2021

Development and Implementation Strategies for Open Innovation Pharmaceutical R&D Projects

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This is to certify that the doctoral study by

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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May 2021

Abstract

US pharmaceutical company leaders who lack strategies for developing and implementing open innovation (OI) Research & Development (R&D) projects may experience weakened competitive positioning in the industry. Grounded in the open innovation capability framework, the purpose of this qualitative single case study was to explore implementation strategies R&D directors use to implement OI R&D projects in the US. Participants were five US pharmaceutical R&D directors from a single organization. Data were collected using semistructured interviews, public information, and OI literature and analyzed using Castleberry and Nolen's five-step model. Four themes emerged: roles and responsibilities, business and OI strategy alignment, leadership attention, and OI decision-making. A key recommendation for pharmaceutical R&D directors is to develop a clear OI strategy aligned with the business strategy and assemble two teams, a search and evaluation team and an alliance management team, to help identify and assimilate OI projects. Positive social change implications include the potential for pharmaceutical leaders using more efficient methods of R&D, resulting in the discovery and development of novel therapeutics at a lower cost to patients, making it more affordable to improve their quality of life.

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Dedication

I would like to dedicate my study to a very special person in my life, my wonderful wife, Denise. Furthermore, in memory of my parents I would also like to dedicate my study to James and Helen Maher for their encouragement throughout my life that inspired me to be a lifelong learner and complete my doctorate.

Acknowledgments

Many people have contributed to my success in completing this dissertation. I was fortunate to have an exceptional mentor Dr. Warren Lesser. A special thanks to Dr. Lesser for his valuable input throughout my study. I have learned a lot from Dr. Lesser throughout my doctoral journey. Furthermore, I would like to thank my other committee members, the second chair, Dr. Matasha Murrelljones, and URR Dr. Richard Johnson for reviewing my research and providing candid feedback. Although I cannot mention the names of the participants and the organization involved in the research, they know who they are and a big thank you for your participation in the study. I would also like to thank my sons, Sean and Jimmy, for their support throughout my doctoral studies. I hope that someday they reach their goals.

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Section 1: Foundation of the Study

Background of the Problem

The US pharmaceutical industry supports over 3.4 million jobs across the US in multiple industries and added an estimated $800 billion to the economy in 2015 (Muratoglu, 2017). It is a major contributor to the US economy and considered a significant part of the global market (Lakdawalla, 2018). Downs & Velamuri (2016) said over the last 60 years, inflation-adjusted research and development (R&D) expenditure per molecule brought to market increased significantly. Despite billions of dollars the US pharmaceutical industry collectively spends on R&D annually, the rate of novel therapy output is declining versus historical productivity levels (Schumacher et al., 2016).

Problem Statement

US pharmaceutical company leaders experience challenges in terms of bringing novel therapeutic agents through the R&D process to generate a sufficient return on investment (ROI; DiMasi et al., 2020). OI strategies may increase the net present value of projects by 70% compared to closed innovation projects (Chesbrough, 2017; Hosseini et al., 2017). The general business problem is that US pharmaceutical company leaders' failure to implement an OI business model may lead to less innovative and competitive companies. The specific business problem is that some US pharmaceutical company leaders lack strategies for developing and implementing OI R&D projects.

Purpose Statement

The purpose of this qualitative single case study was to explore strategies US pharmaceutical company leaders used for developing and implementing OI R&D

projects. The targeted population comprised five US pharmaceutical R&D directors in one pharmaceutical firm that successfully used OI strategies to develop and implement R&D drug development projects. The US pharmaceutical company is in the northeastern region of the United States. My research findings may enhance US pharmaceutical leaders' capacities to increase ROI, decrease operational costs, and positively benefit local communities through increased tax revenues and employment opportunities. Furthermore, the efficient discovery and production of novel therapies may lead to a better quality of life for many patients.

Nature of the Study

I used a qualitative single case study design to explore strategies five US pharmaceutical company leaders used for developing and implementing successful OI pharmaceutical R&D projects. Yin (2018) said a qualitative case study method can be used for researching a contemporary topic and providing a detailed description of the unit of analysis. A quantitative methodology was not appropriate for this exploratory study. It is used to measure and analyze variables' characteristics and relationships through statistical analysis (Pessoa et al., 2019). Marshall and Rossman (2016) said the mixed methods approach entails collecting both qualitative and quantitative data. I did not use a mixed methods approach because the quantitative method was not necessary for addressing the purpose of my study.

Soleimani et al. (2018) said researchers can use the case study design to understand the nature and complexity of processes taking place in the context of a phenomenon. Ethnographers focus on studying human society and culture (Merriam &

Tisdell, 2016). The ethnography design was not appropriate for my research because I was not studying culture or social groups. James (2018) said narrative inquiry consists of in-depth interviews to collect, analyze, and interpret peoples' life stories. The narrative inquiry was not a suitable design because the intent of my study was not to provide a summary of personal accounts of participants' life stories related to events. The phenomenology design was not appropriate because I was not researching the fundamental nature of the meanings of human experiences with phenomena. Phenomenologists are interested in people's conscious experience of their everyday life and social action (Smith, 2018). Therefore, a single-case design was the most appropriate design to identify and explore strategies managers used to develop and implement OI pharmaceutical R&D projects.

Research Question

What are the strategies that US pharmaceutical company leaders used to develop and implement OI R&D projects?

Interview Questions

1. What strategies did you use to implement an OI business model for R&D projects?
2. How did you identify new R&D projects to pursue using an OI strategy?
3. How did you decide which OI strategy to use for an OI R&D project?
4. What organizational issues did you consider when pursuing a given OI R&D project?

5. What organizational capabilities did you consider when pursuing a given OI R&D project?
6. How did you decide which capabilities are important to implement an OI R&D project?
7. How did you decide which employees should participate in the implementation of OI R&D projects?
8. If your organizational culture supports OI R&D, describe how your culture supports the implementation of OI R&D projects.
9. If the organizational culture supports OI, describe the strategies used to align the organizational structure to support OI R&D projects.
10. What else can you tell me you did to enhance OI strategies?

Theoretical or Conceptual Framework

Since the inception of the OI theory, many researchers have studied the phenomenon. Hosseini et al. (2017) developed an OI capability framework (OICF), which is intended to serve as a foundation for assessing OI competencies of individuals in an organization. Leaders could use the OICF as a guide for implementing OI in their organization.

Hosseini et al. (2017) identified capabilities with similar characteristics and qualities and grouped these capabilities into six factors: strategic alignment, governance, methods, IT, people, and culture. The OICF is comprised of 23 capability areas stratified among these six factors. The six factors identified are capabilities relevant to implementing OI for R&D projects. I used the principal factors to verify the OICF's

relevance, and for understanding the strategies the participating pharmaceutical organizations' leaders used to select and implement OI R&D projects. I therefore expected the OICF framework to be useful for understanding strategies organizational leaders used to develop and implement OI in the context of the pharmaceutical industry.

Operational Definitions

Open innovation (OI): A distributed innovation process based on purposively managed knowledge flows across organizational boundaries. OI provides insights into how firms can harness inflows and outflows of knowledge to improve their innovation success (Bogers et al., 2018).

Assumptions, Limitations, and Delimitations

In this subsection, I discuss the various assumptions, limitations, and delimitations of my research. Investigators should plan the research process for the study. Furthermore, assumptions, limitations, and delimitations of the study should be outlined.

Assumptions

Assumptions are facts the researcher assumes to be true (Marshall & Rossman, 2016). I made four assumptions in this study. My first assumption was that pharmaceutical R&D directors provided adequate and truthful responses during interviews. My second assumption was that pharmaceutical R&D directors shared valuable rich information regarding their OI implementation strategies and experience. My third assumption was that the OICF applied to the context of the pharmaceutical industry. My final assumption was that a sample size of four pharmaceutical R&D

directors experienced with implementing OI drug development projects was enough to provide rich content for a single case study.

Limitations

One of the limitations of my study involved the choice of a single case study of one pharmaceutical company located in the northeastern region of the US, which may not represent all information possible from companies. Yin (2018) suggested single case studies are exposed to limitations because there are more analytic benefits from having multiple cases. Furthermore, the study findings may not apply to all US pharmaceutical companies because of the limited geographical scope of the study.

Another limitation of my study was the participant sample size, because I interviewed only five pharmaceutical R&D directors. The final limitation of my study involves the use of semistructured interviews as my primary data collection method. Bloomberg and Volpe (2019) suggested that not all interviewees are equally cooperative, articulate, and perceptive. Many studies have limitations, so the investigators need to be transparent regarding the limitations of their findings

Delimitations

Delimitations are limits imposed by the researchers' study design and the intentional choices the researcher makes to investigate the research problem (Bloomberg & Volpe, 2019). The first delimitation of my study will be that the study participants are from one pharmaceutical company in the northeastern region of the US A second delimitation will be that the participants are pharmaceutical R&D directors with experience implementing OI drug projects. A third delimitation of the study will be the

number of interviewees used to collect the data. Researchers should communicate the boundaries of their research study by stating their exclusionary and inclusionary decisions.

Significance of the Study

My study findings could be significant for leaders in pharmaceutical firms seeking to use OI strategies to improve their firms' competitive positions in the market. Pharmaceutical leaders intending to implement an OI business model might be able to use implementation strategies that I discovered through my research. Pharmaceutical leaders may use the prospective framework to lead a more efficient and effective drug development process for reducing the cost of developing drugs and increasing pharmaceuticals firms' efficacy.

Contribution to Business Practice

As pharmaceutical industry leaders struggle with controlling rising costs of drug development, they search for more efficient strategies and methods for discovering and developing novel therapeutics (Downs & Velamuri, 2016). Shaw (2017) said pharmaceutical leaders are leveraging OI business models to improve their biomedical innovation processes. However, proponents of OI typically encounter several barriers and challenges; leaders of pharmaceutical firms need to develop strategies to implement OI. If leaders of pharmaceutical firms had implementation frameworks for the OI business model, pharmaceutical leaders could improve their chances of being successful. If my research supports OICF relevance, pharmaceutical leaders may garner additional insights to help implement OI and increase R&D projects' success rates.

Implications for Social Change

If my research findings are significant, pharmaceutical leaders implementing OI may increase the efficiency of discovering and developing novel therapeutics. An increase in the efficiency of discovering and developing novel therapeutics may lead to cost-effective therapeutic remedies that provide a better quality of life for many patients, and in some cases may save lives (Hunter et al., 2018). In addition, if the research bears favorable results, pharmaceutical leaders who implement proposed strategies may increase the viability of their organizations, which then may lead to employment opportunities for members of local communities and better life quality for communities.

A Review of the Professional and Academic Literature

The purpose of this qualitative exploratory single case study is to explore strategies that are critical to implementing an OI business model for pharmaceutical R&D projects. I examine literature in this review related to OI in general as well as in relation to the pharmaceutical industry and conceptual frameworks used to implement OI strategies. My intention was to discover recent scholarly literature regarding specific strategies for implementing OI in the pharmaceutical industry at the project level. I begin the literature review with an overview of OI, followed by OI and the pharmaceutical industry and a review of conceptual frameworks used to implement OI.

To construct the literature review, I obtained information through searches and reviews of recent research regarding OI. I also accessed peer-reviewed literature by using databases from the Walden University Library. The databases used to search for peer-reviewed articles included Google Scholar, Business Source Complete, and

ABI/INFORM Complete. The search included keywords *open innovation, open innovation AND pharmaceutical industry, open innovation AND implementation, open innovation AND strategy, and open innovation AND projects*. To construct the literature review, I obtained information through searches and review of recent research around OI and selected articles that were relevant to my area of study.

I searched the literature for peer-reviewed, full-text articles from 2016-2021. To maintain relevancy and satisfy university requirements, I selected a minimum of 85% of literature review sources published within 5 years of this study's completion date. From the search results of peer-reviewed articles, I analyzed 83 articles relevant to my area of study and the conceptual framework for the review of the literature. Of the 83 articles, 6 (7%) were published before 2016.

Open Innovation

OI is a business strategy that Chesbrough proposed in 2003. Chesbrough (2017) described the use of purposive inflows and outflows of knowledge to accelerate internal innovation and reduce the cost of R&D. Zhao et al. (2016) said the process of innovation has relied on external participants for many years and that enterprises always rely on both inflow and outflow of ideas, resources, and individuals. Furthermore, Conrado, et al., (2017) asserted that sharing of resources across organizations to support OI is an old idea. Conrado et al. posited that the scientific community is sharing more readily in recent years. External search for information and its integration in the context of OI is one practice that can lead to increased success in R&D (Rauter et al., 2018).

Leaders can no longer rely only on internal resources to innovate. Zhao et al. (2016) said with economic globalization, managers of businesses can no longer rely solely on internal innovation to be successful. Leaders must develop resourceful methods to develop innovative products. Consequently, many leaders are focused on implementing OI to improve their product lines and sustain their competitive advantage. Cammarano et al. (2019) advocated that leaders adopt OI strategies to pursue exploration and diversification that may lead to radical innovation.

Leaders that properly implement OI increase the innovation performance of firms. OI consists of many different practices and is not a dichotomous phenomenon. The main tenets of OI are collaborations with external partners, exploration of knowledge and technology, and exploitation of internal resources (Uribe-Echeberria et al., 2019).

There are currently three recognized forms of OI. Managers engaged in bringing technologies into the firm are involved in inbound OI (Barchi& Greco, 2018; Marcolin et al., 2017; Shin et al., 2018). Inbound OI is a strategy managers' use to enhance employees' knowledge necessary for meaningful innovations. Conversely, managers selling or licensing their internal innovations to other companies are engaged in outbound OI activities (Barchi& Greco, 2018; Marcolin et al., 2017; Shin et al., 2018). Leaders engaging in outbound OI sell unused innovations and technologies to obtain a pecuniary benefit. Collaborating, cooperating, and joint ventures to develop innovations are referred to as coupled OI because the innovation and exploitation process involves joint ventures (Marcolin et al., 2017; Shin et al., 2018). Regardless of the OI practice, the objective is to improve the firm's competitive advantage.

Despite the potential benefits of OI, firm leaders have encountered difficulties of successfully implementing OI. Cui et al. (2015) noted a survey of 107 European firms showed that 48% of managers were concerned with the difficulty of incorporating external knowledge into their innovation process. Incorporating external knowledge and technologies into organizations is one of the central tenets of OI. Cui et al. (2015) said significant internal supporting resources are vital to unlocking OI's potential to contribute to innovation performance.

Absorptive capacity is critical for managers assimilating external knowledge and technologies into a company (Milutinović et al., 2017). Absorptive capacity is the leader's ability to recognize the value of new information, then integrate the information and apply it to marketable products (Fisher & Qualls, 2018; Greco et al., 2016; Xia & Roper, 2016; Xie et al., 2018). Greco et al. (2019) said OI strategies may improve innovation by shortening the innovator's learning curve and fostering organizational learning. Decreasing the innovators' learning curve can lead to value capture more swiftly.

Milutinović et al. (2017) suggested IT-based tools can facilitate access to a large variety of ideas and accelerate the development of innovative new products and services. The joining of the OI paradigm and IT results in platforms for managers to facilitate easier access for customers and other potential participants willing to independently contribute to solving the specific problems of the company.

The success of a business depends as much on the business model design and implementation as it does on the selection of technologies and operation of tangible

assets and equipment (Teece, 2018). Organizational leaders can use a business model as a guide to provide a pathway by which technological innovation and knowledge combined with the use of tangible and intangible assets are transformed into profits.

OI Implementation

To implement OI, organizational capabilities may need a higher level of development than closed innovation. Von Briel and Recker (2017) said the implementation of OI is not a straightforward process. Von Briel and Recker argued that even in an organization comfortable with embracing innovation a failed OI project implementation is possible. It is important to consider several potential barriers before engaging in OI such as the industry context, legal environment, supportive processes, innovation maturity, commitment, and the participants (Von Briel& Recker, 2017).

Hosseini et al. (2017) said OI implementation needs a different employee mentality in comparison to a closed innovation environment. Hosseini et al. identified six high-level capabilities that are needed to implement OI strategies: strategic alignment, governance, methods, IT, people, and culture. Hosseini et al. proposed OICF expounded on the inbound OI and the coupled OI forms but Hosseini et al. proposed OICF did not address the capabilities needed for outbound OI. Outbound OI is less common than the other two categories of OI.

The foundational theory that OICF draws from is related to capability development. Proponents of the resource-based view (RBV) consider capabilities and assets as resources. With the RBV, assets can be tangible or intangible that organizational leaders can use to create a competitive advantage (Barney,1991; Barney et al., 2011;

Hosseini et al., 2017). Managers have resources that can help them to achieve a competitive advantage (Barney, 1991; Barney et al., 2011; Hosseini et al., 2017). Managers can sustain competitive advantage if their product or service has four attributes: value, rareness, imitability, and non-substitutable (Barney, 1991; Barney et al., 2011). An organization's employees have capabilities that are considered resources and if developed can provide a competitive advantage.

Proponents of the dynamic capability theory (DCT) extend the RBV and differentiate between operational and dynamic capabilities. The concept of dynamic capabilities arises from a key limitation of the RBV of the firm. Dynamic resources help leaders of firms adjust their employee's capability mix to adapt and keep the firm's competitive advantage (Smart et al., 2007; Teece, 2018).

Firms will inevitably not be strong in all aspects. A manager of a firm might excel at discovering new opportunities but be weak in terms of identifying new business models to exploit them. Leaders can use an OI business model to achieve competitive advantages providing they implement OI properly. Strategic alignment, governance, methods, IT, people, and culture can potentially provide a framework to guide managers in the pharmaceutical industry to implement OI successfully.

Strategic alignment.

Leaders in organizations must be able to adapt their OI processes in response to changes in their corporate environment. Leaders of firms need to make strategic decisions for OI to be successful. One such decision leaders need to make is how many channels and external resources will be used for implementing OI. Furthermore, leaders should

consider levels of engagement in terms of these different collaborations. To garner benefits from OI, organizational leaders must align OI strategies with business strategies and engage with external partners.

A proper degree of engagement with external partners that aligns with corresponding internal resources and processes is essential for improving the organization's innovation performance with OI strategies (Dahlander et al., 2016). Leaders implementing OI need to provide systems and resources to discover opportunities and absorb ideas into their companies. Cui et al. (2015)said IT strategy alignment is directly linked to the success of the OI strategy. The alignment between IT strategies and the extent to which a leader uses OI strategies is critical for innovation success.

IT is a vital component for leaders searching for OI projects. A proper degree of openness that goes along with corresponding internal resources and processes is essential for improving organizations' innovation performance with OI strategies. Leaders of firms implementing OI need to provide mechanisms and resources to discover innovative opportunities and absorb them into the company.

Cui et al. (2015) analyzed data from 225 firms engaged in OI in China and concluded that the alignment between IT flexibility and breadth enhances innovation and innovation volume, while the alignment between IT integration and depth positively affects innovation volume only. Cui et al. suggested firms need IT to transfer both external and internal knowledge to be competitive. Significant advances in IT have

helped leaders to transfer knowledge into and out of companies, easing the pathway to implementing OI.

For a firm to benefit from OI, there is an initial investment in resources needed to increase the firm's absorptive capacity. Absorptive capacity is the ability of an organizational leader to manage new knowledge and integrate new information into the organization and across departments (Xia & Roper, 2016; Xie et al., 2018). Rafique et al. (2018) argued that absorptive capacity is a function of infrastructure as well as the employees of the organization.

Furthermore, Brunswicker and Chesbrough (2018) reported that in their most recent survey compared to their 2014 findings, 2.5 % of respondents abandoned the OI strategy for several reasons. Brunswicker and Chesbrough (2018) reported the respondents that abandoned the OI strategy frequently chose a "lack of required organizational structure," followed by "no perceived benefits," "too risky for assets and IP," "too difficult to manage," "lack of management capabilities," and "too expensive. These results led to Brunswicker and Chesbrough (2018) to conclude that difficulties organizing for OI and implementing OI, may have led to manager's frustration resulting in the abandonment of the OI strategy. Manager's frustration and difficulties with organizing for OI are other reasons supporting the need for an OICF.

Leaders who can establish the availability of several external channels for gathering knowledge may grant access to innovation capabilities that a firm does not hold (Fu et al., 2018). The innovations that leaders discover using these external channels may need infrastructure, technology, resources, and trained employees in the firm to

successfully integrate these innovations into the business. Moreover, the firm's managers may need to decide which channels provide the largest return on investment as the manager decides which channels to implement. R&D managers may find existing ideas or technologies outside their organizational boundaries and integrate the ideas and technologies to start or enhance internal R&D activities provided they have the available absorptive capacity.

While implementing OI strategies, managers of firms need to be aware of the U-shaped relationship (curvilinear) between adopting external technologies and a firm's innovation performance. Although OI may help bolster a company's innovative performance, if managers start too many projects at one time OI may lead to diminishing returns (Dahlander et al., 2016). Companies need the absorptive capacity to integrate new knowledge and technology. Greco et al. (2016) indicated several authors found that specific OI strategies have a positive effect on economic and industrial innovation performance. However, Greco et al. argued over-search and over-collaboration might reduce the benefit of OIs marginal returns when a business leader engages with many external innovation partners. Greco et al. conjectured that many external innovation channels (search breadth) used by a leader, the extent to which the leader's firm engages with the external channels (search depth), and the extent to which a leader of a firm collaborates through different external channels (coupled OI) is curvilinearly related with innovation performance.

There is a ceiling to the level of new information that employees can master. Qi Dong and McCarthy (2019) argued there is a maximum level of new knowledge

assimilation that employees in a firm can process. Furthermore, the speed at which this knowledge saturation point is reached is influenced by the quantity of information and the degree of difference between the new information and the existing knowledge of the employees in the firm. Once the maximum level of new knowledge is reached, more information can lead to a reduced chance of developing breakthrough innovations (Qi Dong & McCarthy, 2019). As leaders increase the number of external relationships innovation performance increases up to a point and then innovation performance diminishes with the addition of more external relationships. Too many projects started without the absorptive capacity to manage the projects, will lead to failure.

In addition to absorptive capacity, managers should consider their firms' industry and business environment before engaging in OI practices. Naqshbandi (2018) indicated that firms' organizational characteristics are important to OI implementation. In this regard, Naqshbandi et al. (2019) contended that leaders in the pharmaceutical industry chose licensing, mergers, and acquisitions, and external collaborations while adopting OI. Firm leaders use these modes of OI engagement based on their organizational characteristics, such as size, age, market orientation, and industry type.

Naqshbandi (2018) highlighted that most of the firm's organizational characteristics are related to OI and these attributes determine how the firm's managers engage in OI. Naqshbandi (2018) research has practical implications and provides insights to managers regarding the firm, industry, market, and ownership characteristics that are favorable towards engagement in OI. Naqshbandi (2018) showed that leading companies in the pharmaceutical industry such as Novartis and Roche, chose licensing,

mergers and acquisitions, and external collaborations while adopting OI. Naqshbandi (2018) identified how firm leaders that engage in OI in different industries differ in their organizational values, such as internal integration and external adaptation. External adaptation andinternal integration are the core challenges leaders of organizations need to overcome for their organizations to remain viable**.** Naqshbandi (2018) findings indicated that firm leaders' in the computer, electronics, and pharmaceutical industries focused more on internal integration and external adaptation, while most leaders in the aerospace industry placed less importance on internal integration and external adaptation. Managers of firms considering OI strategies should be careful in choosing the appropriate model of innovation for their firm's organizational characteristics to attain a competitive market position.

It is important for leaders to choose the appropriate OI model to be successful. Managers of firms need to identify their OI model based on their industry, market and ownership characteristics (Naqshbandi, 2018). While OI may aid leaders in enjoying a competitive market position through the elimination of traditional barriers, an inappropriate choice of the OI model may lead a firm towards unfavorable outcomes (Bican et al., 2017). Strategically, using OI correctly is important for an organization's success while implementing this business model.

Governance.

Managers implementing OI strategies must decide on a proper governance model. Hosseini et al. (2017) suggested OI governance refers to the establishment and operation of proper mechanisms to monitor and continuously improve innovation

performance. Organizations use the internal processes to manage OI more efficiently and effectively since it has been shown that OI management influences the effect of OI in performance (Musawir et al., 2020; Uribe-Echeberria et al., 2019). Leaders of organizations must decide when to use specific OI strategies (e.g. partnerships, innovation contests, and communities) and closed forms of innovation (e.g. authority-based and consensus-based hierarchy) (Hewitt-Dundas & Roper, 2018). Aligned with Hosseini et al., Bican et al. (2017) posited that using the proper governance for OI is a success factor. Different governance models may be better for some projects but not others and different governance models require distinct approaches to project management and selection.

By selecting the correct innovation implementation strategy, organizational leaders can enhance their followers' speed and efficacy of new knowledge assimilation and utilization and subsequently intellectual property right choices, (e.g. patents, copyrights, or trademarks). Bican et al. (2017) raised awareness of such innovation management challenges within R&D processes, as well as strategic intellectual property management by multiple parties. OI models have porous firm boundaries that result in less proprietary control and increased coordination costs, requiring a joint evaluation of OI and intellectual property (Foege, et al., 2019; Lauritzen & Karafyllia, 2019; Vilas, Lopes, & de Carvalho, 2018). Researchers refer to the balance between OI implementation and managing the intellectual property as the OI paradox.

With OI, managers depend on collaborations with innovation partners external to the organization. The governance of these OI projects requires leaders to address

governance-related issues, such as OI decision making, roles and responsibilities, partner relationship management, and managing intellectual property (IP) (Hosseini et al., 2017; Mi & Feng, 2019). The governance-related issues are also linked to managing the absorptive capacity of the firm, a critical success factor. Clear management processes help managers work more efficiently.

Klarner et al. (2019) multiple-case study of four pharmaceutical companies revealed a sequential process of board members' involvement in governance. Klarner et al. (2019) discovered directors with expertise govern scientific innovation, followed by the full board's involvement in its strategic aspects. Klarner et al. (2019) noted the extent of director involvement varied across board levels in terms of the direction (proactive or reactive), timing (regular or spontaneous), and the extent of formality of exchanges between directors and organizational members. Scholars have argued that directors' knowledge and expertise is a prerequisite for effective board involvement in the strategy. Mi and Feng (2019) findings suggest the board of directors is the main decision-maker in business activities and the larger the board membership the less efficient decision-making. Inefficient decision-making tends to lead to reduced innovation because of a decline in the efficiency of communication among board members. Furthermore, Klarner et al. contend that the director's human capital is important for governing a multifaceted and long-term strategic issue such as innovation, which can be defined as the adoption of new ideas, whether it be a new product, process, service, technology, or practice.

Klarner et al. (2019) research revealed that two elements constitute board involvement in product innovation. First, scientific directors engage through

differentiated involvement, characterized by knowledge exchanges that changed in their direction, timing, and formality. Klarner et al. findings indicated directors shared their human capital with several executives and employees at the lower ranks, and the lower ranks provided information on company-specific innovation activities. Second, the full board monitors and provides advice through controlled involvement, characterized by unidirectional knowledge exchanges with fixed timing and formality. Klarner et al. findings indicated directors were involved in innovation from the early research stage of idea generation and testing to the more advanced innovation stage of implementation.

Moreover, according to some research, middle managers are vitally important to OI processes and activities for their ability to smooth the absorptive capacity of the firm. Rafique et al. (2018) research suggested the importance of role specificity of middle managers to smooth absorptive capacity processes. The role specificity of middle managers aligns with Hosseini et al. findings that official roles and responsibilities can help managers with managing the absorptive capacity problem. Rafique et al. research indicated that middle managers with little absorptive capacity are often pulled in many directions diverting their attention and making them less effective. Undoubtedly, defining the roles and responsibilities of the managers can help lessen this burden on managers by better defining their roles and available resources.

In addition to defined roles and responsibilities, the governance of OI projects need well-defined processes for the assignment of IP evolving from OI collaborations. Toma et al., (2018) used a single-case study of R&D intensive firms to investigate how the leaders of firms adopt IP strategies during OI practices. Toma et al. suggested leaders

of R&D intensive firms tend to engage in OI processes with various research partners, such as customers, suppliers, and employees, and therefore these firms require Intellectual Property (IP) strategies to protect their IP. For this reason, proper IP protection strategy should use all the available tools, such as registered and unregistered IP rights (patents, copyrights, trademarks, non-disclosure agreements (NDA)) (Bican et al., 2017; Biswas & Akroyd, 2016; Brunswicker & Chesbrough, 2018; Toma et al., 2018).

Similarly, Hosseini et al. suggest that IP is very important to the OI business model and conceded the more open a business is the more challenging it is to protect its IP. Leaders sharing selective information with OI partners are rewarded through an improvement in the quality of returned information (Barchi & Greco, 2018). Therefore, organizational leaders need the ability to balance and selectively define the optimal amount of information to disclose. Brunswicker and Chesbrough (2018) researched OI at the project level and their findings suggest the careful design of openness, in terms of knowledge sharing and IP control, the formalization of processes, and the role of top management, play a significant role in managing OI at the project level.

In contrast to Brunswicker and Chesbrough (2018), Toma et al. (2018), and Hosseini et al. (2017), Oltra et al. (2018) suggest that a lower degree of formalization and higher decentralization makes inbound, outbound, and coupled OI more effective at influencing positive firm performance. Oltra et al. (2018) argued that formalization is a moderating variable that decreases the effect of OI on performance. Further, the effect of formalized systems affects employees' work and interactions, possibly impeding the

integration across functions and hindering creativity, collaborative learning, and flexibility (Oltra et al., 2018). Pharmaceutical leaders who emphasize open communication also nurture an environment that is conducive to team member innovation.

Biswas and Akroyd (2016) similar to Brunswicker and Chesbrough (2018), Toma et al. (2018), and Hosseini et al. (2017), suggested the stage-gate process is a common control mechanism used for project management and suggested that a hybrid stage-gate open innovation process may assist managers with the co-development of new products. The hybrid stage-gate open innovation process indicated a process that is a hybrid of a formalized process with less decentralization. Biswas and Akroyd (2016) posited it is important to examine the governance of interfirm co-development projects in an OI context to determine the optimal model for governance. Biswas and Akroyd (2016) argued the stage-gate process can enable the development of trust and cooperation which supports the co-development relationship. Biswas and Akroyd's (2016) study findings imply that a stage-gate process can be a flexible governance mechanism, which leaders can adapt over time in relation to the needs of the co-development partners in an OI setting.

Methods.

Hosseini et al., (2017) suggested to be successful with open innovation (OI) projects, leaders need to have well-defined methods and processes for knowledge exploration, retention, and exploitation. Additionally, methods that help to facilitate interactions among OI partners are also important and increase the effectiveness of OI

relationships (Olk & West, 2020). Processes that encourage social interactions may aid in improving the probability of innovation. Leaders need to consider ways to promote social interactions within the project teams as they develop processes to manage and enhance OI.

Toma et al. (2018), and Biswas and Akroyd (2016) encouraged managers to develop processes that provide some degree of control over the innovation process. Processes that provide control over the innovation process are in contrast to Oltra et al. (2018) assertion that formalization of processes hinders the innovation environment because it obstructs the free flow of information. The stage-gate hybrid method suggested by Biswas and Akroyd (2016), is possibly a logical compromise that may help manage the process of OI without limiting the innovator's creativity.

External collaborations are of great importance to the implementation of OI projects. Cheng et al. (2019) highlighted the importance of relationships external to the organization and suggested collaborations between leaders of firms are positively related to the effectiveness of the outcomes of OI projects. External collaborations are one of the most important requirements of a firm for carrying out its OI business transactions as the external collaborators are the ones, who support OI in varied instances (Olk & West, 2020). Cheng et. al. defined collaborators as the competitors, partners, and even the suppliers, who are responsible for enhancing the knowledge of the firm's leaders and employees in a variety of ways. The social interactions with these external collaborators influence the positive impacts of OI on organizational performance.

Furthermore, Cheng et al. (2019) studied the impact of the organizational learning capability of a firm on the manager's implementation of OI. Cheng et al. concluded OI is a business model, that incorporates not only the internal but also the external organizational factors associated with the organization of the firm for the purpose of attaining competitive advantage and sustaining the advantage in the target market. In this context, Cheng et al. concluded that organizational learning capability plays a significant role in maintaining a proper learning environment in the workplace to enhance the knowledge and awareness of the management and employees regarding their work process. Leaders who cultivate the organizational learning capability may improve the efficiency level and maximize the performance of the company as a whole. Cheng et al. suggested organizational learning capability is positively related to the effectiveness of the outcomes of open innovation.

Moreover, Cheng et al. (2019) research demonstrated that knowledge is enormously important to a firm. Cheng et. al suggested knowledge is one of the primary resources for any organization to innovate or to gain a competitive advantage. The majority of leading companies invest a large number of resources on the process of knowledge sharing as the entire work process depends on the knowledge that is shared not only within the firms but also with the external firms such as the customers (Bican et al., 2017). The large investment in knowledge sharing between firms may result in more successful innovation outcomes.

Cheng et al. (2019) concluded that OI includes the different aspects that an organizational leader can use towards sustainable product development for a longer span

of time. These factors are mostly comprised of the three elements specifically knowledge sharing within and outside the firm, the inclusion of external collaboration/partnership, and lastly the proper implementation of the organizational learning capability within the operational procedures. The knowledge sharing within and outside the firm undoubtedly support ensuring that the outcomes of OI are highly effective concerning the organizational learning capability i.e., and creation of a learning environment within the workplace.

Moreover, with the increase in the amount of knowledge sharing between leaders and employees within and outside the firms, the effectiveness of OI practices rise. Cheng et. al. suggested a second factor that focuses on external collaborations results in positive impacts due to the inclusion of external partners such as the supplier firm's managers and employees. The inclusion of external collaborators increases the effectiveness of the OI strategy.

To ensure compatibility between partnering firms, leaders should select the right partner. Leaders should select partners with similarities in approaches, priorities, and processes that are beneficial for external relations (Bican et al., 2017). Furthermore, partner similarity with regard to knowledge, organizational arrangements, institutional frameworks, or physical distances, support OI, and shared learning. As a source for new knowledge, networking supports the commercialization of internal knowledge and is regarded as a key characteristic of OI firms. Methods of networking include the placement of technology scouts, co-funding activities at incubators, and the creation of collaboration internet portals (Bican et al., 2017).

Bican et al. (2017) suggested that individuals' tendencies to prefer collaboration with existing partners often leads to decreased external networking capabilities. Consequently, these leaders can miss out on new opportunities and new external partnerships. To overcome the complexity of integrating new partners and binding intellectual property arrangements, leaders foster networking capabilities through the formation of transaction-light partnerships (Bican et al., 2017). The transaction-light partnerships involve non-essential development areas and standard intellectual property protection contracts. The transaction-light partnerships are intended to support the building of relationships between the leaders of collaborating firms without significant commitment. Leaders can use transaction-light partnerships to mitigate the risk of engaging in external relationships.

Some leaders establish separate internal business groups to manage OI projects. The establishment of separate OI business groups improves the utilization of internal and external knowledge and resources. The efficient use of resources by a separate internal OI business group can help leaders manage the absorptive capacity.

Managers can expand their firm's reach and increase the probability of their company innovating by developing external alliances. Martinez, Zouaghi, and Garcia (2017) demonstrated expanding a firm's boundaries by engaging in external alliances can enhance the internal R&D efforts. Martinez et al. suggested little is known about how managers can operationally leverage the potential benefits of OI to create an innovative advantage. Hosseini et. al. proposed the OICF to potentially help managers implement OI. However, Hosseini et. al. suggested for an organizational leader to apply the OICF,

the leader of the organization will need to account for contextual factors. Further research should thus focus on specific capability areas considering contextual factors e.g. industry, size, etc.

Fisher and Qualls (2018), through the lens of the knowledge perspective of interfirm OI, posited that managers of firms should source, screen, evaluate, acquire, and leverage external knowledge resources for their innovation processes. Fisher and Qualls (2018) assert OI necessitates an external focus and greater consideration to coordinating the use of external knowledge. Similar to Hosseini et al. (2017) OICF, Fisher and Qualls (2018) suggested managers may need systematic methods for capturing the knowledge that they discover as they scan the external environment. Effectively capturing knowledge is a capability that enables managers to be more aggressive at leveraging external knowledge. Leaders using interfirm OI practices attempt to manage the combination of internal and external knowledge to create new products.

Furthermore, Fisher and Qualls (2018) suggested that proponents of the knowledge perspective emphasize the company's external search processes to actively seek, identify, and gather novel ideas to improve new product design and development. Similarly, Hosseini et al. (2017) described the need for knowledge exploration, retention, and exploitation in the OICF. Fisher and Qualls (2018) posited knowledge search is often conceptualized in terms of breadth, which is the number and range of different types of external channels of information. Also, knowledge search is frequently described in terms of depth, which is how deeply the firm utilizes the different external knowledge sources. The breadth and depth of external knowledge search affect various innovation outcomes,

such as the number of innovations and product innovativeness. Fisher and Qualls (2018) suggested advocates of the knowledge perspective of interfirm OI recognize that the method by which the knowledge output is shared is critical to achieving success. Advocates of the knowledge perspective view explain how freely available external knowledge can be internalized by firms in their efforts to develop new products, and how the internal knowledge that is accumulated by firms can be externalized through various channels.

Fisher and Qualls (2018) also viewed OI through the relationship-based perspective of interfirm open innovation. The relationship-based perspective of interfirm OI advocates cooperation with external leaders of firms similar to the OICF proposition. Interfirm relationships are critical to discovering, sharing, internalizing, and leveraging the external knowledge that is central to interfirm OI (Fisher & Qualls, 2018). The extent that managers can access, and leverage knowledge depends on how they interact with external partners. A leader of a firm's position in an innovation network influences effective collaborative relationships.

Accelerators and science parks. A limitation of the OICF is that it does not address a leader's use of accelerators and science parks. These strategies are in their nascent stage therefore, these strategies have not been thoroughly researched. The accelerators and science parks are recent methodologies for knowledge exploration, retention, and exploitation. Richter et al. (2018) suggested corporate accelerators are organizational strategies intended to bring together leaders of innovative new ventures and startups with specialist knowledge and creativity as well as the experience and

financial resources of established companies (Richter et al. 2018). A leader's objective for the use of an accelerator program is to open the innovation process and actively profit from the innovative capacity of new ventures.

Richter et al. (2018) posited that an accelerator program functions as a performance filter, which excludes likely failures early in the innovation process. The uncertainty, exploration, and ambiguity usually associated with innovation are reduced through the application of strict processes, assessment criteria, and decision points within the corporate accelerator program. A corporate accelerator program provides well-defined conditions supporting managers in keeping the creativity of startups under control and directed in the interests of the firm. Richter et al. suggested an established company can extract innovations from the creative and enthusiastic participants, who often originate from a wide range of educational and industrial environments. Leaders implementing corporate accelerator programs provide a controlled environment away from the functional management of the firm. Richter et al. conceded there is little empirical data to support the corporate accelerator program strategy although the concept sounds feasible.

Science technology parks (STPs) emerged from the relationships among the leaders of universities, industries, and governments (Robaczewska et al., 2019; Silva et al., 2020). Encouraging the cooperation of leaders in university-industry to promote innovation and increase innovation performance is one of the most important strategies of developed and developing countries. The concept of the STP was developed as early as

the 1980s. The STP concept was called the Marshallian district (Scaringella & Radziwonb, 2018).

The Marshallian district is based on economies of scale achieved by leaders of firms (Scaringella & Radziwonb, 2018). A high degree of industrial localization offers good opportunities to achieve economies of scale and reduce costs (e.g. STPs) (Silva et al., 2020). Furthermore, the reduction of resistance has a positive impact on reducing transaction costs. Leaders can use an industrial district to divide tasks, jobs, and value chain activities among local small and medium-sized enterprises (SMEs). In a defined setting (e.g. science park), small and medium-size firms benefit from knowledge spillovers (disclosures). The combination of colocation, limited transaction costs, and high specialization are important elements of the Marshallian districts (Scaringella & Radziwonb, 2018). The STP is a strategy that leaders may use to collocate near firms with employees with many different capabilities.

Information Technology

Hosseini et al. (2017) posited that information technology is very important for knowledge search, retention, and exploitation as viewed through the lens of the OICF. Hosseini et. al. emphasized the need for collaborations and sharing of information to effectively implement OI strategies. IT is a tool that can be used to facilitate the collaboration process and information sharing (Ettlinger, 2017; Bican et al., 2017; Milutinović et al., 2017; Matricano et al., 2019). Sharing information is needed externally and internally for innovators to be aware of the resources available to innovate.

Information technology (IT) capability assists leaders of firms to acquire, transform, and leverage external knowledge.

Leaders can leverage IT to search for new knowledge. Information technology (IT)-enabled knowledge exploration may include environmental scanning techniques such as search platforms like the pharmaceutical company Lilly's InnoCentive crowdsourcing platform, or advanced data mining tools that help search web pages, the scientific literature, and global patent databases for relevant ideas and technologies (Carter et al., 2017; Christensen & Karlsson, 2017; Cui et al., 2015; Gkypali et al., 2017; Ettlinger, 2017). Von Briel and Recker (2017) suggested examples of successful OI initiatives found in the literature range from idea gathering to online user innovation communities. Also, managers of organizational innovation networks combine participant resources to generate ideas in the early stages of the innovation process to facilitate successful later stages of development.

Crowdsourcing is another IT tool that leaders can use to elicit ideas for a variety of stages in the innovation process (Ettlinger, 2017; Jespersen, 2018; Stroh, 2019). The internet has helped to decentralize the drug discovery process which has become a more bottom-up process. Crowdsourcing is one tool that has made it possible to search for ideas at a lower cost (Carter et al., 2017; Ettlinger, 2017; Jespersen, 2018; Stroh, 2019). Carter et al., suggested pharmaceutical company leaders typically establish their Internet portals to solicit solutions from community participants. GlaxoSmithKline (GSK) and Bayer are examples of pharmaceutical companies that have an Internet portal for crowdsourcing to solicit ideas from the community. Other pharmaceutical companies'

leaders may use specialist brokers who have crowdsourcing platforms such as NineSigma, or Kaggle (Gillespie et al., 2019). Participants from crowdsourcing platforms have been credited with providing relevant input into ten drug discovery projects at Bayer e.g. Grants4Targets (Carter et al., 2017). Carter et al., suggested Boehringer Ingelheim leaders' have pursued several crowdsourcing projects with InnoCentive that ranged from studying new translational models of psychiatric disease to new approaches for the *in vivo* modulation of gene expression in lymphocytes.

Notwithstanding this scientific progress, some researchers still argue that OI may not be an effective innovation strategy. Von Briel and Recker (2017) argued that OI in its many forms is not necessarily an effective strategy. Practices that have been identified in successful implementations of OI do not necessarily prevent failures. Leaders' OI failures are supported by ample research and so the need for an effective implementation framework (Ettlinger, 2017). Indeed, these idea-generating platforms suffer from one major drawback, innovation requires that a creative idea be reduced to practice in the form of an actionable plan (Matricano et al., 2019). The process of converting an idea into action is an iterative process that needs to be collaborative and free from restrictions (Stroh, 2019). Von Briel and Recker (2017) provide executives in organizations seeking to establish online OI communities with a set of managerial lessons learned and a framework with checkpoints and guidelines. Von Briel and Recker (2017) posited several potential barriers to consider before beginning an online community: (a) Industry context, (b) Legal environment, (c) Supportive processes, (d) Innovation mindset, (e)

Commitment, and (f) Participant community. All these barriers are critical to evaluate before initiating an online OI community.

Von Briel and Recker (2017) demonstrated how the successful implementation of an online OI community depends on several interrelated conditions and that these implementations often face unique challenges associated with the context of the business. While the generalization of the Von Briel and Recker (2017) findings is limited because of the single case study design, their approach provides an unusual opportunity to learn from failure. Von Briel and Recker (2017) posited there is little known about OI failures or the reasons for OI failures. Some prominent examples of OI failures include Boeing, LEGO, and some pharmaceutical implementations. Perhaps studying the causes of these failures could help business leaders avoid these implementation pitfalls.

The underlying reasons for the innovation failures in these leaders' companies were related to strategy, communication, and a lack of knowledge of the complexity and intricacies of using open innovation strategies. The LEGO managers' primary mistake which led them to failure was producing products the customers did not want. LEGO management had lost sight of the needs of their customers. Organizations have traditionally relied solely on internal knowledge to drive innovation (closed innovation). However, such closed innovation limits the flow of ideas and can perpetuate negative groupthink. When the LEGO leaders realized a need to reconnect with their customers the LEGO managers launched a program to engage users in the development of products (Andersen & Gadde, 2019).

The LEGO managers used an open innovation strategy that encouraged customers to interact, share, and vote for ideas regarding the kinds of products or services they would like to see LEGO develop (Cina & Cummings, 2018). The crowdsourcing platform the LEGO managers implemented was called 'Cuusoo' (Japanese for 'wish') (Cina & Cummings, 2018). The LEGO managers, opening lines of communication with customers in this way, improved engagement with their growing customer base and their future product developments came to be informed by the user community. This open innovation strategy brought the company into greater sync with industry trends and customer needs. The LEGO company has come to be recognized as a world leader in toy innovation with high levels of growth and posting a record profit of $1.87 billion in 2016 (Cina & Cummings, 2018).

Boeing experience another example of the difficulty in implementing OI. Boeing managers needed a better adaptation of organizational and development practices to the innovation introduced by their decisions (Shenhar et al., 2016). The Boeing management team experienced difficulties developing its highly innovative Dreamliner aircraft. The Boeings Dreamliner engineers' first major challenge involved designing the aircraft's body using light-weight composite materials. The Dreamliner aircraft was to accommodate 250 passengers on long-haul transportation for about a 20% lower fuel cost (Shenhar et al., 2016). This change in the material was necessary for fuel savings.

Although composite materials were not new, the composite materials were never used in such a large aircraft (Shenhar et al., 2016). The Dreamliner engineers required more sections to assemble the fuselage than previously used for an aluminum-based

fuselage (Shenhar et al., 2016; Tidd & Bessant, 2018). The engineers' lack of experience with the composite materials resulted in having to redesign the plane, which significantly delayed the Dreamliner project.

Boeing managers' confidence in its experience and record of success led project leaders to believe that the new project would be as successful as others. The engineers probably underestimated the challenges and scope of innovation (Shenhar et al., 2016; Tidd & Bessant, 2018). The managers' difficulties were a result of the following major challenges: (a) the use of newly developed technologies, (b) outsourcing a large extent of design to numerous, less experienced subcontractors, (c) a new business model of revenue sharing, and (e) a new assembly model (Shenhar et al., 2016). Using these strategies, Boeing managers helped retain competitive positioning by taking advantage of modern technologies, and practices, but Boeing managers' execution was less than optimal.

Procter & Gamble (P&G) provided another example of an OI failure. The managers made a strategic mistake in trying to implement OI. P&G managers did not understand the complexity and intricacies of using open innovation strategies. P & G was an early adopter of the OI strategy so there was not as much research available to guide the managers. The P & G case study provided some of the learnings for implementing OI.

The P & G managers decentralized the firm's research and development (R&D) to shift P&G's R&D to an OI model (Han et al., 2019).The P&G managers' OI model shifted the burden of innovation from a centralized department to business units categorized by product type. Although shifting the innovation to business units provided

innovators with focus and increased success rates for new product introductions, these products did not address the unmet needs of the customers. The focus of the managers was on the invention of new technology and not addressing the unmet needs with innovation (Han et al., 2019). In P & G's case, there were flaws in both the strategy and the implementation, which ultimately led to failure.

The open innovation strategy led to organizational decentralization and reduced collaboration between separate product groups within P & G (Han et al., 2019). This change failed to utilize one of P&G's competitive advantages, its conglomerate structure. For instance, the innovators of Crest Whitestrips used bleaching technology from the laundry business, glue technology from the paper products business, and film technology from the food wrap department (Han et al., 2019). P & G's centralized R&D allowed these departments to work together to inspire innovation.

Furthermore, the compensation structure of the business unit managers also contributed to the failure of the R&D reorganization because the managers were being rewarded for business unit profitability (Han et al., 2019). Since R&D expenditure lowered profits over the period, investment was not initiated unless it led to an immediate profit, offsetting revenue growth, and rewarding managers for incremental improvements in the products. This led to the transition from high-risk, high reward products to incremental improvements of existing products. Shorter development periods and quicker return on investment became the priority.

P & G re-established distinct R&D departments that pooled knowledge from scientists, engineers, and product developers across all P&G's product lines (Han et al.,

2019). Furthermore, the managers started looking outside the firm for needed capabilities. Scientists, engineers, and product developers across all P&G's product lines were given specific long-term targets and budgets with a significant portion of compensation derived from qualitative metrics. This new system emphasized long-term decision making through focused planning and was flexible enough to reward employees for visionary innovations (Han et al., 2019). A similar compensation structure was implemented at Johnson & Johnson with great success.

In contrast to Von Briel and Recker (2017) findings, Gillespie et al., (2019) suggested that some sectors have embraced the paradigm shift to open innovation. Gillespie et al., (2019) noted there is an increased uptake of OI practices by leaders of the biopharmaceutical sector. Leaders in biopharmaceutical firms have embraced OI models to optimize drug development. Gillespie et al., (2019) suggested the leaders of the traditional proprietary, non-collaborative biotechnology, and pharmaceutical companies are increasingly using principles, processes, and structures of OI to increase drug R&D effectiveness and efficiency. Gillespie et al., (2019) distinguishes three essential elements in the successful creation of OI partnerships: (i) culture, (ii) collaborative management skills, and (iii) strategic capability alignment. Gillespie et al., (2019) three essential elements are three of the six high-level factors that Hoesseini et al., (2017) identified in the OICF proposal.

Gillespie et al., (2019) provided guidance for business leaders and scholars interested in the managerial and strategic dimensions of applying OI to the drug development environment. In addition, business leaders and scholars may find that using

all six factors of the OICF may lead to more effective implementations. Leaders' use of OI has the potential to improve quality, increase speed, and lower costs, and thus yielding positive benefits for global health.

People

Hosseini et al. (2017) said employees and corporate OI teams play an essential role in OI. Important capabilities that can foster innovation performance are technology mastery, personal peer leadership, and capabilities to link to external organizations (boundary-spanning). The latter capabilities do not need to be held by all individuals. However, leaders need to ensure there is a sufficient number of individuals placed in the correct functions or dedicated teams that have these capabilities. Martinez et al. (2017) posited that knowledge, skills, and abilities used by individuals in an organization, determine a firm's potential gains from collaborating with external organizations. Many researchers' findings have highlighted the importance of the employee's knowledge, skills, and abilities for the successful implementation of OI.

Consistent with Hosseini et al. (2017) and Martinez et al. (2017), Kratzer et al. (2017) suggested there is an agreement that the people are central to a company's innovation process and drive the innovation process. Kratzer et al. posited employees in companies perform innovation in an environment with rules and regulations that might support or hinder innovation. The OI paradigm expects leaders of companies to engage in external relationships for innovation. Leaders often neglect to cultivate a culture of employee communication openness.

Creating an internal culture of openness is important for leaders considering OI strategies and before collaborating with external partners. Kratzer et al. (2017) argued that establishing internal openness (unhindered communication) is important before collaborating with external partners. The key challenges in building and developing an innovation culture are the changes in the organization's approach and mobilizing teams to bring products and services to the market quickly. The leader's fundamental challenge with this process is that companies need to incorporate a view on innovation shared not only by the company leaders but also by employees (Hannena et al., 2019). Incorporating a view of innovation shared by the company leaders and employees may require a significant culture change driven from the top down.

Leader and employee behavior and attitudes are important elements in shaping a corporation's work culture and innovation culture. Kratzer et al. (2017) argued employee behavior and attitudes are linked with cultural thinking. Employees' behavior and attitudes are important elements in shaping a corporation's work culture and innovation culture (Hannena, et al., 2019). Employee behavior and attitudes may facilitate the OI process. Leaders considering using OI to enhance their internal innovation process need to put several OI supporting processes in place to facilitate the implementation. Some of the areas that leaders need to focus on to be successful include strategy alignment, governance, OI methodology, employees, corporate OI teams as well as the firm’s culture (Hosseini et al., 2017; Kratzer et al., 2017). To be successful, leaders of a firm need to take a holistic approach when implementing OI to ensure their overall strategy is in alignment with their business strategy, information technology, and culture.

Culture

Hosseini et al. (2017) suggested a different mindset is imperative for OI. Employees currently working in a closed innovation practice will need to change their practices concerning managing ideas, knowledge, and technologies. Leaders' and employees' cultural values and beliefs are critical for OI as are formal practices, which is why leaders of organizations must implement an innovation culture that enables and promotes OI activities (Mahdad et al., 2020). Hosseini et al. said related competencies are OI attitude and behavior, risk attitude toward OI, and attitude toward IP management.

Not-invented-here syndrome. One challenge for leaders implementing OI is shifting employee mindset from a closed to open innovation. As organizational leaders shift strategies, the leaders need to consider ways to overcome the not-invented-here (NIH) syndrome (Hannena, et al., 2019). NIH syndrome is an employee's negative attitude toward external knowledge exploration. Leaders need to develop strategies to change the employees' attitudes to be accepting of the external knowledge exploration strategy (Hannena, et al., 2019). The failure of leaders to mitigate the NIH syndrome may lead to a biased and incorrect evaluation of external ideas and technologies. Biased and faulty evaluation of external ideas and technologies by managers could result in the ineffective implementation of OI.

Not-connected-here attitude. Related to NIH, another barrier that leaders need to overcome is the not-connected-here attitude, which reflects a negative employee attitude toward external knowledge retention, e.g., attributable to a lack of trust in innovation partners (Hannena, et al., 2019; Hosseini et al., 2017; Kratzer, et al., 2017). Employees'

lack of trust in external partners can have a negative impact on information exchange with the external partner. Both the NIH syndrome and the not-connected-here attitude hinders the exchange of information with innovation partners (Hosseini et al., 2017).

Risk-taking tolerance. Employees suspicious of the leaders' intentions for external sourcing may consider external sourcing as a greater risk given a higher level of perceived uncertainty compared with internal sourcing. Leaders being too risk-averse and attempting to minimize risk by implementing too many risk filters may slow down the innovation progress, potentially leading to missed opportunities and potentially leading to failed collaborations. Leaders implementing OI need to encourage an entrepreneurial culture tolerant of risk-taking to benefit from OI.

Leadership commitment. The level of leadership commitment and attention impacts the effectiveness of the OI strategy. Leaders must create a work climate conducive to OI. The articulation of goals and top-down encouragement involves written and spoken communication (Musawir et al., 2020). Leaders' OI success stories can be used to inspire employees to actively search outside of an organization for new ideas and technologies. By implementing the proper incentives, leaders can foster employees' engagement throughout different OI activities. Leaders should consider incentives that foster acquiring innovation from external sources. Providing incentives to employees for acquiring innovation from external sources can support an employee's mindset in abandoning an NIH attitude.

Governance-related culture change. The culture change must entail not only governance-related changes but also cultural changes regarding IP management. A firm's

legal and IP leaders must be encouraged to adopt a positive attitude supportive of OI. Instead of taking an excessive protective position, legal and IP leaders should encourage employees to seek mutually beneficial agreements (Moellers et al., 2020). Sharing knowledge with innovation partners or communities can be beneficial as the quality of returning information improves with the amount of initially revealed information (De Silva & Rossib, 2018). If managers convey an overprotective attitude to employees, this may lead employees to avoid external engagement given the perceived personal and professional risks of the unplanned disclosure of information.

Hosseini et al. posited that culture affects innovation success but concluded that no specific OI culture exists. Nestlea et al. (2019) suggested extant research has found superior innovation performance of firms located in research clusters. It was unclear if the superior innovation performance was a result of the proximity of the firms, or other unknown factors (Nestlea et al., 2019). Nestlea et al. concluded that more research was needed to determine if the differences in the open innovation culture was the result of membership in a cluster. Similarly, Hosseini et al. concluded more research is needed regarding OI-enabling culture.

The high-impact organizational changes related to OI involve the adoption of cultural changes and new approaches to the entire company governance and innovation processes. The spread of an open innovation culture within organizational boundaries appears as the main factor guaranteeing the sustainability of OI as a long-term strategy.

Pharmaceutical Industry and OI Implementation

Pharmaceutical company leaders have been experiencing challenges to bring novel therapeutic agents through the R&D process to generate a sufficient return on investment (DiMasi, et al., 2016). The cost estimate to bring a new drug to the market averages $2.9 billion and 13 years (DiMasi et al., 2016). Leaders in the pharmaceutical industry have trouble discovering and developing novel therapeutics. Chesbrough and Chen (2015) suggested pharmaceutical drug development costs have risen over the past 20 years but the number of new molecular entities (NMEs) approved has not increased.

As pharmaceutical companies reduce their R&D spending significantly to balance their budgets, unmet medical needs will remain unaddressed (Chesbrough & Chen, 2015; Gillespie et al., 2019; Gkypali et al., 2017; Masuccia et al., 2020; Reichman & Simpson, 2016). Much of the rising costs in drug development can be traced to work on failed projects that are abandoned before getting to market (Chesbrough & Chen, 2015; Reichman & Simpson, 2016). Improving the efficiency of R&D may allay the costs and potentially lead to more therapeutics for a variety of conditions. Hosseini et al. reported there is evidence that OI strategies can increase the net present value of projects by 70% compared to closed innovation projects. Leaders using OI strategies are associated with superior firm performance and higher innovative activity in both large and small-to-medium-sized companies (Battistella et al., 2017).

OI is a broad term for diverse strategies that managers use to seek external input and public engagement and has become an essential tool with researchers, who are increasingly turning to research collaborations, crowdsourcing, data sharing, and open-

sourcing to address some of the most pressing problems in medicine. Notable examples of such open drug development include initiatives formed around malaria and tropical disease (Weng et al., 2018). Currently, there is no established OI framework for the pharmaceutical industry that pharmaceutical leaders can use as a guide for the implementation of OI projects.

Searching for strategies to improve the drug discovery process, leaders in the biomedical research field are beginning to embrace OI. Shaw (2017) noted traditional drug development models are perceived as inefficient, with the cost of research and development continuing to rise even as production of new drugs stays constant. Shaw (2017) noted the changes in leaders' strategies are starting to reshape the industry. OI practices have found their way into the drug discovery process, from target identification and compound screening to clinical trials. Shaw (2017) argued the OI perspective poses some risks-which include the management of collaboration and the protection of proprietary data but in many cases, OI strategies are a more efficient and ethical way to conduct biomedical research. In the pharmaceutical industry, practical limitations, cultural norms, and intellectual property (IP) concerns have resulted in a development process traditionally conducted in a carefully protected proprietary environment often referred to as closed innovation.

Consistent with Shaw (2017), Banerjee and Siebert (2017) studied the effect of pharmaceutical and biotech R&D leaders' collaborative business relationships on the firms' research activities and drugs offered on the market. Banerjee and Siebert (2017) indicated that large firm managers' collaborating in the late research stage re-optimize

their R&D pipelines and eliminate similarly aligned research projects. Managers streamlining R&D can reduce costs and eliminate drug candidates that could potentially limit the profits of each product. Late-stage R&D collaborations formed among leaders of larger firms increase a firm's research activities but reduce the number of drugs launched in the product market. Leaders reduced the number of drugs launched in the product market by eliminating overlapping drug products. Some researchers have highlighted that R&D collaborations between leaders of companies have helped overcome innovation obstacles and resulted in an increase in R&D activities. Banerjee and Siebert (2017) studied leaders' strategies who were engaged in R&D collaborations throughout the different stages of the drug development process from early to late stages.

Engaging in R&D collaborations at all stages of the R&D process can help leaders manage the increasing cost of R&D. Banerjee and Siebert (2017) studied firms where leaders engage in R&D collaborations to manage the increasing costs of drug development. Banerjee and Siebert's (2017) findings revealed that early and late-stage R&D collaborations have differential impacts on the technology and product markets. More specifically, early-stage collaborations allow firms to increase R&D activities that may eventually be transmitted to the product market and lead to an increase in the number of drugs offered on the market.

In contrast, when leaders engage in late-stage R&D collaborations among larger companies, leaders have less of an impact on a firm's R&D activity. Late-stage products are less likely to need an intense R&D effort than early-stage products. Research collaborations have been analyzed frequently in the literature and are considered to have

socially and ethically beneficial impacts such as avoiding wasteful duplications in research. In the pharmaceutical industry, findings from several research studies indicated leaders engaging in R&D collaborations increase the probability of developing new drugs. R&D collaborations allow the leaders to exploit the synergy effects and share the costs of R&D.

Developing and exploiting innovation activities in collaboration with external parties requires new decisions that should be delineated in *when, how, with whom, with what purpose* and *in what way* (Battistella et al., 2017; Carter et al., 2017; Namkuk et al., 2015). West and Bogers (2017) said inbound OI practices are more commonly used than outbound practices in the pharmaceutical industry. Few researchers have studied the outbound OI practices in the pharmaceutical industry. Yet, even with the extensive OI research that has been performed, there are still many areas that remain unexplored and warrant more research such as the use of outbound OI.

Open Innovation Capability Framework

This research project is intended to identify a potential OI implementation framework for OI projects that phamaceutical managers can use to engage in OI projects. The research on OI implementation is sparse and fragmented. Few researchers have attempted to identify the factors that may support the successful implementation of OI. OICF comprises the outside-in and coupled OI processes and provides a comprehensive overview of related capabilities compared to many of the other studies. The holistic approach of the OICF can assist decision-makers in prioritizing, selecting, and customizing the proposed capability areas for their context. Hosseini et al.

(2017)posited that leaders of organizations should carefully analyze the relevance of the OICF distinct capability areas in their context (e.g. industry, environment, and size).

OICF

While compiling the OICF, Hosseini et al. focused on keeping the included capability areas as OI-specific as possible. Henceforth, the OICF captures specific capability areas, but not necessarily unique to OI (Hosseini et al., 2017). The OICF framework provides practitioners with a framework to further explore open innovation. Hosseini et al. posited that most research on OI frameworks focuses on single facets of OI. The OICF framework introduced by Hosseini et al. only covers two modes of OI, the outside-in and coupled processes of OI. The OICF framework takes several of the proposed theories and merges them for a more comprehensive implementation framework.

Hosseini et al. (2017) collected the data through a literature review of OI theories and integrated them into a larger OICF theory that takes pieces from all the theories used to explore OI. Subsequently, Hosseini et al. validated the assumptions with a 7-point Likert scale survey using academia and industry OI experts. One shortcoming of the proposed OICF is that Hosseini et al. did not address the inside-out model of OI where leaders sell unused technology or abandoned compounds for financial gain.

Inside-out model

The inside-out model may be an effective OI mode for the pharmaceutical industry and is only beginning to be researched (Chesbrough & Chen, 2015). Toma et al. (2018) suggested the biopharmaceutical sector could benefit from adopting OI strategies

but conceded that pharmaceutical leaders engaging in OI may have to differentiate their IP protection tools depending on the R&D phase. The development of therapeutic agents goes through several stages before being a marketed product.

Additional OI framework

Battistella et al. (2017) explored the different practices, actors, and tools adopted for opening the innovation process by small and medium-sized companies facing difficulties in OI implementation. Battistella et al. discovered 23 practices, 20 actors, and 11 tools used in the OI processes of small and medium-sized companies. Battistella et al. methodology used to develop the framework are consistent with the methodology Hosseini et al. used to develop the OICF. Both researchers searched the literature and identified the different OI practices and tools used to develop the proposed frameworks to implement OI.

Few researchers have studied the implementation of OI projects. Battistella, et al. (2017) suggested previous research of OI studied management challenges for effective OI implementation, yet there was still little research on putting OI into practice and therefore a need to study OI implementation. Battistella et al. reported that other researchers introduced frameworks that support managers in identifying the OI practices that best fit a specific innovation project. Battistella et al. studied different combinations of variables related to OI practices e.g. access mode and variables related to a company's innovation context in terms of knowledge channels. Battistella et al. concluded, similar to Hosseini et al. (2017) that leaders of companies need to adopt new approaches to access external

knowledge and create competitive businesses. Identifying and engaging in external relationships to acquire new capabilities are important to the implementation of OI.

Most empirical investigations about OI have been case studies of successful early adopters of open innovation, and their analyses have mostly been at the company level. Inbound OI involves a wider variety of actors and tools than outbound OI practices (Battistella et al, 2017). OI practices such as crowdsourcing, external networking, and scouting from external sources involve the use of external sources of knowledge through the application of two to three different tools (Battistella et al., 2017). Consistent with Hosseini et al. (2017) proposed OICF, the tools used for targeting, sourcing, and acquiring valuable knowledge involved the use of IT.

Project level antecedents

Namkuk et al. (2015) suggested that future research needs to look at the project level implementation of open innovation (OI). The project level is where the innovation begins in R&D (Battistella et al., 2017). Namkuk et al. explored systematic relationships between various antecedent factors and the degree of openness. Project-level openness could be affected by team and task characteristics, such as team size, learning distance, strategic importance, technology, and market uncertainty, and relevance to the main business. Namkuk et al. collected data from 303 companies in Korea to identify the antecedents that affect inbound and outbound openness. The Namkuk et al. findings suggested six factors at the project level that could be expected to affect OI behaviors.

Subsequently, Namkuk et al. (2015) conducted an exploratory field study to learn more about the factors six factors identified. The exploratory interviews revealed that

teams that already possessed sufficient capabilities to succeed on their own did not engage in OI. Project leaders of teams should consider their teams' knowledge and capability gap (learning distance) as an antecedent of open innovation.

Furthermore, Namkuk et al. (2015) suggested one of the most critical resources for an R&D project is human resources, and so team size is used as a measure of the number of employees available to a team. Accordingly, the amount of resources available to a team is expected to affect its OI activities. Advocates of the social capital perspective inferred that opportunities to form relationships with external parties grow as team size grows; therefore, larger teams are more likely to benefit from more sources of external resources than smaller teams.

Five design principles

Five design principles posited by Ollila and Ystrom (2016) were (a) presence of participants equals influence, (b) diversity is the source of creativity, (c) multiple identities of participants created an extended view, (d) a higher purpose unites the participants, and (e) the participants are creators of the collaboration. Ollila and Ystrom (2016) noted practitioners should discuss the expectations and preconceptions when engaging in collaborative activities and the practitioners benefit by using the design principles to facilitate the communications. The themes emphasized by Ollila and Ystrom, (2016) are closely related to the six factors postulated by Hosseini et al. (2017).

Limited scope framework

Ya Juan Wu et al. (2016) performed a single case study using an ethnographic approach to become closely engaged in a project for developing drugs for diabetes.

Identifying potentially suitable drug candidates to fit the product portfolio is a very small but important aspect of inbound OI. Ya Juan Wu et al. used a grounded approach like Ollila and Ystrom (2016) to let the themes discovered by the researchers inform their theory. Although Ya Juan Wu et al., research was very limited in scope their findings discovered principles closely related to some of Hosseini et al. (2017) open innovation capability framework (OICF).

Conclusion

The OI paradigm has received an extensive number of contributions from different researchers that studied a variety of OI dimensions such as strategy, leadership, and organizational structure. Inbound OI practices seem to be more prevalent than outbound practices and not a lot of research has been performed on outbound OI practices. Furthermore, researchers suggested that more research is needed at the project level in different contexts. Also, OI researchers suggest organizational leaders need a more comprehensive OI implementation framework. Currently, the approach to OI implementation is fragmented because little research has been dedicated to this topic.

The OI approach to innovation has become very important for innovation and technology and therefore captured the attention of managers and other leaders. These OI practices of organizing research, development, and innovation activities could be an effective way of sharing knowledge, obtaining complementary assets, and generating new technologies in most sectors where technological advances are rapid such as the pharmaceutical industry.

Transition

In Section 1, I provided the foundation for this study and discussed the basis of the problem and the purpose of the study. The conceptual framework provided a path to understand how pharmaceutical leaders implement OI drug development projects, and the significance of the study supports the purpose statement. Also, in Section 1, I introduced the research question for the study. In the review of the literature, I analyzed and synthesized various sources of literature to achieve an in-depth analysis as it relates to the research topic.

In Section 2, I explain the role of the researcher, participants, chosen research method and research design, sampling method, ethical research, data collection instrument, techniques for data collection, data organization techniques, and data analysis. At the end of Section 2, I detail aspect of reliability and validity as it applies to qualitative research and describe the rigor of my qualitative research.

Section 3 comprised research findings, how the findings apply to professional practice, implications for social change, the recommendations for action. I conclude Section 3 with my recommendations for future research, a discussion of the foundation of the study, implementation of OI drug development projects, and my research conclusions.

Section 2: The Project

In Section 2, I discuss my role as a researcher and describe my study participants. This is followed by a description of the qualitative research method and single case study research design. I describe the population and sampling followed by a discussion of ethical research. Section 2 also includes discussion of data collection instruments, data collection techniques, data organization techniques, and data analysis. I conclude Section 2 by explaining my strategies for improving the rigor of my research.

Purpose Statement

The purpose of this qualitative single case study was to explore strategies US pharmaceutical company leaders used for developing and implementing OI R&D projects. The targeted population was five US pharmaceutical R&D directors in one pharmaceutical firm who have successfully used OI strategies to develop and implement R&D drug development projects. The firm was headquartered in the northeastern region of the US. My research findings may enhance US pharmaceutical leaders' capacity to increase ROI, decrease operational costs, and positively influence local communities through increased tax revenues. Furthermore, efficient discovery and production of novel therapies may lead to a better quality of life for many patients.

Role of the Researcher

The role of the researcher is central to the data collection process. The researcher needs to be aware of how their role in research is significant. In this qualitative research, I was the data collection instrument and played a vital role in understanding the practices and behaviors of participants. My role was to listen to each participant's responses and

refrain from being judgmental while remaining focused and attentive. Furthermore, my responsibility was to conduct ethical research following the Belmont Report. The Belmont Report provides researchers with a set of ethical standards and guidelines they must adhere to for the protection of participants. My role was to interview five participants from one company, collect and analyze data, and manage interviews while protecting the privacy of participants. I used semistructured interviews with 10 open-ended questions that addressed significant areas of the OICF. I used an interview protocol to help maintain consistency in data collection between participants.

Transparency in terms of the researcher's position, potential biases, and assumptions is vital in terms of judging accounts of qualitative research and the authenticity of findings. I have no direct professional relationship with participants involved in the study; however, I work for the same employer. Participants are geographically located in the northeast of the US. Also, participants work in a different department at a higher pay grade than myself.

I worked in biomedical R&D for over 36 years and played an integral role in managing *in vivo* research and research facilities within public and private organizations in New York. Because of my years in biomedical research, I needed to be aware of potential biases. Confirmation bias occurs when the researcher filters participants' information and uses a subset of the information according to the researcher's preexisting beliefs (Gatlin et al., 2017; Reid et al., 2018). Confirmation bias makes people more willing to select information that confirms a prior belief or opinion. Researchers

practicing reflexivity while interviewing can avoid these biases (Pessoa et al., 2019). I mitigated confirmation bias via reflexivity and questioning of my conclusions.

Participants

I used purposive nonprobability sampling to select participants for this research study. Nonprobability sampling is appropriate for qualitative research. The purposive sample consisted of participants who possessed the knowledge to contribute relevant information regarding strategies for developing and implementing OI R&D projects. Researchers using nonprobability sampling rely on their judgment when choosing members of the population to participate in their study. Some types of research design require researchers to decide which individual participants would be most likely to contribute appropriate data, relevance, and depth.

The research participants selected possessed the experience and ability to contribute relevant information regarding developing and implementing OI R&D projects and agreed to be audiotaped. To gain access to participants, I requested organizational cooperation to assist in identifying relevant participants. I sent a letter of organizational cooperation (see Appendix A) to the company's human resources and legal departments to get permission to do research. After I received pharmaceutical organization and Walden University Institutional Review Board (IRB) approval, I sent a recruitment letter (see Appendix B) via email to participants to request their participation. Participants who agreed to be interviewed were sent consent forms (see Appendix C) with the IRB approval number (# 09-14-20-0674379) via email.

Before interviewing participants, I received affirmative consent forms from their email addresses. I needed to select a minimum of four participants. Gaya and Smith (2016) said three participants are enough for a single qualitative case study design. Creating a systematic and transparent way of obtaining participants is beneficial to providing adequate information for a qualitative single case study (Benoot et al., 2016). After data saturation was achieved, I determined the number of participants needed for the study was five participants. Sim et al. (2018) said determining a qualitative sample size a priori is problematic. Qualitative case studies do not have a set number of participants in terms of sample size, but when data saturation is reached, more information will no longer bring value to the study (Boddy, 2016). The initial set number I determined for this study was four participants, but after collecting data, data saturation was achieved with five participants.

Transcripts and audio recordings will be stored for 5 years so that only I have access to the data. Consent to participate in the study was obtained from each participant before conducting each interview. Sending consent forms in advance for participants to review expedited the process of using the data for this doctoral study. Raw data is important to save from interviews. Data will be stored on a flash drive, my computer, and on cloud management software (OneDrive). All stored data will be password-protected and retained for a minimum of 5 years after the study's completion.

Research Method and Design

The research method used for this study was qualitative, and the research design was a single case study. I chose this research method and design based on the

nature of the topic, which involved strategies US pharmaceutical company leaders used for developing and implementing successful OI pharmaceutical R&D projects. The qualitative research method and the single case study design were appropriate for this study because they can increase researchers' understanding of a contemporary phenomenon with the use of multiple data sources from a single organization and not multiple organizations (Yazan, 2015; Yin, 2018).

Research Method

When conducting a research study, three research methods are available for researchers to use qualitative, quantitative, and mixed methods. The choice of the research method is related to the research problem and purpose (Bloomberg & Volpe, 2019). Qualitative research involves the use of multiple data sources to discover patterns or themes under given circumstances (Kegler, et al., 2019; Merriam &Tisdell, 2016). Qualitative data sources include interviews, observations, and company documents. Quantitative research involves the use of instruments to accumulate data for statistical analysis to test a theory or hypothesis (Bryant et al., 2018). The quantitative research method was not appropriate for this study because it requires the examination of multiple numerical variables, which was not the emphasis of this study. Mixed-methods research combines both qualitative and quantitative methods (Bloomberg & Volpe, 2019). Because the mixed methods approach uses the quantitative method, it did not provide the information needed for this study, thus making it unsuitable for this research. A qualitative research method was the most appropriate method for this study because the qualitative methodologist relies on data sources in everyday occurrences. According to

Kegler et al. (2019), the qualitative research method helps us understand the context, explore new phenomena, identify new research questions, and helps to construct a complete description of the themes or patterns relevant to the phenomenon.

Research Design

A single case study research design was the research design used for this study. A single case study research design aligns with the qualitative process that deals with exploring a phenomenon thoroughly in real circumstances to establish connections that are not easily seen but are important to understanding the phenomenon (Ganz & Ayres, 2018). The tools I used for data collection were interviews and publicly reported company documents. A single case study research design incorporates real situations to collect data from a variety of sources, which highlights a conclusion or set of conclusions (Merriam &Tisdell, 2016; Yin, 2018). The single case study was most appropriate for this study because I was exploring one organization by interviewing five R&D directors to gain knowledge on strategies US pharmaceutical company leaders used for developing and implementing successful OI pharmaceutical R&D projects. My comprehensive analysis of the specific business problem provides strategies for developing and implementing successful OI pharmaceutical R&D projects.

Researchers may also use other qualitative research designs for a study, including ethnography, narrative inquiry, and phenomenology. Ethnographers focus on studying human society and culture (Merriam & Tisdell, 2016). Ethnography was not suitable for my study because my intention was not to focus on studying a group of people within a culture. The narrative inquiry focuses on the first-person accounts of experience told in

story form. Biography, life history, and autobiography are examples of narrative inquiry (Merriam & Tisdell, 2016). The narrative inquiry was not appropriate for my research.

The main purpose of the phenomenology design is to explore human experiences from the perspective of participants within a phenomenon (Bloomberg & Volpe, 2019). Studying human experiences was not my intent for this study. The objective of my study was to explore strategies US pharmaceutical company leaders used for developing and implementing successful OI pharmaceutical R&D projects. Therefore, a single case study design was the most appropriate design for this study.

Population and Sampling

The population sample for this qualitative single case study was five R&D directors in a single US pharmaceutical company located in the northeast. Participants of the qualitative single case study included male and female R&D directors who were chosen through purposeful sampling and were interviewed via WebEx. The choice of interview method was to make the participant comfortable during the interview and to transcend geographical barriers. Purposeful sampling is a standard technique used in qualitative research studies where a researcher selects information-rich cases for the study that will provide insight and understanding to a phenomenon or topic of interest (Benoot et al., 2016). The conditions for selecting participants in this study included R&D directors in a single pharmaceutical company with knowledge and experience with using OI strategies to implement pharmaceutical R&D projects.

In qualitative research, data saturation is important. Fusch and Ness (2015) identified that data saturation is necessary when determining the sample size for a study

and that data gathered must be rich quality data and a dense quantity of data. Saunders, et al. (2018) posited that data saturation is commonly taken to indicate that, based on the data that has been collected or analyzed, further data collection and/or analysis are unnecessary. Data saturation is met when there is no new data being collected, no new patterns being discovered, and no new coding being conducted (Tran et al., 2016). In a qualitative research study, once data saturation is met, the sample size will be set. In this study, I interviewed five participants to ensure data saturation. I ensured data saturation for this study by collecting comprehensive data and identifying essential themes of the open innovation capability framework (OICF) by interviewing five participants who are R&D directors and have met the study conditions. Saunders, et al., (2018) concluded that saturation should be consistent with the research question (s), the theoretical position, and the analytic framework adopted for the study.

Ethical Research

Throughout the research process, I focused attention on the application of ethics to the research process. Sobočan et al. (2019) said ethics when viewed broadly are intrinsic in the research process, from the decision about what to study and how to study it, through data analysis and dissemination of the research findings. The principles of the *Belmont Report* such as autonomy, beneficence, and justice were maintained through informed consent, non-deception, the prevention of psychological or physical harm, privacy, confidentiality, and a commitment to collecting and presenting accurate research findings. The three major components of the *Belmont Report* (respect for persons, beneficence, and justice) serve as an ethical framework for research involving humans.

Each participant enrolled in my study signed a written consent form (see Appendix C.) to take part in the interviews which is the data collection phase of the research. Moreover, I followed the protocols of the *Belmont Report* and ensured that the study participants had a full understanding of their part in the study. I provided a copy of the consent form before the data collection to allow participants time to review the form and understand the study. Nusbaum et al. (2017) said potential participants should be provided a copy of the consent form before or after the consent meeting, which they will receive via email. Nusbaum et al. argued participants supported this commonly used approach because it provided individuals with more time to read the consent form.

Privacy and confidentiality were further protected by coding the interview sessions with all participants and organizations. Coding the interview sessions will protect the identity and confidentiality of all participants. Researchers have the responsibility of conducting ethical research and safeguarding the confidentiality of all participants (Miracle, 2016). Participant names and identifiers will be saved in an EXCEL file under a coding system to guarantee confidentiality.

Participants were informed that they may withdraw from the study at any time without penalty. The time and location of the interviews were at the convenience of the participants. Each participant interview was given an allotted time of 1 hour, but time was increased or decreased depending on the responses given by each participant. Participants were able to disengage from the interview at any time without consequences by contacting me through email or by phone.

For participants that provided interviews a twenty-five-dollar Amazon gift card was provided for their time. Kelly et al. (2017) conducted an experiment with a nationally representative sample to test the impact of different incentive types and amounts on willingness to participate in a qualitative interview. Kelly et. al. study findings suggested increased participation with incentives as low as twenty-five dollars. Researchers may increase the study participation by providing a least the minimum incentive.

Each research study comes with its own set of specific ethical issues and in this case, the study was conducted at my employer. The participants do not report to me and are also at a level above my pay grade. Furthermore, the participants were located hours from my current location, so I do not know them personally. The data from the study is stored on OneDrive and my personal computer. All data storage will be password protected and saved for five years.

The participating research site signed a letter of organizational cooperation permitting participation (see Appendix A). Once the IRB approved the study, I sent invitations to the study participants through email and answered any questions the participants had about the research. All participants read and signed an informed consent form before the interviews.

Data Collection Instruments

The primary data collection instrument for the study was the researcher. I used semistructured interviews for data collection. A well-designed semistructured interview should ensure data are captured in key areas while still allowing flexibility for participants to bring their own experiences and perspectives (Barrett & Twycross, 2018).

The interviews for this research consisted of 10 open-ended questions, which were intended to uncover the viewpoints and experiences of five pharmaceutical R&D directors with experience successfully developing and implementing OI pharmaceutical R&D projects.

I used a voice recording device to document the interviews with each participant. Heath et al. (2018) suggested recording interviews, then transcribing the interviews verbatim, and storing the interviews as a word document for analysis. Recording interviews, then transcribing the interviews verbatim facilitate accurate data collection. All data files were anonymized and stored securely.

After the completion of each interview, I had the voice recording transcribed. Member checking was performed by emailing the interview transcripts, interpretations of the data from the interview, and the conclusions of the data from the interview to the participants. Marshall and Rossman (2016) proposed member checking can be used to improve the accuracy and validity of the interview data. The follow-up interview process included the participants' evaluations of my understanding of the interview discourse for accuracy.

Along with accuracy the reliability and validity of the data collection instrument were improved through this member checking process. Furthermore, public company documents and other external website content were used in the data collection process to corroborate the data collected with interviews. Bloomberg and Volpe (2019) suggested the combination of interview data with public company documents and external website content can improve the validity of the data.

Upon the approval of the study from the Institutional Review Board (IRB), I emailed an invitation to potential participants along with an informed consent form clarifying the risks and benefits of participating in the study. I was also available to answer any questions the participants had about the study. The allotted time for each interview was approximately 1 hour, but more or less time was needed depending on the participant's responses. The interviews were conducted via WebEx (synchronous computer-mediated communication). Merriam and Tisdell (2016) proposed synchronous computer-mediated communication will help overcome the geographical barrier of participants and researchers.

The participants for this study were several hours away so the use of synchronous computer-mediated communication made it more cost-effective and timelier to collect the data. Lo Iacono et al., (2016) suggested synchronous computer-mediated communication is a system that provides users with a way to send voice and video across the internet via a synchronous (real-time) connection. The use of this technology provided convenience because the interviews of participants at a distance were conducted without the expense of travel. The time for the interviews was at the convenience of the participant. Another advantage of the synchronous computer-mediated communication was that a venue did not need to be secured. All the participants answered the same 10 interview questions (Appendix D), which helped to explore the experiences of each participant in answering the central research question. The data obtained helped uncover themes that pharmaceutical R&D directors have experienced while successfully developing and implementing OI pharmaceutical R&D projects.

After each interview, I transcribed, coded, and analyzed the data. The data collected from the interviews are stored in a computer file on OneDrive cloud storage, a USB flash drive, and my computer hard drive and will be saved for 5 years. Each device is password protected and only I have access to the data. After 5 years, I will destroy the flash drive along with any other resources and documents. Data collection was essential to gathering the relevant data needed to answer the principal research question "What are the strategies that US pharmaceutical company leaders use to develop and implement open innovation R&D projects?

Data Collection Technique

Researchers can gather case study evidence from many sources. Yin (2018) proposed that interviews, documentation, and archival records are three sources of data that can be used for case study research. This qualitative case study included the data collection instruments of semistructured interviews, public company documents, and external website content intended to uncover the viewpoints and experiences of pharmaceutical R&D directors with experience successfully developing and implementing open innovation (OI) pharmaceutical R&D projects. Belotto (2018) suggested semistructured interviews allow the researcher to ensure that the same core information is elicited from each participant while providing the flexibility to probe more deeply into the rich descriptions of experiences that participants share.

I used the following procedure to schedule the semistructured interviews. For each participant, I scheduled a date and time for each interview based on the agreement obtained from the participant. Participants of the study answered the same 10

questions about their experiences in successfully developing and implementing OI pharmaceutical R&D projects. The 10 interview questions were asked via synchronous computer-mediated communication with the five pharmaceutical R&D directors in a single pharmaceutical company. Each interview was allotted one hour; however, more or less time was needed depending on the responses of the participants. The interviews included a question on what strategies the pharmaceutical R&D directors used to develop and implement OI pharmaceutical R&D projects. The interviews of each participant were via synchronous computer-mediated communication (e.g. WebEx) and their responses were recorded using a digital voice recorder. Also, for confirmability and to use methodological triangulation I collected data from public company documents and external website content relevant to the research question.

The analysis of the data collected uncovered strategies that could help pharmaceutical R&D directors develop and implement open innovation (OI) pharmaceutical R&D projects more efficiently. Data collection techniques have advantages and disadvantages for qualitative research studies. Doody and Noonan (2013) posited advantages include (a) gaining insight and context on the topic, (b) gaining an understanding of a topic from a participant's experience and knowledge, and (c) gaining useful information for the research study. The disadvantages of collection techniques include (a) intrusiveness to the participant, (b) time-consuming to both participant and researcher, (c) expensive data collection methods, and (d) may be susceptible to bias.

Once I received approval from the Institutional Review Board (IRB), the following procedure for the research study was followed. Contact information was

collected from the participants of the study. Initial contact was made with the participant to clarify any questions or concerns they may have about the study and the informed consent form. The informed consent form was collected through e-mail. I scheduled the interviews and then interviewed the participants via synchronous computer-mediated communication. Upon completion of the interviews, the data voice files were transcribed and shared with the participants to confirm the accuracy.

Member checking is the process by which participants check and approve the understanding of the researcher of the data collected from the interview (McGrath et al., 2019). I performed member checking with the participants after the interviews. If the participants made any changes to the transcription, I notated the changes on the initial transcript. I then imported the transcript into the data analysis software. Yin (2018) suggested computer-assisted tools can help analyze qualitative data. The computer-assisted tool can help novice researchers code and categorize large amounts of data (Saldana, 2016). I used data analysis software to help identify themes and categories from the data.

Data Organization Technique

The organization of data was a critical aspect of examining and understanding data in the study. The iterative inspection and organization of data are necessary in a qualitative case study (Castleberry & Nolen, 2018). I was the primary data collector of information from each participant of the study. I classified each participant by a letter and number, which will be documented and coded in a Microsoft Excel spreadsheet for confidentiality. Confidentiality and anonymity can be reached within a study by using a

coding system for each participant (Clark & Vealé, 2018). The data collected were recorded, examined, transcribed, and stored on OneDrive (cloud storage), a flash drive, and my personal computer. All devices are password protected and only I have access to the data. To safeguard the rights of participants, confidential data can be secured and stored (Clark &Vealé, 2018). After 5 years, I will destroy the flash drive along with any other resources and documents used in the study.

Data Analysis

Qualitative case study methodologists can use up to six sources of evidence for their research including documentation, archival records, interviews, direct observations, and physical artifacts (Yin, 2018). The major strength of the case study research is the opportunity to use multiple sources of evidence. I conducted a qualitative single case study, which included participant semistructured interviews, public company documents, and external website content. Fusch et al., (2018) suggested case study researchers should use multiple sources of data to improve the quality of their research. Data triangulation adds depth to the data that are collected. Yin (2018) posited that there are no set guides to use to begin analyzing qualitative data, therefore, all data analysis of the single case study should use a broad analytic approach. Castleberry and Nolen (2018) suggested a model of qualitative data analysis outlined in five steps: compiling, disassembling, reassembling, interpreting, and concluding.

The qualitative data analysis is an iterative process and preferably should be performed concurrently with data collection (Miles et al, 2020). Miles et al. (2020) posited researchers should cycle back and forth between thinking about the existing data

and generating strategies to collect new data. Miles et al. presented three streams of data analysis (a) data condensation, (b) data display, and (c) findings and verification. After each interview, I transcribed the data and familiarized myself with the interview transcript.

Raskind et al. (2019) suggested many researchers used verbatim transcripts as the primary data source. I created a matrix using the 10 interview questions and the responses from each participant to get started. Raskind et al. reported that 20% of researchers reported using matrices during analysis. Matrices were used to compare codes or themes across participants (Raskind, et al., 2019). I manually went through the transcripts to identify similarities and differences between participants and then tried to identify themes from the participants' responses.

Next, I uploaded the transcripts into a computer-assisted software program (e.g. NVivo) to help identify themes to understand the data and generate codes. After collecting relevant content from company documents and external websites I followed the same iterative process to identify themes. These main themes provided strategies pharmaceutical R&D directors have used to successfully develop and implement OI pharmaceutical R&D projects.

The purpose of the data analysis was to uncover themes that can answer the research question of this qualitative single case study. Discovering the topical similarities and differences could potentially inform the answer to the overarching question. The data analysis process of a qualitative study is an important step. Saldana (2016) suggested using a provisional list of codes related to the conceptual framework to start the data

analysis. I used 23 codes from the OICF and some keywords identified during interviews with participants to begin coding the interviews. To provide direction and organization to the data analysis I used the 23 codes that compose the high-level categories of the OICF to begin my analysis. Researchers need to analyze data to uncover significant patterns and themes that answer the main research question of the qualitative study (Yin, 2018). I consolidated the data collected into sections similar to the sections in the literature review related to the OICF framework: strategic alignment, governance, methods, IT, people, and culture.

I used NVivo, a qualitative data analysis software, to help organize and code the data analysis in this study. Researchers can use software like NVivo to identify patterns and themes in the data that may otherwise be overlooked (Davidson et al., 2017). Davidson et al. (2017) suggested NVivo helps researchers to see into the depths of a qualitative research project. The strengths of using the NVivo software included working with very rich text-based and/or multimedia information, where deep levels of analysis on small or large volumes of data were required. I used the NVivo software to verify the patterns and themes uncovered through the manual analysis of the data and the sections described in the literature review. The connection between the methodology, the literature review, and the findings of the study is the OICF. I used the OICF as the lens to analyze the data.

Reliability and Validity

The significance of a qualitative research study is contingent on the level of confidence others have in the findings of the researcher. Qualitative research

methodologists ensure trustworthiness in a case study approach by demonstrating credibility, confirmability, transferability, and dependability (Yin, 2018). Trustworthiness in qualitative research includes both the validity and reliability dimensions (Quintão et., 2020). The following sections provide information on the use of case study procedures in a qualitative research study.

Reliability

Reliability refers to how qualitative methodologists will address the dependability of the study results. Some of the ways a qualitative methodologist enhances the dependability of a study are member checking of data interpretation, transcript review, using an interview protocol, and reaching data saturation. Qualitative researchers produce findings not derived using statistical procedures or other means of quantification. Cypress (2017) posited qualitative researchers use naturalistic inquiry to understand a phenomenon in a context-specific setting. A qualitative research methodologist does not attempt to manipulate the phenomenon of interest.

Qualitative research methodologists ensure reliability based on consistency and care in the application of research practices. In this qualitative study, I followed the interview protocol for each participant to ensure each participant was asked the same questions. Furthermore, the participants had experience developing and implementing open innovation (OI) pharmaceutical projects. To establish trust and confidence in the findings of the research, rigor will be necessary to confirm the consistency of the study methods. Reliability and validity should be taken into consideration by qualitative inquirers while designing a study, analyzing results, and judging the quality of the study

(Belotto, 2018). The foundation for the reliability of the research study is determined through the dependability of the research process, which included the research question, data collection method, data interpretation, and the instrument (me).

Merriam and Tisdell (2016) suggest that reliability in research design is based on the assumption that there is a single reality and studying repeatedly will yield the same results. In addition to the semistructured interviews of the five participants, I used documentation to methodologically triangulate the data collected from semistructured interviews, and finally, I performed member checking after each interview to ensure the accuracy of the results.

Dependability

When researchers follow research procedures, they improve the consistency of data collection. When the audit trail of a researcher is duplicated by another researcher, dependability will occur (Connelly, 2016). I ensured dependability by having participants check the information gathered through member checking and confirm the accuracy of my understanding. Gaus (2017) explained member checking is a participant's validation, which confirms the data, interpretations, and conclusions of the researcher with the interview participant. Member checking is imperative and a common way to ensure the truthfulness and authenticity of the data (Fitzpatrick, 2019). I performed member checking after each interview to confirm my understanding.

Validity

The qualitative research methodologist seeks to ensure validity by establishing trust in the inferences that they put forth. Validity refers to the accuracy of the research

findings. Validity consists of two types of validity, internal and external (Fitzpatrick, 2019). Gaus (2017) posited internal validity is the extent to which the findings can be interpreted accurately and in a qualitative study, internal validity is most important. Sound internal validity is established by using multiple sources of data collection (e.g. interviews, document analysis, etc.) and interviewing multiple sources of people and triangulating their stories within the case (Gaus, 2017). An assessment of data by the researcher for consistency among the participants of the study will help achieve internal validity within the qualitative research study (Yin, 2018).

Qualitative methodologists can use purposeful sampling in qualitative research so that the participants are the appropriate people to respond to the intent of the research. Fitzpatrick (2019) suggested that purposeful sampling requires the selection of participants who know about the research topic. I collected information from multiple sources, which included conducting interviews, company documents, and external website content to address validity.

The interviews conducted by me were consistent for all participants using an interview protocol (Appendix D). Furthermore, I will improve internal validity with the use of member checking and triangulation. Member checking is the process of seeking participant validation and the most important way to rule out the possibility of misinterpreting the meaning of the participants' interviews (Gaus, 2017). Member checking was an important way of identifying my biases and misunderstandings of what I heard. Furthermore, to increase the credibility of the findings and reduce bias, researchers try to establish triangulation by searching for convergent results from multiple and

different sources of data, multiple qualitative methods, or multiple researchers (Gaus, 2017).

Credibility

Credibility is an accurate and truthful portrayal of a participant's lived experience (Cypress, 2017). The credibility of the study is assurance in the truth of the findings. A qualitative research methodologist can enhance credibility by member checking of the data interpretation, participant transcript review, triangulation, and an interview protocol (Gaus, 2017). Demonstrating qualitative credibility ensures the reviewers that the researcher addressed the findings from the perspective of the participants (Fitzpatrick, 2019). I improved the credibility of this study with participant transcript review, member checking, triangulation, and an interview protocol.

Confirmability

A qualitative research methodologist can enhance the confirmability by ensuring that the results can be confirmed or supported by others. The researcher may conduct member-checking with study participants to ensure confirmability (Belotto, 2018). Confirmability is the degree findings are consistent and could be repeated. This is analogous to objectivity in quantitative research. Qualitative researchers keep detailed notes of all their decisions and their analysis as it progresses (Connelly, 2016).

I asked probing questions during interviews and followed up with member checking. Cypress (2017) suggested data triangulation should also help

ensure confirmability. Data saturation was obtained in this qualitative single case study by interviewing five participants until no new themes were evident. The sample size of this qualitative single case study was determined when data saturation was met (Fusch et al., 2018). I made sure the sample size was sufficient to reach data saturation and address the research question.

Transferability

The nature of transferability is the extent to which the findings can be useful in other contexts. The reviewers of qualitative research determine the applicability of a researchers' findings to their circumstances (Bloomberg & Volpe, 2019). Qualitative methodologists can support the study's transferability with a rich, detailed description of the context, location, and people studied (Yin, 2018). Qualitative researchers need to provide a vivid picture that will inform and resonate with the reviewers (Amankwah, 2016).To improve the transferability of the findings I meticulously adhered to the data collection and analysis techniques for the research design, used an interview protocol and ensured I reached data saturation. Furthermore, I used a notebook to document my thoughts, reflections, and decisions regarding the study to further improve the ability to make the study transferable.

Transition and Summary

In Section 2, I described how I conducted a qualitative single case study to explore strategies US pharmaceutical company leaders use for developing and implementing successful OI pharmaceutical R&D projects. I audio-recorded

semistructured synchronous computer-mediated communication interviews to collect data and explore the experiences and strategies of the participants. In addition to semistructured interviews, I reviewed public company documents and other external website content to triangulate data. I used purposeful sampling to select five R&D directors in a single US pharmaceutical company located in the northeast. Before the collection of data proceeded, I obtained permission from Walden University's IRB to execute data collection. Once transcriptions of interviews were complete, I used NVivo to uncover common themes and patterns in the study. Also, I explained the purpose statement, role of the researcher, population and sample size, research method and design, ethics, data collection instrument and techniques, data analysis, and the reliability and validity of the study. In Section 3, I incorporate the presentation of findings, applications to professional practice, implications for social change, recommendations for action, and recommendations for future research. This is followed by reflections and conclusions.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative single case study was to explore the strategies that US pharmaceutical company leaders use to develop and implement OI R&D projects. Five R&D directors in a US pharmaceutical company located in the northeast who had successfully implemented OI strategies were interviewed via NVivo. The five R&D directors discussed four major themes: OI roles and responsibilities, business and OI strategy alignment, leadership attention, and OI decision making.

Presentation of the Findings

The overarching research question in this study is: What are the strategies that US pharmaceutical company leaders use to develop and implement OI R&D projects? I used pseudonyms to anonymously identify the five participants as P1, P2, P3, P4, and P5. Four major themes emerged during data analysis to indicate strategies US pharmaceutical company leaders use to develop and implement OI R&D projects. The following discussion is organized around these four themes (see Table 1).

OI is an established approach to improve innovation performance, but many organizational leaders have unsuccessfully embedded strategies permanently in their innovation processes.

Table 1

Major OI Implementation Themes

	Total frequency of themes from Interviews	% of themes occurrence
OI roles and responsibilities	108	29
Business and OI strategy alignment	101	27
Leadership attention	87	23
OI decision making	81	21

Table 2

Frequency of Major Themes for Each Participant

Themes	P1	P2	P3	P4	P5
OI roles and responsibilities	33	28	9	22	16
Business and OI strategy alignment	16	44	3	15	23
Leadership attention	20	28	6	12	21
OI decision making	22	31	4	11	13

OI Roles and Responsibilities

A leader needs to clearly define OI roles and responsibilities in their organization to ensure the successful adoption and implementation of OI strategies. In this study, five directors in a US pharmaceutical company shared their experiences regarding the

implementation of OI pharmaceutical R&D projects. The five participants described the roles and responsibilities of many of the staff involved in the process. Participants described OI actors as scouts, scientists, business development staff, alliance management, integration management, and academic researchers. P1 said:

> We involve all the department stakeholders that are important for the success of the project. Projects are selected at different stages of development and each project is unique so there is no one size fits all. Aside from the scientists, many departments often need to be involved to some degree e.g. patent attorneys, tax accountants, etc.

Each project is unique and may require different capabilities. Therefore, it is important to have staff involved in OI projects with defined roles and responsibilities. Individual competencies of team members, including knowledge, skills, and attitude are of the greatest importance to the success of the OI project. OI strategies require leaders to find, identify, select, and evaluate projects that are aligned with overall business strategies and then integrate projects seamlessly into the organization.

All interview participants (P1-P5) stated that to find and identify new OI projects aligned with high-level strategies, they implemented search and evaluation teams within the R&D organization. Search and evaluation teams are integral to the success of finding the right projects. They are scouts for the organization that assist in implementing strategies defined by research units. Zynga et al. (2018) said scouts identify advances in science and technology that can be useful for the company. Hosseini et al. (2017) said scouts and idea connectors are complementary roles that are of high importance in terms

of creating successful OI outcomes. Strategies involve either directed searches in a specific technological area or via an undirected search for new technological opportunities.

All participants stated search and evaluation teams are external facing the organization's R&D department. The role of the employees in search and evaluation teams is looking for specific external partnering collaborations, licenses, or acquisition opportunities, typically in the preclinical or discovery space across a span of technologies or therapeutic areas. P1 said: "The employees in search evaluation are often former researchers; therefore, they understand the needs and the technologies. The staff in search and evaluation teams have a specific scientific skill set that helps to serve their purpose" P5 stated:

> I start with a clear understanding of our internal strengths and the areas we have gaps. If I understand our strengths and weaknesses accurately, then this information helps to define the space broadly and provides direction to external innovative opportunities.

P5 said: "The specific areas that I am scouting externally are technologies around large molecule discovery and development, and digital platforms." P2 said: "The search and evaluation team is a global group that helps all the research units find projects. After the search and evaluation team find the projects, then it is up to the business development department to execute a contract."

Search and Evaluation Team Strategy

Search and evaluation teams in the pharmaceutical industry use several strategies to find projects that are aligned with the overall business strategy. Some of the strategies scouts use to search and find projects include their personal and professional networks, literature searches, academic institutions, patent data, and conferences. Zynga et al. (2018) said scouts are very important to developing a robust open innovation program. In addition to helping pharmaceutical leaders discover novel technology, scouting techniques, data mining, data access systems, and information technology support the absorptive capacity of firms (Zoebel & Hagedoorn, 2020). The absorptive capacity of the firm is the leader's ability to recognize the value of new technology and then acquire and integrate the asset into operations and apply it in the development of new products.

When leaders implement OI strategies, they must create additional processes to deal with the scale and scope of external inputs. The ability to be able to accommodate these additional processes to evaluate new technologies and innovations is a firm's absorptive capacity. An external technology scouting team commonly uses an open search method to facilitate finding innovations (Wang & Quan, 2019). Organizational leaders must develop processes to select the most valuable ideas and integrate them with their existing knowledge base (Rasiah, 2019). Having enough absorptive capacity in a firm is critical to successfully implementing open innovation strategies.

Networks: personal and professional. Networking is an important method that scouts use to find new technologies. Scouts and scientists are key individuals in open innovation capability and improve the chances of finding novel technology and

exploiting it (Rasiah, 2019). Scouts help connect individuals, firms, and organizations to support innovations openly across innovation systems. Hosseini et al., (2017) discussed peer leadership in the OICF. Hosseini et al., (2017) suggest peer leadership helps ensure OI progress and success despite the absence of a formal hierarchy. I would argue that networking is a form of peer leadership because networking is an informal method to connect with others. P5confirmedthe importance of peer leadership commenting:

> Scientific connections are the other place where ideas and projects are discovered. The scientists that are in the search and evaluation team and all the PhDs that are all within the research unit have connections. This staff has contacts from the universities where they received their PhDs. Scientists use these networks to bring forward ideas that look promising.

Furthermore, P5 said:

> Our group is externally facing, those of us who are externally facing through going to conferences and staying current with the literature learn who are the key collaborators and subject matter experts and leaders in the field, whether they are academic, startups, or pharma peers.

Conferences and meeting attendance. Search and evaluation scouts attend conferences and scientific meetings where they can network and find new technologies. Conferences such as the annual BIO International Convention play a critical role in the pharmaceutical industry leaders' sources of information and networking. The conferences are valuable sources of information, industry trends, and current news and provide opportunities for interactions between industry participants searching for new

technologies and opportunities. Professional conferences facilitate the convergence of these informal leaders with mutual interests that may increase the occurrences of collaborations.

In addition to numerous networking events, many conferences also facilitate one-on-one meetings. The one-on-one meetings are organized scheduled interactions called partnering meetings. Partnering meetings are scheduled in advance of the conference so the interactions between participants are deliberate. Scheduling the partnering meetings is enabled through an online portal provided by the meeting organizers that is accessed on the conference's website. The partnering meetings typically last only 30 minutes. Although the duration of the initial meeting is short, the relationship between the parties may continue after the initial interaction. P1 said:

> We attend conferences such as JP Morgan and the BIO conferences, those are big partnering conferences that offer a lot of networking opportunities. The conferences offer one-to-one partnering sessions that we can register for. These partnering sessions are an opportunity to meet with company representatives that want to pitch their technologies. Each company will meet with the business development staff and search and evaluation scouts at these conferences for 30 minutes. Each company has representatives who provide a brief presentation of their technology and value proposition. Some of these presentations are unproductive and others lead to professional relationships. If the technology is early in development, we may stay in contact with company leaders and check with them every six months to a year to monitor their progress. For the

technologies that are further in development, if we are interested, we may start a smaller research agreement together and then if it is successful, we build upon it. Not all conferences have partnering meetings.

The J. P. Morgan Healthcare Conference referred to by P1, is a premier event for conferences and do not have centrally organized partnering sessions. P1 noted with the J. P. Morgan Healthcare Conference business development, scouts, and executives arrange meetings with the innovators. Nonetheless, conferences are gathering forums for large numbers of participants interested in a similar topic. Therefore, there is an increased opportunity of meeting other participants who may have an interest in partnering.

Hosseini et al. (2017) OICF did not specifically address conferences and scientific meetings as sources of innovation. However, Hosseini et al. did reference boundary spanning and social brokerage as important aspects of OI implementation. Individuals with social brokerage capabilities can connect the right actors that would normally not be in contact and ensure that external ideas and knowledge are utilized. Conferences enable social brokerage between individuals and organizations.

Another important concept noted in the OICF is boundary spanning, which is the ability of individuals to manage heterogeneous information and clearly articulate the value proposition. Boundary-spanning enables cognitive distance to be overcome and mutual understanding established between partners within and outside organizational boundaries (Hosseini et al., 2017). Conferences promote boundary-spanning interactions between internal and external the participants. Social brokerage and boundary spanning are some of the components of the high-level OICF capability of people.

Literature search. Scouts' other method for identifying projects is by searching the scientific literature and consulting with thought leaders. Recent scientific literature and thought leaders can provide direction for the scout's searches. P1said: "In addition to the big conferences, scouts and scientists also scour the scientific literature, looking for technologies and projects that fit our business strategy. The scouts use the literature as leads to find innovations and subject matter experts. In support of the OI business model, P1 said:

> Well, there's no way that the organization has all the resources to do everything internally. We need to be realistic and understand we cannot be the best at everything. There are people out there that are better than us in certain areas and maybe ahead of our organization in the development timeline. When these circumstances exist, we may go outside the organization.

Universities/academia. Another source of innovation that scouts use to identify new projects is academic sources. P4 suggested search and evaluation scouts visit with researchers in academia to identify potential projects that are aligned with our goals and therapeutic areas. To participate in the program the researcher must sign an agreement that explicates the terms of the partnership. P4 said:

> We intentionally recruited staff from outside the company because we needed staff that thinks differently. With the agreement we have with academics there is very much an open sharing of information. Just as we run a drug discovery and development program we would envision needing to prove or disprove the hypothesis at every step of the way and that is very much an open dialogue

> around the knowledge the academic principal investigator brings to the project regarding the biology and the drug target.

P4 also said:

> Our researchers can go in and work in the academic institutions' labs, and the PIs can come in and work in our labs as well. We share the data in real-time, and we have joint project team meetings where we problem solve, and we review the data. The academic institution becomes an extension of the company to share knowledge and improve the chances of producing a product.

P4 suggested:

> The approach I would call a passive approach is when we put out a call for proposals, through our network community, once or twice a year, where we state the type of project we are interested in and the stage at which the research needs to be at. The interested party would also need to agree to disclose information requested by the company related to the project for due diligence. The other approach is a more active targeted approach, and this is where our scouting team focuses a lot of their activities. The scouts deliberately go out and search for academic principal investigators (PI) who they know are working in research areas of interest to us. The scouts then build relationships with these PIs and see if there is a research project, they can work on together.

To succeed in OI, organizations must develop capabilities related to knowledge exploration, retention, and exploitation. Hosseini et.al. (2017) does not specifically mention academia in the OICF as a source of innovation but addresses *Methods* as one of

the high-level capabilities. Hosseini et.al. *Methods* capability includes the adoption of appropriate tools, techniques, and practices that support knowledge capabilities and integration. Establishing collaborations with academia could be considered a strategy.

Universities scientists produce science-related knowledge that is the output of fundamental research in basic sciences. Researchers in universities can potentially generate radically new technologies (Colombo et al., 2021). University researchers possess state-of-the-art technical knowledge that is generated by applied research programs and has a broad range of applications in different technological areas.

Scientific knowledge in academia is potentially a valuable input to firms' innovation activity but is often generated with little consideration for its direct commercial application. Researchers in academia can be thought of as an extension of the company's labs and workforce and therefore, relationships with academia could potentially expand the company's absorptive capacity (Tajudeen et al., 2019). Academic researchers' efforts are often not generated with a commercial product in mind; therefore, a pharmaceutical company leader would need a process to harness the researchers' efforts directing them toward the intended endpoint of developing a therapeutic for a particular disease. The pharmaceutical managers in this single case study use an agreement with the university and PI to help direct the research efforts toward the intended therapeutic area.

The relationship with academia has been successful. P4 stated "After 10 years, this collaboration with academia has been fruitful." P4 stated the open innovation model with the universities started as an experiment and has been successful in the 10 years the program has been in place:

External knowledge exploration refers to methods to develop potential absorptive capacity. Because academia is an extension of the company's labs this agreement with academia expands the organizations networks and their available absorptive capacity (Burcharth et al., 2017). The complementary nature of internal and external knowledge exploration requires an integrative approach when implementing OI.

Business and OI *S*trategy Alignment

The second theme identified was business and OI strategy alignment which is one of the components of the OICF strategy alignment. To benefit from OI, organizational leaders must align their OI strategy with their business strategy. Organizational leaders who are searching for opportunities have different priorities than organizational leaders in a defensive mode (Hosseini et al., 2017). Firms searching for opportunities want to balance their search breadth, the number of sources and channels used to search for OI projects, and the intensity of each effort (Cammarano et al., 2019; Naqshbandi et al., 2019). Absorptive capacity has been thoroughly researched and therefore R&D leaders should be aware of the negative impact when their organization reaches an imbalance of search breadth and intensity that results in decreasing productivity. This inverted-U relationship between search breadth and intensity is because the absorptive capacity is exceeded.

To prevent the problem of exceeding absorptive capacity from occurring, the R&D leaders need to have a clear business strategy. P1 said:

> Our job is to find the science and technology that is considered the best science with our internal search and evaluation partners. Then to either bring the science

into the organization through a license or to work collaboratively with the partner organization.

The overall strategy needs to be communicated by the leaders. Barham et al. (2020) research findings showed that there is a positive correlation between management support of OI and the possibility of successful adoption of OI. Moreover, Barham et al. results offered insight on some of the dynamics of how management support affects OI adoption. P1's comment suggests that the senior leaders in this organization have provided a clear strategy and support for OI to employees. Barham et al. posited employees' perceptions of management support for open innovation will correlate positively with firm adoption of open innovation. The provision of resources to support the OI strategy can demonstrate the leaders' support.

To identify projects aligned with the high-level strategy the leaders of the organization implemented search and evaluation teams within the R&D organization. The search and evaluations team's role are described in an earlier section, roles, and responsibilities. The organizational leaders have demonstrated support of OI through the implementation of the search and evaluation scouts. The scouts drive the strategy by implementing the action plans provided by the management of each research unit.

Moreover, each research unit has a triad which is the three leaders that are responsible for each research unit, research, development, and commercial. The leaders of the research units provide a more detailed strategy for the scouts. The triad explicates the strategy for the therapeutic area of interest and the potential platforms and

technologies of interest. The elucidation of the strategy provides a focus for the scouts' searches. P1 stated:

> Business development reports to the Chief Business Officer (CBO) this department is separate from the R&D organization. Each Chief Scientific Officer (CSO) in the research units creates its strategy. The CSOs of the research units create a strategy in conjunction with, the Chief Development Officer and the president of the business unit and these three leaders need to be aligned with regards to the early-stage assets that will be developed and commercialized within the organizations business unit. The organizational structure promotes alignment throughout the organization.

Furthermore, P1 said:

> We must prioritize our portfolio because each research unit only has a finite budget to spend on their assets. The leadership of the research units goes through an annual prioritization exercise where they look at the budgeted dollars available and all the programs and decide which programs they can afford to pursue.

P1 said:

> Since it is unlikely, we can afford all the programs, sometimes the leaders will look to partner one of our assets with someone else. There is no one size fits all for R&D projects. It is important to consider risk and reward. The circumstances are going to be unique for each asset and therapeutic area.

P1 stated:

> The research and development teams and the commercial teams need to have their goals aligned. If the business unit has no interest in the research deal or the program is not commercially viable then the business unit will not want to allocate a budget to buy the asset from the research unit. This is a deal that should not be executed.

P2 suggested the importance of teamwork: "We need to have a mentality to support open innovation working together and collaborating to take advantage of science beyond our walls."

Hosseini et al. (2017) confirmed the importance of the organization's strategic alignment suggesting the high importance of an organization's strategic alignment regarding OI. The strategic alignment in this pharmaceutical organization seems to be very important for implementing OI based on the interview data. Hosseini et al. indicated that contextual factors strongly impact an organization's strategic orientation. In this single case study, the context is the US pharmaceutical industry where leaders are always looking for new opportunities to improve patients' lives.

Leadership Attention

Leadership attention is the third theme identified in this study. Leadership attention is one of the components of the OICF high-level strategy culture. Employees' perceptions of management support for OI will correlate positively with firms adoption of open innovation (Barham et al., 2020). Hosseini et al. (2017) proposed in the OICF that the level of leadership commitment and attention impacts the effectiveness of OI. Senior management must create a climate conducive to OI. The leaders at all levels of the

organization must articulate OI goals via written and spoken communication. Hosseini, et al. suggested sharing success stories with the employees is one technique that can be used to encourage employees to actively search outside of the organization for new ideas and technologies.

By implementing appropriate incentives, senior management can also foster employees' engagement throughout different hierarchy levels in OI activities. Incentive structures that foster acquiring innovation from external sources can support moving from a NIH to a proudly-found-elsewhere (invented anywhere) attitude (Hosseini et al., 2017). Senior management providing metrics for OI implementation can also be an effective method to engage the employees and encourage their OI participation.

P5 stated:

> First, I think my role is important and valued at the corporate level. So organizationally I am part of a group that has its explicit mandate to essentially use open innovation strategies. We are intentionally separate from those core science and technology lines, so we do have that independence and autonomy to objectively look at assets and technologies outside of the company so organizationally that's very supportive in that regard.

Secondly, P5 said:

> The CEO articulated quantifiable metrics directly geared towards open innovation. Specifically, we have quantifiable metrics and goals of projects, clinical programs specifically that we need to bring in from the outside in any

> given year, so that once again organizationally creates a mandate that will be assessed on that the whole organization needs to embrace.

P5 also said:

> On the cultural, softer side, several individuals are well regarded in the company and well respected in terms of their scientific and strategic leadership that fully embrace and promote open innovation programs, both in terms of supporting funding for these projects from their budget, as well as advocating for projects that don't necessarily come from inside.

P5 suggested: “I think that it is a lot harder to quantify culture because it is more of a qualitative cultural piece that also supports the open innovation model. It is not uniform across the organization, but some individuals drive OI.” P2 stated:

> Yeah, so the Oncology department has always been very open to collaborating with outsiders. I think it is a great strategy and culture that this is how we become more successful. Using a business model that is including open innovation so that we can get access to the best talent and technologies and information to move things forward as quickly as possible and be competitive. So, I think, because the strategy has always been there, and the leaders are all very supportive. I think the leaders of the group certainly sets the tone for open innovation culture, and how we do business.

All the participants comments suggest employees’ perceptions of management support were very important for OI adoption and implementation.

OI Decision-Making

The fourth theme identified in the study was OI decision-making which is one of the four elements composing the high-level strategy of governance in the OICF. Hosseini et al. (2017) suggested OI experts have highlighted the relationship between culture and governance among the capabilities related to OI decision-making. Organizations that have a risk-averse culture may struggle with the implementation of OI projects. Many decisions need to be made for implementing and an OI strategy.

Also, according to all participants, there is no one size fits all approach, each project has unique challenges and needs to be managed. Since the participants suggested that there is no standardized approach to implementing a project and each project has unique challenges, it would follow that there will likely need to be a greater amount of decisions. The heterogeneity of the challenges naturally leads to more decisions that need to be made. For an organization to improve OI performance improving decision making would be a step in the right direction.

Empowering employees to make a decision is an important step in improving OI performance. Naqshbandi et al. (2019) suggested that an empowering leadership style creates an employee involvement climate and empowers employees to involve them in relevant decision-making. Empowering employees to make decisions will subsequently enhance a firms' OI performance.

Decision-making is a very important aspect for the success of open innovation projects. The time parameter in decision-making is critical; an organization that can reduce the time between decision and action will have a key competitive advantage.

P5 said: “In deciding to implement OI we need to have a good idea of our internal capabilities. If the project can be completed internally then the leaders of the organization will likely do the project internally.”

The interview participants’ statements are consistent with Lee et al. (2019) findings that suggest if the employees of the firm possess the capabilities then the leaders will use closed innovation. If the firm does not have the capabilities, then the leaders will use an open innovation strategy.

P1 said:

> We evaluate our internal team and their capabilities. Is the project something that we can do successfully on our own? Does the project need to be supplemented with capabilities that we do not have? Will this project take us longer if we do it on our own? If another company is 18 months ahead of us in development, we may want to partner with them to increase the speed to market. Therefore, we may pay for a collaboration with a partner who is further ahead. So, if an organization is way ahead, and their science looks as good or better than ours we will likely partner with them.

Lee et al. (2019) also suggested that when the projects have high complexity that organizations tend to use OI strategies. Conversely, when the complexity of the project is low then the organizations tend to use a closed innovation strategy.

P1 suggested:

> When we got into gene therapy, there was a lot of early-stage research, but we did not have the manufacturing capabilities. So, when we committed to doing several

> gene therapy deals, we also had to commit to building a 100 million-dollar facility to build up our capabilities to manufacture. Also, we needed to hire staff that had the knowledge to manufacture gene therapy products and scale them up for larger clinical trials and eventual commercialization.

P5 stated:

> We need to justify additional expenses and opportunity costs to work and collaborate outside of the organization. We need to be able to justify the investment in OI. If we do not have very strong alignment, and particularly technical champions from within those expert lines then we have little chance of getting senior managements' approval. Also, we need a good internal advocate (champion) or our chances of success with the OI project are very low.

The decision to advance a project needs to have support from senior management. When there is a project advocate who can articulate the value proposition of a project then the project is likely to move forward. If a project does not have an internal advocate (champion) then it will likely not be successful. Having a project advocate that can articulate the value proposition of the OI project is essential to the success of OI projects. P5 suggested for a project to be successful the project needs a champion (advocate). P5 said:

> Scientific thought leaders from within a research unit in the organization need to understand and be able to articulate the value proposition. The scientific thought leaders need to be able to help communicate the value proposition up through leadership to gain approval for the resource allocation to advance the project.

In R&D intensive firms, innovation decisions have a strategic nature and are critical drivers of a firms' competitive advantage (Bogers et al., 2018). Therefore, we would expect innovation decisions to be more centralized at the top of the corporate hierarchy. The pharmaceutical organization in this single case study is aligned with Bogers et al. (2018) study findings. The decision making is at the research unit level driven by the high-level strategy and portfolio prioritization.

P5 observed:

> Without a scientific thought leader that can articulate the value proposition that there have been several failed attempts, where even some technologies I have seen that I thought could be incredibly valuable and disruptive for our industry and potential for the organization but they are a bit outside of the realm of our traditional capabilities and traditional approaches, and not necessarily filling incremental gaps in our capability

P5 suggested:

> I would say if the gap in skills is too large for a given project this would not be a good project to pursue. If it would require significant advances along with a large trajectory of technology and capabilities it may be too far to the side of our core expertise. If the technology is something so radical to the way we do things today, that it is seen as too disruptive we may not want to pursue it.

P5 suggested that they have tried to advance some projects that were radical innovations but were not successful because the supporting technology needed to catch up. Chimeric antigen receptor is a technology that is very close to personalized medicine

and can be very effective at combatting certain cancers. The challenge with implementing this technology was the time and cost to personalize the T-cells. This project failed internally because of the large gap in capabilities. The leaders of the firm were able to acquire a company that had the capabilities to get closer to implementing this paradigm.

Kim and Park (2013) said firms incorporating technologically distant knowledge into their organization are likely to face difficulties in assimilating and utilizing the knowledge. The gap in knowledge from other technological contexts that made it attractive for high-impact innovation creates problems in integration and assimilation at the firm level. Significant effort and expertise on the part of the firm are required to assimilate and exploit the knowledge. In this single case study, the leaders of the firm found it was more cost-effective to partner with an outside organization that possessed CAR-T expertise. Three of the participants (P1, P3, and P5) suggested projects that are incremental improvements are less risky and more likely to be pursued if the project aligns with the business strategy. P3 stated: “We use OI to improve the product for the patient and to make things better for the patient.”

P5 suggested:

> The scouts can use their knowledge of the organization's technical strength to bolster the case and ultimately progress, any kind of an open innovation project. Those open innovation ideas that are too far away from our strengths are much harder for the organization to take the risk to engage in. If we are too far out of our core alignment and our capability, it's much harder for us to engage in those

> projects that would require a lot more resources. I guess the amount of resources needed to raise the project would be most of the problem.

An important aspect of risk management and decision making is to evaluate each project thoroughly before investing too much time and resources. P1, P2, and P4 suggested due diligence for any OI project is important because they have found that sometimes the science supporting the innovation is not reproducible, an important decision point. P2 said:

> We can understand the science and the mechanism of action, but we still need to confirm it is reproducible. We have found some projects are not reproducible internally. So, the project looks great on paper, but when you do your due diligence you cannot reproduce the results. This will result in not pushing through a deal. We have terminated deals because we were not able to reproduce the results internally.

All participants indicated due diligence is an important method to mitigate the financial risk of the project.

Applications to Professional Practice

I conducted this study to explore the strategies that US pharmaceutical company leaders have used to develop and implement OI R&D projects. The themes I discovered from the use of five semistructured interviews, were strategies pharmaceutical managers should contemplate if they plan to implement an open innovation business model for their company. Pharmaceutical managers should be particularly attentive to these four areas when implementing the OI business model: OI roles and responsibilities, business and OI

strategy alignment, leadership attention, and OI decision making. The findings in this study have significant applications to professional practice that are relevant to implementing OI in the pharmaceutical industry to develop novel therapeutics.

Of the four themes discovered, OI roles and responsibilities and business and OI strategy alignment was revealed more frequently than leadership attention and OI decision making. The increased frequency of OI roles and responsibilities and business and OI strategy alignment would suggest that these strategies may be more important areas to focus efforts. Nonetheless, leadership attention and OI decision making are also important factors for implementing OI and are often closely related to OI roles and responsibilities and business and OI strategy alignment.

The applications for professional practice would be to first define roles and responsibilities for all key positions related to OI implementation. One role that seems to be of significant importance is the search and evaluation function. These employees typically have a graduate degree or medical degree and have experience doing biomedical research. Formal training and research experience are important training and skills for the scouts searching and identifying opportunities aligned with the leaders' business strategy. In a pharmaceutical company, these staff can be recruited from within the company because many of these organizations have many employees with PhDs and/or MDs. Alternatively, leaders can recruit qualified staff from outside the company.

Also, encouraging staff in the OI positions to network, attend conferences and meetings, and keep up to date with the literature will be helpful for all roles. The OI implementation requires the participation of many stakeholders, therefore if each

employee tries to expand their professional network, the network will be much larger. The additive effect of each employee's network expands the network reach, increasing the chances of finding novel innovations.

Staying up to date with literature is imperative for all employees involved in the OI process. The scientific literature was found to be a good place to find leads, subject matter experts, and thought leaders in areas of interest. Pharmaceutical leaders should lower the barriers to obtaining access to the literature with subscriptions to multiple journals. Pharmaceutical leaders will benefit from implementing or improving upon these strategies, which may have a largely positive effect on improving the odds of finding novel innovations that can help maintain or achieve a competitive position in the pharmaceutical industry.

Implications for Social Change

The results of this study will have direct implications for social change by helping improve pharmaceutical leaders' efficiency in discovering and developing novel therapeutics. OI activities result in a diverse network of collaborations with partners that positively influence a company's innovation success (Rauter et al., 2018). Pharmaceutical leaders implementing the findings from this study may increase the efficiency of discovering and developing novel therapeutics. An increase in the efficiency of discovering and developing novel therapeutics may lead to cost-effective therapeutic medicines that provide a better quality of life for many patients and in some cases may save lives (Hunter et al., 2018). Pharmaceutical leaders implementing OI strategies will improve their probabilities of discovering novel therapeutics more efficiently. This result

of discovering and developing novel therapeutics more efficiently could lead to a decrease in R&D costs with a resultant decreased cost of novel medicines.

Recommendations for Action

The findings from this study may be beneficial for pharmaceutical leaders intending to implement OI strategies to discover and develop novel therapeutics. Based on the findings of this study, defining the employees' roles and responsibilities, and aligning their actions to implement the strategy should lead to success in implementing OI.

Recommendation 1

Leaders need to create a clear strategy for the employees to advance their mission. The participants (P1-P5) consistently acknowledged that the OI strategy was set forth by the managements' innovation strategy. de Oliveira et al. (2018) suggested the leaders' strategy should clearly define the innovation-related strategic positioning. A defined strategy is a critical success factor for implementing OI strategies (de Oliveira et al., 2018). The leaders need to decide if they are going to search for radical innovations, incrementally improve existing technology, or a combination. To be successful the leaders will need to ensure they have enough absorptive capacity and that absorptive capacity is managed throughout the innovation process. Managing knowledge and technological competencies will improve a leader's chances of success.

Recommendation 2

After defining the business strategy, I would recommend defining the roles and responsibilities of the employees in the organization particularly those employees

involved in the OI process. One of the positions that participants indicated was key is the search and evaluation function. The leaders of the team need to have a focused approach to best utilize finite resources. Having a team skilled in identifying innovations that fit the overall business strategy is a critical factor. All participants were well aware of absorptive capacity and understood they were not able to accomplish everything.

The search and evaluation staff help to moderate the absorptive capacity. The participants suggested that the company develops absorptive capacity through routines and processes, especially information search practices, market monitoring procedures, and risk management. Senior management prioritization and portfolio optimization were often cited as drivers of their OI search strategy. I would recommend prioritizing the goals and then using OI to explore and exploit those areas that will bolster and advance the business strategy.

Recommendation 3

The third recommendation would be to explicate an OI strategy that would achieve the business goals. Creating an OI strategy would provide direction for the staff involved in the OI processes to ensure that resources are being used efficiently. Having an OI strategy will be imperative to managing absorptive capacity. The P1-P5 suggested that they consider the feasibility of doing a project internally before committing to establishing external collaborations. Furthermore, senior management's explication of the OI strategy will help to reduce the chances of not-invented-here syndrome (NIH). Senior managers clearly stating the goals and justifying the strategy will help overcome NIH.

Recommendation 4

My fourth recommendation is to assemble an alliance management team that is skilled at managing employee relationships in collaborating organizations. Managers should develop high internal capabilities to integrate external knowledge and enhance potential absorptive capacity for future knowledge transfer and knowledge sharing (Martinez et al., 2017). Once innovations are discovered and secured, assimilating those innovations into the organization is important for the success of the project and to ensure it is productive. One participant, P3 was directly involved with managing external alliances and suggested alliance management is a critical function for OI projects to be productive. P3 suggested keeping the staff focused on the patients waiting for the medicines helps to reduce resistance between the organization's teams and focus their efforts. After investing the time and resources into securing a collaboration, P3 suggested managers of both organizations want to ensure the project is productive. One of the reasons OI projects fail is because of the lack of project assimilation into the organization resulting from uncertainty on the benefits of an alliance, a lack of information on potential partners, and concern over sharing information with potential competitors (Hewitt-Dundas et al., 2018).

Recommendations for Further Research

One of the limitations of this study is that it was a single case study in a large US pharmaceutical company. To improve on this limitation researchers could use a multiple case study for future research to explore strategies US pharmaceutical leaders use to implement OI projects. One important aspect I noted was that the company in this single

case study did not use crowdsourcing as one of its strategies. Crowdsourcing is a strategy used by some pharmaceutical companies; therefore it would be a good reason for a multiple case study because there may also be other differences between companies. Furthermore, a researcher could also use the open innovation capability framework as a lens to research implementation strategies in small and medium-sized companies that have fewer resources.

Another limitation of my research was the participant sample size. Interviews with five pharmaceutical R&D directors is a relatively small sample. The final limitation of my study was the use of semistructured interviews as my primary data collection method. Semistructured interview participants may not be equally articulate and perceptive and thus may lead to less robust data.

Reflections

I started the doctoral journey to achieve the height of my education career and give back to my chosen industry, the pharmaceutical industry. I chose to use a qualitative approach because to me it was a new methodology, it was something new to expand my knowledge. Having worked in biomedical research for over 36 years I was comfortable with quantitative approaches. I was informed at the beginning of my doctoral journey as I considered topics that most qualitative researchers are extroverts and quantitative researchers tend to be introverts. Using a qualitative approach would be a stretch for me since I am more introverted.

I found the qualitative approach to be more challenging but rewarding. As the researcher is the instrument for collecting the data, I needed to ensure that my own biases

did not creep into my decisions on data collection and analysis. Throughout the research, I needed to reflect on my experience to guard against my personal biases that might have an impact on my decisions. Furthermore, the research was performed at my employer and therefore I needed to be more vigilant in guarding against my biases and protecting the participants.

Conclusion

The purpose of this qualitative single case study was to explore strategies US pharmaceutical company leaders used for successfully developing and implementing OI R&D projects. I conducted semistructured interviews via synchronous computer-mediated interviews to explore the implementation experiences of five directors of R&D. I used the OICF as a lens to explore the implementation of OI strategies and discovered four themes. The four themes discovered associated with successfully developing and implementing OI R&D projects were: (a) roles and responsibilities, (b) business and OI strategy alignment, (c) leadership attention, and (d) OI decision-making. I triangulated these themes with public websites of the organization in the single case study and available literature and found the information discovered was in alignment with these themes.

Pharmaceutical R&D directors may benefit from this study by modifying their implementation strategies for OI projects. The modification of their strategy may lead to greater success in the efficient implementation of OI projects and a reduction in R&D costs. Pharmaceutical leaders implementing these strategies may have a beneficial impact on their organization and society in general.

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Appendix A: Letter of Organizational Cooperation

08/24/2020

Dear John Maher,

Based on our e-mail communication and your description of the research proposal, you are free to conduct the study entitled "Development and Implementation Strategies for Open Innovation Pharmaceutical R&D Projects" As part of this study, you are permitted to interview employees from my organization as part of the data collection process. Individuals' you contact are free to decline participation in your study and should be afforded the opportunity to review their answers. [redacted] reserves the right to withdraw permission to conduct the study at any time for any reason should circumstances change.

I understand that the data collected will remain entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission from [redacted] and the Walden University IRB.

Sincerely,

[redacted]

[redacted]

Appendix B: Recruitment Letter

Doctoral Student seeks participants for an Interview study

The research *Explores strategies US pharmaceutical company managers use for developing and implementing open innovation pharmaceutical R&D projects*. The researcher is inviting participants who possess the knowledge to contribute relevant information to the research. This interview is part of the doctoral study for John A. Maher D.B.A. student at Walden University. Interviews will take place during the weeks of XX/XX/XXXX to XX/XX/XXXX.

About the study:

- One 40-60-minute interview via WebEx, Skype, or Zoom that will be audio recorded.
- After the interview you will review a summary of the interview transcript for accuracy (~15-20 minutes) and follow up questions if applicable (5-10 minutes).
- You would receive a $25 Amazon gift card as a thank you.
- To protect your privacy, you will be assigned a pseudonym.

Volunteers must meet these requirements:

- Possess knowledge and experience with open innovation projects.
- Director level

To confidentially learn more about the study or request a consent form please contact the researcher:

John Maher 845-XXX-XXXX

john.maher@waldenu.edu

Appendix C: Consent Form

You are invited to take part in a research study that explores strategies US pharmaceutical company managers use for developing and implementing open innovation pharmaceutical R&D projects. The researcher is inviting participants who possess the knowledge to contribute relevant information regarding strategies for developing and implementing Open Innovation R&D projects to participate in the study. I obtained your name/contact info via the guide. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part. This study is being conducted by a researcher named John A. Maher, who is a doctoral student at Walden University.

Background Information:

The purpose of this study is to explore strategies US pharmaceutical company leaders used for developing and implementing Open Innovation R&D projects. The participants will comprise US pharmaceutical R&D directors in one pharmaceutical firm that has successfully used Open Innovation strategies to develop and implement R&D drug development projects.

Procedures:

If you agree to be in this study, you will be asked to:

- Answer 10 interview questions via Webex or Skype (30 -60 minutes).
- The interview will be recorded and kept confidential.
- The time for the interview will be at your convenience.
- You will review the interview transcript to confirm accuracy.

- Answer follow up questions if applicable.

  Here are some sample questions:

  1. What strategies did you use to implement an open innovation (OI) R&D projects?
  2. How did you identify new R&D projects to pursue using an OI strategy?
  3. How did you decide which OI strategy to use for an OI R&D project?
  4. What organizational issues did you consider when pursuing a given OI R&D project?
  5. What organizational capabilities did you consider when pursuing a given OI R&D project?

Voluntary Nature of the Study:

This study is voluntary. You are free to accept or turn down the invitation. No one will treat you differently if you decide not to participate in the study. If you decide to participate in the study now, you can still change your mind later. You may stop at any time.

Risks and Benefits of Being in the Study:

Participating in this type of study involves minimal risk and minor discomforts that can be encountered in daily life such as being asked about your experience with OI R&D projects. I anticipate that being in this study would not pose risk to your safety or wellbeing.

My study findings could be significant for leaders in pharmaceutical firms seeking to use OI strategies to improve their firms' competitive positions in the market.

Pharmaceutical leaders intending to implement an OI business model might be able to use the implementation strategies that may be discovered through my research. Pharmaceutical leaders may possibly use the prospective framework to lead a more efficient and effective drug development process for reducing the cost of developing drugs and increasing the resultant pharmaceuticals 'efficacy

Payment:

For your participation in the interviews process and follow-up questions for this study a $25 Amazon gift certificate will be provided after the completion of the study.

Privacy:

Reports coming out of this study will not share the identities of individual participants. Details that might identify participants, such as the location of the study, also will not be shared. The researcher will not use your personal information for any purpose outside of this research project. Data will be kept secure by use a code for each participant so their identity will be revealed. Furthermore, all files will be password protected. Data will be kept for a period of at least 5 years, as required by the university and then destroyed.

Contacts and Questions:

You may ask any questions you have now. Or if you have questions later, you may contact the researcher via john.maher@waldenu.edu or 845-[redacted]. If you want to talk privately about your rights as a participant, you can call the Research Participant Advocate at my university at 612-312-1210. Walden University's approval number for

this study is **09-14-20-0674379** and it expires on **September 13, 2021.** Please print or save this consent form for your records.

Obtaining Your Consent

If you feel you understand the study well enough to decide, please indicate your consent by replying to this email with the words, "I consent."

Appendix D: Interview Protocol/Questions

Primary Research Topic

Development and Implementation Strategies for Open Innovation Pharmaceutical R&D Projects

The Overarching Research Question

What are the strategies that US pharmaceutical company leaders use to develop and implement OI R&D projects?

Primary Research Goals of the Interview

The purpose of this interview is to explore the organizational factors and capabilities that are critical to employing open innovation strategies for research and development projects. The two most important questions in the exploration are 1.) How is the decision to use an open innovation strategy for a single R&D project reached? 2.) How is the decision to employ any particular strategy reached?

Initial Probe Questions

1) What is your title?
2) What is your role in the organization?
3) In your own words, what is open innovation?

Targeted Interview Questions

1) What strategies did you use to implement an OI business model for R&D projects?
2) How did you identify new R&D projects to pursue using an OI strategy?

3) How did you decide which OI strategy to use for an OI R&D project?
4) What organizational issues did you consider when pursuing a given OI R&D project?
5) What organizational capabilities did you consider when pursuing a given OI R&D project?
6) How did you decide which capabilities are important to implement an OI R&D project?
7) How did you decide which employees should participate in the implementation of OI R&D projects?
8) If your organizational culture supports OI R&D, describe how your culture supports the implementation of OI R&D projects?
9) [If the organizational culture supports OI] Describe the strategies used to align the organizational structure to support OI R&D projects?
10) What else can you tell me you did to enhance OI strategies?

Targeted Follow-Up Questions

If time allows targeted questions will be follow up *Why* questions to discover underlying reason for a decision if not already clear.

Targeted Wrap-Up Questions

If time allows targeted questions will be follow up *Why* questions to discover underlying reason for a decision if not already clear.

Interview Closure

I will thank the interviewee(s) for his or her valuable contribution and promptly record my reflections of each interview process. I will also explain the follow up member checking process.