authority letters).	Excludes submissions outside the US, EU, Japan, and China. Excludes any submissions & approvals solely based on new route of administration or formulation to improve patient's convenience (e.g., from parenteral to oral, vial to autoinjector).
New Molecular Entity (NME) Approvals	Defines first approval of small molecules or biologics which contain active moieties that were not previously approved in the EU or with new fixed-dose combinations of existing APIs. Unit of measure: number of NME approvals	Data collected via regulatory affairs monthly dashboards and submission/approval tracker.	