Integrating ESG Pillars for Business Model Innovation in the Biopharmaceutical Industry

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Abstract

The study explores critical factors that impact the Business Model of Biopharmaceutical firms and assess how ESG pillars can aid in Business Model innovation. Semi-structured personal interviews were conducted in face to face meetings with experienced industry professionals from cross-functional domains to attain diverse insights. The objective was to explore the relevance of ESG factors and their interplay, during Business Model Innovation from the perspective of experts in the Biopharmaceutical industry. Analytical Hierarchy Process (AHP) – a structured approach is applied to understand the criticality of various factors in sustainable business models. The study revealed that special emphasis should be laid on the Business Model and Governance Pillar – for re-designing innovative and sustainable business models. Social and Environment factors, although important, were rated lower on priority as such issues are usually focused upon by organizations at a higher level of maturity, after the basic hygiene factors are met. Some of the factors which were prioritized for Business Model innovation are Patient Health and Safety, Ethical marketing and advertising, Waste/ Effluent Management, Employee Health, Safety and Wellness, Patient value propositions, Building strategic resources and competencies, Product Quality & Safety and Business ethics and competitive behavior. Integrated reporting is another value-added dimension that was stressed by the respondents, to have a seamless and transparent communication channel established with all stakeholders. Aligning business metrics with ESG metrics is the focal point of this study, and the impact of each pillar on Biopharma Business Models was evaluated by industry experts. Integration of ESG parameters for Business Model Innovation is the new mantra for forward looking companies, and this study would help frame strategies for the Biopharma industry for sustainable value creation. The impact created by Business Model Innovation at an industry level will help create value for the society at large (who are the key beneficiaries of Biopharma products and services), and such studies would help add to the knowledge base.

JEL Classification: I14, L10, O32, M13

Keywords: Business Model Innovation, ESG Pillars, Biopharmaceutical Industry, Sustainability, Integrated reporting, Value based investing

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Introduction

As per the Sustainability Development Goals – Agenda 2030, formulated by United Nations, "Equitable Healthcare For All" is a key focus area to reduce the burden of life-threatening diseases. A pandemic like Covid-19 has further stimulated industry, government and nations to prioritize work in this direction. With the increasing levels of awareness among patients, customers, partners, investors, employees and society at large, Biopharmaceutical companies are being heavily scrutinized for their contribution towards ESG (Environment, Social and Governance) factors and the holistic impact created by the industry. Emphasis on ESG Pillars has found greater prominence in the Biopharma industry post Covid, as it depicted social inequality and disparity in access to essential medicines and healthcare facilities, amongst the privileged and underprivileged sections of society (Lee et al., 2020).

Biopharmaceutical organizations are often held to an unmatched standard regarding business profit and intent, although research, innovation and product development depend on it. Developing trust and a positive image is a crucial pathway to establishing the true/real value offered by biopharma companies to society at large, while also being accountable to stakeholders and investors (Reh et al., 2021).

Biopharmaceutical drug development is a high risk, high reward segment, which requires high upfront investment and companies to stay invested over a long period of time. Biopharmaceutical drug pricing is correlated with high development costs, which often impacts social sustainability factors like affordability and accessibility of drugs. Empirical studies done over the last two decades have focused on dimensions of financial sustainability, investments, risks, returns, technological innovation etc. However, recent studies have shown that globally, companies with a strong focus on "sustainable growth" tend to attract the highest funds from investors. Companies are ranked globally based on Sustainability Scores, based on their performance on the ESG parameters, and they are encouraged to report their Sustainability Initiatives and Scores through Integrated Annual Reporting (Bulik, 2021). A high ESG score has been found to have a positive impact on company valuations and is also positively co-related with investor funding decisions. (Bulik, 2021).

With global ESG standards being established for Biopharma, the companies need to lay added focus towards material dimensions impacting this industry with value-based initiatives and enhanced disclosures. They need to align their core values and decision-making framework in line with the sustainability efforts for attracting global, value-based investments. Hence, it's a strong need of the hour to integrate ESG Pillars with Business Model Pillars to attain long term value propositions for the industry (Greffet et al., 2022)**.**

Although ESG score is widely studied, ESG pillars and understanding its core elements in the Biopharmaceutical industry have not been widely reported in the literature. Therefore, a study on the influence of ESG pillars on the Business Model or business performance of firms is needed, considering that the impact of each ESG pillar depends on the sensitivity of the respective industry. (Baldini et al., 2016; Min et al., 2017). Wenzel et al., 2014 noted that "an increasingly competitive environment, reduced drug pipelines, multiple patent expiries and payers' increasing demands for outcomes-based evidence are all factors currently presenting challenges to the pharmaceutical industry".

Government regulations in the evolved markets are also being framed with a similar philosophy – wherein tenders or contracts are being awarded to companies with higher ESG scores and impact, while in the recent past, "Price" was always considered the main decision criteria.

This has been the fundamental motivation to conduct an exploratory study in the Biopharma industry – to evaluate areas where Business Model innovation should be targeted. The research questions that this study aims to answer are:

I. What are the critical factors impacting the business model of Biopharmaceutical firms?

II. What is the relative prioritization of these factors impacting the development of Biopharmaceutical business models?

III. How can the Biopharma industry innovate its business model framework by integrating ESG Pillars with Business Performance Pillars?

The study was conducted with Senior Management Professionals from the Biopharma industry, who have provided strategic insights about the unique challenges faced by this industry and suggested preferable areas to carve out innovative business models.

This research is structured as follows:

In the following Section 2, we have reported the Theoretical Framework, encompassing relevant theories. In Section 3, we elaborated on the research design and method of analysis. In Section 4, we reported the results and empirical findings. In Section 5, we have critically evaluated the findings. In Section 6, we reported on the implications of the study and further scope of research.

Theoretical Framework

Evolution of the Business Model Concept

"Business Model" is considered a complex concept, because of the ambiguity in its definition; also, there is no clear set of criteria for its classification. A business Model is a multi-dimensional construct that impacts the overall performance of a firm. Some of the commonly used definitions of a Business Model: "A methodological concept of how firms can generate and deliver values" or "a plan, tool or device for exploiting the economic value" (Osterwalder and Pigneur, 2005). Osterwalder and Pigneur, proposed a business model canvas, encompassing nine dimensions.

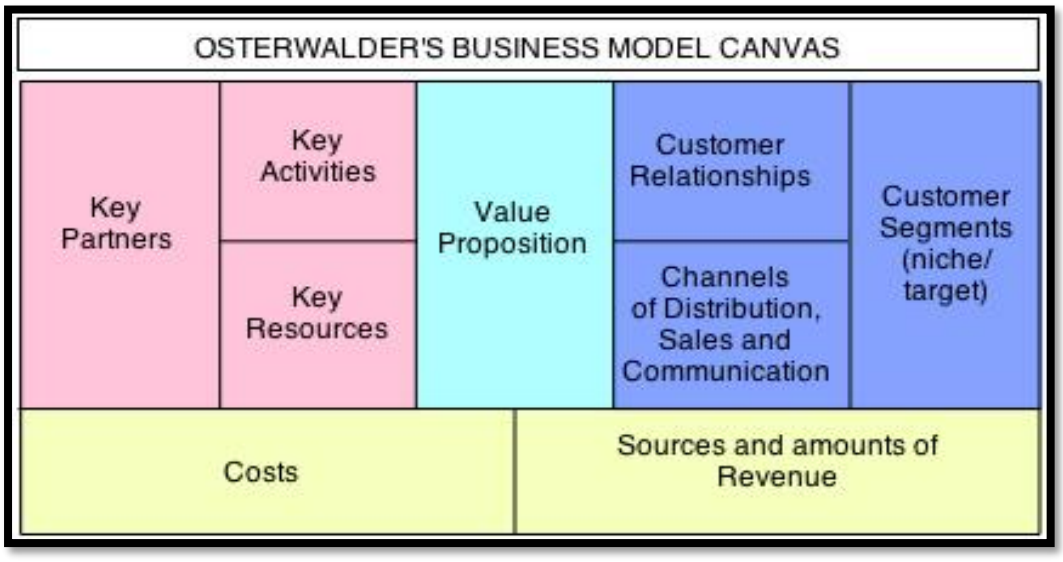

Figure 1: Business Model Canvas, Osterwalder and Pigneur (2005)

The nine building blocks are briefly described below:

I. Customer Segments: Market categorization and Customer segments

II. Value Proposition: "set of benefits or values" to satisfy customer's needs – could be a mix of quantitative and qualitative parameters

III. Channels: distribution, communication and sales channels

IV. Customer Relationship: engaging with the customer via personal relations

V. Revenue Streams: pricing decisions, revenue sources, capital/ financing options

VI. Key Resources: tangible assets, infrastructure, financial, intellectual or human capital

VII. Key Activities: key activities in the value chain

VIII. Key Partnerships: complementary alliances along the value chain

IX. Cost Structure: Spread of fixed and operational costs

Odyssey 3.14 Approach developed by Lehman-Ortega et al. (2022) further refined the concept of business models. They defined the three elements as: Value Proposition, Value Architecture and Profit Equation.

a. The value proposition offered by an organization includes its customers/clients, products/ services offered and the price at which it is offered.

b. Value Architecture defines how the value is delivered through the organizational value chain by developing the right resources and competencies.

c. The profit Equation measures the financial implication of this value by accounting for the revenue/sales, costs and capital employed.

Value Proposition and Value Architecture need to be well aligned to generate profit. Hence business Models are proving to be a valuable tool in strategic reflection. The value proposition in the Biopharmaceutical industry may have different implications for different stakeholders: Eg. Patients, healthcare professionals, Pharmacists, Caregivers, Insurance Providers etc. Hence Business Models must be designed considering their suitability and impact towards each.

Evolution of Business Models in the Biopharma Industry

During its inception years in the 20th century, Biopharma companies like Genentech and Eli Lilly adopted Fully Integrated Business Models (FIBCO), which focusses on end-to-end in-house development, manufacturing and commercialization of products (Song and Shin, 2019). All activities of the value chain were handled internally, thus ensuring maximum authority and control. Conventional business models based on operational role in the value chain were classified as: RIBCO (research intensive bio-pharma company), the technology platform model, NRDO (no research, development only) and FIBCO (fully integrated bio-pharmaceutical company) (Burns, 2005). Another classification of the Biopharma industry was based on level of business diversification into therapeutic product segment: eg. FIBCO (fully integrated bio-pharmaceutical company) and a platform and service segment, E.g. Custom Research Organization (CRO) and Custom Manufacturing Organization (CMO) (Casper, 2000)**.**

Drivers of business model performance in the Biopharma industry were studied, linking it to the life cycle management of a firm. Customer engagement, External linkages and Internal processes were classified as Static Drivers, while Strategic awareness and Reconfiguration capacity were categorized as dynamic drivers (Haggège et al., 2017). A systematic literature review done during the study of Business Models in the Biopharmaceutical industry, lead to identifying areas of opportunity for further development: "External Orientation, Learning capabilities, Cluster participation, Qualified management team, Organizational controls" (Downs et al., 2016).

Contemporary or Open business models, which emerged in the 21st century, focused on diversification and strategic alliances. Out-sourcing non-core activities became a key driver, emphasis was laid on finding the right partners across the value chain. Partnerships with NGOs, govt., competitors, or complementary service providers are the rising trend in the industry **(**Song and Shin, 2019).

Open business models studied in European Biopharma Industry over the last two decades have focused on collaboration and strategic alliances. Concepts like "Bundling", "Crowd-sourcing", "Virtual Collaboration", "Collaborative Discovery", "Patient Centricity", "Contract Mfg" etc were introduced in the industry (Horvath et al., 2019; Valerie Sabatier, Mangematin et al., 2010, 2012; Fisken & Rutherford, 2002). Studies have also shown that firms with hybrid business models (with a mix of internal and external focus) attract more investment because of their reduced risks and increased Return on Investment (Fisken & Rutherford, 2002).

Research done on American Biopharma Business Models established that investments in the U.S. were driven by sound capital markets and government-led research. External Research & Development strategies were found preferable. The Business Model Risk and Uncertainty framework was developed under I.P., portfolio, financial viability and business environment (Hagedoorna et al., 2012; Lazonick et al., 2011; Brillinger et al., 2019).

During the literature review, it was understood that the application of Sustainability concepts or decision-making frameworks in Biopharma Business Models, to address socio-economic challenges is limited. Biopharmaceutical Industry has the potential to contribute to this cause by innovating its Business Model in sync with the Sustainability Pillars.

Evolution of the ESG Concept

ESG factors have been referred to as the "three modern pillars" of Corporate Social Responsibility (Miralles-Quirós et al., 2018), while some studies conceptualized ESG as a parameter or score for evaluating a firm's CSR performance (Cheng et al., 2014). Thus, the association between ESG and CSR is well studied (Han et al., 2016; Nollet, Filis and Mitrokostas, 2016), and the concepts of CSR and ESG have well evolved over the last decade**.** According to (Nussbaum, 2009), CSR investment is not adequate to improve the marketing performance of a firm, especially in the pharmaceutical sector. Far-reaching changes in the business model may be necessary to make a substantial, long-term impact.

It is important to understand the trade-offs between Financial and ESG performance, as an investment in one typically implies a cost to the other (Eccles et al., 2013). Investment in ESG initiatives could mean the substantial deployment of funds in the short term to gain a long-term competitive advantage. Studies conducted in the recent past have evaluated how incremental innovation in any of the ESG issues can impact the financial performance of firms (Bhattacharya, and Sharma, 2019; López-Toro et al., 2021).

Contemporary business models have a strong impetus towards integrated reporting, stepping up from the narrow focus of financial reporting in traditional annual reports (Atkins et al., 2015). Value creation is the key Mantra in Integrated reporting – which requires disclosures around six capitals: natural, social, intellectual, financial, social and manufactured **(**IIRC (integratedreporting.org)**).** Integrated reporting could also be termed as an "outcome and part of reputational risk management processes" (Bebbington et al., 2007**).**

Research Design

The objective of this exploratory study was to understand the critical factors impacting Business Models in the Biopharmaceutical industry and assess how ESG pillars can aid in Business Model innovation. Innovation in business models can be scrutinized under three key lenses (Lehmann-Ortega et al., 2013)

a. Desirability: What is needed?

b. Feasibility: Does this work, or is it possible?

c. Viability: Will customers pay for it?

Source of Data for Base/Exploratory Model

Environment, Social and Governance factors and sub-factors relevant to the Biopharmaceutical industry were chosen basis the materiality map devised by Sustainability Accounting Standards Board (SASB). Sustainability Disclosure Topics and accounting metrics for Biotechnology and Pharmaceutical industry have been published by the Sustainable Accounting Standards Board-SASB (Gilman, and Schulschenk, 2012.**),** which serves as a guiding tool for companies in disclosing financially material information to investors, and ultimately aids various stakeholders in decision making. SASB's standard setting procedures are transparent and include procedural consultation with investors, companies and field experts. The materiality of an issue is evaluated through a robust process that examines "evidence of interest and evidence of economic impact" by surfing multi-dimensional source documents from respective industries, media reports etc. and by assessing whether management or mismanagement of an issue will impact financial parameters of a firm like revenue growth, return on capital etc.

Apart from SASB, there are multiple rating agencies with unique methodologies, metrics and tools to measure a company's performance on ESG material factors – it is a daunting task for organizations to choose the apt rating agency as the results and ranking may vary between one evaluator to the other (Pinchot et al., 2019). Novartis, considered a leader in the ESG segment, publishes its ESG rating and performance metrics by various agencies. (https://www.novartis.com/esg/reporting/esg-rating-performance).

Many prominent Biopharma companies, including Amgen, Bristol Myers Squibb, Merck, Johnson & Johnson, Novartis, Astellas, Bayer, Gilead, GSK, Novo Nordisk, Roche and Pfizer have collaborated together to form "Biopharma Investor ESG Communications Initiative", which developed the "Biopharma Investor ESG Communications Guidance 2.0". According to the Guidance, the following ESG topics should be prioritized by Biopharma companies: accessibility and affordability of medicines; business ethics, integrity, and compliance; environmental impacts; climate change; clinical trial practices; ESG governance; human capital management; innovation; waste disposal, antimicrobial resistance; product quality and patient safety; and supply chain management.

Business Model factors and sub-factors were derived from the base elements described in Osterwalder's Business Model Canvas (Osterwalder et al., 2005) and Business Model Innovation tools mentioned in Odyssey 3.14 Approach (Lehmann-Ortega et al., 2013)

Methodology

The following methodology was adopted for conducting this research:

Step 1: Designing the base model

A multi-dimensional base Model was designed using the ESG Pillars and Business Model Pillars, and a questionnaire was formulated to understand the prioritization of these factors during Business Model Innovation.

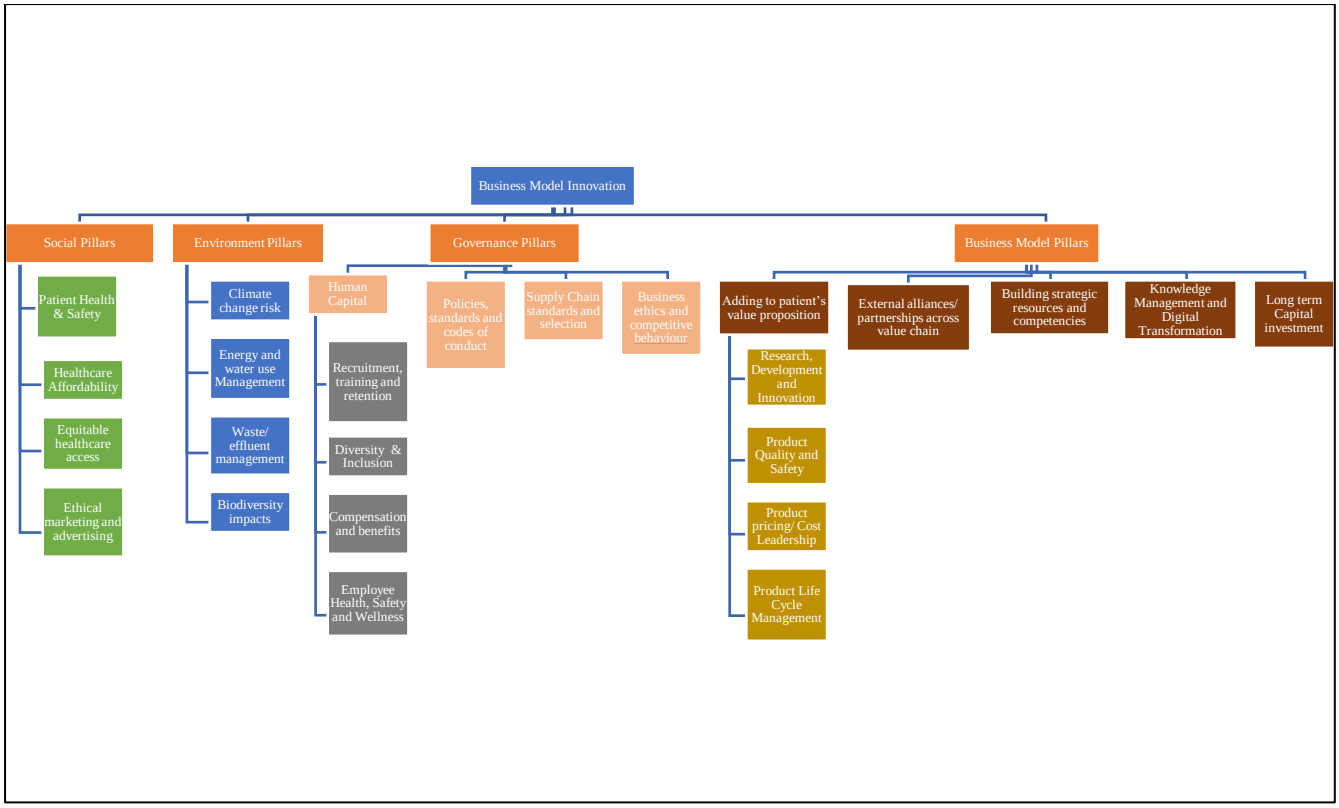

Figure 2: Base/exploratory Model for Business Model Innovation

The Four Pillars considered for the study are:

Table 1: Four Pillars for Sustainable Business Model Development in Biopharmaceutical Industry

S.No	Sub-Factors	Description
1.	Social Pillar	This pillar examines Patient Health and Safety, Affordability, Accessibility of Healthcare and Ethical Marketing and Advertising. (Gilman, K. and Schulschenk, 2012)
2.	Environment Pillar	This Pillar examines Climate change risk, Energy and Water use management, Waste/ effluent Management and Biodiversity impacts (Gilman, K. and Schulschenk, 2012)
3.	Governance Pillar	This Pillar considers Human Capital, Policies, standards and codes of conduct, Supply Chain standards and selection, Business ethics and competitive behavior (Gilman, K. and Schulschenk, 2012).

4.	Business Model Pillar	This pillar comprises of Research, Development and Innovation, Product Quality and Safety, Product pricing/ Cost Leadership and Product Life Cycle Management . (Gilman, K. and Schulschenk, 2012).

The Social pillar was further categorized into the following sub-factors:

Table 2: Social Pillars for Sustainable Business Model Development in Biopharmaceutical Industry

S.No	Sub-Factors	Description
1.	Patient Health and Safety:	The basic premise for the existence of healthcare companies is to cater to unmet medical needs and provide safe and efficacious drugs (Gilman, K. and Schulschenk, 2012)**.** The health and safety of clinical trial participants is a critical factors for successfully launching a product. Biopharma companies that effectively manage clinical trials, focus on diversity and inclusion, human rights and data privacy may be better positioned to enhance shareholder value through the revenue associated with new products (Reh et al., 2021). Information on product safety can often surface after the completion of clinical trials and regulatory approval. Biopharma companies that limit the incidence of recalls, safety concerns, and enforcement actions for manufacturing concerns may be better positioned to protect shareholder value (Biopharma Investor ESG Communications Guidance 2.0.).
2.	Healthcare affordability	Despite the long development lead time, high upfront investment and high risk – high return associated with new drug development; the Biopharma industry is under increasing pressure worldwide to provide affordable healthcare to the masses (Gilman, K. and Schulschenk, 2012)**.** Stakeholder expectations on health care cost containment and increased access will continue to exert downward pricing pressures on the Biopharmaceutical industry. As a result, companies that have relied on escalating drug Prices to cover drug development costs and maximizing profits may be challenged to enhance value by optimizing costs (Biopharma Investor ESG Communications Guidance 2.0.).
3.	Equitable healthcare access	Ensuring access to lifesaving medicines in underserved markets is a social cause that requires special initiatives from the industry to establish reach, develop infrastructure and enhance marketing channels/commercialization partners in underserved markets (Gilman, K. and Schulschenk, 2012)**.** Biopharma companies are expected to develop pricing frameworks that account for varied levels of economic development and unmet medical needs across various countries. Strategic initiatives related to access to medicines can promote opportunities for innovation, growth, and unique partnerships, which may enhance shareholder value. (Biopharma Investor ESG Communications Guidance 2.0.).
4.	Ethical marketing and advertising	Transparent pricing, inclusive clinical trials (across ethnic groups and races) and fair advertising or disclosures from Biopharmaceutical companies is a very important dimensions of the social pillar. (Gilman, K. and Schulschenk, 2012. Anti-bribery, anti-corruption, anti-competitive behavior approach, including marketing practices, are governed by the ethical standards of an organization. Challenges arising from marketing off-label uses, can result in significant fines and settlements. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern marketing activities will allow shareholders to better understand performance in this area. (Biopharma Investor ESG Communications Guidance 2.0.)

The Environment pillar was categorized into the following sub-factors, most of them being globally relevant, across multiple industries:

Table 3: Environment Pillars for Sustainable Business Model Development in Biopharmaceutical Industry

S.No	Sub-Factors	Description
1.	Climate change risk	This risk deals with global warming, natural calamities and visible climatic changes associated with the reduction in forest cover and growing industrialization. (Gilman, K. and Schulschenk, 2012). The Biopharma industry needs to find strategic solutions related to climate change effects, such as new disease patterns, shifts in disease distribution (based on geography or ethnicity), and changing health issues related to environmental changes (Biopharma Investor ESG Communications Guidance 2.0.).
2.	Energy and water use management	Adoption of renewable sources of energy and optimal water management is a key focus area (Gilman, K. and Schulschenk, 2012)**.** Biopharmaceutical production is associated with high consumption of raw materials, solvents and energy, producing a high volume of waste, and, in many cases, leading to water pollution. Furthermore, once consumed and excreted, pharmaceutical products can enter the environment and be found in groundwater and soil, with harmful effects on aquatic organisms **(**López-Toro et al., 2021). Share of renewable energy use has to be maximized (Biopharma Investor ESG Communications Guidance 2.0.).
3.	Waste/ effluent management	This factor deals with a global challenge - uncontrolled dumping of biomedical wastes, greenhouse gas and carbon emissions (Gilman, K. and Schulschenk, 2012; Biopharma Investor ESG Communications Guidance 2.0.)
4.	Biodiversity impacts	Genetic manipulations and mutations at a microbial level pose a significant risk to Biodiversity. Covid is a relevant example in recent times. (Gilman, K. and Schulschenk, 2012).

The Governance pillar was categorized into the following sub-factors:

Table 4: Governance Pillars for Sustainable Business Model Development in Biopharmaceutical Industry

S.No	Sub-Factors	Description
1.	Human Capital	The most prized possession of any organization is human capital, and its quality and governance can be a success factor for the organization. Biopharma companies face intense competition for managing the right talent pool. The industry relies on highly skilled employees to develop new products, conduct clinical trials, manage government regulations, and commercialize new products (Reh et al., 2021). Firms that can attract and retain employees considering a constrained talent pool, and deploy talent based on evolving customer expectations may be better positioned to protect and enhance shareholder value (Biopharma Investor ESG Communications Guidance 2.0.). Human Capital in Governance Pillar was further classified into a. Recruitment, training and retention b. Diversity & Inclusion c. Compensation and benefits d. Employee Health, Safety and Wellness(Gilman, K. and Schulschenk, 2012).
2.	Policies, standards and codes of conduct	This factor deals with the general codes of conduct and legal policies/ standards followed in the organization (Gilman, K. and Schulschenk, 2012). Process and structure of oversight committees and governance communications are key aspects to consider (Biopharma Investor ESG Communications Guidance 2.0.)

3.	Supply Chain standards and selection	Governing value-added activities in the supply chain is an important dimension. It includes sourcing strategy decisions, Managing channel partners, and vertical integration (Gilman, K. and Schulschenk, 2012). Biopharma firms that fail to ensure quality throughout their supply chains are susceptible to lost revenue, supply disruptions, and reputational damage (Biopharma Investor ESG Communications Guidance 2.0.). The World Health Organization has estimated that counterfeit drugs represent more than 10 percent of the pharmaceutical supply chain in low and middle-income countries. Biopharma companies may incur added costs as numerous governments and agencies have implemented drug supply chain regulations to prevent counterfeit, substandard, or mislabeled drugs from entering the pharmaceutical distribution system (Biopharma Investor ESG Communications Guidance 2.0.).
4.	Business ethics and competitive behavior	Dealing with diverse stakeholders and society at large is governed by the core values and ethics of an organization. Organizations conforming to high ethical standards have a stronger brand value or reputation, which is important for long term sustenance and value creation (Gilman, K. and Schulschenk, 2012)**.** Biopharma companies are subject to various international, national, and state laws pertaining to healthcare fraud and abuse. For example, in the U.S., anti-kickback laws and the Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with healthcare professionals may allow shareholders to monitor performance in this area. (Biopharma Investor ESG Communications Guidance 2.0.).

Factors and sub-factors included in the Business Model Pillar were derived from the base elements mentioned in Osterwalder's Business Model Canvas (Osterwalder et al., 2005). and Business Model Innovation tools mentioned in Odyssey 3.14 (Lehmann-Ortega et al., 2013)**.**

Table 5: Business Model Pillars in Biopharmaceutical Industry

S.No	**Sub-Factors**	**Description**
1.	Adding to patient's value proposition	Enhancing the value proposition to patients and other stakeholders is the fundamental theme of any business model. This requires a deep understanding of market requirements and creating products/ services to cater to unmet needs (Reh et al., 2021). This factor was further drilled down into subfactors: a. Research, Development and Innovation (for new drugs) b. Product Quality and Safety c. Product pricing/ Cost Leadership d. Product Life Cycle Management (strategies specific to the stage of the drug and market maturity). (Osterwalder et al., 2005; Lehmann-Ortega et al., 2013).
2.	External alliances/ partnerships across the value chain	Contemporary or Open business models focus on diversification and strategic alliances. Out-sourcing non-core activities is a rising trend (Osterwalder et al., 2005; Odyssey 3.14 (Lehmann-Ortega et al., 2013; Horvath et al., 2019; Valerie Sabatier, Mangematin et al., 2010, 2012; Fisken & Rutherford, 2002).
3.	Building strategic resources and competencies	The value architecture of an organization is largely defined by its strategic resources and competencies across the value chain, also a competitive edge and long-term strategic advantage to the organization. (Osterwalder et al., 2005; Lehmann-Ortega et al., 2013).

4.	Knowledge Management and Digital Transformation	Post Covid, digital transformation initiatives in the Biopharmaceutical industry have gained new-found momentum – to improve access and reach across multiple touch points, like a Customer (hospitals, distributers, retailers), end user (patient), Healthcare Practitioners (HCPs), suppliers, investors **(**Lago et al., 2021**;** Reh et al, 2021**).** New product launches can be given a boost by using digital platforms, to deepen understanding of patient journeys and customer preferences and promote data driven decision making. (Osterwalder et al., 2005; Lehmann-Ortega et al., 2013).
5.	Long Term Capital Investment	The inherent nature of the Biopharmaceutical industry calls for Long Term Investment – for companies adopting fully integrated business models. (Osterwalder et al., 2005; Lehmann-Ortega et al., 2013; Hagedoorna et al., 2012; Lazonick et al., 2011; Brillinger et al., 2019)

Step 2: Sample Selection

The exploratory study was conducted with six senior professionals in the Biopharmaceutical industry with diverse backgrounds like H.R., Business Development, Procurement, Strategy, General Management, I.T., R&D etc., with practical knowledge and wide exposure in the industry. The professionals are currently working with three leading Biopharmaceutical companies having a presence in Indian and global markets. Although of Indian origin, they have had global exposure while working within the Biopharma industry, while some have experience across varied industries. The identity of the respondents and corresponding organizations have not been disclosed, to maintain confidentiality. The Respondent Profile and Organization description is tabulated below:

Table 6: Respondent Profile and Organization Description

	Profile/ designation	**Organization description**	**Years of industry experience**
Respondent 1	President and SBU head	Indian multinational pharmaceutical company headquartered in Mumbai. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions. 2022 Revenue: USD 2 Billion Employee base: 18000+	28+ years of industry experience, working with five different Biopharma companies in the U.S. and India.
Respondent 2	Vice President and Head R&D		25+ years of industry experience, working with four different Biopharma companies in India.
Respondent 3	Chief Information Officer		25+ years of industry experience, working with six different companies in E.U., Middle East and India – across Biopharma and FMCG sector.
Respondent 4	Vice President HR		25+ years of industry experience, working with four different companies in India – across Biopharma and automobile sectors.
Respondent 5	Regional Procurement head	American Multinational corporation, headquartered in the U.S. It develops medical devices, pharmaceuticals, and	15+ years of industry experience, working with four different companies

		consumer packaged goods. The corporation includes 250 subsidiary companies with operations in 60 countries and products sold in over 175 countries. 2021 Revenue: USD 95 Billion Employee base: 1.4 Lacs	in India – across Biopharma, I.T. and Consulting.
Respondent 6	Academician and Research Scholar, Ex-Vice-President of Marketing and Business Strategy	Indian multinational pharmaceutical company headquartered in Hyderabad. The company develops and markets a wide range of pharmaceutical and biotechnology derived products. 2021 Revenue: USD 2.8 Billion Employee base: 21,000+	Twenty years of industry experience, working with four different Biopharma companies in India.

Step 3: Conducting Interviews

With the ultimate objective of Business Model Innovation, preference for each of the ESG and Business Model Pillars in the Biopharma industry was discussed with the participants, as depicted in the base model in Figure 2. As fuzzy logic was used to identify the factors of importance for sustainable business models, it was important to assign a quantitative measurement or ranking tool, to understand the relative preference of one factor over the other.

The factors and sub-factors chosen across the ESG and Business Model Pillars have inter-relationships or dependencies amongst each other, while impacting Business Model choices in the industry. The objective of this research paper was to study the factors or sub-factors that matter most to the industry and should be shortlisted for further research on Business Model Innovation.

Informed consent was taken from the participants, and their willingness to participate in this study was confirmed. Semi-structured interviews and face to face meetings were conducted with the participants.

Step 4: Analytical Tool

Analytical Hierarchy Process (AHP) – a structured approach is applied for multi-criteria decision making, to prioritize factors using a pairwise prioritization matrix. (**Saaty, 2008).** Ratings and weights were assigned to each of the factors – to understand their relative significance over the other. This tool serves as a platform to quantify qualitative factors.

Table 7: Fundamental Scale for Pairwise Comparison in Analytical Hierarchy Process

Intensity of Importance	**Definition**	**Explanation**
1	Equal importance	Two elements contribute equally to the objective
3	Moderate importance	Experience and judgement moderately favor one element over another
5	Strong importance	Experience and judgement strongly favor one element over another
7	Very strong importance	One element is very strongly favored over another. Its dominance is demonstrated in practice

9	Extreme importance	The evidence favoring one element over another is of the highest possible order of affirmation.
Intensities of 2, 4, 6, 8 can be used to express intermediate values. Intensities of 1.1, 1.2, 1.3 etc, can be used for elements that are very close in importance.		

Step 5: Calculation of global weights and score

The priority/ weightage assigned to each factor was further utilized to calculate the global weightages of each of the sub-factors. Further insights were sought from the respondents based on why they prioritized some factors over others and the relative magnitude of prioritization. The observations were carefully documented and have been captured in the Results and Discussion section. The global priority/ weightage for each of the factors was averaged across all respondents to determine the average industry score.

Results

The respondents provided valuable feedback on the factors and sub-factors chosen in this study, across ESG and Business Model Pillars, based on their relevance to the Biopharma industry. All of them acknowledged that ESG is the new corporate sustainability yardstick, and integration of ESG concepts into core Biopharma business models is a step in the right direction. Table 8 provides the average weightage across Environment, Social, Governance and Business Model Pillars, based on the preferences assigned.

Table 8: Weightage assigned to the four Pillars of a Sustainable Business Model

Weightage – BMI	
Categories/ Factors	**Weightage %**
Social Pillars	17
Environmental Pillars	20
Governance Pillars	32
Business Model Pillars	30
SUM	100.00

It was observed that the Governance and Business Model Pillars were found to receive a higher priority score, as compared to the Social and Environment Pillars for Business Model Innovation.

Discussion on the Social pillars in the Biopharma industry provided further insights into the factors to be prioritized, and the analysis is captured in Table 9 below. One of the respondents commented that Patient Health and Safety is the basic premise for the existence of this industry, and this factor should be non-negotiable.

Table 9: Weightage assigned to the Social Pillars of Sustainable Business Model in the Biopharmaceutical Industry

Weightage - Social Pillars	
Categories/ Factors	**Weightage %**
Patient Health and Safety	8
Healthcare affordability	2
Equitable healthcare access	3
Ethical marketing and advertising	5
SUM	17

Among the Social Pillars, Patient Health and Safety and Ethical Marketing and Advertising have a higher weightage amongst the other factors like Healthcare Affordability and Equitable Access.

Discussion on the Environment pillars helped gain further insights into the sub-factors, and the respondents had a common feeling about this factor being largely neglected in the developing nations. Some of them mentioned the lack of adequate practical measures in the Biopharma industry to address the environment related issues. The results are showcased in Table 10 below.

Table 10: Weightage assigned to the Environment Pillars of Sustainable Business Model in the Biopharmaceutical Industry

Weightage - Environmental Pillars	
Categories/ Factors	**Weightage %**
Climate Change Risk	4
Energy and water use management	5
Waste/ effluent management	6
Biodiversity impacts	5
SUM	20

Weightages assigned in the Environment Pillar between the four sub-factors are very close, indicating similar priorities for each of them. It was difficult for the respondents to choose one factor over the other, and the same is reflected in the scores. Waste/ effluent management is ranked slightly higher and indicates that companies need to be more diligent in their efforts to handle this burning issue.

Key factors contributing to the Governance Pillar were discussed with the respondents, and the priorities are showcased in Table 11 below. The respondents commented that the Governance Pillar largely impacts the functioning and success of any organization.

Table 11: Weightage assigned to the Governance Pillars of Sustainable Business Model in the Biopharmaceutical Industry

Weightage - Governance Pillars	
Categories/ Factors	**Weightage %**
Human Capital	6
Policies, standards and codes of conduct	7
Supply Chain standards and selection	5
Business ethics and competitive behavior	14
SUM	32

Amongst the sub-factors listed in the Governance Pillar, Business Ethics and Competitive Behavior were rated highest in terms of organizational priority.

Table 12 showcases the average industry weights assigned to the Human Capital sub-factors. The respondents agreed that the quality of Human Capital goes a long way in determining the success of any organization; employee friendly policies and governance framework help in retaining talent and developing them.

Table 12: Weightage assigned to the Human Capital Pillars of Sustainable Business Model in the Biopharmaceutical Industry

Weightage - Human Capital	
Categories/ Factors	**Weightage %**
Recruitment, training and retention	1
Diversity & Inclusion	1
Compensation and benefits	1
Employee Health, Safety and Wellness	3
SUM	6

Amongst the Human Capital sub-factors, employee health safety and wellness were prioritized higher than the others.

Business Model sub-factors mainly focus on the business performance aspects, which are evolving with the changes in patient and other stakeholder expectations. It defines the basic fabric of an organization, and the focus is to maximize the Value Offering. Table 13 describes the Business Model sub-factors and average weights assigned by the respondents.

Table 13: Weightage assigned to the Business Model Pillars in Biopharmaceutical Industry

Weightage - Business Model Pillars	
Categories/ Factors	**Weightage %**
Patient's value proposition	11
External alliances/ partnerships across the value chain	3
Building strategic resources and competencies	10
Knowledge Management and Digital Transformation	3
Long Term Capital Investment	3
SUM	30

Two factors that were rated highest in the Business Model Pillar are Adding to the patient's value proposition and building strategic resources and competencies.

The responses laid strong emphasis on the concept of value creation and the need for fresh ideas to enhance the value proposition offered by the Biopharma industry. The key value proposition sub-factors for this industry were discussed in detail and the weightages assigned are tabulated in Table 14 below.

Table 14: Weightage assigned to the Value Proposition Pillars of Sustainable Business Model in the Biopharmaceutical Industry

Weightage - Value Proposition	
Categories/ Factors	**Weightage %**
Research, Development and Innovation	2
Product Quality and Safety	5
Product pricing/ Cost Leadership	2
Product Life Cycle Management	2
SUM	11

The highest priority was given to Product Quality and Safety – which is undoubtedly the most important dimension for Biopharmaceutical companies.

Discussion

As demonstrated in the study, the basic sustenance of a business is determined by its Business Model and Governance Pillars, which need to be strengthened to make an impact on the Social and Environment Pillars at the next level. Organizations that struggle to establish strong Business Models and Governance Pillars would find it hard to concentrate on the Social and Environment aspects – which in a way, determines the hierarchical maturity of an organization. The size of an organization, number of years in business, number of employees, location, company culture, leadership style etc, could be further determinants for understanding an organization's evolution on the maturity curve. Nevertheless, the chosen pillars would be prioritized for advancing this research.

Amongst the Social Pillars, Patient Health and Safety, rated highest by the respondents, is an uncompromised factor for Biopharma companies – and is the core value offering for this industry. The respondents further commented that ensuring the efficacy and safety of drugs throughout the drug development process is the primary responsibility of Biopharmaceutical companies. In the current age, digital platforms need to be developed to promote accessibility to patient data and improve patient experience towards healthcare.

Maintaining Ethical standards during Marketing and Advertising is another important social factor in addressing core industry issues like inadequate Product disclosures and preferential launch/distribution of products in evolved markets. Few of the respondents commented that ethical issues like transparent Product Pricing, integrity in reporting Clinical trial results etc., have been long discussed as a gap in the industry. Business models need to emerge from the right set of values, which can help establish a base for high integrity and moral standards amongst the employees. Integrated reporting and enhanced disclosures by Biopharma companies may help bridge the gap between stakeholder perception and reality and promote transparency in the operating model.

Although prioritized marginally high, as compared to the other Environment Pillars, the study indicated that Effluent and waste management initiatives should be ingrained as part of the business model of Biopharmaceutical companies. The participants in the study commented that this factor needs special attention in emerging and under-developed economies, which have by far neglected this aspect – thus causing enormous damage to the ecosystem. Govt. regulations also play an important role in incentivizing emission disclosures and proposing industry norms for waste reduction. However, in the absence of such regulations, it was suggested that each organization should have its own metrics/ targets to control greenhouse gas and carbon emissions and ensure the safe disposal of biomedical wastes.

The prioritization of the Governance Pillar and its sub-factors, like Business ethics and competitive behavior was established during the study. Corporate Governance requires planning and monitoring the key performance areas of an organization, its internal operation and corporate behavior. The respondents commented that ethical business practices require a strong governance model across the organizational hierarchy and should be prioritized while taking Business Model decisions. Biopharmaceutical organizations are often criticized due to patent and price wars and uncompetitive market practices, which strongly impact their reputation and brand-value. It is a "sector where any activity that could be detected, suspected or labelled as unethical, is not tolerated by patients, the media and stakeholders at large" (Valverde, 2012). This factor is further governed by the core values in an organization and the decisions based on these core values. At the outset, it is important to create a strong foundation of Business ethics in Biopharmaceutical organizations, which in a way, would help govern the

other factors like Human Capital, Supply Chain and adoption of general policies and codes of conduct.

When probed further about the governance over Human Capital and how companies can differentiate on this key aspect, the respondents agreed that post-Covid, Employee Health, Safety and Wellness as a factor had gained higher visibility and prominence. To become an employer of choice, it is important that the organization gives high regard to its well-being, and governance practices/initiatives should be designed around it. The other factors - Recruitment, training and retention, Diversity and Inclusion, Compensation and benefits were prioritized equally, as they are fundamental focus areas for the functioning of any organization. Factors like Recruitment, training and retention and Compensation and benefits had higher prominence in the Conventional Business Models. However, Diversity and Inclusion as a factor are industry agnostic and have gained prominence over the last decade.

Recent trends in the Biopharmaceutical industry have also demonstrated greater participation of women in senior positions and as CEOs. During Covid, it was observed that organizations with women in senior positions demonstrated a different leadership style – with a focus on empathy, accountability and adaptability. If Biopharmaceutical companies are to be truly understanding of the varied patient base they seek to serve, then board members and employees should also have an equally diverse representation (Barrell, 2018).

Supply Chain Standards and selection is an emerging area of the Business Model that is also being scrutinized under the lens of ESG performance. Germany is one of the first nations to introduce the Supply Chain Act to be enforced from Jan 2023, which lays stringent standards for the selection of supply chain partners (from Raw material sourcing to Market distribution channels). Guidelines for due diligence have been introduced with multi-level requirements: a defining system for risk management, ensuring compliance, conducting periodic risk analyses, adherence to the policy statement, preventive risk measures for in-house business and direct suppliers, proposing remedial action, setting up a mechanism to address complaints, conducting due diligence and estimating risks from indirect suppliers, and maintaining a transparent documentation procedure. These activities are mandated for conduct on an annual basis or upon request. Introducing digital touchpoints for interacting with all layers of the supply chain has become inevitable if organizations have to streamline the assessment and activities across the supply chain. Developing an agile, responsible, and resilient supply chain is the need of the hour (Lago et al., 2021).

During the discussion on Business Model Pillars, Enhancing Patients' Value Proposition was an outright choice of focus and was highly prioritized by all respondents. It is possible to enhance value by reducing the Customer/Patient hassles and/or costs. More functionality/ emotion could be added to the product/ service offering, and market expansion strategies should be designed accordingly Odyssey 3.14 (Lehmann-Ortega et al., 2013)

Amongst the Value Proposition sub-factors, Product quality and safety is a link between the Social and Business Model Pillars – as it is linked to Patient Health and Safety. It has received the highest rating across both segments and needs special attention during Business Model Innovation. The other sub-factors under Value Proposition, like R&D and innovation, are extremely important for maintaining a steady pipeline in this industry and addressing unmet medical needs with new therapy regimes. Some of the respondents commented that emerging economies like India and South Korea need to upgrade their research base and create an ecosystem of technological innovation. The lack of disruptive innovation is a core challenge being addressed by the Biopharma industry in such markets. However, the respondents emphasized that the introduction of novel products does not surpass the emphasis laid on

Product Quality and Safety. Transparency in reporting clinical trial results, stringent quality systems and strong business ethics go a long way in ensuring fair communication of Quality and Safety data observed among patients.

Value Proposition factors like Cost leadership and Product life-cycle management are important aspects as they promote the affordability and accessibility of drugs to the masses. These factors, although having a strong impact in emerging and under-developed markets, were rated lower than Product Quality and Safety, as the safety and efficacy aspect of drugs should not be compromised to promote affordability. Maintaining high quality standards at affordable costs – is a paradox that this industry needs to deal with. Countries like India, with low R&D and manufacturing cost base, can contribute to this cause. Hence Business Model innovation ideas need to be adopted, such that they help overcome the industry challenges while maintaining focus on prioritised elements.

Amongst the Business Model Pillars, Building Strategic resources and competencies was prioritized highly by the respondents, as it provides a significant competitive advantage and long-term growth prospects for the organization. Strategic resources are productive assets owned by the firm, and they are often made of non-visible elements. They must be developed, nurtured and managed. Tangible resources like Financial capital, physical assets etc., are easily imitable. However, intangible assets like reputation, technology patents, company culture etc., are unique and impossible to imitate – hence companies need to focus on this direction for innovating their business model Odyssey 3.14 (Lehmann-Ortega et al., 2013). Strategic resources and competencies can be enhanced by the introduction of a new technology or by modifying one or several steps in the value chain. Optimization of resources and competencies in the value chain often involves Value vs Cost analysis and out-sourcing low value creating activities. Going a step further, Value System in the industry involves suppliers and distributors with their value chain, and it is important to understand the multiple levels of value creation (Lehmann-Ortega et al., 2013).

Knowledge Management and Digital Transformation, although not rated highest among business model pillars, are important tools for Business Model Innovation. Digital transition efforts could have business applications in areas like Portfolio selection, Supplier Management, Business process streamlining, superior, data driven decision making, and patient compliance, to name a few. The development of digital infrastructure with real-world patient data management can help include baseline measurements across varied races and ethnicity, which in a way, can contribute towards the value proposition (Ronte et al., 2021). Contemporary business models lay high emphasis on this aspect, and Biopharma companies should use this effective tool to differentiate their value proposition and creating a sustainable impact.

Long Term Capital Investment has always been an important dimension for Biopharma – however, the concept of integrating ESG Pillars as part of the Business Model will help in attracting value added investments within this industry. Partnerships and out-sourcing decisions will also help in streamlining the investment needs across the development span of products.

Further it was understood from the respondents that the impact of ESG Pillars on the Business Model design is incumbent on the firm's strategy to adopt integrated reporting – encompassing ESG goals. ESG reporting can help certify that the efforts/ strategies of the firm are being laid in the right direction. Emphasis must be laid on the quality and quantity of ESG reporting – as not all factors lead to a favorable ESG score. Addressing sustainability issues often requires a long-term outlook (like the development of corporate culture, brand and technological know-how), while an organization's incentive structure rewards short-term performance. Hence,

companies need to associate the leadership team's performance ratings and bonuses with ESG as well as Business Model Pillars, such that decision making and practices in the organization are driven with a focus on all four aspects. The development of relevant tools that can factor in non-financial metrics into the valuation methods and capital budgeting process of Biopharma firms is an evolving concept and will be refined further through experience and empirical research. By building sustainable business models and strategies, the Biopharma industry can carve the path for a sustainable society that meets the needs of the current generation without sacrificing those of the future ones.

Conclusion

Since the introduction of SDGs in 2015, there have been debates around "how ESG investing can be scaled up to meet the new global targets of sustainable development". Thus, the concept of "Equitable healthcare to all", as a key Sustainability Development Goal is better envisioned with the amalgamation of ESG factors to Biopharma Business Models – to attract the attention of corporates towards financial and non-financial factors such as corporate governance, environmental footprint, human rights issues etc.

This exploratory study demonstrates that ESG Pillars in sync with Business Model Pillars are conducive to sustainable Business Model development. The Governance Pillar was highest rated among ESG pillars, which can help maximize value creation through Business Model Innovation, thus reinforcing the role of corporate governance as a top focus area for this industry. The industry needs to develop a long-term, value added and transparent governance strategy while focusing on Business indicators like Value Proposition and Strategic Resources and Competencies.

Firms must simultaneously integrate the inherent factors that boost ESG performance and integrate it with their business strategy in the following way:

Firstly, Firms must identify the Materiality maps in the Biopharma industry – by focusing on ESG issues that matter the most. The unique challenges faced by the Biopharma industry would help identify areas that can impact Business Model decisions to generate long term shareholder value. Biopharma companies must list down their industry-specific challenges or barriers to change – like investor expectations or short-sighted incentive systems that focus on near-term performance, strategic competencies and capabilities that need to be developed to build long-term expertise, capital budgeting limitations that fail to measure the Social and Environmental value of initiatives.

Secondly, Innovative strategies must be deployed for re-designing business models in Biopharma, by focusing on the materiality map and prioritizing factors that need improvisation. This study has demonstrated that higher focus should be laid on Business Model and Governance pillars for Business Model Innovation in the Biopharma sector. After the focus areas are listed, the companies must assess where they stand on the factor with respect to their peers in the industry – and industry-specific benchmarks/ metrics can be a useful tool to compare with. Business model innovation can streamline efforts towards solving ESG material issues with a "bundled approach", – which can shift the performance frontier of a company by developing a holistic outlook (Eccles et al., 2013).

Finally, the stakeholders and shareholders must be informed about those improvements through integrated reporting by combining financial and ESG performance in one document. Major innovation decisions in Biopharma often entail strategic investments – the benefits of which

will not be seen in the short term. However, if the company expects investors to stay committed to these causes in the long term, it needs to keep them informed of such investment decisions and provide justification for the same.

The findings from this exploratory study are in sync with the study conducted by Nussbaum, 2009, which reported that Environment, Social and Governance challenges are largely intertwined with Business Performance, and hence their integration is the need of the hour. ESG goals need to be integrated as a holistic part of business goals with defined targets and metrics. Companies looking to adopt innovative business models should encourage the participation of varied stakeholders to promote strategic business decisions in sync with ESG goals.

This exploratory study sets the tone for doing an in-depth analysis of the chosen, high-priority factors which impact Business Model Innovation. The major limitation of this study is the small sample size. A larger sample size is needed to test the observations from this exploratory study – such that the findings can be generalized to the Biopharma industry. Novel drug pricing should balance the element of innovation while overcoming ESG challenges. Affordability and accessibility of medicines, although important, cannot be prioritised over Product Quality and Safety – this realization should reflect in the Business Models adopted by Biopharmaceutical Organizations. Integrating Business Model Pillars with ESG Pillars and integrated reporting is important as it impacts stakeholder perceptions, ESG ranking as well as investor valuations, thereby generating significant business value.

The results from the exploratory study would help organizations reflect upon the factors prioritized for Business Model Innovation across each of the pillars. A deep dive into the high-priority factors would help derive recommendations for the Biopharma industry – for adopting a Sustainable Business Model. The integration of ESG and Business Model Pillars may also be contingent upon a firm's size, capability and maturity level – and a focused study could be done at the next level.

The results from this study are also similar to the results observed by Paolone et al., 2021**,** where they conducted a configurational analysis in the European Biopharma industry to determine the impact of ESG pillars on the firm's marketing performance. They concluded that ESG scores have a positive impact on a firm's marketing performance, and the governance pillar score had a much stronger correlation with marketing performance as compared to the social and environmental pillar. Such studies are relevant in the health sector, as they help Biopharma companies to adjust their focus towards relevant factors for business model innovation. Biopharma companies need to actively promote social, governance and environmental initiatives and their integration into the firm's business model while reporting their value proposition to varied stakeholders. A sustainable and endurable business model must address the needs of all stakeholders: patients, customers, employees, investors, governments and society at large.

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