

# 科技部 104 年度科技行政研究報告提要表

研究報告名稱：Developing a market-driving strategy-Key Opinion Leaders to drive medical device industry in Taiwan: From the relationship of strategic alliance perspective (從策略聯盟夥伴關係分析醫療器材 KOL 行銷模式)

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## 一、計畫目的

近年來企業間的策略聯盟已然是企業合作發展的重要趨勢，亦是企業組織提升競爭力、追求營運綜效的重要途徑之一。但是，過去的研究卻發現聯盟關係不必然導致較佳的企業績效。已有學者從聯盟關係的角度，探討夥伴關係與聯盟績效之間的因果。由於聯盟關係的建立是希望透過廠商合作，達到彼此互利的目標，但是，聯盟合作的重心畢竟是在資源與策略的相互對應。所以，從探討策略聯盟夥伴間的相對資源屬性、策略屬性與知識移轉之關係，進而探討醫療器材廠商在學習能力、網絡關係、行市場驅動策略與企業經營績效間之相互影響。

南科醫材產業聚落一條龍服務平台中，為協助區內產業發展、擴大企業出口動能，進一步推動經濟發展，透過論文發表、國外招商、參與國際展會、國際通路商機媒合及體驗展示室建置，建構 KOL 行銷模式以提升信賴度等方式，提高台灣自有品牌產品知名度，拓展產業觸角，協助廠商爭取國內外訂單。

本計畫試圖從策略聯盟夥伴之資源配置與策略相關性，識別出醫療器材廠商可行市場驅動策略之關鍵因素，以及發展後續醫療器材 KOL 行銷之可行發展模式。

## 二、計畫方法與過程

本計畫透過文獻探討，以資源基礎理論、資源依賴觀點與策略相似等學術理論觀點，分析探討策略聯盟夥伴間的相對資源屬性及採行的相對策略屬性，以及策略聯盟夥伴的相對資源屬性與相對策略屬性之配適度對企業績效的影響。接續，對南科醫材廠商、周邊學研醫機構等進行調查與訪談，以識別出 KOL 模式之關鍵因素，並瞭解產學研醫各界對於 KOL 行銷的需求、模式及相關建議，加以並探討如何制定醫療器材國際行銷策略。最後，整合性的分析並推演出南科後續進行醫療器材 KOL 行銷之可行發展模式、相關對策、規劃及治理策略。

### 三、計畫結論

#### (一) Key Opinion Leader (KOL)策略及 Evidenced-Based Medicine (EBM) 策略 是醫療器材廠商作為市場驅動策略的關鍵

醫材產品憑藉一個強的 KOL 策略或一個強的 EBM 策略，是可成功發現其產品確實具有使用資格的重要支持，參與醫材產品的 KOL 具有高度的可信度和影響力，廠商最共同的好處將包括標竿測試、曝光、宣傳、建立信譽和傳播新科技資訊。然而，這些好處需來自於支付 KOLs 的高度行銷費用；另 EBM 策略考慮到成本效益和臨床結果(亦即更好、更快速及更強)，因此 EBM 策略比 KOL 策略更加昂貴，畢竟廠商可能無法長期支應臨床研究費用及後續引發臨床糾紛之辯解費用。

#### (二) 醫材產品必須確保其功能性、安全性及可靠性，始能擁有好的關鍵意見領袖 (KOL) 協助行銷

透過與這些德高望重的醫生或關鍵影響力建立良好關係，醫材製造廠商可以成功建立產品信譽，以及提高市場佔有率。通常，這些 KOL 專家代表一個公司或一個品牌，因此，要了解 KOL 對於產品使用後的回饋呈度，製造廠商必須擁有行銷計畫，這樣不僅能表現出臨床安全性、產品功能性和可靠性，同時也能使醫療費用隨著時間的推移而減少，此外，行銷工具(如案例研究)亦可是證明功能性、安全性及可靠性之關鍵因素。

#### (三) 醫材產品應透過系統整合，以共同產品與服務創造共同通路及品質精進

成功的製造廠商會根據不斷變化的法規認證規定 (TFDA、FDA 或 CE)、行銷工具 (社交媒體、展會宣傳)，以向醫師、病人、KOLs、公眾媒體等都確保會有改善及預防等措施。當醫材產品可系統整合，進行技術精進與深化，持續改良並與疾病管理方案、案例管理服務等整合管理，將成功提升醫師的依從性，也能證明製造廠商能整體考量並人與醫師之雙方權益。

## 科技部 104 年度科技行政研究發展計畫

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Developing a market-driving strategy-Key Opinion Leaders to drive medical device industry in Taiwan: From the relationship of strategic alliance perspective.

### **ABSTRACT**

Alliance is a critical mechanism for a company to acquire different resources to enhance its own internal capabilities and advantage. This paper suggested how different partnership interactions, such as inter-partner resource alignment and strategic relatedness, influence relational capital development and knowledge transfer in the strategic alliance. Here, a conceptual framework in form of a model is developed by integrating organizational learning and the resource-based view literature. This paper also suggested that internal capability and external activity of medical device firms will influence market-driving strategy and firm performance. Therefore, the other study to drive medical device industry is key opinion leader marketing critical model. There are three viewpoints is following: Key Opinion Leader (KOL) strategy and Evidenced-Based Medicine (EBM) strategy are critical market-driving strategies to drive medical device industry; Good Key Opinion Leader (KOL) depend on ensuring product's functionality, safety and reliability; and bundle medical device products and services should leverage such marketing opportunities.

**Key Words:** Inter-Partner Resource Alignment; Strategic Relatedness; Relational Capital; Knowledge Transfer, Learning Capability; Network Relationship, Market-Driving Strategy, Key Opinion Leader

## **1 Introduction**

In the last two decades, strategy alliances are becoming increasingly popular in an age full of blurring industry boundaries, fast-changing technologies, and global integration (Kale and Singh, 2009; Zhang, Shu, Jiang, and Malter, 2008). The purpose of strategic alliance is to achieve inter-organizational cooperating as well as strategic and transaction cost considerations. Since the early 1980s, there has been a global proliferation of strategic alliances in many different forms. The essence of strategic alliances is that a collaborative effort provides incentives for a firm to combine its own competencies with that of its partners and, in the process, achieve strategic benefits that the partners can share (Makino and Inkpen, 2003). Alliances offer several benefits such as learning from partners, increasing efficiencies, accessing new or critical resources or capabilities, and entering new market (Shan and Swaminathan, 2008; Rothaermel and Boeker, 2008).

Whereas some well-known alliances – for example, IBM-Apple alliance, Open Handset Alliance, Star Alliance – have clearly benefited the partner firms, many other alliances have been plagued by unsatisfactory cooperation and poor performance in the marketplace - for example, Benq and Siemens, AOL and TimeWarner. Studies have shown that between 30% and 70% of alliance fails; in other words, they neither meet the goals of their parent companies nor deliver on the operational or strategic benefits they purport to provide (Bamford, Gomes-Casseres, and Robinson, 2004).

Until about two decades ago, researches dealing with strategic alliances primarily were focused on areas such as governance forms and task structures. The issue of resource sharing was largely unexamined. More than a decade ago, researchers accurately predicted that learning capability and learning organization would become two key concepts of future management thinking (Simonin, 2004; Tsang, 2008). Today, it is well accepted that organizational knowledge is perhaps the most valuable firm resource and that an organization's ability to learn is crucial for its competitiveness. As a subfield within the broader field of organizational learning, the literature on alliance learning has evolved into a well-developed and legitimate research area (Inkpen and Tsang, 2007).

There is little doubt that alliances and partnerships among companies will be a critical component of strategy management, including playing a major role in the transfer and management of competitively resources. Alliances are a critical mechanism for a company to acquire useful resources to complement its own internal capabilities and resources. Resource sharing among two different firms provides opportunities for commitment, information exchanging and inter-firm cooperating that stimulate the creation of new competitiveness and, at the same time, contribute to firm's ability to innovate (Khamseh and Jolly, 2014; Inkpen and Tsang, 2007).

Current research argues that a market-driving strategy leads to a competitive advantage. However, a market-driving strategy tries to change established rules in the marketplace and thus, is difficult to pursue (Ghauri, Elg, Tarnovskaya, and Wang, 2014). This paper argue that a market-driving strategy must be based on distinct capabilities and that firms using this strategy will perform a set of external activities and possess certain critical capabilities that are required to make the strategy successful.

Market-driving strategies in all industries are forced with various hurdles. However, market-driving strategies in the medical device industry face novel and unique challenges. This could be because the medical device industry is heavily regulated, the purchasing decision is based on multiple factors (i.e., safety, efficacy, efficiency, and politics) and marketing requires a combination of medical, scientific and business knowledge. Innovative medical devices require specific and focused marketing strategies that are unlike most other newly released products. Therefore, it is important for medical device market-driving strategies in order for their innovations to be adopted by the medical community.

There are numerous factors that have been shown to increase customer acceptance/buy-in of medical innovations including (but not limited to): evidence for clinical benefits, economic benefits and increased patient welfare; product safety; transfer of evidence into clinical practice (e.g. clinical guideline development); and expanding product use to new indications. Medical device companies heavily rely on market-driving strategies to increase adoption. However, due to regulations and the very nature of the medical devices, market-driving strategies in this industry are very different from standard industries, say, and consumer products. Much like the entertainment industry and the high-tech industry, marketing in the medical device industry requires specific knowledge and strategies. Market-driving strategies used by medical device companies include advertising, digital/social media, awards/recognition, exposure through trade shows and exhibits, direct marketing via a savvy sales team, key opinion leader (KOL) programs and evidence-based medicine (EBM) strategies (Smith, 2015).

This paper developed a theoretical framework and propositions on the role of inter-partner resource alignment, strategic relatedness, relational capital, market-driving strategy and firm performance. The purpose of this paper is to gain insight and better understand the importance of key clinical market-driving strategies employed by medical devices companies: key opinion leaders. By better understanding the impact of these strategies, medical device marketers can construct effective marketing strategies that will be guided by tested and proven methods. However, this paper will inform strategic decisions and therefore will be important to companies that are developing market-driving strategies for medical device innovation.

## **2 The Relationship of Strategic Alliance**

Inter-partner resource alignment refers broadly to the pattern, whereby the resources of partner firms are matched and integrated in the alliance (Das and Teng, 2003). This pattern defines the resource-based relationship between partners. However, alliances have been examined as means for developing and exploiting the firm's resource base (Tseng, 2000). As suggested by Das and Teng (2000a), the two dimensions related to resource alignment are resource similarity and resource utilization.

The sociopsychological aspects embodied in relational capital are important since they act as coordinating mechanisms and determine the quality of the relationship in the collaboration. Kale, Singh, and Perlmutter (2000) suggested that relational capital can help firms to successfully balance the acquisition of new capabilities with the protection of existing proprietary assets in alliance situations. In this study we consider one key aspects of relational capital - mutual trust. Mutual trust encourages behavior such as open communication and the willingness to share information.

Supplementary inter-partner resource alignment exists when the partner firms contribute similar resource that is performing in alliance (Das and Teng, 2003). It is important to note that by amassing supplementary resources an alliance deprives competitors of those same resources. Relational capital reflects the belief that a partner's word or promise is reliable and that a partner will fulfil the obligations of the relationship (Inkpen, 1998a). We suggest that the more the collective strengths alliance accumulates, the better its chances to increase relational capital.

Complementary inter-partner resource alignment refers that the partner firms contribute dissimilar resource performing in alliance (Das and Teng, 2003). The potential for partners to synergistically leverage on the pooled resources in the market-place would increase with resource complementarity (Sarkar, Echambadi, Cavusgil, and Aulakh, 2001). However, we suggest that firms learning from other companies with similar resources would perform better than those with dissimilar resources. In other words, when partners bring in same and valuable strengths and resources, the firm's relational capital is likely to be enhanced.

### **Proposition 2-1:**

*Supplementary inter-partner resource alignment is more positively associated with relational capital than complementary inter-partner resource alignment.*

It is difficult to exchange resource between two unrelated firms because of the lack of shared language and common interests which are important for effectiveness of their communication. When two firms are strategically related, their common interests may

motivate them to exchange information and resources in a way that both parties can benefit. Moreover, it is generally assumed that the higher the strategic relatedness between two firms, the higher their incentives to exchange or share their resource through alliances.

By making commitments and living up to expectations, a firm can earn its partner's trust (Zaheer and Harris, 2006). Strategic relatedness may strengthen the effect of relational capital among alliance partners. Relational capital leads to partner's satisfaction and the achievement of joint actions and goal fulfillments (Schreiner, Kale, and Corsten, 2009). In this study, we suggest that the higher strategic relatedness between two firms, the higher relational capital will exist.

**Proposition 2-2:**

*Strategic relatedness is positively associated with relational capital.*

Inter-partner learning and knowledge transfer in alliances have drawn the attention of researchers. Several studies have clarified the determinants of knowledge transfer in alliances (e.g. Simonin, 2004; Sampson, 2007). Knowledge-specific, partner-specific (especially the level of the knowledge seeker, knowledge provider, and their inter-relationship), and context-specific variables are in the heart of alliance learning process (Simonin, 1990a). Over the past decades, alliances have become not only one of the most successful modes of internationalization, but also one of usual forms for absorbing and creating knowledge. Several researchers have emphasized the added value of alliance relationships in organizations' knowledge transfer and learning processes (Khamseh and Jolly, 2014).

Existing literature identifies various interrelated ways in which mutual trust affects inter-firm exchanges. Mutual trust encourages behaviors such as open communication and the willingness to share information. In addition, mutual trust has been shown to increase cooperation and improve flexibility, to lower the cost of coordinating activities and to increase the level of knowledge transfer. On the other hand, participative and frequent exchange of information and maintaining open-door policies to each other result from the partners' willingness to create transparency in the relationship. This study argues that trust-based relational capital can contribute to a freer and greater exchange of knowledge. Therefore, we propose that strong relational capital between alliance partners will lead to greater knowledge transfer.

**Proposition 2-3:**

*Relational capital is positively associated with knowledge transfer.*

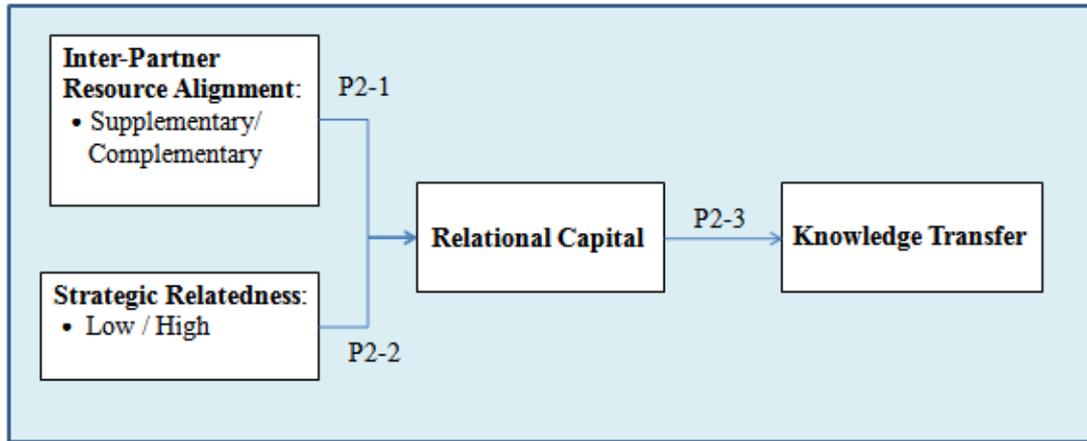


Fig1. The framework of the relationship of strategic alliance and knowledge transfer

In studying the antecedents of alliance performance, one stream of research has underscored the alignment between partners' characteristics whereas another has concentrated on relational mechanisms such as mutual trust, relational embeddedness, and relational commitment. This paper integrated these two perspectives by examining how different partnership interactions, such as inter-partner resource alignment and strategic relatedness, influence relational capital development and firm performance in the strategic alliance. Here, a conceptual framework in form of a model is developed by integrating organizational learning and the resource-based view literature.

Earlier studies suggested that a link between organizational learning and marketing orientation. They arguing that a strong learning capability is critical fir market-driving firms (Baker and Sinkula (1999); Hurley and Hult (1998)). This paper developed follow that learning capability and alliance relationship are important to market-driving strategy.

### 3 Market-driving Strategies on Medical Device Industry

#### 3.1 Studies on Market-driving Strategy

The market-driving approach is often treated as a form of market orientation and thus as a part of the firm's marketing strategy (Jaworski, Bernard, Kohli, and Sahay, 2000). However, if we look at it from a broader strategic perspective, we can see it as an overall strategic orientation (Hills and Sarin, 2003). This paper grouped earlier studies on market-driving strategy along two major perspectives: an internal one that focuses on internal organizational systems and factors facilitating a market-driving approach, and external perspective that encompasses external market activities aimed at different market actors (Harris and Cai, 2000; Lorentz and Ghauri, 2010).

The internal perspective is best represented who propose that market-driving firms are characterized by radical business innovation (Kumar, Nirmalya, Scheer, and Kolter, 2000). These new measures include both unique business systems and a revolution in the customer value proposition effected through pricing or a superior service level. The market-driving capabilities of firm are a result of a specific organizational culture of ad hoc/market type (Carrillat, Francois, Jaramilo and Locander, 2004).

According to the external perspective, market driving is associated with “changing the composition and/or roles of players in a market and/or behaviors of players in the market”. A firm can proactively influence its market and change the customers’ behavior and perceptions, labelling it as a proactive market orientation. Some studies have identified specific market-driving activities, including changing customer preferences, relationship formation, and local sensitivity (Elag, Ghauri, and Tarnovakaya, 2008; Harris and Cai, 2002).

A market-driving firm builds sustainable competitive advantage through the provision of superior and unique customer benefits. These benefits come from change-oriented activities carried out by the firms. The way the firm brings about change and unique customer benefits depends on the firm’s internal capabilities.

Most of the market-driving literature is descriptive and studies empirical examples only to illustrate particular aspects of a marketing-driving strategy. This paper developed the link which is intend to create changes in the target market and unique customer benefits, in turn leading to a competitive advantage. And also show that market-driving firms should be understood from an international perspective, since these firms act in a number of markets and their market-driving strategy is interrelated with their global strategy activities in general.

In response to rapid changes in the external environment, firms should use business network construction and interactive relationship between the resources required to obtain, and in line with its own core competencies and competitive strategies oriented to improve innovation performance. From the literature, the scholars recommended that firms need to understand their core competencies in order to effectively use the network to interact with business to enhance the pursuit of innovation performance, the scholar is more developed in firms from empirical considerations need to have an internal core competence, strategic orientation, and external business competitive thinking of network integrity, and strive to core competencies, optimal allocation strategy and career-oriented interactive network of fitness, in order to effectively strengthen the organizational innovation performance..

**Proposition 3-1:**

*Learning capability is positively associated with market-driving strategy..*

**Proposition 3-2:**

*Network relationship is positively associated with market-driving strategy.*

**Proposition 3-3:**

*Market-driving strategy is positively associated with firm performance.*

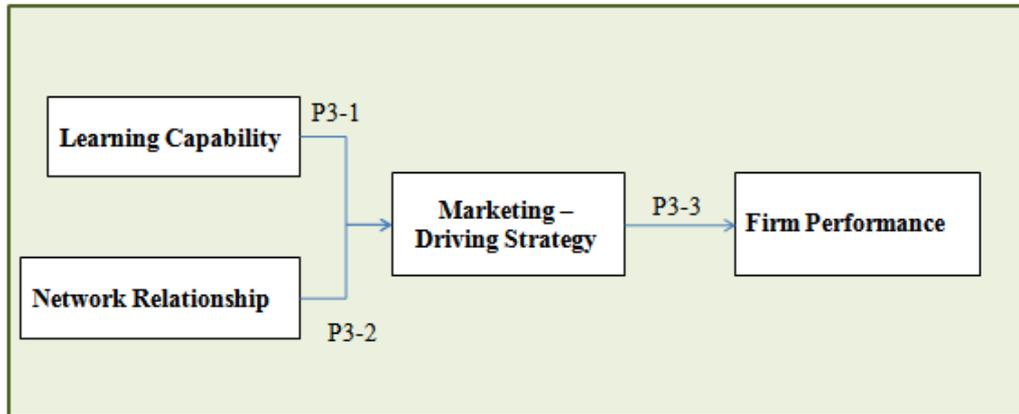


Fig2. The framework of market-driving strategy

**3.2 Medical Devices**

Medical technology products are ‘medical devices’ which cover “any instrument, apparatus, appliance, materials or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or an injury or a physiological process”. Medical devices are extremely important, as healthcare delivery and advancement would not be possible without them. In 2006, the global medical market reached \$209 billion, however the United States (USA) is the largest medical device market in the world with a market size of around \$110 billion, and it is expected to reach \$133 billion by 2016. To put this number in perspective, the USA is home to more than 6,500 medical device companies, mainly small and medium-sized enterprises (SMEs), making it one of the country's largest industries and exports. According to the Food and Drug Administration (FDA), 4,262 medical devices were released into the US market in 2002. In addition to the clear economic importance of medical devices, these products are essential in reducing healthcare costs and increasing patient welfare.

Medical devices are heavily regulated in the USA and most other parts of the developed world. In the USA, the FDA is the governing body that regulates, among other things, medical devices. The FDA has established classifications for approximately 1,700 different types of devices and grouped them into 16 medical specialties. These 16 medical specialties are as follows: Anesthesiology; Cardiovascular; Chemistry; Dental; Ear, Nose, and Throat;

Gastroenterology and Urology; General and Plastic Surgery; General Hospital; Hematology; Immunology; Microbiology; Neurology; Obstetrical and Gynecological; Ophthalmic; Orthopedic; Pathology; Physical Medicine; Radiology; Toxicology. Each of these types of devices can then be classified to one of three regulatory classes based on the level of control necessary to ensure the safety and effectiveness of the device. The three classes and the requirements are as follows:

- Class I (General Controls)
  - ◆ With Exemptions
  - ◆ Without Exemptions
- Class II (General Controls and Special Controls)
  - ◆ With Exemptions
  - ◆ Without Exemptions
- Class III (General Controls and Premarket Approval)

While “medical device” is a rather broad term, it can be further segmented into “medical device innovations”. The main difference being that medical device innovations are produced by knowledge gained from scientific research or by overcoming an engineering problem (i.e., applying existing knowledge to new problems). Typically, patents are used to measure medical device innovation. A medical device innovation is differentiated from a general medical device based on the following parameters:

- It is not medical supplies or disposables
- The product is new and innovative (i.e., serves a new use)
- An innovation is defined as any product, idea or practice that is viewed as new by an individual or the adopting unit 8
- Interacts with a person’s physiology
- Science-based
- Class II or Class III

Additionally, the following can identify medical device innovation<sup>9</sup>:

- Based on engineering problem solving by individuals or small enterprises
- Incremental rather than radical
- Rarely depends on results of long-term scientific research
- Does not reflect the recent graduation of fundamental knowledge

In order for medical innovations to be successful, they must solve an unmet medical need or reduce healthcare costs. Otherwise, adoption will not occur. It is important for the user and/or the buyer to understand how a medical device innovation will either reduce costs or

increase care – preferably both. In order for this message to be adequately delivered, companies rely on effective marketing strategies.

### **3.3 Clinical Marketing-driving Strategies for Medical Device Industry**

The medical device market has been growing rapidly worldwide, and this growth momentum is expected to continue. In developed countries, fueled by aging populations, diagnostic and treatment devices for cancer, as well as devices and equipment in the area of orthopedics, have achieved high sales growth. In emerging markets, with the increase in the number of middle-income earner, lifestyle-related diseases are expected to increase, leading to increase demand for devices and equipment in the area of cardiology. Given the growing demand for medical care, every country is facing pressing need to manage rapidly increasing costs. To address this issue, medical device manufacturers have been striving to develop innovative technologies and new services. In addition to working to develop new technologies on their own, major medical device manufactures have been actively undertaking mergers and acquisitions (M&A) in attempts to acquire new technologies. In view of this situation, making use of their own technologies to develop new technologies that are needed by the growing medical device market will provide good opportunities for manufacturers intending to enter this market from other countries.

What is particularly important for new entrants to achieve success in this market is their ability to develop a strategy aimed at identifying and satisfying the needs of physicians. This is because physicians are often the ones who make purchasing decisions for medical devices offering high added value and thus enabling a company to expect high profitability.

The products for which physicians make purchasing decisions include therapeutic devices and ancillary consumables as well as critical test, measurement and diagnostic equipment and their consumables, which significantly affect treatment outcome. These products are sold to each department of a hospital. In general, such medical device offer high added value, thus enabling manufacturers to earn high profits. However, it is often the case that the world's largest manufacturers have already developed deep relationships with their customers (physicians). On the other hand, as for general-purpose consumables such as syringes, illustrated at the left of

The key factors for success (KFSs) for manufacturers operating in the medical device market are: (1) sales functions that enable a company to build physician loyalty, (2) ability to develop and sell products employing technologies having high levels of novelty in conformity with the Pharmaceutical Affairs Law that applies to medical devices, (3) ability to develop killer products, which play a significant role in building physician loyalty.

Factors affecting physicians' purchasing decisions and business models adopted by

successful manufacturers:

1. Specific affecting physicians' purchasing decisions:

The basic needs of physicians include adopting new medical technologies that are gaining in popularity to improve treatment outcomes, treating patients in the most appropriate manner and in the shortest possible time and equipping themselves with the latest technology within the limited time available to them for choosing the most effective medical devices.

Most physicians try to spend as much time as they can for treating patients and increasing their knowledge about diagnosis and treatment. Therefore, in most they cannot afford to spend time examining new therapeutic and diagnostic devices, learning by trial and error how best to utilize new technologies or instructing their junior colleagues.

As a major principle governing the behaviors of physicians, they have "awareness of unseen horizontal relationships." Rather than the hospital at which they work, they identify themselves strongly with a specific medical society, master-apprentice relationship or the top-ranked hospital in hierarchical permutation for a group of hospitals. By identifying themselves with one of these organizations, they are likely to make purchasing decisions in accordance with the policy of such an organization. 3 specific factors affect physicians' purchasing decisions: (1) contributing greatly to the improvement of one's own treatment outcomes, (2) having high product/company visibility, (3) contributing to the improvement of work efficiency (saving time required for selecting a series of devices, learning by trial and error, instructing junior colleagues and other activities related to medical care.)

There are 5 requirements for medical devices to meet these needs: (1) a product must be a killer product contributing to improvement of treatment outcomes. (2) the product must be endorsed by medical society and/or key opinion leader (KOLs), (3) peripheral devices and instruments that are used for treatment together with the killer product can be obtained as a set, (4) the product enables easy use of an optimal treatment method, (5) a training environment where physicians can learn new therapeutic technology by experience in the shortest possible time is available.

2. Manufacturers that pursued the enhancement of sales functions achieved success:

Medical device manufacturers that have been successful in the market have made efforts not only to develop superior products but also enhance sales functions in consideration of specific factors affecting physicians' purchasing decisions.

For example, DePuy Synthes, which is part of the Johnson & Johnson group of companies and is one of the global leaders in the market, specializes in orthopedic

products and offers a comprehensive portfolio of artificial joints. The company has been expanding its product lineup for each joint part (each surgical treatment) such as hip, knee and shoulder replacement. At the same time, the company also sells educational programs to provide surgeons with a wide array of surgical technologies suitable for each joint part. In order for surgeons to become familiar with surgical technologies using these artificial joints, thereby increasing the visibility of its product as an easier-to use item, the company offers educational seminars for surgeons and provides training courses to impact the latest technologies and procedures at its own training facilities.

Two clinical marketing strategies were notably more prominent. These two strategies were a Key Opinion Leader (KOL) strategy and Evidenced-Based Medicine (EBM) strategy. Key opinion leaders are a source of information, influence and an important determinant of adopting or avoiding new treatments. It is widely believed in the industry that physician-led peer review of new medical technology is the top best practice when making purchasing decisions. Evidenced-based medicine emphasizes the use of evidence from well-designed and conducted research in healthcare decision-making. This strategic marketing tactic has been known to increase customer adoption and market penetration.

### **3.3.1 Key Opinion Leader (KOL) Strategy**

The term “key opinion leader” was coined in 1955 by Katz and Larzarsfeld when they described an individual’s decision-making process. Since then, the term has been widely accepted as a marketing principle. The profound influence of a person’s peers on behavior and decision-making has been well documented throughout social psychology literature. For many years, marketers in many industries have taken advantage of this psychological principle in order to boost sales. It is no surprise that this phenomenon transcends to the medical device industry. A key opinion leader (KOL) (also known as an opinion leader, thought leader or product champion) has been identified anecdotally and in the literature as a critical factor related to adoption of medical device innovations. Studies related to innovation diffusion in medicine dating back to 1966 identified the physicians association with opinion leaders as a source of information, influence and an important determinant of the adoption or avoidance of new treatments. More recently, a 2013 Deloitte annual survey of U.S. physicians revealed that 70 percent of U.S. physicians believe that physician-led peer review of new medical technology is the top best practice when making purchasing decisions. In fact, studies have found that every local medical community has a small group of easily identifiable physicians who are influential in facilitating new learning and adoption of new medical products; these

opinion leaders are looked up to by their colleagues for advice and unbiased information.

When attempting to understand medical KOLs, they can be sub-divided into “market leaders” and “clinical leaders”. Market leaders are tightly connected to the local patient and physician communities. They are typically general practitioners with large practices who gain recognition through the satisfaction and loyalty of their patients. According to “Best Practices”, a leading benchmarking, consulting and advisory services firm serving biopharmaceutical and medical device companies worldwide, KOLs' have “proven to be among of the most effective and critical means of building product awareness in the medical and scientific communities.” Clinical leaders are well-respected experts of a specific disease or therapy with a strong reputation. This reputation is typically strengthened by the number of publications they have and the rankings of the medical journals in which those articles are published in. Their roles vary, but often times clinical leaders are usually involved in bench testing the product before it goes to market. It is thought that market leaders have a greater impact on general practitioners' behavior than clinical leaders, while clinical leaders have a greater impact on hospital-based physicians' behavior than market leaders.

The survey showed that about 70 percent of U.S. physicians believe that physician-led peer review of new medical technology is the top best practice when making purchasing decisions (Wegman, 2013). It is incumbent upon medical device manufacturers to understand that physicians still rely on other physicians and peer reviews of medical device technologies. To put that knowledge into practice with a sound medical device marketing plan, it is critical for manufacturers to use key opinion leaders (KOLs) to help influence others.

Medical device companies invest heavily in training subject-matter experts (SMEs) and building relationships with key opinion leaders (KOLs) in order to establish themselves as thought leaders and provide peer-to-peer perspective on key topics pertaining to their specialties, therapeutic areas, and/or products. They are contracted to give talks, create content, assist with trials, get involved with grant funding, sit on advisory boards, and more. And they can be paid handsomely to do so.

Companies that manage KOLs are not doing it out of the kindness of their hearts. They're likely doing it to drive demand and preference for their products. However, these companies often start with the patient in mind and believe that the right way to get the message out about their products, the right way to target the right patients, and the right way to work with the right clinicians is through KOL engagement.

By creating collaborative relationships with these highly respected physicians or key influencers that drive opinion as speakers, authors, and researchers, you can build credibility and increase market share. Often these experts are speaking on behalf of a company or brand

at industry events and to the press. Unfortunately, after spending thousands of dollars to get them to the podium and participate in a symposium, many times the talk or panel discussion is captured only in transcript form. Or even worse, a poorly recorded video with too much ambient noise and distractions.

In the complex and competitive world of healthcare marketing, Key Opinion Leaders (KOLs) play a significant role in influencing the perception and opinion of various stakeholders. While large marketing budgets are spent, the impact and reach of such influential opinions can be directly associated to the rigor of generating the right influencer pool. Leadership in understanding influence as a potent marketing tool stands apart owing to its KOL identification process, ranking methodology, and ability to combine traditional and social footprints of influencers across therapeutic areas, regions and languages.

For the global pharmaceutical and healthcare industry, KOL services tailored for the scientific, commercial, regulatory/market access, and healthcare and advocacy groups. The approach for KOL identification and profiling includes: (1)KOL identification; (2)KOL profiling and updates; (3)KOL mapping; (4)Insights generation; (5)Strategic support; (6)Custom platforms-led KOL management.

Once the KOLs are identified and aggregated, medical profiles are built with the objective of providing a complete and well-rounded view on the KOL, for both individuals as well as organizations. A typical medical profile consists of: personal information, contact information, biographical information, activity participation history, publications activity, clinical trials activity, educational details, press coverage, specialty information, and network heat-maps.

In tune with the technological advancements and data access needs of clients, some CRO companies offer a range of technology solutions to efficiently and effectively manage influencers. These consulting companies centralize KOL data repository with ready-to-use actionable insights and periodically tracked information provide a robust platform for seamless tracking and reporting of the client's KOL engagement. Comprehensive KOL analytics are made available through any of the following technology options that best suit client needs: system integration (ability to integrate with existing client systems), data services (customized data as per client desired template and format), software as a service (SaaS), KOLM business intelligence (proprietary enterprise-class software).

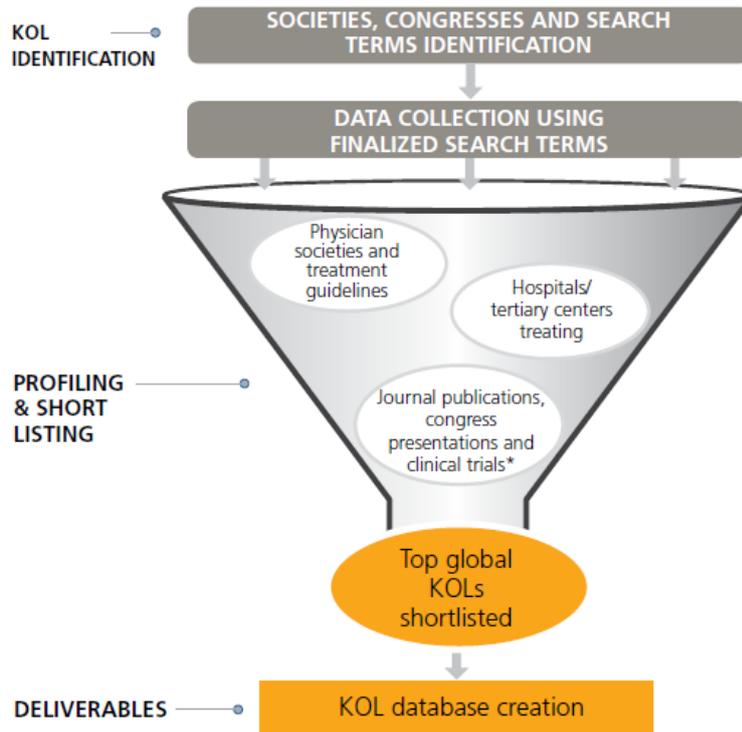


Fig3. The approach for KOL identification and profiling

### 3.3.2 Evidence-Based Medicine (EBM) Strategy

Evidence-based medicine (EBM) has become a “buzz word” in the medical arena. For medical device companies, it has become increasingly important for survival in this competitive industry. Generally speaking, EBM uses thorough, well-designed research studies and empirical evidence to optimize decision-making (i.e., purchasing decisions). In the medical device industry, EBM primarily focuses on a product’s efficacy and effectiveness. Clinical efficacy is proven when there is evidence that the medical device is beneficial when used by experts in a research setting. Clinical effectiveness is proven if there is evidence that the medical device is beneficial when it is used by a representative sample of physicians in a normal clinical setting. This clinical marketing strategy is a tool used to optimize product introduction, adoption, life cycle management and business development of medical device innovations. The key objective of this strategy is to support customer adoption and market penetration of the medical device. Unlike the pharmaceutical industry, in which product development is largely based on the development of strong clinical evidence, medical devices do not necessarily follow the same product development pathway.

Additionally, newly launched medical devices are not always accompanied by clinical or economic evidence to support the product’s effectiveness. Often times this will

negatively impact the company's commercial strategy because there is insufficient data linking the use of the product with a relevant clinical benefit in order to convince a clinician or a hospital manager of the advantages of this new medical device.

#### **4 Market-driving strategies to drive Medical Device Industry**

##### **4.1 Medical Device Industrial Cluster in Southern Taiwan Science Park**

In lieu of the export orientation of Taiwan's medical device industry, issues such as the improvement of international marketing abilities of park enterprises, the enhancement of cooperation between park enterprises and international partners, and increasing product visibilities need to be addressed by the Southern Taiwan Science Park Bureau (STSPB). Under the promotion of the STSPB, the first phase of the Southern Taiwan Medical Device Industrial Cluster Development Project (between 2009 and 2012) successfully assisted with the technology upgrading of traditional industries. With the core strategy of "Upgrading of Traditional Industries", the STSPB cumulatively attracted the presence and investment of 50 tenant enterprises; some of them have gradually developed their own brands. The industrial cluster was gradually formed. After finishing the process of product development, the park enterprises are facing the challenge to access into the market. Therefore, in order to help park enterprises to promote their products and assist them to access into the global market, the objective in the second phase of the Southern Taiwan Medical Device Industrial Cluster Development Project (2013-2016) is to develop innovative medical device products and build new marketing model to drive the formation of industrial cluster.

Unlike Europe and the US, 97% of the enterprises are small and medium enterprises (SMEs) in Taiwan. To compare with other industries, it is quite difficult for medical device industries to develop from a new idea to real products and it always takes a long time for the medical device manufactures to launch their new products into the market. It needs more resources input from central and local government, private or public organization, universities, and research centers. Therefore, in addition to the assistance to technology upgrading of enterprises provided by STSPB, what is more important for the park enterprises is the assistance to enter the market to gain profits. Thus, commercialization and marketing are both the most important issues in science parks, especially in the medical device field. As for the marketing strategies of the medical device products, there are three main dimensions involved: first, the completeness and integration of production lines; second, effective product exposure; and third, the increasing trust and loyalty of physicians. The original concept of developing innovative medical device products is the satisfaction of the "Unmet Needs" from the clinical needs. Through the direct communication between physicians and manufacturers, the manufacturers obtain the clinical information from the physicians, and such information will

be the reference sources of developing a new innovative product. On the other hand, when the clinical needs from physicians have been met, the physicians will be willing to use the product and become the “Key Opinion Leader (KOL)” after the product launch into the market. To establish the mechanism of communication will be one of the important factors of developing innovative medical device products.

To help park enterprises to promote their innovative products efficiently, STSPB has established three mechanisms to speed up the realization of industrial profitability. The first one is joint marketing mechanism to integrate the joint marketing of products of park enterprises; the second one is the joint participation in the annual medical conferences and exhibitions to showcase the products and increase their visibilities; and the third one is the establishment of “KOL” marketing strategy and experiential marketing. With the building of complete marketing mechanisms, the revenue of park enterprises will grow, and the growing revenue will attract continuous investment in R&D that can facilitate the innovation of the industrial cluster.

Facing the continuous global competition, the STSP needs to think towards the comprehensive product lines. Through the platform that allows quick product launch, industrial matching, and international marketing, park enterprises will be assisted with concrete activities of R&D, pre-production, mass production, and product sales. In addition to continuous construction of channel marketing, clinic matching, international investment invitation and sales expansion, more market shares will be obtained with more comprehensive product lines.

In the future, through the organization of international matching seminars, global channel and manufacturing leaders are introduced to park enterprises in the field of orthopedics, dentistry, and medical cosmetics to exchange and interact for R&D, accreditation and marketing in order to improve the STSP’s international visibility and assist the park enterprises to gain more orders. Furthermore, international leading physicians will also be invited to share their experiences in the application and surgeries with the innovative medical devices and to enhance the clinic visibility of Taiwan’s medical device industry and the acceptability of international end-users (physicians). From manufacturing to marketing, it is expected to create higher added-values with the dual-core comprehensive marketing model of the STSP that combines with marketing and clinic practices.

#### **4.2 Marketing Strategies in Southern Taiwan Science Park**

Medical device industry is a “reliable industry”, how to provide the acceptable, reliable medical device products to the user and experiential marketing are the important strategies. Most of the universities in Taiwan are promoting international academic exchange and

cooperating with foreign universities. STSPB connects with the universities in the surrounding area very well. STSPB uses the resource from the universities and combines such good connections between the universities and companies with the R&D and marketing to launch the products into global market. The marketing strategies are as follows:

The first one is industry-university research projects.

In the past, industry-university research projects were referred to bellow: (1) Universities should actively understand internal research results for effective use and promotion; (2) Through governmental grants and subsidies, universities conduct innovative studies for the early acquisition of relevant patents and seize the opportunities for technology development; (3) Talent cultivation should be based on the demands in the market for suitability. The facilitation of international academic exchanges for internationalized industries is the model that the STSP attempts to operate. There are several key factors behind this model. First, nearby academic and research institutions shall be sufficiently allied. Second, academic and research institutions need to be abundantly linked to companies. Third, international KOL should be built. Finally, segment market concept and specialized positioning of marketing concepts should be introduced.

The second one is the model that builds the cooperative relationship with international distributors.

When a company works alone without any integration, it needs to take all the work to find its own distributors. Overall, within the STSP cluster, key enterprises of dental devices are integrated. Additionally, the existing optoelectronics and IC clusters have already attracted international industrial leaders. The high reputation of the STSP indirectly attracted other international companies and distributors. Due to the chain of international distribution built among enterprises, the STSP is able to organize match meetings for international distributions and manufacturers. This helps to build integrated marketing system and international well-known physicians will come to Taiwan to market products as local KOL.

#### **4.3 The effective promotion model for the STSP to assist its tenant enterprises to develop and market innovative medical device products**

Recently, the overall turnover of Taiwan's medical devices has continuously grown. It is worth noting that we face the emergence of China and countries in Southeast Asia, Central and South America, and East Europe and manufacturing of many low-end products have been moved out gradually. It seems that Taiwan does not retain its advantages, yet from the perspective of export, the volume is in the rise. Besides, major export products have been replaced for the lost turnover and volume; Taiwan's medical devices still retain some tacit advantages that keep our industry competitive.

If we analyze the industrial value of Taiwan's medical devices, there are two main dimensions. The first dimension is high-end medical devices developed through updated technologies that punctuate Taiwan's industrial power and further increases added values. This method has been commonly used; however, the medical device industry is quite conservative and trust oriented. The market for the high-end products has been dominated by international big players, for example, medical images by Philips and Simens and cardiovascular implants by Medtronic, Boston Sci and J&J. Hence, not technology but brand trust, teaching network, and tacit competitiveness accumulated play the important roles in high-end medical devices.

As a result, brand image building of the medical device industry matters the most. High GDP countries such as Japan and those in America and Europe still regard the medical device industry as their major industry. The researcher categories these intangible brand values into two types built on accumulated trust of users as well as the experience acquired from brand values and trust. In the past, Taiwan's medical device industry built its image through B2B including image creation and service image perceived by clients.

(1)Image creation of relative confidence

With the concept of globalization, production has been processed with labor division in all regions. But in terms of health care field, the marketing process of medical devices, health food, and biochemical products relies heavily on the existing image of confidence in the origin countries. In fact, due to the global visibility of Taiwan's 3C products, the "Made in Taiwan" image comes only next to Japan and countries in Europe and America and surpassed China and South East countries in the regard of global confidence interval of medical devices made in Taiwan.

Although the main medical device market is in countries in Europe and America and the acceptability of Taiwan's products is lower than that of those made locally, yet recently, Taiwan's opportunity lies in the quick rise of newly emerging countries. In addition to the quick market growth in those countries, they demonstrate higher acceptability towards products made in Taiwan. Acceptability refers to the consumer confidence in the quality of products made in Taiwan than in that of those made locally. Furthermore, they show higher price acceptability towards products made in Taiwan than that of those made in Europe and America. These have brought promising opportunities for Taiwan's medical device industry, and it reflects the increase of export volume of some products. For example, because of the enhancement of economic power of newly emerging countries in recent years, we have witnessed quick infrastructure related to health care and the huge demands for medical furniture including hospital and medical beds, sterilizers, surgical lamps, and

dental beds have been created accordingly driving the increase of Taiwan's export in this field. For newly emerging countries, these types of products "made in Taiwan" give them strong confidence.

In addition to medical furniture, the confidence is also found in the field of orthopedic implants that require more advanced technology and take higher risks. If we carefully analyze orthopedic products, although the overall technology is mature, yet 85% production remains in the US due to one of the important factors: stronger confidence in implants made in the US. But because of two factors below, the US manufacturers are strongly inclined to outsource their production. First, most orthopedic devices in advanced countries are paid by the health insurance system, but due to poorer economic growth than expected and the increasingly aging population, health insurance policies all adopt the thinking of contracting economy and that results in higher and higher deductible ratio of orthopedic implants. Driven by cost pressure, leading orthopedic manufacturers are motivated to move their production out. On the other hand, orthopedic implants in developing countries are often paid by users and diversified production specifications force major orthopedic manufacturers to develop products at relatively lower and higher prices to respond to different demands. Price elasticity of manufacturers in Asian countries gives them the opportunity to win over outsourcing orders. Taiwan, due to the long-term investment in orthopedic field becomes the destination of value chain shift of countries in Europe and America. The most distinct example was in 2007, ODM products of United Orthopedic Corporation were launched in the US market. Additionally, United was also granted with the five-year long-term outsourcing contract by the global 5th leading orthopedic company Smith & Nephew. A Taiwanese manufacturer in Central Taiwan received orders of vertebral treatment products and devices from the big US player in the orthopedic industry, Zimmer. In fact, the confidence of international leading companies in Taiwan's orthopedic products is the result of Taiwan's long-term investment and it allows the value activities to be extended to Taiwan.

(2)Manufacturers with the mindsets of those in the service industry

In the past, the advantages of Taiwan's manufacturing industry has been recognized internationally, but more service elements have been now added to this pure manufacturing oriented industry to extend the life. For example, in the past, Taiwanese traders took orders by participating global exhibitions and then found manufacturers to produce. These traders now are replaced due to globalization and the emergence of the Internet. But from another angle of thinking, manufacturers have integrated this piece of value chain into their own companies. Manufacturers can

market their own products on the Internet and take orders by participating in related exhibitions of medical devices. More importantly, they are able to directly respond to the demands of clients including small changes and the provision of quicker services when facing to them. Other countries will learn from Taiwan quickly, and Taiwanese manufacturers will face greater challenges.

In fact, due to the competition from big players, Taiwanese manufacturers have come out with more diversified service strategies. A dental drill machine maker, for example, starting from maintenance, has developed machines compatible to all big brands to enter the market. A similar case has been seen in the field of ultrasonic transducers, products have been extended to the hospital channel with maintenance services. We also observe the inclusion of more innovative service concept to market medical devices through the model of overall home care services.

But the STSPB would like to make use of existing product and marketing model as well as to promote enterprises to adopt more innovative and reliable industrial promotion model. This requires the links of academic and research institutions and derived alliance with international hospital universities. By establishing KOL mechanism and publishing in international journals after participating in clinic experiments, the marketing value of products can be built with professional physicians (the client end) and further innovative product R&D concepts can be created to have the cycle of industrial innovation and profitability. It will create another cluster ecosystem and more importantly, the past triple- helix structured academic and research institutions, the government, and the industry became the key element to transform the innovative concept of cluster industry into the innovative operation model.

# Promotion Element

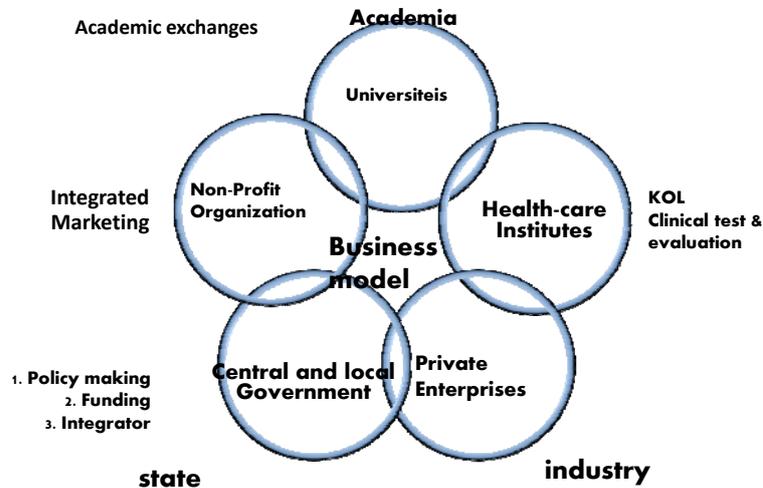


Fig4. The promotion element of medical device industrial cluster in STSP

## 4.4 The effectiveness and results under the marketing strategies to help the park enterprises in STSP to promote their products

The product effectiveness under this project lies mainly in the advantageous technology possessed by the precision industry based on both domestic and international growth trend of the medical device industry as well as the characteristics of existing domestic manufacturing industry to develop implants and surgery and medical devices for dentistry and orthopedics. The existing foundation of domestic optoelectronics and software and hardware information is integrated to develop the high-end and high-value medical treatment systems such as medical laser, dental scanner and 3D dental milling machine. Systematic development can help to improve product value and facilitate technology integration for the purpose of the cultivation of high class professional researchers. Furthermore, in coordination with social and economic development that results in the increasing demands for plastic surgeries as well as the police promotion of medical tourism in Taiwan, the development of manufacturing and production core technology and the optoelectronics technology are applied to the medical devices of plastic surgeries. In terms of strategies, domestic clinic experts and professionals in the medical devices are first recruited to conduct in-depth interviews and evaluations for existing manufacturers of medical devices. According to the evaluation outcomes, suggestions

of technology and product upgrading and objectives are proposed. Experts in relevant fields are then identified according to the planning to give assistance. Through medical centers around Taiwan, relevant clinic and medical device experts are invited to talk on relevant professional knowledge of clinic treatment, medical device rules and regulations, accreditation of intellectual property rights, and design and manufacturing to assist enterprises to conduct talent training. In the regard of enterprise consultation, first, we evaluate the existing technology and resource conditions of enterprises so as to assist to determine product development direction and market positioning, coordinate with relevant medical and engineering experts of product development and accreditation, and arrange enterprises to go abroad to visit relevant enterprises and participate in trade shows. These help to build the connection between and among manufacturers, relevant clinic personnel, experts and foreign manufacturers with the aim to assist enterprises to introduce R&D concept developed from actual medical treatment behavior of clinic personnel before product development. This concept is practically realized to improve existing medical technology and devices or develop new medical technology and devices. Additionally, enterprises are able to actually present, rent factories or build their own plants; they are also consulted with the application for GMP to speed up production and manufacturing. Important outcomes and goals achieved are described below.

- (1) Consultation for the upgrading traditional industrial technology, assisting technology and product enhancement of existing medical device manufacturers, and improvement of industrial value: Park enterprises including Hung Chun Bio-S Co., Ltd, Huang Liang Biomedical Technology Co., Ltd, Biomate Medical Devices Technology, Taiwan Implant Technology Co., Ltd, and Alliance Global Technology Co., Ltd. have successfully developed artificial roots and have continuously accredited and registered. They began selling artificial roots and relevant surgery devices and continuously apply for relevant FDA and CE accreditation to gain the sales opportunities.
- (2) The gap between product line and value chain is closed by constructing the Kaohsiung Science Park into the procurement center or R&D center of international medical device enterprises and facilitating the cluster effect.
- (3) The STSPB have successfully consulted five enterprises to develop artificial roots and registered under Ministry of Health and Wealth, 24 certified with good manufacturing practices (GMP), five qualified under the “New Pharmaceutical Development Act,” 32 accredited by TFDA, 11 approved by the US FDA, and 18 ratified by CE logos.
- (4) Among the relevant enterprises of medical devices participating in this project, products in the dental field including pizosurgery, dental CT, X fluorescent lamp,

medical sensors, high and low speed dental milling machines, dental units, 3D dental milling machines, corrective devices, high-end medical implants, and relevant surgery instrument and devices. Now there has been small-scale clustering, and in the future, we will work towards the one-stop shopping industrial cluster.

- (5) The STSPB has successfully recruited the presence of leading enterprise, United Orthopedic Corporation that has invested 320 million at the Kaohsiung Science Park of the SPSP for the building of new factories at Phase I and II. At present, factories of Phase I and II are undergoing mass production. Currently, United Orthopedic Corporation takes up about 0.1% of global artificial joint market. With the increase of new production capacities and the growth of Central and South American markets, it will gradually increase its global market shares.
- (6) After the formation of industrial cluster, the gap of the dental industry, production line and Taiwan's value chain can be closed. In the future, more international buyers will come to purchase directly at the STSP via the one-stop shopping to increase cluster effectiveness. Meanwhile, we will also construct the Kaohsiung Science Park as the international procurement center of medical devices or the research center to facilitate cluster effect.
- (7) The newly emerging markets are also our focus. The STSPB participated in exhibitions with the STSP Pavilion including four international ones and four to five domestic ones. They also organized international channel matching seminars to invite channel members from Japan, Russia, Hong Kong, and Thailand for discussions and visits to park enterprises. There have been initial discussion results, and we have discussed with six Vietnam hospitals, two Thailand hospitals, and two distributors (Germany and Vietman) for the cooperation and development of KOL marketing model.
- (8) Through academic and industrial cooperation, we developed KOL marketing with NCKU, University Malaysia, and park enterprises to set up the international university-industry alliance of medical devices, and the dental product experiential exhibition room is set up in Kaohsiung Medical University. Products of park enterprises are used for teaching demos and provided for the use at NCKU Hospital. In addition to give feedbacks to park enterprises after the practical operation of physicians so as to improve product function, the familiarity and trust of physicians towards the STSP products can also be enhanced. Physicians from Chi Mei Hospital were invited to lecture on module courses of clinic demands. Through dental and surgery clinic cases, park enterprises, academic and research institutions, and clinic physicians can exchange with each other. It is expected that the STSP will work with

University of Medicine and Pharmacy, Ho Chi Minh City and its affiliated hospitals to build the KOL marketing model for the university-industry cooperation for the facilitation of marketing of medical device products at the STSP to Vietnamese market.

- (9) Let physicians and manufactures do more to understand each other, but also introduce more domestic and foreign hospitals can visit in Kaohsiung medical device cluster. And make more hospital physicians recognize domestic medical material goods. STSPB will integrate medical device manufactures related resources, and alliance industry entered matchmaking through the government public sector, the "multi-multi-center coalition" approach to "a multi-center alliance" or, continued construction of a service-oriented model of collective marketing, prompting hospital procurement country products to MIT products and medical services combined were the whole plant output.

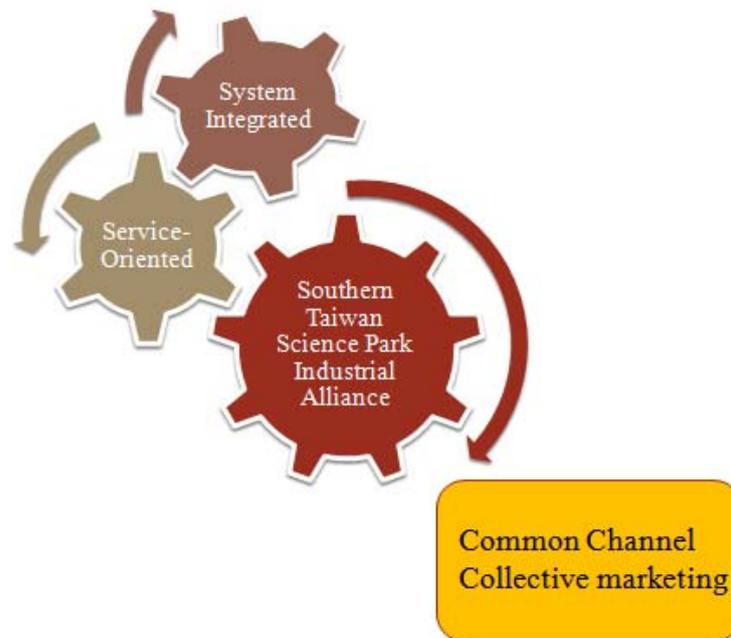


Fig5. The marketing strategy of medical device industrial cluster in STSP

## 5 Conclusions

### 5.1 Key Opinion Leader (KOL) strategy and Evidenced-Based Medicine (EBM) strategy are critical market-driving strategies to drive medical device industry

This paper assessed whether embracing both a Key Opinion Leader (KOL) strategy and an Evidenced-Based Medicine (EBM) strategy will increase adoption of an innovative medical device. Based on the literature review and the results of this paper, key opinion

leaders and evidence-based medicine are critical components of medical device marketing strategies. It is clear that engaging KOLs is necessary to build credibility and influence peers. The most common benefits included bench-testing, exposure, publicity, building credibility and disseminating scientific information. However, these benefits come at a cost, as it was revealed that paying KOLs may have a positive impact on success. Conveniently, there are also various ways in which KOLs can be identified, with networking and requesting references being the most common.

With regards to EBM strategies, clinical evidence to support both economic viability and patient welfare is essential to medical device innovation. Smith (2015) argued that a KOL strategy is more important and more powerful than an EBM strategy. However, in order to attract and retain KOLs, it is important to have strong, empirical evidence to support claims. Conveniently, these clinical claims may be achieved through FDA certification. When compared to the FDA, an EBM strategy is much more robust and requires proof of not only safety, but also economical effectiveness and efficacy. The FDA merely ensures safety, while an EBM approach takes into account cost effectiveness and clinical outcomes (i.e., better, faster, stronger cheaper). As noted in the results, an EBM strategy can be very costly and therefore some companies may not be able to afford or justify spending thousands of dollars on clinical studies. Depending on the product, FDA approval may be all the support and evidence a company needs to gain achieve sales.

Therefore, a strong KOL strategy and a strong EBM strategy are critical for success finds qualified support.

## **5.2 Good Key Opinion Leader (KOL) depend on ensuring product's functionality, safety and reliability**

Medical device manufacturers invest heavily in training subject-matter experts (SMEs) and building relationships with key opinion leaders (KOLs) in order to establish themselves as thought leaders and provide peer-to-peer perspective on key topics pertaining to their specialties, therapeutic areas, and/or products. They are contracted to give talks, create content, assist with trials, get involved with grant funding, sit on advisory boards, and more. And they can be paid handsomely to do so.

Manufacturers that manage KOLs are not doing it out of the kindness of their hearts. They're likely doing it to drive demand and preference for their products. However, these companies often start with the patient in mind and believe that the right way to get the message out about their products, the right way to target the right patients, and the right way to work with the right clinicians is through KOL engagement.

By creating collaborative relationships with these highly respected physicians or key

influencers that drive opinion as speakers, authors, and researchers, manufacturers can build credibility and increase market share. Often these experts are speaking on behalf of a company or brand at industry events and to the press. In other words, the ability to understand the return on investment from KOL events is critical information for many manufacturers. Manufacturers must use their medical device marketing plan to not only demonstrate clinical safety and effectiveness, but also prove the reduction of health care costs over time. Marketing tools such as case studies that can demonstrate this will be even more critical in these economic times.

### **5.3 Bundle medical device products and services should leverage such marketing opportunities**

KOL-driven marketing strategies will likely yield to approaches that focus on identifying underserved patient populations with manifest clinical need for products with demonstrable outcomes. The halo effect in the new marketing paradigm will come not from having renowned academics present a firm's PowerPoint deck to auditoriums of doctors, but rather from research demonstrating improved patient outcomes and avoided costs, associated with improved patient compliance, compliance that delays or reverses disease progression and acuity. Successful companies will (pursuant to evolving FDA and FTC guidance) use social media to disseminate such studies to assure that affected prescribers, patients and social-media KOLs are aware of opportunities to improve outcomes. Of course, when products are bundled together with medical foods, nutritional counseling, disease-management programs and case-management services, patient adherence increases and outcomes improve: so successful firms will be those that bundle their products to leverage such opportunities.

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