

Building a Knowledge-Intensive Medical Device Industry: The Effect of
Knowledge Creation in R&D Project Performance
(Pembinaan Pengetahuan Intensif dalam Industri Peranti Perubatan: Kesan Penjana-
an Pengetahuan terhadap Prestasi Projek Penyelidikan dan Pembangunan)

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ABSTRACT

This study aimed to examine the influence of the organizational factors (reward, training, and collaboration) and knowledge creation process on R&D project performance. A quantitative approach was employed with the data obtained from the sample of R&D projects from the medical device firms listed on the Association of Malaysian Medical Industries (AAMI). Smart-PLS 3.0 software was used to check the data validity and reliability, and to test the structural path modeling. A total of 115 R&D project managers participated in this study with a response rate of 27.2%. The results revealed that six sub-hypotheses out of seven sub-hypotheses were supported. Based on the findings, this study implies that organizational factors, such as reward and collaboration, with the knowledge creation process as the mediator, are critical to enhance the R&D project performance among medical devices firms. This study provides theoretical and practical implications as well as suggestions for future R&D performance studies in different industries.

Keywords: Reward; training; collaboration; performance; knowledge creation; R&D project

ABSTRAK

*Tujuan kajian ini adalah untuk mengkaji pengaruh faktor organisasi (ganjaran, latihan dan kerjasama) dan penjana-
an pengetahuan terhadap prestasi projek penyelidikan dan pembangunan. Kaedah kuantitatif telah
digunakan untuk dapatan data dari projek penyelidikan dan pembangunan dalam kalangan firma peranti perubatan
yang tersenarai di Persatuan Industri Perubatan Malaysia (AAMI). Perisian Smart-PLS 3.0 digunakan untuk
menjalankan analisis statistik bagi menguji kesahan dan kebolehpercayaan data, dan juga menguji model laluan
(path modeling). Sebanyak 115 pengurus projek penyediaan dan pembangunan dari firma peranti perubatan di
Malaysia telah mengambil bahagian dalam penyelidikan tersebut dengan kadar respon sebanyak 27.2%. Dapatan
kajian menunjukkan bahawa terdapat enam daripada tujuh hipotesis yang disokong. Melalui dapatan kajian ini,
faktor organisasi seperti ganjaran dan kerjasama dengan penjana-
an pengetahuan sebagai pengantara adalah
penting untuk meningkatkan prestasi projek penyelidikan dan pembangunan dalam kalangan firma peranti
perubatan. Kajian ini memberikan implikasi kepada teori dan praktikal serta boleh dicerakinkan untuk kajian dalam
prestasi penyelidikan dan pembangunan masa hadapan di industri yang berlainan.*

*Kata kunci: Ganjaran; latihan; kerjasama; prestasi; penjana-
an pengetahuan; projek penyelidikan dan
pembangunan.*

INTRODUCTION

We have heard the saying “health is wealth”, and it is true that good health often results in a longer lifespan and higher productivity. In recent years, countries around the world have recognized the need of a robust healthcare system for sustainable growth and development, and, even in many developing countries, affordable medical options

are often being sought-after. In ASEAN countries, the significant economic growth has resulted in the growth of the middle-class population who can afford more quality healthcare, and, hence, has increased the healthcare spending in the region. Malaysia represents one of the vigorous and vibrant medical device markets, which is valued at USD 1.4 billion, and is top in the Southeast Asian region (Pacific Bridge Medical 2019). In addition, Malaysia is predicted to have an aging population of 15% by 2030 (Tan & Ong 2015). With a growing elderly population and quality device servicing needs, a more sustainable healthcare technology solution is needed to cope with the medical costs. The ballooning of healthcare costs (Chin 2018) for Malaysian patients due to the increase in prices in medical supplies and drugs is not new. Hence, the provision of domestically manufactured medical devices has become an ideal solution to enable affordable medical treatments to people from all walks of life.

Besides the internal demand, Malaysia also provides 80% of the world needs for catheters and continues to dominate the world market for rubber gloves at 60%, especially medical gloves (Chin 2018). Hence, the medical device industry is identified as being a high growth sector in the 11th Malaysia Plan (2016-2020). The total investment in the medical device industry is projected to grow by 9% year-to-year, reaching USD 7 billion in 2020. Under the 11th Malaysia Plan, there is a need to develop new and more sophisticated medical gloves and higher end catheters with improved performance; leverage upon Malaysia's strength in original equipment manufacturers (OEM) for medical devices; and move into higher end orthopedic products, contact lenses, and surgical instruments. Looking at the need to broaden the medical product range to the higher-end category, better R&D performance in medical devices will meet the technology requirement of higher quality medical device needs by 2030.

With the promising demand and investment growth, the Ministry of International Trade and Industry (MITI) is driving efforts to develop more capital and knowledge-intensive operations, provide assistance to encourage R&D activities, and foster greater collaboration between industry and research institutes to strengthen the development of indigenous and new medical devices. The industry is encouraged to upgrade the technology and information communication technologies (ICT) applications, moving from basic processes to those involving more innovative and leading-edge technologies. MITI is focusing on shifting the industry towards higher technology products through knowledge workers and better R&D performance to meet the existing and future demands of the industry.

In tandem with the call for collaboration between industry and the research institutes to strengthen R&D performance, this research attempts to answer the key components to increase R&D project performance in Malaysia's medical device industry. Managing R&D projects in the medical device industry requires an understanding of both the organization factors and the type of knowledge required to achieve project objectives. Hence, this study examines three organizational factors and their interactions with the knowledge creation process to bring forth R&D project performance.

Knowledge creation has been identified by past research as an important enabler for organizational success (Baldé, Ferreira & Maynard 2018). R&D projects require organizations to understand the knowledge creation mechanism and provide an ideal innovative environment to achieve the project objectives (Chandrasekaran & Linderman 2015). Given the importance of knowledge creation and its linkage with organizational performance, it is essential to identify the factors and contexts that facilitate project members' knowledge creation. The spiral knowledge creation process, which is based on the socialization, externalization, combination, internalization model (SECI) model of Nonaka and Takeuchi (1995), is one of the most influential theories of knowledge creation (Popadiuk & Choo 2006). In today's business environment, it is rare for R&D project members to work in isolation. The SECI model adopts the notion of the "community of practice" in which project members exchange know-how to make effective decisions. This study examines the utilization of the SECI model among project members to contribute to individual knowledge creation behavior, which, in turn, leads to the outcome of enhancing R&D project performance.

Nevertheless, the role of knowledge creation in leveraging R&D project performance will be emphasized because recent research and practice suggests that an increasing reliance on knowledge capabilities is required to garner competitive advantage. Furthermore, it has been noted elsewhere in the literature that knowledge management implementation is context specific (Nonaka, Toyama & Nagata 2000; Oluikpe 2015). The R&D projects for medical devices are unique, which is partly due to the lengthy regulatory process to obtain new product approval and dependent on the device's risk category and the clinical trials required (Yee, Tan & Ramayah 2017). Therefore, project management is required to adapt models to suit the peculiarities of the nature of R&D activities in the medical device industry.

Many studies of the management and organization of R&D projects show that the creation and the coordination of the organizational resources are interpreted as the key elements for innovation development (Pezzillo et al. 2012). In high technology firms, where technology evolves quickly, firms invest heavily in R&D to promote technological advantages (Yanadori & Cui 2013). Researchers are increasingly interested in the role of

human capital management. Incentives can reduce the loafing tendency among project members and increase knowledge sharing behavior because the visibility of the project members increases when information is shared publicly (Zhang, De Pablos & Zhou 2013). Another organizational factor is training. A new paradigm for organizational theory research has stressed that companies must offer training opportunities to develop and nurture knowledge creation (Nonaka et al. 2014) The ability to recognize opportunities and apply knowledge will increase when relevant training is provided through development programs. Besides incentives and training, collaboration improves the speed and efficiency of knowledge creation (Xue et al. 2018). Project members offer knowledge to others as well as modify, recombine, and integrate the knowledge of what others have contributed through the collaboration networks. Taken together, these components help explain how to create a knowledge-intensive environment to enhance R&D project performance in the medical device industry. From the theoretical perspective, this study is essential to expand the literature of R&D performance by providing empirical evidence for the relationship between the organizational factors and the knowledge creation process. In addition, this study also echoes the nation's goal and provides empirical evidence to help organizations align their project capabilities to increase R&D project performance through the knowledge creation process. In the next section, we examine how these components can be conceptualized into a framework. An analysis is performed and the results are shared in the following sections.

LITERATURE REVIEW

UNDERLYING THEORIES

This study employs the Resource Based View (RBV) theory (Barney 1991) and Knowledge Based View (KBV) theory. RBV is a strategic management theory that is widely used by managers in project management (Almarri & Gardiner 2014). RBV is a promising theory that examines how resources can drive competitive advantage, especially project performance, which is customized to specific organizational factors. Project management aims to create more project value than rivals, and, therefore, generate higher returns on investment through rare, inimitable, and non-substitutable resources. Organizational strategies, such as rewards structures, training programs and collaboration ties, are valuable resources to achieve a sustainable business model. Rewards refer to monetary and moral awards, which have been proven to foster ongoing creativity (Davenport, De Long & Beers 1998). Training prepares project members to implement their current job and equips them for their future engagement (Schwind et al. 2016). Collaboration reduces the risk of complexity when conducting new R&D projects (Park & Lee 2014). Studies have also found that the success rate variations between projects can be explained through the utilization of non-heterogeneous resources and internal capabilities (Caldeira & Ward 2003). Although the RBV theory illustrates the potential of the tangible (i.e., project management methodologies and practices) and intangible (i.e., project facilitation) assets of a project team to achieve superior performance, the assumption that the RBV uses the fullest potential of project resources is critically questioned (Killen et al. 2012). The knowledge-based view of a firm (KBV), an extension of the resource-based view, which focuses on the intangible assets rather than the physical assets, postulates knowledge as the primary strategy of a firm's resources (Grant 1996). KBV illustrates each project entity as a repository of tacit and explicit knowledge, which are critical to sustain competitive advantage. The function of project management as a knowledge repository is crucial to ensure the success of project initiation, planning, execution, and closure so that all learned knowledge is captured and can be used in future projects. Rewarding knowledge-sharers will encourage more participation in the knowledge creation process (Mvulirwenande, Alaerts & Wehn 2016). Training provides project member opportunities to develop critical thinking and fabricate new knowledge rather than being a knowledge recipient (Thomas & Mengel 2008). Collaboration encourages partners to offer knowledge to others as well as modify, recombine, and integrate knowledge of what others have contributed (Wang et al. 2017). Grant (1996) stressed that knowledge hinges on the way in which project members process, combine, and apply projects' know-what (i.e., practices), and know-how (i.e., facilitation). Such knowledge is ingrained in various project capabilities, such as R&D strategies, team structures, manufacturing processes, production operations, documentation system, and project members' attitude. Nonaka (1994) emphasized that when an individual develops new knowledge, internal project practices play an important role in articulating and amplifying knowledge to achieve innovation. Hence, it is vitally important for project management to define an organized knowledge creation process to generate knowledge assets in a systematic manner to maintain competitive advantage.

TACIT AND EXPLICIT KNOWLEDGE

Knowledge is conceptualized into two categories: explicit and tacit. Explicit knowledge is knowledge that can be expressed in words and numbers, such as data and scientific formulas (Nonaka 1994). Tacit knowledge is knowledge that cannot be transcribed in written form but is deeply ingrained in people's minds (Nonaka & Takeuchi 1995). Explicit knowledge is knowledge that can be readily articulated, codified, stored, and accessed. Engineering works and product design can be seen as explicit knowledge in which human skills, motives, and knowledge are externalized. Tacit knowledge contains a cognitive dimension, which comprises ideals, beliefs, and mental models that are difficult to transfer to another person by documentation or communication. In a project team, tacit knowledge has technical, cognitive, emotional, faith, and experience elements (Shao, Feng & Liu 2012). Tacit knowledge is difficult to communicate in words or symbols because this knowledge is based on individual insights, experiences, and intuitions. Knowledge management is a study to capture, distribute and effectively apply both tacit and explicit knowledge.

KNOWLEDGE CREATION PROCESS

Knowledge-based theory places primary emphasis on expanding the knowledge community and enhancing knowledge creation toward better innovation outcomes. In this knowledge creation process, project members can utilize or apply all the existing knowledge in new ways to perform their tasks and to generate new knowledge to solve problems (Sabherwal & Becerra-Fernandez 2003). Knowledge creation is an important source of continuous innovation that is capable of sustaining a project's competitive advantage. Existing knowledge and skills can be used to create new ideas, new products, and new services and also can assist in improving the efficiency of an individual or group if it is being converted and applied in a new context (Grant 1996).

Knowledge creation is an idea conversion process to facilitate individual ability for innovation. To study the process, Nonaka and Takeuchi (1995) developed the spiral knowledge creation processes of socialization, externalization, combination, and internalization (SECI). First, knowledge socialization is the process of converting tacit knowledge to another set of tacit knowledge via experience sharing, such as practice, observation, and imitation (Nonaka & Takeuchi 1995). Knowledge socialization occurs during the process of transmitting tacit knowledge to one another; when sharing they share their thinking with one another. This usually happens during the process of learning and hands-on experience. Tacit knowledge can only be acquired and converted via experience sharing (Nonaka, Toyama & Konno 2000). Knowledge socialization encourages people to spend time in informal meetings, employee cross training, and hands-on experience for exchanging specialized know-how.

The creation process is followed by knowledge externalization. It is the process of articulating tacit knowledge to explicit knowledge (Zhang et al. 2013). Knowledge becomes more valuable when tacit knowledge is converted to explicit knowledge and shared with others as new knowledge. Tacit knowledge should be converted to explicit knowledge to benefit the project. Know-how can be converted into written documents that can be understood easily. There are five mechanisms that help in the tacit knowledge externalization process – metaphors, analogies, concepts, models, storytelling, and hypotheses (Nonaka et al. 2014). Seminars and workshops create opportunities for individuals to share their knowledge with others. The appropriate use of information and communications technology (ICT) also helps to disseminate tacit knowledge.

The knowledge combination is a process by which knowledge can be directly introduced or published to others and is the process for connecting separate elements of explicit knowledge into another set of explicit knowledge in more complex and systematic ways. For example, databases, scientific texts, manuals, computerized networks, and data bank statistics are forms of explicit knowledge that can be added together to create new explicit knowledge. Knowledge combination is the outcome of the process of transforming explicit knowledge into more complex and organized sets of explicit knowledge. To obtain new explicit knowledge, combined and processed explicit knowledge can be collected from outside and inside a firm. The new explicit knowledge can then be distributed through meetings and presentations to project members.

Knowledge internalization is the process of incorporating explicit knowledge into tacit knowledge and embedding them into practices and actions, so that people can gain from what others had undergone in their past experience. The internalization process involves learning by doing and observing, face-to-face meetings, and on the job training. Once project members internalized the knowledge, the knowledge will be imprinted permanently, and it can be utilized in many ways to overcome project crises or problems (Allameh & Teimoori 2007).

REWARD AND KNOWLEDGE CREATION PROCESS

Project management must introduce an environment where project members can autonomously share and collect rewards according to the knowledge they have contributed (Navimipour & Charband 2016). Empowering project members to promote their inputs and claim the authority of their ideas is a way to cherish fairness and collegial spirit. Such an environment allows project members to capitalize on one another's contributions to the accomplishment of the project, which requires specific domain knowledge. Studies showed that when the project leader of a team deals with the behavior of their subordinates by giving rewards and punishment distinctly, it will make project members more willing to do knowledge sharing (Damanpour & Aravind 2012). Rewards motivate the project team to react positively during an unfamiliar knowledge sharing session.

The sharing of tacit knowledge could lessen the value of the knowledge owner, and various incentive systems have to be in place to motivate individuals to share domain knowledge. Kwak & Stoddard (2004) illustrated the natural tendency of an engineer as someone who would withhold technical information since information is a source of power. However, if these engineers are rewarded for sharing information, then the information hoarding tendency can be overcome.

Investment into internal human capital towards open innovation activities enables the integration of external knowledge and ideas, the co-creation of products or services or the commercialization of technologies in new markets. Rewards can also be given to those who borrow good ideas from outside and within the project team, and also to those who share them. A well-designed reward system encourages proactive behavior in voluntary knowledge sharing. Hence, the first hypothesis is postulated as below.

H₁ Rewards have a positive influence on the knowledge creation process.

TRAINING AND KNOWLEDGE CREATION PROCESS

Knowledge is generated from investment in the selection of the preparation for training (learning-before-doing) and the rate and timing for training implementation (Carrillo & Gaimon 2010). Projects should optimally increase investment in training until sufficient accumulation of the project domain knowledge is achieved. In addition, it is essential to leverage the knowledge that already exists within a project team rather than recreating the wheel for each new hire. Hence, the most effective training programs include learning strategies that go beyond the classroom, such as on-the-job training and job-rotation. Job training allows project members to learn both implicit and explicit knowledge without being assessed. Putting project members into the designated workplace directly and expecting contributions does not help new employees to overcome the learning curve to orient to the company culture. A training program that focuses on knowledge sharing helps project members to ramp faster by focusing on critical thinking and open dialogue with team members. A mentor who has showcased the successful implementation of processes and applied over their tenure in the project helps project members who are reluctant to share ideas to speak up and ask questions while learning the best way to put what they have learned into action.

Several studies showed that entities that master innovation have invested considerably in training and development programs (Bell et al. 2017). Project members can develop their creativity and their problem-solving skills, becoming better at adapting to change and improving their flexibility. Although training and development has a long tradition with operational excellence, the interest in the topic has grown with the drastic technical requirements in science and technology practices. There is a need to examine the strategic overviews of what works and what's not on the training list to avoid the pitfall of the negative perspective of project members toward training programs. The right training program will gain employee commitment and ensure their willingness to participate in the program because they want to, not because they have to. Training and development produce a knowledge friendly environment that is beneficial to the knowledge transfer and utilization among project members. Hence, this study hypothesizes as below:

H₂ Training has a positive influence on the knowledge creation process.

COLLABORATION AND THE KNOWLEDGE CREATION PROCESS

With increasing competition, it has become extremely important to encourage creativity in the workspace. Working as a team enables project members to be more effective, as compared to working in isolation. Collaboration can bring people together more efficiently. It can lead to increased team productivity, simplified business processes, and

improved workflows. Collaboration refers to being collaborative with suppliers, individuals, and customers for the innovation of products and services. It is the process of engaging suppliers and customers in creating new products and services. Collaborative innovation is a form of open innovation (Gianiodis, Ellis & Secchi 2010), which is a systematic search, storage and use of knowledge within and outside the businesses to the flow of the innovation process. The concept generally involves the combined processes and knowledge flows inside and outside the business organizations (Lichtenthaler 2011). Incoming processes involve utilizing the discoveries of others, and outgoing processes cover the sharing of technologies developed in the organization. The combination of both knowledge processes gives rise to different forms of association, such as alliances and joint ventures.

Collaboration is the sharing of various innovation elements within and between enterprises, which is referred to separately as internal and external collaboration (Xue et al. 2018). Internal knowledge collaborative innovation is concerned with the interaction mechanisms of interrelated core elements while external knowledge collaborative innovation depends on the interaction for industrial organizations and other stakeholders from both lateral and longitudinal dimensions. Collaboration is a practice that relies on the involvement of various stakeholders who have a unified target, common motivation, and cost-efficient communication to achieve frequent communication and multidimensional cooperation by taking advantage of various innovation-development platforms.

Knowledge collaboration is related to the strategic partnership between firms in an innovative effort aimed at producing new ideas, products, or services, specifically, it refers to the partnership in knowledge repositories and data systems (Grant & Baden-Fuller 2004). The strengths of two knowledge firms are combined to discover and commercialize new technologies, products, and services efficiently. It promotes long-term economic growth and regional competitiveness. It allows the two firms to utilize their individual strengths to overcome the weaknesses of each company. This is particularly applicable in the context of the study where the entry barrier for the medical device industry is relatively high. From the established firm's perspective, knowledge collaboration allows the firm to gain creative entrepreneurialism to complement the company's brand strength and reputation for expanding into existing and emerging markets. Hence, we hypothesize as below:

H₃ Collaboration has a positive influence on the knowledge creation process.

KNOWLEDGE CREATION PROCESS AND R&D PROJECT PERFORMANCE

Research and development (R&D) are creative projects that are conducted systematically to increase the level of knowledge and use it to innovate (OECD 2011). R&D projects could accomplish organizational objectives and bring forth significant innovations through the creation of knowledge repositories (Hung, Lai & Chang 2011). The performance of R&D projects is a multi-faceted and intricate construct via the re-structuring of organization resources, such as people, technology, and knowledge content (Pinho & de Sá 2014). Nevertheless, the level of performance describes the ability of the organization to use the available resources efficiently and effectively in pursuing project goals and objectives. From the theoretical perspective, R&D project performance highlights an organization's "resource-collection" abilities to acquire new knowledge with an aim to achieve specific pre-determined objectives, such as long-term economic or social benefits (Chiesa et al. 2009).

R&D projects are one of the knowledge management project variations identified in Davenport and Prusak (1998). The linkage between the knowledge creation process and R&D project performance is particularly relevant to medical devices projects because the tasks to develop safe products within time and budget are known as knowledge intensive activities. While R&D projects are knowledge intensive, we also do not want to forgo the idea that the management of projects falls under the traditional triple constraints – time, cost, and scope (Muller & Jugdev 2012). The project management triangle is also called the iron triangle or triple constraints where the quality of work is constrained by the project's cost (budget), time, (deadlines) and scope (features). The projects can be completed by trading in between constraints. Changes in one constraint necessitate changes in others to compensate or the quality will suffer (PMBok 2013). However, looking at time, budget, and scope only is insufficient to define performance because it omits crucial dimensions, such as the impact on stakeholders, customer satisfaction, and long-term benefits (Shenhar et al. 2001). It is proven that even if a project is on time, on budget, and meeting the scope, a change of circumstances may indicate that a project is no longer worth its value to proceed (i.e., the value for Nokia to deliver a 2G phone while smartphones are conquering the market). Considering the benefits helps organizations to distribute organization scarce resources among projects that provide a greater return on the market. From the perspectives of stakeholders, product users will be more concerned about the overall quality and usage satisfaction; project developers will normally think of the achievement of pre-determined project goals, such as overall scope completion that meet the time and cost constraints. On the other hand, organizations would like to see

long-term benefits from the completion of projects, such as brand reputation. As such, this study measures project performance in cost performance, adherence to schedule, customer satisfaction, and long-term benefits (Mir & Pinnington 2014).

Knowledge creation in high-tech organizations occurs by creating an innovative and collaborative society to influence R&D project performance. A successful knowledge creation process has the potential for enhancing competitive advantage, customer relations, employee development, and for lowering project cost (Skyrme & Amindon 1997). Many companies are finding efficient and successful approaches to different types of R&D projects, particularly those that involve a high level of innovation (Brettel et al. 2012). Reich, Gemino and Sauer (2014) theorized that knowledge is instrumental to the attainment of the project schedule, budget, and performance. Hence, this study hypothesizes as below:

H₄ The knowledge creation process has a positive influence on R&D project performance.

KNOWLEDGE CREATION PROCESS AS MEDIATOR

Knowledge creation plays an important role in affecting R&D project performance. Reward systems, training programs, and collaboration modes can be optimally utilized if an organization has a knowledge creation process implemented. A knowledge creation process is one of the knowledge management activities that can enhance innovativeness, and, eventually, increase R&D project performance. A well-designed reward system encourages project members to share and exchange knowledge or ideas (Al-Alawi, Al-Marzooqi & Mohammed 2007). Training enables individuals to collect or disseminate the dynamic knowledge or information acquired through workshops and seminars. Collaboration provides opportunities for downsizing, externalizing risks, and sharing knowledge among R&D intensive firms (Bustinza et al. 2019). When alliances exchange knowledge, the innovation level increases. Hence, the mediation roles of the knowledge creation process are hypothesized as below:

- H₅ The knowledge creation process mediates the relationship between rewards and the R&D project performance.
- H₆ The knowledge creation process mediates the relationship between training and the R&D project performance.
- H₇ The knowledge creation process mediates the relationship between collaboration and the R&D project performance.

Figure 1 shows the research framework of the study and the hypotheses postulated.

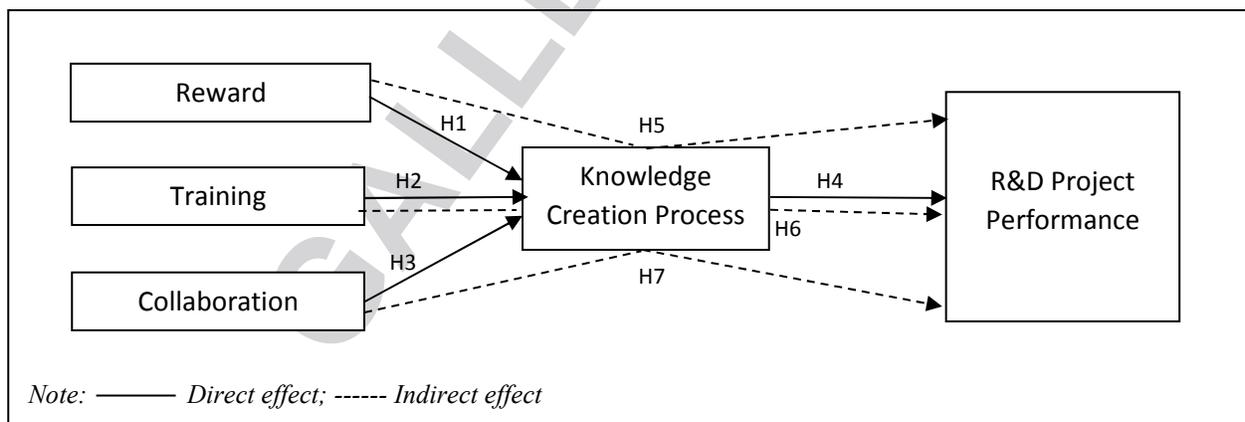


FIGURE 1. Research framework for investigation of factors affecting R&D Project Performance in the Malaysian medical device industry

RESEARCH METHODOLOGY

SAMPLE AND DATA COLLECTION PROCEDURE

The unit of analysis for this study was project level since the dependent variable is R&D project performance. The respondents of this study were R&D project managers who have the best knowledge to respond to the study context. Project managers are identified as key informants in this study because they are experienced in leading the project teams on the design of the reward structure, training program, and collaboration ties, hence their inputs are essential for the R&D projects they involved. The sampling frame to obtain the R&D project managers' responses are those medical device companies listed under the Association of Malaysian Medical Industries (AMMI). From the list, there are 91 medical device companies conducting R&D activities in Malaysia. These companies are mostly located in big cities, such as Kuala Lumpur, Selangor, and Penang. A telephone survey was conducted to gauge the number of R&D project managers in these companies and a total of 423 R&D project managers were found at the time of data collection. All of these R&D projects managers declared that they were involved in at least one project team at that point of time. In view of several conditions pre-determined for the selection of subjects to form the survey sample of this study, a purposive sampling technique was employed. A cross-sectional survey was used whereby data were collected from March 1, 2019 till April 1, 2019 via walk-in and post. A total of 423 sets of questionnaires were delivered to 91 medical device companies according to the number of R&D project managers reported in the telephone survey. The respondents received a hardcopy questionnaire, which they could access and answer during the data collection period. After several follow-ups, a total of 115 usable questionnaires were returned, resulting in a response rate of 27.2%. In this study, G*Power 3.1 software was used to determine the minimum sample size. An effect size of 0.15, α probability of 0.05, and power level of 0.80 were used together with four predictors in the research framework in the calculation of the sample size using G*Power 3.1 software. The computed minimal acceptable sample size using G*Power was 85. Therefore, a sample size of 115 was considered sufficient.

PROJECT AND RESPONDENTS' PROFILE

Based on the samples collected, most of the R&D projects take more than a year for completion, and 80.0% recorded a project duration of more than 12 months. The project team size revealed that 98.3% of the R&D projects comprised at least five members and above. The average project duration was 25.5 months, and the average size of the R&D project team was 12.2 people. The project profile showed that R&D projects are usually moderately large and take time. Of the respondents who participated in this survey, the majority are male (82.4%) and have at least 3 years job tenure with the current position (89.6%). The summary of the project and respondents' profile is presented in Table 1.

TABLE 1. Profile of projects and respondents

		Frequency	%
<i>Profile of Project</i>			
Project Duration	< 12 months	23	20.0
	13 – 24 months	63	54.8
	> 25 months	29	25.2
Team size	< 5 members	2	1.7
	5 – 10 members	56	48.7
	> 10 members	57	49.6
<i>Profile of Respondents</i>			
Gender	Male	103	82.4
	Female	22	17.6
Current Job Tenure	Less than 3 years	13	10.4
	3-5 years	44	35.2
	6-10 years	52	41.6
	11 years and above	16	12.8

The questionnaire consists of 35 items adapted from previous research. The measurements of the reward construct comprised four items adapted from Choi, Kang and Lee (2008). Four items measured reward: job will be honored when teach or share skills; the more knowledge shared, the more reputation would be enhanced; when sharing knowledge, more chance to show skills to the other colleagues; when sharing knowledge, will get recognition within the team. The measurements of the training construct comprised four items adapted from Schmidt (2009). Four items assessed training: training is provided to meet the changing needs of the project context; training is planned and purposeful rather than accidental; project team encourages both personal and professional development; training is encouraged and rewarded. The measurements of the collaboration construct comprised four items adapted from Thomson, Perry and Miller (2009). Four items gauged the collaboration with the project partner: take opinions seriously when decisions are made; agree about the goals and missions; benefited from using each other's resources; trustworthy. There are 16 instruments to measure the knowledge creation process adapted from Li, Huang and Tsai (2009). Of these 16 items, four items measured socialization: cooperative projects across directorates; the use of apprentices and mentors to transfer knowledge; brainstorming retreats or camps; and employee rotation across areas. Five items assessed externalization: a problem-solving system based on a technology like case-based reasoning; groupware and other collaboration learning tools; pointers to expertise, modeling based on analogies and metaphors; and capture and transfer of experts' knowledge. Four items gauged combination: web-based access to data; web pages; databases; and repositories of information, best practices, and lessons learned. Three items assessed internalization: on-the-job training; learning by doing; and learning by observation. The measurements of the R&D project performance construct comprised six items adapted from Shenhar et al. (2002). The items measuring R&D project performance were meeting time goals; meeting budget goal; meeting technical specifications; fulfills customer needs; solves major operational problems; generated a large market share. All questions were measured using a seven-point Likert-scale to gauge the level of agreement or disagreement for each instrument. Respondents responded to the items from 1 = "strongly disagree" to 7 = "strongly agree" with each statement in the questionnaire.

MEASUREMENT OF MODEL RESULTS

The measurement model is designed such that reward, training, collaboration, and R&D project performance are first order reflective constructs while the knowledge creation process is a second-order reflective-formative construct. To determine the validity and reliability of the reflective constructs, it is necessary to assess the convergent and discriminant validity of the constructs through the use of factor loadings, composite reliability (CR), and average variance extracted (AVE) (Hair, Ringle & Sarstedt 2011). Three indicators with a loading below 0.4 (RW1 (0.221), CLB2 (0.270), KC_EXT4 (0.365)) were removed. The composite reliability for all constructs (ranging from 0.84 to 0.96) exceeded the recommended value of 0.7 (Hair et al. 2011). The AVE for all constructs is above 0.5 (ranging from 0.51 to 0.82) (Hair et al. 2011). Thus, it can be concluded that all constructs had satisfactory convergent validity. The results are shown in Table 2.

TABLE 2. Measurement model of reflective constructs

First-order constructs	Items	Loadings	AVE	CR
Reward	RW2	0.762	0.72	0.89
	RW3	0.875		
	RW4	0.904		
Training	TR1	0.723	0.57	0.84
	TR2	0.787		
	TR3	0.617		
	TR4	0.860		
Collaboration	CLB1	0.933	0.82	0.93
	CLB3	0.889		
	CLB4	0.901		
R&D Project Performance	PP1	0.907	0.51	0.85
	PP2	0.579		
	PP3	0.504		
	PP4	0.850		
	PP5	0.867		
	PP6	0.433		

Discriminant validity is defined as a situation when two or more distinctively different concepts are not correlated to one another (Sekaran & Bougie 2016). The discriminant validity of the measurers was determined by utilizing HTMT criterion. As shown in Table 3, HTMT values greater than 0.90 were found between the correlations of the constructs. Hence, HTMT inference (Henseler, Ringle & Sarstedt 2015) is used. When the confidence interval of HTMT values for the structural paths contains the value of 1, it indicates a lack of discriminant validity. Conversely, if the value of 1 falls outside the interval's range, it suggests that the two constructs are empirically distinct. In the measurement model, discriminant validity is established because the 90% bootstrap confidence interval of HTMT does not show the value of 1, which confirms discriminant validity. The HTMT inference is shown in Table 3.

TABLE 3. Discriminant validity of constructs using HTMT criterion

HTMT .90 (conservative criterion)				
	Collaboration	R&D Project Performance	Reward	Training
Collaboration				
R&D Project Performance	*0.90			
Reward	0.58	0.81		
Training	*0.93	*0.92	0.66	
HTMT inference (liberal criterion) (Henseler et al. 2015)				
	Collaboration	R&D Project Performance	Reward	Training
Collaboration				
R&D Project Performance	0.89			
Reward	0.70	0.82		
Training	0.99	0.96	0.74	

* Failed to meet HTMT .90 conservative criterion but passed HTMT inference (bootstrap at 90% confidence interval of HTMT (-1<HTMT<1) (Henseler et al. 2015)

As for the formative construct, the collinearity among the indicators and the significance of outer weights must be assessed. Since the indicators are not essentially inter-changeable, high correlations are not expected between the indicators in the formative measurement models. The issue of collinearity exists in the formative model if two indicators are highly correlated (Hair et al. 2017). The Variance Inflation Factor (VIF) is examined to diagnose the collinearity issue. Combination (VIF=4.02) Externalization (VIF=6.54), Socialization (VIF=5.13) and Internalization (VIF=4.39) have a VIF below the threshold value of <10 (Hair et al. 2010). Analysis of the significance level for each formative indicator is carried out using Bootstrapping. Combination and Socialization are found to be significant (p<0.01). These two indicators can provide the relevance of capturing the knowledge creation process (Klassen & Whyback 1999). However, Externalization (p=0.11) and Internalization (p=0.25) are found to be insignificant. Hence, further analysis is carried out to assess the outer loadings on Externalization and Internalization. It is found that the outer loading for Internalization is 0.89 and the outer loading for Externalization is 0.94. Both loadings are more than 0.5 and have t-values of more than 1.645, hence, these two indicators are also retained because they can provide absolute contribution to the knowledge creation process (Hair et al. 2017). The results are shown in Table 4.

TABLE 4. Measurement model of second order formative construct

Second-order construct	Items	Weights (t>1.645)	VIF (VIF<10)	Outer loadings (value>0.5)
Knowledge creation process	Socialization	3.093**	5.13	0.94
	Externalization	1.579	6.54	0.94
	Combination	5.798**	4.02	0.94
	Internalization	1.162	4.39	0.89

STRUCTURAL MODEL RESULTS

After computing the path estimates in the structural model by bootstrapping analysis, the statistical significance of the path coefficients was determined. According to Hair et al. (2010), the bootstrap sample should be high and exceed the number of valid observations in the data. Therefore, the bootstrapping procedure for this study was done with 5000 subsamples to produce the path coefficient and their corresponding t-values. Table 6 shows the direct relationship of the independent variables to the mediating variable, the direct relationship of the mediating variable to the dependent variables as well as the indirect relationship. Three direct relationships showed a significant positive relationship ($t > 2.33$, $p < 0.05$), namely H_1 ($t = 10.33$), H_3 ($t = 2.96$), and H_4 ($t = 28.69$). Two indirect relationships showed a significant positive relationship ($t > 1.965$, $p < 0.01$), namely, H_5 ($t = 9.11$) and H_7 ($t = 2.97$). Hence, five out of the seven hypotheses were supported.

TABLE 6. Results of the hypothesis testing

Effects	Hypothesis	Path	Standard Error	t-value	Decision
Direct	H_1	RW→KCP	0.12	10.33*	Supported
	H_2	TR→KCP	0.14	1.76	Not supported
	H_3	CLB→KCP	0.11	2.96*	Supported
	H_4	KCP→PP	0.03	28.69*	Supported
Indirect	H_5	RW→KCP→PP	0.05	9.11**	Supported
	H_6	TR→KCP→PP	0.13	1.74	Not Supported
	H_7	CLB→KCP→PP	0.11	2.97**	Supported

* $p < 0.05$, ** $p < 0.01$, Bootstrapping (n=5000)

RW=reward, TR=training, CLB=collaboration, KCP=knowledge creation process, PP=R&D project performance

DISCUSSION AND LIMITATIONS

The aim of the study was to investigate the direct relationship of the organizational factors (reward, training, and collaboration) with the knowledge creation process and the mediation of the knowledge creation process on R&D project performance. The study found that reward and collaboration have a positive relationship with the knowledge creation process, whereas training has no significant positive relationship with the knowledge creation process. On the other hand, the knowledge creation process mediates the relationship between reward and R&D project performance as well as the relationship between collaboration and R&D project performance.

In many organizational performance studies, reward, training, and collaboration have been linked directly to innovation performance. The findings of this research, however, have indicated the presence of the mediating effect of the knowledge creating process. From the theoretical perspective, this study provides evidence that both reward and collaboration are critical to foster knowledge creation process in the R&D project team. Thus, the knowledge creation process is necessary to be integrated into the R&D project for enhancing performance. Additionally, the findings contribute to the expansion of RBV with the presence of project resources can be used at the fullest potential for enhancing knowledge creation within the project team. Besides, the knowledge as the intangible resources also reveals the extension of the KBV is equally important as RBV for improving the project performance.

The results indicated that organization could maximize the results of R&D project performance if a knowledge creation process is being put in place to reward employees who share their tacit knowledge in the organization. The tacit knowledge is then externalized by the other project members during project execution. Team members use the explicit knowledge and combine it with another explicit knowledge to create new knowledge in the organization. This is then followed by project members internalizing new knowledge to become new tacit knowledge. The spiral of tacit to explicit and from explicit to tacit will continue as long as the reward system is properly designed to compensate the sharing and combination of knowledge. Besides reward, the results also indicated that organizations could maximize the results of R&D project performance if the knowledge creation process is implemented together with collaboration. Knowledge socialization allows project members to share their tacit knowledge in “community of practice”. The know-how is then applied inter-projects during alignment meetings. Forming alliances also allows the combination of know-how and old knowledge to form new knowledge, i.e., airline alliances allow pilots from different airlines to share skills and know-how to further improve airline security. Lastly, knowledge internalization enables new knowledge to be registered and shared again as skills among project members.

However, training does not show a significant positive relationship with the knowledge creation process in this study. One of the reasons could be due to the lack of training analysis before the training program is offered to

project members. Although measurement items TR1, TR2, and TR4 received loadings >0.70 , TR3 was not favored by most of the respondents. This could indicate that the projects surveyed emphasized project domain knowledge training rather than the personal and professional development required by the job market. Studies show that project leaders should eliminate blanket training solutions and start matching the right solution to each project member's needs because there was no improvement observed with the general and ambiguous training program (Ramazani & Jergeas 2015; Schwind et al. 2016). Furthermore, the knowledge creation process does not mediate the relationship between training and R&D project performance. Recent studies on training that focused on trainer and trainee attributes (Chukwu 2016; Cohen 2017) show the effectiveness of training impacted by trainer and trainee attributes instead of training programs. Based on previous studies, this study suggests that the relationship between training and R&D project performance could be moderated by trainer and trainee attributes.

From the managerial perspective, the positive results of this study underline that organization strategies should be designed with the knowledge creation process in mind as having reward and collaboration as stand-alone systems are inadequate for organizations to attain imitable and competitive advantage. This study proves that introducing a carrot and stick approach to knowledge creation encourages project members to share and transfer knowledge more effectively. Besides, project management should be looking for collaborative opportunities since knowledge collaboration could increase the success rate of projects. Building a comprehensive knowledge creation system allows the practice of identifying, creating, communicating, socializing, measuring, and improving internal knowledge to support strategic objectives (Hislop, Bosua & Helms 2018). Having integrated organizational factors and a knowledge creation system can transform an organization to using strategic know-how effectively for competitive advantage in the global knowledge economy. Additionally, an organization can capitalize on the knowledge flows generated through the systematic approaches of managing know-how, best practices, and standard operating procedures (Yee, Tan & Thurasamy 2019).

The limitation of this study is that the result is only applicable to the medical device industry because the study of knowledge is context specific (Oluikpe 2015). As the medical device industry has special regulation and clinical trial requirements, the result is not to be generalized and applied to other industries. Hence, it is recommended that studies on different industries be conducted, such as services, education, tourism, and the information technology industry. Furthermore, it was noticed that training has a weak positive relationship ($t < 1.77$) with R&D project performance. There is a need to examine a moderating factor in this relationship so that the training and knowledge creation process can work hand-in-hand with an increase in R&D project performance.

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