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Strategic Management

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1 Introduction

Since its founding in 1978, Biocon has evolved from a modest enzyme manufacturer to a major player in the global pharmaceutical industry [21]. The focus of this paper is on the strategic integration of Clinigene and its implications for Biocon's broader strategy, particularly how strategic management can leverage this to enhance Biocon's competitive advantage and market position in a dynamic and competitive industry [5].

Strategic management is not merely a needful requirement; it forms the very pivot of Biocon's success in steering the meandering complexities of the international pharmaceutical market. The strategic choices properly enabled Biocon to exploit the emerging market opportunities effectively and in line with its core competencies and foundational cultural values. This was considered essential in upholding growth and innovation within Biocon: to protect competitive advantage within a sector that had become so dynamic.

The paper proposes strategic recommendations that uphold Biocon's ethical standards and operational strengths, guiding the company toward enhanced growth, innovation, and competitive positioning. It will assess the interplay between Biocon's internal capabilities and the external business environment, aiming to develop strategies that both align with and enhance its organizational values and market presence.

2 External Environment Analysis

2.1 PESTEL Analysis

In the following section, a PESTEL analysis is carried out on the case study, in order to identify the macro (external) forces facing our organization. Specifically, the acronyms stand for: Political, Economic, Social, Technological, Environmental and Legal dimensions.

2.1.1 Political

Continuously, the hand of the government has influenced the pharmaceutical industry in India through one policy or another [17]. For example, the Drug Price Control Order has always favored local manufacturers [40], thereby making their competitive advantage even stronger against multinationals. However, the changes in the regulation and the intervention of government in drug pricing and the norms for clinical trials could be a potential hindrance and opportunity for com-

panies like Biocon.

An example of challenge could be the implementation of stricter drug approval regulations, which would likely increase the costs of drug development. On the other hand, while stricter regulations can pose significant initial challenges, they also offer substantial opportunities, like enabling Biocon to access to new markets.

2.1.2 Economic

Economically, the pull factor for pharma outsourcing is India's cost advantage, characterized by low costs of labor and operational expenses [45]. Nevertheless, the economic gain has to be balanced with the risks such as fluctuation in exchange rates and possible negative potential economic downturns that might affect funding and profitability in the sector.

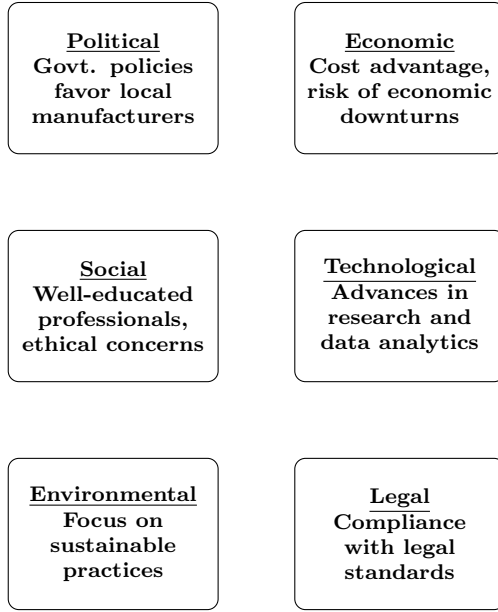


Figure 1: PESTEL Analysis Diagram

2.1.3 Social

The position is highly supported by the vast array of educated professionals in India who feel that their country has emerged as a hub for clinical research and trials. This has been a key asset in the country's rising as one of the preferred destinations for outsourcing pharmaceutical services including social research and development (R&D) apart from clinical trials [25] [11]. Nonetheless, there may still be fundamental importance in some ethical issues related to, for example, patient consent or treatment effectiveness about the way clinical trials are carried out.

2.1.4 Technological

The latter has a strong bearing on CRO operations, given the technological advances in pharmaceutical research and data analytics today. Biocon, therefore, has an opportunity to gain an edge in the industry, given its ability to integrate modern technologies into its operations [8], enhancing the efficiency and precision of clinical trials.

2.1.5 Environmental

With global concerns shifting towards sustainable operations, it is time that pharmaceutical companies shifted towards adopting processes that are friendly to the environment, too [50]. Ultimately, the brand of sustainability Biocon may have its impacts on the reputation and consumer preferences, more particularly in the Western market environment, which sounds loud with environmental concerns [22].

2.1.6 Legal

The human face in all these, however, is compliance with the standards of international and national law that govern the conduct of clinical trials and drugs upon approval. The legal environment under which non-compliance may lead to substantial legal implications and financial penalties [36] remains the guiding operational framework for Clinigene.

2.2 Porter's Five Forces Analysis

The *Five Forces Analysis* is a framework for understanding the competitive forces at work in an industry, and which drive the way economic value is divided among industry actors. [41]

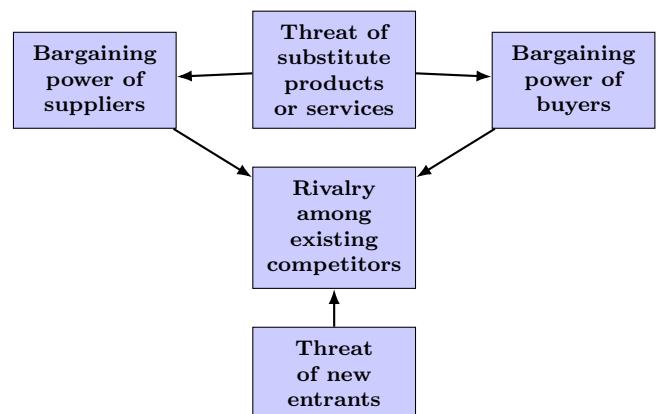


Figure 2: The five forces to be discussed for the case study are as follows.

2.2.1 Threat of New Entrants

Some entry barriers are pretty obvious in the pharmaceutical industry: high capital requirements and strict regulatory standards [43]. On the other hand, the constantly growing market of outsourced clinical research presents some opportunity for potential new players and may provide a stimulus for increasing competition with Biocon.

2.2.2 Bargaining Power of Suppliers

In the pharmaceutical sector, suppliers have moderate power; however, their power will depend on the specificity of materials and proprietary knowledge required [20]. Therefore, Biocon needs to manage these relationships judiciously to ensure the stability of its supply chain.

2.2.3 Bargaining Power of Buyers

Significant buyers in this sector are large drug companies whose size of orders and the critical nature of the products on offer afford them excellent bargaining power [54][27]. Biocon

provides a unique service (it defines itself as a “*global biopharmaceutical company*”), but it may still be susceptible in the event, for example, that it diversifies its client base and increases its uniqueness.

2.2.4 Threat of Substitute Products

The threat of substitutes in pharmaceutical outsourcing is relatively low, given the specialized nature of clinical trials and drug development [44]. On the other hand, technological innovations, such as synthetic trials and digital simulation, could potentially disrupt traditional models, as it can be seen in the following *old* article in 2016 [51].

2.2.5 Industry Rivalry

Cutthroat competition prevails in this outsourcing sector, where quite a few big players rule the market [34]. The strategy of Biocon should be such that it differentiates them through a higher level of service, integration with technology, and exercises strong ethics practices.

3 Internal Environment Analysis

3.1 VRIO Framework

The VRIO framework analyzes a firm’s internal resources and capabilities that can lead towards sources of sustained competitive advantage. The term VRIO comes from value, rarity, imitability, and organization. [24]

3.1.1 Value

The significant value of Biocon is in its integrated business model, which ranges from enzyme manufacturing to complex biopharmaceutical production and clinical research [7]. This has been contributed by the fact that the company can turn around its R&D capabilities in biotechnology and; thus, diversify into generics and contract research with diver-

sified revenue streams that facilitate reduced risk and market stabilization.

3.1.2 Rarity

Rarely does such experience come to the Indian context for biopharmaceuticals. Only a few firms have made significant inroads at the same time into manufacturing and clinical research [16]. Its subsidiary, Clinigene, offers something rare in the crowding CRO market by bringing together local market knowledge and international quality standards.

3.1.3 Imitability

For Biocon, it can happen that the integration of operations is complex: from the re-

search and development phase to final production and clinical trials, everything must be properly done, the level of granularity is very high. Such complexities form a kind of protective or insulating barrier against competitors, mainly because of Biocon’s established intellectual property base and fine knowledge of biopharmaceutical production.

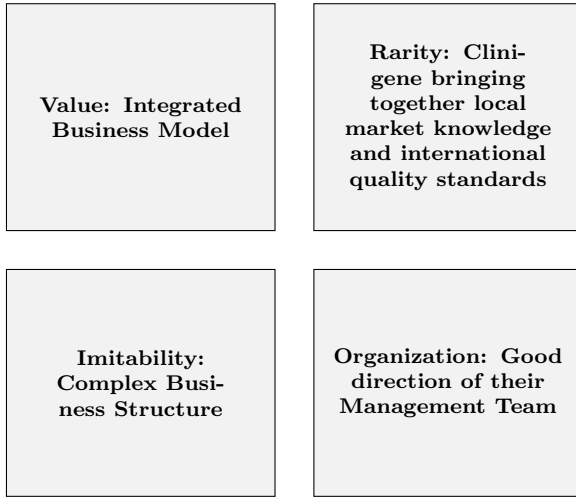


Figure 3: VRIO framework analysis for Bio-gene

3.1.4 Organization

Biocon is an excellent organization aimed at harnessing its resources and capabilities under the direction of a strong management team headed by Kiran Mazumdar-Shaw [15]. This structure supports innovation and operational efficiency, which is essential for the enablers of sustaining competitiveness. However, as the organization grows, it can happen that preserving its agility and innovative culture gets more challenging due to many factors.

3.2 Value Chain Analysis

The value chain is a term that includes different business activities and the processes involved in creating a product or performing a service. The value chain could comprise many stages in the life cycle of a product or service, including, among others, R&D, sales, and everything in between. [42]

3.2.1 Inbound Logistics

Hence, the effectiveness of inbound logistics is very important to Biocon to ensure cost-effectiveness and smooth operation [23]. Raw material management for the production of biopharmaceutical products of good quality needs strong relationships and effective inventory management systems from a reliable supplier.

3.2.2 Operations

The strength of its core operations in Biocon lies in its state-of-the-art manufacturing facilities, which stand to comply with global standards [6]. The ability to operate in strict regulatory environments speaks to the company’s operational excellence and quality commitment.

3.2.3 Outbound Logistics

The way pharmaceutical products require careful handling during their distribution, storage, and timely delivery systems with regard to the international markets, such requirements are ensured by way of strategic partnerships and logistic capabilities [52] [10] of Biocon for efficient and safe product distribution.

3.2.4 Marketing and Sales

Biocon has customized its marketing for different market segments, especially for emerging markets, with due emphasis, and the company has a brand reflecting an innovative and reliable image through other channels, such as digital marketing, conferences, and direct efforts in selling. [1]

3.2.5 Service

In the pharmaceutical industry, post-sales service is sometimes also like patient education about and monitoring drug therapy’s effectiveness [1]. Biocon’s concern for service re-

flects its concern for patients, with active customer engagement.

3.2.6 Technology Development

As opined by Casadesus-Masanell and Zhu (2013, p.466), technology is one of the most critical factors in maintaining the competitive advantage of Biocon. Continuous investment in new technologies, especially in research and development and production processes, ensures driving innovation and the ability of the company to enter new therapeutic areas.

3.2.7 Human Resource Management

Human resources at Biocon are significant to its operations, especially so in its role in scien-

tific knowledge and specialization [48] that the company upholds. The investment in training, development, and retention activities of the workforce would be significant to make good practices of innovation and cooperation.

3.2.8 Infrastructure

The human face of this robust corporate infrastructure [28] of Biocon comprises an aggressive and extensive organizational set-up and strategic initiatives. These include compliance, finance, and administrative systems designed in line with the complexities [3] of the global pharmaceutical market.

4 Current Competitive Position Overview

One of the Indian companies that emerged as a world leader in the biopharmaceutical business, especially in the growing market of outsourcing clinical research, is Biocon India Group through their subsidiary, Clinigene. This part attempts to do a strategic analysis of Biocon with the help of the SWOT analysis and further looks into the sources of competitive advantage and its types.

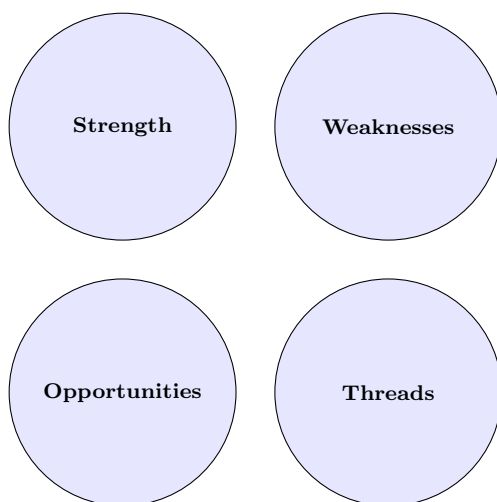


Figure 4: SWOT framework dimensions to be studied

4.1 Strengths

- **Integrated Business Model:** As we've seen before, Biocon's ability to manage an extensive value chain from R&D to manufacturing and clinical research provides a comprehensive service offering that is difficult for competitors to match.
- **Strong Finance:** The strong finances at Biocon Biologics allow for investment in novel and diverse projects, leading to diversification of revenue and an increase in Return on Sales (RoS) and other metrics. [49]
- **Innovation and R&D Capabilities:** The company's focus on innovation and new product development through research and development has kept it at the forefront of the biopharmaceutical industry.
- **Reputation:** Established in a highly regulated market, Biocon's long-standing reputation for quality and compliance enhances trust among stake-

holders and customers. [46]

4.2 Weaknesses

- **Inadequate Workforce Diversity:** Biocon's Biologics may not be diversified enough, due to the fact that the company has developed a large part of its growth in its domestic market. This will, therefore, limit the success of Biocon's Biologics in the international market. [32]
- **Organization Culture:** There may be an organizational culture that is still weighed down by turf wars [13] within divisions and/or departments at Biocon's Biologics, thereby making it difficult for managers to open up and share information. This can provide a critical roadblock to further growth, since siloed information can lead to missed market opportunities.



(a) Workforce Diversity (b) Organization Culture

Figure 5: Identified weaknesses for Biocon

4.3 Opportunities

Opportunities are the areas where a company's efforts can be concentrated in order to improve results, sales, and, eventually, profit. Here are some strategic opportunities for Biocon:

- **Growth in Emerging Markets:** With its cost-effective production capac-

ities, Biocon is well-positioned to expand significantly in emerging markets where there is a growing demand for affordable biopharmaceuticals.

- **Technological Advancements:** Reinvesting in new technologies like artificial intelligence for drug discovery [14] and blockchain for supply chain transparency [35] can open new avenues for growth and efficiency.
- **Aging population:** As the global population ages [47], there is an increasing need for drugs and treatments related to age-associated health issues. This situation presents both opportunities and challenges for the pharmaceutical industry, as companies must develop new products that meet these needs while managing healthcare costs. [47]

4.4 Threats

There are many threads regarding the pharmaceutical sector, among which we can mention the following [2]:

- **Regulatory Changes:** The global pharmaceutical regulatory framework is complex and variable [31]. Changes can impact market access and profitability for Biocon's Biologics. Current trends to watch include changing rules in environmental and labor safety, which Biocon's Biologics should closely monitor as they are on an upswing.
- **Intense Competition:** The global pharmaceutical industry is characterized by very intense competition [4], with numerous players vying for market share, especially in the Contract Research Organization (CRO) space.
- **Data security:** Pharmaceutical companies collect and store vast amounts of sensitive data, from patient information to clinical trial data. Ensuring the security and integrity of this data is critical

but can be challenging in an age of cyber threats and data breaches [30].

4.5 Sources and Types of Competitive Advantages

Taking into account all the information we have so far, we can deduce that Biocon's competitive advantages stem from both its resource-based capabilities and market positioning:

• Sources of Competitive Advantage

- *Proprietary Knowledge and Expertise*: Decades of experience in biopharmaceuticals have created a deep knowledge pool and technical expertise that is difficult for competitors to replicate.

- *Strategic Alliances*: Partnerships with global pharmaceutical companies enhance market access and strengthen Biocon's standing in the international market.

• Types of Competitive Advantage

- *Cost Leadership*: Operating in India allows Biocon to produce at lower costs, enabling competitive pricing compared to Western counterparts.
- *Differentiation*: In a competitive market, Biocon differentiates itself with high-quality products and services that meet stringent international standards.

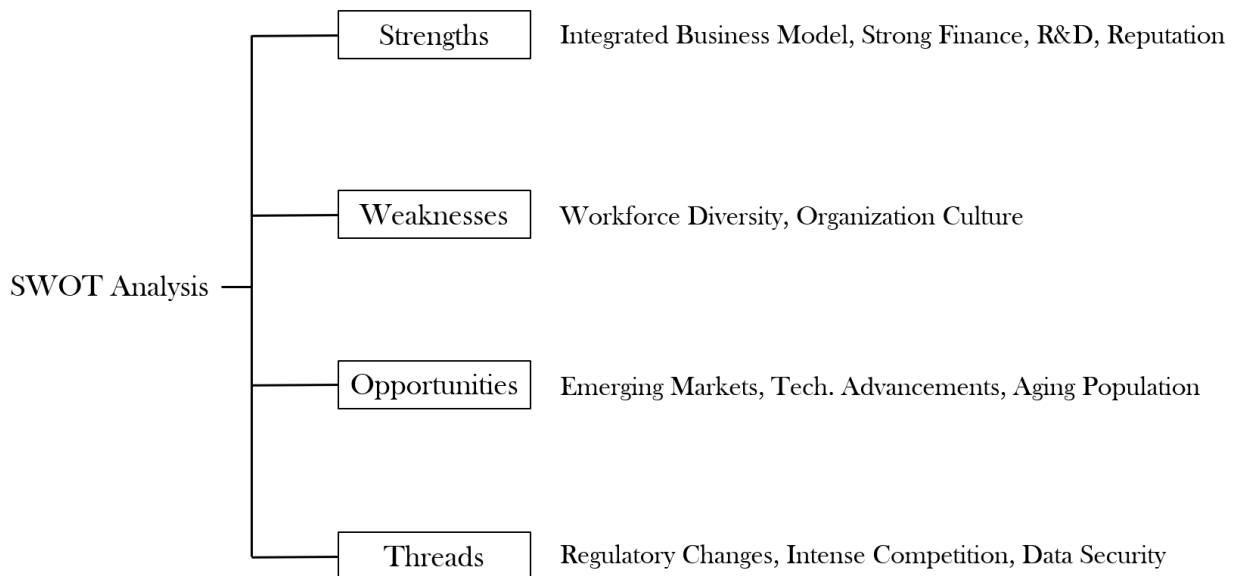


Figure 6: Diagram Summarizing the SWOT Analysis made for Biocon

5 Identification of Strategic Alternatives

5.1 Expansion into New Geographical Markets

Biocon could expand its operations into new geographical markets, particularly focusing on emerging economies in Africa [39] and South America [33], where there is a growing demand for affordable biopharmaceuticals and clinical research services. Although I could also bet on other countries such as Spain (my native country), which is a good connection point between the continents of America, Africa and Europe and which also has very powerful biotechnology companies, for example, Grifols [18].

Strengths	Leveraging its cost-effective production capabilities and established reputation.
Opportunities	Accessing new markets provides a significant growth opportunity, aligning with global trends towards healthcare expansion in emerging markets.
Risks	Navigating new regulatory environments and establishing supply chains can be challenging and resource-intensive.
Potential	High, given the increasing demand for healthcare services in these regions and Biocon's ability to deliver cost-effective solutions.

Table 1: Table for *Expansion into New Geographical Markets*

5.2 Diversification through Digital Health Ventures

Biocon could diversify into digital health, developing or partnering in the creation of digital therapeutics platforms, which utilize software to treat diseases and manage patient

care. This venture could also include leveraging AI and big data analytics for drug development and personalized medicine.

Strengths	Building on its strong R&D capabilities and innovative culture.
Opportunities	Addressing the burgeoning field of digital health, which is expected to revolutionize healthcare delivery and patient management.
Risks	Requires substantial investment in new technologies and skills, and the market for digital therapeutics is still nascent and uncertain.
Potential	Medium to high, dependent on timely technology adoption and effective market penetration strategies.

Table 2: Table for *Diversification through Digital Health Ventures*

5.3 Strategic Alliances or Acquisitions

Biocon could strategically pursue acquisitions or form alliances with other pharmaceutical or biotech companies to enhance their offerings, share R&D expenses, and expand their market reach.

This approach could specifically target companies with complementary strengths in areas where Biocon aims to bolster its position, such as next-generation biologics or specialized clinical research.

Strengths	Utilizing its reputation and financial strength to form mutually beneficial partnerships.
Opportunities	Expanding its product portfolio and technological capabilities through partnerships, while mitigating the high costs and risks associated with solo R&D efforts.
Risks	Challenges in integration and maintaining company culture post-acquisition. Potential dilution of brand identity if not managed properly.
Potential	High, as successful alliances and acquisitions can rapidly scale operations, diversify risk, and enhance market positioning.

Table 3: Table for *Strategic Alliances or Acquisitions*



Figure 7: Identified Strategic Alternatives for Biocon

6 Conclusion and Recommendations

Since its founding in 1978, Biocon has evolved from being a modest enzyme manufacturer to a dominant global biopharmaceutical entity, showcasing significant capacity for innovation and strategic acumen. This analysis has delved into the strategic challenges and opportunities facing Biocon, particularly through its subsidiary, Clinigene, assessing its market position and competitive strength. External factors such as economic fluctuations, regulatory changes, and technological progress have significantly influenced Biocon's operations and strategic decisions. Internally, VRIO and value chain analyses highlight Biocon's formidable integration of operations and focus on innovation, establishing it as a major player in the pharmaceutical sector.

As market dynamics continue to evolve, Biocon must adapt its strategies to sustain growth and maintain its competitive edge. The strategic alternatives discussed, such as geographic expansion, diversification into dig-

ital health, and forming strategic alliances or acquisitions, highlight pathways for Biocon to not only bolster its existing strengths but also to capture new opportunities. Another implementation considerations or recommendations are:

1. Conduct thorough market research and feasibility studies before entering new markets or launching new ventures.
2. Establish robust risk management frameworks to mitigate potential risks associated with regulatory changes, market entry, and technological investments.
3. Ensure alignment of new ventures and alliances with Biocon's core values and strategic objectives.
4. When it comes to monitoring and evaluation:

4.a. Regularly review the performance of new ventures and market expansions against predefined KPIs and adjust strategies as necessary.

4.b. Utilize feedback mechanisms to gauge market response and customer satisfaction in new markets and with new products or services.

Recom.	Pros	Cons	Risks	Benefits
Expand into New Geographical Markets	Access to new markets and diversification of market risk.	Regulatory and logistical challenges in unfamiliar markets.	Potential difficulties in navigating different regulatory environments.	Increased market share and revenue streams.
Diversify Through Digital Health Ventures	Positions Biocon at the forefront of technological innovation in healthcare.	High initial investment and uncertain return in a nascent market.	Technological and market risks associated with early-stage industries.	Potential to revolutionize patient care and secure a first-mover advantage in new therapeutic areas.
Pursue Strategic Alliances or Acquisitions	Rapid scaling of operations and access to new technologies and markets.	Challenges in integration and potential dilution of company culture.	Integration risks and potential misalignment with Biocon's core values.	Strengthened market positioning and diversified product offerings.
Conduct Market Research & Feasibility Studies	Informed decision-making and identification of viable markets.	Time-consuming and resource-intensive process.	Incomplete or inaccurate data can lead to poor strategic decisions.	Reduced risk of market entry failures and targeted investment.
Establish Risk Management Frameworks	Proactive handling of potential risks.	May require significant upfront investment in resources and systems.	Inadequate risk management can result in unforeseen complications.	Mitigation of financial and operational risks enhances stability.
Align Ventures with Core Values	Ensures consistency and preserves brand integrity.	Can limit flexibility in aggressive market conditions.	Misalignment can dilute brand and alienate stakeholders.	Long-term sustainability and stakeholder trust.
Regular Review & KPI Assessment	Enables dynamic response to market changes.	Requires continuous resource allocation for analysis.	Potential misinterpretation of data can lead to misguided strategies.	Continuous improvement and strategic refinement.
Utilize Feedback Mechanisms	Direct insights into customer needs and satisfaction.	Can be challenging to interpret diverse feedback effectively.	Neglecting feedback can result in market disconnect.	Enhanced customer relationships and product/service improvements.

Table 4: Summary of Strategic Recommendations for Biocon

7 Monitoring and Evaluation

KPI stands for *Key Performance Indicator*, a quantifiable measure of performance over time for a specific objective. KPIs are crucial for ensuring that teams support the overall goals of the organization, providing insights into the progress and efficacy of strategic initiatives and informing necessary adjustments [38].

1. Strategic Alliances or Acquisitions

- (a) *Number of strategic partnerships formed or acquisitions completed annually.* Measures Biocon's success in negotiating and finalizing strategic deals, crucial for expanding capabilities and market presence.
- (b) *Revenue growth from new partnerships or acquisitions.* Assesses the financial impact of these ventures on Biocon's bottom line, indicating if the strategic moves are enhancing business growth and profitability.
- (c) *Integration success rate, measured by employee retention and satisfaction post-integration.* Gauged by employee retention and satisfaction post-integration, this KPI evaluates the effectiveness of integrating new partnerships or acquisitions into the company's structure, impacting employee morale and retention essential for sustaining productivity and innovation. [53]

2. Expansion into New Geographical Markets

- (a) *Market entry success rate.* Defined by achieving set revenue targets

within the first two years of entry, this monitors the effectiveness of Biocon's market expansion strategies [29].

- (b) *Customer acquisition rates in new markets.* Important for measuring how quickly Biocon can establish a customer base in new regions, impacting overall success of market entry efforts [37].
- (c) *Regulatory approval times.* Tracks efficiency in navigating new market regulations, crucial for assessing operational efficiency in new markets [26].

3. Diversification through Digital Health Ventures

- (a) *ROI from digital health investments.* Determines the financial return on investments in digital health, highlighting the viability of these initiatives [19].
- (b) *Adoption rate of new digital products or services among target customers.* Measures market acceptance and usability of new digital solutions, indicating success of innovation efforts and alignment with customer needs [9].
- (c) *Innovation index.* Tracks the number of new digital solutions developed and commercialized, measuring Biocon's effectiveness in sustaining innovation within the digital health sector, crucial for maintaining a competitive edge [12].

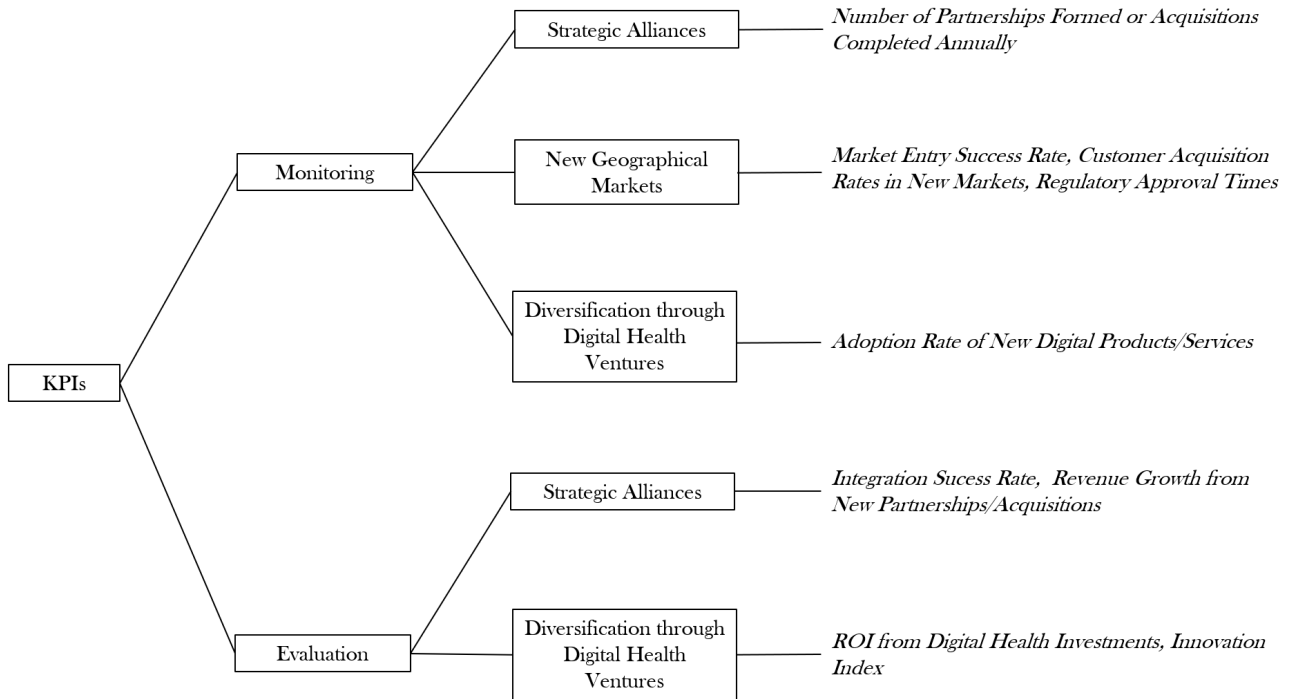


Figure 8: Proposed KPIs for Biocon's Monitoring and Evaluation

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