# Ethics, Risk & Compliance

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**UNOVARTIS** Reimagining Medicine

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### Agenda

Novartis Overview

ERC Strategy & Program ERC Deep Dive Topics



## **Novartis Overview**

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### At Novartis, our purpose is to reimagine medicine to improve and extend people's lives



#### We are a focused medicines company

Our organization is made up of different units, functions, regions, countries, and sites who all contribute to this purpose and our strategy in unique ways.

Regardless of where we sit or what we do, our purpose unites us and makes us greater than the sum of our parts.

# Our vision is to become the most valued and trusted medicines company in the world

We continue to strengthen our foundations across three areas



#### UNLEASH THE POWER OF OUR PEOPLE

- Our culture
- Our values
- Our ethical principles



#### SCALE DATA SCIENCE AND TECHNOLOGY

 Leverage data and technology to fuel innovation and growth



### BUILD TRUST WITH SOCIETY

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

### We believe the greatest strength of Novartis is our people, whose diversity, energy, and creativity are crucial to our success



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Driven by a strong sense of purpose, we have made significant progress to reimagine medicine

~284 m

patients reached in 2023

with Novartis medicines

45.4 bn USD

in net sales



### **98.4 m USD** invested in R&D for malaria and neglected tropical diseases



approvals for new medicines (US, EU, Japan & China)

22

-63%

greenhouse gas emissions in own operations since 2016



Source: Novartis Integrated Report 2023 - All numbers are for continuing operations

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# ERC Strategy & Program

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2.0

### Our ERC program consists of three pillars that cover ethics, enterprise risk, and regulatory compliance



#### **Build a sustainable** foundation

We empower associates to do what's right so that every day our decisions benefit patients, society and Novartis.





#### **Develop enterprise assurance** standards

We establish effective risk management that identifies, analyses, and addresses risks that can affect our ability to operate.



Manage our compliance risks

We ensure Novartis acts in compliance with applicable regulations, laws, policies and guidelines.

# The strength of each pillar combined enables us to deliver integrated assurance across the enterprise



Build a sustainable foundation

- Ethical Culture
- SpeakUp Program
- Human Rights Commitment



### Develop enterprise assurance standards

- Enterprise Risk Management
- Enterprise Policy & Control Management
- Business Continuity & Emergency Management
- External Partner Risk Management
- Transparency Reporting



Manage our compliance risks

- Compliance Risk Management
- Compliance Policies\*
- Policy Training & Communications
- Monitoring & Remediation
- Enterprise Monitoring Coordination
- Complaints Intake & Management

\* Compliance Policies include: Doing Business Ethically, Conflict of Interest, Data Privacy, Digital & Artificial Intelligence, Human Rights, Health, Safety, & Environment, & Trade Compliance

## ERC Deep Dive Topics

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### **Ethics**

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# To embed ethics, we focus on changing the mind and the environment

Our Code of Ethics and supporting tools support ethical decision making

#### **Thinking about ethics**

Changing behaviors by changing how people think about ethics

We shape our environment by removing blockers and supporting associates to do what's right

### **Being ethical**

Changing behaviors through changing the context and shaping the culture with **ethical leadership** 

# Our Code of Ethics signals our commitment to doing what's right, and was designed by our associates for our associates

Code of Ethics consists of two key elements:

12Ethical principles define what<br/>'doing what's right' means in<br/>the context of Novartis.Clear statements<br/>on our commitme<br/>to do what's right

Clear statements on our commitment to do what's right across key areas nominated by our associates

Supported by: an Ethical Decision-making Framework and a suite of resources

Launched in **Jun 2020** Effective as of **Sep 2020**  Our Code of Ethics replaced our Code of Conduct

Anchored in behavioral science and created by our associates for our associates.



# Our ethical principles are fully aligned with our values and are an integral part of our culture

| Our values             | Integrity   | Inspired  | Curious   | Unbossed   |
|------------------------|---|---|---|--|
|                        |   |   |   |  |
| Our ethical principles | Be honest   | Be bold   | Be open-minded  | Be accountable   |
| $\checkmark$           |   |   |   |  |
| Ask yourself           | Am I acting with clear<br>intent?<br>Am I avoiding harm?<br>Am I speaking up? | Am I standing up for<br>what I believe?<br>Am I putting patients<br>first?<br>Am I making a positive<br>difference? | Am I actively listening to<br>ideas or concerns?<br>Am I questioning the<br>impact of my decisions?<br>Am I valuing the<br>perspective of others? | Am I taking<br>responsibility for my<br>decisions?<br>Am I treating others as<br>I would like to be<br>treated?<br>Am I putting the team<br>before myself? |

# Our decision explorer tool helps our people navigate ethical dilemmas, enabling us to see our blind spots and personal biases

15 carefully designed and tested questions. Aligned with our ethical principles to help us to think clearly and impartially about ethical situations and help us identify biases



#### **Ethical Intent & Decision**

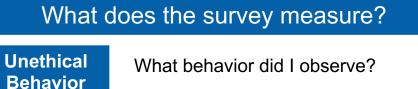
### Our annual global ethics survey helps us take a pulse of our ethical culture

### Survey design

Survey questions selected and adjusted from existing validated, reliable and cross-culturally relevant scales

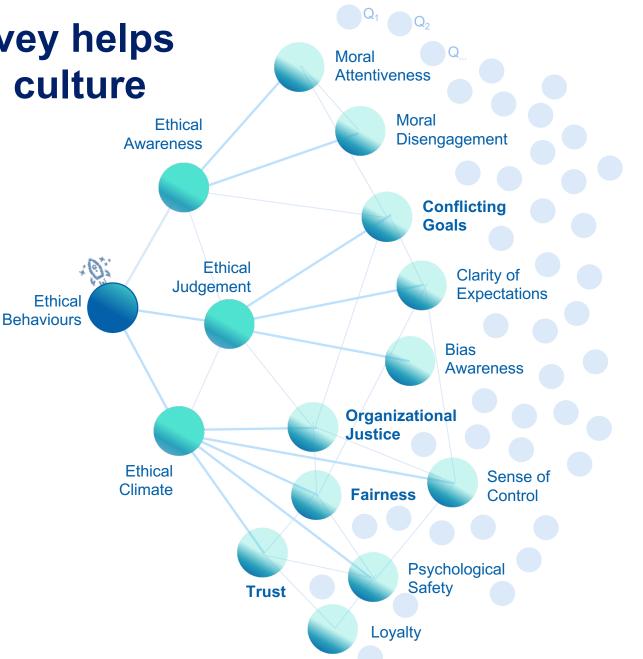
Available in the top **15** Novartis languages representing **~97%** of Novartis population

All of our people, both internal & external, are invited to participate



Did I speak up? What were the consequences?

Were my concerns addressed?



Speaking

Addressing

concerns

Our speak up process is an easy and transparent way to raise concerns about potential misconduct



### Report

Report of concern on one of the **SpeakUp** platforms\*

### Review

The matter is closely evaluated by a team of experts

Investigate

The matter is thoroughly investigated

Action

Appropriate remedial actions are taken

Close

The case is closed, and the reporter informed accordingly

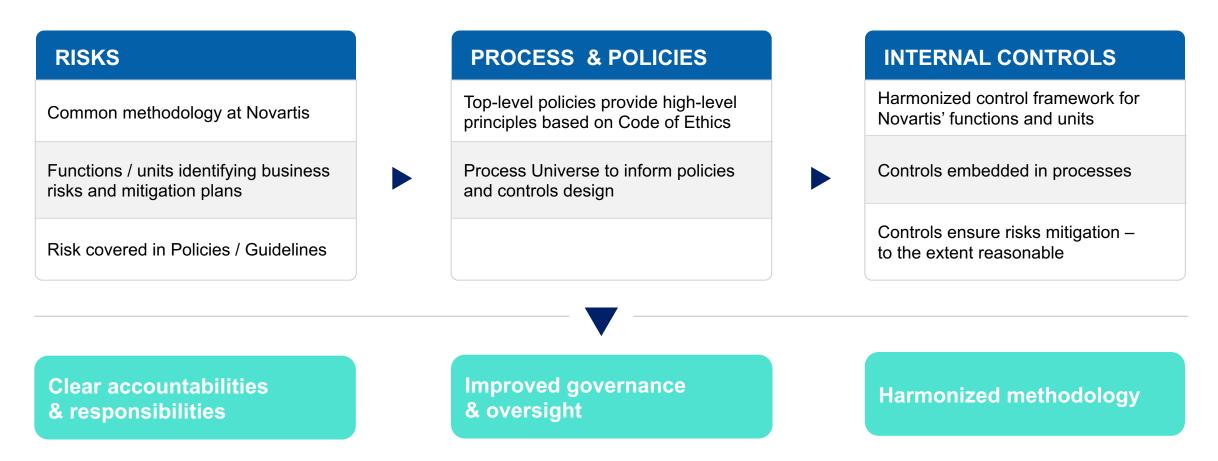
\*Speak Up App (on all Novartis iPhones / iPads), Webform/hotline accessible at go/Speak Up or via local channels (your manager, ERC, P&O, Legal functions and senior management) SpeakUp reverts within 3 working days after concern is received

## **Risk Management**

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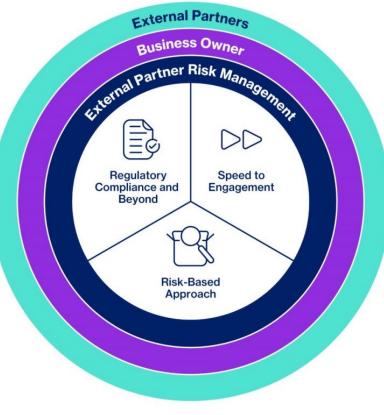


## Based on our risks, we ensure strong governance across enterprise policies, processes and internal controls



### Connecting our processes, policies and controls to our enterprise risks

# Our External Partner Risk Management is based on three principles



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The purpose of EPRM is to assure that Novartis works with external partners who are capable and willing to comply with our standards. We want to achieve this in an effective and efficient way with a risk-based approach.

### 1. Regulatory Compliance & Beyond

We are addressing the trend of increasing regulations and support delivery on commitments to strengthen trust with society.

### 2. Speed to Engagement

Providing risk assurance is just as important as running efficient and fast processes in order to increase internal acceptance.

### 3. Risk-Based Approach

Our due diligence efforts will be proportionate to the level of identified risks which is determined by probability and severity of adverse events.

# External Partner Risk Management scope covers the following risk areas

External Partner Risk Management (EPRM) covers the following risk areas and external partners:

| Buy-side  | Risk areas in-scope*   |   |
|---|--|---|
| All External Partners, excluding Health Care<br>Professionals (HCPs) when they act in scope of<br>their direct profession.<br>HCPs are governed under the Doing Business<br>Ethically framework | <ul> <li>Anti-Bribery</li> <li>Health, Safety &amp; Environment</li> <li>Substances of Concern in Products</li> <li>Contractor Safety</li> <li>Labor Rights</li> </ul> | <ul> <li>Information Security Risk<br/>Management &amp; Data Privacy</li> <li>Animal Welfare</li> <li>Global Trade Sanctions</li> <li>Business Continuity Management</li> <li>Raw Material Certification</li> </ul> |
| Sell-side   | Risk areas in-scope  |   |
| Wholesalers<br>Distributors   | <ul><li>Anti-Bribery</li><li>Global Trade Sanctions</li></ul>  |   |

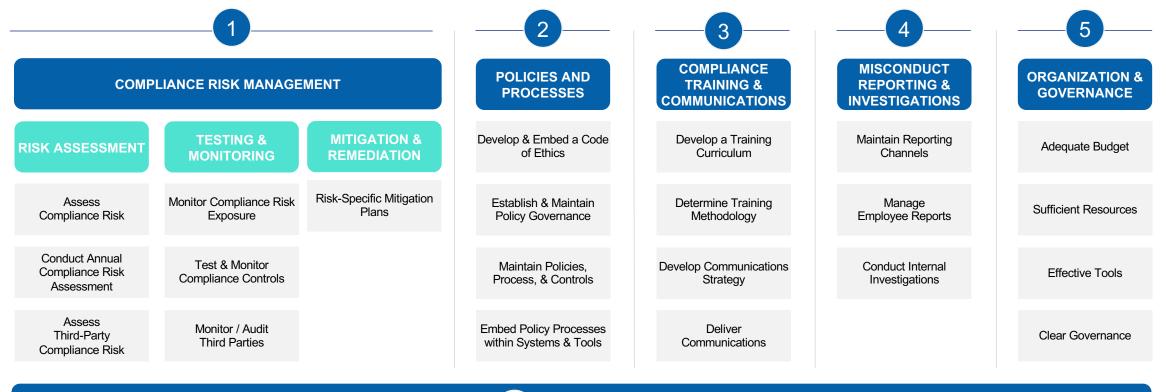
\*Human Rights aspects are integrated in several of the above risk areas

## Compliance Management



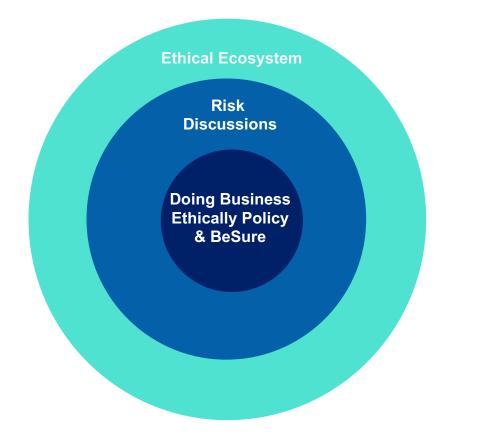
### A core objective of our Compliance Management System is to maintain a culture of integrity

Novartis Compliance Management System is designed to manage compliance risk and support compliance with laws and regulations, preventing harm to our customers. Our work is divided in the following Pillars:



6 CULTURE

# Our Doing Business Ethically policy & BeSure platform are designed to strengthen risk management



Success of the Doing Business Ethically program hinges on the implementation of three interdependent areas:

- 1. Policy & system: Foundation to help associates confidently navigate the process.
- **2. Risk discussions**: Meaningful risk coaching, using the 4-step risk framework.
- **3.** Ethical Ecosystem: An environment that supports ethical behaviour, safe discussions, sharing of lessons learnt, trusting relationships enabled by ethical leadership.

### Doing Business Ethically policy addresses the risk of bribery and undue influence across the lifecycle of our products

## We do not tolerate any form of bribery or corruption

Bribery can take a variety of forms. Even common business practices or social activities, such as the provision of gifts and hospitality, can constitute bribes in some circumstances.



### We will maintain high standards of ethical business conduct

We are accountable for our actions, decisions, and how we interact with our stakeholders. We adhere to all legal and regulatory requirements and comply with selfregulations established by our industry.

#### **Our Interaction Types**

Interactions with External Stakeholders may take various forms. We classify these interactions into the following three broad categories:



### Engagement



#### **Funding & Collaboration**



#### Gifts, Samples, and other Items

# Our risk-based approach covers multiple dimensions strengthening risk management and overall assurance



**The Risk Framework** 

The Doing Business Ethically Policy & Global Handbooks introduce a new risk framework which forms the basis for how we have standardized risk management within the program.



**Risk Dimensions** 

At the very beginning of each activity request, we assess four dimensions to determine the level of risk, and additional support needed to ensure robust decision making.



**Built-In Controls** 

Within the BeSure workflows, we embedded the policy and handbooks requirements, which trigger additional controls.

Depending on the specifics, additional documentation or reviewers may be required.



**Risk Experts Involvement** 

As an outcome of the assessment, certain high-risk activities will require additional consultation by risk experts.

This ensures we are assessing the risk from all necessary angles, and we focus our efforts where it matters most.

# Our BeSure platform guides users and supports review, approval and reconciliation of activities

#### **Explore policy requirements:**

All Policy, Handbooks and Training materials are accessible through the Knowledge Hub to support in managing the risks related to certain activity types. Based on the country local industry requirements, content is adjusted to show the relevant information.

#### Fair Market Value & Other:

Relevant information and supporting materials, such as Fair Market Value is included or referenced in BeSure.

|       | e information you need regarding our<br>icy and handbooks that provide detaile |   | <b>N</b>                                    |
|-------|--|---|---|
| ✓ Cho | oose a topic area  |   |   |
|       | =  |   |   |
|       | Our Handbooks A breakdown of how to apply the Doing Business                   | Fair Market Value<br>Determine the appropriate<br>remuneration for engaging | Doing Business<br>Ethically Policy          |
|       | Ethically policy to your<br>activities.  | professionals.  | Bribery and Professiona<br>Practices Policy |

Review and approval with built in risk classification: The Activity Owner enters a new request into the system. The system helps them assess the risk based on a series of questions

As a result of the risk assessment, the activity is classified as either low, medium or high-risk. This determines the level of support needed from the relevant functional Risk Expert and determines the approval needed.

### Our data product Control Room enables country ERC to stay on top of their risks and successfully reach ERC goals

Control

P3 Tool

Trainings Ethical Behavic

Ethical Culture

### Control Room

#### **Key features**

- Upcoming and overdue action overview
- Interactive tables for data exploration
- Data exports
- Ethical Behavior and culture insights

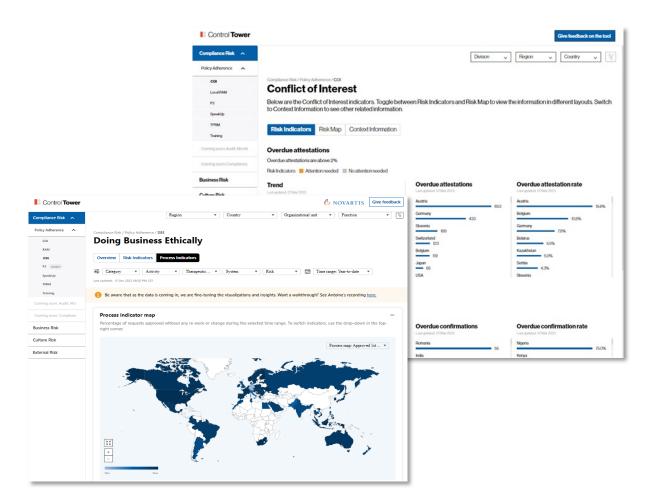
|  | Control Room   |   | Country (All)           | Division (All)           | BU (AII)              | Site (All)             |
|--|--|---|-------------------------|--------------------------|-----------------------|------------------------|
|  | Overview   |   |                         |                          |                       |                        |
|  | со   | COI - Conflicts of Interest   |                         |                          |                       |                        |
|  | Local RAM  | The Conflicts of Interest page in the Control Room is here to he<br>information on Conflicts of Interest, have a look at the COI Lear |                         | e actions to ensure      | the COI campaig       | n's success. For more  |
|  | P3 Tool  | In case you have any remaining questions contact coi.tool@no  |                         |                          |                       |                        |
|  | SpeakUp  | The COI data in Control Room refreshes daily. Completed atte<br>Information restricted.   | stations, confirmations | s and disclosures w      | ill be visible in the | tool the following day |
|  | TPRM   |   |                         |                          |                       |                        |
|  | Trainings  | <b>2943</b> Total overdue actions   | 31                      | 8 Total upo              | oming actions         |                        |
|  | Ethical Behaviors  | Overclue Attrestations  | Incoming                | Attestations             |                       |                        |
|  | Ethical Culture  | 2004 actions   97.3% completed  | 0                       | Confirmations            |                       |                        |
|  | Country (1) Division (All)   | BU (All) Site (All)   |                         | 76<br>Disclosure Actions |                       |                        |
|  |  |   |                         |                          |                       |                        |
| The Control Room is here to help you identify and take action<br>Unsure where to start? Browse the summary below and<br>actions.<br>There is at least one action (1990   | visit the sections for more information of   | on flagged issues and recommended   | estation campaign goals |                          |                       |                        |
| Unsure where to start? Browse the summary below and actions. There is at least one action (1999 Tool Star Action S | yesit the sections for more information of<br>gaction (220 E Noaction<br>SpeakUp T 6<br>0 Action 60  | on flagged issues and recommended ove the highlighted me ove the highlighted me Decent RAM obtain Obtain Obtain Obtain                |                         |                          |                       |                        |
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# Our data product Control Tower enables ERC leaders to have a holistic view of the risks for different markets and regions

### Control **Tower**

#### **Key features**

- Holistic ERC function overview
- Overview of dynamic risk indicators
- Interactive map, trend and threshold
   analytics for data exploration
- Context information in every section
- Live-view for continuous presentation



## Review, Monitoring & Remediation helps ensure compliance across our value chain

| Compliance Reviews<br>& Remediation  | Anti-Bribery Audit   | HSE Audit & Compliance  |
|--|--|---|
| <ul> <li>Country/Unit Compliance<br/>Reviews and remediation<br/>oversight &amp; support</li> <li>Global Risk Remediation of<br/>systemic issues, e.g., SpeakUp</li> </ul> |  | HSE Conformance and Legal<br>Compliance Audits and<br>remediation oversight, mainly at<br>manufacturing sites and large<br>office locations |
|  | • External-Partner Anti-Bribery<br>Audits and remediation support,<br>at high-risk external partners | <ul> <li>HSE Audits at in scope contract<br/>manufacturers</li> <li>HSE Due Diligence for Merger&amp;<br/>Acquisition projects</li> </ul>   |

#### **Enterprise Monitoring Coordination**

- Coordinate compliance monitoring to minimize disruption in audited units
- Roll out common root cause analysis across assurance functions to strengthen remediation

Internal

External

## Thank you

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