WHITE PAPER

How the health care industry can prepare for CSRD/ESRS

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We believe ESG reporting should be on every CEO's agenda, starting now. Faced with increasing ESG disclosure obligations, many companies will perceive this as a "compliance only" exercise. However, there is an opportunity to take a pragmatic implementation approach to ESG reporting which also acknowledges the strategic implications. With reporting requirements as early as FY2024, businesses should view the rapidly evolving landscape of ESG regulations as a driver for change.

The Corporate Sustainability Reporting Directive (CSRD) and European Sustainability Reporting Standards (ESRS) are considered the most stringent ESG regulations, which are likely going to result in the harmonization of ESG reporting in Europe. The regulator's demand for 100 disclosure requirements (DRs) will significantly increase the level and complexity of ESG-related data requirements for health care companies. CSRD/ESRS introduces heightened regulatory expectations with a strong focus on social topics, which extend beyond the health care industry's current focus on access to medicines and health care equity. Thus, a strategic approach is needed to tackle this evolving ESG reporting landscape.

The regulatory ESG requirements have advanced rapidly since the Paris Agreement in 2015, with an inevitable impact on the health care industry. Both CSRD and ESRS are driving the harmonization of sustainability data in the EU. While CSRD extends the Non-Financial Reporting Directive (NFRD), compelling significantly more companies to disclose comprehensive ESG criteria, ESRS addresses and formulates CSRD requirements for in-scope entities. Given the high level of complexity and the volume of ESG-related data requirements, these regulatory commitments will pose significant challenges for health care companies. The CSRD/ESRS extensive disclosure requirements oblige health care providers to not only adjust reporting processes, but also consider the impact on their current business strategy.

Presented with new, fast-approaching compliance obligations, health care companies should take a pragmatic implementation approach to ensure timely compliance. The resulting strategic impact of ESG reporting should then be considered accordingly.

Corporate Sustainability Reporting Directive (CSRD)

- Extends and strengthens the existing Non-Financial Reporting Directive (NFRD) as uniform sustainability disclosure standard
- Expands scope to include more companies than the NFRD and requires corporations to report on a wider range of sustainability-related issues
- Improves data availability on companies' sustainability risks and the effects of their activities on the environment
- Based on the principle of "double materiality", as introduced by the NFRD, obliges companies to report on how their business is affected by sustainability issues, and how their activities impact society and the environment
- Scope:
  - From 2024 onwards: large entities of public interest with more than 500 FTE already subject to the NFRD. First reporting in 2025 (on FY 2024)
  - From 2025 onwards: large entities which are currently not subject to the NFRD. First reporting in 2026 (on FY 2025)
  - From 2026 onwards: Listed small and medium-sized enterprises (SMEs) and small, non-complex credit and captive insurance undertakings. First reporting in 2027 (on FY 2026) with a postponement option to 2029 (on FY 2028)
  - Non-EU companies from other countries will also become subject to the CSRD if certain criteria are met

European Sustainability Reporting Standards (ESRS)

- Developed by the European Financial Reporting Advisory Group (EFRAG)
- Builds on CSRD requirements, and can be viewed as the operational guidance for companies
- Standards aim to synchronize underlying methodologies and therefore harmonize ESG reporting while also aligning with existing standards, e.g., the Global Reporting Initiative (GRI)
- ESRS covers 12 different standards (ESRS 1–2, E1–5, S1–4, G1), including climate change, biodiversity as well as social and governance
- Draft Delegated Act published by the European Commission allows
  - more flexible and voluntary disclosure of certain data points
  - phase-in of data points after the first year's disclosure
- Applies to companies within the EU and to non-EU companies, both as defined as per the CSRD

Growing urgency to prepare for CSRD/ESRS reporting

The deadline for CSRD/ESRS implementation is imminent

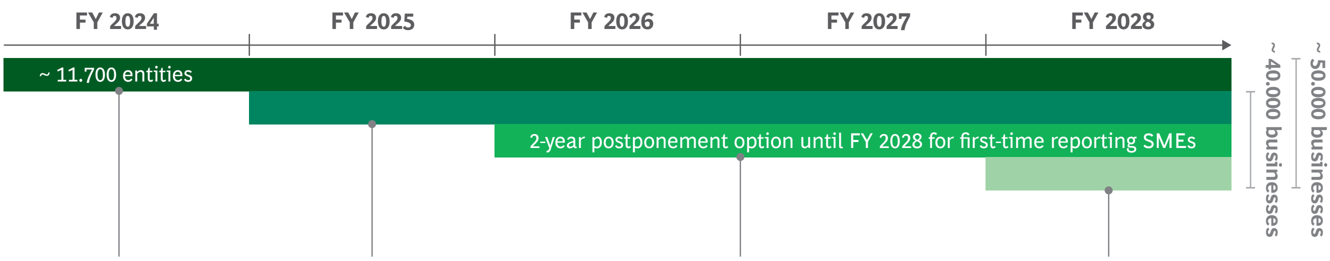
The deadline for the implementation of CSRD/ESRS is fast approaching, as the CSRD became effective from January 1, 2023 and was adopted in the Delegated Act 31st July 2023.

CSRD and ESRS will be implemented in multiple stages – first focusing on large public-interest entities, and later moving to cover small and medium-sized entities. For large public-interest entities already subject to the NFRD, the CSRD and ESRS requirements will apply from financial year 2024 onwards. For these in-scope entities, timely and accurate CSRD/ESRS reporting will be of significant strategic importance. It is vital, therefore, that such companies make immediate preparations for the 2024 requirements by devising and institutionalizing the relevant processes.

For other large entities that are currently not subject to the NFRD, reporting obligations will start a year later, with data to be captured for financial year 2025 onwards and initial reports to be prepared in 2026. Starting from financial year 2026, listed SMEs will also be required to report, but with an option to opt out until financial year 2028. In addition, EFRAG is planning to develop distinct and proportional standards for SMEs in the coming years.

Exhibit 1 - CSRD/ESRS will apply progressively to entities in the EU from Financial Year (FY) 2024 onwards

CSRD reporting requirements for in-scope entities (FY)



Large public-interest entities (PIEs)[1]:
- Including listed companies and other PIEs[1] only
- Reporting under NFRD
- With > 500 FTE

Large EU undertakings:
- Listed & unlisted companies
- Meeting at least 2 criteria:
  > 250 FTE
  > €25M total assets
  > €50M net revenue

Small and medium-sized EU enterprises (SME), which are also PIEs[1]:
- Listed SMEs and other PIEs[1] only
- Meeting at least 2 criteria:
  > 50 FTE
  > €5M total assets
  > €10M net revenue

Third-country undertakings (Non-EU companies):
- > €150M net revenue in EU
- Meeting at least 1 criteria: EU Branch (> €40M net rev.) AND/OR EU subsidiary

Complete DR Phase-in

All entities may omit reporting in the first year:
- Anticipated financial effects related to non-climate environmental issues (pollution, water, biodiversity, and resource use)
- Certain datapoints related to their own workforce (social protection, persons with disabilities, work-related ill-health, and work-life balance)

Entities with <750 employees may omit reporting:
- Scope 3 Emissions (E1-6) & DRs related to own workforce (S1) in the first year
- Disclosure Requirements for the first two years in the standards of Biodiversity (E4), Value-chain Workers (S2), Affected Communities (S3) and Consumers & End-users (S4)

Partial DR Phase-in

Source: BCG analysis.

Notes: CSRD = Corporate Sustainability Reporting Directive; FY = Financial Year.

[1]Public-interest entities include listed companies, as well as banks and credit institutions, insurance companies, and other companies designated by national authorities to be of public interest.

[2]Meeting thresholds considered to be a large undertakings or a SME undertaking.

CSRD/ESRS require a large amount of ESG data

The CSRD/ESRS regulations include granular qualitative and quantitative disclosure requirements across ten categories, covering all the dimensions of ESG – for example, climate change, pollution, and biodiversity for "E", workers in the value chain for "S", and business conduct for "G". The types of disclosure requirements that health care companies need to submit across all dimensions are consistent: including descriptions of policies, targets, action plans, transition plans and potential financial impact. The proportion of quantitative and quantitative disclosure requirements varies across dimensions and topics.

Assurance of CSRD/ESRS requirements must be effectively managed

With ESG requirements expanding rapidly, health care companies should be aware of the consequences if they do not comply. These could potentially include fines, legal consequences, or damage to reputation and business relationships.

The CSRD is a much broader than its predecessor directive the NFRD. It has introduced an audit requirement, for which health care companies need to prepare accordingly. This statutory audit requirement applies for three main reasons: 1) more companies are affected by CSRD; 2) the CSRD/ESRS regulations demand additional information; and 3) CSRD/ESRS requires limited (and in the future, reasonable) assurance on sustainability information when undergoing report auditing.

Exhibit 2 - CSRD/ESRS specifies qualitative and quantitative disclosure requirements across ten categories

Mandate to report full spectrum of E, S, and G topics in addition to cross cutting requirements

ESG topic areas from CSRD/ESRS	DR type[1]	Governance	Strategy	IRO[3] mgnt. (incl. Policies, Processes, Actions)	Metrics	General disclosures	Targets	(Sample of DR per topic, not exhaustive)	DR Metrics[2]
E	Climate change	✓	✓	✓	✓	✗	✓	• Gross Scopes 1–3 GHG Emissions • GHG removals and mitigation	5/12
E	Pollution	✗	✗	✓	✓	✗	✓	• Pollution of air, water and soil	3/7
E	Water & marine resources	✗	✗	✓	✓	✗	✓	• Water consumption	2/6
E	Biodiversity & ecosystems	✗	✓	✓	✓	✗	✓	• Impact metrics related to biodiversity and ecosystems	2/8
E	Resource use & circular economy	✗	✗	✓	✓	✗	✓	• Resource outflows • Resource inflows	3/7
S	Own workforce	✗	✓	✓	✓	✗	✓	• Social protection • Health and safety metrics	12/19
S	Workers in the value chain	✗	✓	✓	✗	✗	✓	• Policies related to value chain workers	-/7
S	Affected communities	✗	✓	✓	✗	✗	✓	• Processes for engaging with affected communities about impacts	-/7
S	Consumers & end-users	✗	✓	✓	✗	✗	✓	• Interests and views of stakeholders	-/7
G	Business conduct	✓	✓	✓	✓	✗	✗	• Payment practices	3/8
GR	ESRS 2	✓	✓	✓	✗	✓	✗	• Statement on due diligence	-/12

✓ DR required ✗ DR not required

#DR Metrics/ Total DR

Source: BCG analysis.

Notes: ESRS = European Sustainability Reporting Standards; CSRD = Corporate Sustainability Reporting Directive; DR = Disclosure Requirements.

[1]The overview shown represents a rough classification of Disclosure Requirements - within the categories, individual DRs can vary per topics.

[2]CSRD/ESRS contains 100 DRs of which 30 DRs of metrics type can be scoped out of reporting requirement through the information materiality filter in addition to the materiality filtering.

[3]Impacts, Risks, and Opportunities management.

The challenge of implementation for health care companies

One of the main challenges for health care companies is that CSRD/ESRS requirements have been written with a sector-agnostic lens in mind. In addition, due to development needed elsewhere, EFRAG recently decided to postpone its sector-specific standards and now plans to develop these under a "modified timetable". The absence of sector-specific standards for health care poses a challenge, as although health care companies have historically been aware of ESG topics, the current EFRAG disclosure requirements do not clearly align with healthcare terminology. A particular issue is common ESG healthcare social topics such as healthcare equity and access to medicines, which do not easily map to EFRAG's topic list. However, EFRAG does provide disclosure requirements in ESRS 2 (cross-cutting standards) for health care companies to report on legacy topics, if relevant policies, actions, targets and metrics associated with the topic are also disclosed.

It is anticipated that health care-specific standards will call for further disclosure requirements, and potentially some additional guidance on existing standards. That said, the current interpretation of standards is not likely to change significantly. As a result, health care companies should continue preparing their data-capturing capabilities and develop their initial report according to certain hypotheses. Luckily, health care companies do not approach the upcoming regulatory changes completely unprepared. We analyzed reported disclosure requirements of selected European health care companies and found that between 35–65% of the disclosure requirements required by ESRS were already reported in 2022, which is lower than other industries.

Key hypotheses for health care companies to consider when setting out their CSRD/ESRS reporting objectives

Health care companies need to integrate CSRD/ESRS requirements into their existing operating model. This involves not only strategy and steering, but also governance, risk management, as well as quantification and enablers. We have identified four critical hypotheses that health care companies will need to consider when incorporating CSRD/ESRS reporting into their target operating model:

1. **Drafting a transition plan: target disclosure requirements and how to reach them will go beyond climate to other environmental, social, and governance topics**

   As part of ESRS, health care companies should disclose time-bound transition plan, and provide a high-level explanation of how it will adjust their strategy and business model to ensure compatibility with the transition to a sustainable economy. Companies are required to state the target of global warming to 1.5°C in line with the Paris Agreement (or an updated international agreement on climate change). Moreover, companies need to present the target of achieving climate neutrality by 2050. Although CSRD/ESRS does not explicitly require companies to achieve the targets discussed above, companies are required to detail the investments and funding supporting the implementation of the transition plan to reach the targets. Influencing transition plan targets, including GHG emissions, biodiversity loss, and pollution, is often difficult for health care suppliers, who are dependent on complex supply chains with a limited number of suppliers. Thus, close relationships with suppliers will be key to enable transition plans for health care companies.

   Current CSRD/ESRS requires health care companies to now publish existing ESG targets externally. Although health care companies will not need to initially formulate new targets, with the increasing ESG momentum among other competitors in the market, it can be expected that this will lead health care companies to formulate new ESG targets; particularly in relation to non-climate CSRD topics such as biodiversity and ecosystems. These will need to be incorporated into strategies and processes and should be aligned to existing initiatives, such as Science Based Target Initiative.

Exhibit 3 - BCG ESRS Health Care Benchmarking of Pharmaceutical Players

Outside-in view

Assessment of Health Care CSRD/ESRS coverage

DR

	ESG topic areas from CSRD/ESRS	Peer 1	Peer 2	Peer 3	Peer 4	Peer 5
E	Climate change	3 / 3 / 6	2 / 3 / 7	3 / 2 / 7	6 / 3 / 3	2 / 9 / 1
E	Pollution	4 / 3 / –	5 / 1 / 1	1 / 2 / 4	7 / – / –	4 / 3 / –
E	Water & Marine Resources	2 / 2 / 2	1 / 1 / 4	2 / – / 4	2 / 3 / 1	1 / 5 / –
E	Biodiversity & Ecosystems	7 / 1 / –	1 / 3 / 4	4 / 4 / –	7 / 1 / –	8 / – / –
E	Resource use & Circular Economy	5 / 2 / –	4 / 2 / 1	4 / 2 / 1	6 / 1 / –	4 / 3 / –
S	Own Workforce	6 / 6 / 7	9 / 6 / 4	6 / 7 / 6	9 / 3 / 7	7 / 11 / 1
S	Workers in the Value Chain	1 / 1 / 5	6 / 1 / –	3 / 3 / 1	5 / 1 / 1	5 / 1 / 1
S	Affected Communities	2 / 2 / 3	5 / 2 / –	4 / 2 / 1	6 / – / 1	6 / 1 / –
S	Consumers & End-users	2 / 1 / 4	4 / 2 / 1	2 / 3 / 2	5 / – / 2	6 / 1 / –
G	Business Conduct	2 / 4 / 2	2 / 3 / 3	2 / 4 / 2	5 / 1 / 2	4 / 4 / –
GR	ESRS 2	1 / 4 / 7	1 / 4 / 7	1 / 5 / 6	1 / 9 / 2	1 / 6 / 5
	Total	35 / 29 / 36	40 / 28 / 32	32 / 34 / 34	59 / 22 / 19	48 / 44 / 8

Not covered / Partially covered / Covered

Insights

E

- All peers report in average 75% of Climate Change disclosure requirements
- Reporting among peers are lagging for resources use & circular economy

S

- ~At least 50% coverage of Social DRs in own work force across all peer
- Gaps pronounced in affected community

G

- All peers report at least 50% of Governance disclosure requirement except for one

GR

- All peers report on at least 90% of General Requirements disclosures

Source: BCG analysis.

Note: DR = Disclosure Requirements.

2. **Establishing governance and process structures: to institutionalize ESG reporting, ESG reporting structures need to be critically reviewed**

   For the implementation of CSRD/ESRS reporting, departments across the entire organization (including group sustainability, human resources, compliance, and finance) will be involved. In comparison to a fragmented and siloed approach by individual business units, views on all ESG topics from across the entire organization should be gathered. As the ESG landscape has evolved beyond climate for CSRD/ESRS reporting, sustainability teams will similarly need to enrich their current disclosure requirement ownership outside of Environmental topics towards a coordinated role including Social and Governance. A suitable governance structure which sees the Chief Sustainability Officer's responsibilities (or those of another similar-level executive) expanded across all ESG topics will be vital to manage the organization's reporting and allow for comprehensive steering.

   In addition, regulators are also moving towards integration of ESG reporting with current financial reporting processes, including associated auditing requirements. Hence, qualitative, and quantitative disclosure requirements provided in the ESG report will need to be traceable and verifiable across the organization. However, many companies currently rely on manual processes for ESG data acquisition and disclosure which are not aligned with financial reporting. Both finance and ESG reporting processes require inputs from all business operations; thus, integrating ESG into financial reporting is a key vehicle to ensure adequate quality.

   A close alignment between the Chief Sustainability Officer, the Chief Financial Officer and the rest of the Board will be required to ensure the strategic implications of CSRD/ESRS reporting are considered.

3. **Expanding data capabilities: to meet CSRD/ESRS requirements, companies should dramatically boost their IT capabilities**

   To fulfill CSRD/ESRS requirements, current IT capabilities will need to be significantly upgraded to create a holistic ESG perspective. Given the expectation of initially limited and eventually reasonable assurance requirements for CSRD/ESRS reporting, the traceability of data when reporting will be crucial. This is not dissimilar to the tagging of data currently required as part of the EU Taxonomy. Thus, companies will need to evaluate their current data and reporting capabilities to meet disclosure requirements.

   The initial starting point for evaluating data capabilities is to understand what ESG data is available, where it is being created and to what extent it is already managed in an IT system. Typically, an ESG report will contain data collected from many different IT systems. CSRD/ESRS data collection processes and IT systems landscapes should ideally follow the same structure and processes as financial reporting. There should be an established organizational structure, risk management and internal controls to support the reporting process, which will require workforce upskilling. Companies will also need to address data collection outside their own operations with the requirement for upstream and downstream value chain reporting. EFRAG acknowledges the complexity of collecting data outside of own operations, so associated disclosure requirement will be on a disclose or explain basis for the first 3 years of a company reporting.

Practical implementation: our recommended approach

To assess CSRD/ESRS readiness and build a future ESG reporting target picture, we suggest a four-step approach, which involves carrying out a gap analysis, conducting a materiality assessment, defining an implementation roadmap for execution, and introducing smart compliance.

Gap analysis to assess CSRD/ESRS readiness and develop a target picture

To assess CSRD/ESRS readiness and derive a clear view of the maturity of health care companies' ESG reporting, the latest sustainability report – if available – should be examined against upcoming CSRD/ESRS requirements. The aim of this analysis is to identify reporting gaps and to determine whether the current availability of data and the system landscape meet future CSRD/ESRS reporting requirements. For a first outside-in assessment, disclosure requirements can be systematically analyzed from an operations perspective and then cross-checked against published sustainability reports. After the initial gap assessment, health care companies should develop concrete measures to resolve potential issues. This would include devising internal and external system solutions to support ESG reporting across the value chain. To gauge readiness, the company should design a future governance model based on the ESG target picture and define an implementation roadmap.

Double materiality assessment

Health care companies are obliged to conduct a double materiality assessment, which can also be leveraged as a tool to capture stakeholders' perspectives on ESG. Furthermore, such an assessment can inform ESG strategies and indicate where future investment may be required. Introduced by the CSRD, the double materiality assessment involves reporting from two angles: how ESG-related issues affect the company; and how the company's own actions affect people and the environment. Due to the double materiality assessment criteria, health care companies may not need to report against all 100 disclosure requirements but can optimize the scope of their reporting strategically. However, given the analysis suggests many health care companies currently report between 35–65% of disclosure requirements, companies are still expected to need to significantly increase disclosure requirement reporting capabilities.

BCG has developed a proven approach to effectively conduct a double materiality assessment for CSRD/ESRS in-scope companies, which takes a strategic perspective to assessing the compliance requirements. First, draw up a shortlist of relevant ESG topics, based on EFRAG standards, market practices and distinctive characteristics of the client. Second, conduct a baseline quantitative and qualitative analysis using a materiality scoring tool, aligned to EFRAG guidance, to determine an initial materiality score for each ESG topic. Third, carry out a materiality survey and additional key stakeholder interviews to validate the materiality matrix. The last step of the assessment is to aggregate the stakeholder validation results with baseline analysis to produce the final materiality report. The assessment findings should inform the scope of material disclosure requirements required to be reported and inform the implementation roadmap for the coming years.

Implementation roadmap

With the evolving ESG landscape, BCG understands the importance of the relationship between ESG reporting regulations and company strategy.

A roadmap to implementation is recommended which takes a pragmatic approach to reporting readiness. The roadmap will detail how to enrich companies' current reporting capabilities, optimize reporting readiness based on disclosure timelines and future-proof against the evolving ESG landscape. Through the double materiality assessment and gap analysis results, companies can focus their reporting remediation effort on those topics and corresponding disclosure requirements most urgently in need of reporting, i.e. those material to the company and within own operations. Those disclosure requirements upstream and downstream of the value chain will only need to be published as a disclose or explain for the first 3 years of CSRD/ESRS reporting. Given health care players will need to start preparing for reporting as early as FY2024, optimising the effort required now is key.

The implementation roadmap will also consider reporting capabilities and synergies between ESG reporting and strategy. We recommend that companies characterized by complex organizational structures establish a matrix project organization that includes a strong central team and content owners. This matrix project organization would, for example, handle target setting and data computation in a consistent way across the group, ensuring harmonization between ESG reporting and strategy. An ESG committee should also be set up as the ultimate decision-making body and highest escalation authority for ESG issues. The committee should be supported by a coordination group that provides updates on ESG progress, as well as by a CSRD/ESRS steering committee that has the mandate to make rapid decisions based on reporting needs and to execute any relevant iterations.

Conclusion: anticipating requirements

To take advantage of the strategic opportunity presented by ESG reporting regulations, ESG should be a board-level topic. Building a relevant ESG strategy requires a clear understanding of ESG reporting, accounting for a holistic transformation, incorporating multiple stakeholders, technology, and data capabilities. A transformation of this nature is driven by impending reporting obligations but requires board-level initiation. ESG reporting readiness is the first building block towards an ESG strategy which drives company direction.

The complexity of CSRD/ESRS, ambiguity of individual value-chain disclosure requirements and continuously evolving disclosure requirements mean health care companies should start enabling ESG reporting readiness now.

Given the reliance of health care players on supply chains relationships, it is even more important for companies to begin liaising outside the value chain and anticipate additional requirements and commitments well in advance so that they are well prepared for any eventuality. To respond to the upcoming regulatory changes, companies will need to incorporate new ESG reporting requirements in their strategic approach by:

- Evaluating current reporting capabilities through gap analysis to determine how to meet future reporting requirements
- Conducting a double materiality assessment that strategically optimizes reporting scope
- Defining an implementation roadmap which prioritizes reporting disclosure requirements based on company capabilities

As financial disclosure requirements have long been an inherent part of board-level discussions, ESG reporting disclosure requirements will similarly become a cornerstone of company strategy. Boards that treat their ESG reporting targets with the same significance as financial metrics will not only minimize risk but drive company direction and value.

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