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RESEARCH ARTICLE

Is There a Difference in Innovation Performance Depending on the Investment in Each Stage of Development Process? Evidence From Medical Device Industry

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ABSTRACT Though innovation is essential to achieve competitiveness in the medical device industry, it is difficult for most firms in developing countries to invest sufficient resources in research and development (R&D) activities due to their small firm size. Therefore, it is necessary to evaluate a company's R&D performance based on the R&D efficiency, which is R&D output to input, rather than the output itself. Although medical device development (MDD) process in the medical device industry is divided into several stages, moreover, the impact of R&D activities in each MDD stage on R&D performance is still unanswered. This study verifies the difference in R&D efficiency according to three business types: both manufacturing and import, manufacturing only, and import only. The effect of the R&D activities in each MDD phase on R&D efficiency is also verified. The results prove that import-only companies tend to achieve higher level of R&D efficiency than firms engaging in manufacturing-only or both manufacturing and import. However, the difference in R&D efficiency between manufacturing-only companies and both manufacturing and import companies has not been verified. Furthermore, it is also verified that the impact of investment in each MDD stage on R&D efficiency varies depending on business types.

INDEX TERMS Medical device industry, research and development efficiency, business type, medical device development (MDD) process.

I. INTRODUCTION

Not only the aging population has increased the demand of medical devices, but also the development of technology has increased supply – hence, the scale of global health care industry has expanded [1]. The outbreak of COVID-19 further accelerates the trend, and the importance of medical equipment and supplies is becoming more emphasized over time [2]. Countries around the world have been striving to supply medical supplies; for example, the U.S. government is also investing huge amounts of money to supply medical devices by increasing overall COVID-19 testing supply, increasing the number of tests authorized, increasing the number of places to get tested, and increasing access to free testing [3].

The global medical device market is up to 414 billion U.S. dollars as of 2020, indicating that the global medical device market is already large enough and has great potential for future growth. However, the size of the medical device market varies greatly from country to country, with the top 10 countries accounting for 77% and the top 20 countries accounting for 88% of the total global market size ([4]; see Figure 1). South Korea, which is considered as a representative developing country in the field of medical device industry, ranks 8th, but the size of the market is less than 2% of the total market [4].

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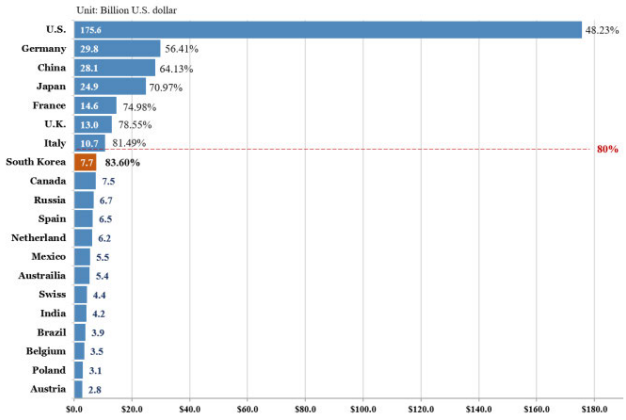

FIGURE 1. World medical device market share of top 20 countries.

The medical device industry is difficult to innovate due to vigorous regulations, but at the same time, the cycle of innovation is very frequent and R&D investment must be accompanied to achieve competitiveness [5]. However, many companies in the medical device industry are small and medium-sized companies (SMEs), which lack the funds and human resources to invest in R&D [5], [6], [7]. In particular, the medical device market in developing countries is dominated by a small number of large foreign companies and the proportion of SMEs in the market is very high, making it difficult for most companies to invest in R&D [5]. This is supported by the fact that the total R&D expenditure of the Korean medical device companies is less than 25% of the expenditure of a single foreign company [7]. Therefore, it is essential for SMEs to achieve R&D efficiency, which is the ratio of R&D output to input, rather than the output itself.

However, achieving R&D output by investing R&D resources to innovate medical devices is not a simple challenge, as MDD process consists of several stages including funding/concept development, verification and validation, production, market release, improve released product, and others [8], [9], [10]. Therefore, SMEs face the challenge of allocating limited R&D resources at each stage of MDD, which is expected to be more serious in the medical device industry in developing countries. Unfortunately, the relationship between investment by MDD-stage and R&D efficiency is still unanswered. Despite the polarization of the medical device market in developed and developing countries, moreover, studies have been utilized data from developed countries while research on the industry in developing countries is very scarce [5].

Using data from medical device industry in South Korea, which is considered as a representative industry in developing countries [5], this study aims to analyze the difference in R&D efficiency by R&D investment on MDD phase. Since the relationship between R&D investment on MDD phase and R&D efficiency could be differ by business type, moreover, this study examines the relationship by dividing the business type into three: manufacturing only, import only, and both manufacturing and import. The following of the paper is consisted as follows. Section II elaborates the literature on the R&D efficiency of medical device industry, as well as the studies on the factors affecting the industry. Section III suggests research methodologies, followed by section IV which presents the results. Finally, section V presents conclusions, implications, and directions for the future research.

II. THEORETICAL BACKGROUND

A. THE MEDICAL DEVICE INDUSTRY IN SOUTH KOREA

The medical device industry (or sometimes called as health care equipment & supplies) is an industry that designs and manufactures various medical products affecting humans [11]. Compared to other industries, it has been found that the medical device industry has the following characteristics in common.

First, the medical device industry has a short product life cycle, and it is necessary to continuously improve the product [12]. The product replacement cycle in the medical device industry is much shorter than in other industries, and accordingly, innovation is achieved at a rapid pace with active R&D investment [5]. It is supported by the fact that patent application in the medical technology have been shown to be more vigorous than in the other knowledge-intensive industries, such as digital communication, computer technology, pharmaceutical, and others as of 2018 [13]. Second, regulations are rigorous due to the safety and validity issues, as medical device directly affects human life [5]. Despite the development of diverse products, only a few are approved by an agency such as the FDA, and even the release of new products takes a long time due to the strong regulations [5]. Other features different from other industries are also being pointed out that major customers in the medical device industry are medical professionals and they play a major role in product development [5], [12].

In addition to the characteristics of the medical device industry as above, the Korean medical device industry, which is regarded as a representative medical device industry in developing countries, has the following characteristics. In South Korea, the quality of medical services, hospital information systems, and medical insurance systems are evaluated to be at a high level, but the level of the medical device industry remains low [7]. The growth rate of the medical device market and the market size is relatively high, but the actual size of the Korean medical device market accounts for less than 2% of the global market [14], [15]. On top of that, most companies in the Korean medical device industry are SMEs, and they lack the resources and employees to invest in R&D activities [5], [6], [7]. Since Korean medical device firms are latecomers, moreover, the brand power is weak and it is difficult to attract sufficient investment [5], [7]. In the end, though the market has high growth potential, the market size is small, and it is even dominated by several large companies with abundant R&D capabilities and employees.

In summary, though innovation is essential to achieve competitiveness in the medical device industry, most companies

in developing countries have limited R&D activities due to their small firm size. Furthermore, the nature of R&D that a certain amount of input does not necessarily guarantee a specific amount of output could make SMEs in the medical device industry reluctant to perform R&D activities. Therefore, it becomes a more appropriate strategy for many SMEs to maximize the ratio of R&D outputs to inputs (the R&D efficiency), rather than the output itself.

B. MDD PROCEESS

Similar to the general engineering design process, which is consisted of (1) determination of a need, (2) conceptualization, (3) preliminary design and evaluation, (4) detailed design and testing, and (5) production [16], the MDD process also goes through several steps. Although the methods utilized to categorize the development phase of medical device vary slightly from study to study, the classification in the large framework is similar. The MDD phase in previous studies is summarized in Table 1.

Based on the literature, MDD phase could be summarized in the following five stages. First, 'funding/concept phase' is a step to derive basic research ideas, which involves attracting investment to implement ideas. The second 'development phase' is a product development research stage that increases effectiveness through repeated prototype development. The third 'verification and validation phase' is a step to ensure safety based on performance certification and clinical trials. The fourth 'production phase' is a step of producing government-certified products, and rigorous quality control and process development research for quality improvement are also conducted. The fifth 'improve existing product' is a stage occurs after the product's launch to the market. During this stage, the focus lies on enhancing and modifying the existing product based on market feedback and opinions.

TABLE 1. MDD phase in studies.

Author	Phase
Panescu [8]	(1) Funding Phase (2) Concept Phase (3) Development Phase (4) Verification and Validation Phase (5) Production Phase (6) Market Release Phase
Shah et al. [9]	(1) Concept stage (2) Design stage (3) Testing and trials stage (4) Production stage (5) Deployment stage
Marešová et al. [10]	(1) Initiation (2) Concept proposing (3) Design and development (4) Verification and validation (5) Production (6) Market device deployment
Aitchison et al. [17]	(1) Feasibility (2) Design (3) Verification (4) Manufacture (5) Validation (6) Design transfer (7) Design changes
Das and Almonor [18]	(1) Product concept (2) Form development team (3) Create attribute driven specification (4) Develop and approve project plan (5) Implement design control (6) Product design activity / process validatio n / Clinical validation (7) Continuous electronic documentation (8) Release product
Alexander and Clarkson [19]	(1) Device user needs / develop verification r equirements / device validation (2) Device design / final device verification (3) Process user needs / develop verification requirements / process validation (4) Process design / final process verification (5) Production development / final process q ualification

C. R&D EFFICIENCY IN MDD

SMEs in the medical device industry face resource constraints in comparison to larger companies, which leads to disadvantages in manufacturing, operations, and risk management [7], [20], [21]. Consequently, unlike their larger counterparts, which have the capacity to dedicate ample resources to the development process of medical devices, SMEs need to devise strategies to effectively allocate their limited resources [22].

Beyond the mere completion of each step in the process, the level of effectiveness with which these steps are carried out holds significant importance, and it is greatly influenced by the resources available to the company [23]. In earlier discussions, the development stage of medical devices can be broadly divided into five distinct stages, and for SMEs, a critical challenge lies in determining how to allocate their limited resources across each of these stages for successful medical device development. While an organization may wish to conserve resources during a particular stage, doing so can entail risks, such as missing out on acquiring essential information [23]. Instead of selectively concentrating on only a few stages, therefore, it is crucial to strike a balance and allocate resources across all stages effectively.

Ultimately, companies can enhance their innovation efficiency by optimizing the allocation of innovative resources and adjusting the ratio of different inputs to maximize the output of these resources [24]. This holds true for numerous SMEs in the medical device industry, as they must carefully determine how much of their limited resources should be allocated to each stage of the medical device development (MDD) process to achieve high innovation efficiency and maximize innovation output based on this allocation [24].

Despite decades of research on R&D efficiency, research measuring R&D efficiency in the medical device industry is still insufficient. Although research on MDD process has been continued for decades, moreover, the relationship between the proportion of R&D resource investment for each stage and R&D efficiency has not been answered. Therefore, this study aims to analyze the relationship between investment in each MDD phase and R&D efficiency. It is expected

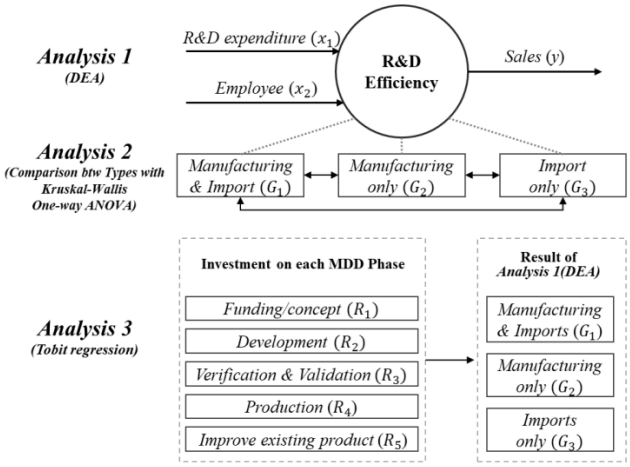

FIGURE 2. Research model.

TABLE 2. Factors and description.

Factors		Description	Reference
Output	Sales	Domestic sales of domestic and imported medical device products corresponding to registration permission and import permission items	[25], [26]
Input	R&D expenditure	Total R&D expenditure by all resources in the medical device field	[25], [27], [28]
	Employees	The number of employees in the medical device field	[26]

not only to suggest appropriate R&D strategies to managers at medical device companies with limited resources, but also to make policy suggestions for the development of the medical device industry.

III. METHODOLOGY

A. RESEARCH MODEL

Following to the purpose of the study, this study first calculates R&D efficiency, and then analyzes the relationship between investment on each MDD phase and R&D efficiency. Following to the previous studies capturing R&D efficiency, this study utilized two inputs (R&D expenditure and employees) and one output (sales) to measure R&D efficiency. The details of the variables used are summarized as Table 2.

In addition, MDD phase are classified into the following five: Funding/concept phase, development phase, verification and validation phase, production phase, and Improve existing product phase. Accordingly, the research model for measuring the relationship between investment in each MDD phase and R&D efficiency is established as Figure 2 below.

B. RESEARCH METHODS

As this study analyzes the effect of R&D investment by each MDD phase on R&D efficiency, the research methods utilized are twofold: data envelopment analysis (DEA) and regression analysis. DEA is one of the most widely used methods to estimate efficiency. It is a non-parametric method using linear programming (LP), which identifies efficient boundaries consisting of efficient decision making units (DMUs) and calculates the relative efficiency of each DMU [29].

The DEA model could be divided into two models: CCR model and BCC model. Charnes et al. [30] developed a CCR model capable of calculating efficiency values for multiple input and output factors, based on the efficiency measured by Farrell [31]. The CCR model assumes constant returns to scale (CRS), and it has a limitation in that the model could not distinguish between scale efficiency and pure technological efficiency. Accordingly, Banker et al. [32] developed a BCC model assuming variable returns to scale (VRS), which enables the distinction between scale efficiency and pure technological efficiency.

The BCC model takes a form where the convexity requirement is added to allow for variability in scale, and this requirement fixes the weighted sum of inputs or outputs to 1. The scale indicator derived after solving the LP problem of the BCC model distinguishes the returns to scale of DMUs, such as increasing returns to scale (IRS), constant returns to scale (CRS), and decreasing returns to scale (DRS). Unlike CCR model, which assumes that all DMUs operate at their optimal scale, the BCC model has the advantage of more accurately reflecting the reality where individual DMUs cannot operate at their optimal scale due to factors such as imperfect competition or financial constraints.

The DEA could also be divided into input-oriented and output-oriented models, depending on whether input or output factors are controllable. The input-oriented model minimizes inputs for given outputs, while the output-oriented model maximizes outputs for given inputs. This study adopts the input-oriented DEA-BCC as it is reasonable to regard that R&D inputs are controllable rather than output.

The efficiency score derived as a result of DEA becomes a dependent variable of regression analysis. As DEA maximizes efficiency while constraining the efficiency score not to exceed 1, however, the dependent variable has a value between 0 and 1. Accordingly, tobit regression is adopted instead of ordinary least squares (OLS), since the dependent variable of the regression analysis could not satisfy the normality of the distribution [33], [34].

C. DATA

This study utilizes the 'medical device industry survey' released by Korea Health Industry Development Institute in 2018. The survey is highly reliable as it is designated as government-approved statistics by the National Statistical Office of Korea and is used for establishing policies to foster the medical device industry. The data is used as it contains overall information required for this study, including the characteristics of the enterprise and their R&D activities. The medical device industries for treatment purposes except for cosmetic purposes are selected as the subject of

TABLE 3. Descriptive statistics (unit: million KRW).

	Factors	Max	Median	Min	Mean	St.dev
Group 1	Sales	443,267	3,700	130	16,890	54,559
	R&D expense	1,038	28	2	84	158
	Employee	26,746	320	10	1,481	3,988
Group 2	Sales	52,129	948	1	2,935	6,319
	R&D expense	1,006	10	1	30	69
	Employee	49,031	140	0	622	2,402
Group 3	Sales	230,227	1,722	10	8,654	29,462
	R&D expense	265	10	1	24	47
	Employee	2,550	100	0	211	370

the analysis, and 743 firm samples are utilized for the analysis after excluding data with missing values.

The descriptive statistics of the input and output factors by business type are summarized in table 3. It is noteworthy that group 1 is higher than others in all factors, suggesting that it consists of larger firms compared to group 2 and 3. Business model innovation through diversification often demands significant resource allocation, which is why it is mainly undertaken by large-scale firms [35]. In contrast, SMEs with limited resources are more likely to focus on either manufacturing or import exclusively. There are also differences by factors between group 2 and 3; group 2 surpasses group 3 in R&D expenses and the number of employees (input factors), while group 3 outperforms group 2 in terms of sales (output factors).

IV. RESULTS

Figure 3 shows the box and whisker plot showing the results of Kruskal-Wallis One-way ANOVA for the efficiency of the medical device industry. The X- and Y-axis represents the business type and efficiency distribution, respectively. The pairwise comparison results of the difference in the efficiency distribution by business type is summarized Table 4. The results show that group 3 (import only) tends to achieve higher R&D efficiency than group 1 (both manufacturing and import) and group 2 (manufacturing only), while difference between group 1 and 2 is not significantly verified.

Given that group 1 is higher in both input and output factors compared to group 2 in general, the result suggests that medical device manufacturers with insufficient R&D resources could achieve similar level of R&D efficiency to those engaging in both manufacturing and import with sufficient R&D resources. However, firms could achieve the highest level of R&D efficiency by converting business type into import only, which could be a more appropriate strategy for firms with insufficient R&D resources.

It is in line with the study which argues that SMEs in the medical device industry may choose a strategy to import rather than produce by themselves to overcome their limitation of resource shortages [5].

In order to examine the detailed causes of inefficiency in the medical device manufacturing industry, this study further

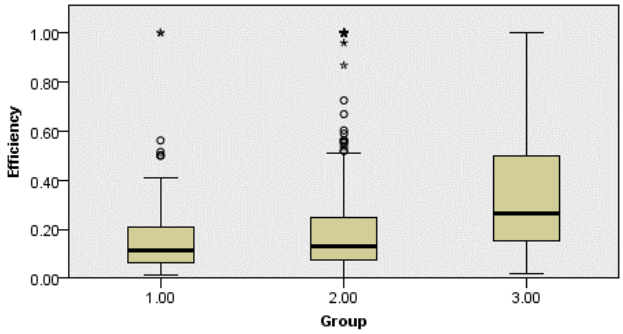

FIGURE 3. Box and whisker plot of R&D efficiency by group.

TABLE 4. Pairwise comparison test results.

	Test Statistics	Std. Error	Std. Test Statistics	Sig. Test Statistics
G1 – G2	-32.605	23.750	-1.373	.509
G1 – G3	-193.807	34.085	-5.686	.000***
G2 – G3	-161.202	27.505	-5.861	.000***

*** p < .01

TABLE 5. Tobit regression results by MDD phase.

		Coefficient	Std. Error	z-Value	Sig.
Group 1	R1	-4.389e-04	.000	-1.519	.129
	R2	1.038e-04	.000	2.345	.019**
	R3	-1.289e-04	.000	-1.167	.243
	R4	1.404e-04	.000	.370	.712
	R5	1.294e-04	.000	.469	.639
Group 2	R1	2.063e-04	.000	1.757	.079*
	R2	-8.038e-05	.000	-1.493	.135
	R3	1.383e-04	.000	1.023	.306
	R4	-8.305e-04	.000	-3.193	.001***
	R5	-2.598e-04	.000	-2.458	.014**
Group 3	R1	-2.982e-03	.001	-2.489	.013**
	R2	2.026e-03	.002	1.212	.226
	R3	-2.607e-04	.001	-.202	.840
	R4	-1.102e-03	.002	-.581	.561
	R5	-1.299e-03	.001	-1.275	.202

* p < .10, ** p < .05, *** p < .01

verified the R&D efficiency by R&D investment phase by performing regression analysis. Table 5 shows the results of tobit regression on the effect of R&D investment by MDD phase on R&D efficiency depending on business type. It is verified that firms in group 1 (both manufacturing/imports) tend to achieve higher level of efficiency when investing in the development stage (R2). Such companies have a certain level of financial stability and company size with information on imported medical devices, which makes R&D on existing product improvement more advantageous rather than developing new devices.

In case of group 2 (manufacturing only), funding/concept phase (R1) has a positive effect, while production phase (R4) and improve existing product phase (R5) have a negative effect on R&D efficiency. Given that firms belong to group 2 achieve small sales but invest a lot in R&D activities, there is

a possibility that such firms have limited amount of available funds, and investing in developing idea and/or concept rather than investing in production process and marketing could increase R&D efficiency.

Group 3 (import only) shows that R&D expenditure on funding/concept phase (R1) tends to lower R&D efficiency. Since the medical device importer (group 3) purchases devices from outside of the firm itself, investment in new device concept which is expected to be required for device manufacturers rather than importers has been proven to have negative effect on the efficiency. The relationship between other MDD phase and efficiency has not been significantly verified.

V. CONCLUSION

A. IMPLICATIONS

This study verifies the difference in R&D efficiency between business types – manufacturing only, import only, and both manufacturing and import –, and further analyzes the difference in efficiency depending on the degree of investment in MDD phase. The study has the following implications.

Academically, this study expands the discussion on the R&D output to efficiency in medical device industry. Despite the importance of R&D activities, most companies have difficulties in performing R&D activities because of insufficient R&D resources due to small firm size. Therefore, R&D outcomes in the medical device industry should be evaluated as efficiency rather than output itself, and this study suggests R&D efficiency as a measure of R&D performance in the industry. Since R&D efficiency is a concept applied not only in the medical device industry but also in other industries [36], [37], it can be employed to measure the innovation performance of SMEs that lack R&D resources in those industries.

Moreover, this study analyzes the effects of R&D activities at different phases by dividing the process of MDD into several stages. Although it has been studied for decades that R&D activities in the medical device industry consist of several processes, the effect of R&D has been studied without considering MDD phases. This study verifies that R&D efficiency may vary depending on the proportion of investment by MDD phase, indicating that allocating R&D inputs to each stage could also affect R&D performance. Given that the MDD process bears similarities to a general engineering process [16], this study, although conducted in the medical device industry, suggests that it is likely applicable to other industries as well.

This study also has the following practical implications. First, a strategy to enhance competitiveness is provided to companies with insufficient R&D resources by discussing methods for achieving R&D efficiency. Though studies have emphasized the importance of R&D activities in the medical device industry, SMEs that are difficult to input sufficient R&D resources face the reality that it is difficult to perform R&D activities sufficiently. This study measures efficiency based on R&D input to output rather than output itself, providing indicators that not only large companies but also SMEs with insufficient R&D inputs could utilize. Indeed, a shortage of capital or manpower has been identified as a hindrance to R&D in numerous companies [38]. As a result, companies with limited resources in industries other than the medical device industry can establish effective R&D strategies aimed at R&D efficiency focusing on input-to-output approaches rather than solely on the R&D output itself.

Furthermore, this study verifies the difference in R&D efficiency depending on business type and the proportion of investment by MDD phase. Most of the firms in developing countries lack the resources to invest in R&D, but at the same time, they have to decide how much limited resources to allocate for each MDD phase. This study can suggest strategies for companies to invest in the appropriate MDD phase according to their business types in order to achieve high R&D efficiency. Accordingly, companies belonging to other industries other than the medical device industry that carry out R&D in accordance with the engineering design processes can also establish appropriate input strategies for R&D resources according to their business type (manufacturing and/or import). This study can suggest not only to the managers at firms but also to the government's policymakers. The effect of the policy could be further increased if support for an appropriate MDD phase is provided depending on business type of the company. Above all, selective support depending on company's R&D capability is expected to lead the growth of not only large companies but also SMEs, and ultimately, the growth of the entire medical device industry.

B. LIMITATIONS AND SUGGESTION FOR FUTURE RESEARCH

Despite the implications above, the following limitations could be pointed out. First, this study uses only data from the Korean medical device industry, and the representativeness may not be guaranteed. Since it does not reflect national characteristics, it is unreasonable to interpret that the results will be applied equally in other developing countries. Therefore, it is expected that future studies will be able to present valuable implications by comparing the differences in R&D efficiency depending on business type and investment on each MDD phase by countries.

Second, the data utilized in this study is from 2018, which does not reflect the impact of COVID-19 that has occurred since 2019. This is due to the limitation that this study used secondary data and that the latest accessible data is from 2018, as the 'medical device industry survey' was discontinued in 2019 in order to implement statistical improvements. In the future research, therefore, it is expected that more meaningful results will be presented by securing panel data over several periods, and comparing the R&D efficiency of the medical device industry before and after COVID-19.

Third, while it is possible to determine the proportion of R&D expenses for each stage of MDD phase, it remains challenging to ascertain the allocation of manpower to each stage and the extent to which each stage contributes to sales,

as they are only available in aggregate. Consequently, due to the inability to comprehensively assess both inputs and output for each stage of MDD, a direct calculation of efficiency is not feasible in this study. If future research could calculate the efficiency of each MDD stage, it could reveal the relationship between stage-specific and overall R&D efficiency, providing valuable insights for companies to refine their R&D strategies tailored to each MDD stage.

Finally, the proportion of investment in MDD phase is the only environmental variable considered in this study which could affect the difference in R&D efficiency. Identifying factors which may affect R&D efficiency and verifying their impact could also be an important study, and we leave it to the future research.

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