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Exploring Preclinical Contract Research Organization Strategic Partnerships

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Abstract

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MS, University of Nevada, 2002

BS, Texas A&M University, 1996

Doctoral Study Submitted in Partial Fulfillment

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Abstract

The strategies contract research organizations (CROs) use to develop relationships with pharmaceutical/biotech company clients are not well defined but can bring drugs to market faster, safer, cheaper, and with an innovative approach to partnership and scientific collaboration. Grounded in Porter's competitive advantage theory, the comparative advantage theory of competition, and the resource-based view of strategy, the purpose of this qualitative multiple case study was to explore the lived experiences of nine key senior level decision makers in the pharmaceutical, biotech, and CRO industries, selected using a stratified purposeful sampling technique, to determine the benefit of partnerships between the CRO and client. Data were collected using semistructured interviews, public company documents, current market research, and literature. The data were analyzed using Yin's five-step data analysis process and Moustakas's modified van Kaam method. Three themes emerged: defining a strategic/essential partnership, understanding the benefit of building a relationship, and the study director is an essential asset. By understanding the importance of business relationships, the intangible value of human capital, client relationships, and the significance of trust in maintaining relationships, business leaders can implement strategies that provide business advantage and competitive value throughout drug discovery/development. By understanding interactions required for success, partnerships between the CRO and client may lead to innovations in contracted pharmaceutical research that may not only help save lives but provide for a healthier and improved quality of life.

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Table of Contents

List of Tables

List of Figures

Section 1: Foundation of the Study

Following the economic recession of 2008, mergers and acquisitions, large pharmaceutical company (pharma) consolidation, and acquisition of biotechnology/biopharmaceutical companies by pharma created industry dynamics that resulted in corporate downsizing and economic uncertainty caused by the restructuring of the pharmaceutical research sector to streamline operations, reduce costs, and improve efficiencies (Green, 2009). To remain competitive, pharmaceutical research company leaders focused on the productivity of their research and development (R&D) investments (PAREXEL, 2013).

Contract research organizations (CROs) were directly and adversely impacted by client consolidation and tight funding, resulting in overcapacity, pricing pressures, and project delays, all of which negatively affected revenue (Green, 2009). By improving process efficiencies and evaluating strategic opportunities and business engagement between the CROs and pharma, both industries stood to gain as the economy recovered (Green, 2009). Strategic relationships were part of rethinking of the traditional R&D paradigm at global pharmaceutical/biotech companies (Miller, 2013). Forward strategic thinking focused on the CRO assuming more responsibility through strategic partnerships. As a result, the strategic partnerships between pharmaceutical/biotech companies and CROs drove flexibility, reduced costs, and expanded expertise (PAREXEL, 2013). The objective of this research study was to explore the outsourcing methods used by biopharmaceutical and pharma companies in the preclinical research industry and understand current and future trends for strategic partnerships.

Background of the Problem

The financial crisis of 2008 had a substantial negative budgetary impact on pharmaceutical biotechnology companies. Pharmaceutical and biotechnology companies found that because of downsizing and restructuring, they no longer had the expertise to perform scientific/research tasks that they previously accomplished in-house. As a result, outsourcing increased to supplement or replace the expertise no longer available internally (Getz, 2014). In 2018, the global biopharmaceutical R&D spending was projected to reach $172 billion. Approximately $112-117 billion was estimated to be allocated to the total drug development market opportunity (Bank of America Merrill Lynch, 2018). William Blair & Company representatives estimated more bullish total drug development spending of $124 billion in 2018, $130 billion in 2019, and $134 billion in 2020 despite the impact of the COVID-19 pandemic on the industry (William Blair, 2020). Of the total CRO market size (i.e., 67% of global R&D spend), it was estimated that 29% of the drug development spend is outsourced to CROs (Bank of America Merrill Lynch, 2018). Growth in the CRO industry is interrelated to pharmaceutical and biotechnology company R&D spending.

Similarly, CROs were adversely impacted by the same client consolidation and tight funding, resulting in overcapacity, pricing pressures, and project delays, all of which negatively affected revenue (Green, 2009). However, following this period, the demand for and importance of the CRO grew. Increased outsourcing to CROs resulted in a more integrated and coordinated engagement between the CRO and pharma (Getz, 2014). This qualitative study explored the experiences of key decision makers at

pharmaceutical/biotech companies and CROs to describe and understand the collaborative approach to science and business that has fostered the strategic partnership paradigm.

Problem Statement

Following the financial crisis of 2008, increased outsourcing to CROs resulted in a more integrated and coordinated engagement between the CRO and pharma (Getz, 2014). In 2018, global R&D spending allocated to the total drug development market opportunity was projected to reach approximately $112-117 billion, of which the CRO market size (drug development spending that is outsourced and may involve strategic partnerships) was estimated to be approximately $33 billion (Bank of America Merrill Lynch, 2018). The general business problem was that the role preclinical CROs assume in strategic partnerships with their pharmaceutical/biotech company clients is not well defined. The specific business problem was that some leaders of CRO and pharmaceutical/biotech companies lack strategies to develop strategic partnerships in the drug discovery and development process (Harris Williams, 2014).

Purpose Statement

The purpose of this qualitative multiple case study was to explore the strategies that CRO and pharmaceutical/biotech leaders use to develop strategic partnerships during the drug discovery and development process. The targeted population consisted of nine key decision makers at pharmaceutical research companies (large and small pharma), biopharmaceutical research companies, and CROs in the United States, Europe, and Asia. The implications for positive social change include the potential to provide an efficient

and collaborative drug discovery and development process that may result in novel lifesaving compounds receiving regulatory approval and getting to market faster and safer.

Nature of the Study

A qualitative study explores possible shared elements and opinions from the independent inquiry of personal thoughts, attitudes, and perceptions of participants and provides an in-depth understanding of the social world by asking open-ended questions to learn about the social circumstances, experiences, perspectives, behavior, knowledge, and histories of those participants (Kelly, 2016; Ritchie et al., 2014). Researchers use quantitative research phenomena by testing a theory consisting of construct variables, which are analyzed by means of mathematically based methods (Barnham, 2015; Yilmaz, 2013). Mixed methods research incorporates quantitative and qualitative elements and is appropriate for research that includes both types of data (Almalki, 2016; C. B. Gibson, 2017). A qualitative research method was appropriate for this study because it provided an in-depth understanding of the lived experiences of the participants, derived from first-person reports (Moustakas, 1994), to determine if strategic partnerships between the CRO and pharma have been mutually beneficial.

I considered three research designs for a qualitative study examining business strategies: (a) case study, (b) ethnographic, and (c) phenomenological. A case study delineates a single individual, group, program, or event and concentrates intrinsically on it to learn more about a poorly understood situation, phenomenon, or real-world experience (Freeman et al., 2015; Njie & Asimiran, 2014). Ethnography describes a

culture's characteristics through direct observation and interaction with participants (Mohajan, 2018). Although an ethnographic design would provide an in-depth description of the pharmaceutical industry's culture, a more specific understanding of individual experiences and opinions is needed. Descriptive transcendental phenomenology allows a researcher to gain meaning from lived experiences, perspectives, and knowledge (Kelly, 2016; Moustakas, 1994) and to examine business strategies focused on strategic partnerships, but the sampling methodology and sample size lead to an ambiguity and randomness that results in less concentrated data that could make the scope of the research too broad (Njie & Asimiran, 2014). A case study focuses on the sample (i.e., sample size) that provides the most appropriate, in-depth and up-close, detailed accounts of information by concentrating on the depth and quality of information obtained rather than the number of research participants (Njie & Asimiran, 2014; Yin, 2014). As such, the multiple case study research design was determined to be the most appropriate for this qualitative study.

Research Question

What strategies do service providers (i.e., CROs) and pharmaceutical/biotech companies use to develop strategic partnerships during the drug discovery and development process?

Interview Questions

Listed below are the interview questions:

1. What do you think the role of a CRO is in a strategic partnership during drug discovery and development?

2. What is your strategy in terms of deciding what work (i.e., projects, programs, etc.) is outsourced to a CRO?
3. How would you describe a strategic partnership with a CRO during the drug development process?
4. Describe the most important factors that influence your selection of a strategic partner (ranked from most important to least important).
5. What do you think currently differentiates the preclinical CRO(s) that you have strategic partnership(s) with and were similar strategies used to develop that/those relationship(s)?
6. As strategic partnerships evolve, what are your concerns considering your current partnerships/relationships and the expectations you have now and in the future?
7. How do you measure the financial success of your outsourcing (strategic partnership, if applicable) project(s)?
8. How do you assess and manage outsourcing (strategic partnership) risks?
9. Describe the risk-sharing responsibilities/assumptions you currently have with your outsourcing partner.
10. What else can you add regarding strategies service providers (i.e., Contract Research Organizations) and pharmaceutical/biotech companies use to develop strategic partnerships during the drug discovery and development process?

Conceptual Framework

The conceptual framework of this case study supported the proposition that the risk in strategic partnerships formed between CROs and biopharmaceutical and pharma companies is not shared and that facts demonstrating real benefit are difficult to identify. The objective of this study was to explore the beliefs held by leaders in such companies about the phenomenon of strategic partnerships and their effect on project outsourcing. The concepts and theories that shaped this study include the market-based view (MBV) of strategy outlined in Porter's competitive advantage theory (Porter, 1980; Wang, 2014), the comparative advantage theory of competition (Hunt & Morgan, 1995), and the resource-based view (RBV) of strategy (Wang, 2014). The amalgamation of these theories provided the framework for this study.

Porter's (1980) competitive advantage theory described a strategy where firms identify activities that could provide the company a competitive advantage. A competitive advantage strategy can be evaluated in terms of cost leadership, differentiation, and focus (Porter, 1980). A company's internal environment is the focus of the RBV of strategy allowing for competitive advantage and the resources (internal and external) needed to compete in the market (Wang, 2014). In this study, I explored how key business leaders within the preclinical pharmaceutical CRO arena apply the competitive advantage theory when developing strategic partnerships during the drug discovery and development process.

The comparative advantage theory of competition proposes a set of foundational premises that explain key macro and micro phenomena better than neoclassical perfect

competition theory (Hunt & Morgan, 1995). Most salient to this study was the premise that humans in the role of both consumers of products and managers of companies are constrained in their self-interest seeking by considerations of what is right, proper, ethical, moral, and/or appropriate (Hunt & Morgan, 1995). In addition, Hunt and Morgan (1995) suggested that resources, categorized as financial, physical, legal, human, organizational, informational, and relational, are the tangible and intangible entities that enable a company to provide a service that has value for some market segment(s). Salavou (2015) suggested that strategies of low cost (cost leadership), differentiation, and focus define how a company develops an advantage with respect to competitors and how that company can develop relative merits in terms of performance outcomes. This study ascertained if strategic partnerships result in expected value and risk sharing, or if firms are inhibited by their self-interests and seek services outside an established strategic partnership.

Operational Definitions

CDC: The Centers for Disease Control and Prevention (CDC) is a United States federal agency under the Department of Health and Human Services headquartered in Atlanta, Georgia. The CDC works to protect public health and safety by providing information to enhance health decisions, and it promotes health through partnerships with state health departments and other organizations. The CDC is the United States' national public health institute and is a founding member of the International Association of National Public Health Institutes (CDC, 2015).

CRO: A contract research organization is a service organization that provides high profile support to the pharmaceutical and biotechnology industries in the form of research services (e.g., target identification and validation, lead identification and optimization, preclinical testing and research, clinical research, clinical trials management, and postmarketing surveillance) outsourced on a contract basis (Bonacci & Tamburis, 2016).

IPO: An initial public offering is the first sale of stock by a private company to the public. IPOs are often issued by smaller, younger companies seeking the capital to expand, but can also be done by large privately-owned companies looking to become publicly traded. Companies often decide to go public to raise equity capital in order to fund company growth, finance R&D and capital expenditure, pay off existing debt, and/or gain greater visibility, stronger legitimacy and higher market value (Cirillo et al., 2018)

NIH: The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's medical research agency—making important discoveries that improve health and save lives (NIH, n.d.).

USFDA: The Food and Drug Administration (FDA or USFDA) is an agency of the U.S. Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics (FDA, 2015).

VC: Venture capital (VC) is capital (equity financing) provided by investors (individuals, business angels, corporations, governments, pension funds, and/or venture-capital funds) to small business and start-up firms that have potential high growth opportunities. Venture capital investments have a potential for considerable loss or profit but are generally designated for investors who seek to generate a positive return on investment (Gantenbein et al., 2019).

Assumptions, Limitations, and Delimitations

An assumption is an idea presumed to be true but that cannot be verified by the researcher (Dahan & Shoham, 2014). Gorylev et al. (2015) defined limitations as potential weaknesses or general methodological problems of a research study. Assumptions and limitations are conditions beyond the control of the researcher and outside of proposed constraints (Bailey, 2014; Bloomberg & Volpe, 2015). Delimitations relate to the phenomenon; they are both analytical and contextual and are restrictions that the researcher places to focus the scope of the study (Bloomberg & Volpe, 2015; Marshall & Rossman, 2016; Rule & John, 2015).

Assumptions

I assumed that the participant pool would be representative of the key decision makers in pharmaceutical and biotechnology companies. Although these key decision makers were identified by key market intelligence, the specific decision-making process within any given company may not be fully understood. It is possible that those identified as key decision makers were part of a more complicated process by which business strategy is the result of a collective and not any individual person. Also, I assumed that

the interview questions in this study would be answered truthfully and that the participants would be honest, forthright, cooperative, and available for/during the interview.

Limitations

Data accuracy and completeness was dependent on the level of participation by the participants and willingness to share company information and strategy. The results of the study were limited by the honesty and thoroughness of the participants' responses, and interview participation was not guaranteed. The participants' availability to respond to interview questions in sufficient detail or specific knowledge of the subject may have limited the results of the study. To maximize participation, most interviews geared toward business evaluation and trending are accompanied by a monetary honorarium/gift. Given the target sample size, providing a monetary enticement to maximize participation was not possible or was not allowed by some of the participants' employers. As a result, survey participation may have been less than anticipated, and the sample size may have consisted of a limited number of participants adequate to establish validity but not able to offer a larger representation of the population (Bernard, 2013). However, a small sample size is a common limitation in the validation of any study, regardless of the research method (Flicke, 2014). The availability of documentation to support the participants' interview responses may have limited the results of the study.

Delimitations

Delimitations are topics, boundaries, or restrictions that the researcher imposes prior to the inception of the study to narrow the scope of the research and which cannot

be controlled by the researcher (Bloomberg & Volpe, 2015; Marshall & Rossman, 2016; Simon & Goes, 2015). The study delimitations included restricted participant selection/participation of key senior level decision makers in competitor CROs (i.e., CROs in direct competition with my employer that may have had confidentiality concerns with providing information that could result in an actual or perceived business advantage/liability). The senior level participants who were interviewed were currently employed and were assumed to have the experience and breadth of knowledge required to provide in-depth responses to the interview questions; therefore, no additional eligibility criteria were required.

Significance of the Study

Contribution to Business Practice

Understanding and improving existing company processes and evaluating strategic partnerships implemented between the pharmaceutical/biotech companies and preclinical CROs could result in business opportunities that may be mutually beneficial. Preferred provider arrangements have enabled global pharmaceutical/biotech companies to realize cost savings across several fronts including reducing their fixed operating costs, leveraging operating efficiencies, and enabling collection of research data quickly and accurately (Miller, 2013).

Strategic partnerships have been portrayed as beneficial to the sponsor companies implementing them (Parrett, 2013). However, based on the ownership of risk by the client company, the true benefit associated with the partnership is unknown. By appropriately understanding the role each company has in the partnership and the risk each company

assumes, transparency is gained, and clearly defined expectations could improve business processes and practices.

Implications for Social Change

Strategic collaborations between the pharmaceutical research and contract research industries have the potential to bring new drugs to market faster, for less cost, and with improved efficiency because of an innovative approach to business partnership and collaboration (Green, 2009). Pharma companies and the biotech industry have increasingly been relying on the CRO to complete FDA required testing as part of the regulatory submission process (Banerjee & Martin, 2014). Methods for promoting strategic opportunities and business engagement between the CRO and pharma are needed in the atmosphere of client consolidation, decreased funding, pricing pressures, and project delays. To reduce the cost and time of drug development, some pharma companies have pursued R&D joint ventures and outsourcing (strategic partnership) strategies (Banerjee & Martin, 2015). Innovation management in CRO-pharma/biotech collaborations is possible by identifying the existence of different options within an organization to develop this collaborative innovation. Innovation relates to how an institution decides to develop this partnership and how efficiently it can produce products and services that are superior to its competition (Jeng & Pak, 2016). By understanding the mutual interactions that are required for improved success, strategic partnerships between pharmaceutical/biotech companies and preclinical CROs may lead to innovations in contracted pharmaceutical research that may not only help save lives but provide for a healthier and improved quality of life. These strategic partnerships have the potential to

help bring pharmaceutical drugs to market faster, cheaper, and with improved efficacy because of a clear understanding of the role each organization plays in the drug approval process, the assumed risk each organization assumes in the partnership, and the continued innovative approach to business partnership and scientific collaboration.

A Review of the Professional and Academic Literature

A literature review is a systematic way of collecting and synthesizing previous research conducted by scholars and practitioners to map and assess the research area motivating the aim of the study and justify the research question and problem (Snyder, 2019). The research described in this literature review provided the background information necessary to explore and understand the strategies used to develop strategic partnerships in the drug discovery and development process. The literature review begins with an overview of the drug development process and how outsourcing has and continues to impact drug development and the role of the preclinical CRO. I discuss funding and investment trends in the pharmaceutical research industry, and describe how strategic partnerships with CROs can foster lucrative and opportune financial outcomes. Porter's (1980) competitive advantage theory is explained, and the market-based view strategy and the resource-based view strategy are introduced.

Corporate downsizing and economic uncertainty have caused the pharmaceutical research sector to restructure and streamline operationally, reduce costs, and improve efficiency (Green, 2009). Pharmaceutical companies have focused efforts on productivity from their R&D investments to remain competitive (PAREXEL, 2013). Pharmaceutical and biotech companies have increased their level of open innovation to improve drug

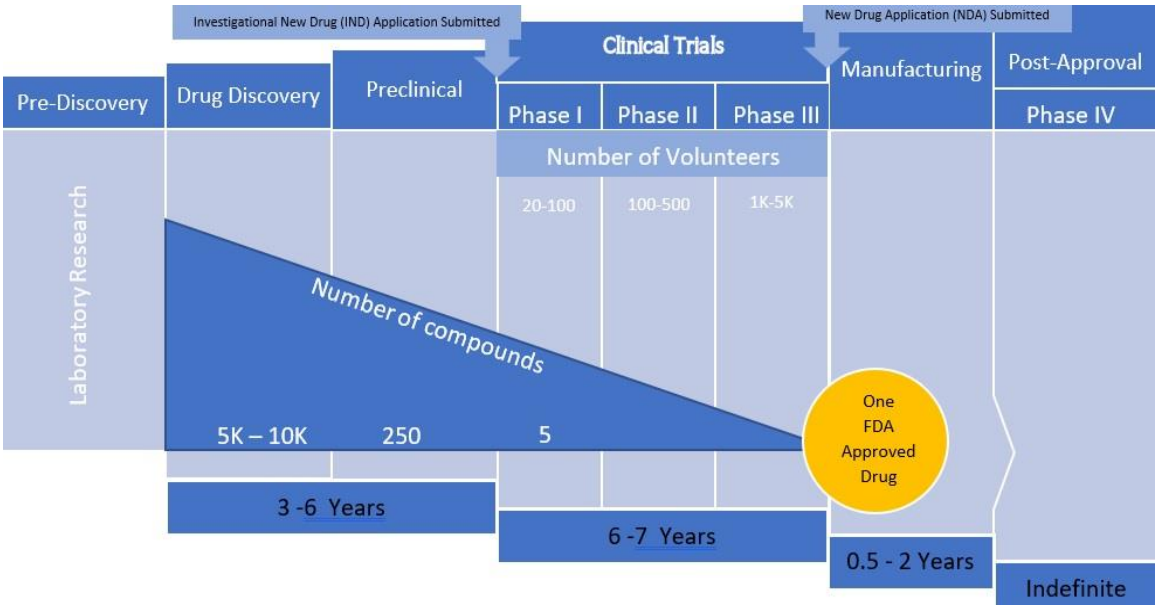
development timelines and reduce costs in drug development and commercialization by improving market capitalization and revenue growth rate (Michelino et al., 2015). The literature review includes the strategic partnership model and how this could impact competitive advantage, an analysis of outsourcing effects, risks, and rewards, recent outsourcing (i.e., CRO) trends during the 2020 global COVID-19 pandemic, and the future of outsourcing and the preclinical CRO strategic partnership strategy.

Drug Discovery and Development

The pharmaceutical drug discovery and development process is a challenging undertaking that can take approximately 10 to 15 years and cost $1.0 to $1.5 billion (Harris Williams, 2014). This process requires sophisticated technology and expertise. To identify one effective and safe drug, millions of potential compounds and molecules are screened (Patil, 2016). For every 5,000 to 10,000 potential drugs evaluated, ultimately only one will receive approval from the FDA (Harris Williams, 2014; see Figure 1). Given the time and costs associated with drug development, pharmaceutical and biotech companies have increasingly been outsourcing development and preclinical activities to remove fixed costs and gain efficiencies (Harris Williams, 2014).

Figure 1

Drug Discovery and Development Process



Note. The drug discovery and development process is divided into four main phases: pre-discovery, discovery (late discovery), preclinical, and clinical trials. A successful IND application requires that the drug company demonstrate reasonable evidence concerning safety of the potential candidate molecule. Adapted from "Contract Research Organization Industry Overview," by Harris Williams & Company, 2014, p. 1. Copyright 2014 by Harris Williams & Company.

Outsourcing

Outsourcing R&D processes has the potential to lead to cost reduction when implemented and conducted properly (Yerkic-Husejnovic, 2017). New outsourcing processes were put in place to ensure seamless workflows to accelerate delivery of new medicines to patients (Martin et al., 2017). When managed improperly, the outsourcing

process can add to operational costs, terminated agreements, and strategic loss of internal R&D growth (Yerkic-Husejnovic, 2017). Outsourcing knowledge-intensive activities to knowledge process organizations (KPOs) serves to reduce obstacles to the innovation process (Gupta et al., 2009). Pharmaceutical and biotechnology companies have generally engaged CROs on a project-by-project basis to manage costs and utilize internal resources more efficiently (PAREXEL, 2013). Outsourcing to CROs allows pharmaceutical companies to use only the internal resources that are required at any given time and subcontract the expertise that they would not usually employ in-house (PAREXEL, 2013). By strategically outsourcing specific activities, companies can depend on the expertise of the outsourcing partner, thereby reducing costs associated with having to introduce innovation. Therefore, these companies strategically benefit from the KPO/CRO core competencies, economies of scale and scope, and knowledge sharing and learning (Gupta et al., 2009). Increased efficiency, time-savings, and lower cost have been the expected outcome of integrated technologies and multifunctional alliances (Getz, 2014). By focusing on improving the efficiencies of existing processes and evaluating strategic opportunities, both industries (i.e., pharma and CROs) would expect to benefit. Both industries form closer ties and business integrations to theoretically build efficiencies and save money (Henderson, 2013).

Traditional large or midsized companies have usually assumed responsibility for most of the pharmaceutical value chain from drug discovery/development through production, marketing, and sales. Hiring contract service providers during the past 20-25 years resulted from the need to access an available and variable head count to adapt to

peak periods of drug development activity and to gain access to scientific expertise no longer available internally because of downsizing and other cost saving measures (Getz, 2014). While large and midsized pharmaceutical companies gradually increased outsourcing efforts, in contrast, emerging pharmaceutical companies, biopharmaceutical and biotechnology early-stage start-up companies focused on select stages of the pharmaceutical value chain that required expertise and logistics that they did not have. This required an earlier, more integrated and coordinated engagement with a KPO/CRO (Getz, 2014).

As use of outsourcing increased, pharmaceutical and biopharmaceutical/biotechnology companies implemented more integrated engagements with CROs to take advantage of expertise in terms of capabilities, technologies, experience, time/cost efficiency, and regulatory requirements (Getz, 2014). Representatives of Credit Suisse (2018) reported that 40% of respondents to a market survey indicated that more than half of their preclinical budget was outsourced to a CRO, of which nearly 75% of these represent small pharmaceutical or biotechnology companies. The amount of preclinical budget that is outsourced is an indication that smaller to midsized biopharmaceutical companies use CROs because they lack the internal infrastructure that larger pharmaceutical companies already possess. Small and midsized pharmaceutical and biotechnology companies expected a 4.1% and 6.5% increase in preclinical budgets in 2018, respectively, compared with a 3.3% increase expected for large biopharmaceutical companies (Credit Suisse, 2018).

CRO Industry Overview

Pharmaceutical companies introduced cost saving initiatives to stabilize profitability levels and maintain operating margins with R&D being a core target (Harris Williams, 2014). During the economic recession beginning in 2008, CROs were directly and adversely impacted by client consolidation and tight funding, resulting in overcapacity, pricing pressures, and project delays, all of which negatively affected revenue (Green, 2009). Pharmaceutical companies shifted focus to late-stage R&D development to drive drugs to market and replace lost revenue (Harris Williams, 2014). This shift in focus to late stage R&D development resulted in decreased total R&D preclinical development spend of -25%, -8%, -4%, and -2% year-over-year growth from 2009 through 2012, respectively (William Blair, 2018). However, as expected, total outsourcing to clinical CROs increased, and with increased outsourcing, a more focused engagement between the CRO and pharmaceutical companies was expected (Green, 2009, William Blair, 2018). CRO outsourcing by pharmaceutical companies across all therapeutic areas and phases increased 44% between 2007 and 2011 (Henderson, 2013). The pricing pressure that early stage (preclinical) CROs experienced began to stabilize in 2013 as capacity levels normalized because some large preclinical CROs closed capacity.

Growth in the CRO market is interrelated to pharmaceutical and biopharmaceutical R&D spending and was expected to be driven by growth in R&D spending and increased outsourcing of R&D activities (Harris Williams, 2014). In 2017, William Blair & Company representatives estimated that total R&D spending was $145 billion and would increase year-over-year by 5% to an estimate of approximately $152

billion in 2018 (William Blair, 2018). Of the total CRO market size (i.e., 67%), approximately 71% of the drug development spend was still performed in-house, while the remaining 29% was outsourced to CROs (Bank of America Merrill Lynch, 2018). R&D *budgets* were expected to grow an average of 1.8% and 2.1% year-over-year in 2018 and 2019, and 3.0% year-over-year in 2020 (William Blair, 2018). Actual R&D spending is expected to grow in the low-to mid-single-digit range in 2021 despite the impact of the COVID-19 pandemic, increasing to above 5.5% in 2022 and 2023 (William Blair, 2020).

In 2015, the outsourced preclinical market was estimated to be approximately $3.3 billion with an outsourcing penetration rate of approximately 47% and expected 4-year compound annual growth rate (CAGR) of approximately 6% on average for 2016 through 2020 (Harris Williams, 2014; Jefferies, 2015). William Blair & Company representatives estimated the outsourced preclinical development market to be $4.7 billion for 2018 and $5.1 billion for 2019 representing a 9% and 10% year-over-year growth rate, respectively, and forecasted the market to be $5.6 billion in 2020 (William Blair, 2020). The increased growth estimated for 2019 and 2020 are the result of increased outsourcing of preclinical services as a result of the COVID-19 pandemic. Year-over-year growth is expected to be 9% for 2020, 8% for 2021, and 7% for years 2022-2025 (William Blair, 2020).

Table 1

Outsourcing Outlook for 2016 – 2020

	Outsourced market	Outsourcing	4-Year CAGR
Credit Suisse	$3.5B	53%	5%
Jefferies	$3.2B	42%	7%
UBS	$2.9B	44%	3%
William Blair	$3.9B	36%	8%
Average	$3.4B	44%	6%

Note. Adapted from "CRO Industry Update," by William Blair, 2015; and "Pharmaceutical Svcs. Part II: Growing Pie, Unless Someone Eats a Big Slice," by Jefferies, 2014.

The CRO has typically been a service provider delivering single or multiple tasks on a per-project basis (PAREXEL, 2013). This relationship has evolved to one of strategic partnership where the CRO provides single or multifunctional support for entire programs reaching various portions of a pharmaceutical/biotech company portfolio (Getz, 2014). These strategic partnerships (i.e., multiyear, highly integrated engagements between pharmaceutical/biotech companies and CROs) were created to provide functional support for entire drug development programs (Brocair Partners, 2013). Large pharma experienced significant challenges associated with the threat of revenue loss due to patent expiries, slowing chemistry-based research, and regulatory (i.e., FDA) scrutiny as the result of serious adverse reactions noted for well-publicized commercialized compounds. Large pharma has become open to strategies that (a) commercialize

compounds faster and (b) lower the total cost of developing compounds to commercialization. These strategies along with the high-throughput capabilities and expertise possessed by CROs increased the willingness of large pharma to outsource more of their development work and responsibilities to CROs.

Funding and Investments

Venture capital investors do not expect emerging bio/pharma companies to commercialize their drug pipeline candidates on their own; rather they anticipate that a global bio/pharma company will acquire these companies or in-license the pharmaceutical candidate (Miller, 2017). In 2016, venture capital maintained a pace close to that seen in 2015 and nearly 60% higher than it was in 2012 (Miller, 2017). Venture biotech funding was down 6% y/y in the first quarter of 2018 following a 10% increase year-over-year in 2017 compared to 2016 (William Blair, 2018). Conversely, IPO biotech industry funding was up 30% y/y in the first quarter of 2018 following a 20% decline in 2017 compared to 2016 (William Blair, 2018). Total biotech industry funding was up 45% year-over-year in the first quarter of 2018 following 37% growth in 2017 (William Blair, 2018).

Table 2

Pharmaceutical/CRO Relationships

	Contract research organization		
	Charles River	Covance	WuXi
Pharmaceutical company	Early stage/preclinical relationship		
Abbott			R
Amgen		S	R
AstraZeneca	S		R
Biogen Idec			
Bristol Myers Squibb	R		S
Daiichi			
Eisai			
Elan			
Eli Lilly		R	R
GE Healthcare			S
Gilead			
GlaxoSmithKline	R	R	R
Johnson & Johnson			R
Merck	S	R	R
Novartis			R
Otsuka			
Pfizer			R
Roche/Genentech		R	R
Sanofi-Aventis		S	R
Takeda			

Note. R = relationships that have been verified through company filings/reports or information obtained from news articles, industry contacts, etc.; S = 'Strategic' partnerships/relationships. Adapted from "Pharmaceutical Svcs. Part II: Growing Pie, Unless Someone Eats a Big Slice," by Jefferies, 2014.

Strategic Partnerships

Business challenges emphasize the need for effective communication and knowledge dissemination, either between information systems or between people (Pappa et al., 2009). Open integration has been an objective for the adoption of technology and collaboration to leverage the benefits of strategic planning. These benefits include compatible, standardized, and interoperable systems; accessible and transparent data and information; shared governance, risk, and operating practices; dedicated staffing and reduced numbers of sponsor staff overseeing execution (Getz, 2014). Specific business models could foster this strategic engagement allowing for risk-reward sharing opportunities that afford lucrative and opportune financial partnerships. Some business relationships result in different levels of involvement. Tactical transactional relationships do not require the same degree of communication, governance, or detail as more transformational relationships. Strategic clinical research partnerships were expected to evolve away from transactional models toward integrated relationships that drive value through specific alignments and efficiencies (PAREXEL, 2013). Market survey data collected by Credit Suisse representatives (2018) indicated that the move toward strategic partnerships continues to be a sustainable trend with preferred strategic partnerships in place for 82% of respondents.

Festel et al. (2010) analyzed the stimulation of innovation in the pharmaceutical industry through outsourcing of R&D activities within the drug discovery and development process. This outsourcing opportunity provides a collaborative partnership that creates efficiency and improves profitability. Miller (2010) reported that Eli Lilly

and Company formed strategic outsourcing relationships to help reduce its fixed cost structure while providing quality development and manufacturing services. Eli Lilly representatives indicated that the company recognized 20% savings on data management and monitoring (Parrett, 2013). However, there is evidence that cost savings were not materializing in these partnerships (Parrett, 2013).

As strategic partnerships evolve, they should provide a strong foundation for pharmaceutical and biopharmaceutical companies and preclinical CROs to address key concerns and challenges that are apparent in present CRO-sponsor relationships. Key factors affecting current relationships are:

- limited alignment of goal and objectives
- inadequate number of *go-to* labs
- high CRO employee turnover
- revised study pricing resulting from incorrect cost estimates
- inadequate and often untimely information sharing

PAREXEL representatives (2013) found that industry executives viewed future changes in the strategic partnership model would need to be driven by greater collaboration and improved operational efficiencies. Key factors affecting future relationships are:

- dedication
- risk-sharing
- value
- transparency

PAREXEL representatives (2013) described clinical CROs that chose to engage in strategic partnerships would need to focus on achieving specific metrics such as quality and timeliness. Dedication was defined as the CRO's commitment to the client's results and success, and alignment with the company's specific needs. Risk-sharing covers a wide range of activities including investment in operational efficiencies such as technology, processes, staffing, and time as well as financial incentives and penalties demonstrating that the CRO is vested in shared success. Value was driven by the expectation that the relationship would yield cost and operational efficiencies without sacrificing quality. The model also provided for better communication between the two *partners* and greater sharing of information and expertise resulting in understood transparency (PAREXEL, 2013). Credit Suisse representatives (2018) described a sustainable trend toward strategic partnerships for outsourcing needs.

Strategic forward thinking should focus on the CRO assuming a greater up-front risk in the drug development process by forming strategic partnerships with pharma. This risk-sharing model ensures that the CRO is operationally or financially vested in shared success (PAREXEL, 2013).

Competitive Advantage

Porter's (1980) competitive advantage theory describes a strategy where firms identify activities that could provide the company a competitive advantage. Competitiveness is the tactical strategy for achieving goals and outperforming competitors (Soloducho-Pelc, 2014). Caiazza et al. (2015) described a firms' competitiveness as dependent on the creation of knowledge through internal investment

and adoption/adaptation of external knowledge created by other organizations. Industrial organization economists propose that competitive advantage is achieved if a company has a better value creating strategy (i.e., market position) not simultaneously implemented by concurrent or potential competition, while resource-based view researchers suggest that competitive advantage is the result of a company's specific capital and specific capabilities (Huang et al., 2015; Liu & Huang, 2017; Wang, 2014; Whalen et al., 2016). These conceptualizations of competitiveness suggest that a service provider is perceived and evaluated in comparison to other providers (i.e., the competition) in the industry, and this perception likely contributes to customer loyalty (Baumann et al., 2017). Ultimately, competitiveness can drive customer loyalty and the level of competition (a market condition) moderates the relationship between service quality and customer loyalty (Baumann et al., 2017; Chen, 2015).

Market-Based View

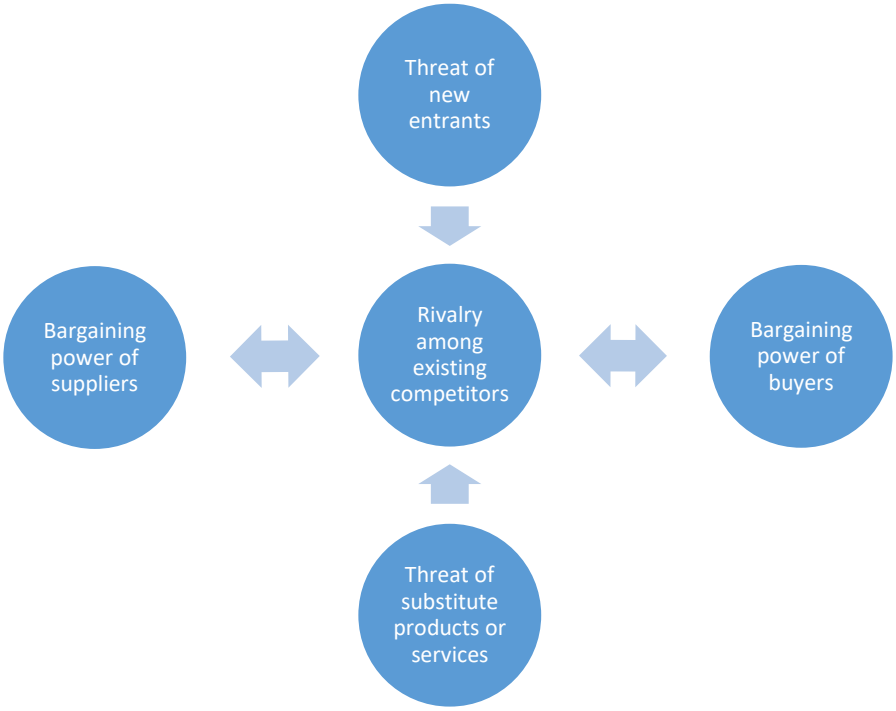
Industry factors and the external market condition are the primary determinants of an organization's performance in the MBV of competitive strategy (Porter, 1985; Wang, 2014). Wang (2014) argued that in this model, the sources of value for the organization are linked to the competitive characteristics of the end-product strategic position and that position is the organization's unique attribute that is different from the competition. The strategic position can be described as how an organization performs similar activities to other companies, but in very different ways (Wang, 2014). Profitability and performance are therefore tied directly to the structure and competitive dynamics of that specific industry (Schendel, 1994; Wang, 2014). In formulating strategy, companies often assess

competitive advantage based on the external competition using Porter's (1985) five forces model (see Figure 2). This model consists of

- barriers to entry;
- threat of substitutes;
- bargaining power of suppliers;
- bargaining power of buyers; and
- competitor rivalries (Porter, 1985).

Figure 2

Summary of Five Forces – Key Drivers



Note. An industry structure framework is built around five competitive forces that can impact the sustainability of profits. This framework functions to explain profitability against bargaining and against direct and indirect competition. Adapted from "Competitive Strategy: Techniques for Analyzing Industries and Competitors," by M. E. Porter, 1980, p. 4. Copyright 1980 by The Free Press.

Wang (2014) concluded that there is considerable diversity in how strategy is conceptualized and no clear consensus that any one view is correct. Obtaining a certain market position involves competitiveness and competitiveness is about the ability to create competitive advantage using the company's internal or relational resources (Baumann et al., 2017; Wang, 2014).

To create a competitive advantage, an organization must understand the benefit their product provides, the target market and target market needs, and who/what is the competition. An organization needs to have clear and specific goals, strategies, and processes to build sustainable competitive advantage. Porter (1985) outlined three ways organizations achieve a sustainable advantage:

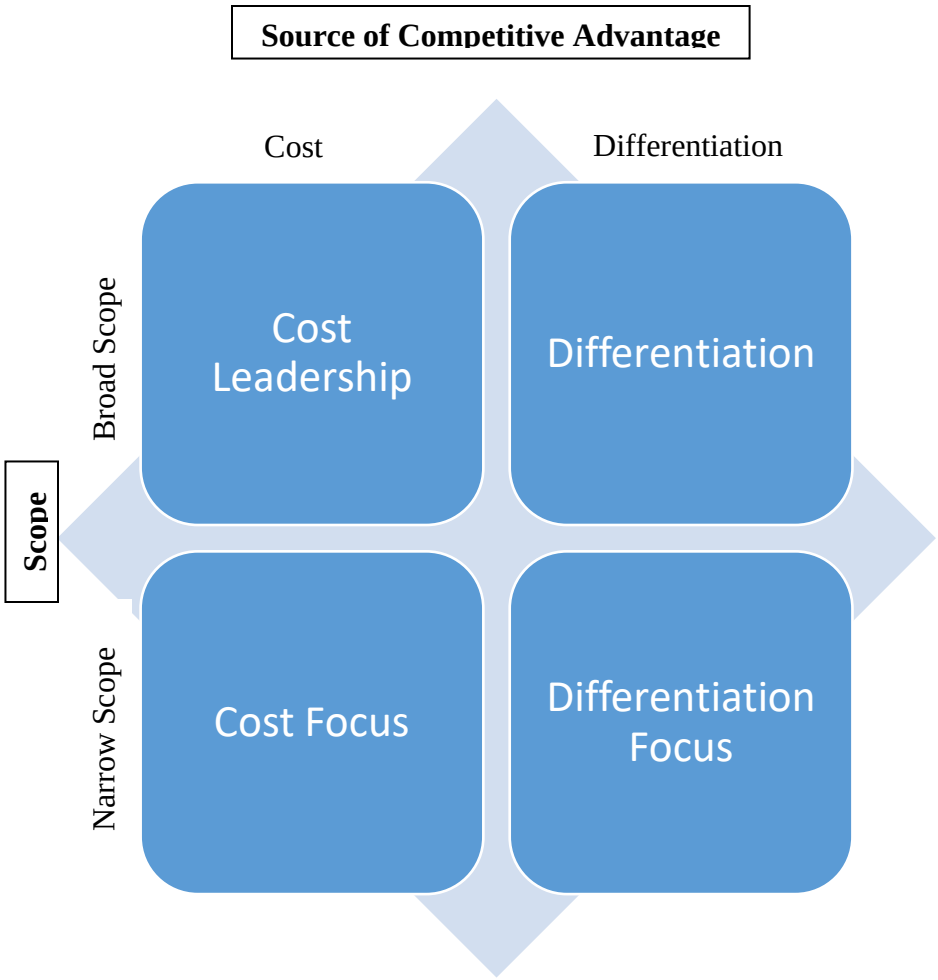
- cost leadership
- differentiation
- focus

Cost leadership is an organizations ability to provide reasonable value at a lower price. Cost leadership is a competitive strategy aimed at maximizing profits by providing the best possible product with a low production cost resulting in a higher market share than the competition (Brett, 2018; Porter, 1985). Differentiation is achieved when an organization is able to deliver a better product than the competition. Brett (2018) described this strategy as an organization's ability to charge higher prices (higher profit margin) based on a higher quality product, or the customer's perception of a higher quality product, compared to the competition. An organization typically achieves differentiation through innovation, quality, and/or customer service. Focus describes the

ability for an organization to understand and service the target market better than the competition. Focus strategy has two variants: (a) cost focus, and (b) differentiation focus (see Figure 3). In cost focus, an organization looks for a cost advantage for a specific and targeted segment of the market, while in differentiation focus an organization looks to create a differentiated focus for a particular market segment (Brett, 2018). Porter (1985) suggested that the three strategies are approaches that an organization should consider when dealing with competition. If an organization attempts to combine an emphasis on low cost *and* differentiation and fails to develop one of the three strategies, they will likely experience below average profits and end up in a weak strategic position (Brett, 2018; Porter, 1985). In some cases, an organization may not have sufficient capital and market share for the cost leadership approach or may not have the expertise to pursue a differentiation focus strategy (Brett, 2018). As a result, the organization will not be able to attract high-end customers and may lose them to other companies who are able to successfully differentiate (Brett, 2018; Porter, 1985). It is important to identify a difference between an organization's usual customer base and an identified segment of the market otherwise outside of the scope of the organization's business (Brett, 2018). Porter (1991) described competitive advantages as two basic types: (a) "lower cost than rivals" or (b) "the ability to differentiate and command a premium price that exceeds the extra cost of doing so".

Figure 3

Achieving a Competitive Advantage



Note. Porter's Competitive Advantage Strategies. Adapted from "Competitive Advantage: Creating and Sustaining Superior Performance," by M. E. Porter, 1985, p. 12. New York, NY: The Free Press.

Porter (2015) cautioned that organizations that are competing on the same product have a significant challenge because a truism of competition and strategy is that you cannot meet the needs of every customer. Competitive strategy is about competing to be unique. “If you try to meet everybody’s needs, the chances are that you won’t be very good at meeting anybody’s needs” (Porter, 2015).

Strategic partnerships between a CRO and its client(s) are often the result of customer loyalty and service quality. Understanding market factors (budgets, timelines, regulations, etc.) and partnership resources and capabilities allows the formulation of strategy in response to industry dynamics, potentially resulting in competitive advantage for both the CRO and the pharmaceutical or biotech client. Lin and Darnall (2015) suggested that a company’s decision to form a strategic alliance or partnership was influenced by resource-based and institutional factors. The decision to outsource to a CRO and often to develop a strategic partnership is many times the result of categorizing the outsourced project as either an opportunity or a threat. In rationalizing between options, the outsourcing manager must evaluate their organization’s internal competencies, capital investments, technology, as well as the competencies, cost, and technology of the partner being considered (Lin & Darnall, 2015). Evaluation of these factors will identify the project as being a strategic business opportunity or a business threat resulting in a business partnership/alliance that is either proactive (opportunity driven) or reactive (threat driven) (Lin & Darnall, 2015). This process is an example of the RBV of strategy that focuses on the strategic partnership as a driver for competitive advantage (Lin & Darnall, 2015; Wang, 2014).

Comparative Advantage Theory

Hunt and Morgan (1995) introduced the concept of resource advantage as a counter to the neoclassical theory of perfect competition. Competition involves the constant struggle for a comparative advantage that will yield a market position of competitive advantage and superior financial performance (Hunt & Morgan, 1995). This theory was introduced to explain how a competitive and dynamic market is preferable to one that is command driven. The comparative advantage theory expands on an organization's tangible resources (e.g., land, labor, and capital) to include intangible competencies such as organizational culture, brand equity, knowledge (e.g., consumer and competitive intelligence), human capital (e.g., skills and knowledge of individual employees), and relationships (e.g., with suppliers and customers) that enable the achievement of superior financial performance (Hunt & Morgan, 1995). A comparative advantage in resources exists when an organization's resources enable it to produce a product that (a)is perceived by the market to have superior value and/or (b) can be produced at lower costs (Hunt & Morgan, 1995). Figure 4 explains nine possible competitive positions of an organization relative to a competitor in terms of resource-produced value and relative resource cost for that value.

Figure 4

Competitive Position Matrix

Relative Resource Costs	Relative Resource-Produced Value: Lower	Parity	Superior
Lower	1 Indeterminate Position	2 Competitive Advantage	3 Competitive Advantage
Parity	4 Competitive Disadvantage	5 Parity Position	6 Competitive Advantage
Higher	7 Competitive Disadvantage	8 Competitive Disadvantage	9 Indeterminate Position

1 Demand is heterogeneous across industries, heterogeneous within industries, and dynamic
2 Consumer information is imperfect and costly
3 Human motivation is constrained self-interest seeking
4 The organization's objective is superior financial performance
5 The organization's information is imperfect and costly
6 The organization's resources are financial, physical, legal, human, organizational, informational, and relational
7 Resource characteristics are heterogeneous and imperfectly mobile
8 The role of management is to recognize, understand, create, select, implement, and modify strategies
9 Competitive dynamics are disequilibrium-provoking, with innovation endogenous

Note. The marketplace position of competitive advantage identified as Cell 3 results from the organization, relative to its competition, having a resource assortment that enables it to produce a product that is (a) perceived to be a superior value and/or (b) produced at lower costs. Adapted from "The Comparative Advantage Theory of Competition," by S. D. Hunt and R. M. Morgan, 1995, *Journal of Marketing, 59,* p. 7 (https://doi.org/10.2307/1252069).

Resource-Based View

Porter's (1985) five forces model enables organizations to structurally analyze current industry situations. However, this model is limited in assuming a classic perfect market as well as static market structure (Wang, 2014). In 21st century dynamic markets, this model is increasingly challenging as industries have become more complex with inter-relationships that focus on firm-specific determinants of profitability rather than industry-specific ones (Rumelt, 1991; Wang, 2014). Focus on the capabilities and the heterogeneous resources that organizations use has become more important than solely based on products and market positioning as the primary source of competitive advantage (Rumelt, 1991; Wang, 2014). This approach further describes the RBV strategy.

The RBV of the organization focuses on the internal environment as a driver for competitive advantage. Kay (2018) described a firm as a collection of capabilities that provide a more illuminating perspective for understanding the diversity of business organization over geographies and over time. Porter (1991) argued that the origins of competitive advantage are valuable, often intangible resources (competencies) that an organization has such as skills and reputation. An organization's resources are often classified as skills, knowledge, and technology (Wang, 2014). A key for achieving competitive advantage is a business system which harmonizes the resource base, system of operation, and the range of products offered to achieve effective value-creation (Otola et al., 2013). Barney (1991) stated that an organizations resources are "all assets, capabilities, organizational processes, firm attributes, information, etc. controlled by a firm that enable the firm to conceive of and implement strategies that improve its

efficiency and effectiveness". The RBV is a concept that identifies an organization's resources and inherent competencies as determinants of its success (Otola et al., 2013). Barney (1991) indicated that resources that determine competitive advantage should be valuable, inimitable, rare, and non-substitutable. Otola et al. (2013) further summarized Barney (1991), Krupski (2011), and Bratnicki (2000) and postulated that that resources (core competencies) that are strategic should be

- important and represent a strategic value to the organization;
- rare in terms of occurrence in current and potential competitors;
- difficult to be copied by the competitors;
- have limited mobility;
- ensure permanent competitive advantage;
- non-substitutable (irreplaceable); and
- expensive when imitated.

In the RBV, competitive advantage is created from the efficiency of the resources that enable the organization to produce greater perceived benefits for the same costs or the same perceived benefits for a lower cost (Brahma & Chakraborty, 2011).

Porter (1991) provided a counter-narrative and suggests that resources are not valuable in and of themselves but are valuable because they allow organizations to perform activities that create advantage in specific markets. The competitive value of resources can be enhanced or eliminated by competitor behavior, buyer needs, or changes in technology (Porter, 1991). Peteraf and Barney (2003) explained that the resource-based view is not a substitute for industry level analytic tools such as five-forces analysis,

strategic group analysis, or macro environment analysis, but rather a complement to these tools.

CROs and COVID-19

During the early months of the COVID-19 pandemic beginning in early 2020, preclinical CROs were largely open for business. However, in some regions of the country (and world), the restrictions on movement due to COVID-19 caused some pharmaceutical and biotech companies to slow, and in many cases end, their internal preclinical activities (BioCentury, 2020). Although representatives of the Department of Homeland Security included and identified workers conducting research critical to COVID-19 response as essential critical infrastructure workforce, pharmaceutical and biotech companies held back from conducting in-house R&D discovery research in favor of clinical trials or critical investigational new drug-enabling (IND-enabling) studies (BioCentury, 2020). These companies chose to restrict/limit company access and as a result, most internal preclinical programs were stopped and ended.

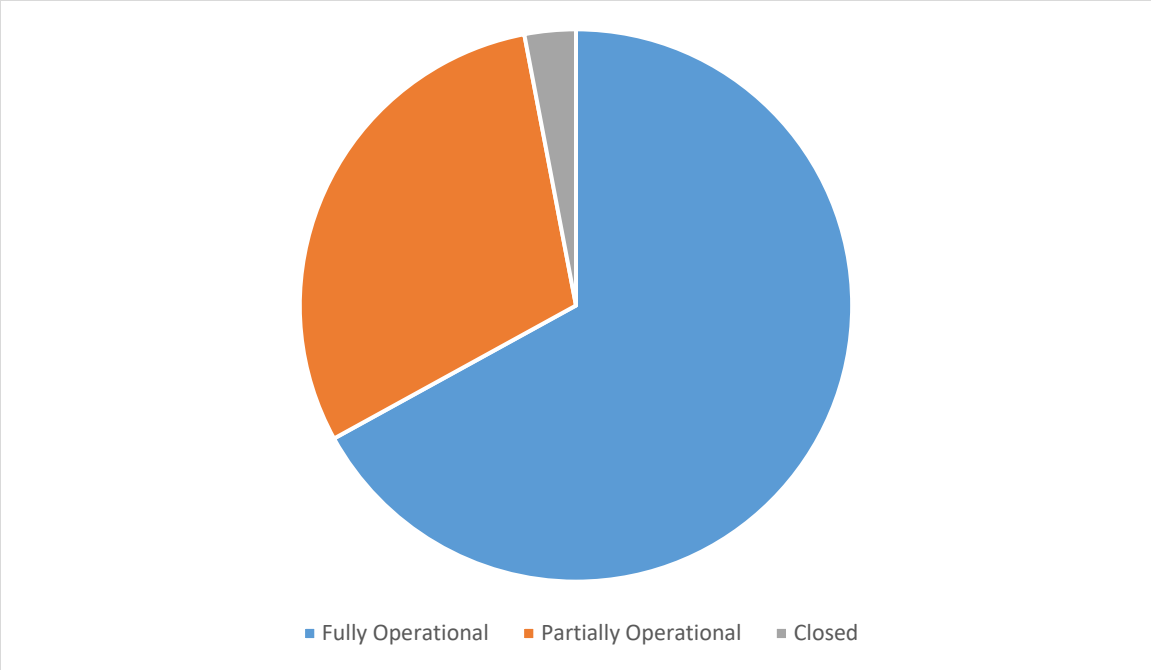
Only 3% of 368 global preclinical CROs indicated they had closed and suspended operations (BioCentury, 2020). Most (67%) were open and fully operational, and 30% were open but only minimally staffed and operating at partial capacity (BioCentury, 2020). While 60% of the CRO representatives surveyed by BioCentury indicated they were working on non-COVID-19 projects, almost 25% had programs related to the outbreak (BioCentury, 2020).

The COVID-19 pandemic will likely affect the biopharmaceutical industry by impacting the CRO and biopharmaceutical companies financially, by directly impacting

production and demand, and by creating market disruption. Continued CRO outsourcing during the COVID-19 pandemic may provide some pharmaceutical and biotech companies the opportunity to establish relationships/partnerships with a CRO that may lead to continued work and outsourcing in the future. As outsourcing continues, a shift in business priorities may occur that may place more perceived risk on the outsourced preclinical project not being conducted in-house but may forge a strategic partnership with the CRO that builds continued trust and a lasting relationship. It is likely that because of the pandemic, outsourcing will increase in the 2020s and beyond. The outcome of this outsourcing trend may result in possible structural changes in the drug development process. As the industry navigates a new post-pandemic normalcy in the coming years, further research exploring the effects of increased outsourcing and the partnerships and relationships required to ensure business continuity and financial success will be possible as data become available.

Figure 5

Preclinical CROs Open During COVID-19



Note. Most preclinical CROs remain open during the pandemic as pharmaceutical and biotech companies aim to meet their goals by outsourcing more projects. Adapted from "CROs Might Be the Engine That Keeps Preclinical Research Moving During COVID-19," by Biocentury Inc., 2020. Copyright 2020 by BioCentury Inc.

Transition

The types of partnerships that CROs are engaging in are changing. Pharmaceutical companies are now outsourcing entire programs and the CRO is becoming a permanent supplier of certain critical functions. With the recent budgetary pressure pharmaceutical and biotech companies are under, there has been a shift to more strategic outsourcing where CROs are no longer mere service providers, but full-service

collaborators and strategic business partners. The resulting increased outsourcing has caused a more focused engagement between the CRO and Pharmaceutical companies, and this partnership will be a synergistic collaboration that provides incentives for both industries. However, as a service provider, the preclinical CRO does not share equal risk in these strategic partnerships. The preclinical CRO has different business interests than their pharmaceutical/biotech company clients (Parrett, 2013) and as a result, strategic partnerships must be agreed to and understood with complete transparency. In Section 1, I provided the background of the problem, the research purpose, the research methodology, and a review of the scholarly and professional literature.

In Section 2, I include the purpose and method of the study, the application and implication for business use, and implications for social change. In Section 2, I also discuss the role of the researcher and study participants, data collection and organization techniques, as well as describe efforts to ensure the validity and reliability of the research study. In Section 3, I present the findings of the research and implications for social change. In Section 3, I also draw overall conclusions and list recommendations for further study/research.

Section 2: The Project

Corporate downsizing and consolidation and economic uncertainty led the pharmaceutical research sector to streamline operationally, reduce costs, and improve efficiencies (Green, 2009). Pharmaceutical companies are now outsourcing entire programs and the CRO is becoming a permanent supplier of critical functions (Lin & Darnall, 2015; Parrett, 2013). With the budgetary pressure pharmaceutical and biotech companies are under, there has been a shift to more strategic outsourcing where CROs are no longer mere service providers, but full-service collaborators and strategic business partners (Getz, 2014; PAREXEL, 2013). By understanding the mutualistic interactions that are required for improved success, decision makers may be able to improve strategic collaboration between pharma and CROs, which may lead to scientific innovations in pharmaceutical research that will not only save lives but provide for a healthier and improved quality of life. The intent of this qualitative study was to explore and evaluate current business strategies that have focused engagement between the CRO and pharma to create synergistic collaborations that are financially and scientifically mutually beneficial. Based on known data and industry trends, I used a multiple case research strategy to collect and analyze qualitative data to explore empirical innovative approaches to strategic collaborations between a CRO and pharma/biotech.

Purpose Statement

The purpose of this qualitative multiple case study was to ascertain the perceptions and experiences of key industry decision makers regarding the risk associated with strategic partnerships between the CRO and pharmaceutical/biotech companies. The

targeted population consisted of nine key decision makers at pharmaceutical research companies (large and small pharma), biopharmaceutical research companies, and CROs in the United States, Europe, and Asia. Qualitative data were collected through interviews of chief executive officers (CEO), corporate presidents/vice-presidents, and/or scientific directors from the United States, Europe, and Asia. This population was appropriate for this study because these key industry decision makers provided accurate data describing the attitudes and experiences they have toward strategic business collaborations with each other, and how those collaborations have influenced the pharmaceutical research industry. The implications for positive social change include the potential to provide an efficient and collaborative drug discovery and development process that may result in novel lifesaving compounds receiving regulatory approval and getting to market faster and safer.

Role of the Researcher

Clark and Veale (2018) described that the role of a qualitative researcher is to collect and analyze data. I collected and analyzed data during this study. In qualitative research, the researcher's involvement is defined as participatory and interpretive (Clark & Veale, 2018). Specifically, as the main source of data collection (i.e., the researcher), I examined and evaluated current market research and literature and built categories and themes to organize the information into a coherent and substantive review of the research topic. As the researcher, I mediated the data collection process by asking questions that provided insight into the outsourcing aspect of pharmaceutical research. Moreover, I conducted interviews with participants to evaluate how preclinical CROs view risk

responsibility as a service provider in strategic partnerships, knowing they have different business interests than their pharmaceutical/biotech company clients.

In this study, I adhered to the protocols provided in *The Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) and followed basic ethical principles of (a) respect for persons, (b) beneficence, and (c) justice. I applied these general principles by (a) providing a consent form to ensure that the participants understood and were informed of the purpose of the study, (b) examining whether the research was properly designed and justified on the basis of a favorable risk/benefit assessment for participating in the study, and (c) creating a fair selection process for participants. To ensure confidentiality, protect the privacy and identity of individuals and/or organizations, and to minimize researcher bias, alphanumeric identifiers were used as pseudonyms instead of participant or company names, as suggested by Saunders et al. (2015). Further, Sorsa et al. (2015) indicated that scholarly researchers need to be nonjudgmental, professional, and without any prejudice.

I conducted 30- to 45-minute interviews by phone or through Microsoft Teams as the data collection method for this study with nine key decision makers in the pharmaceutical, biotech, and CRO industries. The target population included participants who were company presidents/vice presidents, CEOs, and directors. Key nonclinical pharmaceutical industry decision makers were interviewed to gain insight describing the attitudes and experiences they have toward strategic business collaborations with each other, what risk responsibilities service providers (i.e., CROs) assume in a scientific/business strategic partnership, and how those collaborations have influenced the

pharmaceutical research industry (see Appendix A). The in-depth, one-on-one semistructured interview technique allowed me to solicit direct answers from the research participants. The unstructured format of the interview questions allowed participants to provide thoughtful answers and opinions (Bernard, 2013; Moustakas, 1994).

As a member of the preclinical research field, I interact with key decision makers at biotech (bio) and pharma companies and can influence their scientific programs and business strategy. Some of the participants were current or past business clients. Bracketing mitigates unacknowledged preconceptions related to the research to increase the objectivity of the project (Taverno Ross & Francis, 2016). The bracketing process built perspectives for a comprehensive summation of current pharmaceutical research trends in the context of outsourcing and strategic partnerships. Clark and Veale (2018) suggested that, during the interview process, the interviewer should avoid leading the participants' responses by reacting indifferently to their answers and engaging conscientiously in a subjective perception of their experience. The interview questions were open-ended and specifically related to outsourcing and strategic partnerships. The interviewing process continued until data saturation was reached. Data saturation is reached when no new information is gained and no new coding or themes are determined from the interviews (Fusch & Ness, 2015). The interview process begins to replicate results when data saturation is reached (O'Reilly & Parker, 2013; Saunders et al., 2018). Evaluation and analysis of the collected information may provide an understanding of the mutual interactions and risks that are required for improved success between

pharmaceutical/biotech companies and CROs in efforts to foster business innovations that will not only help save lives, but also provide for a healthier and improved quality of life.

Participants

The target population included nine participants who were key senior level decision-makers in the pharmaceutical, biotech, and CRO industries (e.g., company presidents/vice presidents, CEOs, and directors). I used a stratified purposeful sampling technique to identify the key decision makers (Bryman, 2016). The participant population was selected from national and international pharmaceutical research companies, biotech companies, and CROs throughout the preclinical pharmaceutical research industry. The selection and solicitation of participants for this study was thoughtful, targeted, and nonrandom. I contacted participants for interviews directly via Microsoft Teams. Although a minimum of at least one participant could be studied and deemed an appropriate sample size in a case study (Njie & Asimiran, 2014), the pursuit of a rich data sample from each business segment within the preclinical research industry required purposive sampling from several participants from each business segment to provide the most in-depth information. Participants were selected from a client database made available to me by my employer. The participants were selected from appropriate business segments that represent national and international pharmaceutical research companies, biotech companies, and CROs, and were initially contacted via email or telephone using the contact information made available to me by my employer to solicit participation in this study. The senior level participants who were interviewed were assumed to have adequate experience and breadth of knowledge, based on position/title

(e.g., company president/vice president, CEO, and director), necessary to provide in-depth responses to the interview questions; therefore, no additional eligibility criteria were required.

To develop a positive relationship with participants, I notified each participant of aspects of the research that could influence their decision to participate (Marrone, 2016). I ensured that each participant was provided complete anonymity by using a pseudonym (e.g., PharmBio1, PharmBio2, CRO1, CRO2) to conceal the participant's specific identity, and ensure that each participant understood and voluntarily agreed to participate in the research. I provided an informed consent form to each participant after receiving IRB approval. Drake (2013) indicated that a participant can withdraw from the study at any time via any form of written communication. Participants were not forced to answer any questions that they were uncomfortable or unwilling to answer (Rodrigues et al., 2013).

Research Method and Design

Research Method

A qualitative study design is used to explore possible shared elements and opinions from the independent inquiry of personal thoughts, attitudes, and perceptions of participants and provides an in-depth understanding of the social world by asking open-ended questions to learn about the social circumstances, experiences, perspectives, behavior, knowledge, and histories of those participants (Kelly, 2016; Ritchie et al., 2014). Whereas quantitative research is typically objective, tangible, empirical, deductive, and appropriate to study a topic when knowledge of the subject is already

known (Antwi & Hamza, 2015), a qualitative research method is used to provide insight into the motivations, attitudes, perceptions, experiences, and values of participants by allowing a subjective, open, confidential, and anonymous dialogue from individuals who may not otherwise share their thoughts and opinions (Kelly, 2016; Smollan, 2015). Quantitative and qualitative elements constitute mixed methods research and are appropriate for exploration that includes both types of data (Almalki, 2016; C. B. Gibson, 2017). A qualitative research method was appropriate for this study because it was used to provide an in-depth understanding of the lived experiences of the participants, derived from first-person reports (Moustakas, 1994), to determine if strategic partnerships between the CRO and pharma have been mutually beneficial. Based on known data and industry trends, empirical innovative approaches to strategic collaborations between a CRO and pharma/biotech were evaluated. Using deductive reasoning, I evaluated these business models to determine if risk-reward collaborations can be mutually beneficial. I evaluated outsourcing trends and general financial information. Additionally, a qualitative analysis of specific CRO/pharma collaborations provided a general industry overview of business relationships between pharmaceutical research companies and the biotech industry and their outsourcing partners (i.e., CROs).

Research Design

I considered three research designs for a qualitative study exploring business strategies: (a) case study, (b) ethnography, and (c) phenomenology. Case study research is a strategy of inquiry whereby the researcher investigates a phenomenon to provide an analysis of the context and processes that define the theoretical issues being studied for a

group of research participants (Njie & Asimiran, 2014). Case study research is defined by interest in individual cases rather than the methods of inquiry used, is typically used to investigate and analyze a single or collective case, and is particularistic, descriptive, and heuristic (Hyett et al., 2014). A single case study delineates a single individual, group, program, or event and concentrates intrinsically on it to learn more about a poorly understood situation, phenomenon, or real-world experience (Freeman et al., 2015; Njie & Asimiran, 2014). Multicase studies (multiple case studies) include a collection of data from multiple individual sources such as groups and people (Sugar, 2014). Ethnography describes a culture's characteristics (e.g., pharmaceutical industry) through intimate, often face-to-face, direct observations and interactions with subjects (e.g., interviews and documentary data), which are triangulated using multiple data sources, and offers a qualitative approach that results in detailed, inductive, interactive, recursive data collection and analytic strategies to build comprehensive accounts of different social phenomenon (Mohajan, 2018). Phenomenology describes experiences as they are lived from an individual perspective (Moustakas, 1994). The researcher's aim in case analysis is to learn strictly from the point of view of the study participant as an immediate state in consciousness (Creely, 2016; Marshall & Rossman, 2016) that provides the most in-depth information relevant to the questions that are asked (Njie & Asimiran, 2014).

Although an ethnographic design would have provided an in-depth description of the pharmaceutical industry's culture, a more specific understanding of individual experiences and opinions was needed. Descriptive transcendental phenomenology would have allowed me to gain meaning from lived experiences, perspectives, and knowledge

(Kelly, 2016; Moustakas, 1994). Creely (2016) described this Husserlian sense of meaning as a transcendent attribute of describable consciousness, cogent for a phenomenological approach to investigative research. However, a phenomenological design is subjective and integrates the collective views of the researcher and participants by exploring the emotional and affective reactions experienced by those going through the phenomenon (Tuohy et al., 2013). This would have been beyond the scope of this research.

A case study is an embodiment of details about specific subject matter that results in an intensive analysis of complex social phenomena that allows the researcher to retain holistic and meaningful characteristics of real-life events (Njie & Asimiran, 2014). The case study design focuses on a sample that provides the best and the most in-depth information, where the sample size is less important than the depth and richness covered by the purposive sampling of a single or a few participants necessary to arrive at interpretations and conclusions rich in details reflective of the case (Njie & Asimiran, 2014). Further, a multiple case study provides basis for transferability of the same phenomenon in a variety of contexts that may reveal a broader trend significant on a wider scale (Rule & John, 2015). A case study research approach was used to draw conclusions from the experiences of decision makers in the pharmaceutical, biotech, and CRO industry regarding strategic partnerships/collaborations between CROs and pharma/biotech companies. I considered the multiple case study research design appropriate to explore business strategies focused on strategic partnerships.

Data saturation is reached when new data repeat what was expressed in previous data (Saunders et al., 2018) and when no new data have been found (Fusch & Ness, 2015; O'Reilly & Parker, 2013), what Sandelowski (2008) refers to as *informational redundancy*. Saunders et al. (2018) suggested a similar description of data saturation as the point when the researcher begins to hear similar comments repeatedly during interviews. Strauss and Corbin (1998) assessed saturation as a matter of degree, suggesting that saturation occurs when further data collection becomes counterproductive and does not add anything new to the data.

Population and Sampling

The purpose of this qualitative multiple case study was to ascertain the perceptions and experiences of key industry decision makers regarding the risk associated with strategic partnerships between the CRO and pharmaceutical/biotech companies. I used purposive sampling of key decision makers in the pharmaceutical, biotech, and CRO industries. The data were collected using the purposive sampling technique/method by conducting interviews with participants selected because of their personal experience or knowledge of the topic (as recommended by Bryman, 2016, and Cleary et al., 2014) and examining and evaluating current market research and literature. All of the interviews were conducted over the phone or via a Microsoft Teams meeting due to the national or international proximity of the selected key decision maker's physical location or that of their company.

Speaking with participants over the phone (or similar communication technology) provides inherent advantages (compared to face-to-face interviews) which include (a)

confidentiality, (b) mitigating bias, and (c) promoting flexibility (Morse & Coulehan, 2015). When no new data are obtained from the study participants (saturation) and the information gathered becomes redundant, the interviewing process is ended as the required sample size has been met (Cleary et al., 2014; O'Reilly & Parker, 2013). The required sample size is based on the ability to reach theme saturation without new concepts or themes emerging (Bryman, 2016; Cleary et al., 2014; O'Reilly & Parker, 2013). The criteria for key decision makers in this study were roles of company presidents/vice presidents, CEOs, and directors. Participation in the study was voluntary, and therefore, there was no remuneration for participation.

The population for the study was suitable to evaluate how key industry decision makers regard the risk associated with strategic partnerships between the CRO and pharmaceutical/biotech companies. A sample size of nine key decision makers allowed for comprehensive and substantive data from an appropriate sample distribution of both national and international pharmaceutical research companies throughout the pharmaceutical research industry.

In this study, I used the stratified purposeful sampling method. Emmel (2013) explained that qualitative sampling is an iterative set of decisions throughout the research process and not a single planning decision. Anney (2014) explained that qualitative sampling is assumed to be naturalistic and conforms to the inquiry and divergent reality and purpose of the study in a cohesive logic to develop idiographic knowledge. Purposeful sampling provides informed perspective that can enhance the quality of exploration synthesis (Flick, 2015). Information-rich cases (e.g., participants) provide the

logic and power of purposeful sampling and yield in-depth comprehension rather than empirical generalizations (Palinkas et al., 2015; Patton, 2015). In stratified purposeful sampling, maximum variation is critical in providing the widest variety of perspectives possible within the sampling population and between groups of participants within that population to allow for comparison (Koerber & McMichael, 2008; Palinkas et al., 2015; Patton, 2015). I, as the researcher, was reflexive and followed the iterative nature of qualitative research to make decisions in response to empirical findings and theoretical developments, as described by Emmel (2013).

Ethical Research

The Walden University Institutional Review Board (IRB) representatives are responsible for ensuring that all Walden University research complies with the university's ethical standards as well as U.S. federal regulations. The IRB reviewed and approved this study (IRB approval number 10-30-20-0223395) to protect the rights, interests, and welfare of the study participants, and maintain the ethical standards of the university (Amdur & Bankert, 2011). *The Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) and its principles focus on respect for the research participants' individual autonomy and its derivative application, informed consent (Tene & Polonetsky, 2016). Informed consent is further based on the principles of privacy and a process of communication between the researcher and the research participant that culminates in the authorization or refusal to participate in a research study (Bhattacharya et al., 2016; Grady, 2015). I notified participants of aspects of the research that could influence their decision to participate. I

ensured that each participant understood and voluntarily agreed to participate in the research. There were no incentives for participation in this study and withdrawal from the study at any time was an option. An informed consent form was provided to the participant pool after receiving IRB approval. A participant could have withdrawn from the study at any time by simply informing me via any form of communication (e.g., phone call, email, other form of written correspondence). The consent form included background information of the study and described the voluntary nature of the study.

The interpersonal capacity to respect each participant should be a primary aim of the qualitative researcher as it demonstrates esteem for the participants (O'Grady, 2016). Specifically, protecting the privacy and confidentiality of the study participants was an important aspect of this research. To ensure confidentiality and protect the identity of individuals and/or organizations, and to minimize researcher bias, alpha numeric identifiers (pseudonyms) were used instead of participant or company names (Saunders et al., 2015). All research data including interviews and any study related documents will be secured and maintained for 5 years following completion of the study and will then be destroyed.

Data Collection Instruments

The primary data collection instruments for this study was a qualitative research interview with each participant and the collection and evaluation of current public company documents, market research, and/or literature. Since real-world phenomena cannot be measured by external instruments, Yin (2016) explained that the qualitative study researcher serves as the principal research instrument to make inferences about

lived experiences by interviewing the research participants. The in-depth, one-on-one semistructured interview technique allowed me to solicit answers from the research participants to approximately 10 questions. The semistructured format of the interview questions allowed participants to provide thoughtful answers and opinions (Bernard, 2013; Moustakas, 1994). The interview was a social interaction where the validity of the data was the result of cooperation between the researcher and the study participant and appropriate congruency with the purpose of the research as explained by Castillo-Montoya (2016). I used observation, documentation, and evaluation/interpretation of each participant's interview question answers to ensure the reliability, validity, and accuracy in the study as described by Yilmaz (2013). Each study participant was asked the same interview questions to ensure consistency. I used an interview protocol (see Appendix A) that set the overall tone and parameters for the interviews. By implementing an interview protocol, the reliability of the study was further solidified (Yin, 2014). During and after the approximate 30-45- minute interviews, I used a reflective journal to make comments that may further clarify any issues/observations made during the discussions as suggested by Muswazi and Nhamo (2013).

To ensure that the data collected from participants' interviews was reliable and valid, I used member checking to validate that the collected information was accurate. Member checking is a process where the researcher shares a concise summary of the collected data with the participant allowing the participant the opportunity to review and provide clarifications and/or confirmation that the information is accurate (Bekhet & Zauszniewski, 2012; Harper & Cole, 2012).

Data Collection Technique

Using a semistructured interview technique, outsourcing trends were evaluated, business collaborations and partnerships were identified, and supporting information was collected and analyzed to explore and evaluate current business strategies that have focused engagement between the CRO and pharma to create collaborations that are financially and scientifically mutually beneficial. The primary instrument that was used for data collection was a qualitative research interview method (Marshall & Rossman, 2016) and extensive review of current public company documents, market research, and/or literature. Using multiple data sources and data collection procedures enhance the information gathered (Robinson, 2013) and result in further credibility and trustworthiness through the data triangulation process (Carter et al., 2014; Yin, 2014).

The interviews provided a timely and accurate description of the current attitudes that key decision makers have toward strategic business collaborations with each other, and how those collaborations have influenced the pharmaceutical research industry. The information was collected during Microsoft Teams meeting interviews to obtain opinions, business strategy and theory, and current views/perceptions. As the principal instrument in this qualitative multiple case study, I asked specific open ended questions (see Appendix B) during the interview (Freeman et al., 2015) to (a) elicit information from the participants, (b) understand the underlying basis for that information, and (c) adequately appreciate participants' perceptions (O'Reilly & Parker, 2013). The interviews were recorded and were then transcribed electronically into text documents using voice recognition software. Face-to-face interviews (when possible) may have allowed me to

capture verbal and nonverbal data, behaviors, and/or emotions (Speer & Stokoe, 2014), but may have also resulted in a smaller sample size (participant pool) and potentially rushed responses because of the predetermined interview time (duration set by protocol).

To mitigate potential disadvantages of the interview process, participants were offered the option to participate in a Microsoft Teams meeting interview (video conference) or simply participate via audio in a Microsoft Teams meeting without the video capture option. These processes allowed for an environment that can promote privacy, confidentiality, and the level of comfort/ease most appropriate for each individual participant. Microsoft Teams meeting interviews were recorded using the software-recording feature to ensure the accuracy of the participants' responses. I continued the interviewing process until data saturation had been reached and no new data was discovered, as explained and suggested by O'Reilly & Parker (2013), Palinkas et al., (2015); and Sandelowski (2008).

The member checking process involved reviewing, interpreting, and summarizing the interview recordings. As suggested by Bekhet and Zauszniewski (2012) and Harper and Cole (2012), I shared a concise summary of the collected data with each participant allowing the participant the opportunity to review and provide clarifications and/or confirmation that the synthesis of their information was accurate and appropriately represented the content and intent of their responses. Based on follow-up conversations with each participant, the summary responses were updated as necessary, therefore confirming the data, and enhancing the dependability and credibility of the research.

Data Organization Technique

W. Gibson et al. (2014) suggested the use of software to keep track of and organize data. For this study I created and maintained password-protected electronic data logs through Microsoft Word and Excel that were used to categorize the data. These software programs allowed me to code and identify data themes to appropriately categorize and organize the collected data as suggested by Fusch & Ness (2015) and Patterson et al. (2014). The electronic data will be stored on a password-protected universal serial bus (USB) flash drive and computer for 5 years, after which all data will be deleted and/or destroyed.

I used a reflective journal to document information about the study. The journal allowed me to go through a reflective process and critical thinking with the ability to self-monitor, be self-directive and autonomous, while allowing for the development of new perspectives and potential outcomes as described and suggested by Constantinou and Kuys (2013) and Peredaryenko and Krauss (2013). The journal also allowed me to use bracketing to examine preconceived assumptions and/or ideas I may have had about the phenomenon, as described by Chan et al. (2013).

Data Analysis

Yin (2014) described a five-step process for data analysis when conducting a case study: (a) compile data, (b) disassemble the data, (c) reassemble the data, (d) interpret the data, and (e) draw conclusions from the data. Key themes and opinions should emerge from the data analysis process that should inform the research question. The overarching research question for this study is: *What strategies do service providers (i.e., Contract*

Research Organizations) and pharmaceutical/biotech companies use to develop strategic partnerships during the drug discovery and development process? Using the open-ended interview questions should allow responses to be grouped into overarching themes (Irvine et al., 2013). Descriptive analysis was performed, and any response bias was determined.

Data triangulation is used by researchers to ensure appropriate objectivity by referencing multiple sources (Denzin, 2012; Patton, 2015; Yin, 2014). Methodological triangulation was used in this study and involved utilization of data from different sources including detailed responses from interview questions and data from various respective company and industry documents. I collected data via interviews, evaluation of current public company documents, market research, and/or literature. Further, using Yin's five step process (described previously) I identified themes, codes, categories, and descriptions to analyze the data appropriately and efficaciously (Campbell et al., 2013; Yin, 2014). Through this data analysis, I gained an understanding of specific themes, patterns, and relationships associated with key words from the participant interviews. I used these data to evaluate the relationship between the emerging themes and the conceptual framework as described/suggested by Klag and Langley (2013). I compared and analyzed responses from the interview process, available company documents, current market research, and/or literature in order to substantiate the research study, the collected data, conclusions, and outcomes. By reviewing emerging concepts in the literature and identifying possible relationships to the identified themes, I analyzed how they were linked to the conceptual framework and how they related to competitive advantage.

The collected data was organized using an electronic filing system based upon the apha-numeric identifiers assigned to each participant. NVivo (Release 1.4) software was used to code and identify themes for the transcribed interview data. By using NVivo software, accuracy and consistency was assured throughout the data analysis process (Corbin & Strauss, 2015).

Reliability and Validity

Reliability and validity strategies ensure that the research study results are trustworthy, accurate, replicable, appropriate, and well-founded (Barnham, 2015; Leung, 2015; Tracy, 2013). The quality of the qualitative research is evaluated based on the credibility (internal validity), transferability (external validity), dependability (reliability), and conformability (objectivity) of the data (Leung, 2015; Morse, 2015). Reliability and validity are intended to make qualitative research rigorous; and therefore, trustworthy (Morse, 2015; Reinecke et al., 2016).

Reliability

Reliability in qualitative research addresses the extent that the results of the study can be replicated and the consistency of the investigator's research approach throughout the investigation (Marshall & Rossman, 2016). Reliability in qualitative studies includes the dependability, consistency, and repeatability of the data collection, interpretation, and analysis (Morse, 2015; Zohrabi, 2013). Reliability of the interview process was achieved through stratified purposive sampling. To be more specific with the term of reliability in qualitative research, Lincoln and Guba (1985) use *dependability* in qualitative research, which closely corresponds to the notion of reliability in quantitative research.

Dependability of the data collection was ensured by using the modified van Kaam method for data analysis (Moustakas, 1994). Dependability describes when researchers replicate previous research by using similar resources in a similar context or background (Venkatesh et al., 2013). The interview protocol also contributed to the rigor of the study and further demonstrated dependability. Dependability uses an audit trail concept to establish the trustworthiness of the research findings (Jones, 2014) and stability of those findings over time (Anney, 2014). I employed the strategies noted above to ensure the reliability of the study research.

Validity

In qualitative research, credibility describes the accuracy of the collected data to reflect the observed social phenomena (Morse, 2015) and the confidence and believability of that data (Anney, 2014). Data credibility was ensured by the interview participants using member-checking of their interview responses. Participants were allowed to review and provide clarifications and/or confirmation that the synthesis of their information was accurate and appropriately represented the content and intent of their responses (Bekhet & Zauszniewski, 2012; Harper & Cole, 2012). The member-checking process confirmed the accuracy and completeness of the interview question answers (Lub, 2015; Morse, 2015; Wilson et al., 2014), and enhanced credibility and ensured trustworthiness (Beck, 2014). Confirmation of credibility included methodological triangulation involving the use of multiple data collection methods as described by Heale and Forbes (2013) and included (a) a research interview method using open-ended questions, (b) an extensive evaluation of current public company documents

and/or market research, and a peer-reviewed literature review, and (c) data analysis and characterization through coding. Transferability (external validity; generalizability) describes the applicability of the data to another context or individuals (Leung, 2015; Morse, 2015; Sousa, 2014). The extent to which others can confirm the study findings to ensure the data reflect the opinions and experiences of study participants rather than those of the researcher (as parallel to objectivity) is confirmability (Abdalla et al., 2018). Hussein (2009) suggested that confirmability and transferability are enhanced by using methodological triangulation and utilization of data from different sources. The use of comprehensive, detailed, and consistent processes to collect information (e.g., using interview questions) and confirm the credibility of the data using peer-reviewed sources, current market research, and public company information (i.e., triangulation), will provide the future researcher the ability to repeat/replicate the study results or apply the study conclusion(s) (Beck, 2014; Heale & Forbes, 2013; Yin, 2014). Confirmability is linked to dependability and objectivity and is increased by data triangulation (Yin, 2014). Confirmability ensures that the researcher builds on the audit trail using clear and concise journal notes to interpret the study data based on the research findings and not personal biases (Rapport et al., 2015; Zitomer & Goodwin, 2014). Data saturation for this study was reached when there was enough information to replicate the research (described by Saunders et al., 2018) and when the point of no new data had been reached (described by Fusch & Ness, 2015; O'Reilly & Parker, 2013). A main objective of qualitative research is to provide valid and reliable factors that support the study design and reduce researcher bias or false interpretations (Bernard, 2013). The study design ensured data validity

through a controlled, intentional interview process (with informed consent), and by using logical and observable steps to ensure credibility (e.g., member-checking and methodological triangulation) and trustworthiness of study results as explained by Tracy (2013). Bekhet and Zauszniewski (2012) and Denzin (2012) suggest that triangulation be used to review, compare, and contrast multiple data sources to establish credibility of the study data and results. I employed the strategies noted above to ensure the validity of the study research.

Transition and Summary

In Section 2, I provided a detailed review of the research methodology, identified the study population and participants, and defined the role of the researcher. Ethical research practices were discussed, and data collection/organization and analysis techniques were identified. Efforts to ensure the validity and reliability of the research study were also described. In Section 3, I include a complete report and description of the study results and evaluation/analysis of the study data. A summary of study findings is presented and a discussion of the study results, along with study conclusions are presented. Areas for future research were identified at the conclusion of Section 3.

Section 3: Application to Professional Practice and Implications for Change

The purpose of this qualitative multiple case study was to explore strategies to develop partnerships between the CRO and pharmaceutical/biotech companies and risk-sharing collaborations that aim to provide financial and scientific value and benefits. The data were obtained from published current market research, and from interviews conducted with key senior level decision makers in the pharmaceutical, biotech, and CRO industries selected from national and international companies throughout the preclinical pharmaceutical research industry. The research findings provide an understanding of the mutual interactions and risks that are required for improved success between pharmaceutical/biotech companies and CROs to foster business innovations and strategic collaborations that will not only help save lives but also provide for a healthier and improved quality of life.

Presentation of the Findings

The goal of this study was to answer the research question: What strategies do service providers (i.e., s) and pharmaceutical/biotech companies use to develop strategic partnerships during the drug discovery and development process? To gain an in-depth understanding of the business strategies and collaborative processes used in developing and/or sustaining a partnership, I interviewed nine key senior level decision makers in the pharmaceutical, biotech, and CRO industries (i.e., company presidents/vice presidents, CEOs, and directors). These participants were assumed to have adequate experience and breadth of knowledge, based on position/title, necessary to provide in-depth responses to the interview questions.

Yin (2014) described a five-step process for data analysis when conducting a case study: (a) compile data, (b) disassemble the data, (c) reassemble the data, (d) interpret the data, and (e) draw conclusions from the data. This data analysis process resulted in key themes and opinions that informed the research question for this study. By using open-ended interview questions, I was able to group the responses into overarching themes as suggested by Irvine et al. (2013).

Denzin (2012), Patton (2015), and Yin (2014) suggested that researchers reference multiple sources (i.e., data triangulation) to ensure appropriate objectivity. Methodological triangulation was used in this study and involved utilization of data from different sources including the detailed responses from the interview questions and data from current published market research, and/or literature. Through this data analysis, I gained an understanding of specific themes, patterns, and relationships associated with key words from the participant interviews. Using semistructured interview questions, I evaluated outsourcing trends and identified the concepts behind business collaborations and partnerships to explore and evaluate current business strategies that have focused engagement between the CRO and pharmaceutical/biotech to create financially and scientifically mutually beneficial collaborations. I continued the interviewing process until data saturation had been reached and no new data were discovered.

NVivo software was used to transcribe the recorded interviews. I ensured data credibility through member-checking, that is, by having the interview participants check their interview responses (i.e., transcripts). Participants reviewed and provided clarifications and/or confirmation that the synthesis of their transcribed information

accurately and appropriately represented the content and intent of their interview responses. I then used NVivo to code and identify themes from the transcribed interview data.

I used these data to evaluate the relationship between the emerging themes and the conceptual framework as described/suggested by Klag and Langley (2013). I compared and analyzed responses from the interview process, current published market research, and/or literature in order to substantiate the research study, the collected data, conclusions, and outcomes as recommended by Anney (2014) and Heale and Forbes (2013). Descriptive analysis was performed by reviewing emerging concepts in the literature and using Yin's five-step process to analyze how they were linked to the conceptual framework and how they related to competitive advantage and a strategic partnership.

Once the data were coded and patterns and relationships associated with key words from the participant interviews were identified, key categories emerged identifying relationships and themes. Analyzing the data further, I established three overarching themes: (a) defining a strategic/essential partnership, (b) understanding the benefit of building a relationship, and (c) the study director is an essential asset. These themes were used to answer the research question.

Analysis of the coded data resulted in specific words and key phrases that suggested a relationship between emerging concepts and ideas, and how they potentially were linked to the conceptual framework of the study and strategic partnerships. The incidence of key words/phrases that described factors that affect or influence an existing

or potential strategic partnership were tabulated and used to identify key thematic responses from each individual participants' interview and collectively across all participant interviews (see below).

Table 3

Overarching Themes – Participant Interviews

Participant	Theme 1 Defining a strategic/essential partnership	Theme 2 Understanding the benefit of building a relationship	Theme 3 The study director is an essential asset
CRO1	6	4	0
CRO2	1	6	4
CRO3	5	3	1
CRO4	9	1	3
CRO5	8	2	0
PharmBio1	1	4	2
PharmBio2	1	0	6
PharmBio3	3	5	2
PharmBio4	5	1	11
Total Responses[a]	39	26	29
Mean[b]	4.3	2.9	3.2
Total (%)[c]	41.5	27.7	30.8

[a] Incidence specific thematic response was recorded (sum of all individual participant interviews).

[b] Average of the incidence for specific theme response across all participants.

[c] Percentage of specific theme total response across all themes (i.e., sum of total responses, all themes).

Analysis of the participant interviews and the resulting key categories of specific words and phrases identified three overarching themes. For Theme 1, there were 39

responses by the nine participants that included the term *partnership(s)*. This represents an average of 4.3 responses per study participant and a total of 41.5% of all responses by all study participants across all key themes. For Theme 2, there were 26 responses by eight participants that included the term *relationship(s)*. This represents an average of 2.9 responses per study participant (nine total study participants) and a total of 27.7% of all responses by all study participants across all key themes. For Theme 3, there were 29 responses by seven participants that included the terms *study director(s)*. This represents an average of 3.2 responses per study participant (nine total study participants) and a total of 30.8% of all responses by all study participants across all key themes.

Theme 1: Defining a Strategic/Essential Partnership

The move toward strategic partnerships continued to be a sustainable trend with preferred strategic partnerships in place for 82% of respondents in market survey data collected by Credit Suisse representatives (2018). These innovative outsourcing opportunities provide for collaborative partnerships that create potential efficiencies for R&D activities within the drug discovery and development process and improved profitability for the outsourced partner (i.e., CRO).

The word *partnership(s)* was used a total of 39 times across all nine study participants, which represents an average response of 4.3 times per participant for this specific theme and 41.5% of total responses across the three overarching themes (see Table 4). The key word *partnership(s)* was used 269 times across all nine study participants and was most used by participant CRO3 (mentioned 46 times).

Table 4

Incidence of Individual Participant Response to Theme 1 and Key Words

	Theme 1	Key words			
Participant	Defining a strategic/essential partnership	Partnership	Partner	Strategic	Transaction(al)[d]
CRO1	6	8	1	2	1
CRO2	1	1	3	3	0
CRO3	5	26	10	2	4
CRO4	9	12	4	10	0
CRO5	8	16	0	12	4
PharmBio1	1	5	3	5	2
PharmBio2	1	2	7	2	2
PharmBio3	3	5	4	5	8
PharmBio4	5	15	5	5	0
Total responses[a]	39	90	37	46	21
Mean[b]	4.3	10	4.1	5.1	2.3
Total (%)[c]	41.5	NA	NA	NA	NA

Note. NA = Not applicable.

[a] Incidence specific thematic response/key phrase was recorded (sum from all individual participant interviews).

[b] Average of the incidence for specific theme/key phrase response across all participants.

[c] Percentage of specific theme total response across all themes (i.e., sum of total responses, all themes).

[d] Business model/concept between the CRO and a pharmaceutical company/biotech company.

In defining what a partnership is between a pharmaceutical company/biotech company and a CRO, and the role that the CRO has in that partnership during the drug discovery and/or development process, study participants were generally in agreement with a few slight distinctions. Study Participant CRO5 described a strategic partnership as "providing some sort of value above and beyond the transactional relationship that occurs in the industry in general." Additionally, participant CRO5 stated the following:

> From our perspective, a strategic partnership, and we don't typically use this terminology, preferred partners, strategic partnership, really what it is, is that it's just a relationship, just developed [*sic*] a relationship to the point to where when you end up with a hurdle, be it price, regulatory, timing, et cetera, that you can work together with that individual to focus on the solution and not the problem. It's really purely a relationship.

Study Participant PharmBio3 explained a strategic partnership by stating the following:

> I think large companies are looking for any way that they can leverage that, whether it's continuing to be transactional or whether it's trying to build more strategic partnerships, outsourcing operations, it's generally financially good for a pharma company. Most of the time, CROs can do things cheaper, quicker, better than pharma companies can internally, because that's what CROs do. It's in their wheelhouse. I mean, that's the core competency, whereas pharma companies do a lot of other stuff.

Study Participant PharmBio4 described a strategic partnership in terms of capacity constraints and indicated, "And so that's a piece of the equation for the strategic

partnership, is to take advantage of the facilities that are built [i.e., existing CROs] to take on big studies with lots of animals."

The phrase *strategic partnership* was used a total of 19 times by seven of the nine study participants. Fourteen of the 19 references (73.7%) were made by three participants representing the CRO industry and the remaining five references (26.3%) were made by the four participants representing the pharmaceutical/biotech industry. This suggests that the CRO participants overwhelmingly consider the concept of partnerships to be strategic. The word *transaction* or *transactional* was used a total of 21 times by six of the nine study participants to describe a business process/collaboration between the CRO and a pharmaceutical company/biotech company. Nine of the 21 references (42.9%) were made by three participants representing the CRO industry and the remaining 12 references (57.1%) were made by three participants representing the pharmaceutical/biotech industry. Only one CRO participant and one pharmaceutical/biotech participant (two of nine total participants) described a *partnership* as generally transactional in nature. Similarly, one CRO participant and one pharmaceutical/biotech participant (two of nine total participants) considered a partnership as not transactional. The remaining two participants, one CRO participant and one pharmaceutical/biotech participant, described a partnership as likely transactional early in process, but evolving beyond transactional with time. Study Participant CRO3 explained the following:

> Ideally, in a partnership, we should evolve. We should evolve into a relationship that goes beyond simply just transactional. However, I do think that a lot of

> innovators still treat that partnership as a simple transaction, and I don't know that that partnership is still depending on the client. I think different sponsors are more or less comfortable in their control and oversight over that product or project. I think there are different levels of, basically, trust that exists in that paradigm. But in what I would say is certainly a more elegant, a more sophisticated measure of partnership, one that if you kind of, and we've all seen scenarios that are most slow, show slopes of that evolution of a partnering relationship [*sic*]. I think a true partnership is where you are part of each other's team. A CRO would simply be an extension of that sponsor's team. They would be treated with respect. They would be treated with accountability. They would be expected to not only do a job, but to help innovate, to help create value. Not simply a pair of hands, but really helping to contribute intellectual property that helps not only the CRO be successful, but certainly helps the sponsor to be successful.

Study Participant PharmBio1 further explained, "The sponsor [i.e., pharmaceutical/biotech client] doesn't just treat it as buying a product, right? It's actually, it's not transactional, it's a relationship. So that to me is the overall theme of all this stuff. And that's what I look for."

The general sentiment that a partnership, or perceived partnership, is an evolution from a typical transactional process to an established relationship with the client, supports a similar evolution from a market-based view of competitive strategy to a resource-based view of comparative advantage. Comparative advantage expands on an organization's tangible resources to include intangible competencies such as organizational culture,

brand equity, knowledge (e.g., consumer and competitive intelligence), human capital (e.g., skills and knowledge of individual employees), and relationships (e.g., with suppliers and customers) that enable the achievement of superior financial performance (Hunt & Morgan, 1995). The evolution of a partnership into the intangible competency of a client relationship may likely define future business strategy for the industry. It is this resource (i.e., the partnering client relationship) that has the potential of becoming a comparative advantage for an organization resulting in a resource-produced superior value relative to what the competition can offer. Rahman et al. (2019) described an intangible resource as one that allows an organization to attain and sustain competitive advantage. The evolved client relationship becomes a valuable and inimitable resource that is used to gain an edge over competition.

Theme 2: Understanding the Benefit of Building a Relationship

The suggested evolution of a partnership to a more focused relationship is a trend that has occurred or is occurring in the industry. Miller (2013) explained that strategic relationships were part of rethinking of the traditional R&D paradigm at global pharmaceutical/biotech companies and this forward strategic thinking focused on the CRO assuming more responsibility. Typically, the CRO has been a service provider delivering single or multiple tasks on a per-project basis (PAREXEL, 2013). Getz (2014) described that this relationship has evolved to one of a strategic partnership where the CRO provides single or multifunctional support for entire programs reaching various portions of a pharmaceutical/biotech company portfolio.

The word *relationship(s)* was used a total of 26 times in the context of an overarching theme across eight study participants, which represents an average response of 2.9 times per total participants for this specific theme and 27.7% of total responses across the 3 overarching themes (see Table 5). The specific key word relationship(s) was used 94 times across all nine study participants and was most used by participants CRO3 and PharmBio1 (mentioned 15 times each). Fifty-seven of the 94 references (60.6%) were made by the five participants representing the CRO industry and the remaining 37 references (39.4%) were made by the four participants representing the pharmaceutical/biotech industry.

Table 5

Incidence of Individual Participant Response to Theme 2 and Key Words

	Theme 2	Key words		
Participant	Understanding the benefit of building a relationship	Relationship(s)	Risk	Trust
CRO1	4	11	7	1
CRO2	6	14	6	1
CRO3	3	15	20	4
CRO4	1	4	9	6
CRO5	2	13	5	0
PharmBio1	4	15	16	6
PharmBio2	0	6	7	7
PharmBio3	5	13	3	0
PharmBio4	1	3	7	4
Total responses[a]	26	94	80	29
Mean[b]	2.9	10.4	8.9	3.2
Total (%)[c]	27.7	NA	NA	NA

Note. NA = Not applicable.

[a] Incidence specific thematic response/key phrase was recorded (sum from all individual participant interviews).

[b] Average of the incidence for specific theme/key phrase response across all participants.

[c] Percentage of specific theme total response across all themes (i.e., sum of total responses, all themes).

In describing a *relationship* between a pharmaceutical company/biotech company and a CRO, and the role that the CRO has in that relationship during the drug discovery and/or development process, most study participants used the terms *partnership* and *relationship* interchangeably. Upon further inquiry, specific participant responses were noted that support the evolution to the *relationship* paradigm. Study Participant CRO2 indicated the following:

> I've really never been part of what I would say was a true partnership. Every CRO uses that word and even clients will sometimes use words like "we're looking for a partner." You're looking for a provider that you will have a good relationship with. I think this is somewhat different than being a partner.

Participant CRO2 also stated, "I think the term [partnership] is overplayed by both industry and pharma and CRO. It's a close, very close working relationship…" Study Participant CRO3 previously described the evolution of the partnership to a relationship and added the following:

> Ultimately, that relationship is founded in the shared vision and mission of really having a benefit on all of our mutual customer [*sic*], which is the patient who desperately, desperately deserves for a world class partnership. Because I think that the better we can truly partner, we will deliver a higher quality product to the patient and we will deliver it faster. And that will take time off of an already long drug development cycle, which saves lives.

Many of the participant responses that described a relationship alluded to *trust* or *establishing trust*. The word *trust* was used 29 times by seven of the nine study

participants. Twelve of the 29 references (41.4%) were made by four participants representing the CRO industry and the remaining 17 references (58.6%) were made by three participants representing the pharmaceutical/biotech industry. Study Participant CRO4 indicated the following:

> I think that is first and foremost, most important when people are talking about being strategic partners. Because I do think to the point of partnerships, we're talking about it being a give and take, and you have to trust that your partner is giving and taking as much as you are and doing absolutely what's best in the name of accuracy and speed to drug development.

When asked what differentiates the preclinical CROs that they are doing business with (i.e., strategic partnerships/relationships), participant PharmBio1 stated the following:

> I think the differences lie in the trust and the personal relationships that are built. Honestly. I think most CROs are highly capable of doing the work. They all can do it. Many have been around for a long time and some have, of course, acquired others that have been around a long time. And so the subject matter experts, the experienced study directors and study teams are there at all times. So they can all do that. It's the communication, the support that you get.

Study Participant PharmBio1 further summarized/reflected on the interview by saying the following:

> I think the overall theme for me is to have and build a relationship with the study team and the SME [subject matter expert] at a CRO. Providing that comfort and trust that I know the study is getting executed. I like to say things are going to

> happen…Something's going to happen [*sic*]. But you trust that the study team is experienced. They know how to respond to it. They communicate all those sorts of things.

When asked to describe a strategic partnership with a CRO, Study Participant CRO3 explained the relationship as follows:

> The heart of the question is that, partnership means, if you asked one hundred different sponsors or even one hundred different innovators, that might mean something different to each of them, because it's a personal question. So in my mind, a partnership should be more than just a transactional relationship. And the optics of, "oh, you're important to us" and it's kind of fake and somewhat superficial [*sic*]. So in my ideology, my theology, a partnership is at the most simple level, it's where I think there is a higher level of intimacy. There's a higher level of trust, a higher level of just vulnerability where we're more willing to share, to act, all the action words that my brain is thinking of. And also the sponsor is as well. I mean, we're just more forthcoming. We're more vulnerable.

This concept of a built upon and evolved relationship with a seeded establishment of trust between the CRO and the pharmaceutical/biotech client further supports a resource-based view of the organization that focuses on the internal environment as a driver for competitive advantage. Porter (1991) argued that the origins of competitive advantage are valuable, often intangible resources (i.e., competencies) that an organization has such as skills and reputation. As previously defined, the comparative advantage theory expands on an organization's tangible resources to include intangible

competencies such as organizational culture, brand equity, knowledge (e.g., consumer and competitive intelligence), human capital (e.g., skills and knowledge of individual employees), and *relationships* (e.g., with suppliers and customers) that enable the achievement of superior financial performance (Hunt & Morgan, 1995). By understanding the benefit of building a client relationship, an organization can focus on the intangible resources necessary to create a lasting competitive advantage. Rahman et al. (2019) described this type of resource as valuable and nonsubstitutable.

An established relationship built on trust still presented a level of risk associated with aspects of a project outside the direct control of the pharmaceutical/biotech company (e.g., regulatory requirements). The relationship also allowed for a level of internal risk mitigation for these regulatory concerns through the outsourcing process. The word *risk* was used a total of 80 times by all nine study participants. Forty-seven of the 80 references (58.8%) were made by the five participants representing the CRO industry and the remaining 33 references (41.2%) were made by the four participants representing the pharmaceutical/biotech industry. Study Participant PharmBio2 stated the following:

> From my perspective as a sponsor [i.e., pharmaceutical/biotech company] and having worked at a CRO, I think that the sponsor in the current environment has one hundred percent of the risk in that relationship [partnership] and because of that, the individual study director and the relationships that I have with that person are paramount and my trust of that person and the level of expertise.

Describing risk and risk mitigation, Study Participant CRO3 indicated the following:

> Pharmaceutical companies have elected to outsource some aspects of their work to partners, contract research organizations…the reasons for that desire to outsource could vary based on capacity. It could vary based on speed, on value. It could even be a motivation based on minimizing the pharmaceutical companies' internal risk and kind of putting that a little bet on the shoulders of a partner.

Study Participant CRO3 further explained:

> Small mid-tier biotechs, most of these facilities, many don't even have a lab. So partnering with a contract organization isn't an option. It's a requirement. But even organizations that do [have an on-site lab], they may elect to outsource work based on, again, on the capacity of their resources internally, their expertise within that area. And many cases, though, I think what has driven a lot of outsourcing is the fact that, frankly, suppliers can often do that, work more cost effectively and in many instances more expeditiously than many of the sponsors can do themselves…But then I also commented on risk. And some of this is just regulatory risk, you know, particularly in a highly regulated, non-clinical environment, I think outsourcing work to a supplier like, you know, a large contract research organization or any size organization is also a way of potentially mitigating some internal business risk.

This intangible competency, that being the relationship with the skills and knowledge of the study director (i.e., human capital), may be key for achieving competitive advantage and effective value-creation.

Theme 3: The Study Director is an Essential Asset

Strategic partnerships between a CRO and its client(s) are often the result of customer loyalty and service quality. Lin and Darnall (2015) suggested that a company's decision to form a strategic alliance or partnership was influenced by resource-based and institutional factors. Focus on the capabilities and the heterogeneous resources that organizations use has become more important than solely based on products and market positioning as the primary source of competitive advantage (Rumelt, 1991; Wang, 2014). The RBV is a concept that identifies an organization's resources and inherent competencies as determinants of its success (Otola et al., 2013). Barney (1991) indicated that resources that determine competitive advantage should be valuable, inimitable, rare, and non-substitutable. Rahman et al. (2019) explained that these resources can be divided into two performance categories: resources that allow organizations to attain competitive advantage and others which enable organizations to sustain competitive advantage. In evaluating the data collected from the participant interviews conducted for this study, an interesting and unexpected theme emerged from the participant responses; that of the role and significance of the study director. The study director resource can function to attain competitive advantage by providing valuable and rare attributes for an organization. The study director can also provide inimitable and nonsubstitutable attributes that help an organization sustain competitive advantage. Rahman et al. (2019) classified these resource attributes into two categories: *ex ante limits to competition* (i.e., valuable and rare attributes) and *ex post limits to competition* (i.e., inimitable and nonsubstitutable attributes).

The study director role is defined by the Code of Federal Regulations Title 21, Volume 1, Part 58, Subpart B, section 58.33 (2020) which states the following:

> For each nonclinical laboratory study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of control.

Although the legal significance is well understood in the industry, the intangible value of this human capital competency and the relationships developed by and with the study director may not be completely appreciated in terms of a comparative business advantage and competitive value.

The phrase *study director* was used 29 times in the context of an overarching theme across seven of the nine study participants, which represents an average response of 3.2 times per participant for this specific theme and 30.8% of total responses across the three overarching themes (see Table 3). Eight of the 29 references (27.6%) were made by three participants representing the CRO industry and the remaining 21 references (72.4%) were made by the four participants representing the pharmaceutical/biotech industry. This suggests that the pharmaceutical/biotech participants overwhelmingly considered the role of the study director to be noteworthy in their responses. Descriptive words such as experienced, good, individual, quality, and specific were used to qualify the role. Additionally, the study director was discussed in terms of the relationship and trust factor described in the previous section. Study Participant PharmBio1 indicated the following:

> I mean, personally, what I'd like to see, where I see the value is, and the bonus for me is if possible, I have the same study team or reasonably consistent study team across all the studies. I have the same study director, the same pathologist potentially working on the slides. So people have seen this and are familiar with the program. They're familiar with me, with my company, et cetera. And I think that increases the trust in the relationship. So I think there's the benefit there.

When asked what differentiates the preclinical CROs that they are doing business with (i.e., strategic partnerships/relationships), participant PharmBio1 previously stated the following:

> I think the differences lie in the trust and the personal relationships that are built. Honestly. I think most CROs are highly capable of doing the work. They all can do it. Many have been around for a long time and some have, of course, acquired others that have been around a long time. And so the subject matter experts, the experienced study directors and study teams are there at all times. So they can all do that. It's the communication, the support that you get.

When describing capacity constraints and strategy in terms of deciding what work is outsourced to a CRO, Study Participant PharmBio2 explained the following:

> Our strategy right now is all of our GLP work is outsourced 100% because we don't have a GLP laboratory. So that's the first decision that we make point wise. The next piece is the specific capability at a specific CRO. And on top of that, the relationships or the experience we have with the specific study directors that are going to be running our studies.

Participant PharmBio2 continued:

> The relationships with individual scientists [i.e., study directors], in my view, is the most important and that kind of gets into trust. And my bedrock principle for working with CROs is communication. So communication is the number one reason why I'll stop using a provider.

When asked to describe the strategy used in deciding what work is outsourced to a CRO, participant PharmBio4 stated the following:

> I think we go to places that have certain expertise. And part of that is it's learned over the years … that these partnerships develop … It's experience with both the client liaisons and importantly the study directors. And so I think there's a comfort level that you get with people who over time learn, the specific way of writing things and what ends up happening is as that partnership develops, it costs us less time when we are reviewing reports, because we're talking the same language.

Applications to Professional Practice

In this study, I explored the experiences of key decision makers at pharmaceutical/biotech companies and CROs to describe and understand the collaborative approach to science and business that has fostered the strategic partnership paradigm. The specific business problem researched for this study was that some leaders of CRO and pharmaceutical/biotech companies lack strategies to develop strategic partnerships in the drug discovery and development process. The results and findings of this study are applicable to division leaders, client services personnel, procurement groups, program managers, and study directors that directly or indirectly make business

decisions that can impact a collaborative relationship between the service provider (CRO) and the client (pharmaceutical/biotech companies).

Although some outsourced work by a pharmaceutical/biotech company to a CRO may be in its simplest form transactional, the evolution of a partnership into the intangible competency of a client relationship should be the business strategy for any company aiming to achieve effective value creation and competitive advantage. The comparative advantage theory expands on an organization's tangible resources to include intangible competencies such as organizational culture, brand equity, knowledge, human capital (e.g., skills and knowledge of individual employees/teams), and relationships (e.g., with study teams and study directors) that enable the achievement of superior financial performance. This study highlighted an organization's intangible resources and inherent competencies as determinants of success. The human capital factor and focus on relationships enable an organization to produce greater perceived benefits for similar costs. These perceived benefits are defined by how well a partnership evolves into an established relationship with a client. The relationship can be further strengthened by the trust established between the study director (CRO) and the pharmaceutical/biotech company. As suggested by participant CRO3, "A partnership is at the most simple level, it's where I think there is a higher level of intimacy. There's a higher level of trust, a higher level of just vulnerability."

Implications for Social Change

The pharmaceutical drug discovery and development process is a daunting process that can usually take 10 to 15 years and cost billions of dollars. To identify one

effective and safe drug, millions of potential compounds and molecules are screened and for every 5,000 to 10,000 potential drugs evaluated, ultimately only one will receive approval from the FDA. To reduce the cost and time of drug development, most pharmaceutical/biotech companies strategically outsource much of their discovery and preclinical work/projects. By strategically outsourcing these activities, companies can depend on the expertise of the outsourcing partner (i.e., CRO), thereby reducing costs associated with having to introduce innovation.

The results of this study suggest that focused attention on the client relationship as an evolution to the strategic partnership and a better understanding of how a client perceives trust and associated risk, can improve efficiency and therefore also reduce costs. These focused working relationships have the potential to help bring pharmaceutical drugs to market faster, cheaper, and with improved efficacy because of a clear understanding of expectations and the role each organization plays in the drug approval process, the assumed risk each organization assumes in the relationship, and the continued innovative approach to business and scientific collaboration. As stated by participant CRO3:

> Ultimately, that relationship is founded in the shared vision and mission of really having a benefit on all of our mutual customer, which is the patient who desperately, desperately deserves for a world class partnership. Because I think that the better we can truly partner, we will deliver a higher quality product to the patient and we will deliver it faster. And that will take time off of an already long drug development cycle, which saves lives.

By focusing on establishing lasting relationships, the CRO and pharmaceutical/biotech industries have the potential to shorten drug development timelines, further improving quality of life by providing a higher quality product to the patient, and ultimately saving lives.

Recommendations for Action

The key senior level decision-makers who participated in this study provided suggestions and insight on the strategies that CRO and pharmaceutical/biotech company leaders use to develop strategic relationships during the drug discovery and development process. Answers to the interview questions provided the basis for three overarching themes and opinions presenting business strategies focused on engagement between the CRO and pharmaceutical/biotech companies to create financially and scientifically mutually beneficial collaborations. The recommendations associated with the 3 overarching themes of (a) defining a strategic/essential partnership, (b) understanding the benefit of building a relationship, and (c) the study director is an essential asset, are listed below in Table 6.

Table 6

Recommendations for Action

Theme	Recommendations
Defining a strategic/essential partnership	• Evolve to more focused relationships beyond the 'transaction' • Establish key contacts • Maintain innovation • Treat each other with respect but with accountability
Understanding the benefit of building a relationship	• Establish trust • Maintain constant/consistent communication • Focus relationship on the SME/study director • Create a higher level of business intimacy • Understand inherent risk(s); perceived, individual, shared
The study director is an essential asset	• Encourage substantive business relationships with the client • Establish trust • Maintain constant/consistent communication

These recommendations for action will be made available to business professionals within the pharmaceutical/biotech industries through online platforms, industry publications, and/or market research literature. Additionally, these recommendations will be made available to the study participants and/or specific companies represented by the study participants.

Recommendations for Further Research

This qualitative multiple-case study included nine participants who were key senior level decision-makers in the pharmaceutical, biotech, and CRO industries (e.g., company presidents/vice presidents, CEO, and directors). Although I maintain that the multiple-case study research method was appropriate to draw conclusions from the lived

experiences of the study participants and the number of participants was adequate to represent the various industry sectors across a global representation of organizations sufficient to reach data saturation, there are aspects of the study that could benefit from further research and potentially more participants. The concept of trust in a business relationship can be further investigated to establish the expectations for building that trust. A longer duration evaluation of established business relationships can be conducted to determine actual time saved and reduced costs associated with the drug approval process. Additional research can be conducted to investigate the role of a pandemic on the partnership/relationship paradigm. Specifically, how the COVID-19 pandemic impacted CRO relationships with pharmaceutical/biotech companies racing to develop vaccines and treatments during 2020 and 2021 can be explored, and how/if relationships were made stronger/weaker by the expedited timing requirements can be investigated.

Reflections

The process of conducting this qualitative research study was informative and provided insight to a question I had early in my career. While my career and experience lend themselves to a very analytical and quantitative paradigm, the qualitative approach to case study research was an intensive and often challenging learning process. The substantial information that emerged from the semistructured interviews provided an interesting and comprehensive data set for answering the research question.

Although I attempted to mitigate bias by contacting participants that I did not know personally or had previously worked with, it was very difficult to secure study participation. As a result, many of the study participants were colleagues that I knew and

had worked with previously in my career. Realizing I may have bias with these specific study participants, I adhered to preset guidelines and the interview protocol to ensure any biases and assumptions, real or perceived, were limited as suggested by Yin (2014). However, my previous relationships with some of the participants resulted in familiar conversation during the interviews. Nonetheless, I was able to manage the interactions so as not to influence the participants' answers.

Conclusion

An organization's intangible resources and inherent competencies are determinants of success. The evolution of a partnership into the intangible competency of a client relationship may likely define future business strategy for the industry. Understanding and improving existing company processes and evaluating strategic business relationships implemented between the pharmaceutical/biotech companies and CROs can result in business opportunities that are mutually beneficial. By understanding the importance of general business relationships, the intangible value of human capital competency, the relationships developed with clients by that human capital, and the significance that trust plays in how relationships are maintained and/or improved, business leaders can implement strategies that provide comparative business advantage and competitive value throughout the drug discovery and development process.

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Appendix A: Interview Protocol

Interview: Key nonclinical pharmaceutical industry decision makers' insight describing the attitudes and experiences they have toward strategic business collaborations with each other, what risk responsibilities service providers (i.e., Contract Research Organizations) assume in a scientific/business strategic partnership, and how those collaborations have influenced the pharmaceutical research industry

Protocol:

A. The study and a general overview will be provided via a formal email and/or telephone conversation.

B. The subsequent formal telephone or Skype interviews will begin with introductions followed by an overview of the study.

C. Appreciation will be conveyed to each participant for agreeing to contribute in the study, and each participant will be assured of the confidentiality of our conversations.

D. Each participant will be assigned an identifying code to protect his or her anonymity and this identifying code will be defined at the beginning of each interview and subsequent audio-recording.

E. The participants will be instructed as to the following:

1. Each participant will be asked to provide responses to 10 open-ended interview questions (the interview should last approximately 30 to 45-minutes).
2. Each participant will be informed that they will be digitally (audio) recorded during the interview to ensure accuracy of data and their responses.

3. Each participant will be asked to share their lived experiences and/or perceptions regarding strategic business collaborations, what risk responsibilities service providers assume in a scientific/business strategic partnership, and how those collaborations have influenced the pharmaceutical research industry.

F. Member-checking will be explained to each participant and a follow-up member-checking interview will be scheduled to review data findings to ensure accuracy of the data and to ensure that it is a correct representation of the participants' perceptions.

G. Following the study conclusion, each participant will be provided a synopsis of the study findings.

Appendix B: Interview Questions

Appendix B lists the open-ended interview questions used to understand what risk responsibilities service providers (i.e., Contract Research Organizations) assume in a scientific/business strategic partnership with a pharmaceutical/biotech company client. The following are the interview questions:

1. What do you think the role of a CRO is in a strategic partnership during drug discovery and development?
2. What is your strategy in terms of deciding what work (i.e., projects, programs, etc.) is outsourced to a CRO?
3. How would you describe a strategic partnership with a CRO during the drug development process?
4. Describe the most important factors that influence your selection of a strategic partner (ranked from most important to least important).
5. What do you think currently differentiates the preclinical CRO(s) that you have strategic partnership(s) with and were similar strategies used to develop that/those relationship(s)?
6. As strategic partnerships evolve, what are your concerns considering your current partnerships/relationships and the expectations you have now and in the future?
7. How do you measure the financial success of your outsourcing (strategic partnership, if applicable) project(s)?
8. How do you assess and manage outsourcing (strategic partnership) risks?

9. Describe the risk-sharing responsibilities/assumptions you currently have with your outsourcing partner.
10. What else can you add regarding strategies service providers (i.e., Contract Research Organizations) and pharmaceutical/biotech companies use to develop strategic partnerships during the drug discovery and development process?