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Effective Competitive Strategies of U.S. In Vitro Device Manufacturers

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This is to certify that the doctoral study by

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Abstract

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MS, TA University of Technology, 1997

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Doctoral Study Submitted in Partial Fulfillment

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Abstract

Medical manufacturing leaders struggle to maintain their competitive position due to inefficient business strategies. The purpose of this multiple case study was to explore strategies that in vitro diagnostics (IVD) medical manufacturing's leaders have used to gain and maintain a competitive advantage in the global marketplace. Porter's competitive advantage theory was used to understand how IVD medical business leaders maintain their competitive edge. Data were gathered through interviews with a purposive sample of 3 IVD medical device leaders from companies in California, Connecticut, and New York who had run IVD medical businesses for at least 10 years and who attended a 2014 medical exhibition in Dusseldorf, Germany. To reduce the risk of bias in measurement, triangulation methods included a literature review and intensive analyses of the interview responses, participant observation notes, company websites, and organizational records. Data were analyzed using thematic analysis to find essences of the participants' perceptions. The themes were derived from coding and the number of references coded during the data analysis. Eight themes emerged representing strategies for improving competitive advantage: customer support; marketing, e-marketing, and branding; competitive collaboration; quality; cost structure; regulation; innovation; and information technology. The 8 general themes have been divided into 3 categories: cost leadership, differentiation, and focus strategies base on Porter's competitive advantage theory. Results can help U.S. IVD organizational leaders develop strategies to thrive and secure market advantages, which could provide the resources for creating new products and increasing employment opportunities.

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Dedication

I would like to dedicate this study to the love of my life and my two sons, Nicollo Borna and Pietro Davin. Your support, encouragement, and patience through this educational journey have been remarkable. You contributed time and treasure for all steps I took. Thank you for sacrificing so much in the hope that I would achieve success. This dissertation is for all those nights that you have been waiting for me to come home from work and the library to hold you in my arms. I hope that this accomplishment helps me give insight into your lives. This journey was inspired by my mom and dad, who have devoted their lives and education to me, and now I have tried to do the same for you.

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First, I want to thank God for blessing me to pursue a doctoral degree. I owe deep gratitude to my committee, mentors, and esteemed academic leaders, Dr. Thomas Schaefer and Dr. Steve Ross, for all their wisdom, insight, guidance, expertise, and strength that they have imparted to me during this life-enhancing journey. I would not be able to get this far without your guidance. Thank you to my URR, Dr. Al Endres, and to Dr. Taylor and Dr. Burrus for their contributions to this accomplishment. I appreciate the time you dedicated to my educational growth.

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Section 1: Foundation of the Study

Today's dynamic external environment, cutting-edge technologies, and globalization have forced company leaders to reevaluate their market positions to avoid losing market share to competitors (Aghamirian, Dorri, & Aghamirian, 2015). One such competitive industry is diagnostic medical devices (Porter, 2012), a market led by the United States worth approximately $350 billion a year (Public Citizen, 2012). In a competitive global industry, manufacturers require effective strategies to maintain their leadership position (Prajogo, 2016). U.S. diagnostic medical device manufacturing leaders must reconsider, develop, and reshape their current business strategies to maintain their position in the global market.

Background of the Problem

Many companies fail to redesign their position and find appropriate competitive strategies to retain their position or keep their strategies in line with their competitive environment (Govindarajan & Euchner, 2012; Koveos, 2013; Porter, 1980). As corporations continue to expand into the global market, the efficiency of strategies becomes the core factor to increase their overall competitiveness (Lee, Madanoglu, & Ko, 2013). The developing global business environment, rapid technology, and competitive pressures have forced organization leaders to adopt strategies to maximize market share (Bereznoy, 2015).

According to Porter (1980, 1985), leaders need to develop effective strategies to maintain or regain a competitive position among competitors. A competitive position is defined as the position that a company acquires in comparison to its competitor (Isaksson,

Garvare, Johnson, Kuttainen, & Pareigis, 2015). In the United States, in vitro diagnostic (IVD) medical device manufacturers need to reshape their strategy to maintain their global leadership position (IVD Australia, 2016).

Problem Statement

Medical manufacturing organization leaders struggle to maintain their competitive position due to inefficient strategies (Jovanović & Petrović, 2015). Sull, Homkes, and Sull (2015) studied 400 global CEO leaders in Asia, Europe, and the United States and found that 75% of the organizational leaders struggled to implement effective strategies to maintain their market position. The general business problem was that leaders in IVD medical device manufacturing fail to gain and preserve their competitiveness, which results in a loss of the organization's position in the competitive marketplace. The specific business problem was that some leaders in IVD medical manufacturing organizations lack strategies to gain and maintain a competitive advantage.

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies IVD medical manufacturing leaders use to gain and maintain a competitive advantage. The population consisted of the leaders of three IVD medical businesses in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more. The implication for positive social change is that assisting U.S. IVD organizational leaders to develop strategies to thrive and secure advantages could provide the resources for creating new products and boosting employment.

Nature of the Study

Parylo (2012) stated that qualitative research methods are the best approach to explore and develop a rich description of the decision-making of the participants in a study. With the qualitative approach, researchers gain a comprehensive understanding of the phenomenon and explore the subject based on the participants' experiences and perceptions (Anyan, 2013; Nutov & Hazzan, 2014; Yin, 2014). I conducted a qualitative study to explore the strategies that IVD medical business leaders have used to gain and maintain a competitive advantage in a competitive marketplace.

Researchers test hypotheses, describe numerical changes, and examine relationships and differences among variables in quantitative studies (Harrison, 2013; Hope, 2015; Shelton, Smith, & Mort, 2014; Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). A mixed-methods approach combines qualitative and quantitative methods to answer research questions (Harrison, 2013). The quantitative and mixed-methods approaches were not appropriate for this study because the purpose was to explore how IVD medical device leaders achieve and maintain the competitive advantage.

The research designs available for the qualitative method include phenomenology, case study, and ethnography (Rowley, 2012; Yin, 2014). A phenomenological researcher's primary task is to explore the lived experiences of participants regarding a significant event (Quay, 2015). Ethnographic researchers identify and explore patterns of groups' culture (Yin, 2014; Zhu & Bargiela-Ciappini, 2013). Researchers use a case study design to obtain an in-depth understanding of a complex phenomenon within its

real-world context (Yin, 2014) and to identify the connections among events over time (Klonoski, 2013; Yin, 2014). I determined that a case study design was appropriate.

Research Question

What strategies do IVD medical manufacturing leaders use to achieve and maintain a competitive advantage?

Interview Questions

1. What strategies have you as a U.S. IVD medical leader used over the past 10 years to achieve and maintain a competitive advantage?
2. How have you measured the effectiveness of the strategies?
3. What strategies have your competitors demonstrated over the past 10 years to achieve competitive advantage?
4. What kind of barriers did you face during the implementation of the strategies to maintain a competitive advantage?
5. How did you cope with barriers to the implementation of these strategies?
6. What other information would you like to provide?

Conceptual Framework

The basis of Porter's competitive advantage theory is to understand a firm's position in its external environment and what competitive advantage the firm has over its competitors (Evans, 2016; Snipes & Pitts, 2015). Porter (1979) developed the competitive advantage theory to examine the effect of competitive advantage in shaping entrepreneurial strategies (Snipes & Pitts, 2015). Managers have employed the competitive advantage theory to create competitive strategies (Evans, 2016). Kharabsheh,

Jarrar, and Simeonova (2015) noted that organizations adopt the competitive advantage theory to differentiate themselves from competitors in superior business positions.

Porter (1989) identified low cost and differentiation as two primary factors underlying the theory that leads to three generic strategies: cost leadership, differentiation, and focus. Porter's competitive advantage theory provides a potential foundation to understand the effective strategies that leaders employ to gain and maintain their competitive position. Porter's competitive advantage theory can be an acceptable approach to adopt competitive advantage in organizations. I applied Porter's competitive advantage theory as a conceptual framework to understand effective strategies that IVD medical manufacturing's leaders use to gain and maintain their competitive edge.

Operational Definitions

Competitive advantage: A competitive advantage is an advantage a company has over its competition that creates differentiation (Roy & Singh, 2015).

Customer relationship management (CRM): CRM refers to the strategic management of customer relationships involving integration of people, systems, and processes to achieve customer satisfaction throughout the product life cycle (Awasthi & Sangle, 2013; Leligdon, Quinn, & Briggs, 2015).

Globalization: Globalization is the evolution of the global economy as communication, transportation, and trade are used to integrate regional economies (Damijan & Kostevc, 2014; Lechevalier, 2015).

IVD products: In vitro diagnostics medical products are tests that can be used to prevent or treat diseases in health professional settings or home settings (FDA, 2015).

IVD manufacturers: In vitro diagnostics manufacturers are producers who make the medical device or subcontract part of the production process (FDA, 2015).

Assumptions, Limitations, and Delimitations

Assumptions refer to assertions in the study that the researcher believes to be true (Scates, 2015). Limitations are external conditions and possible shortcomings beyond the researcher's control that restrict the generalizability of the findings (Goldberg & Allen, 2015). Delimitations are conditions and limitations imposed by the researcher to limit the scope of the study, including age, gender, or other criteria (Goldberg & Allen, 2015).

Assumptions

Assumptions help reviewers consider the findings from their perspectives and the facts that an author considers genuine and unverified (Leedy & Ormrod, 2013). Qualitative research starts with certain assumptions made by researchers (Yin, 2014). The first assumption in the current study was that a qualitative method was more appropriate than a quantitative method for conducting an inductive study through observations of the target population in the real world. The second assumption was that conducting face-to-face interviews would be the most appropriate way to collect the data from the participants. I also assumed respondents were honest in expressing their ideas and experiences.

Limitations

Limitations are the conditions, shortcomings, and influences that the researcher cannot control and that have an impact on the interpretation of the methodology and conclusions (Moustakas, 1994). The first limitation was the cost and time associated with

interviewing the targeted IVD manufacturers for this study, which limited the number of participants. The second limitation was participants might not have disclosed all information because of business confidentially. The third limitation was the results might not be relevant to all companies or demographic locations. One inherent limitation in qualitative research is selection bias, or the methodological factor that may limit transferability to a larger population (Prowse & Camfield, 2013). In the current study, researchers' and participants' biases were not entirely avoidable.

Delimitations

Delimitations are bounds placed on study in which the researcher defines areas irrelevant to answering the research question (Leedy & Ormrod, 2013). Delimitations are restrictions that researchers impose to focus the scope of a study (Perry, 2012). The population for this study was leaders in IVD medical manufacturing organizations in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more who were willing to be interviewed face to face. This limitation may have reduced the diversity of the sample. Respondents agreed to the informed consent form provided as part of the research protocol.

Significance of the Study

Results of this study may provide U.S. IVD manufacturing leaders with sustainable strategies that could help improve and maintain a competitive edge. IVD leaders are encouraged to use effective strategies to improve and retain their business performance, productivity, consumer satisfaction, competitiveness, and company profitability. U.S. IVD medical manufacturers can benefit from the results by gaining

insights into the strategies of competitive advantage for improving market positions and overall success. In addition, a comprehensive understanding of effective strategies for competitive advantage could help IVD medical leaders identify the most appropriate approaches to improve and maintain their market positions. The implications for positive social change include the potential for reducing unemployment in the local workforce by assisting U.S. IVD manufacturers develop strategies to thrive and to secure advantages that could provide the resources for developing new products.

A Review of the Professional and Academic Literature

In this section, I explore the literature pertaining to effective business strategies. To do so I created a list of key words related to strategies for gaining competitive advantage. In this subsection, I offer a critical analysis and synthesis of previous studies that support the research problem, and a summary of themes that frame the research question. The critical review of the literature focuses on Porter's competitive advantage theory and a synopsis of previous research on the topic. The literature I review includes an overview of the background on the importance of developing a strategic competitive advantage in the IVD medical device manufacturing industry.

The following sections include a discussion of Porter's competitive advantage theory and gaps in the knowledge base. Search terms included Porter competitive advantage, Porter competitive strategy, transnational model, innovation, innovation management, innovation and competitive advantage, customer and competitive advantage, information technology, and competitive tactics. I searched EBSCOhost, ProQuest, Sage, and Google Scholar for relevant literature.

The literature review included peer-reviewed journal articles published between 2012 and 2017 by authors who contributed to research on competitive strategy, customer relationship management, innovation, and information technology. Articles published prior to 2012 appear because they contributed directly to the research in this study. Table 1 contains a summary of the sources.

Table 1

Research Source Identification

Total documents	Total 2012 or newer	Total peer-reviewed documents	Total peer-reviewed 2012 or newer	% of the total peer-reviewed documents 2012 or newer
428	416	385	379	89%

Porter's Competitive Advantage Theory

Porter's body of work has been widely used by industry leaders to create competitive advantage strategies (Evans, 2016). The purpose of Porter's analysis is to understand firms' positions in their external environment and what competitive advantage they have vis-a-vis their competitors (Evans, 2016). Porter (1980) contended that competitive advantage-based strategies are divided into three types: cost leadership, differentiation, and focus.

Cost Leadership

In the global marketplace, price is a core factor in buyers' decision to select vendors (Porter, 1989). According to Handoko, Aryanto, and So (2015), the competitive advantage occurs when a firm can supply similar products or services as competitors but

at a lower price. Business managers can leverage cost leadership through marketing or efficient operations (Tansey, Spillane, & Meng, 2014).

With competitive cost strategy, companies focus on discounting their product to maximize sales and have a significant cost advantage over the competition to increase their market share (Agyapong, Ellis, & Domeher, 2016; Wang, Liang, Zhong, Xue, & Xiao, 2012). Firms endeavor to decrease the production, operation, and distribution costs to gain a competitive advantage in price markets (Barbos, 2015; Porter, 1989).

Differentiation

Many business leaders have used a framework based on Porter's (1989) theory to create a long-term competitive advantage strategy for differential advantage. Competitive differentiation accrues when the firm can deliver benefits that exceed competitors' products or service. Differentiation is a singular characteristic that sets the organization apart from others in the industry to gain competitive advantage (Porter, 1991) through distinguishing products and service from others (Prajogo, 2016; Vieira, O'Dwyer, & Schneider, 2016). Business leaders employ differentiation strategies to compete on non-price-based factors. Aagaard and Lindgren (2015) contended that companies charge a premium price for the innovated product to cover the higher production and innovation cost.

Hanaysha (2016) identified core business processes and quality improvement practices as strategies for brand differentiation and enhancing competitive advantage. Davcik and Sharma (2015) suggested that a company differentiates its brands through innovation because it hopes to soften any price competition. Choosing the right

technology with low cost is imperative to differentiate an organization through the latest innovations (Wu & Raghupathi, 2015).

Focus

Companies may need to have a focused strategy with the distinct market segment's needs. Managers may obtain a competitive edge through cost leadership, differentiation, or both strategies combined within chosen market segments (Porter, 1991). According to Porter (1991), companies can employ cost leadership, brand identification, high product quality, technology, and service leadership or a combination of these as strategies to gain competitive advantage in the market. The company may increase the strong marketing leadership in an industry if it encounters a superior differentiation and lower cost leadership (Porter, 1989).

Managers may find an advantage in superior products, differentiation approaches, superior management skills, cost leadership, innovations, or information systems. Companies adopt a focused strategy to maintain their position in the global marketplace to compete against the large multinational businesses to gain profits and steady growth rates (Picone & Dagnino, 2015). For example, in the IVD manufacturing sector, mature participants such as U.S. manufacturers can differentiate based on their extensive product innovation (Porter, 1991) while new entrants—for example, China and India—can differentiate on pricing because of the heavily subsidized government support.

Prior Studies Grounded With Porter's Competitive Advantage Theory

Business leaders gain a competitive advantage in various industries by applying different competitive strategies (Arthur & Hracs, 2015). For example, the Apple

Company offers a customer-friendly product, branding, technology, and customer orientation differentiation as a core competitive advantage (Contractor, Kumar, & Dhanaraj, 2015). IBM's innovation strategy saved the company from the market crash in 2001 (Marshall, Mueck, & Shockley, 2015). McDonald's has used the Porter focus strategy as a competitive advantage to win the competitor market (Njeri, Kambona, & Odhuno, 2015).

However, a prime example of the lack of effective strategies exists in U.S. multinational corporations and the U.S. manufacturing industry. Several U.S. major industries lost competitive advantage to other countries because of a lack of effective strategies, including Boeing (Yi, 2014), U.S furniture manufacturers (Selle, 2013), and U.S. auto dealership businesses (William, 2012). In 2012, approximately 160 U.S. auto dealership businesses closed their businesses and autoworkers lost their jobs (U.S. Department of Commerce, 2012). The Boeing Aircraft Company has lost its leadership position to China and European Aircraft Manufacturers since 2003 (Pritchard, 2010). Yi (2014) studied competitive advantage in aircraft industries in the United States based on Porter's competitive advantage theory. Yi sought to find effective strategies to retain Boeing`s leading market position in the global market. Yi contended that aircraft industries operate in an increasingly global competitive environment requiring new strategies to maintain their market position. Boeing managers have been challenging smaller and less experienced global aircraft manufacturers that have a low-cost advantage. Yin conducted interviews with 20 Boeing managers from six commercial aircraft manufacturing branches in Seattle, WA. Yin identified 10 effective strategies

including customer support and customer knowledge; leadership in technology and innovation; quality, productivity, and affordability; global mindset; people strategy; product strategy; anticipating new entrants; managing outsourcing and suppliers; partnership with the U.S. government; and competitive strategy development.

Selle (2013) studied leaders' perceptions about how product quality and customer satisfaction are considered in the development process of effective strategies for gaining a competitive position in the U.S. upholstered furniture industry. Selle's focus in this qualitative phenomenological research was identifying the influences of globalization on the furniture industry and efficient strategies that might yield the competitive advantage for U.S. furniture manufacturers. The U.S. upholstered furniture industry has been challenged by global competition and has lost its market position to China, impacting 80,000 furniture-manufacturing jobs in the United States since 2000 (Dugan, 2009). Selle used the competitive advantage theory to understand the global competitive forces shaping the U.S. furniture industry position. Selle collected data from 31 industry leaders in the U.S. and Chinese furniture industry. Three important themes from the data emerged: (a) cost structure, (b) react and adapt to rapid global change, and (c) market focus niche.

In Vitro Diagnostics Medical Device Manufacturers

Manufacturers introduced medical device technology to the market in the 1950s and 1960s (Vockley, 2016). The top multipliers in the U.S. medical device industry are the IVD and the electro-medical products (Foe Owono, 2015). In vitro diagnostics manufacturers are considered the producer whether they make the medical device or

subcontract part of the production process (FDA, 2015). In vitro diagnostics medical products are tests that can be used to prevent or treat diseases in health professional settings or home settings (FDA, 2015). Raw material vendors, medical device suppliers, manufacturers, distributors, and end users are the various stakeholders involved in the supply chain of the IVD market (Allied Market Research, 2014; IVD Australia, 2016).

IVD Medical Device Global Market

The medical device market continues to grow in response to changing lifestyles, the aging population, and the use of point-of-care testing devices (Gao et al., 2015). Demographic changes are the core driver for medical device companies' growth and continue to shape the medical device industry (FDA, 2015). Over the past 50 years, IVD medical products such as diabetes medical device kits have trickled from clinical laboratories and hospitals to doctors' offices and homes to improve health care (FDA, 2015).

The overall global medical devices market was worth approximately $479.5 billion in 2015 (International Trade Administration [ITA], 2016). The United States has the largest medical device market in the world, about one third of the global medical devices market (U.S. Department of Commerce, 2016). According to the 2012 research at International Trade Administration, 76% of global medical devices were used in the United States, Japan, Italy, and France, while these countries accounted for 13.1% of the world's population (ITA, 2012). Markets in Asia-Pacific, Central and Eastern Europe, the Middle East and Africa, and Western Europe were worth about $68.7 billion, $14.6 billion, $10 billion, $79.5 billion respectively in 2015 (ITA, 2016). In 2013, the IVD

global market revenue was approximate $53.32 billion, with a compounded annual growth rate of 5.34%. The IVD market will be worth about $74.65 billion by 2020 (IVD Australia, 2016).

U.S. IVD Medical Device Market Position

The United States is the leading supplier of medical devices in the global market (Porter, 2012). In addition, during 2010-2011, an estimated 40% of medical device revenues garnered by the top 10 U.S. medical device original equipment manufacturers (OEMs) stemmed from beneficial foreign exchange rates (Congressional Research Service, 2015; Schmutz & Santerre, 2012). Entering the new market and building supply and export opportunities are the significant factors for the competitiveness and growth of the U.S. manufacturing economy (Zhang, 2015).

Medical device firms in the United States also face various challenges that could lead to slower domestic growth. The medical device industry compound annual growth rate was 5.34% in 2015 (Holtzman, Ganz, & Gorkhover, 2015; IVD Australia, 2016). Imported medical devices had a value of $54 billion, $9 billion more than exports, in 2015 (ITA, 2016). The value of imported medical devices from the main competitors in China and Mexico has increased (ITA, 2016).

U.S. Food and Drug Administration (FDA) and European Commission (EC) barriers. The FDA is the executive body that has responded to an increase in the rate of recalls and the risks associated with the use of medical devices (FDA, 2015). In 1938, the FDA's regulatory systems included the classification, device approval, health-hazard evaluation, safety assurance, and the objective of protecting health systems (Shore &

Freije, 2016). In 1976, the U.S. Congress passed an amendment bill to ensure the safety and effectiveness of medical device products in the market. U.S. IVD medical manufacturers are required to follow FDA regulations that are necessary to protect consumers but create barriers for domestic and international manufacturers. As such, U.S producers can be at a competitive disadvantage because of increased costs and long processing time compared to international competitors (Foe Owono, 2015). McHugh, McCaffery, and Casey (2012) argued that FDA regulations are the core obstacles for international medical device manufacturers to market and sell their products within the U.S. market.

In addition, the European Union Medical Device Directive (MDD) 2007/47/EC regulation presents another barrier for U.S. medical device exports into the European market. U.S. medical device manufacturers and distributors need to gain Conformité Européenne (CE) certification to market their products within the European Union (Kramer, Xu, & Kesselheim, 2012; McHugh et al., 2012). The Council of European Communities has practiced CE in the European medical device market since 1990 to ensure human health protection (European Commission [EC], 2012). European medical device regulations create barriers for global medical manufacturers to improve the traceability and monitoring of devices before getting to the EU market (Sorenson & Drummond, 2014). Browning and Rowell (2015) added that the EC affects the medical device market with high approval costs and the lengthy approval process. Other challenges for U.S. medical device companies seeking entry into foreign markets are

intellectual property laws, counterfeits, and no standard rules (Office of the United States Trade Representative, 2015; Wattanapruttipaisan, 2014).

Competition in the current global environment. North America accounted for 43% of the IVD market in 2014, followed by Western Europe, Asia-Pacific, and the rest of the world (IVD Australia, 2016). Roche Diagnostics (Switzerland), Siemens Healthcare (Germany), Sysmex Corporation (Japan), bioMérieux (France), and emerging markets are the major U.S. competitors in the global IVD market. Europe had the highest share of the total global IVD market, followed by North America, in 2012 (Torsekar, 2014).

The European medical technology market is the second largest after the United States (Jovanović & Petrović, 2015). According to the European Diagnostic Manufacturers Association (EDMA), the European IVD industry reinvests approximately $1.79 billion annually in research and development (R&D). Ninety five percent of the European IVD industry includes small and medium-sized enterprises. However, this mature market has slow annual growth rates of between 3%-5% annually (ITA, 2016).

Since 1995, there has been a sudden growth in the markets in developing countries, especially in China, Latin America, and India because of economic development, industrial growth, health care sector improvement, and changes in health and culture (Jovanović & Petrović, 2015). China has become a strong competitive force in the world's fastest growing market for IVD products (Boyer, Morshed, & Mussivand, 2015). Over the past several decades, China has boosted the number of manufacturers of medical devices for domestic and international customers to nearly 13,000 companies

(Nguyen & Imholte, 2016; Zhang et al., 2015).

Compared to the United States, China has strength in economic, labor, favorable currency laws, transportation costs, and national resources (Harpaz, 2016; Holslag, 2015). China's lower cost structures put tremendous pressure on many U.S. manufacturing businesses (Ito & Shimizu, 2015). In addition, China's growth strategies have shifted from leadership cost and labor-intensive manufacturing to differentiation strategy with technologically advanced manufacturing, sustainable innovation, and energy saving and environmental protection (Cheung, Kong, Tan, & Wang, 2015). The United States' leading players need to adapt continuously new strategies to maintain their position across the globe (Volonté & Gantenbein, 2015). Global IVD market participants need to employ a diverse set of strategies rather than rely on comprehensive product portfolios to grow in the market (Euramet, 2015).

Porter's Five Forces Analysis in the In Vitro Diagnostic Industry

Porter's five-force analysis is a tool that provides a concise view of the companies' position in their industry environment (Dobbs, 2014). Business managers can use Porter's five competitive forces model to identify strategies to gain the competitive edge. Managers leverage Porter's five forces analysis to identify external factors that affect company activities, goal, and position, and to evaluate their competitive environment, opportunity, strengths, and a path for verifying their ability of innovation and corporate technical competency (Wilkins, 2016). The five competitive forces model provides a foundation for developing business strategies that generate strategic

opportunities. Porter's five-force analysis explains how a firm's environments can shape the company strategies (Moreno-Izquierdo, Ramón-Rodríguez, & Perles-Ribes, 2016).

Porter (2008) indicated that acknowledging the five forces is the starting point to creating a competitive strategy. According to Porter, the five primary forces are (a) the threat of new entrants, (b) rivalry among existing firms, (c) the threat of substitute products or services, (d) the suppliers bargaining power, and (e) the buyers bargaining power. Organization managers analyze a firm's external environment and decide how companies can affect their competitors to gain competitive advantage (Porter, 2012). Dobbs (2014) contended that there is a need to have a practical and user-friendly platform to adopt Michael Porter's five forces in industry analysis.

Business leaders can employ a competitive forces analysis to select the most efficient competitive strategy to create barriers for potential rivals (Prajogo, 2016). Leaders use the forces analysis to identify trends and forecasts in the organizational environment (Toro-Jarrín, Ponce-Jaramillo, & Güemes-Castorena, 2016). Organizations practice these five competitive forces in a given industry to reshape the strategy at those points where the forces are weak (Porter 1985). As such, leaders in the IV industry can use Porter's five-force model to evaluate their competitive environment, opportunity, strengths, and weaknesses to design effective strategies to maintain their leadership position in the national and international market.

Threat of New Entrants

Companies should initially try to prevent the entrance of new competitors (Porter, 1980) because they can decrease the profit of the firm (Hsu, Tan, & Mohamad Zailani,

2016). Dobbs (2014) stated that the threat of new entry puts pressure on market prices and increase costs and customer expectation. Low-cost manufacturers from India, China, Brazil, Korea, Taiwan, and Mexico are the biggest threat to U.S. IVD manufacturers (ITA, 2016). The threat of entrants in the IVD medical industry is high because of significant opportunities and the potential for great profits (Boyer et al., 2015).

Porter (2008) indicated that barriers to new entries include factors such as customers' high switching costs, high costs of market entry, business technology, business knowledge, and governmental rules and regulations. These are the same barriers for new IVD entrants (Foe Owono, 2015). Entrants from developing countries must manage risk and seek standard regulatory approval for the quality of the devices (Foe Owono, 2015). The European Union and U.S. FDA have created strict regulations to protect consumers and prevent medical defect products from being manufactured (Sorenson & Drummond, 2014).

Power of Suppliers

Porter (2012) indicated that lack of substitutes and high product differentiations affect the power of suppliers. Dobbs (2014) added that powerful suppliers lead the industry to higher prices and limit products. In addition, information technology has changed the balance of power in relationships between buyers and suppliers (Aghamirian et al., 2015). Suppliers with brand loyalty and innovated products have strong marketing power compare to other companies with less brand loyalty (Kim, Wong, Chang, & Park, 2016). The IVD market has the moderate bargaining power of suppliers because of brand loyalty (Allied Market Research, 2014; IVD Australia, 2016).

Power of Buyers

Consumers demand more value in the products and service in a buyers' market. Dobbs (2014) indicated that power of buyers leads the market for demanding low price, and better quality and service. In vitro diagnostics businesses, consumers, and distributors use information systems in a competitive market. Information technology affects the buyers' power of purchasing (Viio & Grönroos, 2016). Customers have a stronger chance of bargaining the bottom rates in the buyers' market. A variation of the product differentiation would lead the market to moderate buyer's bargaining (Allied Market Research, 2014; IVD Australia, 2016). Customers who judge new product prices rely on existing products in the market; customers use fairness judgment to establish a price with suppliers (Kuester, Feurer, Schuhmacher, & Reinartz, 2015). In addition, the Internet shifts from the bargaining power to customers' power by providing lower costs and search costs (Aghamirian et al., 2015). Information systems enhance a buyer `s power by decreasing the total response time and eliminating the waste cost by minimizing the lead-times that enhance accessing of the vast information in a short period and at minimum cost (Hajli & Sims, 2015). Consumers can leverage the Internet to find suitable manufactured with low prices, high quality, and fast shipment (Setia, Richardson, & Smith, 2015). The Internet also increases competition by expanding geographic markets (Porter, 2001).

Threat of Substitute Products

Substitute suppliers with high-performance and low prices influence company profitability (Porter, 2012). The low-cost manufacturers may target influential buyer

segments to avoid vulnerability from substitutes (Schwenger, Straub, & Borzillo, 2014). It is not easy for IVD consumers to change tools rapidly in the face of high prices, trading cost, registration, and FDA regulation. Manufacturers can introduce innovated and niche products to counteract the threat of product substitutes, new entrants, and competition among existing firms (Yan & Dooley, 2014).

Competitive Rivalry

Firms that have dropped off from the top three ranking positions in their industry increased from 2% in 1960 to 14% in 2008; meanwhile, the probability of being a market share leader has declined from 34% in 1950 to just 7% in 2007 (Reeves & Deimler, 2011). Companies are less profitable in a highly competitive market (Porter, 2012). Dobbs (2014) noted that threat of competitive rivalry drive market to cutting prices, new product development, and service improvements. Overall, company profits decline if their prices are similar to their rivals' prices and if there are market barriers and lagging growth (Porter, 2008). The U.S. IVD market continues to face new competition from Europe, Brazil, Korea, China, and India (IVD Australia, 2016). Indeed, the U.S. ITA (2012) stated that growing global trade in counterfeit medical diagnostics products threat U.S. innovation and the overall economy.

Firms can use the five competitive forces to determine profitability even if suppliers, channels, substitutes, or competitors change (Porter, 2001). Dobbs (2014) added that Porter's five forces have a lack of instruction that it is difficult to connect the five-force analysis to any strategy in action. Allio and Fahey (2012), Dobbs (2014), and Magretta (2012) indicated that there is a challenge in applying five Porter forces due to

the lack of quantitative measures. Egbetunde and Akinlo (2015) argued that digitalization, globalization, and deregulation have changed the industry structure, but they do not affect the structure of Porter's five forces model.

Prasad and Warrier (2016) conducted a study to explore how technology affects Porter five competitive forces and increasing returns to scale. Prasad and Warrier asserted that business develops its competitive positioning, market stance and company's value by adopting the technology. Prasad and Warrier (2016) added that technology influences Porter competitive forces and increase returns to scale. Prasad and Warrier believed that the Porter five competitive forces model is still valid in global technological evolution and the Internet age.

Competitive Advantage

Competitive advantage refers to the organization's ability to implement activities to challenge rivals in the market (Chahal & Bakshi, 2015; McGrattan & Prescott, 2014). The definition of competitors is two or more firms seeking the same goal and undertaking activities to achieve the same purpose and market target (Medlin & Ellegaard, 2015). Rivalry occurs because one or more competitor either experiences the pressure or sees an opportunity to enter or improve its place in an industry (Martín-Herrán, McQuitty, & Sigue, 2012). Competitive advantage identifies the position of the business within the market compared to rival firms (Porter, 1991). Competitive advantage means surpassing the competitors, satisfy customer inquiry and expectations, and provides a superior value proposition to satisfy the company's stakeholders (Alteren & Tudoran, 2016). Porter (1991) added that competitive advantage refers to implementing and sustaining a superior

performance.

Organizations utilize a competitive edge to outperform their competitors' gain a maximum market share (Kapoor & Adner, 2012). Similarly, Roy and Singh (2015) indicated that the company possesses a competitive advantage if it holds a distinct market position with the superior value proposition based on its ability to generate optimal value propositions efficiently for a market segment through lower cost leadership, differentiation, customer satisfaction, and market creation.

Companies can obtain a competitive edge by implementing different strategies. Sölvell (2015) has examined 40 years of researchers who have studied Porter's competitive advantage researchers. Sölvell stated that competitive edge had been divided into static (short-term) and dynamic (long-term) firm competitiveness. Sölvell added that innovation, productivity, microeconomics firm's environment, nation and region, and cluster affect company`s competitiveness.

Globalization and Competitive Advantage

Globalization, rapid technology, and competitive pressures lead organization leaders to adopt effective competitive strategies to attain maximum market share (Bereznoy, 2015). Globalization and new technologies upend the organizational environment in an era of risk and uncertainty. All this uncertainty poses a tremendous challenge for leaders to determine their position in the dynamic environment and adopt effective strategies to the changing environment to survive (Mutlu, Zhan, Peng, & Lin, 2015). In Porter's view, the standard of living depends on nation's business productivity and success in the global market (Lindner & Senn, 2015).

The global competitive environment has changed over the past 2 decades (Beh, Ghobadian, Gallear, & O'Regan, 2016), with a direct effect on international trade and business investments (Petrakis, Kostis, & Valsamis, 2015). Global competitiveness refers to companies competing internationally and businesses cultivating their survival by offering the best service and products (Dereli, 2015). Lindner and Senn (2015), who reviewed Porter`s work, stated that traded clusters are the industries that focus on the markets beyond their local region while boosting their local economy by implementing innovation and high performance. Lindner and Senn (2015) believed that companies might achieve a position in this premier league if they adjust to the new global market instruction to secure their market position or risk losing their ranking position to other global competitors.

Companies must have three capabilities to develop a globally competitive advantage: (a) building global scale efficiency into their existing activities, (b) adapting to international exposure, and (c) implementing their objectives (Bartlett & Beamish, 2014). Business leaders need to design the strategy based on global infrastructure to exploit their scale economies and comparative advantages (Huggins & Izushi, 2015). The multinational corporate strategy leaders must have clear paths to gain strong positions in emerging markets to utilize the richest potential in future development (Chittoor & Aulakh, 2015; Zedtwitz, Corsi, Søberg, & Frega, 2015). International competitive businesses implement high productivity by adopting rapid services, cost leadership, and innovated technology through coordination as a source of competitive advantage (Huggins & Izushi, 2015; Porter 1990).

Emerging Markets

In the 1970s and 1980s, global companies were the simple models of innovation, and global companies separated the world into three major sectors, the United States and Canada, Japan, and Western Europe (Hill & Mudambi, 2010). Such companies considered the rest of the world as unimportant (Salvatore, 2016). Successful global companies have developed excellent products in the home country and have distributed them around the world with some modifications in the local market (Schiavone, 2014; Syed, Dadwal, & Martin, 2013). Singh and Chokshi (2013) stated that the rest of the world has become essential to the new global market. The developed world has struggled to join the emerging markets as they have trapped in the past (Li & Oh, 2016; Singh & Chokshi, 2013). South Asia, Eastern Europe, Africa, and Latin America have most of the world's available purchasing power in emerging markets (Chen, Li, & Shapiro, 2012). The low end of the market is full of potential for making the most of the emerging market opportunities (Brem & Ivens, 2013). The needs between the rich and emerging markets differ (Srivardhini, Rishikesha, & Krishnan, 2013). Leaders in global corporations need to have effective strategies to gain the competitive advantage in emerging markets (Borini, Oliveira, Silveira, & Concer, 2012; Corsi & Di Minin, 2014; Srivardhini et al., 2013).

The wealthiest customers in the most prosperous countries demand the newest technologies. Eventually, new technology costs decrease, and incomes in the developing world increase. Corporations can settle into emerging markets by exporting modified versions of products created for rich-world customers with the use of low-end models

with fewer features (Liao & Yu, 2013; Srivardhini et al., 2013). If wealthy countries and established multinationals stay prosperous, the next generation of managers and innovators must support the needs and opportunities in the emerging markets as their market (Gammeltoft, Filatotchev, & Hobdari, 2012). It is impossible to capture the development possibilities in the developing world without creating new solutions from scratch. Managers need to consider the gaps in the emerging markets, and the rich countries of emerging-economy desires can partially address developed economy desires (Govindarajan & Trimble, 2012; Koveos, 2013).

The performance gap is significant for developing countries given their citizens' low incomes (Govindarajan & Trimble, 2012; Koveos, 2013). While developed countries have established economic structures, developing countries have a weaker infrastructure and require innovative solutions (Govindarajan & Trimble, 2012). Environmental solutions differ between poor and rich countries, as emerging economies have less access to resources than rich countries (Koveos, 2013). In countries with developing regulatory systems, new products may pass through regulatory obstacles quicker than developed countries with established regulatory systems (Govindarajan & Trimble, 2012). The products from developed markets and the customer needs of emerging markets differ as well (Srivardhini et al., 2013). Narayanan (2015) added that leaders supposed to collaborate with their consumers to determine what products or service to innovate and design.

Establishing a competitive advantage includes strategic moves and movement as a strategic tool to outdo the competitors (Porter, 1991; Wang, 2014). Leaders develop

competitive strategies to obtain a competitive position and protect firms from environmental forces (Porter, 1985). McGrattan and Prescott (2014) contended that competitive edge occurs when leaders seek to find the effective strategies to maintain the firm position above of their companies' rivals.

Strategies for Competitive Advantage

Competitive advantage occurs when firms perform a value-creating strategy that rivals cannot duplicate (Martín-Herrán et al., 2012). To compete successfully against competitors and new market entrants, business leaders need to have effective strategies (Martin & Javalgi, 2016). Janvier-James (2012) and Porter (1985) contended that leaders might consider performing different strategies to impact competitive advantage. Leaders develop the business strategies to obtain a competitive advantage over their competitors (Porter, 1980; Porter & Millar, 1985). According to Porter (1980, 1985), only pure strategies lead a company to superior performance.

Companies need to develop a strategic competitive advantage to survive in the dynamic market (Alonso-Almeida, Bremser, & Llach, 2015). The firm strategy identifies how leaders structure their operations, management styles, and the set of organizational objective and goals (Porter, 1991). Competitive strategy is the process of designing competitive advantage in the dynamic market to earn maximum returns for stakeholders. Strategic competitive advantage substantial evidence emerged from taking strategic actions to optimize company performance and efficiency that other firms are unable to duplicate (Bartlett & Beamish, 2014). Successful businesses with the leadership position in a global market might implement different strategies, but their underlying mode of

operation is fundamentally the same (Porter, 1990).

Designing a competitive strategy is a challenging endeavor for many company leaders and systems. Managers dominate their competitors in the market with a superior performance targeted to a unique product or service (Hoffman, Corbett, Joglekar, Wells, & 2014). Leaders need to adapt their strategies with changing consumer demand, new technology, innovation, and product life cycles (Trkman, Mertens, Viaene, Mertens, & Gemmel, 2015). Storbacka and Nenonen (2012) contended that a competitive mapping strategy might allow the organization to adopt the best strategy in different frame and configurations by analyzing the market boundaries and learning the process in the business strategy and practice.

Barbos (2015) introduced organizational flexibility as a core factor in competitive strategy that links company goals to dynamic environments. In addition, Choe, Tew, and Tong (2015) contended that leaders leverage manufacturing flexibility as a competitive strategy to deal with market uncertainty. Companies' leaders using the first mover strategy to employ information technology to innovate new products enhance customer service, differentiate their products from the existing market, and increase revenue (Leonardi, 2015). Dobbs (2014) added that cost leadership, innovated products, advertising, and customer service strategies are driving factors in threat of competitive rivalry.

Daniela (2014) conducted a study on Porter competitive advantage. Daniela concluded that focus on market segmentation, outsourcing, sustainability of the competitive advantage, and embracing employees are vital actives in competitive

strategies. In addition, Malakoti-Negad (2016) conducted multiple qualitative case studies to explore the effective strategies in Canadian small and medium-sized enterprise to maintain their competitiveness based on Porter's theory. Malakoti-Negad concluded that business could gain competitive advantage through outsourcing, customer service, technology, innovation, and cost leadership in refining operational performance productivity.

Cost Leadership Strategy

Managers find a low-cost leadership strategy to supply value comparable product or service to customers at a lower price compared to competitors, without any extra amenities (Porter, 1986). Competitors respond to the market with a low-cost leadership strategy rather than quality or high-quality service (Tansey, et al., 2014). Porter (1980) argued that leaders pursue a cost leadership strategy to cut the significant costs and overheads in all aspects. Leaders need to practice low-cost leadership to gain the competitive edge when there is a lack of strategy to differentiate a product or service (Simon, Fischbach, & Schoder, 2013).

Mir and Rehman (2012) indicated that price reductions have a positive impact on sales and investors' revenue. A company positions itself in the competitive market to be less vulnerable to competitive forces while exploiting its unique advantage (Schwenger et al., 2014). China can present products at very low prices in the global market (Xing, 2016), including medical device products that threaten U.S. manufacturers (Owono, 2015). Xing (2016) argued that global value chains (GVCs) have operated based on made in China products to enter into global markets, especially developed countries. China

leverages the developed countries' high service skills, brand, and advanced technologies to sell their products to international consumers.

Differentiation Strategy

Companies implement differentiation strategy by increasing the quality, value, innovative products, product improvement, superior service, or technical support as perceived by customers even with the higher price (Porter, 1991). Business leaders seek to establish a distinction between their organization and their competitors by utilizing an innovative product or service (Agnihotri, 2015; Randall, 2015). Innovation increases productivity by creating and executing new processes, which increase competitive advantage and provide meaningful differentiation (Alguezaui & Filieri, 2014). Daniela (2014) argued that company resources and capabilities are vital factors in formulating a competitive strategy.

Competitive Strategy and Innovation Management

Innovation management is a process of promoting knowledge and ideas of creativity (Ersun & Karabulut, 2013). The definition of innovation management is the mix of innovation and leadership that determines the quality consumer strategy that organizations need to achieve their success by focusing on producing unique products, services, or systems to lead divergent opinion to convergent solutions (Ersun & Karabulut, 2013).

The innovation management concepts include open innovation, effectuation, and design within a project framework and body of research. Innovation management required an investigation of various strategic approaches and meaningful differentiator

that align with their company `s goal (Zang, Zhang, Yang, & Li, 2014). Enterprise leaders need to employ architectural innovation to find new relationships between new and old technologies to revitalize past products (Idi & Khaidzir, 2015; Kodama & Shibata, 2013; Schiavone, 2014).

Managers need to design their culture and organizational practices to make innovation possible (Bogers & West, 2012). An organization-wide innovation strategy leads the local teams to focus on their innovative thinking activities and align their changes with the organization's overall requirements for innovation (Pantano, 2015). The global corporations have learned the importance of considering culture, values, and tastes in the development of products (Koveos, 2013).

The work environment of an innovation-oriented firm must encourage and facilitate continual creativity and change. To prosper in the global market, every industry leaders need to boost, encourage, and support the creative jobs in the organization (Aagaard, 2015; Martin, Florida, Pogue, & Mellander, 2015). Organizations' managers create a climate where their employees can lead their idea to the action and turn their idea into unique goods and services (Schepers, Nijssen, & van der Heijden, 2016). Kalkan, Bozkurt, and Arman (2014) indicated that while many employees find the innovation environment, challenging and rewarding, others are far more comfortable in a structured, stable, and unchanging environment. In the analysis of organizational patterns in detail indicated that knowledge management exerted an essential impact on product innovation persist while work environment has associated with process change persistence (Le Bas, Mothe, & Nguyen, 2015).

A firm that emphasizes continuous innovation might intensify if the markets fail in the absence of appropriate innovative measurement (Chahal & Bakshi, 2015). Kalkan et al. (2014) stated that innovation-oriented firms might become too enamored with the idea of innovations when leader lose the sight of the innovations cost. Sander-Jones and Linderman (2014) argued that company requires efficiency in innovation and adaptability to gain a competitive edge. Lin, Tan, and Geng (2013) stated that innovation and performance significantly influence the competitive advantage of an organization.

Innovation as Differentiation Strategy

Kalkan et al. (2014) defined innovation as implementing new ideas that create value for the company. Innovation is vital for the business to compete in an era of rapid technological and uncertainty to escalate responsive solutions to complex problems. Innovation is a dynamic process includes industrial product innovation and customer product innovation (Ogawa & Pongtanalert, 2013) and a process of creating societal value that reinforces the global economy (Carayannis, Sindakis, & Walter, 2014; Li et al., 2013). Carayannis et al. (2014) emphasized that sustainable innovation needs to focus on economic, social, and environmental dimensions. Salge and Vera (2012) indicated that innovation has a positive effect on quality, competitiveness, market share, and efficiency and productivity. When innovation occurs, the team consistently creates new value to achieve sustained customer value and employee engagement and remain vital in the future (Bogers & West, 2012). Moreover, technology, information system, and marketing strategy could increase innovation performance (Ling, Tee, & Eze, 2014).

A business's innovation success depends on the firm's response to the challenging

and dynamic environment to gain efficiencies in repetitive innovative endeavors (Breznik & Hisrich, 2014; Midler, Killen, & Kock, 2016). The development, adoption, and implementation of innovations involve considerable market risk. Bucherer, Eisert, and Gassmann (2012) highlighted that innovation is not an isolated event; leaders need to align the innovation strategy with the long-term company strategy.

Najmaei (2016) indicated that strategic innovation is a new innovative invention to exploit a new market to target consumers and satisfy the customers' inquiry. Porter (1990) emphasized innovation as a primary factor in obtaining competitive advantage and noted it as a national competitive performance indicator. Porter indicated that firms might perceive new ways to compete in global markets through innovation. According to Breznik and Hisrich (2014), the innovation strategy is the dynamic capability that leads business to gain the competitive edge through enhancing brand trust, customer fulfillment, and increase marketing performance. Strategic innovation can influence the business, build the new marketplace, and develop new competition rules in the market (Jayashree, Marthandan, & Yang, 2012).

Subramanian, Gunasekaran, and Gao (2016) stated that managers used the innovative approach to develop strategies to produce unique operation, services, or products to generate more profit. A company might use innovation strategy when a new surge of growth lay ahead or, to gain or increase their competitive advantage (Davey & Sanders, 2012). The business leaders can mitigate risk by utilizing an innovation strategy to react to change effectively and create the highly coveted competitive advantage (Koch, 2012; Madadipouya, 2015).

Managers use the innovation strategy and marketing strategy to create value with the low-cost efficiency and gain market share (Petrakis et al., 2015; Huang, Kuo, & Chou, 2016). Managers need to be flexible to look outside of traditional to expose to the possibility of an innovative strategy, and creative networks (Reed, Storrud-Barnes, & Jessup, 2012). Managers might use innovation strategy as one of the leading tools to gain the highest level of competitive advantage and performance. Business managers should take a step back and evaluate the existing strategies of competitiveness and innovation (Govindarajan & Trimble, 2012; Koveos, 2013).

Porter (1990) emphasized that innovation is a core factor of the competitive advantage of nations. Porter stated that companies could create a competitive edge by perceiving innovated product, market, operation, or any better ways to win the market. Innovation is an essential component of competitiveness, embedded in the organizational structures, processes, products, and services within a business (Ghosal, 2015; Subrahmanya, 2014). Innovation creates a competitive edge by making new market opportunity and serving a market segment (Porter, 1990). Breznik and Hisrich (2014) argued that innovation is a dynamic capability that effect on firm's competitive advantage and performance

Business managers regularly face the challenge of gaining the competitive edge over competitors. Change is necessary for any organization because, without modification, companies would probably lose their competitive advantage (Oakey, 2013). Fraj, Matute, and Melero (2015) argued that a proactive environmental strategy and innovation strategy lead the organization to competitiveness. Low prices are a short-lived

competitive advantage, as other competitors can easily imitate the price; only producers with significant economies of scale and low labor costs can afford very low sales prices (Huo, Zhao, & Zhou, 2013; Lii & Kuo, 2016). A much better way for creating competitive edge is to innovate the new products or services to satisfy client's primary needs that no other major competitor can obtain (Huo et al., 2013; Lii & Kuo, 2016).

Competition puts pressure on organizations to be more innovative. Hendrik et al. (2015) determined that competitive pressure seemed to result in enhancing innovation, but in the end, companies faced declining the innovation. Managers could deliver successful innovations if firms could provide the strongest impetus for strategic directions and practice competitive actions that lead the companies to high-performing innovations and gained high returns on their investment (Luoma, Ruutu, King, & Tikkanen, 2016). A nation's competitiveness relates to organizational innovation, challenge, and flexibility (Porter, 2012).

Al-Ansari, Pervan, and Xu (2013) conducted a quantitative study to examine innovative characteristics and business performance in the emerging Dubai market in small- and medium-sized enterprises. The results of this study strengthened the positive impact of innovation on business performance. Evanschitzky, Eisend, Calantone, and Jiang (2012) went one step further in their quantitative study of the relationship between innovation capability and firm profitability. Among 2,400 participants, innovation capacity had a minimum impact on profitability measures in small- and medium-sized enterprises. Evanschitzky et al. concluded that managers might need to consider innovation capacity as a company profitability measure.

Corporations' competitive intensity pushes the firms to innovate (Bäck & Kohtamäki, 2016). The impact of foreign competition on innovation has been a main core in the U.S. economy (Autor, Dorn, & Hanson, 2013; Bayraktar, Hancerliogullari, Cetinguc, & Calisir, 2016). The U.S. medical device manufacturers use innovation to maintain their leadership position in the marketplace. The United States has used an innovative differentiation strategy to become the leader in the medical diagnostic products as its long-term competitive advantage. According to U.S. Census Bureau and National Science Foundation (2011), high rates of U.S. business innovation stem from manufacturing, and low rates from nonmanufacturing industries (Boroush & Jankowski, 2016).

Disruptive Innovation and Reverse Innovation

The current literature suggests that disruptive and reverse innovation depends on how organizations respond to innovation. Organizations must consider many factors, including consumer expectations, including cost, quality, and service in designing an innovation strategy. Govindarajan and Trimble (2012) asserted that the old ways of globalization are no longer adequate and reverse innovation is the way of reducing production costs and generating new market demand in the richer economies.

Reverse innovation. Reverse innovation is a strategy of innovating new products that implemented first in the developing countries before conveying over to a developer market (Borini et al., 2012; Zeschky, Winterhalter, & Gassmann, 2014). Govindarajan and Trimble (2012) and Koveos (2013) stated that reverse innovation is a competitive threat as it opens opportunities in developing economies. The focus of reverse innovation

is the combination of global vision and mission with a focus on local needs and choices (Yelkikalan & Aydin, 2015). Reverse innovation involves understanding the changing underlying forces of global innovation (DePasse & Lee, 2013). Reverse innovation is a strategy of innovating new products implemented in the developing countries (Zeschky et al., 2014), which, according to Singh (2013), "generate half of global GDP and over 40% of world exports" (p. 71). The customers in these markets are fundamentally different from those in developed markets. Reverse innovation entails understanding the differences between rich-country and poor-country desires (Binagwaho et al., 2013). Reverse innovation is a powerful force for the competitive markets to manage (Koveos, 2013). Reverse innovation is restructuring both the offering and its cost structure (Brem & Ivens, 2013). Operating margins and return on investment may be similar or improved (Brem & Ivens, 2013).

Govindarajan and Trimble (2012) stated the reverse innovation is a powerful force for the competitive markets to manage. Leavy (2014) indicated that reverse innovation provides the alternative strategy to globalization as a promising method to propel global growth and innovation platform. For multinationals corporations' innovation in emerging markets, the corporations can solve problems by using reverse innovation instead of using exports (Gammeltoft et al., 2012). Chittoor and Aulakh (2015) stated that India had offered opportunities for business groups, emerging market multinationals and reverse innovations that led Indian companies to join in global markets. Chittoor and Aulakh suggested that the organizational landscape in India offers

opportunities for business groups, emerging market multinationals, and reverse innovation.

Reverse innovation is always built on cost or frugal innovations (Zeschky et al., 2014). Singh (2013) explored the potential of reverse innovations in emerging markets and their effect on commercial prospects in global markets. Sinha concluded that frugal innovated products enable developed countries to adopt themselves to the global marketplace. In addition, Liu, Lu, and Choi (2014) conducted a quantitative study base on knowledge-based perspective and embeddedness theory. Liu et al. examined the effect of reverse knowledge spillovers from domestic Chinese organizations to foreign companies at the high-technology corporations in China. Liu et al. found that the presence of retained employees improved the impact of reverse technological on the innovation and company financial performance.

Salvatore (2016) found that enterprises needed to bring their local market value closer to emerging global standards to be successful at reverse innovation. Corsi, Di Minin, and Piccaluga (2014), who studied China's reverse innovation practices, concluded that the improvement of the product opens challenges and complications were from both the subsidiary and corporate levels. Borini et al. (2012) indicated that the reverse transfer of the innovation relied on the strategic alignment of the foreign subsidiary's research and development function communication between the parent companies.

Disruptive innovation. Disruptive innovation is a strategy that leads an organization to improve the performance of their products and disrupts the old market

(Corsi & Di Minin, 2014). The disruptive innovation theory suggests that innovation is the key to developing new products, seeking new consumer markets and earning unmatched profits (Govindarajan & Trimble, 2012; Koveos, 2013). In contrast, disruptive innovations work differently, and organizations need to dedicate time and resources to come up with a disruptive innovation (Corsi & Di Minin, 2014). In each case, newer companies tend to prosper with the introduction of disruptive innovations (Gobble, 2015).

Disruptive innovations occur when the existing products, target only a select population of consumers (Ruan, Hang, & Wang, 2014). They gained a competitive advantage by providing cheaper and more accessible products to a larger community (Min & Min, 2013). Alexy, George, and Salter (2013) explored how the selective revealing of strategic knowledge could be a coordination mechanism for a disruptive innovation strategy and competitive rivalry.

The disruptive innovation theory suggests that innovation is the key to developing new products, seeking new consumer markets, and earning unmatched profits (Koveos, 2013). Disruptive innovations help businesses gain a position in new or lower-end markets that competitors had overlooked (Reinhardt & Gurtner, 2015). Organizations need to dedicate time and resources to come up with a disruptive innovation (Corsi & Di Minin, 2014). In each case, newer companies tend to prosper with the introduction of disruptive innovation (Gobble, 2015). Corporate leaders need to align their innovation strategy with customers' needs, as each country and its culture have individual tastes and preferences (Govindarajan & Trimble, 2012).

Competitive Strategy and Information Technology

Effective use of information technology (IT) has become imperative for an organization to gain a competitive advantage over its contenders (Wu & Raghupathi, 2015). Managers may leverage IT as a company's competitive advantage, particularly through innovation process and rapid scaling (Evans, 2016). Information technology is fundamentally changing the structure of the business operation and the economy (Luo & Bu, 2016)**.** Ameer, Othman, and Mahzan (2012) indicated that organizations use information technology to store, process, and disseminate information. Salleh, Akma, Rohde, and Green (2016) added that IT benefits a business by allowing systems to operate more efficiently and productively. Leaders need to create collaborations between the environment, business operation, and technology to achieve competitiveness (An, Deng, Chao, & Bai, 2014).

Information Technology as Cost Advantage and Differentiation Strategy

Information technology can enhance efficiencies within the organization through cost leadership and differentiation (Arora, Arora, & Sivakumar, 2016; Nguyen, Newby, & Macaulay, 2013). Mansell (2016) noted that leaders could use the information system to solve global competition barriers. The most significant advantages of efficient information technology for the organization is reducing costs; improving profitability, agility, innovation, sales, and perceived value for the customer; and enhancing customer satisfaction (Nechkoska, Poels, & Manceski, 2015; Rahimi & Gunlu, 2016).

Strategic agility and information systems have had a core role in promoting competitive advantage (Mavengere, 2013). With increasing competition in the global

market, manufacturers can use technology to enhance their company performance and productivity (Gupta & Polonsky, 2014; Zhang, Xu, Sun, & Yang, 2015). Drnevich and Croson (2013) recommended that leaders need to conduct additional investigative on an organization leveraging IT tools along with various organizational strategies to monitor and measure the efficiency of performance to determine the competitive advantage.

In addition, one of the overlooked elements of using information technology (IT) is to differentiate and gain a competitive advantage (Mavengere, 2013; Santos-Vijande, López-Sánchez & Trespalacios, 2012; Wang et al., 2012). Managers can deliver the differentiation through the enactment of an appropriate interrelated technological strategy (Aagaard & Lindgren, 2015). Business leaders can obtain IT as a competitive advantage within an organization by updates the packaging, innovative marketing campaigns, and aftermarket product support that allows for the highest level of IT support (Vieira et al., 2016).

Enterprises that adopt a low-cost product strategy can operate the information technology solutions to increase productivity and agility to decrease cost (Perez & Alegre, 2015). Managers have improved the real-time information by adopting technology as dynamical navigation of company activities (Zhang et al., 2015). In addition, real- time information could enhance collaboration among organization and gain the competitive advantage in the global marketplace. Technology can improve organizational responsiveness, flexibility, cost efficiencies, collaboration, and revenue growth, increase the return on a company's investment in knowledge and expertise, and

maintain a competitive advantage in the marketplace (Lun, Shang & Cheng, 2016; Perez & Alegre, 2015).

Rai, Arikan, Pye, and Tiwana (2015) found that IT had improved inter-firm process capabilities, market valuation, and asset turnover. No matter the size of business, technology has had both tangible and intangible benefits that would contribute to making money and produce results (Peltier, Zhao, & Schibrowsky, 2012). Haarbrandt and Marschollek (2016) noted that small businesses' warehouses use business intelligence technologies to make their decision-making process and convert data information to achieve a competitive edge. A change that results from the adoption of new technology is prevalent in most organizations, and while it can be disruptive at first, in the end, the change tends to increase productivity and service (Oakey, 2013).

Gupta and Polonsky (2014) stated that managers should use technology to adapt to habits, abilities, and preferences for the user. As available data increase, managers and business owners need to emphasize collaborative and innovative approaches to the data process, which enables companies to maximize the value of information held toward the enterprise of competitive business advantage (Perko, & Mlinarič, 2016). Arikan et al. (2015) suggested that IT executives and leaders should collaborate and use the synergies created to provide innovative products and services.

The right information technology must align with the company`s strategies to maintain a competitive advantage (Hazen, & Byrd, 2012). The firm's competitive advantage may not directly link to the implementation of information technology and infrastructure, but instead, result from the alignment of IT with the company's business

strategy (Luo & Bu, 2016). Technology seems necessary for an organization to earn a competitive advantage in today's market, but is not the only element needed for success (McGrattan & Prescott, 2014).

IT Outsourcing and Technology Infrastructure

For more than 30 years, U.S. manufacturers have utilized outsourcing as a corporate strategy to reduce costs and achieve sustained competitive advantages in the global market. Business managers could enhance efficiency and productivity among organization from the smarter use of its IT resources (Yeow & Huat Goh, 2015). Manufacturers utilize outsourcing to eliminate those manufacturing functions that the domestic firms did not consider a core competency and competitive advantage in the market (Yang, Zhao, Yeung, & Liu, 2016).

Javalgi, Benoy Joseph, Granot, and Gross (2013) conducted a study to develop an outsourcing model for India as a source of knowledge and skills for other manufacturers. Javalgi et al. stated that leaders use outsourcing strategy to reduce the cost of operation. In a global economy, manufacturers such as Microsoft, United Airlines, Boeing, and Pepsi have realized that survival in a competitive market requires performing company operations overseas (Javalgi et al., 2013). U.S manufacturers enhance their outsourcing from 6% in 2001 to 45% in 2009 to achieve cost saving or technical expertise (Javalgi et al., 2013).

Outsourcing may influence negatively on competitive advantage due to knowledge leak and lack of protection of proprietary knowledge. Outsourcing may lead the company to skill erosion, declining innovation ability, or delay company agility to

respond to changing customer dynamic demand (Von Faber, 2016). Additionally, investments in IT could produce mixed results, and prior research indicated that this is a stark possibility (Rai et al., 2015; Sabherwal & Jeyaraj, 2015). Kenyon, Meixell, and Westfall (2016) found that production outsourcing has significant adverse effects on operational performance, on-time delivery, and customer loyalty when mediated through operational performance.

Chao and Chandra (2012) determined that owners' IT knowledge was a significant predictor of IT strategy, adoption of traditional IT, and Internet technologies. The IT industry is complex with short product life cycles and a high rate of technological obsolescence; hence, firms need to analyze IT investment decisions accurately (Rai et al., 2015). A manager's IT knowledge is an essential resource of proprietor's tacit knowledge and firm's strategic goals (Chao & Chandra, 2012). Riemenschneider and Weigert (2013) added that leadership is a vital key to driving current technologies, market insights, and establishing competitive position.

Sustainability. Leaders need to address sustainability with technology in business management (Aagaard & Lindgren, 2015; Wu & Raghupathi, 2015). In their research, Sakas, Vlachos, and Nasiopoulos (2014) found that business managers need to avoid unnecessary changes in technology infrastructure, and companies should concentrate on strengthening their current infrastructure. Gottschalk (2016) added that must use technology infrastructure efficiently to optimize knowledge sharing.

Lew, Maizatul, and Yuen (2015) conducted face-to-face interviews with eight organizations to explore how organizations perform competitive advantage with an

emphasis on information technology and product management in Malaysia. The authors found that managers needed to ensure that all IT users understand the benefit of utilizing IT, maximization the operation of information, and accelerating effectiveness by obtaining utility capability.

Technology and customer satisfaction. Sophisticated customers demand, growing inquiry for enhancing efficiency, and improving customer satisfaction have led managers to leverage information technology to develop revolutionary operational and strategic management to gain the competitive advantage (Law, Buhalis, & Cobanoglu, 2014). Wu and Raghupathi (2015) found that the organizations they studied had implemented IT to connect with their clients, recognize the preferences of individuals, and tailor products with reasonable cost to gain a competitive edge. Further improvement in technology would lead to the new products that customers can afford (Di & Tomarchio, 2015; Sinha, 2013). Leaders gain profitable customers through collected consumer data by utilizing information technology to maximize efficiency and profitability (Mithas, Krishnan, & Fornell, 2016). Advanced organizations optimize IT efficiency through consumers and vendor collaboration (Lesser & Ban, 2016).

Competitive Strategy and Consumers

Understanding and maintaining the relationships between the key competitive strategy initiators and customer satisfaction can assist an organization's sustainability and success in the global market (Rahimi & Gunlu, 2016). Firms need to understand their customers' inquiries to design their competitive strategy (Robert & Grover, 2012). The organization has gained the most sustainable, defensible competitive advantage by

creating value for their consumers (Lloyd et al., 2014). The competitive strategies start and end with customer inquiries (Pizam, Shapoval, & Ellis, 2016).

Hana (2013) argued that the goal of each organization is to defeat the competition and win customers. Organization leaders can achieve a competitive edge by either implementing the differentiation strategy to provide greater value for customers; through lower prices or offering more value, which justifies higher prices (Kokkoris & Kühnen, 2015). In addition, customers` perspectives affect the quality of service in the competitive market (Wu & Liao, 2016). The benefits, as perceived by consumers, include price, innovative products, product improvement, or superior service, and technical support (Porter, 1991). Serving consumers better than the competitors is the most efficient route to achieving an organization's success and sustainable competitive advantage (Reider, 2012; Weerakkody, Irani, Lee, Hindi, & Osman, 2014; Xu, Zhang, & Ma, 2013). Roberts and Grover (2012) added that the response time to the consumer is critical in the competitive environment. Drnevich and Croson (2013) indicated that leaders initiate continuous change to remain relevant in the marketplace. Customers companies that understand their requirements and respond to their requests promptly; thus, entrepreneurs need to emphases in implementing customer value strategy instead of responding to rivals' strategic moves (Randall, 2015). Baumann, Elliott, and Burton (2012) argued satisfied consumers are willing to pay a premium for a product or service. Some organizations achieve a competitive advantage by product-orientation and others with service-orientation. In the airline industry, for example, service-oriented corporations require more creativity and capable delivery of service to consumers compared to

product-oriented airlines (Nair, Paulose, Palacios, & Tafur, 2013). Managers can implement the efficient differentiation strategy when the firms provide superior value to the customer through product quality or service (Akan, Allen, Helms, & Spralls, 2006).

Customer Satisfaction

Leaders attain a competitive edge when they align their business performance with their client's needs. Managing customer satisfaction is a potential tool to increase revenues and enhance competitive advantage (Ogawa & Pongtanalert, 2013; Terpstra, Kuijlen, & Sijtsma, 2012). Managers need to obtain three levels of trusts, including share new ideas with customers, understand the customer businesses, and satisfy customers' needs in the marketplace (Lee, 2013). Customer satisfaction is a consumer's sense of contentment derived from their experience and expectation prior to their interacting with the business (Chougule, Khare, & Pattada, 2013). According to Murray and Evans (2013), an entrepreneur's profitability mediates the relationship between firms' capability and customer satisfaction.

Transaction-specific and cumulative are two ways to conceptualize client interactions about customer satisfaction. Transaction-specific customer satisfaction refers to the effect of a single consumer interaction on comfort perception (Chougule et al., 2013). Cumulative satisfaction is the consumers' perception of a company over time in terms of service quality (Chougule et al., 2013; Pantouvakis & Bouranta, 2013). An organization with high performance and efficiency can lead transaction-specific customer satisfaction to cumulative customer satisfaction.

Organizations can measure customers' satisfaction with performance and profitability indicators (Bhatt, 2015). The service-profit chain model establishes relationships between customer satisfaction, customer commitment, employee satisfaction, and firm profitability (Pantouvakis & Bouranta, 2013). Other scholars have argued that performance outcomes link to customer satisfaction, customer loyalty, and employee satisfaction (Evanschitzky et al., 2012). Competitive advantage in all contexts means generating a superior value proposition that best satisfies customers' value perception and the organization's stakeholders (Hoffman, Corbett, Joglekar, Wells, & 2014). The outcome of creating competitive advantage with superior performance includes enhancing customer satisfaction, strong customer relationships, and market leadership (Hoffman, Corbett, Joglekar, Wells, & 2014). The more substantial customer satisfaction leads to loyalty, customer preservation, customer trust, customer referrals, and customer retention and improved financial performance (Rust & Huang, 2012; Terpstra et al., 2012).

Customer Retention

Hsu, Lin, and Tu (2013) stated that clients' steadfast loyalty, commitment, and long-term relationships could lead the organization to gain competitive advantages for their businesses in the global markets. Leaders can generate growth from loyal customers by increasing product purchasing through excellent service (Brahmbhatt, 2015; Lee, 2013). Higher levels of customer satisfaction lead to customer retention, repeating business, improved cash flows, reduced acquisition costs, increased gross margins, and improved long-term revenues (Oakley, 2013). Reider (2012) stated that business

prosperity relies on repetitive sales from existing consumers and through referrals. Evaluating current customer conditions and customer retention is much profitable than attracting new customers (Berman, 2016). Business leaders have realized that retaining valuable consumers is essential for companies' success (Person, Snelders, & Schoormans, 2016).

The customer relationship process can help to gain prospective customers, maintain current clients, and increase customer loyalty (Ogbadu & Usman, 2012). Lahdesmaki and Viitaharju (2012) noted that customer relationship management focuses on exploring the perspectives of buyers. Corporations with strong relationships with their clients have better performance than another group (Josiassen, Assaf, & Cvelbar, 2014). The outcomes of efficient customer relationship management are the development of a value proposition, bonding relationship, negotiation, and decision-making processes (Stein, Smith, & Lancioni, 2013). Leaders need to enhance the organization's market share, revenue, and profitability by identifying the consumer's inquiry to meet customer demands and satisfactions (Lun et al., 2016; Narayanan, 2015; Oakley, 2013; Robert & Grover, 2012; Terpstra et al., 2012). Huggins and Izushi (2015) indicated that firms achieve competitive advantage in global markets if their domestic buyers are demanding with sophisticated needs. To satisfy their clients' needs, entrepreneurs should continuously improve the quality and price of their products and services by catching up with technological advancements and adopting the strategy to achieve these goals (Sharma & Jha, 2016).

Customer Relationship Management (CRM) and Electronic Customer Relationship Management (ECRM)

Managers use the customer relationship management (CRM) and electronic customer relationship management (ECRM) practices to provide valuable and long-term competitive advantage and enable improved financial for an organization (Aghamirian et al., 2015; Hadi, 2015; Mohammed, Rashid, & Tahir, 2014; Saxman, 2015). Rahimi and Gunlu (2016) indicated that efficient transferring of customer relationship management requires skilled and qualified labors executives' commitments, initializing cost, proper organizational structure, and hierarchy, integrated, user-friendly applications, ease of use, safety and security, collaboration among businesses, and customer feedback.

Customer relationship management. Customer relationship management is the process of developing and maintaining customer relationships to honor the superior customer value and satisfaction (Soltani & Navimipour, 2016). Awasthi and Sangle (2013) suggested CRM includes the people and integration of people, processes, and the system to gain customer satisfaction during the product life cycle. A CRM system provides a basis understanding the relationship between the firm and its consumers (Leligdon et al., 2015; Stein et al., 2013).

Managers leverage CRM to create consumer attraction, customer retaining, and customer satisfaction to obtain customer loyalty. According to Riemenschneider and Weigert (2013), leaders should avoid taking unnecessary risk in acquiring high-cost products that may fail to fulfill a consumer's request. Suppliers need to study customer

attitude considers the product, price, place (location), promotion, and consumers to develop and maintain the relationship (Soltani & Navimipour, 2016).

Electronic customer relationship management. Electronic customer relationship management refers to using Internet technology, online analytical processing (OLAP), data storage, data mining, customer-oriented strategies-based business processes, knowledge management, data quality, and social CRM (Soltani & Navimipour, 2016). Soltani and Navimipour (2016) added that the profit of eCRM includes increasing customer loyalty by improving efficiency, lower cost, personification, effective marketing, improve service, and facilitates purchasing. Organizations` managers can leverage the eCRM to reduce information-processing costs and enhance consumer interaction to achieve an organization's competitive power in the dynamic market (Salojärvi & Saarenketo, 2013). All business that practice business-to-business (B2B) and business-to-customer (b2c) activities need to implement eCRM efficiently. Chuang and Lin (2015) argued that the impact of e-service innovation and new information technology (NIT) create value for the organization, provide a customer service experience, enhances operational efficiencies, reduces cost, and the creation of a competitive service. Soltani and Navimipour found a relationship between the role of information technology in CRM structures and competitive advantage.

Competitive Tactics

Competitive tactics are critical to company performance as they link strategy formulation to implementation (Castillo-Apraiz & Matey, 2015). Bourgeois (1980) identified the competitive tactic as competitive weapons. Akan et al. (2006) conducted a

survey to elaborate on the Porter generic strategy implementation in over 200 companies. Akan et al. identified the 10 critical tactics that managers attempt to use to enhance organizational performance (see Figure 1). Akan et al. stated that creativity, innovation, technology, e-marketing, promotion, reducing costs, high skill employees, outstanding customer service, superior products and services, and operation efficiency (p. 45) are the primary keys to Porter competitive strategy implementation and efficient organizational performance.

Differentiation strategy	Cost leadership strategy	Focus strategy with low cost	Focus strategy with Differentiation
* Creativity in technology and marketing techniques. * Promoting creative abilities and innovation. * Building a large market portion	* Reduce distribution costs	* Render a distinctive service to the customer. * Improving operational efficiency. * Control product quality. * Intensive training for individuals who work in the front row in the institution	* Introducing special products. * goods or service production for market share with high price

Figure 1. Generic strategies and their associated tactics. From "Critical tactics for implementing Porter's generic strategies," by Akan, Allen, Helms, & Spralls, 2006, *Journal of Business Strategy*, *27*(1), p. 45. Reprinted with permission.

Su, Linderman, Schroeder, and Van de Ven (2014) added that competitive tactics help firms to implement the competitive strategy. According to Akan et al., 2006 competitive tactics reflect the strategic orientation of the organization. In the pharmaceutical industry, Castillo-Apraiz and Matey (2015) named four main competitive tactics as (a) quality-oriented, competitive tactic (quality), (b) cost-oriented competitive tactic (cost), (c) innovation-oriented competitive tactic (innovation), and (d) marketing-oriented competitive tactic (marketing).

Quality-oriented competitive tactics. This core tactic involves acquiring a high level of investing in research, innovation, controlling the quality of procedures, and extensive customer service. Hoffman, Corbett, Joglekar, and Wells (2014) posited that managers could use the quality-oriented strategy to create unique products and processes to achieve the superior performance to gain customer satisfaction. Chougule et al. (2013) stated that product quality affects customer satisfaction by 40%.

Cost-oriented competitive tactics. Cost innovation involves in reducing costs lower than other competitors and focusing on low-price market segments. Leaders need to understand global infrastructure, lower-cost localities worldwide, diversity, and world trade barriers motivate the movement for national project management (Hall, Matos, & Martin, 2014; Li, Zhang, & Lyles, 2013; Reiner, Gold, & Hahn, 2015). The cost leadership strategy targets a broad market that required the aggressive construction of efficient-scale facilities, vigorous pursuit of cost reductions, overhead control, and R&D and marketing cost control (Porter, 1980).

Innovation and marketing-oriented competitive tactics. The marketing and innovation tactics are mediators between the main tactics and performance (Castillo-Apraiz & Matey, 2015). Innovation consists of developing new products and refining the existing ones; marketing consists of activities to gain strong brand identity, promoting, and advertising (Castillo-Apraiz & Matey, 2015). Kaliappen and Hilman (2014) contended that innovation mediates between cost and performance; marketing mediates the relationship between quality and performance. Lai, Yeung, and Cheng (2012) indicated that marketing affects performance and are interrelated.

Transition

Since 2010, the IVD medical device industry has witnessed a growing number of competitors in global market segments (Hendrik et al., 2015). The global medical devices market is worth approximately $350 billion (Public Citizen, 2012). The United States is the leading supplier of medical devices in the global market (Porter, 2012). In summary, U.S. manufacturers must vie with global competitors, including Brazil, Russia, India, China, and South Korea, to maintain its position in the global market (McNabb, 2016). Therefore, U.S IVD manufacturers require effective strategies to retain their leadership position in the industry. Santarelli and Tran (2015) indicated that business strategies have a major influence on the company efficiency and profitability.

This study addresses how U.S. IVD business owners succeed by utilizing effective strategies that could potentially lead to gains in competitive advantage. Porter (1980) stated that competitive advantage strategies had been divided into three generic types: cost leadership, differentiation, and focus. With cost strategy, companies focus on discounting their product to maximize sales and have a significant cost advantage over the competition to increase their market share (Agyapong et al., 2016; Wang et al., 2012). Companies implement differentiation strategies by introducing (a) a product of superior quality, value, or innovation; (b) product improvements; (c) superior service; or (d) technical support. If perceived by customers as preferable to the competition, the product may be successful even at a higher price (Porter, 1991). Managers may find an advantage in superior products that consumers value, by effective cost or differentiation approach or in superior management skills, or accounting and financial acumen (Cui & Wu, 2015;

Tanima & Bates, 2015).

The medical device market competitors have led the market–to-product substitutability and price erosion over the past decade (Hendrik et al., 2015); therefore, to compete successfully against competitors and new market entrants, business leaders need to have an effective new strategy. Companies must develop an effective strategy to improve responsiveness to a dynamic market (Li & Jia, 2016). Govindarajan and Trimble (2012) argued the old ways of globalization are no longer adequate, and reverse innovation is the way to reduce production costs and generate new market demand in the richer economies.

Industrial managers can use the competitive advantage to define their company's market position, differentiate themselves from their competitors, and strengthen their leadership (Hsu et al., 2016) to obtain a favorable market position to gain desired profit (Porter, 1985). Managers can deliver the differentiation through the enactment of an appropriate interrelated technological strategy (Aagaard & Lindgren, 2015). Companies can employ IT to gain a significant competitive advantage through innovation and the scaling of that innovation for a cost advantage and differentiation to achieve a leadership position in the global market. Petrevska et al. (2015) stated that using IT capabilities efficiently and sustainability might result in cost leadership, innovation, agility, and increased value for consumers. Competitive advantage in all contexts generates a superior value proposition that best satisfies customers' value perception and the organization's stakeholders (Alteren & Tudoran, 2016). Weerakkody et al. (2014)

emphasized that customer satisfaction is as an organization's fundamental measurement for creating and assuring competitive advantages.

Section 2: The Project

The central research question addressed the strategies IVD medical manufacturing leaders use to achieve competitive advantage. Section 2 includes the purpose statement, my role as the researcher, and how I selected participants. Section 2 also contains a description of the research method and design, population and sampling, research instrument, ethical concerns, data collection, data analysis technique, and reliability and validity. Finally, I present a summary of core concepts in the study and provide an overview of the components of Section 3.

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies IVD medical manufacturing leaders use to gain and maintain a competitive advantage. The population consisted of the leaders of three IVD medical businesses in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more. The implication for positive social change is that assisting U.S. IVD organizational leaders to develop strategies to thrive and secure advantages could provide the resources for creating new products and boosting employment.

Role of the Researcher

In qualitative research, the researcher is the primary data collection instrument (Isaacs, 2016). The main role of the qualitative researcher is to collect and analyze data from participants with minimum bias (Hays, Wood, Dahl, & Kirk-Jenkins, 2016). As such, my role was preparing the study interview protocol, selecting the potential participants, collecting data through face-to-face interviews, analyzing the received

information, identifying themes, and presenting the minimally biased results in Section 3.

My work experience as a general manager for more than 15 years (2001 to date) exposed me to various IVD management operations. I have worked with more than 3,000 domestic and international IVD medical businesses. Gaining a deeper understanding of the importance of competitive advantage was critical to deriving the benefits of obtaining and maintaining a competitive position.

Researchers conduct interviews to encourage participants to share their experiences in depth (Whiteley, 2012). Researchers use interviews to obtain comprehensive information regarding the participants' professional experiences and their views about the phenomenon (Brinkmann, 2016). Similarly, I used open-ended interview questionnaires in a face-to-face setting to find a proven business solution for the lack of effective strategies to gain the competitive advantage in IVD medical manufacturers. After capturing the data, I loaded the information into the NVivo software program to produce the findings of the surveys. The data were analyzed for recurring common threads to identify the themes that emerged from the results. I provided the themes in Section 3 of this study.

Belmont Report

The Belmont Report (1979) provided ethical principles for research involving human subjects. The Belmont Report is a set of standards for protecting human subjects in research. Three main ethical principles in the Belmont Report include human respect, beneficence, and justice (Metcalf, 2016; Rogers & Lange, 2013). The Belmont Report includes guidelines for ensuring beneficence for vulnerable research participants

including minority populations (Rogers & Lange, 2013). The Belmont Report also includes basic principles to solve ethical problems of conducting research with human subjects. In compliance with ethical standards, I included an informed consent form in the interview protocol. In addition, I made a clear statement in the contract for using the information provided by the enterprise.

Interview Protocol

An interview protocol is a checklist that researchers use in the interview process that contains questions, procedures, and general rules that researchers need to follow to enhance the reliability of findings (Benia, Hauck-Filho, Dillenburg, & Stein, 2015; Yin, 2014). An interview protocol is a strategy for developing interview questions, identifying interview procedures, collecting data, and interpreting data to maximize interviewers' performance efficiency (Algoso, Peters, Ramjan, & East, 2016; De, Kusumastuti, Hannes, Janssens, & Wets, 2013). Jefferies, Brewer, and Gajendran (2014) added that an interview protocol is vital to mitigate bias, enhance reliability, and ensure repeatability for future research. The interview protocol is essential in qualitative studies to guide the researcher in developing study procedures including obtaining informed consent, defining the interview script, and determining the parameters of responses (Castillo-Montoya, 2016).

Mitigating Bias

Researchers' ideas and philosophical assumptions are expressed in the literature review, research design, data collection, and data analysis (Stafleu, 2014). Bias might occur during any stage of the research study, and a researcher must be aware of personal

perceptions that might affect participant responses (Malone, Nicholl, & Tracey, 2014). Whiteley (2012) posited that researchers need to facilitate the communication flow, determine cues, and set participants at ease. Active listening through clarifying responses and follow-up questions provide another bias-mitigation strategy (Drabble, Trocki, Salcedo, Walker, & Korcha, 2015). Petty, Thomson, and Stew (2012) added researchers might consider maintaining neutrality to ensure the study. I practiced communication skills, self-discipline, and perseverance and maintained a professional tone and neutrality to establish my relationship with participants. Participants contributed their perspectives with no limitations through answers to open-ended questions.

Malone et al. (2014) added that researchers can mitigate personal biases by leveraging prepared interview protocols. Researchers need to eliminate biases when interpreting participant responses to enhance validity (Mecca et al., 2015). An interview protocol helped researchers mitigate the influence of personal bias (Malone et al., 2014). My knowledge, background, experience, and skills informed my approach to the interviews, and I tried to recognize and prevent my bias by not misinterpreting the participants' answers.

Biases might create an imbalance of power during interviews (Anyan, 2013). Researchers need to obtain interview training and practice deliberate mindfulness to minimize bias during the qualitative interview (Pezalla, Pettigrew, & Miller-Day, 2012). Researchers need to recognize and avoid personal biases during the interview, data collection, data interpretation, and data analysis to protect the study results against unintended bias and to improve validity (Baekgaard & Serritzlew, 2015). I mitigated my

personal biases with several approaches including preparing protocols, practicing mindfulness, triangulating data, and doing member checking.

Triangulation enhances validity, ensures reliability, and increases data completeness in the data collection process (Bekhet & Zauszniewski, 2012). Secondary data play the primary role in social science research (Marshall & Rossman, 2016). The use of secondary data can help eliminate the risk of biased responses from participants (Petrova, Dewing, & Camilleri, 2014). I used methodological triangulation from multiple sources including the literature, participant observation notes, interview responses, company websites, and organizational records to reduce the risk of bias in measurement. Company X, Company Y, and Company Z are small multinational corporations with five major divisions: production, technical and QC, purchasing, sales and marketing, and distribution of products and shipping. I collected supportive secondary data to increase accuracy and research reliability of results.

I contacted participants via e-mail to provide them with the results of their interviews. I followed up with participants via e-mail concerning any section of the interviews that may have required more clarification. This method, called member checking, ensures that the participants' responses are not misinterpreted during the interview. Participants' e-mail addresses will remain confidential.

Participants

Purposeful sampling was an effective strategy for selecting the participants. Olsen, Orr, Bell, and Stuart (2013) stated that purposeful sampling helps researchers select the most appropriate participants who meet the study requirements. Cleary,

Horsfall, and Hayter (2014) stated that, based on the data saturation principle, at least three interviewees are required for case studies. Yin (2014) indicated that potential participants must have experience with and an interest in the phenomenon under study. I gathered data for this qualitative multiple case study through interviews with a purposive sample size of three IVD medical device leaders from three companies in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more and who attended a 2014 medical exhibition in Dusseldorf, Germany. The North American Exhibitors Directory contains the names of each company whose representative attended the exhibition, including the owner's name, phone number, business address, city, state, and zip code. I sent follow-up e-mails to those who expressed interest in a consent form to determine whether the business owners met the criteria and agreed to participate voluntarily. The three chosen IVD medical device leaders also received a summary of the purpose of the study via e-mail before I conducted the interviews.

Strategy for Accessing the Participants

Lewis (2015) determined three ways to access participants: (a) traditional face-to-face; (b) online; and (c) hybrid, which involves a combination of traditional and Internet-mediated interactions. In this study, I met with the participants face-to-face in their companies. Over the past 15 years, I had met many of the U.S. IVD medical business leaders directly or indirectly and had established my credibility with them. Participants received a summary of the study findings and recommendations via e-mail.

Interview Protocol

Establishing interview protocols, instructions, and procedures is vital to ensure reliability, reduce bias, and increase the replicability of a study (LePeau, Morgan, Zimmerman, Snipes, & Marcotte, 2016; Malone et al., 2014). I had received Walden University's institutional review board approval (University IRB #06-12-17-0478451) before I began contacting participants. In addition, the interview protocol contained guidelines for the interviews so that participants would share the details of their experiences. Participants needed to sign the consent form prior to taking part in the interview.

Research Method and Design

This was a qualitative multiple case study. A qualitative study provides an in-depth exploration of a phenomenon to better understand the participants' perspectives (Judson & Maller, 2014). Wahyuni (2012) noted that qualitative researchers inquire about experiences as lived in a natural setting. Business scholars and practitioners recommend the case study design as an effective research strategy to gain in-depth knowledge of a phenomenon within real-life experiences (Hasani & Khosrojerdi, 2016). I used the qualitative multiple case study to support the study goal of exploring effective strategies within the IVD medical industry to gain a competitive edge in the global market by exploring real-life experiences.

Research Methods

Researchers must select the appropriate method for the line of inquiry to achieve meaningful results (Harrison, 2013; Yin, 2014). Qualitative, quantitative, and mixed

methods are three types of research methods by which researchers conduct a research study (Isaacs, 2016). Researchers conduct qualitative studies in a real-world setting instead of testing an experimental hypothesis using the quantitative method (Marshall & Rossman, 2016; Reybold, Lammert, & Stribling, 2013). Providing insight into participants' perceptions is the fundamental purpose of the qualitative research method (Gallo, Muylaert, Neto, Reis, & Sarubbi, 2014). Parylo (2012) stated that qualitative research methods are the best approach to explore and develop a rich description of the decision-making of the participants in a study. The qualitative approach was appropriate to understand the business strategies that leaders use to maintain their competitive position (see DeJean, Giacomini, Simeonov, & Smith, 2016).

Researchers use a quantitative method to test hypotheses, describe numerical changes, and find the causal relationships between variables (Goldberg & Allen, 2015; Harrison, 2013; Shelton et al., 2014; Wisdom et al., 2012). Researchers reject or accept hypotheses based on answers to closed questions from valid and reliable instruments (Yin, 2014). Quantitative researchers use numeric data and do not address participants' perceptions, apprehensions, and meanings attributed to the experience (Coenen, Stamm, Stucki, & Cieza, 2012; Harrison, 2013). I used a qualitative approach because a quantitative study would not have provided a broad understanding of the research phenomenon. In a qualitative study, participants describe the phenomenon rather than explicate the phenomenon (Brennan, 2014). The aim of this study was not to examine or formulate a theory, but to seek proven solutions to a business problem.

A mixed-methods approach combines qualitative and quantitative methods (Frels

& Onwuegbuzie, 2013; Harrison, 2013). In mixed methods, scholars examine existing theories and test hypotheses to achieve valid statistical results; in addition, they qualitatively explore participants' perceptions and opinions (Yin, 2014). Scholars leverage a mixed-methods approach for synthesizing elements of the quantitative and qualitative methods in a single study (Petticrew, Refuess, Noyes, Higgins, & Mayhew, 2013). The focus of this doctoral study was not the relationship between variables; therefore, the mixed-methods approach was not appropriate for this study.

Research Design

A study design is a systematic approach to connecting the research elements in the process of answering research questions and drawing conclusions from a study (Perry, 2012). Leedy and Ormrod (2013) noted that research designs link the research components in the study. A researcher uses the research design as a logical plan to collect and analyze data that align with a research question to strengthen the accuracy of the study (Quay, 2015). The qualitative designs that a researcher can use include phenomenology, case study, and ethnography (Rowley, 2012; Yin, 2014).

The case study design allows researchers to identify the connections between events over time (Klonoski, 2013; Yin, 2014). Researchers employ a case study to answer how and why questions when researchers lack control over the phenomenon with a smaller sample (Geist & Hitchcock 2014; Molenberghs et al., 2014). A competitive strategy is a complex undertaking, and through a multiple case study design, I was able to understand the phenomenon.

An ethnographic researcher needs to access the participants' environment, conceptualize and understand participants' experiences (Yanow, 2012). Researchers use the ethnography design to explore a group's culture, one cultural aspect of the population, or patterns of group culture (Leighter, Rudnick, & Edmonds, 2013; Yin, 2014; Zhu & Bargiela- Chiappini, 2013). An ethnographic research study explores cultures in a sequential manner in an extended period instead of understanding the issue or phenomena (Gelling, 2015; Thomson et al., 2011). Therefore, it was not appropriate for this study.

The phenomenological researchers' primary task is to explore the lived experiences of their participants through a significant event (Quay, 2015; Ray, 2015). Phenomenology explores the factors that matter to the participants and focuses on the ability to gain experiences regarding the phenomenon of participants' experiences (Quay, 2015). Phenomenological researchers determine the participants' personal experiences with a generous sample size (Aagaard, 2016; Fernandez, 2016). As the focus of this research as the strategies rather than participants, the phenomenological approach was not germane to this study.

Data saturation occurs when researchers cannot obtain any new information, codes, or themes from the data collection (Tran, Porcher, Falissard, & Ravaud, 2016). Qualitative case study researchers may need to continue conducting case interviews until obtaining data saturation or redundancy (Yin, 2014). I ensured saturation for this study when participant responses became repetitive and I could obtain no new data.

Population and Sampling

Purposeful sampling is the preferred sampling method to permit a qualitative researcher to select participants for the research study, allowing better understanding and insight into the phenomena (Duan, Bhaumik, Palinkas, & Hoagwood, 2015; Pelzer, Arciniegas, Geertman, & Lenferink, 2015; Poulis, Poulis, & Plakoyiannaki, 2013; Walker, 2012). Researchers need to select an appropriate sample size to allow in-depth analyses (Boddy, 2016; Palinkas et al., 2015).

Rowley (2012) noted that researchers employ purposeful sampling to select participants who provide in-depth knowledge of the phenomenon. Researchers use purposeful sampling to obtain a no representative subset of a larger population for a goal (Pirlott, Kisbu-Sakarya, DeFrancesco, Elliot, & MacKinnon (2012). The core factor in narrowing participants in purposeful sampling is identifying the accurate number of participants to answer the research question (Palinkas et al., 2015). The population of this research consisted of IVD medical business leaders in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more. I selected three IVD medical device leaders based on their experience and success in implementing effective strategies to gain competitive advantage.

Researchers need to align the participant professional background, experience, and skills with research purpose and design (Isaacs, 2016; De Medeiros Albano & Caten, 2016). Rowley (2012) advised that more than 10 participants might not be appropriate for a case study, as it might not guarantee richness in data. A sample size of two or three case studies is appropriate if the theory is clear and the degree of certainty is not excessive

(Yin, 2014). With random sampling, researchers cannot gain the in-depth understanding of participants' experiences and perceptions (Green et al., 2014). I interviewed one leader from each of three IVD medical device companies who had attended the 2014 medical exhibition in Dusseldorf. I selected a sample that could provide a level of diversity and comprehensive understanding of the phenomenon.

Ethical Research

Ethical accountability arises at every step of the research strategy, including recruiting, data collection, analysis, and publication, and falls on the researcher's character and principles (Bender, 2016; Dwarswaard & van de Bovenkamp, 2015; Oye, Sorensen, & Glasdam, 2015). Foremost, participants' rights, confidentiality, and dignity must be respected (Dwarswaard & van de Bovenkamp, 2015; Rowley, 2012). In this study, each candidate received an introductory letter with a brief description of the purpose and procedures and a request for his or her consent to participate. Prior to the first visit with the candidates, I informed candidates about the context of consent and provided them with a chance to ask me questions. A consent form is a contract between candidates and researchers to verify that candidates participated in the research study (Yin, 2014). Three components of consent are (a) informing candidates about the research aspects; (b) ensuring that applicants review, understand, and agree to the consent form before the interview; and (c) obtaining permission from participants to conduct an interview (Rowley, 2012). During the research, participants' names, the organization's identity, and demographic description were not disclosed. Participants did not receive any

incentive to participate in this study. I did not use the collected data for any purposes other than research.

Researchers must respect standards related to humanity, dignity, integrity, and anonymity (Cleary et al., 2014). I asked participants if I could record the interviews for future analysis. Participants could withdraw from the study at any time for any reason (Damianakis & Woodford, 2012; Thomas, 2016). I recorded, collected, transcribed, and analyzed the data from participants. Participants sent me the signed consent form via e-mail to confirm their participation. I recorded these documents for future record and referral. The interviews took place face-to-face in California, Connecticut, and New York.

As Thomas (2016) advised, I protected participants' identity by assigning the labels P1, P2, or P3. All interview transcripts and electronic files are stored on a flash-drive and will be held in a locked file cabinet for 5 years, after which I will destroy all such data. After the interview, I provided a copy of the interview transcript to participants for review. I completed the NIH Web-based training course "Protecting Human Research Participants" (see Appendix B).

I conducted the interviews in the following manner.

1. Upon receipt of each approval, I arranged a time and a place for the face-to-face interview in the participant's office.
2. I informed participants in the consent form that participation in the interview is voluntary, and they can withdraw at their convenience.
3. Prior to the interview, I described the nature and the purpose of the research.

4. I recorded each interview in a separate file using the DRAGON Apple voice recorder, which I tested prior to the interview.
5. I identified the participants by a sequential alphanumeric code (P1, P2, and P3).
6. I transcribed the voice into text for data analysis.

Walden University's Institutional Review Board (IRB) reviewed the research plan to ensure the research had met ethical standards before I conducted the study. The IRB form included the study purpose, participants, data collection methods, possible risks and confidentiality, and consent procedures.

Data Collection

In this section, I present the data collection instruments, data collection technique, and data organization technique. The problem and purpose statements provide the method and design of research and data collection process (Bennett & Grant, 2016). Providing insight into the participant perception is the core of the qualitative research method (Anyan, 2013; Gallo et al., 2014). The information was collected through collecting data from the literature, participant observation notes, interview responses, company websites, and organizational record. I used methodological triangulation and member checking to enhance trustworthiness and validity in the study results.

Data Collection Instruments

The researcher is the primary instrument for collecting and analyzing data in a qualitative case study (Leedy & Ormrod, 2013; Thomas, 2016). Three experienced IVD medical leaders in the medical device industry were my primary data sources. One central

research question and six interview questions were designed for this study (see Appendix C). I interviewed participants by asking the research questions with minimal personal bias. I took notes and recorded the interviews, while I was protecting participants` confidentiality, ensuring privacy during data collection, and following the criteria of conformability to maintain the quality of this research study.

Avoiding bias and maintaining the trustworthiness helps ensure the quality of a qualitative case study. I provided an interview protocol for participants consisting of the purpose of the research project; consent form; location, time, and length of the interview; research questions; the interview process; and data collection process (see Appendix D).

In addition, using multiple methods and sources of data collection enable me to evaluate the validity of the results. To reduce the risk of bias in measurement, I used methodological triangulation from multiple sources including the literature, participant observation notes, interview responses, company websites, and organizational records to reduce the risk of bias in measurement. I obtained, organized, and analyzed interview data to discover themes with open-ended questions to explore the factors that could lead to the success of IVD medical companies.

Data Collection Technique

Sangasubana (2011) suggested case study researchers could gather data from three sources: (a) interviews, (b) observations, and (c) archived research material. I conducted interviews and observations and examined secondary data.

Interviews. I collected data through face-to-face interviews with three IVD medical leaders who had designed and implemented their company strategies to gain the

competitive edge (see Appendix C). Each semistructured interview consisted of the same set of open-ended questions (Wilson, 2012; Yin, 2014). Yin (2012) and Vogl (2013) indicated three limitations in face-to-face interviews: (a) high costs, including traveling; (b) participants withdrawing from the study; and (c) increased chances for personal bias. Face-to-face interviews can, however, provide rich data and capture the subjects' perspectives, nonverbal cues, and decrease certain biases (Allen, 2014; Shaw, Scully, & Hart, 2014; Toy & Ok, 2014). Petty et al. (2012) stated that researchers leverage semistructured interviews to explore participants' perspectives in depth. Rubin and Rubin (2012) added that semistructured interviews are the most appropriate method to gain knowledge on a specific research topic.

Member checking. The member checking method allows the researcher to share the result and themes with the participants from their interview to ensure the accuracy of the information and eliminates the misconstrued data. Member checking is a process of discovering whether the collected, analyzed data are congruent with the recipients' perceptions (Birt et al., 2016). I used member-checking method to avoid misinterpreting the participants' responses during the interview.

Data triangulation. Multiple data sources provide the triangulation of evidence, which can increase the reliability of the data collection process (Yin, 2012). In a case study design, researchers need to consider triangulating secondary data from documents to provide richer content (Petrova, Dewing, & Camilleri, 2014). The secondary documents can validate data from other sources, verify consistency, and avoid bias (Marshall & Rossman, 2016). In this study, I used the data triangulation in the data

collection process.

Observation. Observations are an interpretive tool in collecting data in the case study (Smiley, 2015). Researchers can write their observations during the interviews based on participants' diverse perspectives, physical setting, and nonverbal responses in real time (Hayman, Wilkes, & Jackson, 2012). Researchers wrote notes based on participants' actions, body language, and responses to capture impressions, thoughts, and personal biases (Smiley, 2015). Similarly, I used the observation note to triangulate secondary data.

Based on the same set of questions, each interview lasted for about 45 minutes. As noted earlier, each research participant was coded alpha numerically (P1, P2, and P3). I used Dragon software to capture and transcribe the collected data from the interview and then code the interviews as soon as possible. In addition, I gathered the research data, including electronic notes, e-mails, and miscellaneous documents and retained them in one safe location on a USP and an external hard drive, and in the iCloud. Only I have access to the password-protected data.

Data Organization Technique

Researchers need an interview protocol during the interviewing process (see Appendix D; Marshall & Rossman, 2016). I employed research logs and reflective journals to organize and track the non-numeric data for this study. In addition, I compared the transcribed data with audio recording for accuracy. I reduced the data into several controllable clusters. Each interview grouping code includes the letter S for subject followed by the interview iteration, resulting in S1-Sx. Some of the collected data

were eliminated from the data analysis. For example, any data that compromised the identity of the participant were deleted. To identify themes, I organized codes based on descriptive words. In addition, I used NVivo 10 software for data log entries, category system, and coding to add credibility and methodological rigor to the study (Woods, Paulus, Atkins, & Macklin, 2015). Moustakas (1994) posited that the thematic approach enables researchers to identify emerging themes from data interpretation.

Data Analysis

I used thematic analysis to analyze the collected data in the qualitative case study. Thematic analysis is a qualitative data analysis process to identify, analyze, and discover themes within the data (Cleary et al., 2014). Yin (2014) recommended the following phases in data study analysis: (a) transcribing interviews, (b) reviewing the transcribed to gain the general meaning of the data, (c) translating the meaning themes into code (d), data coding, and (b) explaining the study result. I analyzed the data using this thematic analysis method to find the meaning of the participants' perceptions to explore the and themes.

The appropriate data analysis process for this case study was methodological triangulation. Triangulation occurs when researchers use multiple methods of data collection to study a phenomenon (Bekhet & Zauszniewski, 2012; Petrova, Dewing, & Camilleri, 2014; Stewart, Gapp, & Harwood, 2017). Methods of data collection include interviews, observation, notes and journal field, and the organization's internal and external documents (Bekhet & Zauszniewski, 2012, Petrova et al., 2014; Stewart, Gapp, & Harwood, 2017). Organization internal documents include annual sales growth, and

company statement (Archibald, 2016). External documents include published news, blog, and other relevant websites context. Bekhet and Zauszniewski (2012) used the methodological triangulation with multiple data sources as a strategy to enhance reliability and validity in their case study. I used methodological triangulation from multiple sources including the literature, participant observation notes, interview responses, company websites, and organizational records to reduce the risk of bias in measurement.

Hashimov (2014) and Wagner, Hansen, and Kronberger (2014) discussed qualitative data analysis as a three-step process: reducing data (essence extraction), displaying data (organizing for meaning), and designing conclusions (explaining the findings). The first stage of thematic analysis includes identifying and categorizing important segments of themes; and the last steps integrate significant sections to build an interpretation of the participants' perceptions to address building competitive advantage (Cleary et al., 2014). I analyzed the data through essence extraction, organizing for meaning, and designing conclusion.

Data analysis seeks to discover meaningful patterns, themes, and description of participants' responses to address the research question (Chowdhury, 2015). Qualitative data analysis is more subjective than quantitative analysis, and researchers scrutinize the body of data in search of patterns (Leedy & Ormrod, 2013). Finding themes, description, and patterns of participant responses to research question are vital in the finding stage (Cleary et al., 2014; Sung, Hepworth, & Ragsdell, 2013). As recommended by Bazeley and Jackson (2013), I reviewed the transcripts and analyzed the overall meaning of the

contexts, and I loaded the information into NVivo software for coding and thematic analysis.

NVivo is qualitative analysis software for counting, sorting, categorizing, and thematic coding during the analysis stage (Castleberry, 2014; Scales, 2013). I used NVivo 10 software to simplify the process to facilitate coding and identify recurring themes from observable patterns. The step of using the software included placing data in distinct categories, matching groups with sources of evidence, and creating themes (Yin, 2014). Additional steps included tabulating the frequency of certain words or thoughts, examining relationships, and placing data in other relevant classifications (Sinkovics & Alfoldi, 2012). Intersections of data allow thematic classification for repeating context and contrasting across different nodes to achieve the appropriate answer to the research question (Hu, Torr, & Whiteman, 2014). The data analysis needed to respond to the research questions and purpose, and provided a better understanding of the phenomenon of effective competitive strategies in U.S. IVD manufacturers.

The initial analysis involved in reviewing transcripts as identifying codes, creating a code list, refining codes, and collapsing and eliminating codes. According to Yin (2014), a researcher uses coding for the discovery of themes until saturation to ensure reliability and validity. Fusch (2015) and Walker (2012) noted researchers achieve data saturation when they cannot collect any additional information and themes, and they obtain sufficient data to replicate the study. Redundancy in participants' responses determines the saturation of data and enhances reliability in a qualitative research study (Kemparaj & Chavan, 2013; Mâsse et al., 2013). Charach, Yeung, Volpe, Goodale, and

dosReis (2014) implemented refining codes until no new unique codes could be identified. Similarly, I continued the process of codes until no new unique codes were defined in this study.

Reliability and Validity

Reliability and validity are vital when evaluating the quality of the research design, accuracy, and credibility of the findings (Konradsen, Kirkevold, & Olsom, 2013; Yin, 2014). According to Parris, Dapko, Arnold, and Arnold (2016), validity and reliability enhance transparency and decrease researcher bias. The qualitative researcher needs to consider interviewing, interpreting, selecting, grouping, coding and transcribing the interview data in the process of the qualitative research study (Leedy & Ormrod, 2013). Researchers use various sources, including physical artifacts, member checking, methodological triangulation, data description, and data transcribing to verify the accuracy of interview data (Yin, 2014). Member checking improves reliability, validity, credibility, and accuracy of the collected data (Birt et al., 2016; Leedy & Ormrod, 2013). I leveraged member checking and methodological triangulation to interpret the interview data correctly.

Reliability

Perry (2012) noted that qualitative researchers must ensure the quality and trustworthiness of the research study. The reliability in a qualitative research study is the consistency of the data gathered and the results (Leedy & Ormrod, 2013). In addition, reliability is the quality measurement indicator and is a precondition for validity (Venkatesh, Brown, & Bala, 2013).

The goal of reliability is to minimize biases and errors in a study (Perry, 2012). In the qualitative research study, reliability occurs when participants explore with the same responses to the questions (Stevenson & Mahmut, 2013; Trotter II, 2012). Credibility occurs when a researcher interprets the participants' successful experiences accurately (Thomson et al., 2011). Perry (2012) added that the truthfulness occurs when the reader can trust on a research study. Houghton, Casey, Shaw, and Murphy (2013) used member checking to ensure the credibility, dependability, and transferability in a case study. Member checking is the most efficient method of eliminating the possibility of interview misinterpretation of transcribed data (Carroll & Huxtable, 2014; Harper & Cole, 2012; Ray, 2015). Harvey (2015) determined that constant member checking is part of the reliability process. Similarly, member checking was appropriate for this study to review and interpret data with respondents to modify and finalize the information.

Validity (Contextual Validity)

Leedy and Ormrod (2013) defined validity as how accurately a study represents a participant's reality of a social phenomenon. In qualitative research, researchers need to employ strategies to determine the accuracy of the findings. Research validity occurs when that the outcome of the study is accurate, credible, applicable to similar situations, and aligns with the phenomenon under study (Leedy & Ormrod, 2013). The validity of the research occurs when research design and data collection allow the researcher to draw accurate conclusions (Leedy & Ormrod, 2013). In addition, in a qualitative case study, the data validity depends on upon the participant honesty (Leedy & Ormrod, 2013). Goldin, Pinkus, and Ashley (2015) added that qualitative research validity occurs when

participants confirm that the accuracy of the analysis result. Validity suggests truthfulness, and it leads to how well the social reality being measured. The biases might affect researchers' selection of research questions, sampling, variables, data capturing, participants' protection, and dissemination of results (Harnett & Neuman, 2015; Nicholls et al., 2015). Multiple sources of information in a case study, improve the validity of a study (Leedy & Ormrod, 2013). Yin (2014) advised that interviews and notes support triangulating evidence of the qualitative research.

Contextual validity includes the credibility of case study evidence and research results (Savage & McIntosh, 2016). A qualitative study provides an in-depth exploration of a phenomenon to better understand the participants' perspectives (Judson & Maller, 2014). The threats to the contextual validity of qualitative studies include bias during the study and lack of descriptive validity of the study settings (Savage & McIntosh, 2016). The qualitative researcher needs to follow the criteria of dependability, credibility, transferability, and confirmability to maintain the quality of this research study (De Medeiros Albano & Caten, 2016).

Dependability

Dependability refers to when the qualitative researcher connotes the stability of the research evidence over comparable conditions (Houghton et al., 2013). A study is dependable when other researchers agree with the result and decide on research process and activities (Petrova et al., 2014; Stewart, Gapp, & Harwood, 2017). Researchers leverage multiple resources such as memo writing, audit trail, and notes to avoid overlapping data and to assure dependability (Charach et al., 2014; Yin, 2013). A

researcher must document every step of the research procedures (Yin, 2014) and validate the participants' response, avoid bias, to develop research dependability (Konradsen et al., 2013). In qualitative research, audit trail rigor through clear documentation of research decisions to check bias of the methodological achievement and interpretative judgments (Houghton et al., 2013). Member checking is a process of discovering whether the collected, analyzed data, interpret data congruent with the recipients' perceptions (Birt et al., 2016). I used member checking for dependability.

Credibility

In the qualitative study, credibility is representing and interpreting accurate data through participant views in a convincing manner (Stewart, Gapp, & Harwood, 2017). Credibility connotes the value and believability of qualitative study results (Houghton et al., 2013) and what guides the truthfulness of the data (Stewart, Gapp, & Harwood, 2017). The credibility of research depends on the perceived morality of truthfulness, fairness, and lack of bias (Elliott, 2013). The **c**redibility of results determines how well a researcher's collected data corresponds to the participants' successful experiences in a qualitative study (Brouwer et al., 2015; Goldin, Pinkus, & Ashley, 2015). Researchers can use methodological triangulation, member checking, and prolonged engagement to ensure the credibility of a study (Black, Palombaro, & Dole, 2013). In the prolonged engagement, researchers spend adequate time with recipients to understand the phenomenon and review the transcript to establish credibility. I used member checking to increase credibility in the study.

Transferability

Transferability occurs when research findings can apply to and accommodate other contexts or environment settings (Houghton et al., 2013). Transferability refers that investigation results can comply with the situations beyond the research itself (Leedy & Ormrod, 2015). Transferability is the extent to those researchers realizes that can apply the treatment in a different setting (Cambon, Minary, Ridde, & Alla, 2012). Transferability represents when the study results are generalizable or transferable to different settings or groups (Savage & McIntosh, 2016). According to Savage and McIntosh (2016), threats to transferability occur from selective plausibility and when researchers fail to reconnect empirical findings of the study to other similar cases and previous theoretical.

Confirmability

Houghton et al. (2013) posited that conformability occurs when the study of the conclusions, interpretations, and illustrations represents the participants' perceptions and not the researchers' biases viewpoints. In a qualitative study, researchers emphasize on participants' perspectives (Lub, 2015). To maintain validity in a qualitative research study, the qualitative researcher needs to conduct the accurate data collection, interpretation, and analysis. Threats to conformability will jeopardize the study if the qualitative researcher cannot conclude valid inferences from the population. According to Petrova et al. (2014), conformability links to dependability in referring to data accuracy. Member checking and methodological triangulation are the effective strategies to strengthen trustworthiness of the qualitative study and enhance conformability (Leedy &

Ormrod, 2013; Yin, 2014). Similarly, I utilized member checking and methodological triangulation for study conformability. I collected data from triangulated resources as a tool to validate the interview responses.

Transition and Summary

Medical manufacturing organization leaders struggle to gain and preserve their competitiveness, which results in a loss of the organization's position in the competitive marketplace. The business problem of this study was that some leaders in IVD medical manufacturing organizations lack strategies to gain and maintain a competitive advantage. The purpose of this qualitative multiple case study was to explore strategies some IVD medical manufacturing leaders located in California, Connecticut, and New York, use that could help them lead to gain and maintain a competitive edge. The primary research question concerned the strategies IVD medical manufacturing leaders use to achieve and maintain a competitive advantage. The population for this study was three leaders in IVD medical manufacturing organizations in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more.

The primary role of the qualitative researcher is to collect and analyze data from participants with minimal bias (Hays et al., 2016). In this qualitative study, I was the primary data collection instrument. I collected data through face-to-face interviews with the three IVD medical leaders. I took notes, recorded the voices, and discovered themes. I protect participants` confidentiality, ensured privacy during data collection, and followed the criteria of conformability to maintain the quality of this research study. The ethical procedures protected the participants' rights and their confidentiality. I also employed a

research log and reflective journal to organize and track the non-numeric data for this study.

Data were recorded and transcribed to identify patterns and themes. I used NVivo 10 software to simplify the process to facilitate coding and identify recurring themes from observable patterns. The step of using the software includes placing data in different categories, matching groups with sources of evidence, and creating themes (Yin, 2014). Additional steps included tabulating the frequency of certain words or thoughts, examining relationships, and placing data in other relevant classifications (Sinkovics & Alfoldi, 2012). The data analysis led to a better understanding of the phenomenon of effective competitive strategies in U.S. IVD manufacturers. In the next section, I identify the findings and implications for social change and offer recommendations for action and study.

Section 3: Application to Professional Practice and Implications for Change

Introduction

Medical manufacturing organization leaders struggle to maintain their competitive position because of inefficient strategies (Jovanović & Petrović, 2015). The purpose of this qualitative multiple case study was to explore strategies some IVD medical manufacturing leaders use to gain and maintain a competitive advantage. In this section, I present the summary of findings regarding the strategies that IVD medical manufacturing leaders could use to obtain the competitive position in the industry.

I collected data through face-to-face interviews with three IVD medical device leaders in California, Connecticut, and New York. I used pattern coding to organize, categorize, and structure the data into emergent themes to answer the research question. In addition, I used NVivo 10 to analyze the data from observation notes, interview responses, company websites, and organizational records.

I used NVivo 10 software to simplify the process to facilitate coding and identify recurring themes from observable patterns. The analysis yielded eight major strategies that the U.S. IVD medical leaders should consider to maintain their market position in the local and international market: (a) customer support; (b) marketing, e-marketing, and branding; (c) competitive collaboration; (d) quality; (e) cost structure; (f) regulation; (g) innovation; and (h) information technology. The findings included practical strategies U.S. IVD medical leaders might deem essential to enhance competitive advantage. I concluded that customer support was recognized as the most important factor to gain a competitive edge.

Presentation of the Findings

The overarching research question addressed in this study was as follows: What strategies do IVD medical manufacturing leaders use to achieve and maintain a competitive advantage? Three IVD medical device leaders from companies in California, Connecticut, and New York answered six questions during face-to-face interviews. I analyzed data from interview responses, observation notes, company websites, and organizational records to reduce the risk of bias in measurement.

I analyzed the data using a thematic analysis method to find essences and the meaning of the participants` perceptions regarding strategies to obtain a competitive edge. The steps included tabulating the frequency of certain words, finding relationships, and placing the data in the relevant group. The themes were derived from coding and the number of references coded during the data analysis. Yin (2014) stated that data analysis involves examining data to discover meaningful codes and themes that answer the research question.

Themes from the Research

Porter (1985) contended that leaders should incorporate different strategies to improve competitive advantage. According to Porter (1991), companies can employ cost leadership, brand identification, high product quality, technology, and service leadership or a combination of these strategies to gain competitive advantage in the market. The analysis generated eight general themes that I divided into three categories: cost leadership, differentiation, and focus. Table 2 represents the thematic alignment between the literature review, conceptual framework, and findings.

Table 2

Themes, Categories, and Conceptual Framework

Category	Theme	Literature review
Differentiation	Customer support	Competitive strategy and consumers
Focus	Marketing, e-marketing, and branding	Focus strategy and competitive tactics
Differentiation	Quality	Differentiation strategy
Cost leadership	Cost structure	Cost leadership strategy
Differentiation	Information technology	Competitive strategy and information technology
Differentiation	Regulation	Differentiation strategy
Differentiation	Innovation	Competitive strategy and innovation management
Differentiation	Competitive collaboration	Differentiation strategy

Customer Support and Differentiation Strategies

All of the participants commented on this theme. Participants P1 and P3 contributed more than once to the theme with two or more references. The key findings in customer support including the following: be first to respond to customer requests; be in touch with customers; connect and provide solutions to customers; follow up; ensure customers' satisfaction; ensure customers' strengths are in line with company strategies; ensure products are well suited for customers; improve product availability, visit the customer region; enhance responsiveness and competitiveness; evaluate customer satisfaction; ship properly and on time to customers; use proper communication with customers; provide excellent customer service; enhance customer satisfaction; provide clear and prompt action on product replacement; provide high standards of service to ensure long-term business relationships; and offer comprehensive product lines to customers (see Table 3).

All participants reported that customer support and customer satisfaction are the essential factors of competitive advantage for leaders in IVD medical business to gain their leadership position in the medical device industry. Respondents identified customer support as the most important strategy to gain the competitive edge. Participants reported that IVD business leaders need to optimize customer service, logistics, and communication to meet customers' expectations and to ensure their satisfaction. Managing customer satisfaction is a potential tool for increasing revenues, improving sustainability, and obtaining competitive advantage (Ogawa & Pongtanalert, 2013). Customer support aligns with Porter's (1989) differentiation strategy.

Table 3

Theme 1: Customer Support

Interviewee	Coding
P1	First to respond to customers' requests, be in touch with your customers, connecting to our customers, provide solutions, follow up, ensure their satisfaction, their strengths have to be in line with our strategies, the products have to be well suited for our customers, the customer will, availability, and visits to the region, responsiveness, and competitiveness, customers for feedback, constantly visit our customer base, visiting our customers, and constantly evaluating our logistics, ship properly or in time, language and communication.
P2	Excellent customer service.
P3	Service, good customer satisfaction, the clear and prompt action on product replacement, high standard, and good customer service, good customer service, long-term business relationship, customer satisfaction survey, comprehensive product lines to the customers.

Information Technology and Differentiation Strategies

All of the participants commented on this theme. Participant 2 contributed more than once to the theme with two or more references. The key findings in technology and information system were as follows: competition on Search engine optimization (SEO), outsourcing SEO to an expert agency, using the website, competitive SEO and pricing, and technology information and infrastructure (see Table 4).

All participants reported technology expertise is one of the elements of competitive advantage for leaders in IVD medical manufacturing organizations to regain their leadership position in the manufacturing industry. Participant 2 mentioned information technology as a significant element in business success. Participant 2 emphasized that IVD medical leaders can use technology and e-marketing to improve

flexibility, organizational responsiveness, collaboration, and cost efficiencies to gain a competitive advantage. Rai et al. (2015) found that IT had improved Interfirm process capabilities, market valuation, and asset turnover.

IVD medical leaders need to adopt information technology to develop revolutionary operations to gain a competitive edge over their competitors. Participant 3 reported that IVD medical leaders can benefit tremendously in logistics, quality control, and customer service operations by using IT efficiently. One of the overlooked elements of using IT is to differentiate and gain a competitive advantage (Mavengere, 2013; Santos-Vijande et al., 2012; Wang et al., 2012). IT is also aligned with Porter's (1989) differentiation strategy.

Table 4

Theme 2: Information System and Technology

Interviewees	Coding
P1	Website
P2	Competition on SEO, outsourcing our SEO to an expert agency, and competitive SEO and Pricing.
P3	Technology information and infrastructure

Innovation and Differentiation Strategies

Participants 2 and 3 commented on this theme. Participant 3 contributed more than once to the theme with two or more references. The participants reported that innovation is a significant element of competitive advantage for leaders in IVD. The key

findings in innovation were as follows: developing a new platform and new products (see Table 5).

Participant 3 mentioned innovation as an essential element in business strategy. Participant 3 emphasized that lack of innovation in manufacturing processes would impact IVD medical businesses' sustainability. Innovation increases productivity by creating and executing new processes, which increase competitive advantage and provide meaningful differentiation (Alguezaui & Filieri, 2014). Participant 3 reported that U.S. IVD medical leaders adopt an innovation strategy to create new products and services for customers in the marketplace. Porter (1990) emphasized innovation as a primary factor in obtaining competitive advantage and noted it as a national competitive performance indicator. Innovation is aligned with Porter's differentiation strategy.

Table 5

Theme 3: Innovation

Interviewee	Coding
P1	N/A
P2	Researching new products.
P3	Innovate, develop a new platform and/or new products, innovation/new product, and develop new products.

Quality Improvement and Differentiation Strategies

All participants commented on this theme. Participants 1 and 3 contributed more than once to the theme with two or more references. The key findings were as follows: provide high-quality products, supply the United States or FDA approved products, check

the quality of suppliers, establish the quality systems to ensure the product quality, and provide high standards under R&D supervision (see Table 6).

Most of the participants reported that continually improving quality is vital for competitive advantage for leaders in this industry. Participants strongly supported that IVD medical companies need to improve product quality to maintain their market position. Participants reported that FDA regulations assist IVD medical business in meeting international standard requirements. All participants supported that IVD medical leaders need to consider the quality-oriented strategy to create superior products to obtain a competitive edge. Hanaysha (2016) identified core business processes and quality improvement practices as strategies for enhancing competitive advantage. Companies implement the differentiation strategy by increasing product quality as perceived by customers even with the higher price (Porter, 1991). Quality aligns with Porter's (1989) differentiation strategy.

Table 6

Theme 4: Quality

Interviewees	Codes
P1	High-quality products, made in the USA or FDA approved, quality, the quality of our suppliers.
P2	Offering top quality products.
P3	Quality, quality system to ensure the quality of the products, high good standard, R&D, USA and FDA.

Regulatory and Differentiation Strategies

Participants 1 and 3 commented on this theme. Participant 3 contributed more than once to the theme with two or more references. The key findings in regulatory follow: the FDA's strict regulations on developing quality systems in U.S. manufacturers, the FDA's current regulations have put limitations on businesses supplying IVD products, the FDA has limited U.S. manufacturers in producing Class III products, and FDA-approved products are a tremendous marketing tool for U.S. (see Table 7).

Some of the participants believed the regulations are an essential element of competitive advantage for leaders in IVD medical firms. Other countries can market their IVD medical kit products in the United States only under strict regulation rules. The FDA has strict rules to protect U.S. consumers and prevent defective products from being manufactured. Participant 3 reported that FDA rules have a positive and negative impact on U.S. IVD medical businesses. U.S. IVD medical manufacturers are required to follow FDA regulations, which are necessary to protect consumers but create barriers for international manufacturers. As such, U.S. producers can be at a competitive disadvantage because of increased costs and long processing time compared to foreign competitors (Foe Owono, 2015).

Participants 3 supported that FDA strict rules create value and differentiation for U.S. companies in the competitive market. Participant P3 added that FDA regulation is the significant obstacle for international IVD medical companies to sell their products within the U.S. market. Regulatory is aligned with Porter's (1989) differentiation strategy.

Table 7

Theme 5: Regulatory

Interviewees	Codes
P1	FDA.
P2	N/A.
P3	FDA's strict regulation, most US manufacturers, have developed quality system to ensure the quality of the products, US FDA's current regulation has put a lot of limitations on the business who are supplying IVD products to international markets, US FDA has limited US manufacturers to produce class III products, and made in the USA or FDA approved is a tremendous marketing tool.

Competitive Collaboration and Differentiation Strategies

Competitive collaboration plays a vital role in medical device manufacturers. I have indicated the key findings of competitive collaboration in Table 8. The competitive collaboration includes partnership, outsourcing, and resources, as follows.

Partnerships. Participants 1 and 3 commented on this theme. Participant 1 and 3 contributed more than once to the theme with two or more references. The key findings in partnership were as follows: high-quality products can be ensured through the manufacturing partners; partnership with the foreign company manufacturing partners strengths must align with a company's strategies; and the R&D team in China can help the core R&D team in the United States with various activities, from material evaluation to clinical trial (see Table 8).

Participants 1 and 3 believed the partnership is the essential element of competitive advantage for leaders to regain a leadership position in the manufacturing industry. Participant 1 emphasized that partners' strategy need to be aligned with both companies' strategies to achieve the successful objective. Participant 3 indicated that the United State might use China research and development from material evaluation to clinical trial. Chang (2012) stated that the partnership had become a core business strategy because of global competition. The U.S. IVD medical leaders may need to establish the collaboration with international manufacturers to leverage their advantage to enhance company performance. The partnership aligns with Porter's (1989) differentiation strategy.

Table 8

Theme 6: Competitive Collaboration: Partnerships

Interviews	Codes
P1	Ensuring high-quality products through our manufacturing partners, Manufacturing partners, and strengths have to be in line with our strategies.
P2	N/A
P3	The R&D team in China can help the core R&D team in the US with various activities from material evaluation to clinical trial, through the partnership with the foreign company.

Outsourcing. Participants 2 commented on this theme. Participant 2 contributed once to the theme with one reference. The key findings in outstanding were as follows: outsourcing our SEO to an expert agency (see Table 9).

Participant 2 believed outsourcing is one of the elements of competitive advantage for leaders in the IVD medical manufacturing organizations. Participant 2 emphasized on information technology outsourcing. Participant 2 indicated that IT outsourcing assists companies to reduce cost and enhance efficiency.

The U.S. IVD leaders might use outsourcing to reduce operational cost, and enhance company flexibility and performance. Manufacturers use outsourcing to eliminate those manufacturing functions that the domestic firms did not consider a core competency and competitive advantage in the market (Yang et al., 2016). This finding aligns with a differentiation strategy element of competitive advantage.

Table 9

Theme 7: Competitive Collaboration: Outsourcing

Interviewees	Codes
P1	N/A.
P2	Outsourcing our SEO to an expert agency.
P3	N/A.

Resourcing. Participants 1 and 3 commented on this theme. Participant 1 and 3 contributed more than once to the theme with two or more references. The key findings in resourcing were as follows: providing secondary supplier for each product line; enhancing cash flow; decreasing currency fluctuation; improving management of the resources and infrastructure of the company; and managing the internal and external resources (see Table 10).

Participants 1 and 3 believed resources are one of the elements of competitive advantage for leaders in the IVD medical manufacturing organizations to regain a leadership position in the manufacturing industry. Participants 1 and 3 emphasized that managing resources, including suppliers and cash flow, is a significant factor in gaining the competitive edge. Daniela (2014) argued that company resources and capabilities are vital factors in formulating the competitive strategy. Compared to the United States, China has strength in economic, labor, favorable currency laws, transportation costs, and national resources (Harpaz, 2016, Holslag, 2015). This finding aligns with a differentiation strategy element of competitive advantage.

Table 10

Theme 8: Competitive Collaboration Resources

Interviewees	Codes
P1	Cash flow, secondary supplier for each of our lines, and currency fluctuation.
P2	N/A.
P3	Better management of the resources and infrastructure of the company, how to find and utilize both internal and external resources.

Marketing, E-Marketing, Branding, and Focus Strategy

Participants 1, 2, and 3 commented on this theme. Participant 1, 2, and 3 contributed more than once to the theme with two or more references. The key findings in marketing were as follows: attending to local trade shows; marketing U.S. products; visiting the customer region; promoting the United States and FDA-approved products;

offering services based on our core products and abilities; attending trade shows; utilizing a product offering approach; offering a wide range of products; using Web marketing; researching new products; using customer satisfaction survey; and using Internal quality review and market feedback from various sources (see Table 11).

All participants believed U.S. branding and marketing are essential elements of competitive advantage for leaders the IVD manufacturing industry. All participants supported that the global business environment has been changing rapidly, and IVD medical leaders need to adjust the company marketing strategy based on consumers' needs. About 100% of participants emphasized that U.S. IVD medical companies with brand loyalty have better market positions compared to their competitors.

All participants supported that IVD medical leaders can use the marketing strategy to create value and differentiation to obtain a favorable market position to gain desired profit. Participants responded that branding and marketing are important for obtaining customer attraction. In addition, IVD medical leaders can market FDA products as brand loyalty and brand differentiation in the competitive market. Kaliappen and Hilman (2014) contended that marketing mediates the relationship between quality and performance. This finding aligns with Porter's (1989) focus strategy with differentiation.

Table 11

Theme 9: Marketing, E-Marketing, and Branding

Interviewees	Coding
P1	Attending local trade shows, U.S. marketed products, visits to the region, made in the USA or FDA approved, website, offering services based on our core products and abilities, our trade show and product offering approach.
P2	Offering a wide range of products, web marketing, researching new products.
P3	Customer satisfaction survey, Internal quality review and market feedback from various sources, FDA Products, USA Products.

Cost Structure and Cost Leadership Strategy

All three participants contributed more than once to the theme with two or more references. The key findings in cost structure were as follow: reducing the suppliers' cost; managing company cost; managing the SEO and web pricing; reducing the R&D and manufacturing cost; and using lower cost strategy and price advantage (see Table 12).

All the participants believed the cost structure is one of the essential elements of competitive advantage for leaders in IVD medical manufacturing organizations to regain its leadership position in the manufacturing industry. According to Handoko et al. (2015), the competitive advantage occurs when a firm can supply similar products or services as competitors but at a lower price.

All participants reported that U.S. IVD medical leaders need to implement cost strategy to compete against their competitors in the market. Participant 1 and 3 indicated

that IVD Medical consumers seek for suitable companies with low prices and high-value service. Participant 2 emphasized on information technology cost prices. P2 stated that the IT is involved with the high cost; hence, firms need to analyze IT investment accurately with sufficient cost strategy. Participant 3 indicated that IVD leaders should consider managing the QC and manufacturing cost to compete in global markets. In the global marketplace, the price is a significant factor in the buyers' decision to select the vendors (Porter, 1989). The cost structure is aligned with Porter's cost leadership strategy.

Table 12

Theme 10: Cost Structure

Interviewees	Coding
P1	Pricing, pricing of our suppliers, responsiveness and price.
P2	Competitively low prices, SEO pricing.
P3	Reduce the R&D and manufacturing cost, price advantage and lower cost strategy.

Summary of the Findings

All three respondents mentioned customer support with 32% frequency; thus, customer support was recognized as the most important factor to gain the competitive edge. After customer support, marketing with 15% frequency, competitive collaboration with 13% frequency, quality with 10% frequency, cost structure with 9% frequency, regulation with 8% frequency, innovation with 6% frequency, and information

technology with 6% frequency were reported as significant strategies in gaining the competitive edge (see Table 13).

In conclusion, the eight themes emerged were (a) customer support; (b) marketing, e-marketing, and branding; (c) competitive collaboration; (d) quality; (e) cost structure; (f) regulation; (g) innovation; and (h) information technology. As such, customer support was recognized as the most important factor to gaining the competitive edge. In addition, the U.S. IVD medical leaders may consider performing different strategies to gain competitive advantage.

Table 13

Final Themes from Interview

	Themes	Comments	
		Percentage	Frequency
1	Customer support	31.76	27
2	Marketing, e-marketing, and branding	15.30	13
3	Competitive collaboration	12.94	11
4	Quality	10.60	9
5	Cost structure	9.42	8
6	Regulation	8.23	7
7	Innovation	5.88	5
8	Information technology	5.88	5
	Total	100	85

Applications to Professional Practice

A multiple case study was relevant for understanding the effective strategies in

U.S. IVD medical manufacturing organizations. The purpose of this qualitative multiple case study was to explore strategies some IVD medical manufacturing leaders use to gain and maintain a competitive advantage. Other U.S. IVD medical manufacturing leaders can benefit from the findings and recommendations by implementing the strategies to maintain the country's medical manufacturing leadership position and support the U.S. economy. The IVD leaders are encouraged to use effective strategies to improve and retain their business performance, productivity, consumer satisfaction, competitiveness, and company profitability. In addition, a comprehensive understanding of effective strategies for competitive advantage could help area IVD medical leaders identify the most appropriate approaches to sustain their market positions and increase sales.

The findings support Porter's (as cited in Evans, 2016) competitive advantage theory. The basis of Porter's analysis is to understand firms' positions in their external environment and what competitive advantage they have vis-a-vis their competitors. The results indicate that implementing the eight effective strategies may assist some leaders in IVD medical manufacturing organizations to maintain and gain competitive advantage. The result could provide a practical guide for some leaders in IVD medical manufacturing organizations to improve their strategies, thereby promoting sustainability, profitability, and competitive position. The findings and recommendations add to the knowledge of business development by identifying the effective business strategies in the dynamic environment.

Implications for Social Change

The implications for positive social change include the potential of reducing unemployment for the local workforce. These results can help U.S. IVD organizational leaders develop strategies to thrive and secure advantages, which could provide the resources for creating new products and increasing employment. Successful leaders in IVD medical manufacturing organizations contribute to strengthening the U.S. economy through profitability and the growth of the business sector, thus increasing the quality of life for Americans. The results may enhance the availability of U.S. medical products to consumers in IVD health care markets in the United State and global markets.

Recommendations for Action

Medical manufacturing organization leaders struggle to preserve their competitive position because of inefficient strategies (Jovanović & Petrović, 2015). In this qualitative multiple case study, I explored strategies three IVD medical manufacturing leaders use to gain and maintain a competitive advantage. The participants provided valuable insights into knowledge management processes, including their perceptions regarding the effective strategies to maintain U.S. leadership position in the dynamic market environment. Obtaining and gathering this information from successful medical manufacturing organization leaders may help U.S. manufacturing leaders to consider reshaping their strategies in the highly competitive market.

The qualitative data obtained from this study may assist IVD medical manufacturing organization leaders to determine strategies to enhance business performance, sales, and revenue. In previous studies, researchers have not focused on

competitive collaboration (Theme 8) as a core strategy. The results of this research suggest a new consideration in gaining the competitive edge and provide additional insight as a useful source to increase the knowledge management in achieving competitive advantage in the global market.

Recommendations for Further Study

The purpose of this qualitative multiple case study was to explore strategies three IVD medical manufacturing leaders use to gain and maintain a competitive advantage. Future researchers should explore the eight identified themes with the larger population in quantitative studies comparing the impact of these eight strategies for competitive advantage within the larger population. The researcher can seek if the quantitative data supports the result of the qualitative result in response to research question presented in this research. In addition, because the competitive collaboration was explored in only a general framework, researchers should examine competitive collaboration in more detail.

Future researchers may examine the result of this study to provide more comprehensive analysis of business success in the competitive market by identifying participants' demographics. Also, future studies might include examining the effect of leaders' skills on implementing effective competitive strategies in the global market. Competitive advantage occurs when leaders can execute effective strategies to defend a firm position against company rivals (McGrattan & Prescott, 2014). Future researchers may want to explore how individual leadership characteristics may help organizations gain more insight into what best leadership practices can contribute to maximizing

organizational efficiency, and in turn, generate profit in a dynamic market and lead the company in a competitive market.

The targeted participants for this study consisted of three leaders of the IVD medical device manufacturing in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more. Thus, the findings cannot be generalized to participants in another industry or other countries. Therefore, future researchers should replicate this study in other industries to see if similar themes and patterns emerge. Because drivers for competitive advantage vary in different countries as a result of economic, cultural, and social differences, further research is suggested in other parts of the world.

Reflections

This doctoral process provided an opportunity for me to research three areas of personal interest: (a) competitive advantage, (b) competitive strategies, and (c) the medical industry. Conducting the study has broadened my understanding of doctoral research and increased my understanding of IVD medical manufacturing organizations and competitive strategies in the global market. My initial attempt to schedule interviews with participants was difficult because of their responsibilities and organizations' confidentiality requirements. I managed to gather valuable information for IVD medical manufacturing organizations, business practitioners, and future leaders. Having IRB approval letter and the introductory letter were the great help to obtain trust in an educational framework rather than business matter. I had preconceived notions regarding effective business strategies, but my interviews with the three IVD market leaders

enlightened me more about effective strategies in IVD medical industry in today's dynamic environment and globalization.

Summary and Study Conclusions

The overall global medical devices market was worth approximately $479.5 billion in 2015 (ITA, 2016). Medical device firms in the United States face various challenges that could lead to slower growth. Entering the new market and then building supply and export opportunities are the significant factors to the competitiveness and growth of the U.S. manufacturing economy (Zhang, 2015). The problem is that the United States is lagging other countries in medical manufacturing, which may result in a loss of the leadership's position in the marketplace (Levinson, 2017). The U.S. IVD market continues to face new competition from Europe, Brazil, Korea, China, and India (IVD Australia, 2016). Indeed, the U.S. ITA (2012) stated that growing global trade in counterfeit medical diagnostics products threatens U.S. innovation and the overall economy. The value of imported medical devices from the main competitors has been increased; imported medical devices had a value of $54 billion, $9 billion more than exports in 2015 (ITA, 2016).

The purpose of this qualitative multiple case study was to explore strategies IVD medical manufacturing leaders use to gain and maintain a competitive advantage. The findings may serve as the basis for the development of IVD medical manufacturing to achieve economic growth in the United States. The results could become a guide for IVD medical manufacturing leaders struggling to find successful strategies and practices to gain and maintain a competitive advantage.

I conducted face-to-face interviews with three IVD medical device leaders from companies in California, Connecticut, and New York who had run IVD medical businesses for 10 years or more, and who attended a 2014 medical exhibition in Dusseldorf. The conceptual framework for this study was Porter's competitive advantage theory. I used interviews and data triangulation in data collection. I reduced the data into several controllable clusters and analyzed the data by adopting essence extraction, organizing for meaning, and designing a conclusion.

The design of this qualitative multiple case study supports the perceptions of three individuals in the U.S. IVD medical business to identify effective strategies that might yield competitive advantage. Eight themes emerged: (a) customer support; (b) marketing, e-marketing, and branding; (c) competitive collaboration; (d) quality; (e) cost structure; (f) regulation; (g) innovation; and (h) information technology. Participants provided insights into the strategies IVD medical manufacturing leaders need to maintain and achieve competitive advantage. Responses from participants indicated that customer support was pivotal to gaining the competitive advantage among the eight themes listed in Table 2.

These themes provided a framework to answer the overarching question for this research and provided a foundation for recommendations for action and further research. The findings relate to Porter's competitive theory of a firm from the conceptual framework of this study. The implications for positive social change include the potential of reducing unemployment for the local workforce by assisting U.S. IVD organizational leaders in developing strategies to thrive and secure advantages, which could provide the

resources for creating new products and improving employment. The IVD leaders should use effective strategies to improve and retain their business performance, productivity, consumer satisfaction, competitiveness, and company profitability. Conducting the study help me to understand IVD medical leaders' perspectives about competitive advantage and their success in leadership positions.

References

Aagaard, A., & Lindgren, P. (2015). The opportunities and challenges of persuasive technology in creating sustainable innovation and business model innovation. *Wireless Personal Communications*, *81*(4), 1511-1529. doi:10.1007/s11277-015-2484-1

Aagaard, J. (2016, November). Introducing postphenomenological research: A brief and selective sketch of phenomenological research methods. *International Journal of Qualitative Studies in Education*, 1-15. Advance online publication. doi:10.1080/09518398.2016.1263884

Aarikka-Stenroos, L., & Sandberg, B. (2012). From new-product development to commercialization through networks. *Journal of Business Research*, *65*(2), 198-206. doi:10.1016/j.jbusres.2011.05.023

Aghamirian, B., Dorri, B., & Aghamirian, B. (2015). Customer knowledge management application in gaining organization's competitive advantage in electronic commerce. *Journal of Theoretical and Applied Electronic Commerce Research*, *10*, 63-78. doi:10.4067/S0718-18762015000100006

Agnihotri, A. (2015). Extending boundaries of blue ocean strategy. *Journal of Strategic Marketing*, *24*, 519-528. doi:10.1080/0965254x.2015.1069882

Agyapong, A., Ellis, F., & Domeher, D. (2016). Competitive strategy and performance of family businesses: Moderating effect of managerial and innovative capabilities. *Journal of Small Business & Entrepreneurship*, *28*, 449-477. doi:10.1080/08276331.2016.1217727

Akan, O., Allen, R. S., Helms, M. M., & Spralls III, S. A. (2006). Critical tactics for implementing Porter's generic strategies. *Journal of Business Strategy*, *27*(1), 43-53. doi:10.1108/02756660610640173

Al-Ansari, Y., Pervan, S., & Xu, J. (2013). Innovation and business performance of SMES: The case of Dubai. *Education, Business and Society*: *Contemporary Middle East, 6*(3), 162-180. doi:10.1108/EBS-04-2013-0012

Alexy, O., George, G., & Salter, A. I. (2013). Cui bono? The selective revealing of knowledge and its implications for innovative activity. *Academy of Management Review*, *38*, 270-291. doi:10.5465/amr.2011.0193

Algoso, M., Peters, K., Ramjan, L., & East, L. (2016). Adaptation and validation of a survey instrument measuring perceived preparedness of nursing graduates. *Nurse Researcher*, *23*, 37-41. doi:10.7748/nr.2016.e1437

Alguezaui, S., & Filieri, R. (2014). A knowledge-based view of the extending enterprise for enhancing a collaborative innovation advantage. *International Journal of Agile Systems and Management*, *7*(2), 116-131. doi:10.1504/ijasm.2014.061434

Allen, M. D. (2014). Telephone focus groups: Strengths, challenges, and strategies for success. *Qualitative Social Work*, *13*, 571-583. doi:10.1177/1473325013499060

Allied Market Research. (2014). *World in Vitro Diagnostics (IVD) market opportunities and forecasts*, *2013-2020.* Retrieved from https://www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market

Allio, R. J., & Fahey, L. (2012). Joan Magretta: What executives can learn from revisiting Michael Porter. *Strategy & Leadership*, *40*(2), 5-10. doi:10.1108/10878571211209297

Alonso-Almeida, M. Del M., Bremser, K., & Llach, J. (2015). Proactive and reactive strategies deployed by restaurants in times of crisis. *International Journal of Contemporary Hospitality Management*, *27*, 1641-1661. doi:10.1108/ijchm-03-2014-0117

Alteren, G., & Tudoran, A. A. (2016). Enhancing exports performance: Betting on customer orientation, behavioral commitment, and communication. *International Business Review, 25*, 370-381. doi:10.1016/j.ibusrev.2015.07.004

Ameer, R., Othman, R., & Mahzan, N. (2012). Information asymmetry and regulatory shortcomings in profit sharing investment accounts. *International Journal of Islamic and Middle Eastern Finance and Management*, *5*, 371-387. doi:10.1108/17538391211282854

An, X., Deng, H., Chao, L., & Bai, W. (2014). Knowledge management in supporting collaborative innovation community capacity building. *Journal of Knowledge Management*, *18*(3), 574-590. doi:10.1108/jkm-10-2013-0413

Anyan, F. (2013). The influence of power shifts in data collection and analysis stages: A focus on qualitative research interview. *Qualitative Report*, *18*(1), 1-9. Retrieved from http://www.nova.edu

Archibald, M. M. (2016). Investigator triangulation. *Journal of Mixed Methods Research, 10*(3), 228-250. doi:10.1177/1558689815570092

Arora, A., Arora, A., & Sivakumar, K. (2016). Relationships among supply chain strategies, organizational performance, and technological and market turbulences. *International Journal of Logistics Management*, *27*. doi:10.1108/ijlm-09-2013-0103

Arthur, I. K., & Hracs, B. J. (2015). Experience the difference: The competitive strategies of food-related entrepreneurs in rural Denmark. *Geografiska Annaler*: *Series B, Human Geography*, *97*(1), 95–112. doi:10.1111/geob.12067

Autor, D. H., Dorn, D., & Hanson, G. H. (2013). The China syndrome: Local labor market effects of import competition in the United States. *American Economic Review*, *103*(6), 2121-2168. doi:10.1257/aer.103.6.2121

Awasthi, P., & Sangle, P. (2013). The importance of value and context for mobile CRM services in banking. *Business Process Management Journal*, *19*(6), 864–891. doi:10.1108/bpmj-06-2012-0067

Bäck, I., & Kohtamäki, M. (2016). Joint learning in innovative R&D collaboration. *Industry and* Innovation, 23(1), 62–86. doi:10.1080/13662716.2015.1123613

Baekgaard, M., & Serritzlew, S. (2015). Interpreting performance information: Motivated reasoning or unbiased comprehension. *Public Administration Review*, *76*(1), 73–82. doi:10.1111/puar.12406

Barbos, A. (2015). Information acquisition and innovation under competitive pressure. *Journal of Economics & Management Strategy*, *24*, 325-347. doi:10.1111/jems.12096

Bartlett, C. A., & Beamish, P. W. (2014). *Transnational management: Text, cases, and readings in cross-border management* (7th ed.), Boston, MA: McGraw-Hill.

Baumann, C., Elliott, G., & Burton, S. (2012). Modeling customer satisfaction and loyalty: Survey data versus data mining. *Journal of Services Marketing*, *26*(3), 148–157. doi:10.1108/08876041211223951

Bayer, P., Urpelainen, J., & Xu, A. (2014). Explaining differences in sub-national patterns of clean technology transfer to China and India. *International Environmental Agreements: Politics, Law and Economics*, *16*(2), 261–283. doi:10.1007/s10784-014-9257-2

Bayraktar, C. A., Hancerliogullari, G., Cetinguc, B., & Calisir, F. (2017). Competitive strategies, innovation, and firm performance: an empirical study in a developing economy environment. *Technology Analysis & Strategic Management*, *29*(1), 38-52. doi:10.1080/09537325.2016.1194973

Bazeley, P., & Jackson, K. (2013). *Qualitative data analysis with NVivo* (3rd ed.). London, England: Sage.

Beaudreau, B. C. (2016). Competitive and comparative advantage: Towards a unified theory of international trade. *International Economic Journal, 30*(1), 1–18. doi:10.1080/10168737.2015.1136664.

Beh, L.-S., Ghobadian, A., He, Q., Gallear, D., & O'Regan, N. (2016). Second-life retailing: A reverse supply chain perspective. *Supply Chain Management*, *21*(2), 259–272. doi:10.1108/scm-07-2015-0296

Bekhet, Abir K., & Zauszniewski, Jaclene A. (2012). Methodological triangulation: An

approach to understanding data. *Nurse Inquirers*, *20*(2), 40-43. doi:10.7748/nr2012.11.20.2.40. c9442

Bender, A. K. (2016). Ethics, methods, and measures in intimate partner violence research: The current state of the field. *Violence Against Women.* doi:10.1177/1077801216658977

Benia, L. R., Hauck-Filho, N., Dillenburg, M., & Stein, L. M. (2015). The NICHD investigative interview protocol: A meta-analytic review. *Journal of Child Sexual Abuse*, *24*(3), 259–279. doi:10.1080/10538712.2015.1006749

Bennett, J., & Grant, N. S. (2016). Using an ecomap as a tool for qualitative data collection in organizations. *New Horizons in Adult Education and Human Resource Development*, *28*(2), 1–13. doi:10.1002/nha3.20134

Bereznoy, A. (2015). Changing competitive landscape through business model innovation: The new imperative for corporate market strategy. *Journal of the Knowledge Economy*, *3*, 1-22. doi:10.1007/s13132-015-0324-x

Berman, B. (2016). Referral marketing: Harnessing the power of your customers. *Business Horizons*, *59*(1), 19–28. doi:10.1016/j.bushor.2015.08.001

Bevan, S., Baumgartner, F. R., Johnson, E. W., & McCarthy, J. D. (2013). Understanding selection bias, time lags and measurement bias in secondary data sources: Putting the encyclopedia of associations' database in broader context. *Social Science Research, 42*, 1750–1764. doi:10.1016/j.ssresearch.2013.08.003

Binagwaho, A., Nutt, C. T., Mutabazi, V., Karema, C., Nsanzimana, S., Gasana, M., & Farmer, P. E. (2013). Shared learning in an interconnected world: Innovations to

advance global health equity. *Globalization and Health*, *9,* 37. doi:10.1186/1744-8603-9-37

Birt, L., Scott, S., Cavers, D., Campbell, C., & Walter, F. (2016). Member checking: A tool to enhance trustworthiness or merely a nod to validation? *Qualitative Health Research*, *26*, 1802–1811. doi:10.1177/1049732316654870

Black, D., Palombaro, K., & Dole, R. (2013). Student experiences in creating and launching a student-led physical therapy pro bono clinic: A qualitative investigation. *Physical Therapy*, *93*, 637-685. doi:10.2522/ptj.20110430

Boddy, C. R. (2016). Sample size for qualitative research. *Qualitative Market Research*: *An International Journal*, *19*, 426–432. doi:10.1108/qmr-06-2016-0053

Bogers, M., & West, J. (2012). Managing distributed innovation: Strategic utilization of open and user innovation. *Creativity and Innovation management*, *21*(1), 61-75. doi:10.1111/j.1467-8691.2011.00622.x

Borini, F. M., Oliveira Jr., M., Silveira, F. F., & Concer, R. D. (2012). The reverse transfer of innovation of foreign subsidiaries of Brazilian multinationals. *European Management Journal*, *30*(3), 219-231, doi:10.1016/j.emj.2012.03.012.

Boroush, M., and Jankowski, J. (2016). Update on U.S. business innovation: Findings from 2011 Survey. Retrieved from http://www.nsf.gov/statistics/2016/nsf16308/

Bourgeois, L. J. (1980). Performance and consensus. *Strategic Management Journal*, *1*(3), 227–248. doi:10.1002/smj.4250010304

Brem, A., & Ivens, B. (2013). Do frugal and reverse innovation foster sustainability? Introduction of a conceptual framework. *Journal of Technology Management for Growing Economies*, *4*(2), 31-50. Retrieved from http://journal.chitkara.edu.in

Brennan, T. J. (2013). Energy efficiency policy puzzles. *Energy Journal*, *34*(2), 1–25. doi:10.5547/01956574.34.2.1

Brinkmann, S. (2016). Methodological breaching experiments: Steps toward theorizing the qualitative interview. *Culture & Psychology*. doi:10.1177/1354067x16650816

Breznik, L., & D. Hisrich, R. (2014). Dynamic capabilities vs. innovation capability: Are they related? *Journal of Small Business and Enterprise Development, 21*, 368–384. doi:10.1108/jsbed-02-2014-0018

Broadhurst, K. (2015). Qualitative interview as special conversation. *Qualitative Social Work*, *14*, 301–306. doi:10.1177/1473325015578501

Brouwer, H., Stegeman, J. A., Straatsma, J. W., Hooijer, G. A., & Schaik, G. (2015). The validity of a monitoring system based on routinely collected dairy cattle health data relative to a standardized herd check. *Preventive Veterinary Medicine*, *122*, 76–82. doi:10.1016/j.prevetmed.2015.09.009

Browning, P., & Rowell, T. (2015). EU membership and UK medical device innovation. *British Journal of Healthcare Management*, *21*, 518–522. doi:10.12968/bjhc.2015.21.11.518

Boyer, P., Morshed, B. I., & Mussivand, T. (2015). Medical device market in China. *Artificial Organs*, *39*, 520–525. doi:10.1111/aor.12427

Bucherer, E., Eisert, U., & Gassmann, O. (2012). Towards systematic business model innovation: Lessons from product innovation management. *Creativity and Innovation Management*, *21*, 183-198. doi:10.1111/j.1467-8691.2012.00637.x

Buchanan, W. L. (2013). *Exploring sustainability: The key to corporate profitability in the 21st century* (Doctoral dissertation). Retrieved from ProQuest Dissertations and Theses database. (UMI No. 3604426)

Çakır, H., & Cengiz, Ö. (2016). The use of open ended versus closed ended questions in turkish classrooms. *Open Journal of Modern Linguistics*, 6(2), 60–70. doi:10.4236/ojml.2016.62006

Cambon, L., Minary, L., Ridde, V., & Alla, F. (2012). Transferability of interventions in health education: A review. *BioMed Central Public Health*, *12*, 497. doi:10.1186/1471-2458-12-497

Carayannis, E. G., Sindakis, S., & Walter, C. (2014). Business model innovation as lever of organizational sustainability. *The Journal of Technology Transfer*, *40*(1), 85–104. doi:10.1007/s10961-013-9330-y

Carroll, W., & Huxtable, D. (2014). Expose / oppose / propose: The Canadian centre for policy alternatives and the challenge of alternative knowledge. *Labour / Le Travail*, *74*, 27-50. Retrieved from http://muse.jhu.edu

Castleberry, A. (2014). NVivo 10 [software program]. Version 10. QSR International; 2012. *American Journal of Pharmaceutical E*ducation, *78*(1), 25. doi:10.5688/ajpe78125

Castillo-Apraiz, J., & Matey, J. (2015, June). Effect of competitive tactics on performance: The case of the pharmaceutical industry. Proceedings of the 2nd International Symposium on Partial Least Squares Path Modeling, Seville, Spain. Retrieved from http://proceedings.utwente.nl/333/1/UsePLS_2015_submission_54.pdf

Castillo-Montoya, M. (2016). Preparing for interview research: The interview protocol refinement framework. *Qualitative Report*, *21*, 5, 811-831. Retrieved from http://nsuworks.nova.edu/tqr/vol21/iss5/2

Chahal, H., & Bakshi, P. (2015). Examining intellectual capital and competitive advantage relationship: Role of innovation and organizational learning. *International Journal of Bank Marketing*, *33*, 376-399. doi:10.1108/IJBM-07-2013-0069

Charach, A., Yeung, E., Volpe, T., Goodale, T., & dosReis, S. (2014). Exploring stimulant treatment in ADHD: Narratives of young adolescents and their parents. *BioMed Central Psychiatry*, *14*, 110. doi:10.1186/1471-244X-14-110

Chao, C. A., & Chandra, A. (2012). Impact of owner's knowledge of information technology (IT) on strategic alignment and IT adoption in U.S. small firms. *Journal of Small Business and Enterprise Development, 19*(1), 114-131. doi:10.1108/14626001211196433

Chang, L. C. (2012). Subcultural differences in Taiwanese and Burmese Chinese business negotiation styles. *Social Behavior and Personality*, *40*, 1067-1074. doi:10.2224/sbp.2012.40.7.1067

Chen, V. Z., Li, J., & Shapiro, D. M. (2012). International reverse spillover effects on parent firms: Evidences from emerging-market MNEs in developed markets. *European Management Journal, 30*(3), 204-218, doi:10.1016/j.emj.2012.03.005

Cheung, Y.-L., Kong, D., Tan, W., & Wang, W. (2015). Being good when being international in an emerging economy: The case of China. *Journal of Business Ethics*, *130*, 805–817. doi:10.1007/s10551-014-2268-7

Chittoor, R., & Aulakh, P. S. (2015). Organizational landscape in India: Historical development, multiplicity of forms and implications for practice and research. *Long-Range Planning*, *48*, 291-300, doi:10.1016/j.lrp.2015.07.005

Chiu, M. C., & Chiou, J. Y. (2016). Technical service platform planning based on a company's competitive advantage and future market trends: A case study of an IC foundry. *Computers & Industrial Engineering*. doi:10.1016/j.cie.2016.02.019

Choe, P., Tew, J. D., & Tong, S. (2015). Effect of cognitive automation in a material handling system on manufacturing flexibility. *International Journal of Production Economics*, *170*, 891–899. doi:10.1016/j.ijpe.2015.01.018

Chougule, R., Khare, V. R., & Pattada, K. (2013). A fuzzy logic based approach for modeling quality and reliability related customer satisfaction in the automotive domain. *Expert Systems With Applications*, *40*, 800-810. doi:10.1016/j.eswa.2012.08.032

Chowdhury, M. F. (2015). Coding, sorting and sifting of qualitative data analysis: debates and discussion. Quality & quantity. *International Journal of Methodology*, *49*(3), 1135-1143. doi:10.1007/s11135-014-0039-2

Chuang, S. H., & Lin, H. N. (2015). Co-creating e-service innovations: Theory, practice, and impact on firm performance. *International Journal of Information Management*, *35*(3), 277-291. doi:10.1016/j.ijinfomgt.2015.01.002

Cleary, M., Horsfall, J., & Hayter, M. (2014). Qualitative research: Quality results? *Journal of Advanced Nursing*, *70*, 711–713. doi:10.1111/jan.12172

Coenen, M., Stamm, T., Stucki, G., & Cieza, A. (2012). Individual interviews and focus groups in patients with rheumatoid arthritis: a comparison of two qualitative methods. *Quality of Life Research*, *21*, 359-70. doi:10.1007/s11136-011-9943-2

Congressional Research Service (2015). The medical device excise tax: Economic analysis. Retrieved from https://fas.org/sgp/crs/misc/R43342.pdf

Contractor, F. J., Kumar, V., & Dhanaraj, C. (2015). Leveraging India: Global interconnectedness and locational competitive advantage. *Management International Review*, *55*(2), 159-179. doi:10.1007/s11575-015-0239-6

Corsi, S., & Di Minin, A. (2014). Disruptive innovation ... in reverse: Adding a geographical dimension to disruptive innovation theory. *Creativity & Innovation Management*, *23*, 76-90. doi:10.1111/caim.12043

Corsi, S., Di Minin, A., & Piccaluga, A. (2014). Reverse innovation at Speres: A case study in China. *Research Technology Management*, *57*(4), 28-34. doi:10.5437/08956308X5704215

Damianakis, T., & Woodford, M. R. (2012). Qualitative research with small connected communities: Generating new knowledge while upholding research ethics. *Qualitative Health Research*, *22*, 708–718. doi:10.1177/1049732311431444

Damijan, J. P., & Kostevc, Č. (2014). Learning from Trade through Innovation. *Oxford Bulletin of Economics and Statistics*, *77*, 408–436. doi:10.1111/obes.12071

Daniela, P. A. (2014). Competitive advantage in the enterprise performance. Annals of the University of Oradea, Economic Science Series. Retrieved from http://steconomiceuoradea.ro/anale/volume/2014/n1/055.pdf

Davcik, N. S., & Sharma, P. (2015). Impact of product differentiation, marketing investments and brand equity on pricing strategies: A brand level investigation. *European Journal of Marketing*, *49*, 760-781. doi:0.1108/EJM-03-2014-0150

Davey, K. S., & Sanders, T. J. (2012). Serial strategic innovation and sustainable competitive advantage: A longitudinal case study. *Journal of Case Research in Business and Economics*, *4*, 1-19. Retrieved from http://www.aabri.com/jcrbe.html

Davis-Kean, P. E., Jager, J., & Maslowsky, J. (2015). Answering developmental questions using secondary data. *Child Development Perspectives*, *9*(4), 256–261. doi:10.1111/cdep.12151

De, C. T., Kusumastuti, D., Hannes, E., Janssens, D., & Wets, G. (2013). Mapping leisure shopping trip decision making: validation of the CNET interview protocol. *Quality & Quantity* : *International Journal of Methodology*, *47*, 1831-1849. doi:10.1007/s11135-011-9629-4

DeJean, D., Giacomini, M., Simeonov, D., & Smith, A. (2016). Finding qualitative research evidence for health technology assessment. *Qualitative Health Research*, *26*, 1307–1317. doi:10.1177/1049732316644429

De Medeiros Albano, F., & Caten, C. S. ten. (2016). Analysis of the relationships between proficiency testing, validation of methods and estimation of measurement uncertainty: a qualitative study with experts. *Accreditation and Quality Assurance*, *21*, 161–166. doi:10.1007/s00769-016-1194-z

DePasse, J. W., & Lee, P. T. (2013). A model for "reverse innovation" in health care. *Globalization and Health, 9*(1), 1-7. doi:10.1186/1744-8603-9-40.

Dereli, D. D. (2015). Innovation management in global competition and competitive advantage. *Procedia-Social and Behavioral Sciences*, *195*, 1365-1370. doi:10.1016/j.sbspro.2015.06.323

Di, M. G., & Tomarchio, O. (2015). Matching the business perspectives of providers and customers in future cloud markets. *Cluster Computing*: *the Journal of Networks, Software Tools and Applications*, *18*(1), 457–475. doi:10.1007/s10586-014-0364-1

Dobbs, M. E. (2014). Guidelines for applying Porter's five forces framework: A set of industry analysis templates. *Competitiveness Review*, *24*, 32–45. doi:10.1108/CR-06-2013-0059

Drabble, L., Trocki, K. F., Salcedo, B., Walker, P. C., & Korcha, R. A. (2015). Conducting qualitative interviews by telephone: Lessons learned from a study of

alcohol use among sexual minority and heterosexual women [Advanced online publication]. *Qualitative Social Work*. doi:10.1177/1473325015585613

Duan, N., Bhaumik, D. K., Palinkas, L. A., & Hoagwood, K. (2015). Optimal design and purposeful sampling: Complementary methodologies for implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*, 524-532. doi:10.1007/s10488-014-0596-7

Dugan, M. K. (2009). *The furniture wars. How America lost a fifty billion dollar industry*. Conover, NC: Goosepen Press.

Dwarswaard, J., & van de Bovenkamp, H. (2015). Self-management support: A qualitative study of ethical dilemmas experienced by nurses. *Patient Education and Counseling*, *98*, 1131–1136. doi:10.1016/j.pec.2015.05.017

Egbetunde, T., & Akinlo, A. E. (2015). Financial globalization and economic growth in sub-saharan Africa: Evidence from panel cointegration tests. *African Development Review*, *27*, 187–198. doi:10.1111/1467-8268.12140

Elliott, K. C. (2013). Financial conflicts of interest and criteria for research credibility. *Erkenntnis*, *79*, 917–937. doi:10.1007/s10670-013-9536-2

Elo, S., Kaariainen, M., Kanste, O., Polkki, T., Utriainen, K., & Kyngas, H. (2014). Qualitative content analysis: A focus on trustworthiness. *SAGE Open*, *4*, 1-10. doi:10.1177/2158244014522633

Ersun, A. N., & Karabulut, A. T. (2013). Innovation management and marketing in global enterprises. *International Journal of Business and Management*, 8, 76. doi:10.5539/ijbm.v8n20p76

Euramet (2015). *Final publishable JRP summary for JRP hlt08 infect-met metrology for monitoring infectious diseases, antimicrobial resistance*, *and harmful microorganisms.* Retrieved from www.euramet.org

Evans, N. G. (2016). Sustainable competitive advantage in tourism organizations: A strategic model applying service dominant logic and tourism's defining characteristics. *Tourism Management Perspectives*, *18*, 14-25. doi:10.1016/j.tmp.2015.12.015

Evanschitzky, H., Eisend, M., Calantone, R. J., & Jiang, Y. (2012). Success factors of product innovation: An updated meta-analysis. *Journal of Product Innovation Management*, *29*, 21–37. doi:10.1111/j.1540-5885.2012.00964.x

Export. Gov. (2014). *Medica 2014: USDOC business center, Showcase global and exhibitor outreach event.* Retrieved from https://new.export.gov/countries/DE/trade-events/618498

Fernandez, A. V. (2016, May). The subject matter of phenomenological research: Existentials, modes, and prejudices. *Synthese*, 1-20. Advance online publication. doi:10.1007/s11229-016-1106-0

Fielding, N. G. (2014). Qualitative research and our digital futures. *Qualitative Inquiry, 20*, 1064–1073. doi:10.1177/1077800414545237

Foe Owono, G. D. (2015). *Impact of EU medical device directive on medical device software* (Doctoral dissertation). Available from ProQuest Dissertations and Theses database. (UMI No. 3686509)

Fraj, E., Matute, J., & Melero, I. (2015). Environmental strategies and organizational competitiveness in the hotel industry: The role of learning and innovation as determinants of environmental success. *Tourism Management*, *46*, 30–42. doi:10.1016/j.tourman.2014.05.009

Frels, R. K., & Onwuegbuzie, A. J. (2013). Administering quantitative instruments with qualitative interviews: A mixed research approach. *Journal of Counseling & Development*, *91*(2), 184–194. doi:10.1002/j.1556-6676.2013.00085.x

Fusch, P. I., & Ness, L. R. (2015). Are we there yet? Data saturation in qualitative research. Retrieved from http://www.nova.edu/ssss/QR/QR20/9/fusch1.pdf

Gallo, P. R., Muylaert, C. J., Neto, M. L. R., Reis, A. O. A., & Sarubbi, J. V. (2014). Narrative interviews: an important resource in qualitative research. *Revista Da Escola De Enfermagem Da Usp*, *48,* 184-189. doi:10.1590/s0080-623420140000800027

Gammeltoft, P., Filatotchev, I., & Hobdari, B., (2012). Emerging multinational companies and strategic fit: A contingency framework and future research agenda. *European Management Journal*, *30*, 175-188. doi:10.1016/j.emj.2012.03.007

Gao, C., Wang, Y., Su, M., Zhang, L., Song, X., & Yu, J. (2015). A dual functional analytical device for self-powered point of care testing and electric energy storage. *Chemical Communication*, *51*, 9527–9530. doi:10.1039/c5cc01283j

Geist, K., & Hitchcock, J. H. (2014). Single case design studies in music therapy: Resurrecting experimental evidence in small group and individual music therapy clinical settings. *Journal of Music Therapy*, *51*, 293-309. doi:10.1093/jmt/thu032

Gelling, L. (2015). Qualitative research. *Nursing Standard*, *29*, 43–47. doi:10.7748/ns.29.30.43.e9749

Ghosal, V. (2015). Business strategy and firm reorganization: role of changing environmental standards, sustainable business initiatives and global market conditions. *Business Strategy and the Environment*, *24*, 123-144. doi:10.1002/bse.1815

Giessmann, A., & Legner, C. (2016). Designing business models for cloud platforms. *Information Systems Journa*l, *26*, 551-579. doi:10.1111/isj.12107

Green, C. A., Duan, N., Gibbons, R. D., Hoagwood, K. E., Palinkas, L. A., & Wisdom, J. P. (2014). Approaches to mixed methods dissemination and implementation research: Methods, strengths, caveats, and opportunities. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*, 508–523. doi:10.1007/s10488-014-0552-6

Gobble, M. M. (2015). Resources: Managing customers. *Research-Technology Management*, *58*, 64–67. doi:10.5437/08956308x5805005

Goldberg, A. E., & Allen, K. R. (2015). Communicating qualitative research: Some practical guideposts for scholars. *Journal of Marriage and Family*, *77*(1), 3–22. doi:10.1111/jomf.12153

Goldin, I. M., Pinkus, R. L., & Ashley, K. (2015). Validity and reliability of an instrument for assessing case analyses in bioengineering ethics education. *Science and Engineering Ethics*, *21*, 789-807. doi:10.1007/s11948-015-9644-2

Gottschalk, P. (2016). Knowledge management in private investigations of white-collar crime. *Information Resources Management Journal*, *29*(1), 1–14. doi:10.4018/irmj.2016010101

Govindarajan, V., & Euchner, J. (2012). Reverse innovation. *Research Technology Management*, *55*, 13-17. doi:10.5437/08956308X5506003

Govindarajan, V. & Trimble, C. (2012). Reverse innovation: A global growth strategy that could pre-empt disruption at home. *Strategy & Leadership*, *40*, 5-11. doi:10.1108/10878571211257122

Gupta, S., & Polonsky, M. (2014). Inter-firm learning and knowledge-sharing in multinational networks: An outsourced organization's perspective. *Journal of Business Research*, *67*, 615-622. doi:10.1016/j.jbusres.2013.02.043

Gurman, T. A., Ballard, A., Kerr, S., Walsh, J., & Petrocy, A. (2015). Waking up the mind: Qualitative study findings about the process through which programs combining income generation and health education can empower indigenous Guatemalan women. *Health Care for Women International*, *37*, 325–342. doi:10.1080/07399332.2015.1005306

Haarbrandt, B., & Marschollek, M. (2016). Modeling and integration of intensive care data into an open EHR-based enterprise data warehouse. *Current Therapeutic Research*, *78*, S8–S9. doi:10.1016/j.curtheres.2016.05.019

Habtay, S. R. (2013). A firm-level analysis on the relative difference between technology-driven and market-driven disruptive business model innovations. *Creativity and Innovation Management*, *21*, 290–303. doi:10.1111/j.1467-8691.2012.00628.x

Hadi, W. (2015). The relationship between CRM strategies stage on competitive advantage: An analytical perspective. *International Journal of Business and Management*, *10*(8), 245. doi:10.5539/ijbm.v10n8p245

Hajli, N., & Sims, J. (2015). Social commerce: The transfer of power from sellers to buyers. *Technological Forecasting and Social Change*, *94*, 350–358. doi:10.1016/j.techfore.2015.01.012

Hall, J., Matos, S. V., & Martin, M. J. C. (2014). Innovation pathways at the base of the pyramid: Establishing technological legitimacy through social attributes. *Technovation*, *34*, 284–294. doi:10.1016/j.technovation.2013.12.003

Hana, U. (2013). Competitive advantage achievement through innovation and knowledge. *Journal of Competitiveness*, *5*, 82-96. doi:10.7441/joc.2013.01.06

Hanaysha, J. (2016). The importance of social media advertisements in enhancing brand equity: A study on fast food restaurant industry in Malaysia. *International Journal of Innovation*, *Management and Technology, 7*, 46. doi:10.5296/ber.v6i1.9352

Handoko, B. L., Aryanto, R., & So, I. G. (2015). The impact of enterprise resources system and supply chain practices on competitive advantage and firm performance: Case of Indonesian companies. *Procedia Computer Science*, *72,* 122–128. doi:10.1016/j.procs.2015.12.112

Hanssens, L. G., Devisch, I., Lobbestael, J., Cottenie, B., & Willems, S. (2016). Accessible health care for Roma: A gypsy's tale a qualitative in-depth study of access to health care for Roma in Ghent. *International Journal for Equity in Health*, *15*(1), 1. doi:10.1186/s12939-016-0327-7

Harpaz, M. D. (2016). China's coherence in international economic governance. *Journal of Chinese Political Science*, *21*, 123–147. doi:10.1007/s11366-016-9400-8

Harper, M., & Cole, P. (2012). Member checking: Can benefits be gained similar to group therapy? *The Qualitative Report*, *17*, 510-517. Retrieved from http://www.nova.edu

Harnett, J. D., & Neuman, R. (2015). Research ethics for clinical researchers. *Clinical Epidemiology*, 19–30. doi:10.1007/978-1-4939-2428-8_2

Harrison, R. L. III. (2013). Using mixed methods designs in the *Journal of Business Research*, 1990-2010. *Journal of Business Research*, *66*, 2153-2162. doi:10.1016/j.jbusres.2012.01.006

Harvey, L. (2014). Beyond member-checking: a dialogic approach to the research interview. *International Journal of Research & Method in Education*, *38*(1), 23–38. doi:10.1080/1743727x.2014.914487

Hasani, A., & Khosrojerdi, A. (2016). Robust global supply chain network design under disruption and uncertainty considering resilience strategies: A parallel memetic algorithm for a real-life case study. *Transportation Research Part E: Logistics and Transportation Review*, *87*(1), 20–52. doi:10.1016/j.tre.2015.12.009

Hashimov, E. (2014). Qualitative data analysis: A methods sourcebook and the coding manual for qualitative researchers. *Technical Communication Quarterly*, *24*(1), 109-112. doi:10.1080/10572252.2015.975966

Hayman, B., Wilkes, L., & Jackson, D. (2012). Journaling: Identification of challenges and reflection on strategies. *Nurse inquirers*, *19*, 27-31. doi:10.7748/nr2012.04.19.3.27.c9056

Hays, D. G., Wood, C., Dahl, H., & Kirk-Jenkins, A. (2016). Methodological rigor in journal of counseling & development qualitative research articles: A 15-year review. *Journal of Counseling & Development*, *94,* 172-183. doi:10.1002/jcad.12074

Hazen, B. T., & Byrd, T. A. (2012). Toward creating competitive advantage with logistics information technology. *International Journal of Physical Distribution & Logistics Management*, *42*(1), 8–35. doi:10.1108/09600031211202454

Hendrik, S. H., Ludwig, F., Rohr Ulrich, P., Laubender Ruediger, P., Thomas, D., & Roger, M. (2015). Medical value as a new strategy to increase corporate viability: Market chances and limitations in the diagnostic industry. *Journal of Entrepreneurship & Organization Management*, *4*, 131. doi:10.4172/2169-026X.1000131

Hill, T. L. & Mudambi, R. (2010). Far from Silicon Valley: How emerging economies are re-shaping our understanding of global entrepreneurship. *Journal of International Management*, *16*, 321-327. doi:10.1016/j.intman.2010.09.003

Hoffman, A. J., Corbett, C. J., Joglekar, N., & Wells, P. (2014). Industrial Ecology as a Source of Competitive Advantage. *Journal of Industrial Ecology*, *18*, 597–602. doi:10.1111/jiec.12196

Holslag, J. (2015). Geoeconomics in a globalized world: The case of China's export policy. *Asia Europe Journal*, *14*, 173–184. doi:10.1007/s10308-015-0441-y

Holtzman, Y., Ganz, M., & Gorkhover, G. (2015). The state of the U.S. MedTech industry. Retrieved from http://www.anchin.com/admin/Upload/Document/MDDI_2015-01_LS.pdf

Hope, D., & Dewar, A. (2015). Conducting quantitative educational research: A short guide for clinical teachers. *The Clinical Teacher*, *12*, 299–304. doi:10.1111/tct.12457

Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigour in qualitative case-study research. *Nurse Inquirers*, *20*, 12-19. doi:10.7748/nr2013.03.20.4.12.e326

Hsu, C.-C., Tan, K.-C., & Mohamad Zailani, S. H. (2016). Strategic orientations, sustainable supply chain initiatives, and reverse logistics. *International Journal of Operations & Production Management*, *36*(1), 86–110. doi:10.1108/ijopm-06-2014-0252

Hu, J., Torr, J., & Whiteman, P. (2014). Australian Chinese parents' language attitudes and practices relating to their children's bilingual development prior to school. *Journal of Early Childhood Research*, *12*, 139–153. doi:10.1177/1476718X13515429

Huang, H. H., & Chung, T. T. (2016). Building competitive advantages and restructure resources: A case of Taiwan's exhibition industry. *International Journal of Organizational Innovation (Online)*, *8*, 112. Retrieved from ijoi-online.org

Huang, S. K., Kuo, L., & Chou, K.-L. (2016). The applicability of marginal abatement cost approach: A comprehensive review. *Journal of Cleaner Production, 127*, 59–71. doi:10.1016/j.jclepro.2016.04.013

Hudson, K. L., & Collins, F. S. (2015). Bringing the Common Rule into the 21st century. *New England Journal of Medicine*, *373*, 2293–2296. doi:10.1056/nejmp1512205

Huggins, R., & Izushi, H. (2015). The Competitive Advantage of Nations: origins and journey. *Competitiveness Review*, *25*, 458-470. doi:10.1108/CR-06-2015-0044

Huo, B., Zhao, X., & Zhou, H. (2013). The effects of competitive environment on supply chain information sharing and performance: An empirical study in China. *Production and Operations Management*, *23*, 552–569. doi:10.1111/poms.12044

Idi, D. B., & Khaidzir, K. A. B. M. (2015). Concept of creativity and innovation in architectural design process. *International Journal of Innovation*, *Management and Technology*, *6*(1), 16. doi:10.7763/ijimt.2015.v6.566

International Trade Administration. (2012). *Protecting your intellectual property rights (IPR) in China*. Retrieved from http://export.gov/China/doingbizinchina/riskmanagement/ipr/index.asp

International Trade Administration. (2016). *2016 Top markets report: Medical devices*. Retrieved from http://trade.gov

Isaksson, R., Garvare, R., Johnson, M., Kuttainen, C., & Pareigis, J. (2015). Sustaining Sweden's competitive position: Lean lifelong learning. *Measuring Business Excellence*, *19*(1), 92-102. doi:10.1108/MBE-11-2014-0045

Isaacs, D. (2016). Qualitative research. *Journal of Paediatrics and Child Health*, *52*, 911–911. doi:10.1111/jpc.13334

Ito, K., & Shimizu, J. (2015). Industry-level competitiveness, productivity and effective exchange rates in East Asia. *Asian Economic Journal*, *29*, 181–214. doi:10.1111/asej.12054

IVD Australia. (2016). Australian in-vitro diagnostic market report 2014. http://www.ivd.org.au/files/5614/5670/4013/IVD_Australia_Market_Statistics_Report_2013-2014.pdf

Jacob, S. A., & Furgerson, S. P. (2012). Writing interview protocols and conducting interviews: Tips for students new to the field of qualitative research. *Qualitative Report*, *17*(42), 1–10. Retrieved from http://www.nova.edu/ssss/QR/index.html

Janvier -James, A. (2012). A new introduction to supply chains and supply chain management: Definitions and theories perspective. *International Business Research*, *5*(1), 194-207. doi:10.5539/ibr.v5n1p194

Javalgi, Benoy Joseph, Granot, & Gross(2013). Strategies for sustaining the edge in offshore outsourcing of services: The case of India. *Journal of Business & Industrial Marketing*, *28*, 475–486. doi:10.1108/jbim-04-2013-0103

Jayashree, S., Marthandan, G., & Yang, X. (2012). Ideal types of strategic innovation an exploratory study of Chinese cosmetic industry. *International Journal of Business and Management*, *7*, 78-87. doi:10.5539/ijbm.v7n17p78

Jefferies, M., Brewer, G. J., & Gajendran, T. (2014). Using a case study approach to identify critical success factors for alliance contracting. *Engineering, Construction and Architectural Management*, *21*(5), 465–480. doi:10.1108/ECAM-01-2012-0007

Josiassen, A., Assaf, A. G., & Cvelbar, L. K. (2014). CRM and the bottom line: Do all CRM dimensions affect firm performance? *International Journal of Hospitality Management*, *36*, 130-136. doi:10.1016/j.ijhm.2013.08.005

Jovanović, Ž., & Petrović, D. (2015). Implications of redesigning the global pharmaceutical industry on the Serbian market. *Management*, *74*(1), 1-12. doi:10.7595/management.fon.2015.0001

Judson, E. P., & Maller, C. (2014). Housing renovations and energy efficiency: Insights from homeowners' practices. *Building Research & Information*, *42*, 501-511. doi:10.1080/09613218.2014.894808

Kaliappen, N., & Hilman, H. (2014). Does service innovation act as a mediator in differentiation strategy and organizational performance nexus? An empirical study. *Asian Social Science*, *10*, 123. doi:10.5539/ass.v10n11p123

Kalkan, A., Bozkurt, Ö. Ç., & Arman, M. (2014). The impacts of intellectual capital, innovation and organizational strategy on firm performance. *Procedia - Social and Behavioral Sciences*, *150*, 700–707. doi:10.1016/j.sbspro.2014.09.025

Kapoor, R., & Adner, R. (2012). What firms make vs. what they know: how firms' production and knowledge boundaries affect competitive advantage in the face of technological change. *Organization Science*, *23*, 1227-1248. doi:10.1287/orsc.1110.0686

Kemparaj, U., & Chavan, S. (2013). Qualitative research: A brief description. *Indian Journal of Medical Sciences*, *67*, 89. doi:10.4103/0019-5359.121127

Kennon, D., & Schutte, C. S. L. (2015). A strategic framework for improbable circumstances. *The South African Journal of Industrial Engineering*, *26*, 68. doi:10.7166/26-2-977

Kenyon, G. N., Meixell, M. J., & Westfall, P. H. (2016). Production outsourcing and operational performance: An empirical study using secondary data. *International Journal of Production Economics, 171*, 336-349. doi:10.1016/j.ijpe.2015.09.017

Kharabsheh, R. A., Jarrar, K., & Simeonova, B. (2015). The impact of competitive strategies on responsive market orientation, proactive market orientation, learning orientation and organizational performance. *Journal of Strategic Marketing*, *23*, 423-435. doi:10.1080/0965254X.2014.970217

Kibbeling, M., der, B. H., & Weele, A. (2013). Market orientation and innovativeness in supply chains: Supplier's impact on customer satisfaction. *Journal of Product Innovation Management*, *30*, 500-515. doi: 10.1111/jpim.12007

Kim, M. K., Wong, S. F., Chang, Y., & Park, J. H. (2016). Determinants of customer loyalty in the Korean smartphone market: Moderating effects of usage

characteristics. *Telematics and Informatics*, *33*, 936-949. doi:10.1016/j.tele.2016.02.006

Klonoski, R. (2013). The case for case studies: Deriving theory from evidence. *Journal of Business Case Studies*, *9*, 261-266. doi:10.19030/jbcs.v9i3.7805

Koch, A. H. (2012). Authority and managing innovation: A typology of product development teams and communities. *Creativity & Innovation Management*, *21*, 376-387. doi:10.1111/caim.12001

Kodama, M., & Shibata, T. (2013). Strategy transformation through strategic innovation capability: A case study of Fanuc. *R&D Management*, *44*(1), 75–103. doi:10.1111/radm.12041

Kokkoris, M. D., & Kühnen, U. (2015). The need to have an opinion as a driver of consumer choice. *Journal of Consumer Behaviour*, *14*, 92-102. doi:10.1002/cb.1502

Konradsen, H., Kirkevold, M., & Olson, K. (2013). Recognizability: A strategy for assessing external validity and for facilitating knowledge transfer in qualitative research. *Advances in Nursing Science*, *36*, E66-76. doi:10.1097/ANS.0b013e318290209d

Koveos, P. (2013). Reverse innovation: The international opportunity. *Journal of Developmental Entrepreneurship*, *18*, 1301001. doi:10.1142/s1084946713010012

Kramer, D. B., Xu, S., & Kesselheim, A. S. (2012). Regulation of medical devices in the United States and European Union. *The New England Journal of Medicine*, *366*, 848–855. doi:10.1056/nejmhle1113918

Kuester, S., Feurer, S., Schuhmacher, M. C., & Reinartz, D. (2015). Comparing the incomparable? How consumers judge the price fairness of new products. *International Journal of Research in Marketing*, *32*, 272–283. doi:10.1016/j.ijresmar.2014.09.006

Lai, K., Yeung, A. C. L., & Cheng, T. C. E. (2012). Configuring quality management and marketing implementation and the performance implications for industrial marketers. *Industrial Marketing Management*, *41*, 1284–1297. doi:10.1016/j.indmarman.2012.07.003

Law, R., Buhalis, D., & Cobanoglu, C. (2014). Progress on information and communication technologies in hospitality and tourism. *International Journal of Contemporary Hospitality Management*, *26*, 727-750. doi:10.1108/IJCHM-08-2013-0367

Leavy, B. (2014). India: MNC strategies for growth and innovation. *Strategy & Leadership*, *42*, 30-39. doi:10.1108/SL-01-2014-0002

Le Bas, C., Mothe, C., & Nguyen, T. U. (2015). The differentiated impacts of organizational innovation practices on technological innovation persistence. *European Journal of Innovation Management*, *18*(1), 110-127. doi:10.1108/EJIM-09-2012-0085

Lechevalier, S. (2015). Globalization and labor market outcomes: De-industrialization, job security, and wage inequalities—introduction by guest editor. *Review of World Economics*, *151*, 405–408. doi:10.1007/s10290-015-0222-0

Lee, K., Madanoglu, M., & Ko, J.-Y. (2013). Developing a competitive international service strategy: A case of international joint venture in the global service industry. *Journal of Services Marketing*, *27*, 245–255. doi:10.1108/08876041311330735

Leedy, P. D., & Ormrod, J. E. (2013). *Practical research: Planning and design* (10th ed.). Upper Saddle River, NJ: Pearson Education.

Leighter, J. L., Rudnick, L., & Edmonds, T. J. (2013). How the ethnography of communication provides resources for design. *Journal of Applied Communication Research*, *41*, 209–215. doi:10.1080/00909882.2013.782419

Leligdon, L., Quinn, T., & Briggs, L. (2015). Strategic CRM: Improving the business of academic libraries. *College & Undergraduate Libraries*, *22*, 247–260. doi:10.1080/10691316.2015.1067662

Leonardi, P. M. (2015). Ambient awareness and knowledge acquisition: Using social media to learn "who knows what" and "who knows whom." *MIS Quarterly, 39*, 747-762. Retrieved from http://aisel.aisnet.org/misq/vol39/iss4/11/

LePeau, L. A., Morgan, D. L., Zimmerman, H. B., Snipes, J. T., & Marcotte, B. A. (2016). Connecting to get things done: A conceptual model of the process used to respond to bias incidents. *Journal of Diversity in Higher Education*, *9*, 113–129. doi:10.1037/a0039509

Lesser, E., & Ban, L. (2016). How leading companies practice software development and delivery to achieve a competitive edge. *Strategy & Leadership*, *44*(1), 41-47. doi:10.1108/SL-11-2015-0083

Levinson, M. (2017). U.S. manufacturing in international perspective. Retrieved from https://fas.org/sgp/crs/misc/R42135.pdf

Lew, S., Maizatul, A.I., & Yuen, Y., (2015). Information infrastructure capability and organizational competitive advantage. *International Journal of Operations & Production Management*, *35*, 1032–1055. doi:10.1108/IJOPM-12-2013-0553

Lewis, S. (2015). Qualitative inquiry and research design: Choosing among five approaches. *Health Promotion Practice*, *16*, 473–475. doi:10.1177/1524839915580941

Li, H., Zhang, Y., & Lyles, M. (2013). Knowledge spillovers, search, and creation in China's emerging market. *Management & Organization Review*, *9*, 395-412. doi:10.1111/more.12036

Li, J., & Oh, C. H. (2016). Research on emerging-market multinational enterprises: Extending Alan Rugman's critical contributions. *International Business Review*, *25*, 776–784. doi:10.1016/j.ibusrev.2016.01.017

Li, W., & Jia, Z. (2016). Carbon tax, emission trading, or the mixed policy: Which is the most effective strategy for climate change mitigation in China? *Mitigation and Adaptation Strategies for Global Change*, 1-20. doi:10.1007/s11027-016-9710-3

Liao, T., & Yu, C. J. (2013). The impact of local linkages, international linkages, and absorptive capacity on innovation for foreign firms operating in a merging economy. *Journal of Technology Transfer*, *38*, 809-827. doi:10.1007/s10961-012-9265-8

Lii, P., & Kuo, F.-I. (2016). Innovation-oriented supply chain integration for combined competitiveness and firm performance. *International Journal of Production Economics*, *174*, 142–155. doi:10.1016/j.ijpe.2016.01.018

Lin, C., & Chang, C.-C. (2015). The effect of technological diversification on organizational performance: An empirical study of S&P 500 manufacturing firms. *Technological Forecasting and Social Change*, *90*, 575–586. doi:10.1016/j.techfore.2014.02.014

Lin, R.-J., Tan, K.-H., & Geng, Y. (2013). Market demand, green product innovation, and firm performance: evidence from Vietnam motorcycle industry. *Journal of Cleaner Production*, *40*, 101–107. doi:10.1016/j.jclepro.2012.01.001

Lindner, D., & Senn, C. (2015). Fit for global customers: How ALTANA mastered the journey to a customer-centric organization. *Journal of Business Strategy*, *36*, 3–10. doi:10.1108/jbs-08-2014-0088

Ling, L. S., Tee, O. P., & Eze, U. C. (2014). Conceptualizing knowledge management and information infrastructure capability for competitive advantage: A Malaysian perspective. *Journal of Global Information Technology Management*, *17*, 117-138. doi:10.1080/1097198x.2014.930285

Liu, X., Lu, J., & Choi, S. (2014). Bridging knowledge gaps: Returnees and reverse Knowledge spillovers from Chinese local firms to foreign firms. *Management International Review*, *54*, 253-276. doi:10.1007/s11575-013-0185-0

Lloyd, A. E., Chan, R. Y. K., Yip, L. S. C., & Chan, A. (2014). Time buying and time saving: Effects on service convenience and the shopping experience at the mall. *Journal of Services Marketing*, *28*(1), 36-49. doi:10.1108/jsm-03-2012-0065

Lub, V. (2015). Validity in qualitative evaluation: linking purposes, paradigms, and perspectives. *International Journal of Qualitative Methods*, *14*, 1-8. doi:10.1177/1609406915621406

Lun, Y. V., Shang, K. C., Lai, K. H., & Cheng, T. C. E. (2016). Examining the influence of organizational capability in innovative business operations and the mediation of profitability on customer satisfaction: An application in intermodal transport operators in Taiwan. *International Journal of Production Economics*, *171*, 179-188. doi:10.1016/j.ijpe.2015.02.019

Luo, Y., & Bu, J. (2016). How valuable is information and communication technology? A study of emerging economy enterprises. *Journal of World Business*, *51*, 200–211. doi:10.1016/j.jwb.2015.06.001

Luoma, J., Ruutu, S., King, A. W., & Tikkanen, H. (2016). Time delays, competitive interdependence and firm performance. *Strategic Management Journal* [Online prepublication]. doi:10.1002/smj.2512

Mačiulienė, M., & Skaržauskienė, A. (2016). Evaluation of co-creation perspective in networked collaboration platforms. *Journal of Business Research*, *69*, 4826-4830. doi:10.1016/j.jbusres.2016.04.038

Madadipouya, K. (2015). A review on the strategic use of IT applications in achieving and sustaining competitive advantage. *International Journal of Information and Communication Technology, 6*, 21–30. doi:10.5121/ijmpict.2015.6202

Magretta, J. (2012). *Understanding Michael Porter: The essential guide to competition and strategy*. Boston, MA: Harvard Business Review Press.

Malone, H., Nicholl, H., & Tracey, C. (2014). Awareness and minimisation of systematic bias in research. *British Journal of Nursing*, *23*, 279–282. Retrieved from http://www.markallengroup.com/ma-healthcare/

Malakoti -Negad, M. (2016). *Strategies for Small and Medium-Sized Enterprises to Engage Third-Party Logistics Providers*. ScholaWorks, 2016.

Mansell, R. (2016). The market and beyond: Cooperation and competition ln information technology in the Japanese system. *Journal of Economic Issues*, *25*, 1199-1202. doi:10.1080/00213624.1991.11505255

Marshall, A., Mueck, S., & Shockley, R. (2015). How leading organizations use big data and analytics to innovate. *Strategy & Leadership*, *43*, 32-39. doi:10.1108/SL-06-2015-0054

Marshall, C., & Rossman, G. B. (2016). *Designing qualitative research* (6th ed.). Thousands Oaks, CA: Sage.

Martín-Herrán, G., McQuitty, S., & Sigué, S. P. (2012). Offensive versus defensive marketing: What is the optimal spending allocation? *International Journal of Research in Marketing*, *29*, 210–219. doi:10.1016/j.ijresmar.2011.10.003

Martin, R., Florida, R., Pogue, M., & Mellander, C. (2015). Creativity, clusters and the competitive advantage of cities. *Competitiveness Review*, *25*, 482-496. doi:10.1108/CR-07-2015-0069

Martin, S. L., & Javalgi, R. G. (2016). Entrepreneurial orientation, marketing capabilities and performance: The Moderating role of competitive intensity on Latin American international new ventures. *Journal of Business Research*, *69*, 2040–2051. doi:10.1016/j.jbusres.2015.10.149

Mavengere, N. B. (2013). Role of information systems for strategic agility in supply chain setting: Telecommunication industry study. *Electronic Journal of Information Systems Evaluation*, *16*, 327-340. Retrieved from http://www.ejise.com/main.html

McGrattan, E. R., & Prescott, E. C. (2014). A reassessment of real business cycle theory. *American Economic Review*, *104*, 177–182. doi:10.1257/aer.104.5.177

McHugh, M., McCaffery, F., & Casey, V. (2012). Changes to the international regulatory environment. *Journal of Medical Devices*, *6*, 021004. doi:10.1115/1.4006592

Mecca, J. T., Gibson, C., Giorgini, V., Medeiros, K. E., Mumford, M. D., & Connelly, S. (2014). Researcher perspectives on conflicts of interest: A qualitative analysis of views from academia. *Science and Engineering Ethics*, *21*, 843–855. doi:10.1007/s11948-014-9580-6

Medlin, C. J., & Ellegaard, C. (2015). Conceptualizing competition and rivalry in a networking business market. *Industrial Marketing Management*, *51*, 131–140. doi:10.1016/j.indmarman.2015.05.009

Metcalf, J. (2016). Big data analytics and revision of the common rule. *Communications of the ACM*, *59*, 31-33. doi:10.1145/2935882

Meqdadi, O. (2013). Proactive purchasing in the supply chain-the key to world-class procurement. *Journal of Purchasing and Supply Management*, *19*(1), 65. doi:10.1016/j.pursup.2013.02.001

Midler, C., Killen, C. P., & Kock, A. (2016). Project and innovation management: Bridging contemporary trends in theory and practice. *Project Management Journal*, *47*, 3-7. doi:10.1002/pmj.21587

Min, H., & Min, H. (2013). Cross-cultural competitive benchmarking of fast-food restaurant services. *Benchmarking an International Journal*, *20*, 212–232. doi:10.1108/14635771311307687

Miquelutti, M., Cecatti, J., & Makuch, M. (2013). Antenatal education and the birthing experience of Brazilian women: A qualitative study. *BioMed Central Pregnancy and Childbirth*, *13*, 171-179. doi:10.1186/1471-2393-13-171

Mir, I., & Rehman, K. (2012). Two wing models of sales promotion: Theorization and examination. *Journal of Economics & Behavioral Studies*, *4*, 12-25. Retrieved from http://www.ifrnd.org

Mithas, S., Krishnan, M. S., & Fornell, C. (2016). Research note—Information technology, customer satisfaction, and profit: Theory and evidence. *Information Systems Research*, *27*(1), 166–181. doi:10.1287/isre.2015.0609

Mohammadhossein, N., Ahmad, M. N., Zakaria, N. H., & Goudarzi, S. (2014). A study towards the relation of customer relationship management customer benefits and

customer satisfaction. *International Journal of Enterprise Information Systems*, *10*(1), 11–31. doi:10.4018/ijeis.2014010102

Mohammed, A. A., Rashid, B. B., & Tahir, S. B. (2014). Customer relationship management (CRM) technology and organization performance: Is marketing capability a missing link? An empirical study in the Malaysian hotel industry. *Asian Social Science*, *10*, 197. doi:10.5539/ass.v10n9p197

Molenberghs, G., Kenward, M., Aerts, M., Verbeke, G., Tsiatis, A., Davidian, M., & Rizopoulos, D. (2014). On random sample size, ignorability, ancillarity, completeness, separability, and degeneracy: Sequential trials, random sample sizes, and missing data. *Statistical Methods in Medical Research*, *23*, 11-41. doi:10.1177/0962280212445801

Moreno-Izquierdo, L., Ramón-Rodríguez, A. B., & Perles-Ribes, J. F. (2016). Pricing strategies of the European low-cost carriers explained using Porter's five forces model. *Tourism Economics*, *22*, 293-310. doi:10.5367/te.2016.0551

Morse, J. M. (2015). Critical analysis of strategies for determining rigor in qualitative inquiry. *Qualitative Health Research*, *25*, 1212-1222. doi:10.1177/1049732315588501

Moustakas, C. E. (1994). *Phenomenological research methods*. Thousand Oaks, CA: Sage Publications

Murray, L. M., & Evans, K. R. (2013). Store managers, profitability and satisfaction in multi-unit enterprises. *Journal of Services Marketing*, *27*, 207-222. doi:10.1108/08876041311330708

Mutlu, C. C., Zhan, W., Peng, M. W., & Lin, Z. (2015). Competing in (and out of) transition economies. *Asia Pacific Journal of Management*, *32*, 571–596. doi:10.1007/s10490-015-9419-y

Nair, S., Paulose, H., Palacios, M., & Tafur, J. (2013). Service orientation: Effecting business model innovation. *Service Industries Journal*, *33*, 958-975. doi:10.1080/02642069.2013.746670

Najmaei, A. (2016). Revisiting the modularity-performance nexus: Business model innovation as a missing mechanism. *International Journal of Innovation Management*, *20*(7). doi:10.1142/s1363919616500651

Narayanan, V. K. (2015). Customer-focused IT: A process of continuous value innovation. *Strategy & Leadership*, *43*, 11–17. doi:10.1108/sl-05-2015-0037

Nguyen, R. T., & Imholte, D. D. (2016). China's rare earth supply chain: Illegal production, and response to new cerium demand. *Jom: The Journal of the Minerals*, *Metals & Materials Society (TMS)*, *68*, 1948-1956. doi:10.1007/s11837-016-1894-1

Nguyen, T. H., Newby, M., & Macaulay, J. (2013). Information technology adoption in small business: Confirmation of a proposed framework. *Journal of Small Business Management*, *53*(1), 207–227. doi:10.1111/jsbm.12058

Nicholls, S. G., Hayes, T. P., Brehaut, J. C., McDonald, M., Weijer, C., Saginur, R., & Fergusson, D. (2015). A scoping review of empirical research relating to quality and effectiveness of research ethics review. *Plos One*, *10*, e0133639. doi:10.1371/journal.pone.0133639

Njeri, A., Kambona, O. O., & Odhuno, E. (2015). The relationship between the marketing strategies and competitiveness of four and five star hotels. *Educational Research* (ISSN: 2141-5161), *6*, 118-131. doi: 10.14303/er.2015.050

Nutov, L., & Hazzan, O. (2014). An organizational engagement model as a management tool for high school principals. *Journal of Educational Administration*, *52*, 469–486. doi:10.1108/jea-12-2012-0132

Oakey, R. P. (2013). Open innovation and its relevance to industrial research and development: The case of high-technology small firms. *International Small Business Journal*, *31*, 319–336. doi:10.1177/0266242612458942

Office for Human Research Protections, U.S. Department of Health and Human Services. (1979). *The Belmont report*. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Office of the United States Trade Representative. (2015). 2015 National trade estimate report on foreign trade barriers. Retrieved from https://ustr.gov/sites/default/files/2015%20NTE%20Combined.pdf

Ogawa, S., & Pongtanalert, K. (2013). Exploring characteristics and motives of consumer innovators: Community innovators vs. independent innovators. *Research Technology Management, 56*, 41–48. doi:10.5437/08956308X5603088

Olsen, R. B., Orr, L. L., Bell, S. H., & Stuart, E. A. (2013). External validity in policy evaluations that choose sites purposively. *Journal of Policy Analysis and Management*, *32*, 107–121. doi:10.1002/pam.21660

O'Reilly, M., & Parker, N. (2013). "Unsatisfactory saturation": A critical exploration of

the notion of saturated sample sizes in qualitative research. *Qualitative Research*, *13*, 190–197. doi:10.1177/1468794112446106

Ottenbacher, M. C., & Harrington, R. J. (2013). A case study of a culinary tourism campaign in Germany implications for strategy making and successful implementation. *Journal of Hospitality & Tourism Research*, *37*, 3–28. doi:10.1177/1096348011413593

Oye, C., Sorensen, N. O., & Glasdam, S. (2015). Qualitative research ethics on the spot: Not only on the desktop. *Nursing Ethics*, *23*, 455–464. doi:10.1177/0969733014567023

Prasad, A., & Warrier, L. (2016). Mr. Porter and the new world of increasing returns to scale. *Journal of Management Research*, *16*(1), 3-15. Retrieved from http://www.macrothink.org/

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*, 533-544. doi:10.1007/s10488-013-0528-y

Pantano, E. (2014). Innovation management in retailing: From consumer perspective to corporate strategy. *Journal of Retailing and Consumer Services*, *21*(1), 825–826. doi:10.1016/j.jretconser.2014.02.017

Pantouvakis, A., & Bouranta, N. (2013). The link between organizational learning culture and customer satisfaction. *The Learning Organization*, *20*, 48–64. doi:10.1108/09696471311288528

Parris, D. L., Dapko, J. L., Arnold, R. W., & Arnold, D. (2016). Exploring transparency: a new framework for responsible business management. *Management Decision*, *54*, 222-247. doi:10.1108/md-07-2015-0279

Parylo, O. (2012). Qualitative, quantitative, or mixed methods: an analysis of research design in articles on principal professional development (1998-2008). *International Journal of Multiple Research Approaches*, 1419–1462. doi:10.5172/mra.2012.1419

Peltier, J. W., Zhao, Y., & Schibrowsky, J. A. (2012). Technology adoption by small businesses: An exploratory study of the interrelationships of owner and environmental factors. *International Small Business Journal*, *30*, 406–431. doi:10.1177/0266242610365512

Pelzer, P., Arciniegas, G., Geertman, S., & Lenferink, S. (2015). Planning support systems and task-technology fit: A comparative case study. *Applied Spatial Analysis and Policy*, *8*, 155–175. doi:10.1007/s12061-015-9135-5

Petticrew, M., Refuess, E., Noyes, J., Higgins, J., & Mayhew, J. (2013). Synthesizing evidence on complex interventions: How meta-analytical, qualitative, and mixed-method approaches can contribute. *Journal of Clinical Epidemiology*, *66*, 1230-1273. doi:10.1016/j.jclinepi.2013.06.005

Pereira-Moliner, J., Pertusa-Ortega, E. M., Tarí, J. J., Lopez-Gamero, M. D., & Molina-Azorin, J. F. (2016). Organizational design, quality management and competitive advantage in hotels. *International Journal of Contemporary Hospitality Management*, *28*. 762-784. doi:10.1108/IJCHM-10-2014-0545

Perez-Lopez, S., & Alegre, J. (2012). Information technology competency, knowledge processes and firm performance. *Industrial Management & Data Systems*, *112*, 644-662. doi:10.1108/02635571211225521

Perko, I., & Mlinarič, F. (2016). Decreasing information asymmetry by sharing business data: a case of business non-payers sharing agency. *International Journal of Risk Assessment and Management*, *19*, 54-67. doi:10.1504/IJRAM.2016.074435

Perry, A. S. (2012). *Determining the keys to entrepreneurial sustainability beyond the first five years* (Doctoral dissertation). Available from ProQuest Dissertations and Theses database. (UMI No. 3552549).

Person, O., Snelders, D., & Schoormans, J. (2016). Assessing the performance of styling activities: An interview study with industry professionals in style-sensitive companies. *Design Studies*, *42*, 33-55. doi:10.1016/j.destud.2015.10.001

Peter, E. (2015). The ethics in qualitative health research: special considerations. *Ciência & Saúde Coletiva*, *20*, 2625–2630. doi:10.1590/1413-81232015209.06762015

Petty, N., Thomson, O., & Stewa, G. (2012). Ready for a paradigm shift? Part 2: Introducing qualitative research methodologies and methods. *Manual Therapy*, *17*, 378-384. doi:10.1016/j.math.2012.03.004

Petrakis, P. E., Kostis, P. C., & Valsamis, D. G. (2015). Innovation and competitiveness: Culture as a long-term strategic instrument during the European Great Recession. *Journal of Business Research*, *68*, 1436-1438. doi:10.1016/j.jbusres.2015.01.029

Petrova, E., Dewing, J., & Camilleri, M. (2014). Confidentiality in participatory research: Challenges from one study. *Nursing Ethics*, *23*, 442–454. doi:10.1177/0969733014564909

Pezalla, A. E., Pettigrew, J., & Miller-Day, M. (2012). Researching the researcher-as-instrument: an exercise in interviewer self-reflexivity. *Qualitative Research*, 12, 165–185. doi:10.1177/1468794111422107

Picone, P. M., & Dagnino, G. B. (2015). Revamping research on unrelated diversification strategy: perspectives, opportunities and challenges for future inquiry. *Journal of Management & Governance*, *20*, 413–445. doi:10.1007/s10997-014-9305-x

Pirlott, A. G., Kisbu-Sakarya, Y., DeFrancesco, C. A., Elliot, D. L., & MacKinnon, D. P. (2012). Mechanisms of motivational interviewing in health promotion: A Bayesian mediation analysis. *International Journal of Behavioral Nutrition and Physical Activity*, *9*(1), 69. doi:10.1186/1479-5868-9-69

Pizam, A., Shapoval, V., & Ellis, T. (2016). Customer satisfaction and its measurement in hospitality enterprises: a revisit and update. *International Journal of Contemporary Hospitality Management, 28*(1), 2–35. doi:10.1108/ijchm-04-2015-0167

Plonsky, L., & Gonulal, T. (2015). Methodological synthesis in quantitative l2 research: A review of reviews and a case study of exploratory factor analysis. *Language Learning*, *65*, 9–36. doi:10.1111/lang.12111

Porter, M. E. (1979). The structure within industries and companies' performance. *The Review of Economics and Statistics*, *61*, 214-227. doi:10.2307/1924589

Porter, M. E. (1980). *Competitive strategy: Techniques for analyzing industries and competitors.* New York, NY: The Free Press.

Porter, M. E. (1985). Technology and competitive advantage. *Journal of Business Strategy*, *5*, 60-78. doi:10.1108/eb039075

Porter, M. E. (1989). How competitive forces shape strategy. In D. Asch & C. Bowman (Eds.), *Readings in strategic management* (pp. 133–143). doi:10.1007/978-1-349-20317-8_10.

Porter, M. E. (1990). *The competitive advantage of nations.* New York, NY: Free Press.

Porter, M. E. (1991). Towards a dynamic theory of strategy. *Strategic Management Journal*, *12*, 95-117. doi:10.1002/smj.4250121008

Porter, M. E. (2012). Minnesota medical devices cluster. Retrieved from http://www.isc.hbs.edu/pdf/Student_Projects/USA_%28MN%29_Medical_Devices_2011.pdf

Poulis, K., Poulis, E., & Plakoyiannaki, E. (2013). The role of context in case study selection: An international business perspective. *International Business Review*, *22*(1), 304–314. doi:10.1016/j.ibusrev.2012.04.003

Prajogo, D. I. (2016). The strategic fit between innovation strategies and business environment in delivering business performance. *International Journal of Production Economics*, *171*, *2*41–249. doi:10.1016/j.ijpe.2015.07.037

Primc, K., & Cater, T. (2015). The influence of organizational life cycle on environmental proactivity and competitive advantage: A dynamic capabilities

view. *Organization & Environment*, *29*, 212–230. doi:10.1177/1086026615584684

Pritchard, D. J., (2010). A case for repayable launch aid: Implications for the U.S. commercial aircraft supply chain. Canada-United States Trade Center Department of Geograph*y*. Retrieved from http://www.custac.buffalo.edu/documents/CUSTAC-OccasionalPaper39-Pritchard.pdf

Prowse, M., & Camfield, L. (2013). Improving the quality of development assistance: What role for qualitative methods in randomized experiments? *Progress in Development Studies*, *13*(1), 51–61. http://doi.org/10.1177/146499341201300104

Public Citizen. (2012). *Substantially unsafe. Medical devices pose great threat to patients; safeguards must be strengthened, not weakened.* Retrieved from http://www.citizen.org/substantially-unsafe-medical-device-report

Quay, J. (2015). Learning phenomenology with Heidegger: Experiencing the phenomenological "starting point" as the beginning of phenomenological research. *Educational Philosophy and Theory*, *48*, 484–497. doi:10.1080/00131857.2015.1035632

Rahimi, R., & Gunlu, E. (2016). Implementing customer relationship management (CRM) in hotel industry from organizational culture perspective. *International Journal of Contemporary Hospitality Management*, *28*(1), 89–112. doi:10.1108/ijchm-04-2014-0176

Rai, A., Arikan, I., Pye, J., & Tiwana, A. (2015). Fit and misfit of plural sourcing strategies and IT-enabled process integration capabilities: Consequences of firm performance in the U.S. electric utility industry. *MIS Quarterly*, *39*, 865-885. Retrieved from http://aisel.aisnet.org/misq/vol39/iss4/11/

Randall, R. M. (2015). W. Chan Kim and Renée Mauborgne dispel blue ocean myths. *Strategy & Leadership*, *43*, 11–14. doi:10.1108/sl-01-2015-0007

Ray, D. C. (2015). Single-Case Research Design and Analysis: Counseling Applications. *Journal of Counseling & Development*, *93*, 394–402. doi:10.1002/jcad.12037

Reed, R., Storrud-Barnes, S., & Jessup, L. (2012). How open innovation affects the drivers of competitive advantage. *Management Decision*, *50*(1), 58–73. doi:10.1108/00251741211194877

Reeves, M., & Deimler, M. (2015). Adaptability: The new competitive advantage. In M. Deimler, R. Lesser, D. Rhodes & J. Sinha (Eds.), *Own the Future: 50 Ways to Win from the Boston Consulting Group* (pp. 19-26). Hoboken, NJ: John Wiley & Sons. doi: 10.1002/9781119204084.ch2

Reiner, G., Gold, S., & Hahn, R. (2015). Wealth and health at the base of the pyramid: Modelling trade-offs and complementarities for fast moving dairy product case. *International Journal of Production Economics*, *170*, 413–421. doi:10.1016/j.ijpe.2015.08.002

Reinhardt, R., & Gurtner, S. (2015). Differences between early adopters of disruptive and sustaining innovations. *Journal of Business Research, 68*(1), 137–145. doi:10.1016/j.jbusres.2014.04.007

Reybold, L. E., Lammert, J. D., & Stribling, S. M. (2013). Participant selection as a conscious research method: Thinking forward and the deliberation of "emergent" findings. *Qualitative Research*, *13*, 699–716. doi:10.1177/1468794112465634

Riemenschneider, F., & Weigert, M. (2013). Market and technology drivers: shaping an innovation strategy. *Journal of Business Strategy*, *34*, 4–11. doi:10.1108/jbs-05-2013-0034

Roberts, N., & Grover, V. (2012). Leveraging information technology infrastructure to facilitate a firm's customer agility and competitive activity: An empirical investigation. *Journal of Management Information Systems*, *28*, 231-270. doi:10.2753/MIS0742-1222280409

Robinson, O. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Research in Psychology*, *11*(1), 25-41. doi:10.1080/14780887.2013.801543

Rogers, W., & Lange, M. (2013). Rethinking the vulnerability of minority populations in research. *American Journal of Public Health*, *103*, 2141-2146. doi:10.2105/AJPH.2012.301200

Ross, P., & Blumenstein, M. (2013). Cloud computing: The nexus of strategy and technology. *Journal of Business Strategy*, *34*, 39-47. doi:10.1108/JBS-10-2012-0061

Rowley, J. (2012). Conducting research interviews. *Management Research Review*, *35*, 260-271. doi:10.1108/01409171210154

Roy, S., & Singh, S. (2015). Strategic planning for management of technology–an empirical study with Indian steel sectors. *Vision: The Journal of Business Perspective*, *19*, 112-131. doi:10.1177/0972262914567771

Ruan, Y., Hang, C. C., & Wang, Y. M. (2014). Governments' role in disruptive innovation and industry emergence: The case of the electric bike in China. *Technovation*, *34*, 785–796. doi:10.1016/j.technovation.2014.09.003

Rubin, H. J., & Rubin, I. S. (2012). *Qualitative interviewing: The art of hearing data*. Thousand Oaks, CA: Sage.

Sabbour, S., Lasi, H., & Tessin, P. (2012). Business intelligence and strategic decision simulation. *World Academy of Science, Engineering and Technology*, *6*, 980–987. Retrieved from http://waset.org/Publications?p=61

Sabherwal, R., & Jeyaraj, A. (2015). Information technology impacts on firm performance: An extension of Kohli and Devaraj (2003). *MIS Quarterly*, *39*, 809-836. Retrieved from http://aisel.aisnet.org/misq/vol39/iss4/11/

Sakas, D., Vlachos, D., & Nasiopoulos, D. (2014). Modelling strategic management for the development of competitive advantage, based on technology. *Journal of Systems and Information Technology*, *16*, 187. doi:10.1108/jsit-01-2014-0005

Salge, T. O., & Vera, A. (2012). Benefiting from public sector innovation: The moderating role of customer and learning orientation. *Public Administration Review*, *72,* 550–559. doi:10.1111/j.1540-6210.2012.02529.x

Salleh, M., Akma, N., Rohde, F., & Green, P. (2016, April). Information systems enacted capabilities and their effects on SMEs' information systems adoption

behavior. *Journal of Small Business Management*. Advance online publication. doi:10.1111/jsbm.12226

Salojärvi, H., & Saarenketo, S. (2013). The effect of teams on customer knowledge processing, esprit de corps and account performance in international key account management. *European Journal of Marketing*, 47, 987–1005. doi:10.1108/03090561311307047

Salvatore, D. (2016). Growth prospects for advanced and emerging market economies. *Global Economy Journal*, *16*, 599-614. doi:10.1515/gej-2016-0045

Sander-Jones, J. & Linderman, K. (2014). Process management, innovation and efficiency performance. *Business Process Management Journal*, *20*, 335-358. doi:10.1108.BPMJ-03-2013-0026

Sang, S. (2014). Price competition strategy with a common retailer for a fuzzy supply chain. *Journal of Intelligent & Fuzzy Systems*, *7,* 119–130. doi:10.14257/ijca.2014.7.7.10

Santarelli, E., & Tran, H. T. (2015). Diversification strategies and firm performance in Vietnam. *Economics of Transition*, *24*(1), 31–68. doi:10.1111/ecot.12082

Santos-Vijande, M. L., López-Sánchez, J. Á., & Trespalacios, J. A. (2012). How organizational learning affects a firm's flexibility, competitive strategy, and performance. *Journal of Business Research*, *65*, 1079-1089. doi:10.1016/j.jbusres.2011.093002

Savage, T. N., & McIntosh, A. S. (2016). Tackling reliability and construct validity: The systematic development of a qualitative protocol for skill and incident analysis. *Journal of Sports Sciences*, *35*, 449–456. doi:10.1080/02640414.2016.1172722

Saxman, S. B. (2015). Ethical considerations for outcome-adaptive trial designs: A clinical researcher's perspective. *Bioethics*, *29,* 59-65 doi:10.1111/bioe.12084

Scales, B. J. (2013). Qualitative analysis of student assignments: A practical look at ATLAS.ti. *Reference Services Review*, *41*, 134-147. doi:10.1108/00907321311300956

Scates, D. E. (2015). Assumptions underlying research data. *The Journal of Educational Research*, *34*, 241-254.doi:10.1080/00220671.1940.10880997

Schepers, J. J. L., Nijssen, E. J., & van der Heijden, G. A. H. (2016). Innovation in the frontline: Exploring the relationship between role conflict, ideas for improvement, and employee service performance. *International Journal of Research in Marketing.* 33, 797-817. doi:10.1016/j.ijresmar.2016.01.004

Schiavone, F. (2014). Innovation approaches for old products revitalization after technological change: The rise of technology reverse. *International Journal of Innovation Management, 18*, 1450011. doi:10.1142/S136391961450011X

Schmidt, G. M. and Druehl, C. T. (2012). When is a disruptive innovation disruptive? *Journal of Product Innovation Management*, *25*, 347–369. doi:10.1111/j.1540-5885.2008.00306.x

Schmutz, B. P., & Santerre, R. E. (2012). Examining the link between cash flow, market value, and research and development investment spending in the medical device industry. *Health Economics*, 22, 157–167. doi:10.1002/hec.1825

Scholten, K., & Schilder, S. (2015). The role of collaboration in supply chain resilience. *Supply Chain Management: An International Journal*, *20*, 471-484. doi:10.1108/SCM-11-2014-0386

Schwenger, D., Straub, T., & Borzillo, S. (2014). Non-governmental organizations: strategic management for a competitive world. *Journal of Business Strategy*, *35*, 11–19. doi:10.1108/jbs-11-2013-0105

Selle, D. (2013). *Globalization of the U.S. and Chinese upholstered furniture industries* (Doctoral dissertation). Available from ProQuest Dissertations and Theses database. (UMI No. 3564582).

Setia, M. (2016). Methodology series module 5: Sampling strategies. *Indian Journal of Dermatology*, *61*, 505. doi:10.4103/0019-5154.190118

Setia, P., Richardson, V., & Smith, R. J. (2015). Business value of partner's IT intensity: Value co-creation and appropriation between customers and suppliers. *Electron Markets*, *25*, 283–298. doi:10.1007/s12525-015-0189-7

Shaikh, A. A., & Karjaluoto, H. (2015). Making the most of information technology & systems usage: A literature review, framework and future research agenda. *Computers in Human Behavior*, *49*, 541–566. doi:10.1016/j.chb.2015.03.059

Sharma, A., & Jha, S. (2016). Innovation from emerging market firms: what happens when market ambitions meet technology challenges? *Journal of Business & Industrial Marketing*, *31*, 507-518. doi:10.1108/JBIM-12-2014-0265

Shaw, D., Scully, J., & Hart, T. (2014). The paradox of social resilience: How cognitive strategies and coping mechanisms attenuate and accentuate resilience. *Global Environmental Change*, *25*, 194–203. http://doi.org/10.1016/j.gloenvcha.2014.01.006

Shelton, C. L., Smith, A. F., & Mort, M. (2014). Opening up the black box: An introduction to qualitative research method in Anaesthesia. *Anaesthesia*, *69*, 270-280. doi:10.1111/anae.12517

Shore, J. B., & Freije, J. A. (2016). *Proactive supplier management in the medical device industry*. Milwaukee, WI: ASQ Quality Press.

Sigalas, C. (2015). Competitive advantage: the known unknown concept. *Management Decision*, *53,* 2004–2016. doi:10.1108/md-05-2015-0185

Simon, D., Fischbach, K., & Schoder, D. (2013). Enterprise architecture management and its role in corporate strategic management. *Information Systems and E-Business Management*, *12*(1), 5–42. doi:10.1007/s10257-013-0213-4

Sinkovics, R. R., & Alfoldi, E. A. (2012). Progressive focusing and trustworthiness in qualitative research. *Management International Review*, *52*, 817–845. doi:10.1007/s11575-012-0140-5

Singh, P., & Chokshi, D. A. (2013). Community health workers: An opportunity for reverse innovation—authors' reply. *Lancet*, *382*, 1327. doi:10.1016/S0140-6736(13)62136-4

Smiley, S. (2015). Field recording or field observation? Audio meets method in qualitative research. *Qualitative Report*, *20*, 1812-1822. Retrieved http://nsuworks.nova.edu/tqr/

Smit, P. (2012). *A phenomenological examination of supply chain professionals' experiences to improve cash-to-cash positioning* (Doctoral dissertation). Retrieved from ProQuest Dissertations and Theses database. (UMI No. 3510290)

Snipes, R. L., & Pitts, J. (2015). Running with the big dogs (part a): A competitive forces and strategic analysis of the running specialty store industry. *Journal of the International Academy for Case Studies*, *21*, 37-42. Retrieved from http://www.alliedacademies.org

Sorenson, C., & Drummond, M. (2014). Improving medical device regulation: The United States and Europe in perspective. *Milbank Quarterly*, *92*(1), 114–150. doi:10.1111/1468-0009.12043

Sölvell, Ö. (2015). The competitive advantage of nations 25 years: Opening up new perspectives on competitiveness. *Competitiveness Review*, *25*, 471-481. doi:10.1108/CR-07-2015-0068

Srivardhini, K., Rishikesha, J., & Krishnan, T. (2013). Local innovation: The key to globalization. *IIMB Management Review*, *25*, 249-256, doi:10.1016/j.iimb.2013.07.002

Stafleu, M. D. (2014). Nuances in the philosophy of the cosmonomic idea. *Koers - Bulletin for Christian Scholarship*, *79*(3), 1-8. doi:10.4102/koers.v79i3.423

Stein, A. D., Smith, M. F., & Lancioni, R. A. (2013). The development and diffusion of customer relationship management (CRM) intelligence in business-to-business environments. *Industrial Marketing Management*, *42*, 855–861. doi:10.1016/j.indmarman.2013.06.004

Stevenson, R. J., & Mahmut, M. K. (2013). Familiarity influences odor memory stability. *Psychonomic Bulletin & Review*, *20*, 754–759. doi:10.3758/s13423-013-0380-9

Stewart, H., Gapp, R., & Harwood, I. (2017). Exploring the alchemy of qualitative management research: Seeking trustworthiness, credibility and rigor through crystallization. *Qualitative Report*, *22*(1), 1-19. Retrieved from http://nsuworks.nova.edu/

Storbacka, K., & Nenonen, S. (2012). Competitive arena mapping: Market innovation using morphological analysis in business markets. *Journal of Business-to-Business Marketing, 19*, 183-215. doi:10.1080/1051712X.2012.638464

Street, E. (2016). Book review: The collaborators: Interactions in the architectural design process. *Urban Studies*, *53*, 3130–3131. doi:10.1177/0042098016664476

Su, H.-C., Linderman, K., Schroeder, R. G., & Van de Ven, A. H. (2014). A comparative case study of sustaining quality as a competitive advantage. *Journal of Operations Management*, *32*, 429–445. doi:10.1016/j.jom.2014.09.003

Su, N. (2015). Cultural sensemaking in offshore information technology service suppliers: A cultural frame perspective. *MIS Quarterly*, *39*, 959-983. Retrieved from http://aisel.aisnet.org/misq/vol39/iss4/11/

Subrahmanya, M. H. B. (2014). Innovation: Your competitive advantage. *Current Science* (00113891), *107*, 1745-1746. Retrieved from http://www.ias.ac.in

Subramanian, N., Gunasekaran, A., & Gao, Y. (2016). Innovative service satisfaction and customer promotion behavior in the Chinese budget hotel: An empirical study. *International Journal of Production Economics*, *171*, 201–210. doi:10.1016/j.ijpe.2015.09.025

Sull, D., Homkes, R., & Sull, C. (2015). Why strategy execution unravels and what to do about it. *Harvard Business Review*, *93*, 57-66. Retrieved from https://hbr.org/magazine

Sung, H. Y., Hepworth, M., & Ragsdell, G. (2013). Investigating essential elements of community engagement in public libraries: An exploratory qualitative study. *Journal of Librarianship and Information Science*, *45*, 206–218. doi:10.1177/0961000612448205

Syed, S. B., Dadwal, V., & Martin, G. (2013). Reverse innovation in global health systems: Towards global innovation flow. *Globalization and Health, 9*, 36. doi:10.1186/1744-8603-9-36

Tanima, F. A., & Bates, K. (2015). The incidence and perceived managerial merit of customer accounting in New Zealand. *Pacific Accounting Review (Emerald Group Publishing Limited), 27*, 466-485. doi:10.1108/PAR-05-2013-0049

Tran, V.-T., Porcher, R., Falissard, B., & Ravaud, P. (2016). Point of data saturation was assessed using resampling methods in a survey with open-ended questions. *Journal of Clinical Epidemiology*. doi:10.1016/j.jclinepi.2016.07.014

Tansey, P., Spillane, J. P., & Meng, X. (2014). Linking response strategies adopted by construction firms during the 2007 economic recession to Porter's generic strategies. *Construction Management and Economics*, *32*, 705–724. doi:10.1080/01446193.2014.933856

Terpstra, M., Kuijlen, T., & Sijtsma, K. (2012). An empirical study into the influence of customer satisfaction on customer revenues. *The Service Industries Journal*, *32*, 2129–2143. doi:10.1080/02642069.2011.574279

Thomas, D. R. (2016). Feedback from research participants: Are member checks useful in qualitative research? *Qualitative Research in Psychology*, *14*(1), 23–41. doi:10.1080/14780887.2016.1219435

Thomson, O. P., Petty, N., & Hammersley, M. (2016). Abductive analysis: Theorizing qualitative research. *Qualitative Research*, *16*, 748-760. Retrieved from http://journals.sagepub.com/doi/full/10.1177/1468794115592572

Tohidi, H., & Jabbari, M. M. (2012). Organizational culture and leadership. *Procedia - Social and Behavioral Sciences, 31*, 856–860. doi:10.1016/j.sbspro.2011.12.156

Toro-Jarrín, M. A., Ponce-Jaramillo, I. E., & Güemes-Castorena, D. (2016). Methodology for the building process integration of business model canvas and technological roadmap. *Technological Forecasting and Social Change*, *110*, 213-225. doi:10.1016/j.techfore.2016.01.009

Torsekar, M, P. (2014). U.S. medical devices and china's market: Opportunities and obstacles. Retrieved from https://www.usitc.gov/publications/332/id-036workingpaperusmedicaldevicesfinalss.pdf

Trkman, P., Mertens, W., Viaene, S., & Gemmel, P. (2015). From business process management to customer process management. *Business Process Management Journal*, *21*, 250–266. doi:10.1108/bpmj-02-2014-0010

Trotter II, R. T. (2012). Qualitative research sample design and sample size: Resolving and unresolved issues and inferential imperatives. *Preventive Medicine*, *55*, 398–400. doi:10.1016/j.ypmed.2012.07.003

U.S. Department of Commerce, International Trade Administration. (2016). 2016 Top markets report: Medical devices. Retrieved from http://trade.gov/topmarkets/pdf/Medical_Devices_Executive_Summary.pdf

U.S. Food and Drug Administration. (2015). *Medical device. Overview of IVD regulation.* Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm#1

Venkatesh, V., Brown, S. A., & Bala, H. (2013). Bridging the qualitative-quantitative divide: Guidelines for conducting mixed methods research in information systems. *MIS Quarterly, 37*(1), 21-54. Retrieved from http://www.misq.org/

Vieira, R., O'Dwyer, B., & Schneider, R. (2016). Aligning strategy and performance management systems: The case of the wind-farm industry. *Organization & Environment*. Advance online publication. doi:10.1177/1086026615623058

Viio, P., & Grönroos, C. (2016). How buyer–seller relationship orientation affects adaptation of sales processes to the buying process. *Industrial Marketing Management*, *52*, 37-46. doi:10.1016/j.indmarman.2015.07.013

Vockley, M. (2016). The servicing of medical devices: In need of repair, regulation, or redemption? *Biomedical Instrumentation & Technology*, *50*, 316–328. doi:10.2345/0899-8205-50.5.316

Vogl, S. (2013). Telephone versus face-to-face interviews: Mode effect on semistructured interviews with children. *Sociological Methodology*, *43*, 133–177. doi:10.1177/0081175012465967

Volonté, C., & Gantenbein, P. (2014). Directors' human capital, firm strategy, and firm performance. *Journal of Management & Governance*, *20*(1), 115–145. doi:10.1007/s10997-014-9304-y

Von Faber, E. (2016). IT-Outsourcing — Sicherheit neu denken! Datenschutz Und Datensicherheit - *DuD*, *40*, 680–680. doi:10.1007/s11623-016-0681-z

Wagner, Hansen, K., & Kronberger, N. (2014). Quantitative and qualitative research across cultures and languages: Cultural metrics and their application. *Integrative Psychological and Behavioral Science*, *48*, 418–434. doi:10.1007/s12124-014-9269-z

Wahyuni, D. (2012). The research design maze: Understanding paradigms, cases, methods and methodologies. *Journal of Applied Management Accounting Research*, *10*(1), 69-80. Retrieved from http://www.cmawebline.org/jamar

Walker, J. L. (2012). The use of saturation in qualitative research. *Canadian Journal of Cardiovascular Nursing*, *22*, 37-46. Retrieved from http://www.cccn.ca

Wang, M.-L. (2013). An evaluation of customer relationship management in hospital-based and privately run nursing homes in Taiwan. *Total Quality Management & Business Excellence*, *24*, 1004–1021. doi:10.1080/14783363.2011.637783

Wang, N., Liang, H., Zhong, W., Xue, Y., & Xiao, J. (2012). Resource structuring or capability building? An empirical study of the business value of information technology. *Journal of Management Information Systems*, *29*, 325-367. doi:10.2753/MIS0742-1222290211

Wang, Y. (2016). Offensive for defensive: The belt and road initiative and China's new grand strategy. *Pacific Review*, *29*, 455-463. doi:10.1080/09512748.2016.1154690

Wattanapruttipaisan, T. (2014). Competition policy and intellectual property rights in the information and communications technology sector: Policy implications and options for ASEAN. *Asian-Pacific Economic Literature*, *28*(1), 1–28. doi:10.1111/apel.12048

Way, A. K., Kanak Zwier, R., & Tracy, S. J. (2015). Dialogic interviewing and flickers of transformation: An examination and delineation of interactional strategies that promote participant self-reflexivity. *Qualitative Inquiry*, *21*, 720–731. doi:10.1177/1077800414566686

Weerakkody, V., Irani, Z., Lee, H., Hindi, N., & Osman, I. (2014). A review of the factors affecting user satisfaction in electronic government services. *International*

Journal of Electronic Government Research, *10*, 21-56. doi:10.4018/ijegr.2014100102

Whiteley, A. (2012). Supervisory conversations on rigor and interpretive research. *Qualitative Research Journal*, *12*, 251-271. doi:10.1108/14439881211248383

Wilhelmy, A., Kleinmann, M., Konig, C. J., Melchers, K. G., & Truxillo, D. M. (2016). How and why do interviewers try to make impressions on applicants? A qualitative study. *Journal of Applied Psychology*, *101*, 313-332. doi:10.1037/apl0000046

Wilhelm, M., Blome, C., Wieck, E., & Xiao, C. Y. (2016). Implementing sustainability in multi-tier supply chains: Strategies and contingencies in managing sub-suppliers. *International Journal of Production Economics*, *182*, 196–212. doi:10.1016/j.ijpe.2016.08.006

Wilkins, S. (2016). Establishing international branch campuses: A framework for assessing opportunities and risks. *Journal of Higher Education Policy and Management*, *38*, 167-182. doi:10.1080/1360080x.2016.1150547

Williams, D. (2012). *Exploring organizational survival techniques for business resiliency during an economic downturn: A qualitative case study* (Doctoral dissertation). Available from ProQuest Dissertations and Theses database. (UMI No. 3534185)

Wilson, T. (2012). What can phenomenology offer the consumer? *Qualitative Market Research: An International Journal*, *15*, 230–241. doi:10.1108/13522751211231969

Wisdom, J. P., Cavaleri, M. A., Onwuegbuzie, A. J., & Green, C. A. (2012). Methodological reporting in qualitative, quantitative, and mixed methods health services research articles. *Health Services Research*, *47*, 721-745. doi:10.1111/j.1475-6773.2011.01344.x

Woods, M., Paulus, T., Atkins, D. P., & Macklin, R. (2015). Advancing qualitative research using qualitative data analysis software (QDAS)? Reviewing potential versus practice in published studies using ATLAS.ti and NVivo, 1994-2013. *Social Science Computer Review*, *34*, 597–617. doi:10.1177/0894439315596311

Wu, P. H., & Liao, J. F. (2016). Service-oriented organizational citizenship behavior, perceived service quality and customer satisfaction in hospitality industry. *Journal of Applied Sciences, 16*(1), 18-24. doi:10.3923/jas.2016.18.24

Wu, S. J., & Raghupathi, W. J. (2015). The strategic association between information and communication technologies and sustainability: A country-level study. *Journal of Global Information Management*, *23*, 92-115. doi:10.4018/jgim.2015070105

Xing, Y. (2016). Global value chains and China's exports to high-income countries. *International Economic Journal*, *30*, 191-203. doi:10.2139/ssrn.2676477

Xu, W., Zhang, Q., & Ma, J. (2013). The relationship among customer demand, competitive strategy and manufacturing system functional objectives. *Journal of Industrial Engineering and Management*, *6*, 1238-1254. doi:10.3926/jiem.802

Yan, T., & Dooley, K. (2014). Buyer-supplier collaboration quality in new product development projects. *Journal of Supply Chain Management*, *50*, 59–83. doi:10.1111/jscm.12032

Yang, Q., Zhao, X., Yeung, H. Y. J., & Liu, Y. (2016). Improving logistics outsourcing performance through transactional and relational mechanisms under transaction uncertainties: Evidence from China. *International Journal of Production Economics*, *175*, 12-23. doi:10.1016/j.ijpe.2016.01.022

Yelkikalan, N., & Aydin, E. (2015). Evaluating the potential for reverse innovation in BRIC-T countries: A panel data analysis. *Journal of Applied Finance and Banking, 5*, 125-133. Retrieved from http://www.journals.elsevier.com/journal-of-banking-and-finance

Yeow, A., & Huat Goh, K. (2015). Work harder or work smarter? Information technology and resource allocation in healthcare processes. *MIS Quarterly*, *39*, 763-785. Retrieved from http://aisel.aisnet.org/misq/vol39/iss4/11/

Yi, S. L. (2013). *A Boeing strategy to shape a competitive advantage: A phenomenological study.* Available from ProQuest Dissertations and Theses database. (UMI No. 3576353)

Yin, R. K. (2014). *Case study research: Design and methods* (5th ed.). Thousand Oaks, CA: Sage.

Zang, J., Zhang, C., Yang, P., & Li, Y. (2014). How open search strategies align with firms' radical and incremental innovation: Evidence from China. *Technology Analysis & Strategic Management*, *26*, 781–795. doi:10.1080/09537325.2014.899345

Zedtwitz, M., Corsi, S., Søberg, P. V., & Frega, R. (2015). A Typology of Reverse Innovation. *Journal of Product Innovation Management*, *32*(1), 12-28. doi:10.1111/jpim.12181

Zeschky, M. B., Winterhalter, S., & Gassmann, O. (2014). From cost too frugal and reverse innovation: Mapping the field and implications for global competitiveness. *Research Technology Management*, *57*, 20-27. doi:10.5437/08956308X5704235

Zhang, K. H. (2015). What drives export competitiveness? The role of FDI in Chinese manufacturing. *Contemporary Economic Policy*, *33*, 499-512. doi:10.1111/coep.12084

Zhang, Y., Xu, J., Sun, S., & Yang, T. (2015). Real-time information driven intelligent navigation method of assembly station in unpaced lines. *Computers & Industrial Engineering*, *84*, 91–100. doi:10.1016/j.cie.2014.09.007

Zheng, L. (2004). On the comparative advantage of Chinese industries. *The Chinese Economy*, *37*(2), 6-15. Retrieved from http://mesharpe.metapress.com

Zhu, Y., & Bargiela-Chiappini, F. (2013). Balancing emic and etic: Situated learning and ethnography of communication in cross-cultural management education. *Academy of Management Learning & Education*, *12*, 380-395. doi:10.5465/amle.2012.0221

Appendix A: IRB Approval Letter

Dear Ms. Beglari,

This email is to notify you that the Institutional Review Board (IRB) has approved your application for the study entitled, "Effective Competitive Strategies of U.S. In Vitro Device Manufacturers."

Your approval # is 06-12-17-0478451. You will need to reference this number in your dissertation and in any future funding or publication submissions. Also attached to this e-mail is the IRB approved consent form. Please note, if this is already in an on-line format, you will need to update that consent document to include the IRB approval number and expiration date.

Your IRB approval expires on June 11, 2018. One month before this expiration date, you will be sent a Continuing Review Form, which must be submitted if you wish to collect data beyond the approval expiration date.

Your IRB approval is contingent upon your adherence to the exact procedures described in the final version of the IRB application document that has been submitted as of this date. This includes maintaining your current status with the university. Your IRB approval is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, your IRB approval is suspended. Absolutely NO participant recruitment or data collection may occur while a student is not actively enrolled.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB application, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their

occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden
website: http://academicguides.waldenu.edu/researchcenter/orec

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.
Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Sincerely,
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Information about the Walden University Institutional Review Board, including instructions for application, may be found at this
link: http://academicguides.waldenu.edu/researchcenter/orec

Appendix B: Protecting Human Research Participants

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Sofia Beglari** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 03/12/2015

Certification Number: 1722373

Appendix C: Interview Research Questions

Research Question

What strategies do IVD medical manufacturing leaders use to achieve and maintain a competitive advantage?

Interview Questions

1. What strategies have you as a U.S. IVD medical leader used over the past 10 years to achieve and maintain a competitive advantage?
2. How have you measured the effectiveness of the strategies?
3. What kind of barriers did you face during the implementation of these strategies?
4. How did you cope with barriers to the implementation of these strategies?
5. What strategies have your competitors demonstrated over the past 10 years to achieve competitive advantage?
6. What other information would you like to provide that we have not addressed already?

Appendix D: Interview Protocol

Participants will email a copy of the informed consent constituting their informed consent to participate as an unpaid and uncompensated volunteer in this study. The following statements provide the structure and procedure protocols for the interview:

1) Send each participant the interview call and access numbers and electronic calendar with available times and days for the interview.

2) Ask the participant for permission to begin the audio recording of the interview.

3) If participant agrees to the audio recording, move on to protocol 4.

4) Begin the audio recording

5) Ask the person if they read the consent form in its entirety and agree to continue as a participant in this study.

6) Welcome each participant with these opening remarks: "Hello, My name is Sofia Beglari, and I am a Doctoral student at Walden University. Thank you so much for volunteering to participate in this study."

7) The total time for this interview is 45 minutes.

8) If the participants don't give their permission for the recording of the interview: I will "Thank you (participant's name), and I will respect their decision.

I need to take written notes of your responses to capture your perceptions about the effective strategies in gaining competitive advantage. In this case, the interview may take 5-10 minutes longer. Please let me know if you still willing to participate?"

9) Assure the participant that all responses will be confidential: "(Participant's

name) all of your responses are confidential and the published doctoral study will not include any recognizing information to protect your identity.

10) Check to make sure they received an email copy of the written informed consent form. Did you receive the document? The consent form is including the Walden Institutional Review Board (IRB) number for this study, an email address for the Chair of my Doctoral Study Committee, and an email contact for the IRB if you have additional questions beyond this interview about the nature and purpose of this study."

11) Are you still willing to participate in my interview?

12) Explain the study's purpose and interview procedure: "The purpose of this qualitative multiple case study will be to explore strategies some IVD medical manufacturing leaders use to gain and maintain a competitive advantage."

13) "The interview format is open-ended questions. Please feel free to add clarifying

Remarks you deem appropriate.

14) Statement of consent and option to withdraw from the interview process: "(Participant's name) this interview is voluntary, and you may decline to answer any question that makes you feel uncomfortable. Additionally, you may withdraw your consent at any time, during this interview (given by you) and all notes, references, and recorded information previously collected enters a destruction process. Your withdrawal does not impose any reprisal or negatively affect your professional standing."

15) Start asking the interview questions.

16) After participant answers all questions, "Thank you (participant's name) again

for your willingness to participate in the study

17) Advise participant that you will provide them a copy of the transcribed interpretation of the audio recording. (Participant's name), I will send you a copy of the transcribed notes from this audio recording. Once you receive the document, please review for accuracy, sign the document, and return it using sofa.beglari@waldenu.edu. Thank you again for your time and sharing your wisdom."