



Biopharma Investor ESG Communications Guidance 4.0

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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 in mid 2018 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.

A facilitated sector-focused direct dialog between biopharma and investors

BUSINESS CASE

Research shows that companies that effectively manage their material Sustainability and ESG challenges deliver above-average long-term financial returns. However, corporates and investors alike share frustrations on several fronts, including misalignments on the most important sector-specific ESG topics; laborious ESG reporting and research processes; lack of transparency and uneven quality of third-party ESG ratings and performance analyses; and confusion and survey fatigue from proliferating Sustainability surveys and questionnaires.

INITIATIVE FOCUS

The Initiative provides a platform for engaging biopharma sustainability and investor relations executives, together with investors, in finding 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. It offers 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-focused collaboration network for senior biotech and pharma executives, with the aim of driving their Sustainability agendas forward. A core Working Group of biopharma companies leads the work, and a longstanding network of investor companies participates in the ongoing dialog.

Initiative sponsors since 2018 include Amgen, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Merck¹, Novartis, Pfizer, and Teva. Contributors include GlaxoSmithKline, Novo Nordisk, Roche, and Takeda. The High Meadows Institute² was a Strategic Partner until 2020, supporting the Initiative as a pilot for a broader Institutional Investor Industry Engagement program.

Investor participants to date include Aberdeen Standard, Acadian Asset Management, Allianz Global Investors, APG, BlackRock, Calvert, Chardan, Credit Suisse, Domini Impact Investments, EOS at Federated Hermes³, Fidelity, HSBC Asset Management, Manulife, Morgan Stanley, Novo Holdings, PGGM, Robeco, Rockefeller Capital, State Street, TPG Capital, UBS, Vancity, Vanguard, and Wellington Management.

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

2. The High Meadows Institute is a think tank and policy institute focused on strengthening the role of business leadership in creating a sustainable society. <https://www.highmeadowsinstitute.org/projects/institutional-investor-industry-engagement-project/>

3. EOS at Federated Hermes on behalf of its stewardship clients

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Introduction

The Guidance aims to contribute to effective, efficient and decision-useful ESG communications between biopharma companies and their investors. It has been developed by the Biopharma Investor ESG Communications Initiative (the Initiative).

The updated Guidance (version 4.0) distills the consensus developed by the Initiative participants around investor information needs for assessing biopharma ESG strategy, governance, risks, opportunities, and performance. It also reflects insights from an outreach and engagement process with key stakeholder groups, including major standard-setters, rating agencies and industry associations.

The ongoing contributions of a core working group of biopharma companies and a community of investors is driving the Initiative into its fourth year.

As voluntary and mandatory reporting standards and requirements on ESG and sustainability continue to develop, this Guidance provides a resource for the sector-specific lens that can be used by biopharma and investors, as well as policymakers, and standard-setting organizations.

An Investor Statement of Support accompanies this Guidance.

The expectation is 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 and investor-focused**
- **Outcome of biopharma-investor consensus-oriented dialog**
- **A resource and a primer, not a framework or standard**
- **Reflects best thinking**
- **Incorporates influences from SASB and TCFD**
- **Generally aligned with ongoing developments in the global ESG reporting landscape**
- **Validated and improved through use case experience**
- **Dynamic and evolving**

Using the Guidance

The Guidance serves as a resource guide to strategic thinking about biopharma-investor ESG communications and is not, nor does it aspire to become, a reporting standard or framework. It applies the sector-specific lens to ESG topics and recommends an approach on planning and delivering ESG communications from biopharma to investors.

The Guidance aims to:

- Help companies prepare and deliver efficient and effective ESG communications on strategy, governance, risks, opportunities, and performance in a decision-useful, comparable manner to the investor community.
- Help investors engage more effectively with biopharma companies on ESG.

Who can use the Guidance?

Biopharma companies

- That are publicly listed, and/or with external financial stakeholders, seeking guidance on the capital markets' ESG information needs.
- That are embarking on their ESG journey and need a primer on ESG thinking.
- That need to trigger internal company conversations on strategically relevant ESG topics with global implications.

Biopharma investors (asset owners and asset managers)

- Who are integrating ESG analysis into their investment decisions.
- Who want to become familiar with the biopharma sector ESG landscape.
- Who need to provide an ESG primer to biopharma companies they are engaging with.

The Guidance also aspires to contribute to the sector-specific work of policymakers and organizations developing globally applicable sustainability standards, such as the newly formed International Sustainability Standards Board (ISSB) and the European Financial Reporting Advisory Group (EFRAG).

What's in the Guidance

- Biopharma sector high-priority ESG topics
- Recommendations for ESG communications content
- Suggestions for the ESG communications process
- Examples of best thinking on sector-specific metrics
- Key insights from the biopharma-investor dialog
- Insights into relevant global ESG developments

Guidance Use Cases

“ A confirmation that we are on track with our strategic thinking on ESG.

“ A driver of influence and a resource base for standard-setters like SASB.

“ We used the Guidance as a major input for our recent materiality review.

“ Senior Management trusts the Guidance because it has been tested with peers and investors. So, it is a reliable educational tool, internally and externally.

“ We refer to the Guidance in engagements to demonstrate how alignment helps drive the industry’s collective, positive impact on society.

“ We have found the Guidance useful internally to educate colleagues across functions about how to effectively communicate to ESG stakeholders about our highest priority issues. This helps us collaborate with subject matter experts in the relevant disciplines to measure and report effectively on outcomes and impact.
- *Biopharma participants*

“ We use it as an example of what is being developed in the ESG space, particularly in engagements with small and mid-size biopharma that are beginners in ESG.

“ Provides flexibility to cherry-pick topics with varying levels of relevance for different companies and adds focus to our discussions, which is then integrated into our ESG analysis.
- *Investor participants*

In using the Guidance, keep in mind that the recommendations:

- Reflect a consensus on ESG communications best thinking that is 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, as well as furnish recommendations that can be adapted to a company’s own strategies and business context, not a ‘tick-the-boxes’ list of requirements.
- Provide a range of sector-specific 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.
- Encourage disclosure of robust, consistent ESG data and information that is relevant to the sector and to each company’s own high-priority ESG topics.
- Address what, how, and when biopharma companies should communicate high-priority ESG topics to the investor community.

Biopharma Sector High-priority ESG Topics

One of the first steps in the Guidance development was to determine a pool of high-priority ESG topics for biopharma that were important to companies and the investor community alike.

Biopharma and investors were separately asked to identify the high-priority – often termed material⁴ – 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 companies⁵. Topics included in the Sustainability Accounting Standards Board (SASB) Biotechnology & Pharmaceuticals Sustainability Accounting Standard (Annex IV) were taken into consideration as a baseline reference. The final list extends beyond SASB to include topics regarded by investors and biopharma companies as strategically relevant in a forward-looking manner, although not yet “financially material.”

Investor and biopharma representatives converged on a core list of 12 high-priority ESG topics for the biopharma sector (Figure I), acknowledging that each company will address these topics as appropriate for its business model and strategy.

When using the Guidance, this list of 12 ESG topics is indicative – with each company expected to assess its own priorities as appropriate for their business model and strategy, as well as their impacts and dependencies on capitals⁶. We foresee specific priorities differing across companies and investors. The list is 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. The importance of a given topic may also be driven by interactions and interrelations with other ESG topics.

Figure I: Shared High-priority ESG Topics for the Biopharma Sector



[‡] 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.

4. See discussion in Annex III. Definitions

5. The Biopharma Investor Day on April 11, 2019, hosted by BlackRock in NYC, and two Biopharma Investor Workshops, on July 9 and November 4, 2019, hosted by the Rockefeller Foundation in NYC

6. Natural, Social, Human, and Produced Capital as defined by the Capitals Coalition approach. <https://capitalscoalition.org/capitals-approach/>

Recommendations for ESG Communications Content

Recommended Structure of ESG Communications

After reviewing a wide range of existing reporting approaches and based upon initial discussions with the investment community, it was agreed that while there are useful components in many frameworks, none are entirely satisfactory nor do they serve every purpose on their own. Two approaches that were developed with significant input from the investment community – The Sustainability Accounting Standard Board (SASB) and Task Force on Climate-related Financial Disclosures (TCFD) (Annex IV) – 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 thinking 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 ESG information around five elements using a two-tiered approach

The five elements⁷ reflect core operational aspects of a company: Governance (Annex III), 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: Recommended Structure of ESG Communications



7. The structure is influenced by the TCFD, which names these elements “thematic areas”

Summary of ESG Communications Content

The Guidance provides recommendations for both “Cross-organizational” and “Topic-specific” descriptions. This approach responds to investor expectations for strategic high-level information

that provides context, and for robust supporting data. Figure III provides a summary overview of the information recommended for communication under each of the five elements. More detailed recommendations are provided for each of the five elements in the pages that follow.

Figure III: Summary of ESG Content Recommendations: What investors are looking for



Detailed Recommendations for ESG Communications Content

In this section, additional content recommendations are provided within the five elements – Governance, Strategy & Objectives, Risks, Opportunities, Metrics & Performance. Some recommendations are phrased as questions to help companies locate and frame relevant information from their existing reporting and disclosures.

The Guidance does not prescribe the information in

detail as 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.

First, address the five elements at the corporate level (cross-organizational discussion):

Cross-Organizational

GOVERNANCE

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

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?

Management's role:

- Where do ESG responsibilities lie within 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 publicly available and 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

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 used in developing the strategy?
- How are decisions made and communicated throughout 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

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.

Second, address the five elements for each of the high-priority ESG topics relevant to your business model (topic-specific discussion):

Topic-Specific

GOVERNANCE

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

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 executes the reporting process.
- 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 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 implemented or operationalized? Include metrics and data points to support commentary; describe performance review methods and resource allocation.

Topic-Specific

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 explain 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.

About Metrics for Biopharma High-priority ESG Topics

Basic considerations when thinking about metrics

Both biopharma and investor Initiative participants recognize that development of good metrics must be based on a solid conceptual and methodological foundation. The biopharma-investor dialog on metrics demonstrated consensus among participants about what is important to consider when designing metrics for ESG communications:

- Present the progress towards specific targets that are defined through your ESG strategy and objectives.
- Where possible, measure and present the impact that this progress has had on your business as well as on people and the environment (double materiality approach).
- Provide context around quantitative metrics that bring clarity of intent and strategic relevance.
- Consider incorporating forward-looking information with respect to enterprise value and impact on society, which provides the link to long-term performance and effectiveness of corporate purpose.

For well-defined topics, such as the amount of energy or water saved, measuring the progress against specific targets can be straightforward. For others, such as patient reach, more work is needed to arrive at meaningful ways to measure progress. Measuring and valuing impact is a field

where work has been proceeding for years. The recent flux in activity around ESG reporting and disclosure standardization has also increased interest in standardizing impact valuation. It is worth noting, that leading initiatives in this space are converging through systematic efforts to collaborate and combine knowledge, in parallel and even independently of developments in reporting standards. Pioneering work is also taking place on how to benchmark operations and measure and report on impacts in the context of ecological and social sustainability thresholds. Initiative biopharma participants engaged with key organizations that are involved in such work during the 2020 November Stakeholder Dialogs (The Capitals Coalition⁸, the Future Fit Business⁹, the Impact-Weighted Accounts Project at the Harvard Business School¹⁰, the Impact Management Project, now replaced by the Impact Management Platform¹¹, the Value Balancing Alliance¹²).

This section includes principles that help in the design of metrics (Table I) and examples of existing ESG metrics (Table II). A selection of relevant resources on metrics development per ESG topic is included in Annex II. With ESG regulation and standardization in flux, developing metrics remains dynamic and evolving, conceptually and methodologically on a global scale. The Annex will be updated regularly.

8. <https://capitalscoalition.org>

9. <https://futurefitbusiness.org>

10. <https://www.hbs.edu/impact-weighted-accounts/Pages/default.aspx>

11. <https://impactmanagementplatform.org>

12. <https://www.value-balancing.com>

Which principles to employ when designing metrics

Biopharma and investors agree that in developing biopharma ESG metrics, a set of criteria must be employed. These criteria are principles that guide selection, compilation and presentation of metrics

and draw on those of financial reporting and sustainability standards. While each company must weigh the selection and compilation of metrics according to their own priorities as appropriate for their business model and strategy, the biopharma-investor dialog led to a short list of fundamental principles (criteria) to guide the process (Table I).

Table I: Principles for selecting, compiling and presenting metrics

<p>Selection Principle</p>	<p>Highly prioritized (often termed Material)</p> <p>Select and prioritize those metrics and information that are of high priority for biopharma companies and investors alike. This includes metrics that go beyond strict financial materiality to address topics that substantively affect value creation or value destruction in the short, medium and long term.</p>		
<p>Compilation and Presentation Principles</p>	<p>Accurate</p> <p>Metrics and information sufficiently detailed to allow investors to adequately assess performance</p>	<p>Aligned</p> <p>Metrics and information clearly linked to targets and company business strategy, that address the 12 ESG high-priority topics and are being monitored and managed internally</p>	<p>Assurable</p> <p>Information with supporting evidence (records) that has been compiled following specific standards and principles; assurance verifies the information and the process for compiling it</p>
	<p>Comparable</p> <p>Metrics and information that allow comparison over time and comparison within (or even across) the industry</p>	<p>Consistent</p> <p>Metrics and information presented in a consistent manner from year to year, regarding principles, methods, practices and procedures. Changes should be highlighted, with information on how changes might have affected past performance data</p>	<p>Timely</p> <p>Metrics and information presented on a regular schedule and in time for investors to make informed decisions</p>

Examples of Metrics for the 12 High-priority ESG Topics

Table II: Examples of metrics for the 12 high-priority ESG topics

Elements that example metrics address:





G = Governance, **S&O** = Strategy & Objectives, **R** = Risks, **O** = Opportunities, **M&P** = Metrics & Performance

ESG Topic	Examples of what investors are looking for (not a comprehensive list)
 <p>Access to Healthcare and Medicine Pricing¹³</p>	<ul style="list-style-type: none"> G What is the oversight mechanism for “Access” and “Pricing”, especially from a company’s most senior governing body? G Describe how pricing methodology impacts compensation and incentives. S&O Address the “Access to Healthcare” strategy and “Pricing” strategy as well as their link to corporate strategy. S&O Describe the pricing methodology and how it supports corporate strategy. S&O Describe the global “Access” strategy that considers not only low- and middle-income countries (LMICs) but also underserved patients in middle- and high-income countries. S&O Describe the “Access” plan for each new product brought to market. R Describe your approach to future risks, particularly regarding “Pricing”. O Describe potential opportunities to break into new markets by developing and applying innovative “Access” strategies. O Describe potential upside opportunities created by removing specific “Access” or “Pricing” barriers. M&P Indicate number of patients reached with medical products, including information about the magnitude of the disease burden and the size of patient population. M&P Describe actions, initiatives and patient support programs that promote “Access” in global markets, not only LMICs. M&P Communicate pricing history and how changes are tracked over time.
 <p>Business Ethics, Integrity, and Compliance</p>	<ul style="list-style-type: none"> G Describe the governance over political spending. S&O Describe anti-bribery, anti-corruption, anti-competitive behavior approach, including marketing practices. M&P Describe anti-bribery, anti-corruption, anti-competitive behavior outcomes. M&P Describe outcomes related to ethical controversies, corporate political spending and accountability, corporate political lobbying. M&P Provide business conduct hotline statistics. M&P Find indicators to demonstrate systemic improvements and cause-and-effect relationships between behavior, culture improvement mechanisms, and outcomes.
 <p>Climate Change</p> <p>Tip: Consider this topic along with “Environmental Impacts” and “Pharmaceuticals in the Environment and Anti-microbial Resistance”</p>	<ul style="list-style-type: none"> R Describe how climate change considerations (risks and opportunities) are driving business strategy. O R Evaluate the transition and physical risks to facilities and operations due to climate change. S&O Describe how the company is preparing for short and mid-term sector-specific challenges. S&O Describe the response to minimize your carbon footprint. S&O Describe the strategic response and solutions related to sector-specific dependencies effects such as new disease patterns, shifts in disease geographic distribution, exacerbated health issues, shifts in vector populations, population displacement, antimicrobial resistance, etc. M&P

13. For 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.

Elements that example metrics address:

G = Governance, **S&O** = Strategy & Objectives, **R** = Risks, **O** = Opportunities, **M&P** = Metrics & Performance

ESG Topic	Examples of what investors are looking for (not a comprehensive list)	
 <p>Clinical Trials</p> <p>Tip: Consider this topic along with “Product Quality and Patient Safety”, “Access to Healthcare” and “Business Ethics, Integrity and Compliance”</p>	<p>S&O Describe the company’s approach to human rights, including informed consent and data privacy.</p> <p>S&O Metrics that demonstrate how diversity and inclusion is being incorporated in clinical trials, from description of relevant initiatives, to demographic data and equal representation of populations.</p>	<p>M&P Ethical treatment of enrolled patients before, during and after a clinical trial.</p>
 <p>ESG Governance</p>	<p>G Describe the Board’s oversight process.</p> <p>S&O Describe the structure of oversight committees and the process of governance communications.</p> <p>M&P Describe Board remuneration.</p>	<p>M&P Describe ESG integration into the executive compensation system, bearing in mind a typical three-to-five-year time horizon, and how this aligns with the investment cycle of a drug (typically between 10 and 20 years).</p>
 <p>Environmental Impacts</p> <p>Tip: Consider this topic along with “Climate Change” and “Pharmaceuticals in the Environment and Anti-microbial Resistance”</p>	<p>S&O Describe your environmental strategy and objectives addressing the use of natural resources (i.e., natural assets/ raw materials occurring in nature that can be used for economic production or consumption¹⁴).</p> <p>R Discuss how environmental risks have been assessed, and how such risks have been or can be addressed, including whether significant operations (such as manufacturing facilities) in environmentally stressed areas are involved (for example, water-stressed areas, operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value).</p>	<p>M&P Share of renewable energy use</p> <p>M&P Waste reduction and management</p> <p>M&P Water consumed and water discharge</p>
 <p>Human Capital Management</p>	<p>S&O Describe strategies for talent recruitment and retention.</p> <p>S&O Describe your diversity, equity, and inclusion (DE&I) strategy.</p> <p>M&P Employee turnover rates, voluntary and involuntary, with emphasis on context.</p> <p>M&P Gender pay equity</p> <p>M&P Training and career development</p>	<p>M&P Consideration of human rights issues relating to internal operations and supply chain are relevant and meaningful. Investors recommend explicit reference to the UN Guiding Principles on Business and Human Rights to guide due diligence¹⁵ and emphasis on major markets for the company and operations in high-risk countries.</p> <p>M&P Employee health & safety information in combination with a discussion on outcomes from relevant initiatives</p> <p>M&P Workplace stress and mental health-related issues</p>

14. <https://stats.oecd.org/glossary/detail.asp?ID=1740>

15. https://www.ohchr.org/documents/publications/guidingprinciplesbusinesshr_en.pdf

Elements that example metrics address:

G = Governance, **S&O** = Strategy & Objectives, **R** = Risks, **O** = Opportunities, **M&P** = Metrics & Performance

ESG Topic	Examples of what investors are looking for (not a comprehensive list)	
 <p>Innovation</p>	<ul style="list-style-type: none"> S&O Describe the innovation strategy of the company, specific to the business model O Opportunities related to value-based care O New business model development for products based on impact 	<ul style="list-style-type: none"> O Consideration of access to care (incl. social and environmental considerations) as part of the selection criteria for new assets M&P Actions, initiatives for meeting unmet need
 <p>Pharmaceuticals in the Environment and Antimicrobial Resistance</p> <p>Tip: Consider this topic along with “Climate Change” and “Environmental Impacts”</p>	<ul style="list-style-type: none"> S&O Describe activities to address pharmaceuticals in the environment (PiE), including antimicrobial resistance (AMR) if relevant to the business. R Product stewardship and risk management both internally and across the supply chain. 	<ul style="list-style-type: none"> R Discuss how the PiE-related risks, including AMR if relevant to the business, have been assessed, as well as how such risks have or can be addressed across the supply chain. O Discuss R&D efforts related to antibiotics development, if applicable.
 <p>Product Quality and Patient Safety</p> <p>Tip: Consider this topic along with “Clinical Trials”</p>	<ul style="list-style-type: none"> S&O Describe the product quality management system covering product, clinical trial, and patient safety. M&P Information on product recalls with context around the effect, for example what percentage of revenues do the recalls represent. 	<ul style="list-style-type: none"> M&P Product safety improvements M&P Facility certifications to quality standards
 <p>Risk and Crisis Management</p>	<ul style="list-style-type: none"> S&O Describe the mechanism for identifying emerging risks that could have an adverse effect on the company; assess a broad scope of risks, including systemic risks related to ESG (e.g. climate change, Antimicrobial resistance, biodiversity). R Describe the identification and management of risks related to cybersecurity and data privacy (for example, third-party vendors, ransomware, phishing attacks, network vulnerabilities, human error, or oversight, partner/client healthcare providers including hospitals or labs). S&O Describe governance and strategies related to the responsible use of AI throughout the value chain. 	<ul style="list-style-type: none"> R Describe risks and opportunities related to us of AI, for example in avoiding biases (R&D, clinical trials, commercialization). R Describe the assessment process for risks and opportunities in health-related crises, such as outbreaks and pandemics, given the growing concerns. Assess how such incidents could affect the business in both positive and negative ways, and whether the company's pipeline is subject to related risks of disruption or addresses areas of opportunity. O M&P Describe site resilience and preparedness in relation to extreme weather events that could adversely affect research, manufacturing, inventory, critical digital infrastructure, etc. (Link with the “Climate Change” topic.)
 <p>Supply Chain Management</p>	<ul style="list-style-type: none"> S&O Describe the supply chain code of conduct (or related policy, standard, contract) that outlines a set of working conditions, labor practices, environmental health and safety requirements, business integrity and fair competition practices for suppliers and contractors. R Process for identifying ESG risks in supply chain (may be integrated with enterprise risk management) 	<ul style="list-style-type: none"> M&P Designate the % of supplier sites audited, as well as findings and responses to specific issues identified by audits. M&P Process and outcomes of exercising appropriate level of due diligence in the supply chain (for example about environment, human rights, labor rights).

Suggestions for the ESG Communications Process

After a biopharma company has started compiling robust information on its highest-priority ESG 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 gain experience using this Guidance, the summary of ideas and suggestions outlined below will continue to be updated to reflect emerging best practices. There is no best one-size-fits-all approach, so these initial suggestions cannot fully address all situations. 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, inform strategy, and implement improvements.
- Investor presentations and roadshows: The Guidance can be used as a resource to ensure that ESG strategy and performance is part of the long-term value story.
- Quarterly investor calls and engagement discussions: The Guidance can be used to help the CEO and Board members develop a consistent narrative about the company's ESG strategy.
- One-on-one biopharma-investor engagement: The Guidance model can be used to organize and prepare for investment and stewardship discussions.
- Internal company engagement: The Guidance can be used as a tool to trigger internal company conversations on strategically relevant topics that may also become financially material in the mid- to long-term.

TIPS FOR ONE-ON-ONE ENGAGEMENT AND DISCUSSION WITH INVESTORS

- Proactively initiate 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 a single conversation addressing 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 that appear in the media or have been flagged by third-party raters. Disagreement with a third-party assessment is often appreciated if backed up with meaningful information

Additional Considerations

Regulation and Standardization of ESG

As the Initiative dialog has been progressing, an unprecedented rise in ESG policy and regulations is taking place around the world. Policymakers in major markets are defining what activities are considered sustainable, and are asking companies and investors to report how sustainable their activities are. Enforcing mechanisms are leading to a gradual tightening and alignment of sustainability reporting. At the same time, key sustainability and financial framework- and standard-setters are joining forces to update and align their methodologies. Of note is the desire for convergence and collaboration to achieve compatibility among initiatives. Key developments include:

- In November 2021, the International Financial Reporting Standards Foundation (IFRS Foundation) announced formation of the International Sustainability Standards Board¹⁶(ISSB), and consolidation with the Carbon Disclosure Standards Board¹⁷(CDSB) and the Value Reporting Foundation¹⁸, which houses the Integrated Reporting Framework and the SASB Standards. The ISSB is tasked with developing global sustainability standards for corporate reporting that relies on the technical expertise and existing content of the VRF and the CDSB.
- In Europe, the European Commission launched the EU Taxonomy to define what activities are considered sustainable. EU companies will need to report on the sustainability of their activities as per the proposed Corporate Sustainability Reporting Directive¹⁹(CSRD). The regulation will affect EU subsidiaries of multinational companies that fall within the CSRD

scope. The CSRD introduces the adoption of EU sustainability reporting standards, that will begin to roll out by the end of 2022. Technical work is carried out by the European Financial Reporting Advisory Group²⁰(EFRAG), taking into consideration existing standards such as GRI, and staying aligned with initiatives like those of the ISSB. Asset managers will also need to report on the sustainability of their products as per the Sustainable Finance Disclosures Regulation (SFDR²¹).

- In the U.S., the Securities and Exchange Commission has been signaling that new and updated ESG disclosure guidance, expected in 2022, will increase demands on companies to disclose more and better ESG information, with references to standards such as SASB and the TCFD.

The sector-specific view and the importance of defining material ESG topics and metrics with an industry focus is a common theme in all evolving methodologies.

As this Guidance release is being written, there is another significant development underway for biopharma – investor ESG communications. The Value Reporting Foundation is reviewing and researching metrics from the SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard for a potential revision. The Initiative Working Group has been engaging with SASB staff since the launch of the Guidance 2.0 in April 2020, to provide input on the current Standard’s metrics and insights from ongoing biopharma-investor dialog.

16. <https://www.ifrs.org/groups/international-sustainability-standards-board/>

17. <https://www.cdsb.net>

18. <https://www.valuereportingfoundation.org>

19. https://ec.europa.eu/info/business-economy-euro/company-reporting-and-auditing/company-reporting/corporate-sustainability-reporting_en

20. <https://www.efrag.org/Activities/2105191406363055/Sustainability-reporting-standards-interim-draft>

21. https://ec.europa.eu/info/business-economy-euro/banking-and-finance/sustainable-finance/sustainability-related-disclosure-financial-services-sector_en

Digitization of ESG Communications

Technology is enabling and driving the digitization of ESG communications.

In the short term, regulators are already asking for corporate ESG data and information in digital form, and investors prefer reporting formats that are compatible with their assessment dashboards.

As an example, XBRL²² is an open standard for digital corporate reporting mainly used for financial, performance, risk and compliance information, but is also applicable to other types of reporting.

The SEC already requires numbers and footnotes in financial statements to be tagged in iXBRL format, whereby companies prepare a single document that is both human-readable and machine-readable.

As part of its digital strategy, SASB has developed a “SASB Standards XBRL Taxonomy”²³ towards making digital reporting easy for issuers, and data aggregation and analytics easy for investors.

The European Commission’s proposed Corporate Sustainability Reporting Directive imposes reporting in a single electronic reporting format, with digital tagging of information. The reported ESG/Sustainability data and information will be accessible through the European Single Access Point (ESAP)²⁴, a single point of access to public information about EU companies and investment products, expected to be established by 2024.

In the longer term, technology-enabled ESG reporting will begin to bring real world data to the user of ESG information with artificial intelligence and machine learning tools. As natural language processing capabilities advance, processing and analyzing large amounts of natural language data will allow unstructured corporate ESG data to be structured

and delivered in an efficient, effective and decision-useful way to audiences, including investors. This will potentially enable real time assessment of corporate ESG performance year-round, fundamentally changing the format and impact of ESG communications.

Professionalization of ESG Accounting and Reporting

Rising ESG regulation is creating a domino effect for more and better corporate ESG communications. Mandatory ESG disclosure standards can create the conditions for improved reporting, but do not guarantee the quality, accuracy and reliability of the reported information. This shift requires the professionalization of ESG that begins inside a company.

Key elements include top management commitment, establishment of appropriate governance and controls over the flow of ESG information, and setting up processes of measurement, accounting and reporting of ESG information. Applying a similar control framework to that used for a company’s financial reporting should result in strong ESG communications. In addition, a conclusion or an opinion about ESG reporting and controls by an external independent third party, such as an auditor or accountant, can enhance the reliability of reported ESG information. The terms assurance and attestation are terms used in relation to the audit of sustainability reporting with the term “assurance” more widely accepted.

While there is no commonly agreed approach or standard for the assurance of sustainability/ESG reporting, some resources have been developed by professional accounting bodies to guide accounting professionals in assurance engagements:

22. <https://www.xbrl.org>

23. <https://www.sasb.org/blog/sasb-standards-xbrl-taxonomy-now-available-for-public-use/>

24. https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/211125-capital-markets-union-package-esap-factsheet_en.pdf

- The ISAE 3000²⁵, first published in 2005 and revised in 2013 by the International Auditing and Assurance Standards Board. The ISAE 3000, titled ‘Assurance Engagements Other Than Audits or Reviews of Historical Financial Information’, is a standard providing guidance in the form of basic principles and essential procedures for professional accountants on how to conduct assurance engagements other than audits or reviews of historical financial information. The standard is often used for Sustainability/ESG reporting assurance.
- AICPA’s Guide: Attestation Engagements on Sustainability Information (Including Greenhouse Gas Emissions)²⁶ to assist Certified Public Accountants in the U.S. with interpreting and applying the attestation standards (SSAE No. 18) when performing examination or review engagements on sustainability information.

Certification bodies also provide similar services to companies, using their own proprietary protocols and procedures to audit ESG/Sustainability information.

It is anticipated that the development of ESG disclosure regulations and standards will also drive the convergence of methodologies for the auditing and assurance of ESG reporting. Already, the European Commission’s proposed CSRD imposes an audit requirement to sustainability information included in company reports. Relevant guidance is expected in the final Directive document.

Regardless of local assurance requirements, however, companies will need to ensure they have the processes and controls in place to produce robust and timely ESG communications. Auditing the information will provide an additional layer of comfort and trust to ESG information users.

25. <https://www.iaasb.org/publications/international-standard-assurance-engagements-isae-3000-revised-assurance-engagements-other-audits-or-0>

26. <https://www.aicpa.org/cpe-learning/publication/attestation-engagements-on-sustainability-information-guide-including-greenhouse-gas-emissions-information-OPL>

Key Insights from Biopharma-Investor Dialog

This section provides insights from our company-investor dialog to date, focused on what investors say they look for when researching and engaging with biopharma companies regarding ESG practices and performance.

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 avoidance perspective still dominates investors’ approach. There is, however, a growing interest in using ESG-focused strategies to create new opportunities through innovation and market growth.
- Investors have multiple internal groups with differing information needs and interests for ESG data and information:
 - » Most 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 longer-term qualitative and strategic information from corporate boards on how high-priority (or material) ESG priorities are determined, integrated into corporate strategy, monitored, and incentivized.
 - » Active asset management or asset owner teams have a range of strategies to decide which company is worth investing in, from exercising exclusion criteria to looking for evidence of ESG integration and positive social or environmental impacts, such as helping improve access to healthcare.
- Investors do not have a prescribed or preferred methodology for company materiality assessments, but they do want to understand each company’s prioritization process, and 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

PROPRIETARY INVESTOR METHODOLOGIES

- Large investors rely on their own proprietary ESG assessment methodologies for decision-making and draw on a number of information sources. The most important sources are public performance data and direct communications from and with the company.
- There is no generally accepted common 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 their own pre-defined sector-priority topics.

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 substantially, reflecting both the wide range of metrics used and target audiences served, highlighting the challenge for investor analysts.

- Third-party ratings, rankings and indexes cited by investors include, but are not limited to:
 - » The Access to Medicine Index (ATMI), noted as the only third-party resource focused specifically on “Access” despite concerns about its methodology; the Carbon Disclosure Project (CDP).
 - » ISS ESG, MSCI ESG (particularly for aggregate controversy data), Sustainalytics.
 - » Bloomberg, for public information and tools to analyze data and spot trends.
 - » Glass Lewis, for proxy information relevant to current votes.

TOPIC SPECIFIC: QUALITY AND DEPTH ARE 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 the objectives or targets set.
 - » Metrics to enable reporting progress towards objectives or targets, including a discussion of the specific outcomes that the company is trying to drive.
 - » Performance and learning from experience over time, not snapshot data.
 - » Robust data points, linked to strategy, risk, and value creation.
- Investors and companies alike are encouraged to consider the interrelations between ESG topics, and how this could affect longer-term business strategy. For example, supply chain and anti-microbial resistance, or climate change risk and neglected diseases.

Insights from investors about company ESG reporting

- Investors favor information from direct company disclosures, which may appear in many forms: Financial/Annual Report, Sustainability/CR Report, 10-K, 20-F, 10-Q, company policies, country sustainability and ESG reporting obligations (e.g., from the proposed Corporate Sustainability Reporting Directive expected to be negotiated into law by mid-2022²⁷, or from Securities and Markets Authorities regulators like the SEC’s expected Guidance on ESG disclosures).
- Investors use indirect ESG corporate data and information from third parties, such as from raters, as an auxiliary input to their own assessments.
- Quality wins over quantity. Clear, concise, easily accessible information focused on high-priority topics is preferred to detailed storytelling without strategic context.
- Investors are in favor of integrated reports, and the International Integrated Reporting Council (IIRC)²⁸ is viewed by many as the most relevant reporting framework.
- No single framework is considered to be the definitive authority on ESG disclosure. SASB (Annex IV-1) and TCFD (Annex IV-3) are useful because they are investor-focused; GRI²⁹ because it compartmentalizes information and addresses a wider audience.
- Investors favor proactive responses to issues that affect company reputation, 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.

27. https://ec.europa.eu/info/business-economy-euro/company-reporting-and-auditing/company-reporting/corporate-sustainability-reporting_en#review

28. INTERNATIONAL <IR> FRAMEWORK. International Integrated Reporting Council. February 2021. <https://integratedreporting.org/wp-content/uploads/2021/01/InternationalIntegratedReportingFramework.pdf>

29. Global Reporting Initiative (GRI) Standards. <https://www.globalreporting.org/standards>.

Insights from investors about ESG in the boardroom

- Investors do engage with Board directors and look for alignment between the company's ESG messaging and the Board's understanding and perspective.
 - Investors expect to find biopharma sector ESG expertise among the directors of the Board.
 - During engagement with or assessment of a company, investors will look for an ESG strategy that comes top down from the Board, rather than being isolated or siloed in functional departments.
 - Investors want to know how ESG is embedded in the Board oversight process.
 - Investors want to know how ESG is integrated into the overall business strategy and how it supports the company's long-term sustainable value creation objectives.
 - Attention to Board composition and diversity is growing.
 - Investors are increasingly looking at whether and how compensation is tied to ESG objectives.
- Investors are interested in how compensation models link incentives and performance outcomes with ESG objectives at all company levels, from Board and top Management team to mid- and lower executives.
 - Investors prefer concise metrics that can fit into their analysis models, but also need contextualization with qualitative information.
 - For further insights into what type of metrics and narrative investors look for around the high-priority ESG topics, see the relevant section on pages 17-19.

Insights from investors about ESG metrics

- Investors emphasize that arriving at meaningful and decision-useful ESG metrics begins by setting the appropriate ESG mid- and long-term ambitions at the Board level.
- Investors are looking for year-to-year progress against targets, while recognizing that 3-to-5-year trends might be more appropriate in demonstrating progress for some ESG topics.
- Cumulative data is not decision-useful without the context of historical data when trying to understand systemic improvement over a number of years.
- Impact metrics are of growing importance for assessing long-term performance.

Biopharma Investor ESG Communications Initiative Participants

CURRENT BIOPHARMA WORKING GROUP

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Investor participants to date include Aberdeen Standard, Acadian Asset Management, Allianz Global Investors, APG, BlackRock, Calvert, Chardan, Credit Suisse, Domini Impact Investments, EOS at Federated Hermes*, Fidelity, HSBC Asset Management, Manulife, Morgan Stanley, Novo Holdings, PGGM, Robeco, Rockefeller Capital, State Street, TPG Capital, UBS, Vancity, Vanguard, and Wellington Management.

BIOPHARMA SUSTAINABILITY ROUNDTABLE

For more information about the Initiative and this ESG Communications Guidance, or to offer additional feedback, please contact the Biopharma Sustainability Roundtable team through the website (biopharmasustainability.com) or by email (info@biopharmasustainability.com)

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WORKSHOPS & INVESTOR DAY HOSTS

Thanks to BlackRock for hosting Investor Day on April 11, 2019, and the Rockefeller Foundation for providing the venue for our Biopharma Investor ESG Communications Workshops #1 and #2 on July 9 and November 14, 2019.

*EOS at Federated Hermes on behalf of its stewardship clients

ESG COMMUNICATIONS INITIATIVE SUPPORTERS SINCE 2018

SPONSORS



PARTICIPANTS



STRATEGIC PARTNER



WORKSHOPS & INVESTOR DAY HOSTS



ORGANIZER



This Guidance 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.

Annex I

About the Guidance development

The Challenge

Academic research (Annex IV-5 and 6) 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 ESG information companies should disclose and how it should be structured for communication to the capital markets, particularly at a sector-specific level. Furthermore, 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 Roundtable and Investor Day hosted by Roche and UBS in Basel, Switzerland, and planted the seeds for the Biopharma Investor ESG Communications Initiative.

To date, close to 100 executives from a wide range of biopharma and investor companies have participated in interviews, discussions, and workshops. The Initiative has progressed through eight biopharma investor face-to-face meetings; seven one-on-one investor interviews with ESG and biopharma sector experts; a stream of feedback from a larger pool of investors and companies; a series of key stakeholder conversations; and benefited from the ongoing contributions of a core biopharma Working Group.

Introspection: Mid 2018 to early 2020

Work began building consensus on what ESG information from biopharma companies should be communicated to the capital markets, and how it could be most usefully structured.

One of the first steps was to define a pool of key ESG topics for the biopharma sector that were important to companies and the investor community alike. Biopharma and investor working group members 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 compared and discussed during three working meetings between the investor community and biopharma companies: the Biopharma Sustainability Investor Day on April 11, 2019, hosted by BlackRock in NYC, and two Biopharma Investor Workshops on July 9 and November 4, 2019, hosted by the Rockefeller Foundation in NYC.

Investor and biopharma representatives converged on a core list of 12 high-priority ESG topics for the biopharma sector, acknowledging that each company will address these topics as appropriate for its business model and strategy. An early draft version of the Guidance (v1.0) was circulated to Initiative participants and interested parties for comment in August 2019. The insights and recommendations led to a set of guidelines, which were distilled into the Guidance 2.0, launched publicly in April 2020. A companion Investor Statement of Support was released at the same time.

Outreach and engagement: From mid 2020 to present

Starting in mid 2020, the Initiative expanded the dialog beyond biopharma companies and investors.

A series of key Stakeholder Dialogs was organized in November 2020 to seek feedback on the 12 high-priority ESG sector topics and gain insights into the conceptual and technical work that is taking place around metrics:

- Framework and Standard Setters, on November 2, 2020, with input from the Capitals Coalition; the European Financial Reporting Advisory Group (EFRAG); the International Integrated Reporting Council (IIRC); the Impact Management Project (IMP); the Harvard Business School Impact-Weighted Accounts Initiative; SASB; the Value Balancing Alliance (VBA); and the World Economic Forum's Measuring Stakeholder Capitalism Project. A more extensive engagement process was carried out for SASB in particular, as a key organization preferred by investors and the only one with a sector-specific standard.
- ESG rating organizations, on November 9, 2020, with input from the Access to Medicine Foundation, S&P Global DJSI, Morningstar/Sustainalytics, and ISS ESG (Oekom).
- Industry Associations, on November 17, 2020, with input from the Biotechnology Innovation Organization (BIO), the International Federation of Pharmaceutical Manufacturer's and Associations (IFPMA), and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

A focused engagement with SASB (now the Value Reporting Foundation) was initiated. Identified by investors as a leading standard-setter, they are also the only one to already have a biopharma sector-specific standard. An outreach effort to put the Guidance to work in support of executive teams and corporate boards seeking to address ESG-related questions led to a collaboration with Chief Executives for Corporate Purpose (CECP). On June 7th and 8th 2021, nine biopharma CEOs presented their long-

term plans at the first sector-specific Biopharma CEO Investor Forum³⁰, reaching an online audience of nearly 1,000 participants. A joint report, Integrating Sustainability and Long-Term Planning for Biopharma³¹, and a companion Practitioner's Guide³² were prepared to facilitate collaboration among the sustainability, investor relations, and corporate communications teams supporting the CEOs as they planned for the Forum.

Metrics deep-dive

Following the launch of the Guidance 2.0, Initiative participants set out to discuss metrics for the 12 high-priority ESG sector topics. Biopharma and investors were asked separately to provide feedback on metrics for each high priority topic, and were encouraged to suggest or refine existing, or propose alternative, metrics per their professional expert judgement. The views of each group were consolidated for review and discussion at a Initiative Working Group meeting on March 8, 2021. The dialog revealed the state of play for existing metrics and highlighted areas where appropriate conceptual models still need to be developed. The outcomes were collected in an interim internal work-in-progress update of the Guidance (v3.0) for Initiative participants and contributors.

Guidance 4.0

The Initiative continued work throughout 2021 to address global developments and evolve the Guidance towards this updated public version release. In view of ongoing developments in the ESG policy and reporting landscape, work focused around reaffirming the 12 ESG high-priority topics and the Guidance recommendations, examining linkages to metrics resources that reflect current best thinking, and validating and improving the Guidance with use case experience from biopharma and investor Initiative participants.

30. <https://biopharmasustainability.com/biopharma-ceo-investor-forum/>






31. https://biopharmasustainability.com/wp-content/uploads/CECP-BSRT_Integrating-Sustainability-Report_15Mar2021.pdf

32. https://biopharmasustainability.com/wp-content/uploads/BSRT-CECP-Connection_final.1-102020.pdf

Annex II

Relevant Resources for Metrics Development

A selection of relevant resources on metrics development per ESG topic is included here. With ESG regulation and standardization in flux, developing metrics remains dynamic and evolving, conceptually and methodologically, on a global scale. The Annex will be updated regularly to keep these resources current.

ESG Topic	Relevant Resources
 <p>Access to Healthcare and Medicine Pricing³³</p>	<ul style="list-style-type: none"> ◇ Access to Medicines Index ◇ Accounting for Product Impact in the Pharmaceuticals Industry Working Paper by the Harvard Business School ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018 ◇ Sector-Specific SDG-related Metrics for Corporate Reporting by GISD Alliance, Section 4 - Healthcare (pages 17-19)
 <p>Business Ethics, Integrity, and Compliance</p>	<ul style="list-style-type: none"> ◇ Basel Institute: Measuring effectiveness of anti-corruption programmes: Indicators for company reporting ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018
 <p>Climate Change</p>	<ul style="list-style-type: none"> ◇ Financial Stability Board's Taskforce on Climate-related Financial Disclosures (TCFD), which has evolved into the global benchmark of voluntary and mandatory climate-related reporting guidelines ◇ Climate Related Disclosures Prototype and the Supplement: Technical Protocols for Disclosure Requirements by the Technical Readiness Working Group, chaired by the IFRS Foundation ◇ Climate Standard Prototype Working Paper by the European Financial Reporting Advisory Group ◇ Race to Zero ◇ Science-Based Targets Initiative
 <p>Clinical Trial Practices</p>	<ul style="list-style-type: none"> ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018
 <p>ESG Governance</p>	<ul style="list-style-type: none"> ◇ Enacting Purpose Initiative Report #2: Directors & Investors: Building on Common Ground to Advance Sustainable Capitalism ◇ Enacting Purpose within the Modern Corporation: A Framework for Board Directors ◇ Resources from the Good Governance Academy

33. For 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.

ESG Topic	Relevant Resources
 <p>Environmental Impacts</p>	<ul style="list-style-type: none"> ◇ CDP (for water risks) ◇ Future Fit Business Benchmark ◇ GRI Universal Standards ◇ Natural Capital Protocol ◇ Science Based Target Initiative (for climate change related emissions) ◇ Science Based Targets Network ◇ Taskforce on Nature-related Financial Disclosures
 <p>Human Capital Management</p>	<ul style="list-style-type: none"> ◇ SASB Human Capital Project ◇ SASB Human Capital Diversity, Equity & Inclusion standard-setting project
 <p>Innovation</p>	<ul style="list-style-type: none"> ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018
 <p>Pharmaceuticals in the Environment and Antimicrobial Resistance</p>	<ul style="list-style-type: none"> ◇ Antimicrobial Resistance Benchmark 2021 ◇ AMR Industry Alliance ◇ EFPIA work on Pharmaceuticals in the Environment ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018
 <p>Product Quality and Patient Safety</p>	<ul style="list-style-type: none"> ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018
 <p>Risk and Crisis Management</p>	<ul style="list-style-type: none"> ◇ Enterprise Risk Management: Integrating with Strategy and Performance by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) ◇ Applying Enterprise Risk Management to Environmental, Social and Governance-related Risks
 <p>Supply Chain Management</p>	<ul style="list-style-type: none"> ◇ The Pharmaceutical Supply Chain Initiative (PSCI) Principles for a full scope of metrics ◇ SASB Biotechnology & Pharmaceuticals Sustainability Accounting Standard, October 2018

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, see Annex IV-3).

ESG

ESG includes all environmental, social, and economic/governance (ESG) aspects of a company and is the sole term used in the Guidance. However, the term encompasses all labels used within companies, which may also include “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).

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 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.” (Annex IV-7 and 8)

As a result, materiality has a legal significance in the U.S. Material topics 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 compared to European-listed companies, or they may use another term such as “key,” “important,” or “relevant,” rather than “material.”

The financial reporting lens encourages disclosure on ESG topics, performance and impacts relevant to a company’s enterprise value; the multi-stakeholder lens includes ESG impacts that are not captured by enterprise value. While the Guidance is focused on investor needs for ESG information, the Initiative participants recognized that both approaches are inherently connected. This is captured in the definition of “double materiality,” a concept that is gaining ground as it underpins the European Commission’s evolving ESG policy and regulations for corporate reporting (CSRD and SFDR).

“Dynamic materiality,” yet another concept initially presented at the World Economic Forum in 2020, introduces the notion that ESG topics may become financially material over time as a result of the constantly changing “dynamic” conditions. In late 2020, a group of five leading standard-setting organizations³⁴ began work on a “building-block” approach to materiality (and value) metrics, seeking a corporate reporting process that brings

together the best of what their existing standards offer individually. The newly formed ISSB will be taking up this work and developing it along with its sustainability standards.

The different definitions of materiality create challenges for companies, especially for those listed in the US. 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 also in the mid- to long- term. Thus, 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 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.

Metrics

This Guidance reflects the common understanding during the biopharma and investor dialog that metrics for the 12 high-priority ESG topics can be both quantitative and qualitative.

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Annex IV

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About the Biopharma Sustainability Roundtable

The Biopharma Sustainability Roundtable (BSRT) is a sector-focused collaboration platform that works with senior biotech and pharma executives to help drive their Sustainability agendas forward. The BSRT facilitates a program of webinars and topical forums each spring, a sector-focused survey, and an annual conference in the fall, all addressing a broad agenda of ESG interests defined in collaboration with participants. Executives and invited thought leaders come together to explore sustainability challenges and trends, examine cutting-edge industry topics, share best practices, and learn from each other. The Roundtable also facilitates topical initiatives that engage participating biopharma companies and key stakeholders, such as the Biopharma Investor ESG Communications Initiative.

Learn more at www.biopharmasustainability.com