



Biopharma Investor ESG Communications Guidance 2.0

Developed by:

The Biopharma Investor ESG Communications Initiative

Part of the Biopharma Sustainability Roundtable

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The Biopharma Investor ESG Communications Initiative



The Biopharma Investor ESG Communications Initiative (the Initiative) was set up to address the common interest of leading biopharma companies and investors in achieving more effective, efficient, and decision-useful communications about the sector's most important environmental, social, and governance (ESG) topics.

The Initiative is a sector-focused direct dialog between companies and investors that started in mid-2018 and continues to facilitate a series of structured, frank, and open discussions.

BUSINESS CASE

Research shows companies that effectively manage their material Sustainability and ESG challenges deliver above-average long-term financial returns. However, corporates and investors alike are frustrated by several issues, including misalignment on what are the most material ESG topics; inefficient and laborious ESG reporting and research processes; uneven quality and poor transparency of third-party ratings and performance analyses; and confusion and survey fatigue from the proliferation of Sustainability and ESG surveys and questionnaires.

INITIATIVE FOCUS

The Initiative provides an engagement platform for biopharma Sustainability and investor relations executives and investors to find ways of communicating that are both reasonable from the industry perspective and decision-useful from the investor perspective. The Initiative is not meant to be prescriptive, but to offer guidance on what, and resources for how, to most effectively communicate about the core ESG topics of interest to both parties.

PARTICIPANTS

The Initiative is led and facilitated by the Biopharma Sustainability Roundtable, a sector-specific collaboration network that supports senior biotech and pharma executives in driving their Sustainability agendas forward. The High Meadows Institute (HMI), a think tank and policy institute focused on strengthening the role of business leadership in creating a sustainable society, is a Strategic Partner. For HMI, the Biopharma ESG Communications Initiative serves as a pilot for a broader Institutional Investor Industry Engagement project, aimed at improving communications on material ESG topics between investors and companies across sectors.

Working group members include Amgen, Bristol-Myers Squibb, and Merck & Co.* (Sponsors), together with Johnson & Johnson and Novartis (Participants). Additional biopharma companies that have participated in the Initiative process to date include Astellas, Bayer, Gilead Sciences, GlaxoSmithKline, Lonza, Novo Nordisk, Pfizer, and Roche.

Investor participants to date include Aberdeen Standard, Acadian, APG, BlackRock, Calvert, Domini, Federated Hermes, Manulife, Morgan Stanley, PGGM, Rockefeller Capital, TPG Capital, Wellington, and UBS.

* Merck & Co. is known as MSD outside the U.S. and Canada.



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Introduction

This Guidance aims to contribute to effective and efficient ESG communications between companies in the biopharma sector and investors.

The Guidance has been developed by the Biopharma Investor ESG Communications Initiative (the Initiative). This version of the Guidance is the result of an 18-month process that included three face-to-face meetings between representatives of the biopharma industry and investors, seven one-on-one investor interviews with ESG and biopharma sector experts, a stream of feedback from a larger pool of investors and companies, and the ongoing contributions of a core working group of biopharma companies.

Key learnings from the biopharma-investor dialog, collected in Annex I, provide insights into current investor thinking and their considerations when assessing a biopharma company's ESG profile. Annex II provides more detail about why and how this Guidance was developed.

We anticipate that a collaborative dialog between the investment community and the biopharma sector will continue to shape and refine this Guidance.

GUIDANCE KEY FEATURES

- Sector-specific
- Developed through engagement
- Reflects best practices
- A resource, not a framework or standard
- Influences from SASB¹ and TCFD²

Using the Guidance

The Guidance is intended to be used as a resource. It has been developed primarily to help companies communicate their ESG narrative, including strategy, governance, risks, opportunities, and performance, in a well-structured and comparable manner. It also aims to help investors engage with companies more effectively. It is not, nor does it aspire to become, a reporting standard or framework.

In using the Guidance, companies and investors should remember that the recommendations:

- Reflect a consensus on ESG communications best practices that are seen as both useful to the biopharma industry and meaningful to the investor community
- Provide a high-level map that both identifies ESG topics of shared priority, and gives recommendations that can be adapted to a company's own strategies and business models
- Encourage disclosure of robust, consistent ESG data and information that is relevant to the sector and to each company's high-priority ESG topics
- Address what, how, and when biopharma companies should communicate high-priority ESG topics to the investor community
- Are practical for biopharma companies that are publicly listed, and/or have external financial stakeholders
- Are useful for biopharma investors (asset owners and asset managers) that are integrating ESG analysis into their investment decisions
- Are not a content list that companies must address one by one, but should be adapted to individual needs and context, so it is not a "tick-the-box" compliance exercise
- Provide a range of sector ESG topics that extends beyond near-term financially relevant topics (often termed "material"), to include strategically relevant topics that may also become financially relevant in the mid- to long-term
- Are a tool for triggering internal company conversations on strategically relevant topics that could impact corporate performance in the global market environment
- Are designed to be useful to investors who want to become familiar with the biopharma sector ESG landscape or guide biopharma companies on the ESG information for which they are looking

WHAT'S IN THE GUIDANCE

- Biopharma sector high-priority ESG topics
- Recommendations for ESG communications content
- Suggestions for ESG communications process
- Key learnings from biopharma-investor dialog

Biopharma Sector High-priority ESG Topics



One of the first steps in developing the Guidance was to define a pool of key ESG topics for the biopharma sector that are important to both the companies and the investor community. Biopharma and investors were separately asked to identify a list of high-priority – often termed material* – biopharma sector ESG topics. The resulting lists, which turned out to be similar, were discussed and compared during three working meetings between the investor community and biopharma companies†. Topics included in the Sustainability Accounting Standard Board (SASB) Biotechnology & Pharmaceuticals Sustainability Accounting Standard¹ were taken into consideration as a baseline reference. The final list has some overlap but extends beyond SASB to include topics considered by investors and biopharma companies to be strategically relevant in a forward-looking manner although some may not yet be “financially material.”

Investor and biopharma representatives were able to converge on a core pool of high-priority ESG topics for the biopharma sector. The topics, listed below, are not ranked individually, but presented in alphabetical order.

When using the Guidance, this list of ESG topics is indicative; each company should explain their own priorities as appropriate for their business model and strategy. We expect that specific priorities differ across companies and investors. The list is developed and designed to ensure that as the Guidance evolves, the focus remains on the core topics that are high priority for both the investment community and the biopharma sector. High-priority topics may also be considered in relation with each other, as their importance may be driven by their interactions and interrelations with each other.

Figure I ESG Topics



* See discussion in Annex III. Definitions

† The Biopharma Investor Day April 11, 2019, and Biopharma Investor ESG Communications Workshops July 9 and November 4, 2019

‡ For the purpose of this Guidance, access to healthcare is viewed as an outcome of a business strategy that removes access barriers globally – with pricing considered as one such barrier.

Table I Shared High-priority ESG topics for the Biopharma Sector

ESG Topic	Examples of what investors say they are looking for (not a comprehensive list)
ACCESS TO HEALTHCARE AND MEDICINE PRICING[‡]	<ul style="list-style-type: none"> • Link to corporate strategy, and include upside opportunities in both areas • Transparency about pricing methodology and how it supports company strategy, impacts on compensation and incentives, pricing history, and how changes are tracked over time • Company's approach to future risks, particularly with regard to pricing • Number of patients reached with medical products, including information about the magnitude of the disease burden and the size of patient population • Additional upside opportunities opened up by removing specific access or pricing barriers
BUSINESS ETHICS, INTEGRITY, AND COMPLIANCE	<ul style="list-style-type: none"> • Anti-bribery, anti-corruption, anti-competitive behavior approach and outcomes, including marketing practices • Ethical controversies, corporate political spending and accountability, corporate political lobbying
CLIMATE CHANGE	<ul style="list-style-type: none"> • How climate change risks and opportunities are driving company strategy • How the company is preparing for short and mid-term sector-specific challenges • Strategic response and solutions related to climate change effects such as new disease patterns, shifts in disease geographic distribution, exacerbated health issues, shifts in vector populations, and population displacement
CLINICAL TRIAL PRACTICES	<ul style="list-style-type: none"> • Link to product safety • Diversity and inclusion in clinical trials • Approach to human rights, including informed consent and data privacy
ESG GOVERNANCE	<ul style="list-style-type: none"> • Process and structure of oversight committees and governance communications • Board's ESG oversight process • Board and management remuneration
ENVIRONMENTAL IMPACTS	<ul style="list-style-type: none"> • Share of renewable energy use • Waste reduction and management • Water consumed and water discharge
HUMAN CAPITAL MANAGEMENT	<ul style="list-style-type: none"> • Employee turnover rates, voluntary and involuntary • Training and career development • Strategies for talent recruitment and retention • Diversity and inclusion
INNOVATION	<ul style="list-style-type: none"> • R&D resources • Pipeline
PHARMACEUTICALS IN THE ENVIRONMENT AND ANTI-MICROBIAL RESISTANCE	<ul style="list-style-type: none"> • Product stewardship and risk management both internally and across the supply chain
PRODUCT QUALITY AND PATIENT SAFETY	<ul style="list-style-type: none"> • Information on product recalls • Product safety improvements
RISK AND CRISIS MANAGEMENT	<ul style="list-style-type: none"> • Special focus on cybersecurity and data privacy • Identification of emerging topics
SUPPLY CHAIN MANAGEMENT	<ul style="list-style-type: none"> • Oversight of third parties in relation to ESG topics

Recommendations for ESG Communications Content



RECOMMENDED STRUCTURE OF ESG COMMUNICATIONS

Having reviewed a wide range of existing disclosure frameworks, and based upon our initial discussions with the investment community, it was agreed that while there are useful components in many frameworks, none are entirely satisfactory or will serve every purpose on their own. However, two frameworks that were developed with significant input from the investment community – SASB1 and TCFD2 – were deemed as useful starting points. This Guidance has been formulated by adapting some of the best features from both and combining them with best practices and input from the biopharma-investor dialog to meet the goals of efficient and effective ESG communication for the biopharma sector.

The Guidance recommends structuring disclosure of ESG information around five elements using a two-tiered approach.

The five elements reflect core operational aspects of a company: Governance³, Strategy & Objectives, Risks, Opportunities, and Metrics[†] & Performance. The two-tiered approach provides a way for a company to first describe how ESG topics are strategically managed across the entire organization, and then provide more detail at a topic-specific level (Figure II).

Figure II Guidance structure: Five core elements addressed in a two-tiered approach



[†] Metrics are not thoroughly addressed in this Guidance version. A deeper exploration of metrics will be addressed in future phases of the Initiative, beginning in mid-2020.

The Guidance provides recommendations both for the “Cross-organizational” and the “Topic-specific” descriptions. This approach reflects the fact that setting the strategy on how to communicate ESG goals and performance, and then providing the supporting evidence with robust data, are both important to investors. Figure III provides an overview of the information recommended for disclosure under each of the five elements. More detailed recommendations are provided for each of the five elements in the pages that follow.

Figure III Guidance information overview: What investors are looking for



DETAILED CONTENT RECOMMENDATIONS

Additional content recommendations are provided within the five elements below. Some recommendations are phrased as questions to help companies locate and frame relevant information from their existing disclosures.

The Guidance does not prescribe the information in the detailed manner that reporting frameworks and standards do, as this is not its purpose. Instead, it provides a guide as to what kinds of information investors would like to see from biopharma companies, derived from the direct dialog between biopharma and investors. The recommendations are also a tool for initiating and structuring internal conversations about emerging issues that may affect a company.

The Guidance presents cross-organizational recommendations for the five elements first, followed by topic-specific recommendations for each element.

CROSS-ORGANIZATIONAL TIER

GOVERNANCE

»» What is the company's governance and management around ESG topics?

On the Board's role:

- What is the process, format or structure, and frequency by which the Board oversees ESG considerations and performance? Describe organizational chart, committees, decision-making process, layers of ESG information flow, and which function has responsibility for ESG reporting to the Board.
- How does the Board determine the sufficiency of their oversight process?
- What is the level of expertise of Board members, especially independent directors, with regard to the company's high-priority ESG topics?
- How does the Board oversee performance and progress against ESG targets?
- Does the Board consider ESG topics when reviewing and setting strategy, business objectives, risk management, annual financial planning, business plans, mergers, acquisitions, and divestments?

On Management's role:

- Where do ESG responsibilities sit in the organization? Describe Management-level positions, committees, organizational structure, decision-making, and reporting lines to the Board.
- What is the process by which Management assesses and is informed about ESG topics?
- Are ESG goals part of senior Management performance appraisal?
- Are ESG considerations linked to individual performance evaluation and compensation? If so, please describe how they are reflected and at which organizational levels.
- Are ESG goals incorporated into a corporate scorecard and, if yes, how?

CROSS-ORGANIZATIONAL TIER

STRATEGY & OBJECTIVES

- »» How do high-priority ESG topics inform the company's overall business strategy?
- »» What is the company process and methodology for defining its own high-priority ESG topics?

For overall business strategy:

- What are the key goals and objectives for the company's approach to ESG?
- How are ESG considerations integrated into both short-term business objectives and long-term business strategy?
- What are the key ESG drivers relevant to the business strategy?
- How are external stakeholder perspectives utilized in developing the strategy?
- How are decisions made and communicated through the company?
- In the case of a significant change in business strategy (e.g., a merger or acquisition), what is the process to ensure ESG topics are considered in decision making?
- How are forward-looking ESG considerations included in the business strategy development process?

RISKS

- »» How does the company identify, assess and manage ESG-related risks?

Describe the ESG risk identification and assessment process:

- If specific Board or Management committees have mandates related to risk management, what are their specific mandates and responsibilities?
- How is information for ESG risks deemed as "adequate" to the Board?
- How are ESG risks prioritized in relation to other company risks?
- Is the process for identifying and assessing ESG risks integrated into an existing risk assessment framework, and, if yes, how?

CROSS-ORGANIZATIONAL TIER

OPPORTUNITIES

»» How does the company identify and develop ESG-related opportunities?

Describe the business strategy setting and opportunity identification process:

- If specific Board or Management committees have mandates related to strategic ESG opportunities, what are they?
- How is information for ESG opportunities deemed as “adequate” for the Board?
- How are ESG opportunities identified and integrated into business planning?
- Does the company pursue ESG opportunities as part of its strategy, innovation or business development processes?

METRICS & PERFORMANCE

»» What are the company's high-level ESG objectives set at Board level?

Describe high-level ESG objectives set at Board level and provide context to link them to short- and long-term business objectives:

- Describe how the company's ESG objectives and performance indicators link to its business strategy.
- Describe the progress review process related to these high-level objectives.
- Discuss any controversies that exist from third-party assessments, ratings, or rankings.
- Explain any challenges in identifying meaningful metrics that reflect performance and outcomes.

More about metrics on page 15.

TOPIC-SPECIFIC TIER

GOVERNANCE

»» For each ESG topic, describe the flow of responsibilities from the Board through Management to implementation by staff.

On the Board's role:

- For a given ESG topic, is there specific Board oversight?
- What is the process, format or structure, and frequency by which the Board oversees ESG topic-specific considerations and performance? Describe organizational structure, committees, decision-making process, ESG information flow, and which function does the reporting process.
- How does the Board determine the "sufficiency" of their oversight process?
- What are Board members', especially independent directors', level of expertise with regard to the company's ESG topic-specific considerations?
- How does the Board oversee performance and progress against ESG topic-specific objectives?
- Does the Board consider the ESG topic when reviewing and setting strategy, business objectives, risk management, annual financial planning, business plans, mergers, acquisitions, and divestments?

STRATEGY & OBJECTIVES

»» What is the specific strategy for a given high-priority ESG topic, including targets set, and how they relate to overall business strategy?

For each ESG topic:

- What are the key objectives and targets for this ESG topic and what is the rationale behind them? Link with Metrics & Performance section as appropriate.
- What are the key outcomes the company is trying to drive?
- How does the strategy for this ESG topic fit within the overall business strategy?
- Who are key internal and external stakeholders for this ESG topic, and how are their perspectives integrated into the business strategy?
- How is the strategy for this ESG topic being implemented or operationalized? Include metrics and data points to support commentary; describe performance review methods and resource allocation.

TOPIC-SPECIFIC TIER

RISKS

»» **What are the company's top risks related to specific ESG topics, how might they negatively affect the business, and how are they managed?**

For each ESG topic:

- What are the key business risks related to this ESG topic?
- How are these risks managed in order to protect the assets and long-term value of the company?
- For the identified risks, include company-specific examples and explain how the company has addressed them.

OPPORTUNITIES

»» **What are the company's top opportunities related to a specific ESG topic, how might they positively affect the business, and how are they being pursued?**

For each ESG topic:

- What are the key opportunities?
- How are these opportunities being pursued and how will they help create long-term value for the company?
- What are the goals that the company wants to achieve, and what has been the impact and outcome so far?
- For the identified opportunity, include company-specific examples and how the company has pursued the opportunity.

METRICS & PERFORMANCE

»» **What are the metrics used to assess and manage the company's performance on the specific ESG topic?**

Disclose the targets set for each ESG topic, including any stemming from regulatory requirements or voluntary reporting initiatives, and describe how these are monitored.

- Describe how the company sets targets and selects metrics to demonstrate performance for each ESG topic.
- Explain the timeframes applied, each target type (quantitative or qualitative; absolute or relative; context-, impact-, or science-based), base year for measurements, and key performance indicators used to monitor targets.
- Describe how the company manages each ESG topic to reach its targets, including scope, programs, processes, and responsibilities.
- Transparency for each metric should include a long-term target, an annual target, performance vs. target (with explanation), history (across at least three years), and an outlook or forecast.

More about metrics on page 15.

MORE ABOUT METRICS

The current Guidance 2.0 does not prescribe the metrics a company should use from the multitude available among current ESG reporting frameworks and standards.

During the Initiative dialog, investors indicated that they would like to see biopharma companies adopt metrics that are both comparable and common across the sector, but they did not specify a preferred framework or standard. Investors suggested instead an industry-driven effort to define a shared pool of sector-appropriate metrics, from which companies could select according to best fit and purpose. We expect to incorporate this effort into the next stage of the Initiative, tentatively beginning in the second half of 2020. We will seek to identify a core set of metrics for the shared high-priority ESG topics already agreed upon.

For now, the Guidance recommends that companies use the following core principles when selecting and using metrics and performance indicators for their high-priority ESG topics.

- **Relevant to business results**
- **Aligned with targets and linked back to strategy**
- **Accurate and reliable**
- **Comparable and timely**
- **Balanced and objective**
- **Outcomes-oriented**

Adherence to these principles will help investors form a balanced, complete, comparable, verifiable, fair, and decision-useful opinion about the company's ESG performance.

Suggestions for ESG Communications Process



After a biopharma company has compiled robust ESG information on its high-priority topics, the next step is creating an appropriate communications process.

During the Initiative dialog, ideas for engagement, communications methods, appropriate channels, and timing were discussed among biopharma and investors. As companies begin to use this Guidance, we'll update the summary of ideas and suggestions outlined below to reflect emerging best practices. There is no one-size-fits-all approach and these suggestions are not intended to fully address all issues. Engaging investors and communicating ESG performance effectively will be an evolving art for some time.

COMMUNICATION TOOLS AND CHANNELS

- *Stand-alone print or web-based investor communications:* The Guidance can be used as a tool for reviewing existing public materials to identify gaps and improvements.
- *Investor presentations and roadshows:* Ensure ESG strategy and performance is part of the long-term value story.
- *One-on-one engagement with investors:* The Guidance model can be used to organize and prepare for investment and stewardship discussions.
- *Quarterly investor calls and engagement discussions:* The Guidance can be used to prepare the CEO and Board members' narrative about the company's ESG strategy.

TIPS FOR ONE-ON-ONE ENGAGEMENT AND DISCUSSION

- Initiate proactive engagement with investors and analysts about ESG performance on a regular basis; don't wait to be asked.
- Offer investors direct engagement with Board members on ESG priority topics and strategy.
- Create one single conversation on high-priority ESG topics, versus siloed discussions. Bring together investors and their ESG stewardship teams with senior corporate management, investor relations, and ESG subject matter experts.
- Address ESG issues and controversies in the media or that have been flagged by third-party raters. Disagreement with a third-party assessment is often appreciated if backed up with meaningful information.



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This Guidance document has been published by the Biopharma Sustainability Roundtable as part of the Biopharma Investor ESG communications initiative. The findings, insights, recommendations, and conclusions herein are the result of a collaborative process facilitated by the Biopharma Sustainability Roundtable, but do not necessarily represent the views of the Biopharma Sustainability Roundtable nor the entirety of its participants, sponsors, contributors, or other stakeholders.

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WORKSHOPS & INVESTOR DAY HOSTS

Thanks to BlackRock for hosting our April 11, 2019, Investor Day, and to the Rockefeller Foundation for providing the venue for our Biopharma Investor ESG Communications Workshops on July 9 and November 14, 2019.

Annex I

KEY INSIGHTS FROM THE COMPANY-INVESTOR DIALOG

This section provides insights from the company-investor dialog to-date about current investor approaches to ESG, and what investors say they look for in their research and corporate engagement. Key learnings have been derived from the discussions, workshops, interviews and feedback provided by biopharma executives and investors who have participated in the Initiative to-date. This section is not a comprehensive analysis of the ESG investment decision-making process, but is intended to provide sector-specific insights into investor approaches.

Insights into how investors consider ESG in their decision-making

- The role of ESG in investment decision-making is gaining importance. ESG is increasingly being integrated into “mainstream” investment analyses (i.e., moving beyond socially responsible investing).
- A downside risk perspective still dominates investors’ approach. However, there is a growing interest, primarily driven by European-based investment companies, and responsible and impact-oriented investors, in how ESG can drive opportunities through innovation and new market growth.
- Investors have various internal groups with differing information needs and interests when it comes to ESG data and information:
 - Some active managers and analysts in large firms tend to look for shorter-term quantitative and operational ESG performance data.
 - Investor stewardship teams tend to look for more long-term qualitative information from corporate boards on how high-priority (or material) ESG priorities are determined, integrated into corporate strategy, monitored, and incentivized.
 - Asset management or asset owner teams that invest in companies tend to have various strategies: From exercising exclusion criteria, to looking for evidence of ESG integration and/or positive social and environmental impacts or themes, such as a positive contribution to improving access to healthcare or combating climate change.
- Investors do not have a prescribed or preferred method for company materiality assessments, but do want to understand each company’s prioritization process, and to see that a company has addressed an adequate set of industry topics.
- Regardless of where a company stands on any ESG topic – beginner, middle-of-the-pack, leader – the critical issue for investors is measurable progress over time within a well-defined context (strategic intent, target impacts and outcomes) relative to industry best practices.



Insights on how investors collect and evaluate company ESG information

1. Proprietary investor methodology

- Large investors rely on their own proprietary ESG assessment methodology for decision-making that draws on a number of information sources. The most important sources are public performance data and direct communication from and with the company.
- There is no one methodology or approach used in analyzing ESG information, and the level of sophistication varies.
- Most investors perform their own materiality assessment of companies based on pre-defined sector-priority topics.

2. Third-party ESG analysis

- Investors are combining their own ESG analysis with selected information from third-party agencies. However, third-party scores are rarely their single source for assessing a company's ESG performance.
- Investors mainly use third-party ESG analysis providers as an auxiliary to their own analysis and engagement, as signals of market interest and/or as flags for certain issues. Third-party ratings often diverge, reflecting the wide range of metrics used and target audiences served, highlighting the challenge.
- Third-party ratings, rankings and indexes that individual investors cited include, but are not limited to (in alphabetical order):
 - The Access to Medicine Index (ATMI) for being the only third-party resource that focuses specifically on "Access" despite concerns about its methodology;
 - Bloomberg for public information and tools to analyze data and spot trends;

- The Carbon Disclosure Project (CDP);
- ISS;
- Sustainalytics for Governance information;
- MSCI ESG data for aggregate controversy data;
- Glass Lewis for proxy information that is useful on current votes.

3. Topic specific: Quality and depth of what investors look for

- For every ESG priority topic, investors look for context and rationale as the backbone of good information, which should include:
 - Strategic intent
 - Thought process behind targets set
- Metrics demonstrating how a target is achieved, including a discussion of the specific outcomes that the company is trying to drive
- Performance and learning from experience over time, not snap-shot metrics
- Robust data points, linked to strategy, risk, and value creation.
- To view examples of what investors say they look for, refer to *Table I. High-priority ESG topics* shared between Biopharma and Investors on pages 6 and 7 of the Guidance.

Both investors and companies are encouraged to consider the interrelations between ESG topics, and how they could affect longer-term business strategy. For example, supply chain and anti-microbial resistance, or climate change risk and neglected diseases.

Annex I

KEY INSIGHTS FROM THE COMPANY-INVESTOR DIALOG *continued*



Insights from investors on company ESG reporting

- Investors favor direct company disclosure, which may appear in many forms: Financial / Annual Report, Sustainability / CR Report, 10-K, 10-Q, company policies, country non-financial reporting obligations resulting from Directive 2014/95/EU of the European Parliament and the Council of Europe. Indirect information, for example by raters and rankings, is used as auxiliary input to their assessment.
- Quality over quantity wins. Clear, concise, easily accessible information focused on high-priority topics is preferred to detailed story-telling without strategic context.
- Investors are in favor of integrated reports, and the International Integrated Reporting Council (IIRC)⁴ is seen as the most relevant reporting framework by many.
- No single framework is considered to be the definitive authority on ESG disclosure. SASB¹ and TCFD² are useful because they are investor-focused; GRI⁵ because it compartmentalizes information and addresses a wider audience.
- Investors favor a proactive response to issues that affect a company, including those appearing in the media or that have been flagged in third-party analysis. They would like companies to directly address such issues in their communications.

Annex II

ABOUT THE GUIDANCE DEVELOPMENT



Why a Guidance and how was it developed?

Academic research^{6,7} provides evidence that superior performance in the most relevant ESG areas is positively related to long-term corporate financial performance. But there remains a lack of consensus on what and how ESG information from companies should be structured and communicated to the capital markets, particularly at a sector-specific level. Moreover, corporates and investors alike are frustrated by several issues, including misalignments on the most important ESG topics, inefficient and laborious ESG reporting and research processes, dissatisfaction with the accuracy and transparency of third-party ratings and performance analyses, and confusion and survey fatigue from the proliferation of Sustainability and ESG surveys and questionnaires. These challenges were recognized by a group of biopharma company and investor participants at the April 2018 Biopharma Investor Day Roundtable hosted by Roche in Basel, Switzerland, and planted the seeds for the Biopharma Investor ESG Communications Initiative (Initiative).

Since then, more than 30 senior executives from 13 biopharma and 14 investor companies have been involved in the Initiative, resulting in this Biopharma Investor ESG Communications Guidance 2.0.

The Initiative participants began by working toward agreement on a core pool of high-priority ESG biopharma topics that have been judged to be most relevant and important – often termed as most material[§] – to both the investment community and the biopharma sector. The Initiative also collected investor information requirements and needs for assessing corporate ESG strategy, governance, risks, opportunities, and performance. In addition, the sector-based high-priority topics and the Guidance recommendations were informed by the work of SASB (Sustainability Accounting Standards Board) and TCFD (Task Force on Climate-related Financial Disclosures).

Biopharma and investor representatives held a face-to-face dialog on three occasions: At the Biopharma Investor Day Roundtable on April 11, 2019, hosted by BlackRock in New York City and at two Biopharma Investor Workshops – July 9 and November 4, 2019 – hosted by the Rockefeller Foundation in New York City. An early draft version of the Guidance (Guidance 1.0) was circulated to Initiative participants and interested parties for comment in August 2019. After additional consultation, all insights and recommendations led to a set of guidelines, which are distilled into this Guidance 2.0. We will invite feedback on Guidance 2.0 from a broader audience to inform the next phase of implementation and development.

[§] See discussion in Annex III. Definitions

Annex III

DEFINITIONS

During the conversations among biopharma and investors, terminology and mutually agreed definitions were discussed. It was noted and accepted that different companies may use different definitions or terms, as long as the substance of what is reported is well communicated and explained. For clarity and consistency throughout this Guidance, it was agreed to follow the definitions outlined below. Each company will adapt these to its own terminology.

Biopharma

This Guidance's focal sector, comprising the range of pharmaceutical and biotechnology companies involved in developing, manufacturing and distributing human therapeutics.

Global Industry Classification System (GICS) that coincides with SASB Classification System: Healthcare > Pharmaceuticals and Biotechnology

Board

A body of elected or appointed members who jointly oversee the activities of a company or organization.

Some countries have two-tier Boards that separate the supervisory function and the management function into different bodies. Such systems typically have a "supervisory board" composed of non-executive Board members and a "management Board" composed entirely of executives. Other countries have "unitary" Boards, which bring together executive and non-executive Board members. In some countries there is also an additional statutory body for audit purposes. In the two-tiered system, "Board" refers to the "supervisory Board" while "key executives" refers to the "management Board." (G20/OECD Principles)³

ESG

ESG includes all environmental, social, and economic/governance (ESG) aspects of a company and is solely used in the Guidance. However, the term encompasses all labels used within companies, which may also be "sustainability," "corporate responsibility," or something similar.

Governance

Corporate governance involves a set of relationships between a company's management, its Board, its shareholders and other stakeholders. Corporate governance also provides the structure through which the objectives of the company are set, and the means of attaining those objectives and monitoring performance are determined. (G20/OECD Principles)³

For the purposes of this Guidance, ESG Governance is considered as a sub-set of Governance, following the same principles and guidelines.

Goals, Objectives and Targets

Goals, objectives and targets are often used interchangeably by companies. In this Guidance:

- A “goal” or “objective” is a high-level ambition set by the Board or by Senior Management.
- A “target” is a specific quantitative or qualitative outcome that translates a goal or objective into an action plan.

Materiality

In the U.S., the Security and Exchange Commission (SEC) has a legal definition of materiality, whereby “an omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote.” This matches the Financial Reporting Standards’ definition that considers information as “material” if, given its nature or magnitude, “omitting, misstating or obscuring it could influence investors’ decisions.”^{8,9}

As a result, in the U.S., materiality has a legal significance and any topic defined as material must be disclosed in the 10-K form that carries a potential securities law liability. Therefore, U.S.-

listed companies often characterize a narrower range of ESG topics as material in comparison to European-listed companies, or they may use another term such as “key,” “important,” or “relevant,” rather than “material.”

The objective of this Guidance, however, is the same for all biopharma companies — to define a set of ESG topics that have a *significant* impact on business performance and a substantial likelihood of influencing an investor’s decisions about the company not only today, but in the mid- to long-term as well. Certain ESG topics may thus be strategically relevant in a forward-looking manner even though they may not yet be “financially material.” Therefore, within this Guidance, we use the phrase “high-priority” ESG topics.

For the purpose of this Guidance, it was agreed that the phrases “materiality assessment” and “material topics” may be used informally to characterize a) the process of prioritizing topics for a given company, and b) the list of ESG-related topics that the process determines. However, the term “material” or “materiality” as used in this Guidance is not limited to the narrow U.S. SEC definition.

Annex IV

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About the Biopharma Sustainability Roundtable

The Biopharma Sustainability Roundtable is a sector-specific collaboration platform designed to help senior biotech and pharma executives drive their own Sustainability agendas forward. An annual cycle of events and programs addresses a wide range of environmental, social, and governance (ESG) topics, from strategy through governance, operations, and reporting. Executives and invited industry thought leaders come together in this unique context to explore Sustainability challenges and trends, examine cutting-edge industry topics, share best practices, and learn from each other. An annual two-day Biopharma Sustainability Roundtable is followed by a focused Investor Day, where Roundtable participants discuss Sustainability strategy and ESG performance with capital markets professionals.