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Stakeholder Engagement, Dynamic Capabilities and Innovativeness: A Study on Contract Research Organization (CRO) Collaborated Projects in Pharmaceutical R&D

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Doctor of Management

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Florida International University

May, 2024



BUSINESS  
SCHOOL

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Marketing, Operations and General Management Department

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Projects in Pharmaceutical R&D**

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## Abstract

The pharmaceutical industry faces problems such as declining R&D productivity, escalating costs, and shorter patent periods, so there are many collaborations between pharmaceutical companies and Contract Research Organization (CRO) for new drug development to reduce costs, improve efficiency, and obtain knowledge sources. However, some literature also points out the challenges and difficulties encountered in pharmaceutical companies and CROs collaborated project. The research problem is the dilemma between the benefits and problems brought by stakeholder engagement in the process of open innovation. Focusing on the project team members of CRO and pharmaceutical company clients who participated in R&D collaborated projects as samples, empirical research was conducted, relevant hypotheses were proposed, and the research model was established to explore the relationship and impact of CRO engagement, pharmaceutical client engagement, operational (routine) capabilities, dynamic capabilities, innovativeness, project performance outcome and relational performance. A regression analysis and structural equation modeling empirically demonstrated that CRO engagement and pharmaceutical client engagement significantly and positively affected operational (routine) capabilities and dynamic capabilities, and through these two mediating variables effect significantly and positively affected innovativeness, project performance outcome and relational performance. Among them, operational (routine) capabilities and dynamic capabilities partially mediated CRO engagement and innovativeness, project performance outcome and relational performance, and were complementary mediating effects. While operational (routine) capabilities and dynamic capabilities fully mediated pharmaceutical client engagement and innovativeness, project performance outcome and relational performance. This study fills some of the gaps identified in literature, enriches the existing stakeholder engagement, capabilities, innovativeness, and collaborated project management research area, and provides a theoretical basis and a new practical tool to guide the management of collaborated innovation projects in the future.

**Keywords:** Stakeholder Engagement; Operational (Routine) Capabilities; Dynamic Capabilities; Innovativeness; Project Performance; Relational Performance

**JEL:** O32; L14

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## Resumo

A indústria farmacêutica enfrenta problemas como diminuição da produtividade em investigação e desenvolvimento (I&D), aumento de custos, pressão nos preços e períodos de patente mais curtos. Por conseguinte, a colaboração entre empresas farmacêuticas e Organizações de Investigação Contratada (OICs) no desenvolvimento de novos medicamentos tem sido intensa nos últimos anos, visando reduzir custos, melhorar a eficiência e obter fontes de conhecimento global. No entanto, a literatura também aponta os desafios e as dificuldades encontrados na inovação colaborativa entre empresas farmacêuticas e OICs. O problema de investigação deste estudo é o dilema entre os benefícios e os problemas trazidos pelo envolvimento dos *stakeholders* no processo de inovação aberta. Focando nos membros da equipa de projeto de OIC e nos clientes de empresas farmacêuticas que participaram em projetos de desenvolvimento de recursos colaborativos, foi realizada uma investigação empírica, propostas hipóteses relevantes e estabelecido um modelo de investigação para explorar a relação e o impacto do envolvimento da OIC, o envolvimento do cliente farmacêutico, as capacidades operacionais (rotina), as capacidades dinâmicas e os resultados do projeto - inovação, desempenho do projeto e desempenho relacional. A análise de regressão e a modelagem de equações estruturais (SEM) demonstraram empiricamente que o envolvimento da OIC e do cliente farmacêutico afetam significativa e positivamente as capacidades operacionais (rotina) e as capacidades dinâmicas. Por meio dessas duas variáveis mediadoras, há uma afetação significativa e positiva na inovação, no desempenho do projeto e no desempenho relacional. As capacidades operacionais (rotina) e as capacidades dinâmicas medeiam parcialmente o envolvimento da OIC e a inovação, o desempenho do projeto e o desempenho relacional têm efeitos de mediação complementares. As capacidades operacionais (rotina) e as capacidades dinâmicas medeiam completamente o envolvimento do cliente farmacêutico e a inovação, o desempenho do projeto e o desempenho relacional. Este estudo preenche lacunas na literatura, enriquece a área de investigação existente no envolvimento de *stakeholders*, capacidades, inovação e gestão de projetos colaborativos, e fornece uma base teórica e uma nova ferramenta prática para orientar a gestão de projetos de inovação colaborativa no futuro.



**Palavras-chave:** Envolvimento de Stakeholders; Capacidades Operacionais (Rotineiras); Capacidades Dinâmicas; Inovação; Desempenho do Projeto; Desempenho Relacional

**JEL:** O32; L14

## 摘 要

制药行业面临着研发生产率下降、商业化成本上升和专利期限缩短的问题，因此在新药研发领域制药公司与CRO进行合作近年来十分旺盛，旨在降低成本、提高效率、获得全球知识来源，但一些文献也提到制药公司与CRO合作创新中遇到的挑战和困难。本研究的研究问题就是开放性创新过程中利益相关者参与所带来的好处与问题之间的矛盾和困境，以服务提供商CRO与制药公司客户其参与研发合作项目的项目团队成员，作为样本进行实证研究，提出相关假设，建立研究模型，探究了CRO参与度、制药公司参与度、动态能力、运营（常规）能力和创新性、项目绩效结果和关系性结果之间的关系和影响，采用回归分析和结构方程模型（SEM）进行数据分析，实证了CRO参与度和制药公司参与度正向显著影响运营（常规）能力和动态能力，并通过这两个中介显著正向影响创新性、项目绩效结果和关系性结果。运营（常规）能力和动态能力部分中介CRO参与度与创新性、项目绩效结果和关系性结果，并且是互补型中介效应。运营（常规）能力和动态能力完全中介制药公司参与度与创新性、项目绩效结果和关系性结果。本研究弥补了文献的不足，丰富了现有的利益相关者参与度、组织能力、合作创新项目管理领域的管理研究，为医药研发领域的合作创新项目的管理提供了理论基础和实践工具指引。

**关键词：**利益相关者参与；运营（常规）能力；动态能力；创新性；项目绩效结果；关系性结果

**JEL:** O32; L14

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## **Chapter 1: Introduction**

### **1.1 Research background**

#### **1.1.1 Industry overview of Contract Research Organization (CRO) in pharmaceutical Research and Development (R&D) filed**

##### **1.1.1.1 Concept and emergence of CRO in pharmaceutical R&D filed**

Contract Research Organization (CRO) is a unique academic or commercial scientific institution in the life Sciences that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. CRO provides services as biopharmaceutical development, biologic assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and Real-world evidence (Lucas, 2021). CRO generally provides highly specialized services of new drug R&D to customers such as pharmaceutical companies or biotechnology companies in the form of commission contract. Such services involve various stages and areas of new drug R&D such as drug discovery and screening, pre-clinical research, drug safety evaluation, Phase I-IV clinical trials, trial design, selection of investigators and trial units, monitoring, inspection, data management and analysis, and drug registration application. CRO represents an emerging high-tech industry derived from the field of biotechnology and pharmaceuticals. The International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) defined a contract research organization (CRO), specifically pertaining to clinical trials services as a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions (ICH, 2016).

The early prototype of CRO emerged in the United States in the late 1970s. It was a consulting organization engaging in data processing and statistical analysis, with the aim of providing limited services to the pharmaceutical industry. The concept of CRO evolved in 1982, when biostatisticians from the University of North Carolina in the United States established Quintiles to provide paid consulting service and data support for clinical trials. In the 1980s, as both the National Cancer Institute and pharmaceutical giants were exploring ways to address the rising R&D costs and increasingly detailed requirements for new drug applications to be



submitted to regulatory agencies, CRO was envisioned as a way to outsource pharmaceutical R&D. CRO outsourcing provides pharmaceutical companies with the “spillover capacity” for data management and biostatistical analysis during the peak season when their own staff do not have sufficient capacity and resources to perform all necessary tasks (Roberts et al., 2016).

#### **1.1.1.2 History and business scope of CRO in pharmaceutical R&D field**

The CRO in pharmaceutical R&D was gradually improved in the late 1980s along with the increasing regulations, and developed rapidly in the United States, Europe, and Japan, providing professional services for pharmaceutical companies and R&D institutions through contract outsourcing in the drug R&D process.

In recent years, with the increasing R&D investment, longer R&D cycles and lower R&D success rates in pharmaceutical companies across the globe, CROs, as a product of the specialized social division of labor, have gradually expanded their business scope owing to such features as low cost, high efficiency, and diverse services. Currently CROs engage in a variety of technical services such as new drug R&D, pre-clinical and clinical trials, data management, new drug registration and application, covering the entire process of drug R&D, and have become an indispensable link in the industry chain of pharmaceutical R&D (Sun, 2016).

The heightened demands facing drug developers in managing clinical data, adhering to regulatory standards, and ensuring stringent safety measures are anticipated to fuel the demand for contract research organizations (CROs) in the healthcare sector. Pharmaceutical firms are extending their outsourcing beyond drug manufacturing to include the conduct of clinical trials (Grandviewresearch, 2024).

CROs offer a wide range of pre-clinical and clinical services vital for drug development, including drug screening, compound synthesis, toxicology, and human trials management to ensure regulatory compliance. In an industry where intellectual property is highly valued, the landscape is shifting due to mergers, acquisitions, and the rise of generic drugs, blurring traditional boundaries between companies and their brands. Pharmaceutical industry managers are recognizing the potential for accelerated R&D progress through collaboration with competitors via joint ventures. This collaborative approach enables faster transformation of R&D investments into marketable products. To build trust with corporate partners and regulators, unbiased data generated by independent third-party entities, such as CROs, is crucial.

As a result, CROs are experiencing increased demand and are deeply embedded in every stage of pharmaceutical R&D, from initial concept to eventual commercialization (Shih, 2015).

### **1.1.1.3 Development status of CRO in pharmaceutical R&D field**

The pharmaceutical industry is characterized by high technology, high entry barrier and intense competition. The R&D and production of new drugs is the core element for pharmaceutical companies to maintain their commercial vitality and competitiveness. The main business of CROs is to provide R&D and R&D-related supporting services for their main customers, i.e. pharmaceutical companies.

The international pharmaceutical CRO business has gradually entered a mature stage after long-term development. The global healthcare contract research organization market size was valued at USD 50.55 billion in 2023 and is anticipated to expand at a compound annual growth rate (CAGR) of 7% from 2024 to 2030 (Grandviewresearch, 2024). And it is expected that the compound annual growth rate (CAGR) will still reach 7% by 2026 (Grandviewresearch, 2024). North America is still the largest CRO market in the world and continues to grow steadily (Yang, 2021).

The pharmaceutical R&D outsourcing market, particularly in the Asia-Pacific region, is experiencing rapid expansion, surpassing growth rates observed in other parts of the world. Escalating R&D expenses, coupled with the aftermath of financial crises, have prompted multinational pharmaceutical firms to seek cost-effective solutions, leading to a surge in outsourcing clinical trials to countries like India and China. China has emerged as the preferred destination for pharmaceutical R&D outsourcing in Asia, surpassing India. With its competitive advantages, China is increasingly becoming the top choice for companies seeking to outsource drug research activities, moving beyond its early stages of niche outsourcing to offer a wide array of services at a substantial scale, which has played a pivotal role in driving innovation output within China's pharmaceutical industry (Xia & Gautam, 2015).

### **1.1.2 CRO and Pharmaceutical company collaborated open innovation in pharmaceutical Research and Development (R&D) field**

Since the 2003 publication of Chesbrough's seminal work, *Open Innovation: The New Imperative for Creating and Profiting from Technology*, the concept of open innovation (OI) has garnered increasing attention from academics and practitioners alike (Bigliardi et al., 2020).

The pharmaceutical sector is grappling with declining productivity in research and development (R&D), escalating expenses associated with commercialization, legal challenges, competitive pricing pressures, and shorter periods of exclusivity patent (Hughes & Wareham, 2010). Due to these challenges, there is a growing trend towards fostering collaborations with

external partners in the pharmaceutical industry (Kazadi et al., 2016). Limited attention has been given to researching "Open Innovation in the pharmaceutical industry" compared to other research areas. This is primarily due to the historically high levels of R&D investments in the industry and the critical role of the discovery process in fostering innovation, which have been of particular interest to scholars in innovation management. Interest in this sector grew with the adoption of Open Innovation, as the industry shifted from product to service orientation. Consequently, many pharmaceutical companies began collaborating with academia to discover new drug candidates while maintaining innovation and market competitiveness (Bigliardi & Galati, 2016). In response to the growing challenges and costs associated with discovering new medicines, the pharmaceutical industry turned to Open Innovation as a means to tap into external ideas and expertise, acknowledging its potential for driving innovation forward (Schuhmacher et al., 2013). In summary, pharmaceutical companies employed various forms of Open Innovation, ranging from licensing and acquiring drug candidates to purchasing entire companies, outsourcing, and more (Schuhmacher et al., 2013). The internet facilitated the openness of the drug discovery process by enabling access to ideas from a broader scientific community (Matthew et al., 2017). Laboratories serve as neutral spaces where stakeholders come together to collaboratively develop innovations in practical, real-world settings (Almirall et al., 2012). The pharmaceutical industry's widespread adoption of similar Open Innovation models has set a standard that serves as an exemplary model for other industries to follow (Bigliardi et al., 2020).

### **1.1.3 Challenges in engaging stakeholders during the innovation process, and Service provider (CRO)-Client (Pharmaceutical company)'s collaborated issues and challenges**

Collaboration between firms plays a crucial role in driving innovation within organizations. However, simply having access to a diverse range of resources doesn't guarantee that synergies will be achieved. Cui and O'Connor (2012) argued that the benefits of diverse partner resources relied on effective sharing of information and resources across alliances. This task could be challenging and influenced by factors such as the makeup of the alliance portfolio, market dynamics, and the firm's capability to manage its portfolio effectively. Therefore, while resource diversity can potentially contribute to firm innovation, its impact is contingent upon several conditions rather than being universally beneficial. While resource diversity offered opportunities for synergy, there were circumstances where the challenges of managing diverse resources might outweigh the benefits, potentially hindered innovation. The literature

underscored the complexities and costs associated with overseeing a portfolio of highly diverse partners. Managing interactions within alliances had been a central challenge in alliance research, with factors such as reduced absorptive capacity and coordination difficulties stemming from diverse partner goals. When diversity is not effectively managed, it could lead to information overload, conflicts, and confusion, ultimately impeding innovation efforts (Cui & O'Connor, 2012).

While Open Innovation fosters co-creation among stakeholders, diverse perspectives might lead to conflict within project teams, especially when actors held conflicting goals or values. Addressing such conflict required specific capabilities from the focal firm (Driessen & Hillebrand, 2013). Stakeholder co-creation offered benefits to the focal firm, such as access to unique resources and knowledge. However, it also introduced new challenges due to the diverse characteristics, interests and goals of different involved stakeholders. Understanding and managing these challenges required specific capabilities, which were of great interest to both research and practice. A lead firm might encounter challenges when engaged in co-creation with multiple stakeholders concurrently. These challenges typically revolved around identifying and involving suitable stakeholders, managing conflicts arising from diversity among stakeholders, and effectively handling the knowledge co-created by stakeholders. When a focal firm decided to increase collaboration with external stakeholders, one of the initial challenges is identifying suitable partners for collaboration. This process is complex, requiring the harmonization of conflicting views among stakeholders before the project begins to ensure their participation. Furthermore, the diversity within project teams resulting from the inclusion of multiple stakeholder types could lead to conflicts regarding project goals and the execution of the co-creation process. Despite speaking the same language, stakeholders might have different communication styles, goals, and interests, exacerbating divergence. Additionally, diversity among stakeholders can create conflict regarding intended project outcomes. A third challenge raised from the need to capture the broad spectrum of knowledge generated in stakeholder co-creation projects. Existing knowledge capture capabilities might not be adequate, particularly because external stakeholders might lack familiarity with corporate contexts and methods for articulating and disseminating knowledge. Overall, the multilateral interactions between the firm and diverse stakeholders present novel challenges that cannot be effectively managed with existing capabilities. Therefore, to navigate these collaborations successfully, a lead firm may need to develop a distinct set of capabilities tailored to the demands of such collaborations (Driessen & Hillebrand, 2013). Once the process of knowledge emergence in stakeholder co-creation and the associated challenges were identified, the next step was to

pinpoint the capabilities required to address these challenges and enhance a firm's co-creation efforts and innovativeness (Kazadi et al., 2016).

In the study on innovation, Cui and O'Connor (2012) suggested that when there was high functional heterogeneity, sharing information and resources became more challenging, leading to a reduced impact of resource diversity on innovation.

Traditionally, collaboration enhanced an organization's strategic position by providing access to resources from other entities, fostering cost and risk sharing among cooperating parties, but these theories failed to explicitly account for the motives and interests of stakeholders and their impact on innovation outcomes (Lin et al., 2019; Ozdemir et al., 2023).

## **1.2 Research Problem**

To strengthen corporate performance, companies need to foster links among stakeholder engagement, innovation, and co-creation. While prior studies have explored these connections between from different aspects, including like Vargo and Lusch (2016), existing research on the topic often lacks a comprehensive and systematic conceptual framework to fully grasp these vital concepts. The absence of a well-defined understanding of these concepts posed challenges in developing reliable measures, particularly concerning stakeholder engagement. Furthermore, explaining the relationships between these constructs proved challenging for hypothesis stimulating, limiting progress in this area. Additionally, the insufficient clarity in the field impedes the identification of pertinent hypotheses, hindering the establishment of a foundation for further advancements and insightful managerial conclusions. In summary, prior literature lacked to provide a comprehensive and cohesive conceptualization of these factors, which limited our comprehension of how to effectively utilize stakeholders in innovation and co-creation strategies (Loureiro et al., 2020).

In the pharmaceutic industry, the collaboration between the pharmaceutical company and Contract Research Organizations (CROs) for research and development has seen significant growth (Lowman et al., 2012), driven by motivations such as cost reduction, efficiency improvement, access to global knowledge sources, and enhanced development productivity (Schuhmacher et al., 2018). Innovation service providers, CROs, have emerged as pivotal contributors to clinical product development within the pharmaceutical industry (Lowman et al., 2012). Pharmaceutical companies, as clients of the innovative service recipients, and CROs, as the innovative service providers, are primary stakeholders in the process of drug development. But similar to the issues and risks mentioned in previous literature on stakeholder engagement

and open innovation, some literature also mentioned the increased role of CROs in the innovation process potentially introducing long-term innovation risks, including the possibility of losing control over the innovation process and opportunities for creativity in developing new products, thereby posing challenges to the overall innovation and new product development (Lowman et al., 2012). The research problem of this study is the conflict and dilemma between the benefits and problems brought by stakeholder engagement in the process of open innovation, and CRO- Pharmaceutical company's collaborated R&D project.

We will conduct literature review, expert consultation, questionnaire surveys, to perform empirical research on CRO cooperated projects in pharmaceutical research and development (R&D) filed, to investigate the relationship and effect of primary stakeholders engagement, specific capabilities and innovativeness. To fill in the gaps in literature and guide the industry managers in management practice whether they could develop specific capabilities to address the difficulties and challenges brought by the diverse stakeholders, ultimately to support innovativeness and performance.

### **1.3 Research Questions**

Based on the aims and considering the gaps in the literature and management operational area, we define our three specific research questions:

1. Who are the key Stakeholders driving the innovativeness in Pharmaceutic R&D collaborated projects?
2. What are the effects of engagements from CRO innovation service provider and Pharmaceutic Client on the dynamic capabilities and operational (routine) capabilities in the pharmaceutical R&D collaborated projects?
3. What are the effects of the dynamic capabilities and operational (routine) capabilities on the innovativeness in CRO collaborated projects in Pharmaceutic R&D?

### **1.4 Research Purpose**

The research objective of this study is to through the literature review, expert consultation, and questionnaire surveys to investigate the relationship and effect between the engagement, specific capabilities, and organization innovativeness of primary stakeholders, CRO as the innovation service providers, and pharmaceutical company as the clients, during the Pharmaceutical R&D innovation process. Relevant hypotheses are proposed to conduct

empirical research on cooperated projects between CRO and pharmaceutical companies in the field of pharmaceutical research and development innovation, in order to establish thesis model to compensate for the gaps of the literature. And in management practice aspect, to guide managers in practice to instruct whether they could position and solve the difficulties and challenges brought by the engagement of different stakeholders through the development of their own specific capabilities, to ultimately influence the innovativeness and project outcomes.



## Chapter 2: Literature Review

This chapter reviews the existing literature on open innovation, stakeholders engagement, dynamic capabilities, operational (routine) capabilities, organization innovativeness and measures of several concepts, clarifies the relationships among the main variables, and proposes the theoretical hypotheses of this thesis.

### 2.1 Open Innovation and Stakeholders Engagement in open innovation

#### 2.1.1 The concept of open Innovation

The open innovation concept emanates from the resource-based view theory. This theory assumes that organizations strategically analyze and balance their external and internal resources - such as ideas, material, energy, skills, people - to be competitive (Anning-Dorson, 2018). Open innovation is the use of purposive inflows to accelerate innovation and of knowledge outflows to expand markets (Bigliardi et al., 2020; Chesbrough, 2003), therefore ideas generated when collaborate with internal and external partners to thrive Innovation. By leveraging diverse perspectives and resources, this collaboration fosters creativity and drives further the process of new product development and delivery (Cui & O'Connor, 2012).

Since the 2003 publication of Chesbrough's seminal work, Open Innovation: The New Imperative for Creating and Profiting from Technology, the concept of open innovation (OI) has garnered increasing attention from academics and practitioners alike. The original definition of OI stressed that *"valuable ideas can come from inside or outside the company and can go to market from inside or outside the company as well. This approach places external ideas and external paths to market on the same level of importance as that reserved for internal ideas and paths"* (Chesbrough, 2003).

Since the inception of the term Open Innovation, both innovation scholars and Chesbrough refined its original definition, Chesbrough emphasized the intentional nature of knowledge exchange as open innovation is the use of purposive inflows and outflows of knowledge to accelerate internal innovation and expand the markets for external use of innovation, respectively (Chesbrough et al., 2006). Later in 2014, Chesbrough proposed a definition of OI based on the concept of business models, describing open innovation as a distributed innovation



process grounded in purposively managed knowledge flows across organizational boundaries, using pecuniary and non-pecuniary mechanisms in line with the organization's business model (Chesbrough et al., 2014).

Despite of the definition, Open Innovation is founded on the idea that, within the modern competitive context in which firms have to operate, the linear model of innovation is no longer suffices in today's competitive landscape. Modern organizations must adapt by collaborating with external stakeholders facilitating the iterative exchange of knowledge, technology, and resources across organizational boundaries (Bigliardi et al., 2020). Put simply, to remain competitive, organizations cannot innovate in isolation; they have to actively engage with various partners, including suppliers, customers, universities, research centers and competitors (Bigliardi et al., 2020; Bigliardi & Galati, 2016), to access ideas and resources from the external environment. Consequently, in this paradigm, organizational boundaries need to become permeable rather than closed, as innovation developed within a network of relationships facilitated by intentional inflows and outflows of knowledge external.

Innovation benefits from diverse resources are employed, as diversity expands the range of potential new resource and knowledge combinations, thereby enhancing creativity and learning. Many recent studies acknowledge the synergistic benefits of diverse resources and argue that collaborating with a variety of partners offers opportunities for accessing new information that fuels innovation (Cui & O'Connor, 2012). Innovation is conceptualized as a process of interactive learning between firms and their external environment: the introduction of innovations based on firms' capability to access and utilize external knowledge sources, integrating them with internal capabilities (Simona et al., 2020). These contributions underscore that innovation, as an interactive process, is fundamentally rooted in the generation and diffusion of knowledge with external partners. Evidence of this process can be observed in the interactions of firms with knowledge-intensive business services (KIBS) for innovation (Doloreux et al., 2023). While both open innovation and co-creation are involving collaboration and interaction, there are nuanced differences between the two concepts. Open innovation entails active collaboration among various organizations or stakeholders groups, whereas cocreation tends to focus on specific relationships between an organization and a defined stakeholder, as classic definitions. Additionally, open innovation typically emphasizes a singular process, whereas cocreation can involve multiple processes, such as co-innovation, co-design or co-production. However, these distinctions have become less pronounced in recent years a shift in research focus in co-creation from an organizational level to a network level, which involves exploring systemic processes and social relationships. Co-creation can involve

interactions among multiple stakeholders, and open innovation can be viewed as a specific form of co-creation, aligning with this evolving understanding (Drummond et al., 2018).

Persistent R&D collaboration consistently yields positive effects on innovativeness. Collaborating with partners is widely recognized as a key driver of firms' innovation performance. Such collaboration fosters innovation by providing access to external resources and knowledge that may be lacking internally (Chesbrough, 2003). Recent empirical research emphasizes the importance of distinguishing between types of collaboration partners to better understand the performance outcomes of R&D collaboration. These partner types include vertical partners in the value chain (such as suppliers and customers), competitors, and institutional partners. This differentiation is crucial because each partner type complements the focal firm's resources and capabilities in different ways. Firms engage in collaboration with other entities to acquire necessary resources and broaden their knowledge base, thereby enhancing their capacity to develop new products (Chen et al., 2022; Sousa et al., 2020).

In the pharmaceutical industry, scientific knowledge serves as the fundamental cornerstone for driving technological advancements, and active collaboration stands out as the primary avenue through which pharmaceutical companies engage in the generation and acquisition of scientific knowledge. In the current era marked by intense competition and growing complexity, a prevalent strategy within the pharmaceutical industry involves forging strong partnerships and alliances with universities, research institutes, and partners (Wang & Jiao, 2022).

### **2.1.2 Stakeholders Engagement in Open innovation**

The term “stakeholder engagement” comprises two fundamental concepts in management and marketing. The term “Stakeholder” originates from the stakeholder theory (Freeman, 1984; Kumar & Pansari, 2016). This theory posits that organizations exist not only to generate profits but also to create maximum value for their stakeholders (Voyer et al., 2017), which highlights ideas, metaphors and expressions to achieve such purpose (Strand & Freeman, 2015). Freeman (1984) underscores the significant role stakeholders play in shaping the relationships with organizations and firms. On the other hand, the term “Engagement” encompasses a range of activities such as interactions, service exchanges, co-creation processes or solution development (Kumar & Pansari, 2016). It signifies the active involvement of stakeholders in various aspects of organizational endeavors. In essence, stakeholder engagement underscores the importance of fostering meaningful relationships and collaboration between organizations and their stakeholders, ultimately leading to the creation of shared value and sustainable outcomes.

### **2.1.2.1 Stakeholders Theory**

Stakeholders are groups or individuals who can positively or negatively influence or be influenced by firms' strategic decisions and outcomes. Stakeholders are often defined as "any group or individual who can affect or is affected by achieving the organization's objectives" (Freeman, 1984). These stakeholders can vary widely and include actors who are connected to an organization internally like shareholders, investors, and employees, as well as externally such as customers, competitors, unions and suppliers. Stakeholder theory recognizes that stakeholders hold diverse interests, expectations, needs, and values. Consequently, conflicts often arise among stakeholders due to these differing interests, necessitating a delicate balance to accommodate various stakeholders' concerns (Freeman, 1984). Stakeholders are more likely to support an organization's objectives, such as introducing new products or improving performance, when their interests align with those of the organization. This alignment fosters greater cooperation and collaboration between the organization and its stakeholders (Jones et al., 2018). Moreover, building mutually beneficial relationships is essential for fostering trust among collaborators and gaining a competitive advantage through inter-organizational collaboration (Kull et al., 2016).

### **2.1.2.2 Primary and Secondary stakeholders**

Stakeholders can be categorized into two main types: primary and secondary stakeholders. Primary stakeholders encompass essential entities such as employees, suppliers, shareholders, and customers; On the other hand, secondary stakeholders include groups such as government, competitors, brand communities, consumer advocate groups, social-interest group, and media outlets (Drummond et al., 2018).

Primary stakeholders are directly involved in the organization's operations and are crucial for its survival and success like suppliers and customers, while secondary stakeholders may not directly impact the organization's day-to-day operations or immediate survival such as universities, research centers and competitors. It's generally perceived that primary stakeholders hold a more direct and immediate influence on the organization compared to secondary stakeholders, and managers often prioritize primary stakeholders due to their direct involvement and impact on the organization's operations and objectives through a supply chain (Miles, 2017).

Encouraging stakeholders to invest resources specific to the organization is a critical concern within the Resource-Based View (RBV) framework, which emphasizes that unique and inimitable resources are key drivers of superior organizational performance (Hoskisson et

al., 2018). Reciprocity plays a pivotal role in stakeholder relationships, serving as a central element in creating value for stakeholders and motivating their commitment of resources (Miles, 2017). This suggests that stakeholders' resources such as complementary and diverse assets alone may not guarantee the success of inter-organizational collaborations without alignment from stakeholders sharing compatible interests. Access to a variety of information sources can enhance an organization's knowledge base and align its resources more effectively, thereby increasing its salience and capabilities among stakeholders. It's noteworthy that both the depth and breadth of external information search and access play crucial roles in improving innovation performance (Ardito et al., 2020). A Conducting an information search across a diverse array of stakeholders grants a focal organization a valuable informational or resource advantage. By tapping into information from various sources, the organization enhances its chances of collaborating with primary stakeholders in a manner that yields high-value innovation (Miles, 2017).

Primary Stakeholders, calculated using two variables such as suppliers and clients, play a crucial role in fostering innovation within organizations (Arranz et al., 2021). Ozdemir et al. (2023) suggest that collaboration with primary stakeholders is more likely to result in the development of both process and product innovations compared to collaboration with secondary stakeholders. The results align with previous findings (Aliasghar et al., 2019), indicating that collaborations with stakeholders along the supply chain are particularly conducive to product innovation. In line with Anning- Dorson (2018), Ozdemir et al. (2023) mentioned that information obtained along the supply chain enables organizations to anticipate emerging market needs and respond swiftly and efficiently to emerging opportunities. Suppliers, in particular, have a strong connection with their customers' needs, making collaboration with them highly advantageous for organizations aiming to reduce costs and improve responsiveness (Jajja et al., 2017). Furthermore, the shared knowledge bases and resources between suppliers and customers facilitate communication and collaboration, thus lowering associated costs and fostering collaborative innovation efforts (Ozdemir et al., 2023).

The process innovation is more strongly associated with collaboration with primary stakeholders compared to secondary stakeholders (Medda, 2020; Ozdemir et al., 2023; Terjesen & Patel, 2017), for collaboration with suppliers facilitates the identification and implementing new technologies aimed at enhancing or transforming existing processes. From a stakeholder perspective, these findings underscore the significance of establishing linkages throughout the supply chain and aligning interests among stakeholders, particularly suppliers and customers, contributes significantly to the development of process innovations. Moreover, the research

indicates that stakeholder interests play a crucial role in interorganizational collaborations. Primary stakeholders with a commercial focus are more inclined to support the development of both product and process innovations geared towards commercial ends compared to secondary stakeholders with non-profit orientations, and primary stakeholders with market-based interests over secondary stakeholders with non-market-based interests in driving innovation efforts (Ozdemir et al., 2023). Access to diverse information from various stakeholders provides a significant advantage for innovation performance and competitive positioning, when a focal organization gains this information advantage, it fosters mutual influence between the organization and its primary stakeholders, particularly those directly involved in the supply chain (Shubham & Murty, 2018). Ozdemir et al. (2023) emphasized the importance of considering stakeholders' resource-based competencies and interests when establishing innovation collaborations, and suggested for successful product innovation development, managers should prioritize collaborations with primary stakeholders possessing market-based interests, such as suppliers and customers within the supply chain. Thus, managers can prioritize to facilitate the collaborative engagements with the primary stakeholders, who offer complementary resources and share commercial interests. Effective collaboration between organizations, primary stakeholders, including suppliers and customers facilitates the joint development of innovative products through the exchange and sharing of complementary knowledge and resources, both within and across industries, wield greater influence over the development of process innovations than secondary stakeholders (Ozdemir et al., 2023).

Primary stakeholders like employees, shareholders, and customers, typically maintain formal contractual relationships with the firm, are deeply involved in the organization's operations and play pivotal roles in its survival and success, can poses the ability to influence decision-makers within the firm and emphasize the urgency, importance, and time sensitivity of their needs and demands. Primary stakeholder engagement focuses on the extent to which a firm effectively addresses the concerns and interests of its primary stakeholders like employees, shareholders, and customers (Brower & Dacin, 2020). Primary stakeholders "can make legitimate claims on the firm and its managers and have both urgency and power (utilitarian, coercive, and normative) to enforce these claims", and often make specific, concrete requests related to firm financial performance given their direct relevance to the firm survival and success. Chiu et al. (2023) developed a method to assess a firm's primary stakeholder engagement by aggregating strengths scores across three dimensions governance, relations, and product quality, which capture firm activities that have a more immediate and direct financial

impact on the firm by primary stakeholders. Corporate governance strengths evaluate the firm's efforts to address agency issues between top managers and owners/shareholders (Gamache et al., 2020). Employee strengths assess the firm's initiatives in fostering positive employee relations, including aspects like profit sharing, health and safety measures, and human capital development. Finally, product emphasize gauge the firm's commitment to product quality, consumer data privacy and security, and effective customer service communications (Chiu et al., 2023).

### **2.1.2.3 Engagement**

Engagement has emerged as a concept of significant interest, often described as "conceptually tortuous" yet undeniably important. Despite its recognized significance, there remains a lack of shared understanding regarding its precise meaning and characteristics. This ambiguity is attributed to the multitude of definitions, operationalizations, forms, and treatments associated with engagement (Morehouse & Saffer, 2019, 2023). At its core, Engagement can be understood as *"the dynamic interplay of stakeholder and organizational actions"* (Coombs & Holladay, 2018; Morehouse & Saffer, 2023); In essence, it involves social, relational, and multidimensional interactions that occur through collaboration, exchange, and interaction between different entities. Engagement represents the fundamental tension within decision-making processes within relationships, whether between individuals (both human and artificial), groups, organizations, businesses, communities, or societies (Dhanesh, 2017; Johnston & Taylor, 2018).

The concept of engagement has been approached and applied in various contexts, resulting in different conceptualizations and operationalizations. For instance, engagement may be examined in the context of employee engagement, social media engagement, or corporate social responsibility engagement (Dhanesh, 2017). To address this diversity, Johnston and Taylor (2018) proposed three "tiers" of engagement, each characterized by distinct indicators and outcomes. Morehouse & Saffer (2023) built upon Johnston and Taylor's framework, defining three forms of engagement: manifestation, understanding and connecting. Interactive engagement demonstrates whether "activity is present", while relational engagement emphasizes stakeholders' connections and relationships with others at the individual level. Indicators of relational engagement include intra-stakeholder ties, feelings of embeddedness, and participation in various activities (Johnston & Taylor, 2018). Feelings of embeddedness is another indicator of relational engagement, represent stakeholders' sense of belonging within the organizational community, influenced by the connectedness of their social networks and



access to supportive individuals (Schafer, 2018). Intra-stakeholder relationships manifest tangible forms of relational engagement, while embeddedness captures stakeholders' subjective perception of belonging (Schafer, 2018). It is crucial to perceived (embeddedness) and actual (intra-stakeholder relationships) belonging. Participation in organizational activities serves as an indicator of relational engagement with other stakeholders, the organization, and relevant issues. Morehouse & Saffer (2023) assert that participation behaviors serve as a key indicator of relational engagement.

In business contexts, the term "engagement" encompasses various individuals or groups, objects, or activities, including consumers or customers, brands, civic issues, or employment (Kumar & Pansari, 2016). However, within business academia, there is a lack of a consensus regarding the conceptualization of engagement and its dimensions. Nevertheless, two consistent principles emerge in consistently in engagement-related literature. Firstly, engagement involves the active cognitive processing, attitudinal or emotional bonding, and behavior toward a focal object or activity. Secondly, engagement occurs within a relational or interactive context (Kumar & Pansari, 2016).

These two principles regarding engagement align well with the underlying assumptions of stakeholder theory. Firstly, recognizing shared interests between organizations and stakeholders, fostering a cooperative strategic approach. Secondly, rejects a narrow economic view of the firm, advocating instead for collaboration with stakeholders in enduring relationships for long-term success. In essence, stakeholder engagement signifies a mutual commitment between the organization and its stakeholders in to create value, build trust, and cultivate mutually beneficial relationships over the long term (Beckers et al., 2018; Shams, 2015, 2016).

Stakeholder engagement refers to the actions undertaken by firms to address interests of various stakeholders, thereby fostering shared objectives and values (Freeman, 1984), which has seen a notable surge in importance over the past decade (Brower & Dacin, 2020). The sustained success of a firm hinges significantly upon its adeptness in managing stakeholders' expectations concerning corporate growth, stability, and profitability (Freeman et al, 2008). Chiu et al. (2023) has delved into several factors that precede firms' stakeholder engagement, such as the correlation between stakeholder engagement and industry visibility, firms' resource accessibility, adherence to social contracts, managers ethos, and political stance (Hambrick & Wowak, 2021).

#### **2.1.2.4 Vertical Stakeholders collaborations**

In the contemporary business landscape, collaborations with a diverse array of stakeholders facilitate organizations to access information and knowledge, mitigate costs and risks and amplify opportunities for swift development of new products and services (Ozdemir et al., 2017). Moreover, from an operational standpoint, interorganizational collaborations streamline the acquisition of essential resources for innovation, t positioning them favorably to thrive in dynamic business environments (Ozdemir et al., 2020). Organizations inclined towards innovation typically engage in simultaneous development of multiple innovations and research projects while collaborating with a diverse spectrum of stakeholders, each with distinct objectives and orientations. Scholars have underscored the benefits of collaborating with various stakeholders including suppliers or competitors (Martinez et al., 2019). An essential inquiry arises regarding whether the selection of a specific stakeholder type influences the successful fruition of collaborative innovation endeavors. Inter-organizational collaborations have garnered substantial scholarly attention (Pereira & Bamel, 2021). The Resource-Based View (RBV) and its extension, the Knowledge-Based View (KBV), offer theoretical frameworks to elucidate why organizations initiate inter-organizational collaborations. T Central to this perspective is that such collaborations afford organizations access to resources that would otherwise be inaccessible, thereby facilitating the pooling of resources that can ultimately generate value for the focal organization (Pereira & Bamel, 2021). Prior studies have posited that different types of collaborators like customers and suppliers provide access to distinct types of non-redundant and complementary resources, thereby foster the development of more innovative products compared to collaborations with horizontal collaborators like competitors, who provide redundant and similar resources (Ozdemir et al., 2017).

The RBV conceptualizes firms, or organizations more broadly as collections of resources, (Chahal et al., 2020; Pereira & Bamel, 2021), encompass both tangible and intangible assets, collectively constituting the firm's competitive advantage. An extension of RBV, known as the Knowledge-Based View (KBV), zooms in on the significance of knowledge as a distinct resource category, capable of engendering comparative advantage. Kim (2017) and Caputo et al. (2019) advocated for integrating RBV and KBV with other theoretical perspectives which takes into account not only the resource synergies but also the alignment of stakeholder objectives and motives, thereby maximizing the potential for collaborative success.

Stakeholder research confronts two notable constraints: a broad focus on stakeholder influences and limited insights into the nuanced impacts of vertical stakeholders on



collaborative engagements, which are often more complex compared to horizontal stakeholders (Chakkol et al., 2018). Specifically, stakeholder studies commonly recognize the prevalence of unequal power dynamics among vertical stakeholders within the value chain, which complicates the design of collaborative approaches (Soosay & Hyland, 2015). Some vertical stakeholders may wield significant coercive power, enabling them to dictate or strongly influence the terms of engagement with other organizations rather than collaboration (Busse et al., 2017). The immediate needs and interests of vertical stakeholders compel them to engage in collaboration, irrespective of power relations (Busse et al., 2017). From an interorganizational learning perspective, vertical stakeholders, due to their distinct positions along the value chain, possess a wealth of non-redundant knowledge and experiences thus offer greater comparative knowledge-complementarity advantages compared to horizontal stakeholders operating at the same level of the value chain (Ozdemir et al., 2017). Studies on knowledge transfer further support this notion by demonstrating that firms can enhance their innovativeness by acquiring and integrating knowledge from vertical stakeholders, specially, stakeholders positioned in the upstream position of the value chain can contribute to improving innovativeness by providing high-quality knowledge (De Zubielqui et al., 2019). Absorptive-capacity research complements these findings by emphasizing the importance of not only acquiring and assimilating knowledge but also transforming and exploiting it to develop new and unique capabilities, ultimately leading to improved performance. Despite the potential benefits of learning from vertical stakeholders, navigating their interdependent relationships and varying power dynamics can pose challenges. These stakeholders often have a multitude of conflicting interests, making it more challenging to attain value in these relationships compared to horizontal collaborations (Ozdemir et al., 2020).

#### **2.1.2.5 Stakeholder collaboration in technological turbulence and firm innovativeness**

In highly dynamic technological environments, many innovations originate from research and development efforts external the industries, firms encounter challenges that prompt them to seek new technological knowledge and capabilities from external sources, Extensive exploratory learning beyond the boundaries of the firm is crucial for fostering innovation in turbulent environments. Collaborative partnerships with a diverse range of stakeholders offer an efficient and effective means of addressing the uncertainties associated with pioneering products (De Vaan, 2015), by engaging with stakeholders, firms can glean insights into the latest technological advancements in the marketplace. In technologically turbulent environments, firms may find it advantageous to initiate collaborations with vertical

stakeholders, and such collaborations enable firms to access complementary technological knowledge and resources, streamline the identification of new market opportunities, and expedite the introduction of new products. From a stakeholder perspective, firms wield influence over and are influenced by the external environments (Du & Williams, 2017). In technologically turbulent settings, there is heightened legitimacy and urgency in meeting the demands of vertically linked stakeholders. The mutual necessity for the non-redundant and complementary knowledge offered by vertical stakeholders in the innovation process serves as a catalyst for firms' knowledge-sharing practices and joint learning endeavors aimed at achieving innovation and pioneering new technologies (Ozdemir et al., 2017). What is more, the level of interaction and communication with vertically linked stakeholders during New Product Development (NPD) significantly impacts the innovativeness of a focal firm (Alexiev et al., 2016; Ozdemir et al., 2017). A high degree of communication and interaction among vertically linked stakeholders tends to lead to proactive innovation strategies. Increased interaction fosters greater familiarity between firms, leading to heightened mutual trust and enhanced value creation (Tantalo & Priem, 2016). This increased trust reduces concerns about sharing innovative knowledge, thereby facilitating the transfer of knowledge that could potentially confer a competitive advantage. In technologically turbulent settings, where vertical stakeholders exhibit a higher degree of interdependency compared to horizontally connected counterparts like competitors, collaboration among these stakeholders becomes crucial. Vertically linked stakeholders can offer complementary knowledge and resources, thereby enhancing information utilization and bolstering innovative endeavors, enabling firms to adapt proactively to changing market conditions (Ozdemir et al., 2017). In rapidly evolving technological landscapes, innovations often arise from collaborative networks where firms have ample opportunities to access novel and unique knowledge. Vertical stakeholder collaboration serves as a mediator between technological turbulence and firm innovativeness, significantly influencing the innovativeness of the focal firm. In such environments, firms face heightened pressure to enhance their innovativeness to capitalize on emerging technological opportunities, mitigate the threat of technological obsolescence, and develop new products with greater technological novelty (Alexiev et al., 2016). Vertical stakeholder collaborations play a vital role in enhancing firms' capabilities by providing access to non-redundant partner-specific knowledge and resources, particularly crucial in technologically turbulent environments. Such collaborations facilitate access to explicit and tacit knowledge on emerging technologies, thereby improving innovation outcomes (Walsh et al., 2016). It is consistent with Subramanian and Soh (2017)'s study that as the diversity of partner knowledge expands, the capability to

produce an innovation outcomes by integrating new ideas from diverse knowledge domains is enhanced, while exchanging knowledge and engaging in learning activities with vertical stakeholders can be challenging for the divergence in goals, interests and expectations (Kazadi et al., 2016).

In technologically turbulent environments, stakeholders' mutual dependence on knowledge can underscore the importance of promptly addressing their collaborators' needs concerning New Product Development (NPD). Existing research in supply chain management highlights that supplier innovativeness plays a crucial role in enhancing supply chain agility, which enables the supply chain to swiftly adapt to changes in the business environment, resulting in accelerated time-to-market and improved new product performance (Kim & Chai, 2017). On the other hand, some studies suggest that firms' varying motivations and power relations may hinder their innovativeness (Matanda et al., 2016), but vertical stakeholder collaborations can facilitate the development of innovativeness skills within the focal firm, ultimately leading to enhanced new product performance..

Focusing on individual alliances can hinder the firm's ability to recognize crucial interconnections, resulting in inefficiencies. Adopting a portfolio perspective is crucial for exploring the impact of partnerships on firm innovation. Information and resource sharing among partnerships may occur through explicit procedures or informal interactions of employees during collaborative activities. While information may naturally diffuse between partnerships, effectively harnessing the synergies from diverse partner resources requires active coordination efforts from the firm. This entails viewing all partnerships comprehensively, potential interdependencies among them, and actively managing the flow of information and resources across partnerships to leverage synergistic benefits. Additionally, managing coordination within each partnership should consider the broader context of portfolio-level information and resource sharing (Cui & O'Connor, 2012).

#### **2.1.2.6 Stakeholder co-creation of value during the innovation process**

In the knowledge-based view (KBV), knowledge is recognized as a distinctive resource crucial for successful product innovation. The ability of firms to acquire necessary knowledge, integrate different knowledge bases, and apply this knowledge effectively in product development is paramount for innovation. Product innovation is seen as the outcome of knowledge acquisition and sharing both within and between firms. Adopting an alliance orientation aids firms in achieving effective knowledge acquisition, exchange, and combination. Research also suggests that competitor and alliance orientations can enhance firms' product

innovativeness by enabling them to acquire and utilize the knowledge for successful product innovation and adaptation to environmental changes (Chen et al., 2022).

Furthermore, stakeholders play a pivotal role in shaping corporate success (Freeman, 1984). They are instrumental in driving the development of new projects and realizing the vision and objectives of organizations (Voyer et al., 2017). Stakeholders are encouraged to be actively cooperate with firms in planning, developing, co-creating, or improving products and brands (Kaufmann H., 2016; Kumar & Pansari, 2016). This vision is shared by practitioners, who recognize the importance of engaging stakeholders to attain competitive advantage. The special issue of the Journal of Business Research (JBR) seeks to enhance the comprehension of how entrepreneurs can utilize both external and internal stakeholder networks to exchange knowledge and resources, thereby planning and implementing innovative entrepreneurial strategies collaboratively. Companies must understand how to stimulate innovation through stakeholder engagement which involves fostering positive connections between stakeholders and organizations for a focal object or activity, as well as promoting co-creation, a creation process that unfolds within interactive system-environments (Ramaswamy & Ozcan, 2018).

In today's competitive environments, companies are under mounting pressure to generate valuable knowledge to stay competitive. An individual firm possess only finite resources for this purpose, hence there's a growing recognition that collaborating with external partners can be advantageous for creating unique knowledge during the innovation journey. Consequently, firms are embracing open innovation approaches inviting external actors. Co-creation emerges and denotes the collaborative value creation between stakeholders and organizations in shaping products, services and brands (Merz et al., 2018). The essence of co-creation lies in interactive dialogues and mutual learning, aimed at identifying customers' preferences and aspirations regarding products or brands (Voyer et al., 2017). While prior focus are on primary stakeholders like customers, competitors or suppliers, there is a notable shift towards involving multiple stakeholders concurrently in the innovation process. This shift stems from two key trends: Firstly, the escalating complexity of knowledge required for innovation necessitates inputs from diverse external parties. Secondly, stakeholders are increasingly empowered, interconnected and inclined to share their insights with companies. Recognizing this evolving landscape, firms are awakening to the potential benefits of actively integrating stakeholders, who, when empowered, can serve as invaluable sources of unique knowledge during the innovation journey.

Innovation network theory offers valuable insights into how firms can effectively integrate multiple stakeholders throughout the innovation process. In numerous industries, innovation isn't solely driven by individual firms but rather by their networks. These networks combine

diverse resources, knowledge and capabilities, often inaccessible through conventional market transactions. This combination is gaining significance due to the escalating complexity of new products and services. Research indicates that within such networks, a lead firm assumes a pivotal role in orchestrating its network, necessitating specific capabilities. Marketing and management literature delve into the lead firm's capacity to structure and oversee its network, thereby enhancing its innovativeness and overall outcomes.

Innovation sources span a spectrum, encompassing various stakeholders such as customers, suppliers, government, competitors, NGOs and other interest groups—all active participants within innovation networks, contributing complementary knowledge and experience for value co-creation. These stakeholders can cultivate trust-based relationships with the lead firm, fostering enhanced market insights and revenues. Throughout the product and service development phases, different stakeholders emerge as active, empowered actors within the lead firm's innovation network. Given their diverse goals, needs, and communication styles, firms must reassess the specific capabilities required to manage their innovation networks effectively.

Kazadi et al. (2016) highlight a prevalent focus existing studies on stakeholder co-creation, primarily examining it from a network-level analysis, which explore stakeholders within the supply chain, emphasizing relational practices that facilitate joint learning between customers and suppliers, and delve into how firms enhance value by dedicating additional resources to addressing stakeholder needs and demands within their supply chain. The authors underscore the significance of primary stakeholders within a firm's supply chain and advocate for further research into the capabilities necessary for firms to translate cooperation with multiple stakeholders into valuable knowledge, discuss the nature, antecedents and consequences of stakeholder integration capability. Kazadi et al. (2016) contribute to the advancement of research by pointing the capabilities essential for firms to effectively manage the challenges posed by stakeholder co-creation. From a Resource-Based View (RBV) perspective, they argue that stakeholder co-creation capabilities are essential for a lead firm to leverage its unique knowledge sources such as stakeholders in a manner that generates value for the firm. Additionally, before initiating a project, firms need a stakeholder networking capability and stakeholder competence mapping capability. During the project, to manage the complex interactions with multiple stakeholders, firms need a stakeholder relationship management and a stakeholder knowledge management capability.

Building on the above literature discussed, this study focuses on the primary and vertical stakeholders involved in the open innovation of pharmaceutical research and development,

specifically, selected CROs as the innovation service supplier, and pharmaceutical companies as the innovation service client as the research objects.

## **2.2 Dynamic Capabilities and Operational (Routine) Capabilities**

Capabilities represent the inherent potential of a business to accomplish specific objectives through focused deployment, constituting the fundamental elements upon which firms compete in the marketplace. The process of designing and constructing desired organizational capabilities unfolds gradually over time and reflects strategic choices aligned with a firm's long-term competitive strategy. Organizational capabilities emerge through the strategic utilization and intricate interactions of the resources that a firm possesses or can control, along with the most effective methods of orchestrating and deploying them (Gold et al., 2001).

In accordance with the definition of Winter (2003), a capability can be characterized as a high-level routine or a set of routines, with routines comprising purposefully learned behaviors that are highly patterned, repetitive, or quasi-repetitive, rooted partly in tacit knowledge. Previous research in the area of strategic management has made significant advancements in developing and refining various types of organizational capabilities. It is widely acknowledged that capabilities function differently and yield varying levels of competitive advantage and firm performance, contingent upon numerous internal and external factors (Drnevich & Kriauciunas, 2011). In markets characterized by incompleteness, the diversity of capabilities among firms can become the foundation for cultivating competitive advantages and disparities in rent, and recognizing the imperative for organizations to maintain stability while also being adaptable enough to restructure their value proposition when necessary, there exists a well-established differentiation between operational (routine) and dynamic capabilities (Mikalef et al., 2020).

In organizational theory, the term "ability to perform" is deeply rooted in the collective capabilities of the organization itself, rather than being attributed solely to individual skills or specific machinery, which encompasses the accumulated experience, knowledge, and expertise embedded within the organizational fabric, and unlike mere individual skills or straightforward market access, organizational capabilities represent a complex amalgamation of processes, routines, and tacit knowledge developed over time. Scholars in the capabilities theory domain regard capabilities as a fundamental aspect of firm heterogeneity, and these capabilities are often characterized by their unique and idiosyncratic nature, making them difficult for competitors to replicate or imitate, with the notion of idiosyncrasy or inimitability considered a crucial determinant of a organization's competitive advantage (Helfat & Winter,



2011).

## **2.2.1 Dynamic Capabilities**

### **2.2.1.1 Concept and dimensions of Dynamic Capabilities**

Organizational capabilities represent the firm's capacity to effectively utilize its resources, thereby gaining a competitive advantage (Kazadi et al., 2016). Stakeholders are unique knowledge resources. However, to leverage this potential into a competitive advantage, firms must possess the necessary capabilities to navigate the complex process of engaging multiple stakeholders simultaneously. These stakeholder co-creation capabilities align with Teece et al. (1997)'s definition of dynamic capabilities. Dynamic capabilities refer to firm's ability to integrate, build and reconfigure, internal and external competences or resources to adapt to swiftly evolving customer and technological environments (Kazadi et al., 2016; Teece, 2007). The perspective of dynamic capabilities shifts the attention towards the revitalization of current organizational capabilities as a crucial strategy for the firm's competitive longevity (Winter, 2003). Accordingly, dynamic capabilities are described as those capabilities employed to expand, adapt, transform, and/or create operational capabilities (Drnevich & Kriauciunas, 2011).

The dynamic capabilities theory, emerging from the resource-based view, was initially formalized by Wernerfelt (1984) and further advanced through subsequent research by scholars like Barney. According to the resource-based view, firms achieve competitive advantages through the heterogeneity of their resources and capabilities, encompassing valuable, rare, inimitable, and non-substitutable resources they possess (Wernerfelt, 1984). In contrast to traditional strategic planning approaches, the dynamic capabilities theory emphasizes firms' effectiveness in seizing development opportunities within competitive market environments. Unlike simply discouraging competitors' strategic investments, a company's competitive advantage stems from its distinctive strengths in areas such as cost, quality, and product efficiency (Teece et al., 1997), who and other scholars expanded upon previous research by introducing the dynamic capabilities theory, which posits that dynamic capabilities are a firm's ability to reconfigure and integrate both internal and external resources to adapt to changes in the market environment. They argue that a firm's ability to maintain its competitive advantage hinges on its dynamic capabilities.

The original concept of dynamic capabilities refer to a firm's ability in integrating, building and reconfiguring internal and external competences to address rapidly changing environments

(Guo et al., 2022; Teece et al., 1997). To avoid circular definitions, scholars have proposed various perspectives, from a process viewpoint, Eisenhardt and Martin (2000) offer a broad definition that dynamic capabilities as specific and identifiable processes such as product development, strategic decision-making, and forming alliances. Alternatively, Zollo and Winter (2002) emphasize routines, defining dynamic capabilities as a learned and stable pattern of collective activities directed to the development and adaptation of operating routines. Drawing from entrepreneurship, Zahra et al. (2006) describe dynamic capabilities as the ability to reconfigure a firm's resources and routines according to the vision and judgment of its key decision-makers. Schilke et al. (2018) propose a more concise definition, stating that dynamic capabilities represent an organization's capacity to purposefully create, expand, or modify its resource base. Teece (2018) and Zahra et al. (2006) emphasize the importance of sensing and shaping opportunities and threats, seizing opportunities, and maintaining competitiveness by enhancing, combining, protecting, and, when necessary, reconfiguring the firm's tangible and intangible assets. In environments marked by high uncertainty and volatility, there's a need to focus on strengthening the capabilities to change and readjust operational capabilities. The dynamic capabilities perspective serves as a response to this gap by providing a neo-Schumpeterian understanding of the firm (Mikalef et al., 2020).

Dynamic capabilities manifest as routinized activities aimed at developing and adapting operating routines. Specifically, it underscores two key facets: the shifting nature of the environment and the key role of strategic management in adeptly adjusting, integrating, and reconfiguring internal and external organizational skills, resources, and functional competencies in response to these environmental changes (Boly et al., 2014).

Drawing from previous literatures, dynamic capabilities can be conceptualized as a firms' capacity to systematically address challenges, characterized by its ability to sense opportunities and threats, make timely and market-oriented decisions, and adapt its resource base accordingly (Li & Liu, 2014). It manifests as an organizational routine facilitating changes in the resource base. Teece (2018) stated that dynamic capabilities allow firms to continuously build, renew, and reconfigure resources, assets, and capabilities to innovate and respond effectively to market changes. Studies have indicated that Dynamic capabilities can enhance the value of resources obtained from stakeholders, thereby driving innovation activities (Zhao et al., 2021). For instance, companies possessing strong operational, engagement management, and engagement learning capabilities demonstrate greater proficiency in integrating and leveraging stakeholders resources, leading to enhanced environmental innovation performance (Watson et al., 2018). Moreover, in industry-academia-research collaborations, firms with stronger Dynamic



capabilities are better positioned to acquire knowledge from universities and research institutions, resulting in higher innovation performance (De Silva & Rossi, 2018). Overall, Dynamic capabilities play a pivotal role in promoting innovative activities of stakeholders (Guo et al., 2022).

Scholars offer various perspectives on defining the dynamic capabilities of firms. Since Teece et al. (1997) defined dynamic capabilities as the organization's capacity to integrate, construct, and reconfigure internal and external capabilities to address swiftly evolving environments, scholars had expanded the conceptual boundaries of capabilities. Eisenhardt and Martin (2000) conceptualize dynamic capabilities as the firm's ability to acquire, organize, utilize, integrate, and release resources. Helfat et al. (2009) propose that a firm's dynamic capabilities involve creating, expanding, and modifying existing resources with a clear objective in mind. Augier and Teece (2009) view a firm's dynamic capabilities as the ability to safeguard and reconstruct knowledge assets and complementary assets by identifying and seizing opportunities to gain and sustain competitive advantage. As the theory progresses, Sun et al. (2021) present a more comprehensive definition synthesized from scholars' research, now widely accepted as the prevailing definition of dynamic capabilities. It describes dynamic capabilities as the organization's capacity to continuously perceive the external environment through organizational learning and knowledge innovation, integrating and updating organizational resources in response to environmental shifts, thereby aiding the organization in adapting to the dynamically changing market environment.

The definition of dynamic capabilities has emerged as a valuable theoretical framework for understanding how knowledge is reconfigured within organizations (Li & Liu, 2014). Dynamic capabilities encompass a firm's capacity to adapt its processes and resources, including knowledge, in response to environmental changes. The operationalization of dynamic capabilities, as proposed by Li and Liu (2014), divides them into the sub-dimensions: strategic sensemaking capacity, timely decision-making capacity, and change implementation capacity (Wohlgemuth & Wenzel, 2016). Dynamic capabilities are recognized as a multidimensional concept, with its value contingent on the need to reallocate resources across different contexts (Teece et al., 1997). Schmidt and Scaringella (2020) explored the relationship between dynamic capabilities and value proposition innovation, categorizing dynamic capabilities into sensing, learning, integrating, and coordinating capabilities. Sensing capability involves continuously scanning and exploring technologies and markets, while learning capability entails adapting existing competencies with new knowledge; integrating capability refers to merging personal knowledge into new operational competencies; and coordinating capability involves

orchestrating tasks, resources, and activities within a new operational capacity. Dynamic capabilities distinct roles in business model innovation (BMI) and should be addressed accordingly. While some studies advocate further exploration of specific roles of dynamic capabilities in various innovation activities (Liboni et al., 2017), there remains a scarcity of relevant research. Thus, recognizing the significance of dynamic capabilities, Guo et al. (2022) delved into how dynamic capability fosters innovation and delineated the diverse roles of sensing, learning, integrating, and coordinating capabilities in driving innovation.

Dynamic capabilities encompass the abilities of organizations to acquire, organize, utilize, and integrate resources, as well as to seize opportunities and foster innovation. The essence of dynamic capabilities lies in enhancing the firm's competitive advantage within a fiercely competitive market environment, thereby ensuring long-term stable development. Various scholars have proposed their perspectives on the definition of dynamic capabilities. Regarding the constituent dimensions of dynamic capabilities, previous studies have adopted different approaches based on Teece's seminal work. For instance, Wang and Ahmed (2007) delineated dynamic capabilities into adaptive capacity, absorptive capacity, and innovative capacity. Wilhelm, Schlömer, and Maurer (2015) categorized dynamic abilities into perceptual ability, learning ability, and reconstructive ability. Helfat and Petteraf (2015) assert that dynamic capabilities dictate the development, enhancement, and integration of a company's core capabilities, encompassing abilities such as perceiving and evaluating opportunities and threats, seizing opportunities, mitigating threats, and reallocating tangible and intangible assets to maintain competitiveness. These dimensions encapsulate the ability of an organization to continuously combine internal resources to achieve a competitive advantage, flexibly mobilize resources to meet evolving needs, and innovate across service, technology, and projects.

According to Winter (2003), a capability can be conceptualized as a high-level routine or a collection of routines, with routines consisting of purposefully learned behaviors that are highly patterned, repetitive, or quasi-repetitive, often grounded in tacit knowledge. In the realm of strategic management, extensive research had been conducted to develop and refine various types of organizational capabilities. It's widely acknowledged that capabilities function differently and yield varying levels of competitive advantage and firm performance depending on internal and external factors (Drnevich & Kriauciunas, 2011). Recognizing the dual imperative for firms to maintain stability in delivering value in their distinctive way while also being agile and adaptive to restructure their value proposition as needed, there exists a well-established distinction between operational (ordinary) and dynamic capabilities. The dynamic capabilities perspective shifts the focus towards the renewal of existing organizational

capabilities as essential for competitive survival (Winter, 2003). Dynamic capabilities are defined as those capabilities used to extend, modify, change, or create operational capabilities (Drnevich & Kriauciunas, 2011). Consequently, dynamic capabilities play a crucial role in the competitive survival of firms operating in contemporary dynamic and globalized markets (Mikalef & Pateli., 2017). Thus, the definition of dynamic capabilities highlights their ability to indirectly create value by transforming a firm's operating capabilities (Mikalef et al., 2020).

#### **2.2.1.2 Impacts of Dynamic Capabilities**

Numerous scholars have investigated and confirmed the positive impact of dynamic capabilities on various facets of organizations. Bocken and Geradts (2020) assert that dynamic capabilities are essential for corporations to adapt, refine, and transform their business models in response to change. Consequently, dynamic capabilities enable firms to continuously innovate, gain competitive advantages, and enhance financial performance within ever evolving and highly competitive market environments. Studies have shown that dynamic capabilities have a positive influence on corporate performance (Khalil & Belitski, 2020; Kwon, 2013; Lin & Wu, 2014; Wilden & Gudergan, 2015), although conclusions regarding the specific mechanisms of impact vary. Lin (2014) suggests that dynamic capabilities act as an intermediary variable, mediating their effects on firm performance, specifically, the value-rich corporate resources positively affect firm performance, but the company's dynamic capabilities are needed as an intermediary variable. Wilden and Gudergan (2015) demonstrate that dynamic capabilities significantly enhance the foundational elements of a firm, subsequently bolstering overall performance. Zahra et al. (2006) argued that while dynamic capabilities may not directly create competitive advantages, they indirectly influence competitive excellence by altering firms' resource mixes or practices. Drnevich and Kriauciunas (2011) show that a company's dynamic capabilities can improve its performance. Kwon (2013) reveals that an organizational culture that is willing to take the initiative to learn positively affects the dynamic capabilities of the firm, and the dynamic capabilities of the firm positively affects firm performance. Lin & Huang (2011) explored how dynamic capabilities enable firms to navigate and thrive in rapidly evolving market landscapes. Their findings suggest that companies with robust dynamic capabilities are better positioned to innovate, adapt to market changes, and enhance overall performance compared to their counterparts lacking in such capabilities. Zahra et al. (2006) provided valuable insights into the indirect impact of dynamic capabilities on competitive advantages, by modifying a firm's resource mix and strategic practices, changing some of the underlying behaviors, dynamic capabilities indirectly contribute to enhancing the firm's competitive

position and performance over time. Teece (2007) highlights the foundational role of dynamic capabilities in gaining competitive advantages, particularly in rapidly changing environments, which underscores the importance of organizational agility, innovation, and adaptability in maintaining a competitive edge amidst evolving market dynamics. Wilden and Gudergan's study (2015) emphasize the dynamic capabilities have a significant positive effect on a firm's underlying performance, through effectively harnessing and deploying dynamic capabilities, organizations can enhance their operational efficiency, agility, and resilience, consequently leading to improved overall firm performance. Khalil and Belitski (2020) find that different information technology governance strategies, serving as dynamic capabilities, yield varying effects on firm performance.

Overall, the impact of dynamic capabilities primarily encompasses two dimensions: the effect on the organization's own performance and the influence on clients. Regarding the organization's performance, most studies indicate that enhancing dynamic capabilities facilitates continuous improvement and innovation through resource integration and reconfiguration, thereby leading to competitive advantages and enhanced performance. However, some research suggests that dynamic capabilities may not directly enhance firm performance but instead require intermediary variables to positively affect firm output and performance. In terms of the impact on customers, the majority of studies demonstrate that enhancing firm dynamic capabilities significantly contributes to client satisfaction and service experience.

## **2.2.2 Operational (Routine) Capabilities**

### **2.2.1.1 Concept and dimensions of Operational (Routine) Capabilities**

Strategic management researchers have employed various terms to describe capabilities, yet there is a consensus that capabilities are distinct from mere resources. Instead, they represent a unique and superior approach to allocating, coordinating, and deploying resources (Flynn et al., 2010). The capability of an enterprise pertains to the ability or utilizing a diverse array of resources effectively to attain specific objectives (Story et al., 2017). This notion of capabilities is categorized into two main types: Operational Capabilities and Dynamic Capabilities. Operational Capabilities are concerned with the day-to-day operations and resilience of the company, ensuring its continued functioning and survival. In contrast, Dynamic Capabilities focus on the organization's capacity to adapt and evolve its operational capabilities in response to changes in the environment (Markovich et al., 2021; Story et al., 2017).

As Flynn et al. (2010) pointed out, operational capabilities refer to the unique skill sets, operational processes, and established routines cultivated within a firm's operations management framework. These capabilities are consistently employed to address the challenges encountered by different units within the organization. They empower units, and by extension, the entire firm, to effectively allocate and utilize resources within the operations management system, thereby catering to specific requirements and overcoming distinctive challenges. It's essential to distinguish operational capabilities from related constructs such as resources and operational practices. Resources constitute the foundation of a firm, encompassing its capacity and all stocks, while operational practices are standardized activities, programs, or procedures designed to achieve specific operational goals. Operational capabilities encompass both explicit elements, such as, resources and operational practices, and tacit elements that are less visible, including know-how, skill sets, and leadership, utilized for problem-solving and dealing with uncertainty. In essence, operational capabilities leverage resources and operational practices to generate outcomes aligned with desired results, aiding the firm in generating solutions that “make sense”.

According to Wu et al. (2010), a theoretical framework is established for defining operational capabilities by synthesizing insights from strategic management and operations management literature, who differentiate operational capabilities from related concepts such as resources and operational practices, drawing on the resource-based view of the firm as guiding principle, highlighting the distinctive characteristics of operational capabilities, which confer a competitive advantage by creating barriers to imitation. Despite their strategic importance, operational capabilities pose challenges in measurement due to their gradual emergence and tacit nature, which vary across firms. To address this challenge, they draw on methodologies employed in previous research on organizational culture and dynamic capabilities by Schein (2004) and Eisenhardt and Martin (2000), respectively and identify six primary operational capabilities: operational improvement, operational innovation, operational customization, operational cooperation, operational responsiveness, and operational reconfiguration. To effectively measure each capability, they develop a comprehensive set of measurement scales validated through rigorous testing with two distinct datasets to ensure the reliability and validity of the measurement tools, enabling replication of results and enhancing confidence in the derived measures.

At the core of operations strategy lies the imperative to cultivate and uphold a sustainable competitive advantage. This strategic imperative draws from a complex interplay of organizational capabilities, practices, and resources. Seminal research in strategic management

has laid a solid theoretical groundwork, elucidating how a firm's sustainable competitive advantage stems from its unique and heterogeneous resource base. Concurrently, operations management scholars have extensively studied various operational practices geared towards enhancing performance. However, the conceptual landscape surrounding organizational capabilities remains contentious, with divergent views on its definition and scope. This ambiguity is compounded by inconsistent terminology, with terms like "capabilities," "resources," and "competencies" often used interchangeably. Wu et al. (2010) narrow the focus to operational capabilities, a subset within the broader realm of organizational capabilities and aim to provide clear delineations that distinguish operational capabilities from related constructs by establishing these boundaries, clarify the discourse surrounding operational capabilities and their role in driving competitive advantage.

Resource-based view (RBV) emphasizes the unique combination of resources and capabilities within a firm, with the potential for competitive advantage contingent upon their characteristics: namely, being valuable, rare, inimitable, and non-substitutable (Barney, 1995). Operational capabilities, in particular, hold significant relevance within RBV. These capabilities, rooted in a firm's internal resources, form the cornerstone of its strategy, not only serve as the primary source of profitability but also contribute to shaping the firm's identity and market positioning (Colotta et al., 2003).

Operational capabilities represent a hidden yet vital component in the quest for competitive advantage. Despite their crucial role, they often go unnoticed due to their deep integration within the operational framework of organizations. Decision-makers frequently direct their focus towards more tangible assets like resources and operational practices, overlooking the nuanced nature of operational capabilities. The confusion surrounding operational capabilities arises from their close alignment with resources and practices, blurring the distinctions between these concepts. Consequently, the impact of operational capabilities is often erroneously attributed to these more apparent elements. Gradually emerging and intricately linked with a firm's unique characteristics, operational capabilities tend to fade into the background. However, it's crucial to recognize that operational capabilities possess distinct attributes that set them apart and render them challenging to replicate. Their subtle yet significant influence creates a formidable barrier to imitation, thus positioning them as a potential source of sustainable competitive advantage. Research that establishes a robust theoretical foundation for operational capabilities is essential. Without a clear understanding of their role, there's a significant risk of overlooking a crucial aspect of the competitive advantage development process. Operational capabilities play a pivotal role in shaping how firms leverage their resources and practices to



gain a competitive edge. By delving deeper into the mechanisms through which operational capabilities contribute to competitive advantage, researchers can provide invaluable insights that enhance our comprehension of organizational performance and strategic management. Therefore, investing in research that elucidates the intricacies of operational capabilities is imperative for achieving a comprehensive understanding of the dynamics driving competitive advantage in today's complex business environment. Operational capabilities are considered to be a subset of the broader construct of organizational capabilities. The insights derived from research on organizational capabilities can be effectively applied to the study of operational capabilities. By recognizing the interconnectedness between these two constructs, researchers can leverage existing theoretical frameworks, empirical findings, and methodological approaches developed in the realm of organizational capabilities to enrich our understanding of operational capabilities. This integrated approach allows for a more holistic examination of how organizational dynamics, strategies, and structures influence the development, deployment, and impact of operational capabilities within firms. By bridging the gap between these related but distinct constructs, we can advance scholarship in both fields and generate actionable insights that inform strategic decision-making and organizational performance (Wu et al., 2010).

Researchers in operations management have been captivated by the Resource-Based View (RBV) and its potential implications for operations strategy, particularly regarding organizational capabilities. RBV's "introverted orientation" has been lauded for its ability to highlight the strategic significance of operations, which have often been overlooked in traditional strategic management literature (Pandza & Horsburgh et al., 2003). However, despite the attention paid to defining operational capabilities or outlining methods for their development, operations strategy research has largely neglected the processes enabling coordination, learning, and reconfiguration, essential components squarely within the domain of operations management (Teece, 2007). Operations management researchers have found the application of the organizational capabilities construct to operations strategy challenging: While acknowledging the importance of dynamic capacity accumulation, researchers have been hesitant to tackle the attributes of RBV that render it less operational, such as the idiosyncrasy, path dependency, and context dependency of capabilities. Although the dynamics of capacity accumulation have been acknowledged, they have not been thoroughly investigated (Pandza & Polajnar et al., 2003). In summary, while RBV offers valuable insights into the strategic importance of operations, operationalizing its concepts within operations management remains a complex task, requiring a deeper understanding of its nuances and implications for organizational capabilities.

The notion of organizational capabilities holds significant relevance for operations strategy, while resources serve as the fundamental building blocks of a plant, encompassing its capacity and inventory (Wang & Ahmed, 2007); On the other hand, operational practices, such as just-in-time activities, programs, and procedures, represent standardized approaches designed to achieve specific operational objectives (Flynn et al., 2010). Wu et al. (2010) also pointed out, operational capabilities serve as the cohesive force that unifies and directs both tangible resources and established operational practices within a firm, which encompass not only explicit components like resources and practices but also implicit elements such as expertise, skill sets, and leadership qualities, enabling the firm to navigate diverse challenges and uncertainties effectively, essentially, operational capabilities leverage resources and practices to achieve desired outcomes, facilitating the development of pragmatic solutions tailored to the firm's needs. Drawing insights from the organizational capabilities framework in strategic management, extending these principles to operations management, operational capabilities are defined as unique skill sets, processes, and routines cultivated within the operations system, regularly employed to address challenges and optimize the utilization of operational resources.

Operational capabilities are intricately intertwined with both resources and operational practices, posing challenges in their distinct identification. This interconnection often leads to their oversight, as managers and researchers may inadvertently conflate operational capabilities with resources or operational practices. For instance, while some scholars argue that "best practices" can be considered a form of capability (Eisenhardt & Martin, 2000; Lee & Kelley, 2008), others like Teece (2007) refute this notion, asserting that best practices alone may not confer sustainable competitive advantage. This disagreement underscores the complexity of delineating operational capabilities from other organizational elements. Furthermore, the development of operational capabilities is deeply influenced by a firm's culture, history, and the specific challenges it faces. Two dimensions of fit are particularly relevant: alignment with the organizational culture and historical context, and alignment with the specific problems that the firm aims to address.

Operational capabilities are defined as those capabilities through which a firm makes its living in the short term (Winter, 2003). Two crucial operational capabilities are marketing, which involve addressing customer needs, and technological capabilities which are essential for producing products or services. Marketing capabilities refer to the firm's ability to serve specific customer segments based on collective knowledge, skills, and resources related to market needs (Wilden & Gudergan, 2015), which represent a firm's outward-based competencies, enabling firms to connect with particular customer groups. On the other hand,



technological capabilities are competencies required by the firm to convert inputs into outputs. Technological Capabilities reflect the organizational capacity to employ technologies to convert inputs into outputs, which reflect the organizational capacity to utilize technologies for production. Measurement of technological capabilities typically includes factors such as an efficient production department, technological infrastructure, economies of scale, and technical experience (Mikalef et al., 2020; Wilden & Gudergan, 2015). The differentiation between operational and dynamic capabilities lies in their focus and time horizon. Operational capabilities allow firms to sustain their current living and generate revenue in the present, while dynamic capabilities enable firms to adapt and modify their capabilities in response to the changing external environment (Mikalef et al., 2020; Winter, 2003).

Teece et al. (2016) argued for a useful distinction between dynamic and “ordinary” capabilities. Ordinary capabilities enable the production and sale of a defined, static set of products and services. While organizations require access to such capabilities, they often do not need to possess or practice them in-house, as they can be outsourced. These capabilities stem from proficient utilization of the firm's human resources, assets, processes, and administrative systems, including the coordination necessary to integrate in-house and external resources. The strength of a firm's ordinary capabilities reflects its technical fitness, allowing it to complete defined tasks with some proficiency. However, ordinary capabilities may not enable organizational growth or creative responses to volatility or surprises (Teece et al., 2016).

Operational linkages among stakeholders plays a crucial role in enhancing the value derived from vertical stakeholder collaborations in new product development (NPD). Integrated systems, procedures, and routines facilitate the exchange of knowledge and experiences among stakeholders. The effectiveness of these operational linkages impacts firm innovativeness, influenced by factors such as resource ambiguity and the mechanisms of tacit knowledge. Stakeholder studies emphasize the operational connections between a firm and its various stakeholders in operational terms, highlighting the importance of close, cooperative relationships supported by coordinating systems and procedures, enabling effective knowledge exchange, enhancing the performance of collaborative engagements. Vertical collaborations for new product development often involve the exchange of resources, including technical and operational knowledge to implement NPD processes. Research by Ozdemir et al. (2020) demonstrates that operational linkages serve formal mechanisms for bonding vertical stakeholders, moderating the impact of vertical stakeholder collaborations on firm innovativeness. Through integrated systems, procedures, and routines, firms facilitate the exchange of knowledge and experiences among stakeholders (Karatzas et al., 2016). From a

stakeholder view, operational linkages not only facilitate knowledge sharing and exchange but also mitigate conflicting goals and interests among stakeholders (Karatzas et al., 2016). These linkages ensure continuity of communication and interactions, leading to more mutually beneficial outcomes in NPD collaborations compared to arm's-length relationships or those driven solely by mutual trust. Overall, operational linkages enhance the power, legitimacy, and urgency of vertical stakeholder collaborations in NPD. The findings underscore the significant role of operational linkages as formal mechanisms for bonding stakeholders, thereby improving firm innovativeness in vertical collaborations for NPD initiatives (Ozdemir et al., 2020).

He-Boong (2022) pointed out that operations capabilities, regarded as a fundamental strength rooted in efficiency-driven best practices, empower firms to continuously enhance their performance by excelling in routine operations and business procedures. Focused on achieving managerial proficiency, operations capabilities involve leveraging existing resources to drive incremental improvements and benchmarking practices (Krasnikov & Jayachandran, 2008; Yu et al., 2018). Consequently, operations capabilities play a pivotal role in augmenting a firm's managerial competency, particularly in optimizing short-term profitability through coordinated cross-functional efforts (Saunila et al., 2020).

Saunila et al. (2020) also emphasize the significance of various resources and practices, particularly human capabilities, time management capabilities, and financing capabilities, as precursors to operational capabilities. These capabilities encompass a collection of interconnected routines that transform into capabilities when effectively utilized (Teece et al., 1997). Human capabilities entail the commitment of labor to effectively execute firm processes, necessitating the utilization of specialized skills, knowledge, communication, and motivation (Wu et al., 2010). This ensures that employees' behavior aligns with the desired attitudes conducive to operational advancement. Time management capabilities involve the efficient allocation of time for the development of operations, decision-making processes, and analysis of productivity measurement outcomes (De Toni & Antonella, 2000). Saunila et al. (2020) developed a novel scale to assess preceding operational capabilities, comprising three main components: human capabilities, time management capabilities, and financing capabilities. Human capabilities, characterized by the commitment of labor to effectively carry out firm processes, were gauged using a three-item scale capturing the attitudes of different personnel groups within the firm towards operational development; Time management capabilities were evaluated through a four-item scale assessing the adequacy of time allocated for tasks related to operations management; The financing capabilities scale included three new items designed to measure the availability and allocation of financial resources for operational development.

### **2.2.1.2 Impacts of Operational (Routine) Capabilities**

The correlation between Operational (Routine) Capabilities and performance outcomes has been extensively examined in previous literature. For instance, He-Boong (2022) highlighted the distinction between Operational (Routine) Capabilities and Dynamic Capabilities, attributing them to two separate sources, that were Operational (Routine) Capabilities are driven by efficiency-focused best-practice operations, while Dynamic Capabilities stem from learning and adaptation to change. Compared to Dynamic Capabilities, Operations (Routine) Capabilities, which allowed businesses to improve their management proficiency in clearly defined tasks and operations. From this point of view, unlike Dynamic Capabilities, Operations (Routine) Capabilities, was the essence of competency to maintain the stability of ongoing operations and the proficiency in managing static resources (Laaksonen & Peltoniemi, 2016; Schilke et al., 2018; Yu et al., 2018). Additionally, Ahmed et al. (2014) emphasized that Operational (Routine) Capabilities form the necessary foundation of an organization's ecosystem, regardless of economic conditions, Operational (Routine) Capabilities could greatly impact short-term performance. Song and Liao (2019), as well as Laaksonen and Peltoniemi (2016) pointed out that the impact of Operational (Routine) Capabilities on short-term performance was more pronounced, especially in the short-term performance based on returns. Mikalefet al (2020) demonstrated that Operational (Routine) Capabilities had a positive impact on performance. He-Boong (2022) noted from empirical evidence showed that Operational (Routine) Capabilities had a significant positive impacted on firm performance.

Innovation and novel operational approaches are essential drivers of economic growth, leading to advancements in products, services, and processes (Peng et al., 2008). A significant area of focus lies in understanding how operational capabilities contribute to enhancing innovation performance and productivity (Mazzucato, 2013). Despite the widespread acknowledgment of the importance of operational capabilities in achieving competitive success, there exists a tendency to use terms capabilities (Eisenhardt & Martin, 2000; Lee & Kelley, 2008), resources (Tu et al., 2006), and best practices (Maire et al., 2005) interchangeably, despite their distinct meanings (Flynn et al., 2010). Operational capabilities leverage resources and operational practices to yield outcomes aligned with desired objectives (Flynn et al., 2010; Wu et al., 2010).

As Teece et al. (1997) introduced, firms typically possess two sets of capabilities: one set of capabilities focuses on converting inputs into outputs, while the other set of capabilities pertains to modifying the capabilities of other firms. The former set, known as operational

capabilities, which remains static in the sense that they cannot change by their own and influences to change by other external capabilities (Dangol & Kos, 2014). Given the static nature of operational capabilities and inability to change by their own, there arises a necessity to identify additional types of capabilities that facilitate the integration, reconfiguration, and updating of existing operational capabilities to adapt to environmental changes (Dangol & Kos, 2014). Operational capabilities are directly involved with firm performance (Dangol & Kos, 2014; Helfat & Winter, 2011).

### **2.2.3 Differentiation between Dynamic capabilities and Operational capabilities**

Some literature suggested dynamic capabilities are responsible for instigating changes in other firm capabilities, while operational capabilities are viewed as static. However, Dangol (2014) mentioned this rigid distinction may not be entirely accurate, as all capabilities undergo some degree of change over time. Empirical evidence also demonstrates that even task-level operational capabilities can undergo autonomous changes and influence other capabilities. Instead of solely focusing on whether a capability undergoes change to classify it as dynamic or operational, a different approach is proposed to suggest categorizing capabilities based on the expected nature of their outcomes. Operational capabilities are those that yield predictable outcomes, while dynamic capabilities produce unpredictable outcomes, by shifting the focus to the outcomes of change rather than the changes themselves, offers a more nuanced understanding of capabilities. The dynamic capability framework posits that a firm's operational capabilities and resources directly contribute to firm performance by converting inputs into outputs. However, other studies argued dynamic capabilities play an indirect role in influencing firm performance by updating, integrating, and reconfiguring a firm's existing operational capabilities and resources (Helfat & Winter, 2011; Winter, 2003). Despite the assumption that dynamic and operational capabilities are distinct constructs, some literature has not fully distinguished between them.

The dynamic capability framework hinges on the assumption that firms possess both dynamic and operational capabilities. Yet, without a clear understanding of what distinguishes these capabilities, the literature on dynamic capabilities cannot advance significantly. This distinction is crucial for several reasons. Firstly, without clarity, different scholars may categorize the same capability differently. For instance, Wu et al. (2010) define certain capabilities as operational, while Helfat and Winter (2011) classify them as dynamic. Similarly, Eisenhardt and Martin (2000) view best practices as dynamic capabilities, whereas Teece (2009) disagrees. This lack of consensus hinders progress in the field (Teece et al., 2016). Secondly,

understanding the mechanism by which dynamic capabilities influence operational capabilities and firm performance requires a clear distinction between them. Dynamic capabilities are often associated with change, while operational capabilities are considered static. However, empirical evidence challenges this notion, showing that operational capabilities can indeed change independently and influence other firm capabilities. For instance, studies demonstrate that operational capabilities can autonomously change and affect other capabilities within a firm. Helfat and Winter (2011) also acknowledge the limitations of the traditional zero-order concept in distinguishing between dynamic and operational capabilities, suggesting that change is inherent in all capabilities to some extent. Therefore, there is a need for a framework that goes beyond the traditional dichotomy to accurately distinguish between dynamic capabilities and operational capabilities.

Since the publication of Teece's seminal work, dynamic capabilities research has evolved into two distinct streams. The first stream explores how firms utilize their dynamic capabilities to reconfigure, build, and integrate zero-order operational capabilities (Teece et al., 1997; Winter, 2003; Zollo & Winter, 2002). In contrast, the second stream of literature delves into how firms leverage their dynamic capabilities to reconfigure both tangible and intangible resources (Eisenhardt & Martin, 2000). The first stream of literature posits that firms possess interconnected higher and lower-level capabilities. In this conceptualization, dynamic capabilities are regarded as higher-level capabilities, whereas zero-order operational capabilities are seen as lower-level capabilities. Unlike zero-order operational capabilities, a firm's dynamic capabilities are not directly engaged in the process of converting inputs into outputs (Teece et al., 1997; Winter, 2003; Zollo & Winter, 2002). Instead, they serve to assist a firm in adapting to changes in the external environment by fostering the creation of new capabilities and resources (Teece et al., 1997). Previous dynamic capability literature classifies any capability that can change a firm's existing capabilities and/or create new capabilities as dynamic (Helfat & Winter, 2011; Winter, 2003). Thus, the dynamic capability framework relies on the concept of the zero-order condition to distinguish dynamic capabilities from operational capabilities. On the other hand, the second stream of literature focuses on how a firm utilizes its dynamic capabilities to reconfigure its zero-order resources in response to changes in the external environment. A firm's resources are zero-order because they are unable to change autonomously or influence other resources, hence, dynamic capabilities are essential for configuring and reconfiguring both tangible and intangible resources of a firm to produce goods and services that align with evolving customer demands. Eisenhardt and Martin (2000) further argue that a firm achieves resource reconfiguration by acquiring new resources.

Despite many years of strategic management research on dynamic capabilities, critical conceptual issues persist, one significant, unresolved matter that research has yet to adequately address concerns the differentiation between dynamic and operational (or ordinary) capabilities. Particularly, there is often a perspective that capabilities are considered dynamic only if they facilitate substantial changes within a short timeframe, and this perspective may stem from a desire to establish a clear distinction between dynamic capabilities and operational capabilities (Helfat & Winter, 2011). The line between operational capabilities and dynamic capabilities often blurs due to several factors, including the existence of dual-purpose and multiple-variant capabilities.

Organizations leverage dynamic capabilities to adapt and evolve their operations in various ways. This adaptation may involve modifying operational capabilities, as highlighted by Winter (2003), or adjusting the organization's resource base, as conceptualized by Helfat et al. (2015) to encompass the resources utilized by firms to conduct their activities. Additionally, dynamic capabilities can extend to influencing features of the external environment or ecosystem, as proposed by Teece (2007). The term "dynamic capability" implies consistent and patterned behavior within the organization, as emphasized by Winter (2003) and Helfat et al. (2015). Notable examples of dynamic capabilities include those facilitating acquisitions, alliances, and collaborated new product development, all of which fundamentally alter the firm's methods of generating revenue. These dynamic capabilities serve specific purposes and support distinct activities, as outlined by various scholars (Eisenhardt & Martin, 2000; Helfat & Peteraf, 2015). While some may use the term "dynamic capabilities" more broadly to denote a general capacity for change, there is a concern that such broad usage may dilute its significance and specificity, ultimately rendering the concept less meaningful. Helfat & Winter (2011) thought that distinguishing between dynamic and operational capabilities proves challenging due to several factors: Firstly, change is a constant occurrence across all capabilities, albeit to varying extents, making it difficult to categorize them definitively; Secondly, differentiating between dynamic and operational capabilities based on their support for radical versus non-radical change, or their application to new versus existing businesses, is not always straightforward; Lastly, certain capabilities can serve dual purposes, being utilized for both operational and dynamic objectives. These complexities blur the line between dynamic and operational capabilities, highlighting the need for a nuanced understanding of their characteristics and functionalities. In summary, distinguishing between dynamic and operational capabilities remains challenging due to the ever-changing nature of the business environment. Here are general suggestions for research on dynamic capabilities, on one hand, utilizing categories of capabilities judiciously



with regard to change, recognizing that capabilities enabling economically significant change should be considered dynamic, even if the pace of change appears slow; on the other hand, acknowledging operational capabilities that serve primarily operational purposes, and giving attention to dual-purpose and multiple-variant capabilities that serve both operational capabilities and dynamic objectives, including non-radical change, ongoing businesses, and relatively placid external environments in research, understanding that dynamic capabilities are not limited to new-to-the-world businesses or fast-paced environments. Many dynamic capabilities support existing businesses and can lead to significant outcomes even in relatively stable external environments (Helfat & Winter, 2011). Overall, researchers should approach the study of operational capabilities and dynamic capabilities with a nuanced understanding of the factors influencing change and outcomes in various business contexts.

## **2.3 Organization Innovativeness**

Organizations striving for competitive advantage must prioritize innovation by developing new products, processes, marketing strategies, and organizational methods. Central to become innovative, the development and improvement of the cultivation and enhancement of innovation capability is needed, which involves managing creativity and resources effectively. Managing creativity and capabilities, including innovation capability, is fundamental to fostering an innovative organizational culture (Saunila & Ukko, 2012). Innovation capability can be defined as “a firm's ability to apply the collective knowledge, skills, and resources to innovation activities relating to new products, processes, services, or management, marketing or work organization systems, in order to create added value for the firm or its stakeholders” (Hogan et al., 2011). However, despite the significance of innovation capability, measuring it accurately poses challenges due to the broad and intangible nature of innovative activities. The measurement of innovation capability is further complicated by the continuous and gradual nature of the innovation process (Eggink, 2012). In the literature, innovation capability is a recurrent theme, but the development of measurement scales and models has been limited. This limitation stems from the inherent difficulty in quantifying innovation, given its multifaceted and evolving nature. Moreover, terms such as innovation performance, innovation capacity, innovative capability, innovativeness, organizational innovation, and innovation are often used interchangeably, adding to the complexity of understanding and measuring innovation-related constructs (Hogan et al., 2011).

Edison et al. (2013) proposed a comprehensive approach to innovation measurement which

comprised three main components: innovation capability, innovation output, and innovation performance. In their framework, innovation capability encompasses various aspects such as innovation inputs, determinants, and activities; On the other hand, innovation output refers to the tangible results or outcomes of innovation efforts, including different types of innovations. Distinguishing between innovation capability and output, while innovation capability focuses on the organization's capacity to innovate, innovation output pertains to the actual outcomes or products resulting from innovation activities. They suggest that measuring innovation capability involves assessing its impacts and effectiveness in driving innovation within the organization. Moreover, Saunila and Ukko (2012) adopt a broader perspective that encompasses all elements influencing an organization's capability to manage innovation, including the outcomes of innovation activities.

Innovativeness is defined by Wang and Ahmed (2013) as organizational innovativeness and as an organization's overall innovative capability of introducing new products to the market or explore new markets by combining strategic orientation with innovative behavior and processes. They used the terms innovativeness and innovation capability synonymously and interchangeably. Calik et al. (2017) addressed this confusion by using items to measure innovation capacity which was incorporated into the item pool and considered as a component of innovation capability in the model. These measurement items were categorized as product, process, organizational, marketing, resource, and culture. Measuring innovation capability posed challenges due to the intangible nature of innovation and difficulty of adequately capturing it. This challenge is exacerbated by the interchangeable use of terms such as innovation capability and related concepts in the literature, leading to confusion in defining and measuring innovation capability. To address this confusion, Calik et al. (2017) developed a literature-based model and a corresponding scale for measuring innovation capability. They conducted a comprehensive review of existing literature to propose a model and generate measurement items used in prior studies, aiming to provide clarity in this area. Calik et al. (2017) emphasized the importance of adopting Potential and process focused measurements of innovativeness rather than solely focusing on outcomes. This shift was motivated by the tendency in the literature to prioritize innovation performance, which can contribute to measurement confusion by not distinguishing the distinction between innovation capability and performance. Eggink (2012) emphasized that capabilities of the system were crucial qualifications that facilitate innovation, underscoring the importance of organizational capabilities in driving innovative processes. Additionally, measuring outputs of the system was suitable for only certain types of innovations, and traditional outcome-focused approaches



might not capture the full spectrum of innovation (Saunila & Ukko, 2012). The model should include more than one dimension. Inconsistency also occurs in defining and distinguishing dimensions of innovation that reflects dimensions of innovation capability. To adequately capture the complexity of innovation, a multidimensional model is necessary. For example, Wang and Ahmed (2013) proposed a multidimensional framework comprising five dimensions of innovativeness: product innovativeness, market innovativeness, process innovativeness, behavioral innovativeness, and strategic innovativeness. Innovation capability, inherently supports a multidimensional construct (Hogan et al., 2011), due to measurement of it was difficult to be directly conceivable (Saunila & Ukko, 2012).

In assessing innovation, two key aspects are taken into consideration based on the literature review: potential and process. The potential aspect encompasses innovation resources and culture. Innovation resources encompass elements such as R&D personnel, R&D budget, equipment, training. On the other hand, innovation culture refers to organizational attitude, beliefs, approaches, and commitments towards innovation. Additionally, innovation culture can significantly influence the availability of innovation resources and the execution of activities within the organization. Simultaneously, the process aspect comprises four distinct types of innovation, each consisting of three phases: research, development, and commercialization or exploitation (Com/Exp), as Figure 2.1. These phases represent the sequential stages through which innovative ideas progress from conceptualization to realization and ultimately to market utilization.

Wang and Ahmed (2013) employed perceptual items to measure innovativeness. The choice of using perceptual questions for measuring innovation capability is deemed more appropriate due to the input and process-oriented nature of innovation capability. It's crucial to note that questions can be framed either perceptually or numerically, with perceptual questions focusing on subjective assessments while numerical questions involve quantitative measurements. Calik et al. (2017) concentrated solely on perceptual questions and did not include numerical questions into the item pool. Additionally, there are assumptions regarding the inclusion or exclusion of items used to measure innovation capability, innovative capability, and innovativeness. These terms are often used interchangeably by authors, further complicating the distinction between them. For instance, innovativeness was defined by Wang and Ahmed (2013) as organizational innovativeness which encompasses an organization's overall innovative capability in introducing new products to the market or initiate new markets, by integrating strategic orientation with innovative behavior and process, used innovativeness and innovation capability synonymously and interchangeably.

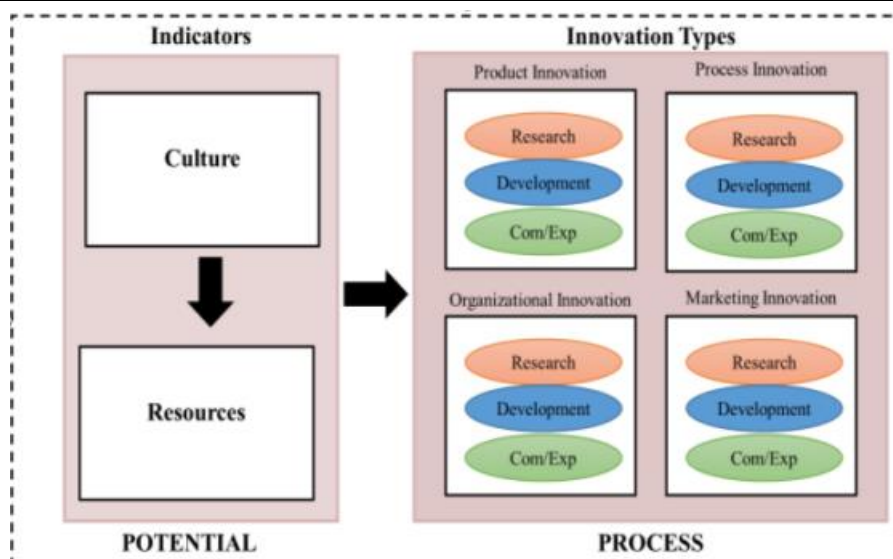


Figure 2.1 Innovation type and process

Source: Calik et al. (2017)

Innovativeness is defined as the capacity of an organization to introduce new process, product, or idea (Hurley & Hult, 1998). These innovations could encompass new products or service, new production processes, or innovative administrative systems or structures. Unlike entrepreneurial orientation, innovativeness does not necessarily entail entering new markets. A crucial aspect of an organization's innovativeness lies in its ability to acquire and utilize market intelligence effectively. Responsive organizations actively engage with market insights and adapt their strategies accordingly. Conversely, organizations lacking in innovativeness may invest resources in market analysis but struggle to translate this knowledge into actionable strategies and innovations. The essential factors contributing to innovativeness include market orientation, learning orientation, and entrepreneurial orientation. Scholars have underscored the significance of market orientation as well as learning orientation in fostering competitive advantages (Hult et al., 2004).

Early pioneers in organizational theory, such as Drucker (1954), recognized the significance of innovativeness, yet noted its underrepresentation in research. Hurley and Hult (1998) viewed firm innovativeness as a collective perspective rooted in the organizational culture's openness to new ideas. They conceptualize the innovativeness from two perspectives: as a behavioral variable, reflecting the rate of adoption of innovations, and as an organization's willingness to embrace change (Calantone et al., 2002).

In current turbulent environment, fostering product innovativeness is crucial for organizations to adapt to changes and maintain competitive advantage by expanding and enhancing market opportunities (Rubera & Kirca, 2012). Firm-level product innovativeness is often assessed based on two key indicators: newness and meaningfulness (Stock, 2014).

Newness refers to the degree of novelty exhibited by a product, with some studies emphasizing its significance from a market perspective, measuring the extent to which a firm's offerings differ from competing alternatives (Chen et al., 2022; Ni et al., 2017; Yuan & Chen, 2015). It's essential to distinguish between innovation and innovativeness: while innovation reflects a firm's orientation toward and propensity for innovation, innovativeness refers to a measurable aspect of this orientation, specifically the level of novelty and distinctiveness of a firm's products and services (Chen et al., 2022).

Firm innovativeness, on the other hand, pertains to an organization's overall capability to proactively explore new opportunities rather than solely relying on existing strengths (Menguc & Auh, 2006). Ozdemir et al. (2020) utilized a set of six items to gauge the extent to which organizations seek innovative ideas, experiment with new concepts, and explore novel approaches to problem-solving. These items provide insights into the organization's proactive stance towards innovation and its willingness to embrace change and experimentation. Furthermore, innovation processes can be viewed as a series of coordinated tasks aimed at achieving a specific outcome, whether it be the development of a new product, service, or technology (Garcia & Calantone, 2002). In the competitive landscape of today's rapidly evolving markets, innovative enterprises are driven by a constant pursuit of differentiation and value creation and seek to adapt to dynamic market conditions grounded on newness (Boly et al., 2014).

Product Innovativeness has garnered considerable attention and can be described as the degree of uniqueness or novelty perceived by customer and encompasses the radicalness, uniqueness, and meaningfulness of a new product, and is often divided into two main dimensions: technological innovativeness and market innovativeness (Ding & Ding, 2022). Technological innovativeness refers to the incorporation of new and advanced technologies embedded in the new product (Sethi et al., 2012). Innovative products with substantial technological differences from existing ones are perceived to offer higher quality and value to customers. By adopting advanced technologies, new ventures can enhance the performance of their products, thereby better serving existing or mainstream customer needs. On the other hand, market innovativeness relates to ability of a new product to target new markets or offer new functionalities, which focuses on providing new customer value, even without significant changes in core technology. Market innovativeness can lead to the creation of new market categories or segments, offering benefits that were previously unmet by competitors' products. Moreover, it can establish first-mover advantages, making it difficult for competitors to enter the market with similar offerings (Talke et al., 2011). Both technological and market

innovativeness contribute to enhancing customer benefits compared to existing products (Ding & Ding, 2022; Troilo et al., 2014). The classification of Product Innovativeness (PI) into these dimensions aligns with the well-established logics of New Product Development (NPD), namely technological push or market pull (Godin & Lane, 2013).

Over time, various methods have been proposed to assess product innovativeness, reflecting its degree of novelty and originality (Chen et al., 2022). Booz et al (1982) introduced a dual-dimensions approach, considering: “Newness to the Market” and “Newness to the Company”, categorizing new products into four levels of innovativeness: new-to-the-world products, new product lines to the firm, additions to an existing line, and product improvement. Kleinschmidt and Cooper (1991) simplified product innovativeness into three categories: low, moderate, and high innovativeness, based on their impact on performance. Garcia and Calantone (2002) further refined this classification into three degrees: radical, really new, and incremental, based on macro and micro levels of novelty and whether it pertains to technology or marketing. Zastempowski (2022) emphasizes the complexity of product innovativeness, influenced by a range of factors at both micro and macro levels (Stahl et al., 2023; Zastempowski, 2022).

Innovation can be conceptualized in two main ways: as a process and as an outcome (Jiménez-Jiménez & Sanz-Valle, 2011; Saunila et al., 2020). Broadly, innovation entails the generation and application of creative ideas in various domains such as products, processes, services, and organizational structures. In this context, innovation performance refers to the achievement of successful outcomes resulting from various inputs dedicated to innovation creation. These inputs can be either tangible, such as resources like human capital, financial investments, time, and equipment, or intangible, including factors like motivation, knowledge, and organizational culture. Studies by Saunila support these findings, emphasizing the significance of management structures, employee roles, attitudes, and adaptability to changing environments in driving innovation. Therefore, innovation performance encompasses the effective implementation of employees' ideas, external knowledge, and emerging technologies, along with the organization's capacity for internal renewal and adaptation. Innovation performance was assessed using a set of five items focused on various aspects: idea generation, technology investments, exploitation of external information, ability to renew, and changes in operations (Saunila et al., 2020).

## 2.4 Project Performance Outcomes and Relational Performance

Butler et al. (2020) characterized projects as the “temporary organizations within organizations,” discussed and measured the project outcomes and project success, and emphasizing the importance of aligning project management approaches with project characteristics to influence outcomes. Some research showed that various project management tools and practices were used to cope with different levels of project uncertainty and complexity, specifically, complex projects tended to achieve greater outcome success when managed with a plan-based approach, while dynamic projects would yield greater project outcome success when managed with an agility-based approach. Project outcome success was defined by the extent to which a project met established goals such as requirements, schedule, budget, quality, and productivity, and focused on two broad and commonly used approaches to managing projects—plan-based and agility-based. The plan-based project management approach involved detailed planning, formal cost and schedule estimates, well-defined change management processes, monitoring and measurement procedures, and command-control leadership styles (PMI, 2021). While the agility-based project management approach emphasized adaptation to changing project conditions, shorter planning cycles, quality control through regular reviews, and a collaborative leadership style (Wysocki, 2009). Expanding project scope and increasing requirements, could negatively impact project performance outcome by extending project completion time (Griffin, 1997). Additionally, project dynamism was negatively related to project outcome success, and the agility-based project management approach moderated the relationship between project dynamism and project outcome success (Butler et al., 2020).

Project outcomes are influenced by the complex interrelationships and interactions among many factors, recognizing this complexity, some scholars advocate for adopting a contingency approach to manage such projects (Barlow et al., 2011). Project management approaches can be categorized along a spectrum from plan-driven to change-driven project life cycles. The plan-driven, or plan-based, approach involves detailed upfront planning, formal change management processes, and a command-and-control management style. On the other hand, the change-driven, or agility-based, approach emphasizes adaptive life cycles, incremental requirements, and collaborative decision-making. While some may see project management approaches as either strictly plan-based or agile-based, it's important to acknowledge a continuum between the two, with organizations often blending elements of both to suit their specific needs (Cobb, 2011).

As outlined by Shi and Liao (2013), the performance was conceptualized with two constructs of operational performance and relational performance, which represented the two main outcomes of supply chains. Operational performance pertains to the outcomes of business operations, including reduced operational costs, lead-time, cycle time, as well as the increased quality, on-time delivery, and quick responsiveness to markets and customer needs; On the other hand, relational performance focuses on the partner's satisfaction, commitment and continuity of the relationship between partners within the supply chain, which is characterized by partners' confidence in their relationships, satisfaction with current partnerships, and their commitment to maintaining and continuing these relationships into the future (Shi & Liao, 2013). Shi and Liao (2013) conducted an empirical investigation into the mediating role of interfirm business process integration and interfirm joint teamwork on the relationship between strategic interdependence, resource complementary, and both operational performance and relational performance. The research model is grounded in the theoretical perspectives of the resource-based view, resource dependence theory, and the relational view, and the empirical findings reveal that interfirm business process integration significantly mediates firm performance, however, interfirm joint teamwork only partially mediates the impact of resource complementary. Specifically, while resource complementary directly influences the relational performance of focal firms, it also indirectly affects relational performance through the mediating effect of interfirm joint teamwork.

The relational view, as proposed by Dyer and Singh (1998), provides a theoretical framework for leveraging interfirm relational resources to achieve competitive advantage. Within this perspective, we conceptualize strategic interdependence as a valuable supply chain resource for several reasons: Firstly, interdependence serves as an exchange tie cultivated through positive exchange experiences, fostering strong bonds between partners and shaping supply chain relationships, consequently, partners can leverage unique or relation-specific assets, such as the exchange of proprietary information, knowledge, and technical expertise (both tacit and sticky resources); Secondly, interdependence plays a crucial role in generating relational rents by reducing negotiation and transaction costs, enhancing the efficiency of just-in-time operations, and enabling swift responses to market and consumer demands (Hult et al., 2007). Acknowledging the significance of relational resources and the collaborative benefits inherent in supply chains, firms proactively form alliances with both upstream and downstream partners.

Drawing upon the extended Resource-Based View (RBV) and empirical research on resource complementarity within alliances, we define resource complementarity as the



heterogeneous resources pooled from supply chain partners. These resources, which are both available and complementary, enable partners to share, explore, and generate synergistic value beyond what they could achieve individually (Richey et al., 2010). Choi and Beamish (2013), for instance, explored the synergy effect of resource complementarity in joint ventures, highlighting the substantial impact of both local and technology-related resources from developed markets on joint ventures performance, indicating their complementary nature. This understanding can be extrapolated to supply chains, where they function as efficient alliance structures for firms to access complementary resources embedded within the network. Within supply chains, resource complementarity can enhance firm performance through interfirm business process integration among partners, leading to synergy effects in two main ways: Firstly, by pooling valuable, rare, imperfect, and imitable resources from partners through cooperative interactions, firms can expand their total pool of resources. Secondly, firms can enhance their operational and technological capabilities, thus improving dynamic competence and leveraging cooperative advantages inherited within supply chains (Richey et al., 2010). Consequently, resource complementarity fosters business process integration among supply chain partners, facilitating the exploration of expanded resource pools, the capitalization of resource value, and the attainment of improved firm performance (Lin et al., 2009).

Lin (2019)'s study reveals that collaboration diversity, knowledge accumulation, and collaboration ambition contribute to enhanced firm performance, whereas the sheer quantity of collaborations has a lesser impact on performance, moreover, the collaboration ambition moderates the positive influence of the number of collaborations on firm performance. In pharmaceutical industry, the impact of scientific collaboration on firms' innovation performance has garnered significant attention in the previous literature (J. Y. Lin, 2019; Yang et al., 2022). However, consensus remains elusive, some studies suggest that scientific collaboration can enhance firms' problem-solving capabilities, facilitate interactive learning, and provide access to specialized expertise, thus boosting innovation performance (Kafouros et al., 2015). Conversely, other research argues that collaboration introduces coordination and monitoring challenges due to cognitive disparities, conflicting incentives, and divergent objectives between firms and partners. Prior research has highlighted that actors' characteristics and network attributes are crucial determinants of pharmaceutical firms' innovation performance, specifically, factors like the number of partners, collaboration diversity, network breadth, and network strength play pivotal roles in enhancing innovation performance (Wang & Jiao, 2022).

Furthermore, there is significant influence of network positions within technical collaborative networks and strategic alliances on firms' innovation performance. According to

Wang et al. (2015), their study results demonstrate that network centrality has a positive effect on organizational innovation and organization performance. Moreover, they found that the influence of network centrality on organizational innovation is more pronounced for small organizations, whereas its impact on organizational performance is stronger for large organizations. Additionally, they observed that the effect of network centrality on overall organizational innovation and organization performance is heightened for organizations operating within developed institutional environments and in knowledge-intensive industries. Mckelvey and Rake (2016) highlighted that the number of partners within the scientific network of pharmaceutical firms plays a role in enhancing product innovation performance. In addition to highlighting the positive role of the partners in promoting product innovation performance, Mckelvey and Rake (2016) also identified two disadvantages associated with pharmaceutical firms occupying a high degree centrality in scientific collaboration networks. Firstly, as the degree centrality increases, pharmaceutical firms accumulate more ties within these networks, leading to a deluge of information and knowledge. This abundance can impede the timely and effective processing of information and absorption of knowledge, potentially overwhelming firms and resulting in poorer technological performance. Secondly, attaining and sustaining high centrality levels escalates collaboration management costs and presents significant challenges to firms' absorption capacity due to the cognitive gap between firms and other partners. Consequently, it becomes a considerable expense for pharmaceutical firms. Failure to effectively absorb or integrate acquired scientific knowledge into their existing technical knowledge may result in wasted resources. Therefore, excessively high network centrality might have adverse effects on the innovation performance of pharmaceutical firms. In summary, prior studies have acknowledged the significance of scientific knowledge and scientific collaboration in influencing the innovation and performance of pharmaceutical firms from various aspects (Wang & Jiao, 2022).



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## Chapter 3: Theoretical Frameworks and Research Hypotheses

Based on the literature review, this chapter established the research theoretical frameworks as below (Figure 3.1), that include two independent variables (CRO Engagement and Pharmaceutical Client Engagement), two intermediary variables (Dynamic capability and Operational (Routine) capability), as well as three dependent variables of the outcomes (Innovativeness, Project Performance Outcomes and Relational Performance).

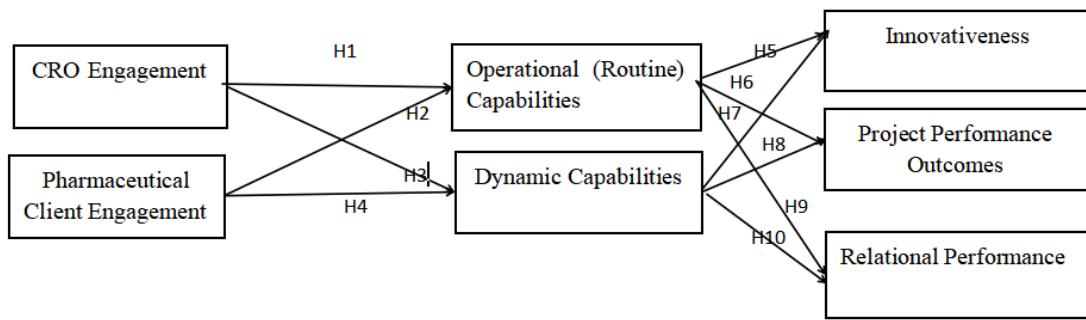


Figure 3.1 Theoretical Frameworks

And the following hypothesis were proposed,

1. The relationship between the main and vertical stakeholders engagement in the value chain and Operational (Routine) Capabilities, including:

Hypotheses 1 (H1), Operational (Routine) Capabilities is positively related to CRO Engagement.

Hypotheses 2 (H2), Operational (Routine) Capabilities is positively related to Pharmaceutical Client Engagement.

2. The relationship between the main and vertical stakeholders engagement in the value chain and Dynamic Capabilities, including:

Hypotheses 3 (H3), Dynamic Capabilities is positively related to CRO Engagement.

Hypotheses 4 (H4), Dynamic Capabilities is positively related to Pharmaceutical Client Engagement.

3. The relationship between Operational (Routine) Capabilities and Innovativeness as well as project outcomes, including:

Hypotheses 5 (H5), Innovativeness is positively related to Operational (Routine) Capabilities.

Hypotheses 6 (H6), Project Performance Outcomes is positively related to Operational

#### (Routine) Capabilities

Hypotheses 7 (H7), Relational Performance is positively related to Operational (Routine) Capabilities.

4. The relationship between Dynamic Capabilities and Innovativeness as well as project outcomes, including:

Hypotheses 8 (H8), Innovativeness is positively related to Dynamic Capabilities.

Hypotheses 9 (H9), Project Performance Outcomes is positively related to Dynamic Capabilities.

Hypotheses 10 (H10), Relational Performance is positively related to Dynamic Capabilities.

## **Chapter 4: Research Method**

This chapter discusses the research methods and processes used in this study. The previous chapters have explained the research model, definitions, and dimensions of variables. The main sections of this chapter include research methodology employed in this study (section 4.1), process and pilot sample used in developing variable measures and questionnaire (section 4.2), measurement validation and modification using a pilot sample (section 4.3), the final study sample data characteristics and collection procedure (section 4.4), and the analysis method structural equation model evaluation criteria (section 4.5). This study mainly used questionnaire survey data collection method. Survey respondents are project team members who had participated in R&D cooperation projects between CROs and pharmaceutical companies. The variables measured and tested in the research model CRO Engagement, Pharmaceutical Client Engagement, Operational (Routine) Capabilities, Dynamic Capabilities, Innovativeness, Project Performance Outcome, and Relational Performance.

Based on the constructed theoretical model and the definition of the studied variables, the variables were measured using items adapted from the existing literature. Q-sorting and interviews with CRO project subject matter experts were conducted to ensure the face or content validity of the measurement items. An initial questionnaire was pre-tested and further improved with CRO project subject matter experts. A pilot sample was then collected and used to validate and modify the measures based on initial reliability and validity tests. Finally, the validated questionnaire was used to collect the large survey data sample for this study. IBM SPSS 25.0 software and SMART PLS 4.0 software are used to perform descriptive statistical analysis, reliability analysis, validity analysis, exploratory factor analysis, and structural equation model testing.

### **4.1 Overview of Research Methodology**

This study employed various research methods such as literature review analysis, expert consultation, questionnaire survey and structural equation modelling (SEM) to assess and evaluate the relationship and impact of CRO Engagement, Pharmaceutical Client Engagement, Operational (Routine) Capabilities, Dynamic Capabilities, Innovativeness, Project Performance Outcome and Relational Performance.

#### 4.1.1 Literature review method

Literature **review** is a method to study the collected literature in a certain area to find out the nature and condition of the object of study and position a study in relation to the literature. It can help researchers to form a general grasp of the research domain, understand the history of the research, what and what has not been examined, and define the contributions of a study in the context of the literature. Literature review is short for comprehensive review of previous literature, which refers to a systematic and comprehensive description and review of the research results and progress of a certain discipline or topic within a certain period by means of induction, analysis and identification based on a collection of relevant literature. There are two types of literature review: comprehensive literature review and thematic literature review. A comprehensive review is specific to a particular discipline or major, while a thematic review is specific to a research question or research method or approach. The literature review is characterized by an in-depth analysis of past and present research results, identification of the current situation, problems that should be solved and future directions of development, and proposition of the researcher's own views, opinions, and recommendations. Based on relevant theories, research conditions and practical needs, various research results are reviewed to provide the basis or conditions for the current research.

By searching international databases such as Science Direct, Web of Science, PubMed, and databases of Chinese journals such as CNKI, VIP, and Wan fang, we searched for journals, related to Stakeholder Engagement, Operational (Routine) Capabilities, Dynamic Capabilities, Innovativeness, Project Performance Outcome and Relational Performance in various industries around the world. We also used search engines such as Google Scholar, and literature management software to improve the theoretical sorting, grouping, and analyzing of the search results related to the study variables. In addition, we searched the Chinese government administration websites such as the General Office of the State Council, the National Health Commission, the National Medical Products Administration (NMPA), and the Center for Drug Evaluation (CDE) to collect the relevant industry policy information and documents. Search keywords used include CRO, CRO and pharmaceutical clients, open Innovativeness, stakeholder engagement, dynamic capabilities, operational (routine) capabilities, Innovativeness, project performance and Relational Performance.

In the literature background, this study firstly summarizes the industry overview of CROs in the field of pharmaceutical R&D, the concept and emergence of CROs, the development

history and business scope of CROs, the development status of CROs, and the cooperation and open Innovativeness between CROs and pharmaceutical companies in the field of drug research and development (R&D). Secondly, in the literature review section, research on stakeholder engagement in open Innovativeness and open Innovativeness, dynamic and operational (routine) capabilities of organizations, and Innovativeness of organizations are summarized, and the evolution of their definitions and concepts is introduced. Finally, the literature review analyzes the relationship between CRO and pharmaceutical client participation, Dynamic Capabilities and Operational (Routine) Capabilities, and project Innovativeness from the theoretical level, puts forward the theoretical model and research hypothesis of this study.

#### **4.1.2 Expert consultation**

Expert consultation refers to consulting experts related to the research topic to give guidance and advice on the study based on their expertise and experience from previous evaluations. Based on our literature review, this study consulted experts to obtain opinions of research model, variable dimensions, and questionnaire design. Specifically, five experts involved in CRO and pharmaceutical industry R&D projects were invited to evaluate the face validity of the questionnaire, the importance of the content, and the accuracy of the expression of the measurement items, with the aim of guaranteeing the clarity of each item and ensuring the consistency, applicability, and ease of understanding of the variables measured.

#### **4.1.3 Questionnaire survey method**

Questionnaire survey is a commonly used method in social study, which collects information in the form of responses to questionnaires, to collect a large amount of reliable information in a short period of time. The questionnaire method is a method in which researchers use this controlled measurement to assess the variables under study. Questionnaires are mostly sent by mail, individually or collectively. The main advantages of the questionnaire method are standardization and low cost.

In this study, we used a questionnaire survey to obtain research data, and the main subjects of this study were project team members who have participated in R&D projects between CROs and pharmaceutical companies. The respondents were employees from multinational and local CRO companies and pharmaceutical companies in China.

Variables examined in this study include CRO Engagement, Pharmaceutical Client Engagement, dynamic capabilities, operational (routine) capabilities, Innovativeness, project

performance and Relational Performance. The questionnaire consists of five parts: Part 1: Project Background Information, Part 2: Project Team (CRO and Pharmaceutical Client) Engagement, Part 3: Project Team Operation and Dynamic Capabilities, Part 4: Project Outcomes - Innovativeness, Project Performance Outcome and Relational Performance, and Part 5: Personal Background Information. In the design of the questionnaire, we adapted all measures from the measures that have empirically used in the literature. The scale is scored on a 7-point Likert scale, with options ranging from "strongly disagree" to "strongly agree".

After the initial pool of measurement items generate adapted from the literature, from 31 October 2023 to 7 November 2023, with the assistance of 5 experts, the survey questions were refined using the Q-sorting method (manual factor analysis) to assess their clarity and consistency with the purpose of the survey (Straub et al., 2004; Thomas & Watson, 2002). From December 20 to December 22, 2023, a Pre-test of the initial questionnaire was conducted with 5 experts, in order to assess the content validity of the measures (MacKenzie et al., 2011) and the wording and format were slightly modified according to their feedback. It was crucial to conduct a pilot test to ensure that the survey effectively gathered the necessary information (Converse & Presser, 1986). A seven-point Likert scale was used to measure survey items. We created an online questionnaire and shared it with the survey participants. Online surveys were easy to distribute and convenient to manage (Bell et al., 2022). From December 25, 2023, to December 28, 2023, a first round of pilot test data sample of 62 valid questionnaire responses was collected and analyzed. The pilot test results enabled us to make further improvements to the questionnaire. An additional sample of 343 valid questionnaire responses were collected from January 5, 2024, to February 7, 2024. The final study sample size used to test our research model and hypotheses included 405 valid questionnaires responses.

#### **4.1.4 Principal component analysis**

Principal component analysis is a multivariate statistical method to examine the correlation between multiple variables. In the questionnaire development stage, according to the principal component analysis procedure, we used SPSS software to perform principal component analysis on the pilot test sample data to assess the initial reliability and validity of the measures. By comparing the calculated values with the test criteria, the items that did not meet the requirements were deleted or modified, and those that met the requirements were retained, thus improving the quality of the questionnaire, and ensuring that each item could better measure the desired content of the study and lay foundation for the subsequent final questionnaire survey.

#### **4.1.5 Structural equation modeling**

Structural equation modelling is a common social science method for multivariate data analysis, which is often used in confirmative factor analysis, higher-order factor analysis, and path analysis. In this study, after validating the reliability and validity of the measurement, we used SmartPLS 4.0 software to perform partial least squares (PLS) regression analyses on the study sample to test the research model and hypotheses. The two steps of structural equation modelling procedures we used are as follows.

1) Measurement model tests. Confirmative factor analysis was used to validate the measurement model. Because of the complexity of the model, the measurement model tests were conducted for first-order and second-order constructs respectively.

2) Structural model tests. The evaluation of the structural model mainly follows three criteria: the  $R^2$  of the endogenous variables, the estimates of the path coefficients, and the effect size ( $f^2$ ) of the hypothesized relationships.

### **4.2 Sample and Questionnaire Design**

Questionnaire is a measurement tool, which contains a set of questions that assess the level of latent variables and aims to reveal the level of theoretical variables that cannot be easily measured by direct methods, and the first step in developing a valid, scientific measurement tool lies in determining the range of variables (constructs), which requires reviewing the literature in advance (Churchill, 1979). Through a comprehensive literature review and referring to the opinions of scholars, questions can be scientifically selected and aligned with the construct properties. Thus, the resulting questions ensure a certain level of reliability and validity.

#### **4.2.1 Questionnaire design process**

The main variables to be tested in this study are: CRO Engagement, Pharmaceutical Client Engagement, Operational (Routine) Capabilities, Dynamic Capabilities, Innovativeness, Project Performance Outcome, and Relational Performance. All measures were adapted from the existing literature. In this study, the development process of the measurement followed in-depth development procedure (Brocato et al., 2012) and well-established research guidelines (Wetzels et al., 2009). Our measurement development process consists of four phases (Karpen



et al., 2015): 1) Questionnaire generation, 2) Questionnaire evaluation, 3) Questionnaire small sample testing, 4) Questionnaire final purification and validation and hypothesis validation. In Section 3.3.3 of Chapter 3, we have explained the definitions of each variable. Stages 1 to 3 are described in this chapter. The pre-test and pilot test sample data and results are presented in this chapter, while the reliability and validity analysis results using the total study sample are presented in Chapter 5. Table 4.1 summarizes the various stages of data collection, samples, and analyses conducted.

Table 4.1 Measurement and Questionnaire Development Steps

Measurement questionnaire development process	Specific research content
Step 1: Generation of initial pool of measurement items	<ul style="list-style-type: none"> <li>- Literature analysis</li> <li>- Q-sorting method (manual factor analysis): Five experts discussed and analyzed the initial pool of measurement items to determine the clarity of the items, the conciseness of the language and the consistency of the purpose of the investigation</li> </ul>
Step 2: Qualitative assessment of measurement items	<ul style="list-style-type: none"> <li>- Pre-test: Five experts evaluate the clarity of each assessment item, the importance of the content, the accuracy and consistency of the measured variables, the applicability of the measurement item (translation), and the ease of understanding of the measurement item</li> </ul>
Step 3: Measurement testing and purification using pilot test sample	<ul style="list-style-type: none"> <li>n=62</li> <li>- Reliability analysis and validity analysis</li> <li>- Exploratory factor analysis</li> </ul>
Step 4: Measurement validation using final study sample	<ul style="list-style-type: none"> <li>n=405</li> <li>- Exploratory factor analysis</li> <li>- Analysis of convergence validity and discriminative validity</li> <li>- Hypothesis validation</li> </ul>

#### 4.2.2 Measures Adapted from Existing Scales

The initial pool of measurement items and reference basis of our study variables in this study were obtained from relevant English and Chinese literature, respectively. In this study, scales obtained from English literature were translated into Chinese. To ensure the accuracy of the translation of the measurement items, two experts were asked to independently make back-translation from Chinese to English and make necessary modifications to the Chinese version until the back-translated English content was consistent with the original English description. With the assistance of five experts, the initial pool of items was subject to a Q-sorting procedure. We went through a sequential incremental improvement process. The first expert Q-sorted the measurement items and helped us to modify the items that were not sorted into their intended variable category. We then repeat the procedure with the second expert, which result will lead to the next expert Q-sorting procedure. There was no further modification needed when we conducted the Q-sorting procedure with the fifth expert. After the Q-sorting process, we created

an initial questionnaire and conducted a qualitative pre-test of the initial questionnaire with five experts. The questionnaire content, including variables, variable definitions, and questions assessing the variables, was discussed with, and evaluated, by the experts to check on clarity, understandability, and ease of response. The wordings and formats of some questions were slightly modified according to the pre-test feedback. Table 4.2 presents the measurement items and their literature sources.

Table 4.2 Measurement items

Constructs	Dimensions	Items	Source
CRO Engagement	2.1 CRO Employee Engagement	CRO team members...	(Fenton O'Creevy, 2001; Kleysen & Street, 2001; Yong, 2018)
		2.1.a. contributed new ideas or solutions to solve problems during this project	
		2.1.b. actively sought opportunities to improve project	
		2.1.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	
		2.1.d. actively participated in the decision-making and implementation of this project	
	2.2 CRO Communication Strategies	2.1.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas CRO team in the project...	(Moroni et al., 2022); (Cramer, 2002)
		2.2.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with pharmaceutical client team	
		2.2.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with pharmaceutical client team	
		2.2.c. adopted the practice of education/training as a communication strategy with pharmaceutical client team	
		2.2.d. disclosed its project performance reports (eg. operational, financial) to pharmaceutical client team CRO team in the project...	
CRO Engagement	2.3 CRO Organizational Relationships	2.3.a. adopted project collaborated learning to engage the pharmaceutical client	(Moroni et al., 2022); (Amoako-Gyampah et al., 2019);(Zhang & Cao, 2018) (Heugens et al., 2002)
		2.3.b. actively sought to solve problems together with the pharmaceutical client	
		2.3.c. actively had good relationship with the pharmaceutical client	
		2.3.d. had good contracting experience with the pharmaceutical client	
		2.3.e. is trustworthy	
		2.3.f. was able to do what the pharmaceutical client need to do	

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Constructs	Dimensions	Items	Source
Pharmaceutical Client Engagement	2.4 Pharmaceutical Client Employee Engagement	Pharmaceutical client team members...	(Fenton O'Creevy, 2001; Kleysen & Street, 2001; Yong, 2018)
		2.4.a. contributed new ideas or solutions to solve problems during this project	
		2.4.b. actively sought opportunities to improve project	
		2.4.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	
		2.4.d. actively participated in the decision-making and implementation of this project	
	2.5 Pharmaceutical Client Communication Strategies	2.4.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas Pharmaceutical client team in the project...	(Moroni et al., 2022); (Cramer, 2002)
		2.5.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with CRO team	
		2.5.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with CRO team	
		2.5.c. adopted the practice of education/training as a communication strategy with CRO team	
		2.5.d. disclosed its project performance reports (eg. operational, financial) to CRO team Pharmaceutical client team in the project...	
Operational (Routine) Capabilities	2.6 Pharmaceutical Client Organizational Relationships	2.6.a. adopted project collaborated learning to engage CRO team	(Moroni et al., 2022); (Amoako-Gyampah et al., 2019);(Zhang & Cao, 2018)
		2.6.b. actively sought to solve problems together with the CRO team	
		2.6.c. actively had good relationship with CRO team	
		2.6.d. had good contracting experience with CRO team	
		2.6.e. is trustworthy	
		2.6.f. was able to do what CRO team need to do	
	3.1 Planning capabilities	In each stage, project team was able to timely and effectively set clear...	(Rai et al., 2014);(Amoako-Gyampah et al., 2019);(PMI, 2021)
		3.1.a. task content objectives	
		3.1.b. schedule performance objectives	
		3.1.c. cost performance objectives	
		3.1.d. quality performance objectives	
		3.1.e. satisfaction performance objectives	

Constructs	Dimensions	Items	Source
Operational (Routine) Capabilities	3.2 Execution capabilities	In each stage, project team was able to consistently execute...	(PMI, 2021)
		3.2.a. established standards and procedures	
		3.2.b. planned objectives	
		3.2.c. Integration plans	
		3.2.d. Human resources plans	
		3.2.e. Risk management plans	
		3.2.f. Procurement plans	
	3.3 Monitoring capabilities	3.2.g. Change management plans	
		In each stage, project team was able to timely and effectively, according to set objectives, to track and analyze...	(PMI, 2021); (Butler et al., 2020); (Hwang et al., 2017)
		3.3.a. task content performance gaps	
		3.3.b. schedule performance gaps	
		3.3.c. cost performance gaps	
		3.3.d. quality performance gaps	
		3.3.e. satisfaction performance gaps	
Dynamic Capabilities	3.4 Adjusting capabilities	In each stage, project team was able to continuously make necessary changes to...	(PMI, 2021); (Butler et al., 2020); (Hwang et al., 2017)
		3.4.f. task content objectives based on task content performance gaps	
		3.4.g. schedule performance objectives based on schedule performance gaps	
		3.4.h. cost performance objectives based on cost performance gaps	
		3.4.i. project quality based on quality performance gaps	
		3.4.j. project activities based on satisfaction performance gaps	
		Project team...	
	3.5 Sensing capabilities	3.5.a. frequently scanned the industry environment to identify new business opportunities	(Guo et al., 2022)
		3.5.b. periodically reviewed the likely effect of changes in our industry environment on the project	
		3.5.c. often reviewed our product/service development efforts to ensure they were in line with what the project wanted	
		3.5.d. devoted time implementing ideas for new business	
	3.6 Responding capabilities	Project team was able to react quickly to changes in... 3.6.a. policy and industry environment	(Guo et al., 2022)
		3.6.b. vendors service	
		3.6.c. client requirements	
		3.6.d. consumer market	

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Constructs	Dimensions	Items	Source
Innovativeness, Project Performance Outcome, Relational Performance	3.7 Transforming capabilities	Project team...	(Calik et al., 2017)
		3.7.a. had effective routines to identify, value, and import new information and knowledge	
		3.7.b. had adequate routines to assimilate new information and knowledge	
		3.7.c. was effective in transforming existing information into new knowledge	
		3.7.d. was effective in utilizing knowledge into new products development	
		3.7.e. was effective in developing new knowledge that has the potential to influence product development	
	3. 8 Integrating capabilities	Project team...	
		3.8.a. was forthcoming in contributing their individual input to the group	
		3.8.b. was fully aware who inside the team has specialized skills and knowledge relevant to our work	
		3.8.c. was fully aware who outside the team has specialized skills and knowledge relevant to our work	
		3.8.d. actively interrelated and interconnect our actions to members inside the team to meet changing conditions	
	3. 9 Coordinating capabilities	3.8.e. actively interrelated and interconnect our actions between members inside and outside the team to meet changing conditions	
		Project team...	
		3.9.a. ensured an appropriate allocation of resources (e.g., information, time, reports) within our group	
		3.9.b. were assigned to tasks commensurate with their task relevant knowledge and skills	
		3.9.c. ensured that there was compatibility between group members expertise and work processes	
	4.1. Innovativeness	3.9.d. Overall, our project team was well coordinated	
		The final deliverable by the project...	
		4.1.a. was new on the market	
		4.1.b. offered unique benefits superior to those of competitors	

Constructs	Dimensions	Items	Source
Innovativeness, Project Performance Outcome, Relational Performance	4.1. Innovativeness	4.1.c. offered unique benefits superior to existing products on the market Through the project, ...	(Butler et al., 2020)
		4.1.d. the CRO organization was enabled to become better in the management of developing new product	
		4.1.e. the pharmaceutical client organization was enabled to become better in the management of developing new product	
		4.1.f. the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	
		4.1.g. the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	
		4.1.h. the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	
		4.1.i. the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions	
		4.1.j. the project members were enabled to develop new process benefit to Innovativeness The project....	
		4.2.a. was completed on schedule	
		4.2.b. was completed within budget	
	4.2. Project Performance Outcome	4.2.c. met quality goals	(Butler et al., 2020)
		4.2.d. deliverable met planned task content scope	
		4.2.e. was satisfied as CRO expected	
		4.2.f. was satisfied as pharmaceutical client expected After the project, CRO team...	
		4.3.a. were more confident in the pharmaceutical client team than before	
		4.3.b. were satisfactory with the relationship with the pharmaceutical client team	
		4.3.c. were more committed to the relationship and collaboration with the pharmaceutical client team	
	4.3. Relational Performance		(Shi & Liao, 2013)

Constructs	Dimensions	Items	Source
		4.3.d. believed that the relationship with the pharmaceutical client team is strategic sustainable	
		After the project, the pharmaceutical client team....	
	4.3. Relational Performance	4.3.e. were more confident in the CRO team than before	
		4.3.f. were satisfactory with the relationship with the CRO team	
		4.3.g. were more committed to the relationship and collaboration with the CRO team	
		4.3.h. believed that the relationship with the CRO team is strategic sustainable	

### 4.3 Pilot test of the measurement

After the qualitative pre-test of the initial questionnaire, we conducted a quantitative pilot-test to further improve the questionnaire based on analyses of measurement reliability and validity using explorative factor analysis method, specifically principal component analyses, on the pilot sample data.

#### 4.3.1 Pilot test sample

A pilot test sample of the questionnaire survey was collected from team members of new drug R&D projects between CRO and the Pharmaceutical Client from December 25, 2023, to December 28, 2023. The number of valid questionnaires obtained was 62 for this pilot test sample test, which was analyzed using IBM SPSS 25.0 software. The descriptive characteristics of the pilot test sample are shown in Table 4.3.

Table 4.3 Characteristics of the pilot test respondents

Variables		Frequency (n)	Percentage (%)
Gender	Male	25	40.3
	Female	37	59.7
Education	Undergraduate and bachelor's degree	25	40.3
	Master's degree	33	53.2
	Doctor's degree	4	6.5
Project phase	Phase I clinical trial project	11	17.7
	Phase II clinical trial project	9	14.5
	Phase III clinical trial project	39	62.9
	Phase IV clinical trial project	3	4.8
Nature of the project	Local clinical trial project	30	48.4
	Global multi-site clinical trial project	32	51.6

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Variables		Frequency (n)	Percentage (%)
Team belonged when participated in the project	CRO	35	56.5
	Pharmaceutical Companies/ Biopharmaceutical/biotech companies	27	43.5
Current company	CRO	30	48.4
	Pharmaceutical company/ Biopharmaceutical/biotech company	32	51.6
Company Ownership Structure	Global/Foreign company	52	83.9
	Local company	10	16.1
	Clinical Operations Department (CRA, CRM)	9	14.5
Department/Function	Project Management Department (PM, PD)	47	75.8
	Regulatory Registration Department (RA)	1	1.6
	Medical Department (Medical Scientist, Medical Monitoring, Medical Writing)	3	4.8
	Pharmacovigilance Department (PV)	2	3.2
	Rank-and-file employees	9	14.5
Position level/Title	Manager/Senior Manager	29	46.8
	Director/Senior Director	21	33.9
	Senior Management/Department Heads	1	1.6
	Company Leader (CEO, VP/P)	1	1.6
	other	1	1.6
	Min ~Max		Average
	Total duration of the collaborated project (month)	4~96	28.53
	Total number of both team members in the collaborated project	6~1100	78.08
	Age (years old)	26~44	36.69
	Working years in the industry	2~31	11.95

As shown in Table 4.3, in terms of gender, 25 respondents (40.3%) of the pilot-test respondents were Male and 33 respondents (59.7%) were Female. In terms of age, the age composition ranged from 26 to 44 years, with an average age of 36.69 years. In terms of educational background, 25 respondents (40.3%) had an undergraduate or bachelor's degree, 33 respondents (53.2%) owned a master's degree, and 4 respondents (6.5%) had a doctor's degree. In terms of work experience, the working years in the current industry range from 2 to 31 years, with an average of 11 years. There were 11 phase I clinical trial projects, accounting for 17.7%; 9 phase II clinical trial projects, accounting for 14.5%; 39 phase III clinical trial projects, accounting for 62.9%; 3 phase IV clinical trial projects, accounting for 4.8%. Among all the projects, 30 projects were local clinical trials (48.4%), and 32 projects were Global multi-site clinical trial projects (51.6%). The total length of the projects ranged from 4 to 96 months, with an average of 28.53 months. In addition, 35 respondents were from the CRO team (56.5%), and 27 respondents were from the client company team (43.5%). Regarding the nature of the



company, 52 respondents were from Global/Foreign company, accounting for 83.9%, and 10 were from Local company, accounting for 16.1%. In terms of work departments and functions, 9 people were from the clinical operations department (clinical research associate (CRA), clinical research manager (CRM)), accounting for 14.5%; 47 people were from the project management department (PM, PD), accounting for 75.8%; 1 person was from the regulatory registration department (RA), accounting for 1.6%; 3 people were from the medical affairs department (Medical Scientist, Medical Monitoring, Medical Writing), accounting for 4.8%; and 2 people were from the pharmacovigilance safety department, accounting for 3.2%. In terms of the Position level/Title, there were 9 Ordinary employees, accounting for 14.5%; 29 Managers/Senior managers, accounting for 46.8%; 21 Directors/Senior Directors, accounting for 33.9%; 1 Function Head, accounting for 1.6%, 1 Company Head (CEO, VP/P), accounting for 1.6%, and 1 other, accounting for 1.6%. From the descriptive statistical analysis results of the above sample, we could see that the sample of this survey has a diverse and reasonable distribution in terms of gender, educational background, work experience, projects phase/stage, nature of projects, projects duration, number of project team members, company nature, work department/function, and position/Title.

#### **4.3.2 Pilot test of reliability and validity**

The reliability and validity tests using the pilot sample were performed using principal component analysis with IBM SPSS 25.0 software. Firstly, the KMO values of the sample was tested to check whether the sample was suitable for factor analysis. The value of KMO is between 0 and 1. When the sum of squares of simple correlation coefficients between all variables is much larger than the sum of squares of partial correlation coefficients, the value of KMO is closer to 1. It means the correlation between the variables is strong and the variables are suitable for factor analysis. Conversely, when the sum of the squares of the simple correlation coefficients between all variables is close to 0, the value of KMO is close to 0. It means that the correlation between the variables is weak, and the variables are unsuitable for factor analysis. A KMO value of 0.9 or more indicates that the sample is very suitable for factor analysis, a KMO value of 0.8 indicates that it is suitable for factor analysis, and 0.7 indicates that the suitability of factor analysis on the sample is general.

Reliability refers to the consistency, stability, and reliability of measurement. The higher the value, the more reliable the measurement. Reliability is measured by composite reliability (CR) and Cronbach's  $\alpha$  values. Cronbach's  $\alpha$  value is the average of the half-reliability

coefficients obtained by all possible item division methods of the scale and is the commonly used reliability testing method. Usually, Cronbach's  $\alpha$  value is between 0 and 1. If it does not exceed 0.6, it is generally considered that the internal consensus reliability is insufficient. When it reaches 0.7-0.8, the scale has considerable reliability, and when it reaches 0.8-0.9, it indicates that the reliability of the scale is very good. CR is the reliability of a new composite variable composed of the sum of more than one variable. If CR is greater than 0.7, it meets the testing standard. Validity refers to the accuracy and usefulness of measurement, which are generally measured using the average variance extraction value (AVE) of each latent variable and the factor loading (FL) of each measured variable. The AVE value reflects the discriminative validity of each latent variable. When the AVE value is greater than 0.50, it means that the latent variable has good discriminative validity. Factor loading reflects the convergent validity of each latent variable. When FL value is greater than 0.50, it indicates that the measured variable has good convergence validity. Reliability and validity evaluation criteria for measurement development are shown in Table 4.4.

Table 4.4 Reliability and Validity Evaluation Criteria

Evaluation perspective	Evaluation content	Test standards
Suitability for factor analysis	KMO	Above 0.9 means very suitable; 0.8 means suitable; 0.7 means average
Reliability	Composite Reliability (CR)	>0.7
	Cronbach's alpha	>0.7
Convergent validity	Factor loading (FL)	>0.5
Discriminant validity	Average variance extracted (AVE)	>0.5

According to the content of the questionnaire, this study divides the measurement items into seven groups for reliability and validity tests: (1) CRO Engagement: CRO Employee Engagement, CRO Communication Strategies and CRO Organizational Relationship; (2) Pharmaceutical Client Engagement: Pharmaceutical Client Employee Engagement, Pharmaceutical Client Communication Strategies and Pharmaceutical Client Organizational Relationship; (3) Operational (routine) capabilities: Planning, Execution, Monitoring and Adjusting capabilities; (4) Dynamic capabilities: Sensing capabilities, Responding capabilities, Transforming capabilities, Integrating capabilities, Coordinating capabilities, (5) Innovativeness, (6) Project Performance Outcome, (7) Relational Performance. Exploratory factor analysis was performed with 62 valid questionnaire responses, and the results were as follows.

(1) CRO Engagement

The KMO value was 0.918, and the reliability and validity results were shown in Table 4.5, which met the criteria.

(2) Pharmaceutical Client Engagement

The KMO value was 0.872, and the reliability and validity results are shown in Table 4.5, which met the criteria.

(3) Operational (routine) capabilities

The KMO value was 0.916, and the reliability and validity results were shown in Table 4.5, which met the criteria.

(4) Dynamic capabilities

The KMO value was 0.918, and the reliability and validity results were shown in Table 4.5, which met the criteria.

(5) Innovativeness

The KMO value was 0.86, and the reliability and validity results are shown in Table 4.5, which met the criteria.

(6) Project Performance Outcome

The KMO value was 0.876, and the reliability and validity results are shown in Table 4.5, which met the criteria.

(7) Relational Performance

The KMO value was 0.896, and the reliability and validity results were shown in Table 4.5, which met the criteria.

The final questionnaire used for the study is shown in Annex.

Table 4.5 Pilot Test Results of Reliability and Validity

High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
CRO Engagement	2.1 CRO Employee Engagement	CRO team members... 2.1.a. contributed new ideas or solutions to solve problems during this project	0.937	0.874	0.968	0.964
		2.1.b. actively sought opportunities to improve project	0.950			
		2.1.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	0.959			

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
CRO Engagement	2.2 CRO Communication Strategies	2.1.d. actively participated in the decision-making and implementation of this project	0.892	0.754	0.918	0.888
		2.1.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	0.935			
		CRO team in the project...				
		2.2.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with pharmaceutical client team	0.886			
		2.2.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with pharmaceutical client team	0.809			
		2.2.c. adopted the practice of education/training as a communication strategy with pharmaceutical client team	0.880			
		2.2.d. disclosed its project performance reports (eg. operational, financial) to pharmaceutical client team	0.895			
		CRO team in the project...				
		2.3.a. adopted project collaborated learning to engage the pharmaceutical client	0.884			
		2.3.b. actively sought to solve problems together with the pharmaceutical client	0.912			
	2.3 CRO Organizational Relationships			0.784	0.954	0.944

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Pharmaceutical Client Engagement	2.4 Pharmaceutical Client Employee engagement	2.3.c. actively had good relationship with the pharmaceutical client	0.870	0.818	0.952	0.944
		2.3.d. had good contracting experience with the pharmaceutical client	0.811			
		2.3.e. is trustworthy	0.920			
		2.3.f. was able to do what the pharmaceutical client need to do	0.913			
		Pharmaceutical client team members...				
		2.4.a. contributed new ideas or solutions to solve problems during this project	0.914			
		2.4.b. actively sought opportunities to improve project	0.911			
		2.4.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	0.936			
		2.4.d. actively participated in the decision-making and implementation of this project	0.916			
		2.4.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	0.844			
		Pharmaceutical client team in the project...				
	2.5. Pharmaceutical Client Communication Strategies	2.5.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with CRO team	0.853	0.619	0.844	0.777
		2.5.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with CRO team	0.796			

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Pharmaceutical Client Engagement	2.6 Pharmaceutical Client Organizational Relationships	2.5.c. adopted the practice of education/training as a communication strategy with CRO team	0.842			
		2.5.d. disclosed its project performance reports (eg. operational, financial) to CRO team	0.637			
		Pharmaceutical client team in the project...				
		2.6.a. adopted project collaborated learning to engage CRO team	0.782			
		2.6.b. actively sought to solve problems together with the CRO team	0.851	0.663	0.914	0.897
		2.6.c. actively had good relationship with CRO team	0.861			
		2.6.d. had good contracting experience with CRO team	0.786			
		2.6.e. is trustworthy	0.873			
		2.6.f. was able to do what CRO team need to do	0.722			
		Project team...				
		3.1.a. frequently scanned the industry environment to identify new business opportunities	0.880			
		3.1.b. periodically reviewed the likely effect of changes in our industry environment on the project	0.918			
Dynamic Capabilities	3.1 Sensing Capabilities	3.1.c. often reviewed our product/service development efforts to ensure they were in line with what the project wanted	0.883	0.816	0.937	0.925
		3.1.d. devoted time implementing ideas for new business	0.932			
	3.2 Responding Capabilities	Project team was able to react quickly to changes in...	0.844	0.743	0.905	0.883
		3.2.a. policy and industry environment				

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Dynamic Capabilities	3.3 Transforming Capabilities	3.2.b. vendors service	0.890	0.869	0.967	0.962
		3.2.c. client requirements	0.865			
		3.2.d. consumer market	0.848			
		Project team...				
		3.3.a. had effective routines to identify, value, and import new information and knowledge	0.934			
		3.3.b. had adequate routines to assimilate new information and knowledge	0.896			
		3.3.c. was effective in transforming existing information into new knowledge	0.953			
		3.3.d. was effective in utilizing knowledge into new products development	0.935			
		3.3.e. was effective in developing new knowledge that has the potential to influence product development	0.943			
		Project team...				
		3.4.a. was forthcoming in contributing their individual input to the group	0.921			
		3.4.b. was fully aware who inside the team has specialized skills and knowledge relevant to our work	0.922			
	3.4 Integrating Capabilities	3.4.c. was fully aware who outside the team has specialized skills and knowledge relevant to our work	0.927	0.861	0.965	0.959
		3.4.d. actively interrelated and interconnect our actions to members inside the team to meet changing conditions	0.931			

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Dynamic Capabilities	3.5 Coordinating Capabilities	3.4.e. actively interrelated and interconnect our actions between members inside and outside the team to meet changing conditions Project team...	0.937			
		3.5.a. ensured an appropriate allocation of resources (e.g., information, time, reports) within our group	0.944			
		3.5.b. were assigned to tasks commensurate with their task relevant knowledge and skills	0.961			
		3.5.c. ensured that there was compatibility between group members expertise and work processes	0.942			
		3.5.d. Overall, our project team was well coordinated	0.929			
		In each stage, project team was able to timely and effectively set clear...	0.839			
		3.6.a. task content objectives				
		3.6.b. schedule performance objectives	0.883			
		3.6.c. cost performance objectives	0.966			
		3.6.d. quality performance objectives	0.879			
Operational (Routine) Capabilities	3.6 Planning Capabilities	3.6.e. satisfaction performance objectives	0.946			
		In each stage, project team was able to timely and effectively, according to set objectives, to track and analyze...	0.916			
		3.7.a. task content performance gaps				
		3.7.b. schedule performance gaps	0.906			
	3.7 Monitoring and Adjusting Capabilities			0.807	0.975	0.973



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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Operational (Routine) Capabilities	3.7 Monitoring and Adjusting Capabilities	3.7.c. cost performance gaps	0.896	0.817	0.966	0.961
		3.7.d. quality performance gaps	0.833			
		3.7.e. satisfaction performance gaps	0.910			
		In each stage, project team was able to continuously make necessary changes to...				
		3.7.f. task content objectives based on task content performance gaps	0.897			
		3.7.g. schedule performance objectives based on schedule performance gaps	0.915			
		3.7.h. cost performance objectives based on cost performance gaps	0.911			
		3.7.i. project quality based on quality performance gaps	0.892			
		3.7.j. project activities based on satisfaction performance gaps	0.903			
		In each stage, project team was able to consistently execute...	0.877			
	3.8 Execution Capabilities	3.8.a. established standards and procedures	0.931			
		3.8.b. planned objectives				
		3.8.c. Integration plans	0.912			
		3.8.d. Human resources plans	0.899			
		3.8.e. Risk management plans	0.924			
		3.8.f. Procurement plans	0.912			
		3.8.g. Change management plans	0.871			
Innovativeness, Project Performance Outcome, Relational Performance	4.1. Innovativeness	The final deliverable by the project...	0.588	0.606	0.943	0.924
		4.1.a. was new on the market	0.548			
		4.1.b. offered unique benefits superior to those of competitors				

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High order construct	Variable	Question item	FL	AVE	CR	Cronbach $\alpha$
Innovativeness, Project Performance Outcome, Relational Performance	4.1. Innovativeness	4.1.c. offered unique benefits superior to existing products on the market Through the project, ...	0.575	0.797	0.956	0.930
		4.1.d. the CRO organization was enabled to become better in the management of developing new product	0.822			
		4.1.e. the pharmaceutical client organization was enabled to become better in the management of developing new product	0.758			
		4.1.f. the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	0.808			
		4.1.g. the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	0.843			
		4.1.h. the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	0.918			
		4.1.i. the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments to produce new approaches and solutions	0.911			
		4.1.j. the project members were enabled to develop new process benefit to Innovativeness	0.892			
	4.2. Project Performance Results	4.2.a. is completed within the scheduled time	0.857			
		4.2.b. is done within the budget	0.894			
		4.2.c. Quality objectives are met	0.896			
		4.2.d. Deliverables meet the expected scope of the task	0.920			
		4.2.e. Expected CRO Party Satisfaction is achieved	0.854			

4.3. Relational Performance	4.3.a. Trust in the pharmaceutical company's customer team is higher than before	0.936			
	4.3.b. Satisfied with the relationship with the pharmaceutical company's account team	0.949			
	4.3.c. Commit to more contact and cooperation with the pharmaceutical company's account team	0.845	0.843	0.976	0.973
	4.3.d. Considers a sustainable strategic partnership with the pharmaceutical company's account team	0.881			
	4.3.e. Trust in the CRO team is higher than before	0.946			
	4.3.f. Satisfied with the relationship with the CRO team	0.939			
	4.3.g. Commit to more contact and collaboration with the CRO team	0.898			
	4.3.h. Believe that a sustainable strategic partnership with the CRO team is sustainable	0.947			

## 4.4 Final Study Sample Data Collection

### 4.4.1 Data Collection Methods and Procedures

As discussed above, the pilot test sample data of 62 responses were conducted from December 25, 2023, to December 28, 2023. Using the modified questionnaire from the pilot test, we collect additional 343 valid questionnaire response from January 5, 2024, to February 7, 2024. The final study sample consisted of a total of 405 valid questionnaire responses.

### 4.4.2 Characteristics of the Final Study Sample

Out of a total of 600 questionnaires distributed, 405 usable responses were collected, resulting a response rate of 67.5%. As shown in Table 4.6, in terms of gender, 142 were males (35.1%) and 263 were females, accounting for 64.9%. In terms of age, the age composition ranged from 24 to 54 years old, with an average age of 37.17 years. In terms of educational background, 177 (43.7%) had the undergraduate and bachelor's degree, 207 (51.1%) had the master's degree, and

21 (5.2%) had a doctor's degree. In terms of work experience, the number of years of working experience in the industry ranged from 1 to 31 years, and the average working experience in the industry was 12 years. In terms of project phase, 73 were phase I clinical trial projects, accounting for 18%; 73 were phase II clinical trial projects, accounting for 18%; 244 were phase III clinical trial projects, accounting for 60.2%; 15 were phase IV clinical trial projects, accounting for 3.7%. Among them, 241 were local clinical trial projects, accounting for 59.5%, and 164 were Global multi-site clinical trial projects, accounting for 40.5%. The total project duration ranged from 2 to 120 months, and the average project duration was 28.52 months. The total number of team members of the collaborated projects ranged from 2 to 1500, and the average total number of team members of the collaborated projects is 84. Among the team members of the projects, 220 respondents were from the CRO team, accounting for 54.3%, and 185 respondents were from the pharmaceutical company team, accounting for 45.7%. In terms of the nature of the company, 271 were from Global/Foreign company, accounting for 66.9%, and 134 were from Local company, accounting for 33.1%. From the perspective of work departments and functions, 115 people came from the clinical operations department (clinical researcher (CRA), clinical research manager (CRM)), accounting for 28.4%; 6 were from the clinical operations department (Clinical Trial Assistant (CTA)), accounting for 1.5%; ; 3 were from the clinical start-up department (clinical start-up specialist/manager), accounting for 0.7%; 199 were from the project management department (PM, PD), accounting for 49.1%; 7 were from the regulatory registration department (RA), accounting for 1.7%; 4 were from the data and statistics department (DM, Bios), accounting for 1.0%; 15 were from the medical affairs department (Medical Scientist, Medical Monitoring, Medical Writing), accounting for 3.7%; 13 were from the quality assurance departments (QA, QC), accounting for 3.2%; 10 were from pharmacovigilance safety department (PV), accounting for 2.5%; and 33 were from other departments, accounting for 8.1%. In terms of Position level/Title, there were 68 ordinary employees, accounting for 16.8%; 176 Managers/Senior Managers, accounting for 43.5%; 130 Directors/Senior Directors, accounting for 32.1%, 18 Function Heads, accounting for 4.4%; 7 Company Head (CEO, VP/P), accounting for 1.7%; 6 others, accounting for 1.5%. The results of the descriptive statistical analysis suggest that the sample of this survey has a diverse and reasonable distribution in terms of gender, educational background, work experience, projects phase/stage, nature of projects, projects duration, number of project team members, company nature, work department/function, and position/Title. The specific results are shown in Table 4.6.

Table 4.6 Descriptive statistics of the final study sample

Variables		Frequency (n)	Frequency (%)
Gender	Male	142	35.1
	Female	263	64.9
Education	Undergraduate and bachelor's degree	177	43.7
	Master's degree	207	51.1
	Doctor's degree	21	5.2
	Phase I clinical trial project	73	18.0
Project phase	Phase II clinical trial project	73	18.0
	Phase III clinical trial project	244	60.2
	Phase IV clinical trial project	15	3.7
Variables		Frequency (n)	Frequency (%)
Nature of the project	Local clinical trial project	241	59.5
	Global multi-site clinical trial project	164	40.5
Team belonged when participated in the collaborated project	CRO	220	54.3
	Pharmaceutical Companies/ Biopharmaceutical/biotech companies	185	45.7
Current company	CRO	178	44.0
	Pharmaceutical company/ Biopharmaceutical/biotech company	227	56.0
Ownership structure of the company	Global/Foreign company	271	66.9
	Local company	134	33.1
	Clinical Operations (Clinical Research Associate CRA, Clinical Research Manager CRM)	115	28.4
	Clinical Operations (CTA Clinical Trial Assistant)	6	1.5
	Clinical Start-up Department (Clinical Start-up Specialist/Manager)	3	.7
Department/Function	Project Management Department (PM, PD)	199	49.1
	Regulatory Affairs Department (RA)	7	1.7
	Data Management and Statistics Department (DM, Bios)	4	1.0
	Medical Department (Medical Scientist、Medical Monitoring、Medical Writing)	15	3.7
	Quality Assurance Department (QA, QC)	13	3.2
	Pharmacovigilance Safety Department	10	2.5
	Other	33	8.1
	Ordinary employees	68	16.8
	Manager/Senior Manager	176	43.5
	Director/Senior Director	130	32.1
Position level/Title	Function Heads	18	4.4
	Company Heads (CEO, VP/P)	7	1.7
	Other	6	1.5
	Min~Max		Average
	Total duration of the collaborated	2~500	29.64

project (month)		
Total number of both team members in the collaborated project	2~1500	84.38
Age (years old)	24~54	37.17
Working years in the industry	1~31	12.0648

## 4.5 Structural Equation Model Evaluation Criteria

The examination of the hypothesized relationship must be based on reliable measurement instruments for the variables. To this end, two objectives shall be achieved: 1) examine the measurement model, and 2) examine the structural model. Anderson and Gerbing (1988) referred to this as a two-step process. The measurement model has been examined in the measurement development stage; however, it still needs a further validation of confirmative factor analysis using study sample. According to the procedure of higher-order variable analysis, the measurement model is examined in two steps, first-order variable reliability and validity analysis and higher-order variable reliability and validity analysis, and finally the structural model examination. The evaluation criteria for the first-order variables, higher-order variables, and structural model (Wong, 2013) are shown in Table 4.7.

Table 4.7 Structural Equation Model Evaluation Criteria

Evaluation Indices		Evaluation Content	Test Criteria
First-order measurement model evaluation	Reliability	Cronbach's alpha	>0.7
		Composite Reliability (CR)	>0.7
	Convergent validity	Factor loading (FL)	>0.5 (Joseph et al., 1998)
		Average variance extracted value (AVE)	>0.5
	Discriminant validity	No factor cross-loading	FL < 0.3 on the other factors
		Fornell-Larcker criterion	The AVE is greater than the square of the correlation coefficients between all the latent variables
Second-order measurement model evaluation	Relative importance of variables	HTMT	<0.85 (Henseler et al., 2015)
		the effects from the first- to second-order factors	$\beta$ coefficient: $p < 0.05$ , $t > 1.96$
	Convergent validity of 2nd-order variables	Factor loading (FL)	>0.5 (Joseph et al., 1998)
		Average variance extracted value (AVE)	>0.5
	Discriminant validity among variables	Fornell-Larcker criterion	The AVE is greater than the square of the

Structural model evaluation			correlation coefficients between all the latent variables <1.0 (Henseler et al., 2015)
	$R^2$ of endogenous latent variables	HTMT  $R^2$ values provide the percentage of explained variance of endogenous latent variables (Barclay et al., 1995; Chin & A., 1995)	Suggested thresholds are 0.19 for weak, 0.33 for moderate, and 0.67 for substantial explanation (Chin, 1998)
	Bootstrap coefficient test after using latent variable scores	Construct t-statistics using Bootstrap self-sampling method to test the significance of coefficients	$\beta$ Coefficient $p < 0.05$ , $t > 1.96$ .
	Total effects	The sum of the direct and indirect effects among latent variables is useful in interpreting variable relationships.	They should be sizable.
	Effect size using Cohen's (1988) $f^2$	$f^2 = (R^2_{\text{included}} - R^2_{\text{excluded}}) / (1 - R^2_{\text{included}})$	Suggested thresholds 0.02 for small, 0.15 for medium, 0.35 for large effects (Cohen, 1988)

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## Chapter 5: Research Results

This chapter is divided into three main parts: the first part summarizes the reliability and validity analysis results of the first-order variables of the research model; the second part summarizes the reliability and validity analysis results of the second-order variables of the research model; and the third part summarizes the results of the structural equation model analysis of the research model. Overall, the data analysis results suggest that (1) the reliability and validity requirements of the first-order factors and second-order variables were met without removing the question items; and (2) the research model and hypotheses were supported.

The results of the first-order variable reliability and validity analysis are as follows. 1) Reliability: the Cronbach's  $\alpha$  values of all latent first-order variables were greater than the standard of 0.8, the CR values of all latent first-order variables were greater than the standard of 0.7, indicating that the measurement model of each latent first-order variable reached a high level of reliability. 2) Content validity: the questionnaire was developed according to standard procedure to ensure the content validity. 3) Convergent validity: all first-order factor loadings were above 0.5 and all AVE values were greater than 0.5, indicating sufficient convergent validity. 4) Discriminant validity: the square roots of the first-order variable AVE were greater than the correlation coefficient among all latent variables. The HTMT values of most of the first-order variables were less than 0.85, although from a statistical point of view, some of the values were slightly apart from the accepted reference range, these indicators were still retained in the data analysis from a theoretical point of view and justification. As such, the discriminative validity criteria of first-order variables were satisfied.

The results of the reliability and validity analysis of the second-order variables are as follows. 1) Significance of factors within second-order variables: The  $\beta$  coefficients of first-order factors to second-order factors were statistically significant, and all  $t$ -values were above 1.96, suggesting the validity requirements of the formative relations of the following variables were met: CRO Engagement, Pharmaceutical Client Engagement, operational (routine) capabilities, and dynamic capabilities, and the project outcomes – Innovativeness, Project Performance Outcome, and Relational Performance. 2) Reliability: the Cronbach's  $\alpha$  values of all latent second-order variables were greater than the standard of 0.8, the CR values of all latent second-order variables were greater than the standard of 0.7, indicating that the measurement



model of each latent second-order variable reached a high level of reliability. 3) Convergence validity of second-order variables: All first-order factor loadings were greater than 0.5, and AVEs were greater than 0.5, indicating convergence validity requirements were met. 4) Discriminative validity: all AVEs were greater than the correlation coefficient between all variables. HTMT ratio values of all second-order variables were less than 1.00, indicating the discriminative validity requirements were met.

The results of the structural equation model are as follows. 1) Explanation variance: The total variance explained by the model was sufficient. 2) Hypothesis testing. The structural model testing results showed that ten hypotheses proposed in this study were all supported. 3) Mediating effect: Operational (routine) Capabilities and Dynamic Capabilities partially mediate CRO Engagement and Innovativeness, Project Performance Outcome and Relational Performance, and was a complementary mediated relationship. Operational (routine) Capabilities and Dynamic Capabilities fully mediated Pharmaceutical Client Engagement and Innovativeness, Project Performance Outcome and Relational Performance. In terms of the First-order variables, the relationship between CRO Organizational Relationship, Pharmaceutical Client Employee Engagement and Pharmaceutical Organizational Relationship and Relational Performance was a partial mediating effect (the mediating variable was Operational (routine) Capabilities and Dynamic Capabilities). The other First-order variables to outcome variables is fully mediating effect. The details refer to below Sections.

## **5.1 Reliability and Validity Tests of First-order Variables**

### **5.1.1 Reliability test of first-order variables**

The Cronbach's  $\alpha$  values for all first-order variables were greater than the criterion of 0.7, and the CR values were greater than the criterion of 0.7, indicating that the measurement model for each latent first-order variable met the reliability requirements. The reliability results of first-order variables are shown in Table 5.1.

Table 5.1 Reliability Analysis of First-order Variables

Latent variables	Cronbach's $\alpha$	Composite reliability (CR)
2.1. CRO Employee Engagement	0.962	0.967
2.2. CRO Communication Strategies	0.869	0.892
2.3. CRO Organizational Relationship	0.961	0.965
2.4. Pharmaceutical Client Employee Engagement	0.938	0.946
2.5. Pharmaceutical Client Communication Strategies	0.814	0.851
2.6. Pharmaceutical Client Organizational Relationship	0.936	0.943
3.1. Planning Capabilities	0.930	0.939
3.2. Execution Capabilities	0.959	0.962
3.3. Monitoring Capabilities	0.957	0.962
3.4. Adjusting Capabilities	0.961	0.966
3.5. Sensing Capabilities	0.952	0.959
3.6. Responding Capabilities	0.912	0.927
3.7. Transforming Capabilities	0.967	0.971
3.8. Integrating Capabilities	0.958	0.963
3.9. Coordinating Capabilities	0.958	0.964
4.1. Innovativeness	0.950	0.956
4.2. Project Performance Outcome	0.949	0.955
4.3. Relational Performance	0.977	0.979

### 5.1.2 Validity tests of first-order variables

As introduced during measurement validation and modification this study using a pilot sample, designed a measurement questionnaire formed based on content analysis of literature review, and expert consultations, as a way to make sure the content validity of the formal questionnaire, the convergent validity and discriminant validity of the questionnaire are the focus at this section.

#### 5.1.2.1 Convergence validity of first-order variables

In the confirmative factor analysis stage, the item loadings are greater than the 0.5 threshold, this result indicates there is no need to delete the question items. As shown in Table 5.2 to Table 5.6, all first-order factor loadings were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Specifically, as detail shown in Table 5.2, the first-order factor loadings of CRO Engagement were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.2 Factor loadings and AVEs-CRO Engagement

	2.1. CRO Employee Engagement	2.2. CRO Communication Strategies	2.3.CRO Organizational Relationship
Average variance extracted (AVE)	0.869	0.718	0.836
2.1.a. contributed new ideas or solutions to solve problems during this project	0.945		
2.1.b. actively sought opportunities to improve project	0.951		
2.1.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	0.953		
2.1.d. actively participated in the decision-making and implementation of this project	0.919		
2.1.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	0.891		
2.2.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with pharmaceutical client team		0.876	
2.2.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with pharmaceutical client team		0.820	
2.2.c. adopted the practice of education/training as a communication strategy with pharmaceutical client team		0.836	
2.2.d. disclosed its project performance reports (e.g. operational, financial) to pharmaceutical client team		0.856	
2.3.a. adopted project collaborated learning to engage the pharmaceutical client			0.895
2.3.b. actively sought to solve problems together with the pharmaceutical client			0.942
2.3.c. actively had good relationship with the pharmaceutical client			0.913
2.3.d. had good contracting experience with the pharmaceutical client			0.869
2.3.e. is trustworthy			0.927
2.3.f. was able to do what the pharmaceutical client need to do			0.938

As detail shown in Table 5.3, the first-order factor loadings of Pharmaceutical Client Engagement were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.3 Factor loadings and AVEs-Pharmaceutical Client Engagement

	2.5. Pharmaceutical Client Employee Engagement	2.6. Pharmaceutical Client Communication Strategies	2.7. Pharmaceutical Client Organizational Relationships
Average variance extracted (AVE)	0.802	0.645	0.758
2.4.a. contributed new ideas or solutions to solve problems during this project	0.904		
2.4.b. actively sought opportunities to improve project	0.931		
2.4.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	0.931		
2.4.d. actively participated in the decision-making and implementation of this project	0.880		
2.4.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	0.829		
2.5.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with CRO team		0.852	
2.5.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with CRO team		0.730	
2.5.c. adopted the practice of education/training as a communication strategy with CRO team		0.879	
2.5.d. disclosed its project performance reports (e.g. operational, financial) to CRO team		0.740	
2.6.a. adopted project collaborated learning to engage CRO team			0.873
2.6.b. actively sought to solve problems together with the CRO team			0.891
2.6.c. actively had good relationship with CRO team			0.907
2.6.d. had good contracting experience with CRO team			0.829
2.6.e. is trustworthy			0.884
2.6.f. was able to do what CRO team need to do			0.839

As detail shown in Table 5.4, the first-order factor loadings of Operational (Routine) Capabilities were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.4 Factor loadings and AVEs-Operational (Routine) Capabilities

	3.1. Planning capabilities	3.2. Execution capabilities	3.3. Monitoring capabilities	3.4. Adjusting capabilities
Average variance extracted (AVE)	0.781	0.778	0.853	0.866
3.1.a. task content objectives	0.865			
3.1.b. schedule performance objectives	0.893			
3.1.c. cost performance objectives	0.884			
3.1.d. quality performance objectives	0.891			
3.1.e. satisfaction performance objectives	0.886			
3.2.a. established standards and procedures		0.879		
3.2.b. planned objectives		0.900		
3.2.c. Integration plans		0.926		
3.2.d. Human resources plans		0.872		
3.2.e. Communication plans		0.840		
3.2.f. Risk management plans		0.896		
3.2.g. Procurement plans		0.850		
3.2.h. Change management plans		0.892		
3.3.a. task content performance gaps			0.942	
3.3.b. schedule performance gaps			0.920	
3.3.c. cost performance gaps			0.918	
3.3.d. quality performance gaps			0.920	
3.3.e. satisfaction performance gaps			0.917	
3.4.a. task content objectives based on task content performance gaps				0.942
3.4.b. schedule performance objectives based on schedule performance gaps				0.959
3.4.c. cost performance objectives based on cost performance gaps				0.920
3.4.d. project quality based on quality performance gaps				0.915
3.4.e. project activities based on satisfaction performance gaps				0.917

As detail shown in Table 5.5, the first-order factor loadings of Dynamic Capabilities were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

As detail shown in Table 5.6, the first-order factor loadings of Innovativeness, Project Performance Outcome, Relational Performance were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.5 Factor loadings and AVEs-Dynamic Capabilities

	3.5. Sensing Capabilit ies	3.6. Respon ding capabili ties	3.7. Transfor ming capabili ties	3.8. Integratin g capabili ties	3.9. Coordinat ing capabili ties
Average variance extracted (AVE)	0.874	0.791	0.884	0.856	0.888
3.5.a. frequently scanned the industry environment to identify new business opportunities	0.928				
3.5.b. periodically reviewed the likely effect of changes in our industry environment on the project	0.941				
3.5.c. often reviewed our product/service development efforts to ensure they were in line with what the project wanted	0.933				
3.5.d. devoted time implementing ideas for new business	0.937				
3.6.a. policy and industry environment		0.891			
3.6.b. vendors service		0.916			
3.6.c. client requirements		0.887			
3.6.d. consumer market		0.862			
3.7.a. had effective routines to identify, value, and import new information and knowledge			0.941		
3.7.b. had adequate routines to assimilate new information and knowledge			0.943		
3.7.c. was effective in transforming existing information into new knowledge			0.948		
3.7.d. was effective in utilizing knowledge into new products development			0.937		
3.7.e. was effective in developing new knowledge that has the potential to influence product development			0.932		
3.8.a. was forthcoming in contributing their individual input to the group				0.908	
3.8.b. was fully aware who inside the team has specialized skills and knowledge relevant to our work				0.933	
3.8.c. was fully aware who outside the team has specialized skills and knowledge relevant to our work				0.917	
3.8.d. actively interrelated and interconnect our actions to members inside the team to meet changing conditions				0.931	
3.8.e. actively interrelated and interconnect our actions between members inside and outside the team to meet changing conditions				0.937	
3.9.a. ensured an appropriate allocation of resources (e.g., information, time, reports) within our group					0.937
3.9.b. were assigned to tasks commensurate with their task relevant knowledge and skills					0.944
3.9.c. ensured that there was compatibility between group members expertise and work processes					0.958
3.9.d. Overall, our project team was well coordinated					0.931

Table 5.6 Factor loadings and AVEs-Innovativeness, Project Performance Outcome, Relational Performance

	Innovativeness	Project Performance Outcome	Relational Performance
Average variance extracted (AVE)	0.691	0.797	0.860
4.1.a. was new on the market	0.705		
4.1.b. offered unique benefits superior to those of competitors	0.791		
4.1.c. offered unique benefits superior to existing products on the market	0.780		
4.1.d. the CRO organization was enabled to become better in the management of developing new product	0.857		
4.1.e. the pharmaceutical client organization was enabled to become better in the management of developing new product	0.838		
4.1.f. the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	0.832		
4.1.g. the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	0.816		
4.1.h. the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	0.899		
4.1.i. the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions	0.897		
4.1.j. the project members were enabled to develop new process benefit to innovation	0.875		
4.2.a. was completed on schedule		0.858	
4.2.b. was completed within budget		0.880	
4.2.c. met quality goals		0.890	
4.2.d. deliverable met planned task content scope		0.926	
4.2.e. was satisfied as CRO expected		0.878	
4.2.f. was satisfied as pharmaceutical client expected		0.923	
4.3.a. were more confident in the pharmaceutical client team than before			0.925
4.3.b. were satisfactory with the relationship with the pharmaceutical client team			0.931
4.3.c. were more committed to the relationship and collaboration with the pharmaceutical client team			0.909

4.3.d. believed that the relationship with the pharmaceutical client team is strategic sustainable	0.916
4.3.e. were more confident in the CRO team than before	0.941
4.3.f. were satisfactory with the relationship with the CRO team	0.947
4.3.g. were more committed to the relationship and collaboration with the CRO team	0.923
4.3.h. believed that the relationship with the CRO team is strategic sustainable	0.925

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#### **5.1.2.2 Discriminatory validity of first-order variables**

The data on the right-angle line in Table 5.7 Fronell-Larcker Criterion represented the square roots of AVE, and the results showed that all square roots of AVEs were greater than the correlation coefficients between all latent variables. The HTMT values of most of the first-order variables were less than 0.85, although from a statistical point of view, some of the values did not meet the accepted reference range slightly, these indicators were still retained in the data analysis from a theoretical point of view and justification. The results suggest that the discriminative validity requirements of first-order variables were satisfied.



Table 5.7 Discriminatory Validity of First-order Variables

	2.1. CEE	2.2. CCS	2.3. COR	2.4. PEE	2.5. PCS	2.6. POR	3.1. PC	3.2. EC	3.3. MC	3.4. AC	3.5. SC	3.6. RC	3.7. TC	3.8. IC	3.9. CC	4.1. Inno	4.2. PPO	4.3. PRP
<b>Fronell-Larcker Criterion</b>																		
2.1. CEE	0.932																	
2.2. CCS	0.788	0.847																
2.3. COR	0.895	0.814	0.914															
2.4. PEE	0.420	0.523	0.501	0.896														
2.5. PCS	0.462	0.678	0.489	0.674	0.803													
2.6. POR	0.419	0.522	0.481	0.719	0.742	0.871												
3.1. PC	0.563	0.618	0.654	0.609	0.598	0.609	0.884											
3.2. EC	0.637	0.661	0.705	0.625	0.597	0.620	0.854	0.882										
3.3. MC	0.594	0.612	0.657	0.583	0.537	0.536	0.846	0.871	0.923									
3.4. AC	0.642	0.599	0.671	0.574	0.544	0.546	0.812	0.852	0.854	0.931								
3.5. SC	0.503	0.528	0.496	0.493	0.584	0.540	0.678	0.697	0.704	0.738	0.935							
3.6. RC	0.624	0.600	0.639	0.539	0.548	0.521	0.740	0.780	0.762	0.795	0.815	0.889						
3.7. TC	0.594	0.574	0.590	0.499	0.552	0.500	0.698	0.735	0.729	0.783	0.818	0.865	0.940					
3.8. IC	0.663	0.642	0.662	0.544	0.542	0.530	0.730	0.788	0.764	0.811	0.720	0.821	0.831	0.925				

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	2.1. CEE	2.2. CCS	2.3. COR	2.4. PEE	2.5. PCS	2.6. POR	3.1. PC	3.2. EC	3.3. MC	3.4. AC	3.5. SC	3.6. RC	3.7. TC	3.8. IC	3.9. CC	4.1. Inno	4.2. PPO	4.3. PRP
3.9. CC	0.666	0.657	0.684	0.552	0.548	0.514	0.734	0.784	0.771	0.804	0.693	0.808	0.803	0.900	0.943			
4.1. Inno	0.641	0.659	0.665	0.542	0.574	0.548	0.727	0.759	0.754	0.769	0.694	0.759	0.775	0.795	0.793	0.831		
4.2. PPO	0.591	0.568	0.649	0.507	0.472	0.479	0.711	0.723	0.739	0.727	0.597	0.683	0.633	0.684	0.704	0.807	0.893	
4.3. PRP	0.697	0.649	0.751	0.458	0.485	0.525	0.649	0.681	0.687	0.681	0.600	0.658	0.665	0.691	0.701	0.808	0.844	0.927
<b>HTMT</b>																		
2.1. CEE																		
2.2. CCS	0.863																	
2.3. COR	0.931	0.894																
2.4. PEE	0.443	0.582	0.530															
2.5. PCS	0.521	0.799	0.553	0.771														
2.6. POR	0.438	0.576	0.504	0.767	0.852													
3.1. PC	0.595	0.688	0.691	0.653	0.683	0.651												
3.2. EC	0.662	0.724	0.734	0.659	0.673	0.653	0.905											
3.3. MC	0.619	0.670	0.685	0.615	0.604	0.564	0.896	0.909										
3.4. AC	0.666	0.654	0.697	0.604	0.612	0.574	0.858	0.887	0.891									
3.5. SC	0.523	0.574	0.516	0.522	0.661	0.570	0.718	0.729	0.737	0.770								

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	<b>2.1. CEE</b>	<b>2.2. CCS</b>	<b>2.3. COR</b>	<b>2.4. PEE</b>	<b>2.5. PCS</b>	<b>2.6. POR</b>	<b>3.1. PC</b>	<b>3.2. EC</b>	<b>3.3. MC</b>	<b>3.4. AC</b>	<b>3.5. SC</b>	<b>3.6. RC</b>	<b>3.7. TC</b>	<b>3.8. IC</b>	<b>3.9. CC</b>	<b>4.1. Inno</b>	<b>4.2. PPO</b>	<b>4.3. PRP</b>
3.6. RC	0.659	0.666	0.675	0.584	0.632	0.561	0.803	0.832	0.814	0.846	0.879							
3.7. TC	0.615	0.621	0.610	0.523	0.619	0.523	0.735	0.763	0.758	0.812	0.852	0.922						
3.8. IC	0.690	0.700	0.689	0.573	0.611	0.558	0.773	0.822	0.797	0.845	0.753	0.874	0.864					
3.9. CC	0.693	0.717	0.711	0.581	0.618	0.540	0.777	0.817	0.804	0.838	0.724	0.860	0.834	0.939				
4.1. Inno	0.662	0.717	0.689	0.574	0.653	0.579	0.772	0.792	0.790	0.800	0.723	0.807	0.802	0.829	0.826	0.848		
4.2. PPO	0.616	0.621	0.677	0.537	0.535	0.506	0.756	0.757	0.774	0.760	0.626	0.730	0.659	0.715	0.735	0.834	0.875	
4.3. PRP	0.719	0.701	0.774	0.477	0.543	0.545	0.680	0.702	0.709	0.701	0.621	0.692	0.683	0.713	0.722	0.263	0.225	0.397

Notes: CEE=CRO Employee Engagement, CCS=CRO Communication Strategies, COR=CRO Organizational Relationship, PEE=Pharmaceutical Client Employee Engagement, PCS=Pharmaceutical Client communication strategies, POR=Pharmaceutical Client Organizational Relationship, PC=Planning Capabilities, EC=Execution Capabilities, MC=Monitoring Capabilities, AC=Adjusting Capabilities, SC=Sensing Capabilities, RC=Responding Capabilities, TC=Transforming Capabilities, IC=Integrating Capabilities, CC=Coordinating Capabilities, Inno=Innovativeness, PPO=Project Performance Outcomes, PRC= Project Relational Performance

## 5.2 Reliability and validity analysis results of second-order variables

### 5.2.1 Relative Importance of Indicators

To validate the second-order constructs of CRO Engagement, Pharmaceutical Client Engagement, Operational (routine) capabilities, Dynamic Capabilities, and Innovativeness, Project Performance Outcome, and Relational Performance, this study followed the guidelines discussed by Marakas et al. (2007). Firstly, we assessed the importance of the factors, which includes only the effect of the factors from first to second order. As shown in Table 5.8, all  $\beta$  coefficients were statistically significant (all  $p$ -values were below 0.05), while all  $t$ -values were greater than 1.96. The results support the validity of the formative second-order constructs of CRO Engagement, Pharmaceutical Client Engagement, Operational (routine) capabilities, Dynamic Capabilities, and Innovativeness, Project Performance Outcome, and Relational Performance.

Table 5.8 Relative Importance of Indicators

Variable	Relationship	Type	Initial coeffic ient	Mean value coefficient	SD	$t$ -value	$p$ -value
CRO Engagem ent	CRO Employee Engagement→ CRO Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.948	0.948	0.007	132.553	0.000
	CRO Communication Strategies→ CRO Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.918	0.918	0.011	82.177	0.000
	CRO Organizational Relationship → CRO Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.959	0.959	0.005	195.824	0.000
Pharmace utical Client Engagem ent	Pharmaceutical Client Employee Engagement→Pharmaceutical Client Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.886	0.886	0.019	47.334	0.000
	Pharmaceutical Client Communication Strategies→Pharmaceutical Client Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.887	0.886	0.014	63.747	0.000
	Pharmaceutical Client Organizational Relationship→Pharmaceutical Client Engagement	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.911	0.911	0.012	76.032	0.000

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Variable	Relationship	Type	Initial coefficient	Mean value coefficient	SD	t-value	p-value
Operational (routine) capabilities	Planning Capabilities →Operational (Routine) Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.932	0.932	0.009	101.066	0.000
	Execution Capabilities →Operational (routine) Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.939	0.939	0.009	109.556	0.000
	Monitoring Capabilities→Operational (routine) Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.948	0.948	0.008	117.621	0.000
	Adjusting Capabilities→Operational (routine) Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.932	0.932	0.014	67.115	0.000
	Sensing Capabilities →Dynamic Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.874	0.874	0.018	48.646	0.000
Dynamic capabilities	Responding Capabilities→Dynamic Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.935	0.935	0.009	102.291	0.000
	Conversion Capabilities →Dynamic Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.938	0.938	0.008	113.502	0.000
	Integrating capabilities →Dynamic Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.932	0.932	0.009	99.796	0.000
	Coordinating capabilities →Dynamic Capabilities	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.917	0.917	0.010	92.744	0.000
	Was new on the market → Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.705	0.705	0.034	20.523	0.000
Innovativ eness	offered unique benefits superior to those of competitors →Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.791	0.790	0.027	29.024	0.000
	offered unique benefits superior to existing products on the market→ Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.780	0.779	0.027	28.839	0.000
	the CRO organization was enabled to become better in the management of developing new product→Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.857	0.857	0.017	51.853	0.000
	the pharmaceutical client organization was enabled to become better in the management of developing new product →Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.838	0.838	0.020	42.343	0.000
	the CRO evaluated and incorporated new ideas that come from the pharmaceutical client →Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.832	0.832	0.022	37.186	0.000
	the pharmaceutical client evaluated and incorporated new ideas that come from the CRO→Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.816	0.817	0.024	33.499	0.000

Variable	Relationship	Type	Initial coeffic ient	Mean value coefficient	SD	t-value	p-value
	the project members were enabled to develop a new innovative culture of cleverly transforming information from 1 <sup>st</sup> - to 2 <sup>nd</sup> - internal and external sources into valuable knowledge for new product development → Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.899	0.899	0.011	84.643	0.000
	the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions →Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.897	0.898	0.012	77.429	0.000
	the project members were enabled to develop new process benefit to innovation →Innovativeness	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.875	0.875	0.016	54.978	0.000
	was completed on schedule →Project Performance Outcome	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.858	0.857	0.022	38.395	0.000
	was completed within budget →Project Performance Outcome	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.880	0.880	0.016	55.648	0.000
Project Performance Outcome	met quality goals→ project performance results deliverable met planned task content scope →Project Performance Outcome	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.890	0.890	0.014	63.721	0.000
	was satisfied as CRO expected →Project Performance Outcome	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.878	0.878	0.021	41.170	0.000
	was satisfied as pharmaceutical client expected →Project Performance Outcome	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.923	0.923	0.012	80.181	0.000
Relationa l	were more confident in the pharmaceutical client team than before →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.925	0.925	0.010	93.303	0.000
Performa nce	were satisfactory with the relationship with the pharmaceutical client team →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> - order	0.931	0.932	0.010	93.188	0.000

Variable	Relationship	Type	Initial coefficient	Mean value coefficient	SD	t-value	p-value
	were more committed to the relationship and collaboration with the pharmaceutical client team→Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.909	0.909	0.013	68.484	0.000
	believed that the relationship with the pharmaceutical client team is strategic sustainable →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.916	0.916	0.012	77.973	0.000
	were more confident in the CRO team than before →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.941	0.941	0.008	113.925	0.000
	were satisfactory with the relationship with the CRO team →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.947	0.947	0.006	154.368	0.000
	were more committed to the relationship and collaboration with the CRO team → Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.923	0.923	0.015	61.945	0.000
	believed that the relationship with the CRO team is strategic sustainable →Relational Performance	1 <sup>st</sup> - to 2 <sup>nd</sup> -order	0.925	0.924	0.015	61.338	0.000

### 5.2.2 Reliability of second-order variables

As showed in Table 5.9, the Cronbach's  $\alpha$  values for all second-order variables were greater than the criterion of 0.8, and the CR values were greater than the criterion of 0.7, indicating that the measurement model for each latent second-order variable met the reliability requirements.

Table 5.9 Reliability Analysis of Second-order Variables

Second-order Variables	Cronbach's $\alpha$	Composite reliability (CR)
CRO Engagement	0.936	0.948
Pharmaceutical Client Engagement	0.875	0.899
Dynamic capabilities	0.954	0.961
Operational (routine) capabilities	0.954	0.961
Innovative	0.950	0.956
Project performance results	0.949	0.955
Relational outcomes	0.977	0.979

### 5.2.3 Convergence validity of second-order variables

As shown in Figure 5.1, Table 5.10 to Table 5.12, all second-order factor loadings are greater than 0.5 and AVE values are greater than 0.5, indicating the convergent validity of second-order variables requirements were met.

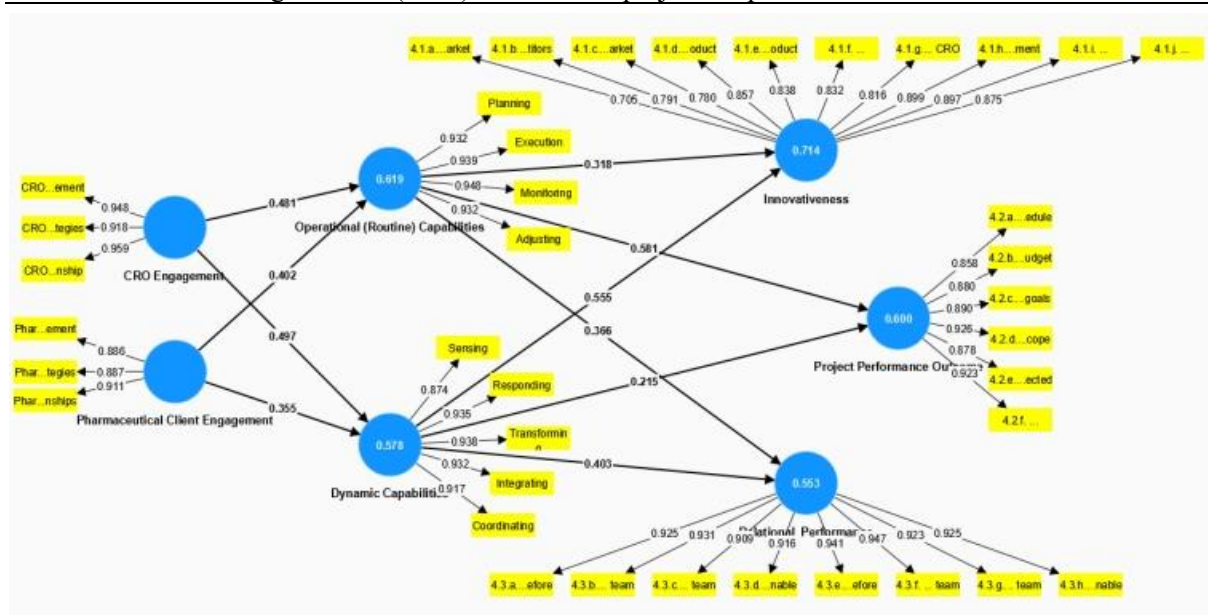


Figure 5.1 Factor loadings

Specifically, as detail shown in Table 5.10, the second-order factor loadings of CRO Engagement and Pharmaceutical Client Engagement were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.10 Factor Loadings and AVEs of Second-order Variables- CRO Engagement, Pharmaceutical Client Engagement

	CRO Engagement	Pharmaceutical Client Engagement
Average variance extracted (AVE)	0.887	0.800
2.1. CRO Employee Engagement	0.948	
2.2. CRO Communication Strategies	0.918	
2.3. CRO Organizational Relationship	0.959	
2.4. Pharmaceutical Client Employee Engagement		0.886
2.5. Pharmaceutical Client communication strategies		0.887
2.6. Pharmaceutical Client Organizational Relationship		0.911

As detail shown in Table 5.11, the second-order factor loadings of Operational (routine) Capabilities and Dynamic Capabilities were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.11 Factor Loadings and AVEs of Second-order Variables-Operational (routine) Capabilities, Dynamic Capabilities

	Operational (routine) capabilities	Dynamic capabilities
Average variance extracted (AVE)	0.880	0.846
3.1 Planning capabilities	0.932	
3.2 Execution capabilities	0.939	
3.3 Monitoring capabilities	0.948	
3.4 Adjusting capabilities	0.932	



3.5 Sensing capabilities	0.874
3.6 Responding capabilities	0.935
3.7 Transforming capabilities	0.938
3.8 Integrating capabilities	0.932
3.9 Coordinating capabilities	0.917

As detail shown in Table 5.12, the factor loadings of Innovativeness, Project Performance Outcomes, and Relational Outcomes were greater than 0.5 and AVE values were greater than 0.5, indicating the convergent validity requirements were met.

Table 5.12 Factor Loadings and AVEs -Innovativeness, Project Performance Outcomes, Relational Outcomes

	Innovativeness	Project Performance Outcome	Relational Performance
Average variance extracted (AVE)	0.691	0.797	0.860
4.1.a. was new on the market	0.705		
4.1.b. offered unique benefits superior to those of competitors	0.791		
4.1.c. offered unique benefits superior to existing products on the market	0.780		
4.1.d. the CRO organization was enabled to become better in the management of developing new product	0.857		
4.1.e. the pharmaceutical client organization was enabled to become better in the management of developing new product	0.838		
4.1.f. the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	0.832		
4.1.g. the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	0.816		
4.1.h. the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	0.899		
4.1.i. the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions	0.897		
4.1.j. the project members were enabled to develop new process benefit to innovation	0.875		
4.2.a. was completed on schedule		0.858	
4.2.b. was completed within budget		0.880	
4.2.c. met quality goals		0.890	
4.2.d. deliverable met planned task content scope		0.926	
4.2.e. was satisfied as CRO expected		0.878	
4.2.f. was satisfied as pharmaceutical client expected		0.923	

4.3.a. were more confident in the pharmaceutical client team than before	0.925
4.3.b. were satisfactory with the relationship with the pharmaceutical client team	0.931
4.3.c. were more committed to the relationship and collaboration with the pharmaceutical client team	0.909
4.3.d. believed that the relationship with the pharmaceutical client team is strategic sustainable	0.916
4.3.e. were more confident in the CRO team than before	0.941
4.3.f. were satisfactory with the relationship with the CRO team	0.947
4.3.g. were more committed to the relationship and collaboration with the CRO team	0.923
4.3.h. believed that the relationship with the CRO team is strategic sustainable	0.925

#### 5.2.4 Discriminative validity of second-order variables

The data on the right-angle line in Table 5.13 Fornell-Larcker Criterion represent the square roots of AVE, and the results showed that all square roots of AVEs were greater than the correlation coefficients between all latent variables. HTMT ratio values of all of the second-order variables in Table 5.13 were less than 1.00 (Henseler et al., 2015), indicating the discriminative validity requirements were met. In summary, the discriminative validity criteria of second-order variables were satisfied.

Table 5.13 Discrimination validity of second-order variables

	<b>CRO Engage ment</b>	<b>Relation al Perform ance</b>	<b>Innovati veness</b>	<b>Pharmac eutical Client Engage ment</b>	<b>Dynamic Capabili ties</b>	<b>Operatio nal (Routine ) Capabili ties</b>	<b>Project Perform ance Outcome</b>
<b>Fornell-Larcker Criterion</b>							
CRO Engagemen t	0.942						
Relational Performanc e	0.743	0.927					
Innovativen ess	0.696	0.808	0.831				

	<b>CRO Engage ment</b>	<b>Relation al Perform ance</b>	<b>Innovati veness</b>	<b>Pharmac eutical Client Engage ment</b>	<b>Dynamic Capabili ties</b>	<b>Operatio nal (Routine ) Capabili ties</b>	<b>Project Perform ance Outcome</b>
Pharmaceut ical Client Engagemen t	0.584	0.544	0.616	0.894			
Dynamic Capabilities	0.704	0.720	0.830	0.645	0.920		
Operational (routine) Capabilities	0.716	0.715	0.798	0.683	0.866	0.938	
Project Performanc e Outcome	0.641	0.844	0.807	0.541	0.718	0.767	0.893
<b>HTMT</b>							
CRO Engagement							
Relational Performance	0.776						
Innovativen ess	0.730	0.834					
Pharmaceuti cal Client Engagement	0.645	0.588	0.677				
Dynamic Capabilities	0.742	0.744	0.865	0.706			
Operational (routine) Capabilities	0.757	0.740	0.835	0.748	0.906		
Project Performance Outcome	0.677	0.875	0.848	0.593	0.751	0.805	

### 5.3 Descriptive statistics for study variables

Descriptive analysis of the scores of each variable was performed using the mean and standard deviation, according to the dimensions and scoring methods corresponding to variables CRO Engagement, Pharmaceutical Client Engagement, Operational (routine) capabilities, Dynamic Capabilities, and Innovativeness, Project Performance Outcome, and Relational Performance. The descriptive statistics of the study variables are presented in Table 5.14.

Table 5.14 Descriptive results for each variable

Second-order Variable	First-order Variable	Items	Mean	SD
RO Engagement	2.1 CRO Employee Engagement	2.1.a. contributed new ideas or solutions to solve problems during this project	5.346	1.474
		2.1.b. actively sought opportunities to improve project	5.427	1.439
		2.1.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	5.222	1.445
		2.1.d. actively participated in the decision-making and implementation of this project	5.333	1.426
		2.1.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	5.662	1.315
	2.2 CRO Communication Strategies	2.2.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with pharmaceutical client team	5.449	1.517
		2.2.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with pharmaceutical client team	6.052	1.098
		2.2.c. adopted the practice of education/training as a communication strategy with pharmaceutical client team	5.148	1.510
		2.2.d. disclosed its project performance reports (eg. operational, financial) to pharmaceutical client team	5.533	1.448
	2.3 CRO Organizational Relationships	2.3.a. adopted project collaborated learning to engage the pharmaceutical client	5.501	1.357
		2.3.b. actively sought to solve problems together with the pharmaceutical client	5.598	1.393
		2.3.c. actively had good relationship with the pharmaceutical client	5.751	1.253
		2.3.d. had good contracting experience with the pharmaceutical client	5.519	1.367
		2.3.e. is trustworthy	5.496	1.384
		2.3.f. was able to do what the pharmaceutical client need to do	5.410	1.361
Pharmaceutical companies Engagement	2.4 Pharmaceutical Client Employee Engagement	2.4.a. contributed new ideas or solutions to solve problems during this project	5.758	1.091
		2.4.b. actively sought opportunities to improve project	5.874	1.031
		2.4.c. actively promoted their new ideas to colleagues or leaders to seek support and recognition	5.741	1.088
		2.4.d. actively participated in the decision-making and implementation of this project	5.933	1.022
		2.4.e. proactively interacted with pharmaceutical clients team to obtain demand information or new ideas	5.620	1.188

Stakeholder Engagement, Dynamic Capabilities, and Innovativeness: A study on Contract Research Organization (CRO) Collaborated Projects in Pharmaceutical R&D

Second-order Variable	First-order Variable	Items	Mean	SD
Operational (routine) Capabilities	2.5. Pharmaceutical Client Communications Strategies	2.5.a. actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with CRO team	5.425	1.378
		2.5.b. regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with CRO team	6.030	1.011
		2.5.c. adopted the practice of education/training as a communication strategy with CRO team	5.422	1.317
		2.5.d. disclosed its project performance reports (eg. operational, financial) to CRO team	4.763	1.679
	2.6. Pharmaceutical Client Organizational Relationships	2.6.a. adopted project collaborated learning to engage CRO team	5.496	1.208
		2.6.b. actively sought to solve problems together with the CRO team	5.706	1.129
		2.6.c. actively had good relationship with CRO team	5.531	1.187
		2.6.d. had good contracting experience with CRO team	5.454	1.197
		2.6.e. is trustworthy	5.696	1.111
		2.6.f. was able to do what CRO team need to do	5.437	1.198
	3.1. Planning Capabilities	3.1.a. task content objectives	5.731	1.088
		3.1.b. schedule performance objectives	5.679	1.153
		3.1.c. cost performance objective	5.388	1.241
		3.1.d. quality performance objectives	5.630	1.144
		3.1.e. satisfaction performance objectives	5.383	1.288
	3.2. Execution Capabilities	3.2.a. established standards and procedures	5.630	1.087
		3.2.b. planned objectives	5.546	1.114
		3.2.c. integration plans	5.533	1.094
		3.2.d. human resources plans	5.304	1.249
		3.2.e. communication plan	5.580	1.063
		3.2.f. risk management plans	5.383	1.229
		3.2.g. procurement Plans	5.252	1.191
		3.2.h. change management plans	5.370	1.246
	3.3. Monitoring Capabilities	3.3.a. task content performance gaps	5.412	1.142
		3.3.b. schedule performance gaps	5.528	1.138
		3.3.c. cost performance gaps	5.373	1.222
		3.3.d. quality performance gaps	5.427	1.160
		3.3.e. satisfaction performance gaps	5.289	1.260
	3.4. Adjusting Capabilities	3.4.a. task content objectives based on task content performance gaps	5.496	1.095
		3.4.b. schedule performance objectives based on schedule performance gaps	5.477	1.114
		3.4.c. cost performance objectives based on cost performance gaps	5.420	1.142
		3.4.d. project quality based on quality performance gaps	5.481	1.121

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Second-order Variable	First-order Variable	Items	Mean	SD
Dynamic Capabilities	3.5 Sensing Capabilities	3.4.e. project activities based on satisfaction performance gaps	5.412	1.193
		3.5.a. frequently scanned the industry environment to identify new business opportunities	4.990	1.379
		3.5.b. periodically reviewed the likely effect of changes in our industry environment on the project	5.188	1.362
		3.5.c. often reviewed our product/service development efforts to ensure they were in line with what the project wanted	5.156	1.303
		3.5.d. devoted time implementing ideas for new business	4.948	1.407
	3.6 Responding Capabilities	3.6.a. policy and industry environment	5.358	1.306
		3.6.b. vendors service	5.348	1.221
		3.6.c. client requirements	5.385	1.257
		3.6.d. consumer market	4.889	1.447
	3.7 Transforming Capabilities	3.7.a. had effective routines to identify, value, and import new information and knowledge	5.156	1.240
		3.7.b. had adequate routines to assimilate new information and knowledge	5.193	1.274
		3.7.c. was effective in transforming existing information into new knowledge	5.207	1.242
		3.7.d. was effective in utilizing knowledge into new products development	5.153	1.258
		3.7.e. was effective in developing new knowledge that has the potential to influence product development	5.106	1.281
	3.8 Integrating Capabilities	3.4.a. was forthcoming in contributing their individual input to the group	5.422	1.170
		3.4.b. was fully aware who inside the team has specialized skills and knowledge relevant to our work	5.491	1.126
		3.4.c. was fully aware who outside the team has specialized skills and knowledge relevant to our work	5.336	1.234
		3.4.d. actively interrelated and interconnect our actions to members inside the team to meet changing conditions	5.432	1.204
		3.4.e. actively interrelated and interconnect our actions between members inside and outside the team to meet changing conditions	5.405	1.175
	3.9 Coordinating Capabilities	3.9.a. ensured an appropriate allocation of resources (e.g., information, time, reports) within our group	5.528	1.151
		3.9.b. were assigned to tasks commensurate with their task relevant knowledge and skills	5.499	1.095
		3.9.c. ensured that there was compatibility between group members expertise and work processes	5.491	1.104

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Second-order Variable	First-order Variable	Items	Mean	SD
Innovativeness, Project Performance Results Relationship outcome s	4.1. Innovativeness	3.9.d. Overall, our project team was well coordinated	5.551	1.098
		4.1.a. was new on the market	5.432	1.266
		4.1.b. offered unique benefits superior to those of competitors	5.296	1.228
		4.1.c. offered unique benefits superior to existing products on the market	5.281	1.259
		4.1.d. the CRO organization was enabled to become better in the management of developing new product	5.207	1.392
		4.1.e. the pharmaceutical client organization was enabled to become better in the management of developing new product	5.454	1.178
		4.1.f. the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	5.311	1.323
		4.1.g. the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	5.301	1.301
		4.1.h. the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	5.314	1.258
		4.1.i. the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions	5.331	1.272
		4.1.j. the project members were enabled to develop new process benefit to innovation	5.323	1.232
	4.2. Project Performance Outcome	4.2.a. was completed on schedule	5.343	1.396
		4.2.b. was completed within budget	5.143	1.502
		4.2.c. met quality goals	5.489	1.210
		4.2.d. deliverable met planned task content scope	5.481	1.246
		4.2.e. was satisfied as CRO expected	5.415	1.250
		4.2.f. was satisfied as pharmaceutical client expected	5.264	1.396
	4.3 Relationship Performance	4.3.a. were more confident in the pharmaceutical client team than before	5.286	1.279
		4.3.b. were satisfactory with the relationship with the pharmaceutical client team	5.272	1.233
		4.3.c. were more committed to the relationship and collaboration with the pharmaceutical client team	5.395	1.244
		4.3.d. believed that the relationship with the pharmaceutical client team is strategic sustainable	5.380	1.291
		4.3.e. were more confident in the CRO team than before	5.160	1.418
		4.3.f. were satisfactory with the relationship with the CRO team	5.138	1.439
		4.3.g. were more committed to the relationship and collaboration with the CRO team	5.086	1.447

Second-order Variable	First-order Variable	Items	Mean	SD
		4.3.h. believed that the relationship with the CRO team is strategic sustainable	5.148	1.445

## 5.4 Structural Equation Model Analysis Results

After measurement model tests (reliability and validity examination), the structural model was examined in this study using SmartPLS 4.0 software. The evaluation of formative structural model was based on three main criteria: 1) the  $R^2$  of the endogenous variables, 2) the estimates of the path coefficients, and 3) the effect size ( $f^2$ ) of the hypothesized relationships.

### 5.4.1 Structural Model Analysis Results for research model and hypothesis testing (direct effects) between second-order variables

The analysis results of the structural model are displayed in Figure 5.2 and summarized in Table 5.15. The values showed in Figure 5.2 include the path coefficients and corresponding  $t$ -values. To reiterate, good model fit is established with acceptably high  $R^2$  values and significant path coefficients. Overall, the current model demonstrates good fit when considering these criteria. Five dependent variables (latent constructs) had  $R^2$  values above 0.197 which Rai et al. (2006) suggests moderate explanatory power. In the current study, the total variance explained by the model (shown in the center of the endogenous variables) was adequate: the model explained 61.9% of operational (routine) capabilities, 57.8% of dynamic capabilities, 71.4% of Innovativeness, 60.0% of Project Performance Outcomes, and 55.3% Relational Performance.



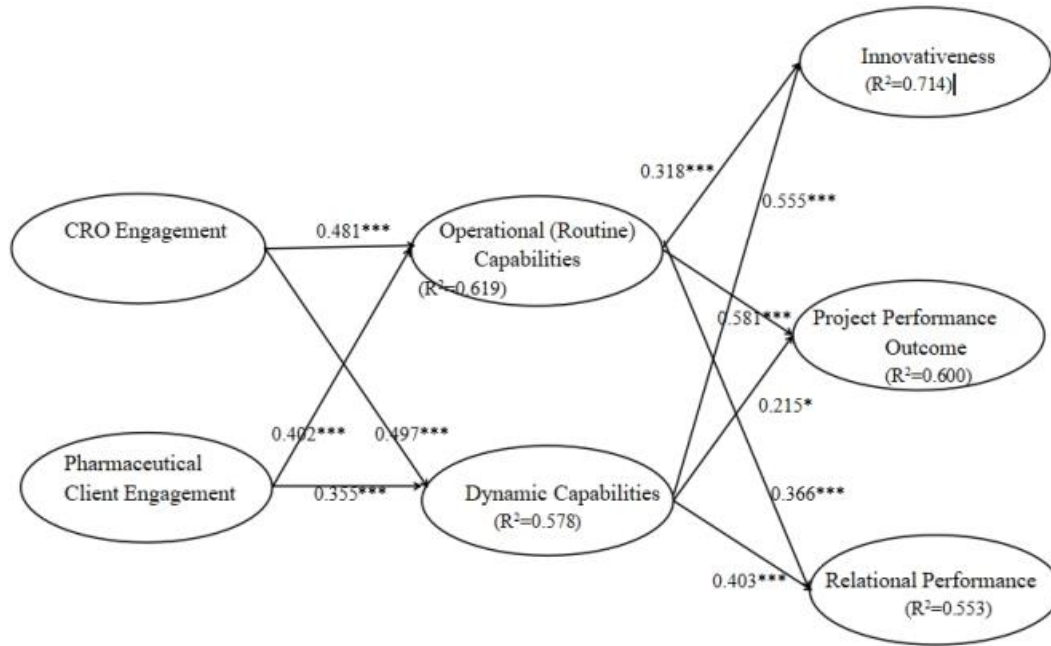


Figure 5.2 Structural Equation Model Test Results

Note: \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$

The structural model testing results showed that ten hypotheses proposed in this study were all supported. CRO Engagement had significant effects on operational (routine) capabilities ( $\beta=0.481$ ,  $p < 0.001$ ) and dynamic capacity ( $\beta=0.497$ ,  $p < 0.001$ ), supporting hypotheses H1 and H3. Pharmaceutical Client Engagement had significant effects on operational (routine) capabilities ( $\beta=0.402$ ,  $p < 0.001$ ) and dynamic capabilities ( $\beta=0.355$ ,  $p < 0.001$ ), supporting hypotheses H2 and H4. Operational (routine) capabilities had significant effects on Innovativeness ( $\beta=0.318$ ,  $p < 0.001$ ), Project Performance Outcome, ( $\beta=0.581$ ,  $p < 0.001$ ) and Relational Performance ( $\beta=0.366$ ,  $p < 0.001$ ), supporting hypotheses H5, H6 and H7. Dynamic Capabilities had significant effects on the Innovativeness ( $\beta=0.555$ ,  $p < 0.001$ ), Project Performance Outcome ( $\beta=0.215$ ,  $p < 0.05$ ) and Relational Performance ( $\beta=0.403$ ,  $p < 0.001$ ), supporting hypotheses H8, H9 and H10. An overall analysis of the  $R^2$  values, path coefficients, total effects and the  $f^2$  values for effect size suggests good model fit. As shown in Table 5.15. These tests provided not only statistical validation of the model and proposed hypotheses but were also capable of lending valuable insights for researchers and practitioners.

Table 5.15 Hypotheses, and Path Coefficient, and Test Results

Hypothe- tical num- ber	Support- ed	Hypothesized Relationship	Begin- ning coeffi- cient	Mean coeffi- cient	Stand- ard Devia- tion	<i>t</i> - value	<i>p</i> - value	<i>f</i> <sup>2</sup> - value
H1	Support- ed	CRO Engagement →Operational (Routine) Capabilities Pharmaceutical Client	0.481	0.480	0.049	9.837	0.000	0.400
H2	Support- ed	Engagement →Operational (Routine) Capacity CRO Engagement	0.402	0.404	0.045	9.029	0.000	0.280
H3	Support- ed	→Dynamic Capabilities Pharmaceutical Client	0.497	0.496	0.047	10.528	0.000	0.385
H4	Support- ed	Engagement →Dynamic Capabilities Operational (routine)	0.355	0.357	0.042	8.409	0.000	0.197
H5	Support- ed	Capabilities → Innovativeness Operational (routine)	0.318	0.316	0.073	4.366	0.000	0.089
H6	Support- ed	Capabilities →Project Performance Outcome Operational (routine)	0.581	0.581	0.080	7.248	0.000	0.211
H7	Support- ed	Capabilities →Relational Performance	0.366	0.367	0.081	4.507	0.000	0.075
H8	Support- ed	Dynamic Capabilities → Innovativeness Dynamic Capabilities	0.555	0.557	0.068	8.181	0.000	0.270
H9	Support- ed	→ Project Performance Outcome Dynamic Capabilities	0.215	0.215	0.085	2.527	0.012	0.029
H10	Support- ed	→Relational Performance	0.403	0.403	0.080	5.012	0.000	0.091

#### 5.4.2 Structural model results for mediating relationships between second-order variables

Although the framework for mediating effects analysis proposed by Baron and Kenny in 1986 is considered a "standard" framework, there have been increasing skepticism in recent years (Zhao et al., 2010). On the basis of previous mediating effect tests, Zhao et al. (2010) proposed a new mediating effect test, which considered that only indirect mediating effects need to be considered, as shown in Figure 5.3. Following this, we tested the mediating effects using Smart PLS 4.0 with the Bootstrap (5000).

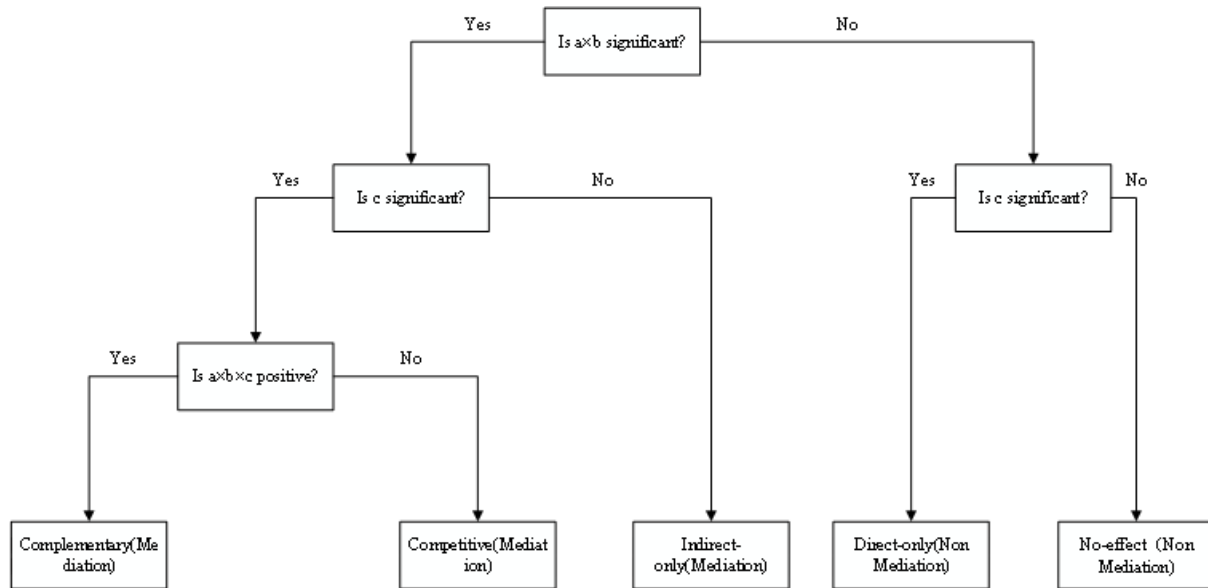


Figure 5.3 Types of mediating effects

Source: Zhao et al. (2010)

To examine the mediating roles of operational (routine) competence and dynamic competence in second-order variables, we tested the direct relationship between CRO Engagement and Pharmaceutical Client Engagement and three outcome variables: Innovativeness, Project Performance Outcomes, and relational outcomes. Since the direct effects of pharmaceutical firm engagement on Innovativeness, Project Performance Outcomes, and relational outcomes were not significant, pharmaceutical firm engagement was a complete mediating effect (the mediating variable is operational (routine) Capabilities or dynamic Capabilities), i.e., the impacts of Pharmaceutical Client Engagement on Innovativeness, Project Performance Outcomes, and relational outcomes were entirely mediated by operational (routine) or dynamic capabilities, as shown in Table 5.16.

Table 5.16 Results of mediating effect test between second-order variables-1

Relationships	Initial coefficient	Mean value coefficient t	Standard deviation	t-value	p-value	Mediating Type
CRO Engagement →Innovativeness	0.164	0.163	0.044	3.750	0.000	Partial mediation
CRO Engagement →Project Performance Outcome	0.497	0.496	0.047	10.560	0.000	Partial mediation
CRO Engagement →Relational Performance	0.432	0.426	0.068	6.387	0.000	Partial mediation
Pharmaceutical Client Engagement→ Innovativeness	0.054	0.053	0.044	1.245	0.213	Full mediation
Pharmaceutical Client Engagement→ Project Performance Outcome	-0.014	-0.015	0.053	0.257	0.798	Full mediation

Pharmaceutical Client Engagement → Relational Performance	0.000	-0.002	0.051	0.003	0.998	Full mediation
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Since the direct impacts of CRO Engagement on Innovativeness, Project Performance Outcomes, and relational outcomes were significant, the relationships between CRO Engagement and Innovativeness, Project Performance Outcomes, and relational outcomes were a complementary relationship mediated in part by operational (routine) capabilities or dynamic capabilities, and by operational (routine) capabilities or dynamic capabilities. The specific results are shown in Table 5.17.

Table 5.17 Results of mediating effect test between second-order variables-2

Relationships	Initial coefficient	Mean value coefficient	Standard deviation	t-value	p-value	Mediating Type
CRO Engagement → Dynamic Capabilities → Innovativeness	0.243	0.243	0.043	5.687	0.000	Complementary mediation
CRO Engagement → Dynamic Capabilities → Project Performance Outcome	0.081	0.081	0.042	1.925	0.054	Complementary mediation
CRO Engagement → Dynamic Capabilities → Relational Performance	0.128	0.130	0.043	2.973	0.003	Complementary mediation
CRO Engagement → Operational (Routine) Capabilities → Innovativeness	0.106	0.106	0.039	2.751	0.006	Complementary mediation
CRO Engagement → Operational (Routine) Capabilities → Project Performance Outcome	0.249	0.249	0.054	4.649	0.000	Complementary mediation
CRO Engagement → Operational (Routine) Capabilities → Relational Performance	0.088	0.092	0.044	1.998	0.046	Complementary mediation

#### 5.4.3 Structural model results for mediating relationships between first-order variables

To further examine the mediating roles of Operational (Routine) Capabilities and Dynamic Capabilities in the first-order variables, we tested the direct relationship between CRO employee engagement, CRO communication strategy, CRO organizational relationship, Pharmaceutical Client employee engagement, Pharmaceutical Client communication strategy, Pharmaceutical Client CRO organizational relationship, and three outcome variables: Innovativeness, Project Performance Outcome and relational outcome. As shown in Table 5.18, since the direct impacts of CRO communication strategy on Innovativeness, Project Performance Outcomes and relational outcomes were not significant, CRO employee

engagement, CRO communication strategy to Innovativeness, Project Performance Outcomes and relational outcomes were complete mediating effects (the mediating variable is Operational (Routine) Capabilities or Dynamic Capabilities) , i.e., the impacts of CRO employee engagement, CRO communication strategies on Innovativeness, Project Performance Outcomes, and relational outcomes were entirely mediated by operational (routine) capabilities or dynamic capabilities. Since the direct impacts of CRO organizational relationship on Innovativeness and Project Performance Outcome were not significant, the CRO organization relationship with Innovativeness and Project Performance Outcome were complete mediating effects (the mediating variable is Operational (Routine) Capabilities or Dynamic Capabilities), i.e., the impacts of CRO organizational relationships on Innovativeness, Project Performance Outcomes were entirely mediated by operational (routine) capabilities or dynamic capabilities.

Since the direct impacts of Pharmaceutical Client employee engagement, Pharmaceutical Client communication strategy, and Pharmaceutical Client organizational relationship on Innovativeness and Project Performance Outcomes were not significant, Pharmaceutical Client employee engagement, Pharmaceutical Client communication strategy, and Pharmaceutical Client organization were related to Innovativeness, and Project Performance Outcomes through complete mediating effects (the mediating variable was Operational (Routine) Capabilities or Dynamic Capabilities), that is, the impacts of Pharmaceutical Client employee engagement, Pharmaceutical Client communication strategy, and Pharmaceutical Client organizational relationship on Innovativeness, Project Performance Outcome were entirely mediated by operational (routine) capabilities or dynamic capabilities. Since the direct impact of the communication strategy of the Pharmaceutical Client on the relational outcome was not significant, the communication strategy of the Pharmaceutical Client was completely mediated by the relational outcome (the mediating variable was the Operational (Routine) Capabilities or the Dynamic Capabilities), that is, the influence of the communication strategy of the Pharmaceutical Client on the relational outcome was completely mediated by the Operational (Routine) Capabilities or the Dynamic Capabilities.

Since the direct impacts of CRO organizational relationship, employee engagement of Pharmaceutical Client and Pharmaceutical Client organizational relationship on relational outcomes was significant in the first-order variables, the relationships between CRO organizational relationship, Pharmaceutical Client employee engagement and Pharmaceutical Client organizational relationship and relational outcome were through partial mediating effects, that is, the influences of CRO organizational relationship, Pharmaceutical Client employee engagement and Pharmaceutical Client organizational relationship on relational outcomes were

partly mediated by Operational (Routine) Capabilities or Dynamic Capabilities. The specific results are shown in Table 5.18.

Table 5.18 Results of mediating effect test between first-order variables

Relationships	Initial coefficient	Mean value coefficient	Standard deviation	t-value	p-value	Mediating Type
2.1. CRO Employee Engagement →4.1. Innovativeness	0.018	0.021	0.076	0.241	0.809	Full mediation
2.1. CRO Employee Engagement →4.2. Project Performance Outcome	-0.002	-0.002	0.102	0.015	0.988	Full mediation
2.1. CRO Employee Engagement →4.3. Relational Performance	0.023	0.022	0.081	0.279	0.780	Full mediation
2.2. CRO Communication Strategy →4.1. Innovativeness	0.105	0.107	0.067	1.558	0.119	Full mediation
2.2. CRO Communication Strategy →4.2. Project Performance Outcome	-0.057	-0.052	0.082	0.693	0.488	Full mediation
2.2. CRO Communication Strategies →4.3. Relational Performance	-0.019	-0.018	0.077	0.254	0.800	Full mediation
2.3. CRO Organizational Relationships →4.1. Innovativeness	0.043	0.036	0.079	0.550	0.582	Full mediation
2.3. CRO Organizational Relations →4.2. Project Performance Outcome	0.216	0.212	0.110	1.953	0.051	Full mediation
2.3. CRO Organizational Relationships →4.3. Relational Performance	0.472	0.464	0.094	5.016	0.000	Partial mediation
2.4. Pharmaceutical Client Employee Engagement→4.1. Innovativeness	-0.014	-0.019	0.047	0.293	0.769	Full mediation
2.4. Pharmaceutical Client Employee Engagement →4.2. Project Performance Outcome	0.015	0.006	0.057	0.261	0.794	Full mediation
2.4. Pharmaceutical Client Employee Engagement →4.3. Relational Performance	-0.116	-0.117	0.057	2.046	0.041	Partial mediation
2.5. Pharmaceutical Client Communication Strategies →4.1. Innovativeness	0.017	0.018	0.059	0.290	0.772	Full mediation
2.5. Pharmaceutical Client Communication Strategies →4.2. Project Performance Outcome	-0.005	-0.008	0.074	0.064	0.949	Full mediation
2.5. Pharmaceutical Client Communication Strategies →4.3. Relational Performance	-0.049	-0.051	0.073	0.680	0.496	Full mediation

2.6. Pharmaceutical Client Organizational Relationships →4.1. Innovativeness	0.057	0.058	0.048	1.179	0.239	Full mediation
2.6. Pharmaceutical Client Organizational Relationships →4.2. Project Performance Outcome	0.009	0.017	0.062	0.140	0.889	Full mediation
2.6. Pharmaceutical Client Organizational Relationships →4.3. Relational Performance	0.198	0.197	0.070	2.854	0.004	Partial mediation

## 5.5 Summary of Analysis Results

The results suggest that the measures used to assess the study variables met the reliability and validity requirements. In addition, the research model and hypotheses are supported by the results. Furthermore, our results reveal a set interesting mediating relationships among the study variables. The  $R^2$  value of Operational (routine) Capabilities (0.619), Dynamic Capabilities (0.578), Innovativeness (0.714), Project Performance Outcome (0.600), Relational Performance (0.553), suggest that the model can explain well the mechanism by which Engagement affects Innovativeness and project performance through Operational (routine) Capabilities and Dynamic Capabilities. The main results of this study include the followings. CRO Engagement and Pharmaceutical Client Engagement, had significant positively effects on Operational (routine) Capabilities and Dynamic Capabilities, and through these two mediators, which had significant positively effects on Innovativeness, Project Performance Outcome, and Relational Performance. In the new drug R&D collaborated projects with CROs, Operational (routine) Capabilities and Dynamic Capabilities partially mediated CRO Engagement and Innovativeness, Project Performance Outcome and Relational Performance, and was a complementary mediated relationship; Operational (routine) Capabilities and Dynamic Capabilities fully mediated Pharmaceutical Client Engagement and Innovativeness, Project Performance Outcome and Relational Performance. Comparatively, in the new drug R&D projects cooperated with CROs, the impacts of CRO Engagement on Innovativeness through Operational (routine) Capabilities and Dynamic Capabilities were greater than those of Pharmaceutical Client Engagement through Operational (routine) Capabilities and Dynamic Capabilities, with path coefficients of 0.428 (the sum of the two indirect effects,  $0.481*0.318+0.497*0.555$ ) and 0.350 (the sum of the two indirect actions,  $0.482*0.318+0.355*0.555$ ).

## **Chapter 6: Discussions**

### **6.1 Interpretations of Study Results**

The analysis results of this empirical study show that the measurement model met the reliability and validity requirements, which proved that the empirical tests of the research model and hypotheses were based on the reliability and valid measurements. In addition, the ten direct hypotheses proposed by the research model were supported by the empirical testing. More specifically, CRO Engagement and Pharmaceutical Client Engagement significantly and positively affected Innovativeness, Project Performance Outcome and Relational Performance through two mediating variables: Operational (Routine) Capabilities and Dynamic Capabilities. Among the mediating relationships, Operational (Routine) Capabilities and Dynamic Capabilities partially mediated the effects of CRO Engagement on Innovativeness, Project Performance Outcome, and Relational Performance, while Operational (Routine) Capabilities and Dynamic Capabilities fully mediated the effects of Pharmaceutical Client Engagement on Innovativeness, Project Performance Outcome, and Relational Performance. Among the mediating relationships between first-order variables. The effects of CRO Organizational Relationship, Pharmaceutical Client Employee Engagement, Pharmaceutical Client Organizational Relationship on the outcomes variables through the routine and dynamic capabilities were partial mediating effects, and the rest of the first-order variables to the outcome variables were full mediating effects.

#### **6.1.1 Direct relationships between second-order variables**

##### **6.1.1.1 Relationship between CRO Engagement, Pharmaceutical Client Engagement and Operational (Routine) Capabilities, Dynamic Capabilities**

The results of this study showed that the path coefficients of CRO Engagement on Innovativeness, Project Performance Outcome, and Relational Performance through Operational (Routine) Capabilities and Dynamic Capabilities were greater than those of Pharmaceutical Client Engagement through Operational (Routine) Capabilities and Dynamic Capabilities on Innovativeness, Project Performance Outcome, and Relational Performance. The results showed that in the Pharmaceutical R&D project with CROs, the impacts of CRO Engagement on Innovativeness, Project Performance Outcome and Relational Performance were greater than those



of Pharmaceutical Client Engagement.

#### **6.1.1.2 Relationship between Operational (Routine) Capabilities and outcome-Innovativeness, Project Performance Outcomes and Relational Performance**

Operational (Routine) Capabilities had positive effects on Innovativeness, Project Performance Outcome, and Relational Performance. Operational (Routine) Capabilities had the greatest effect on Project Performance Outcome, which was greater than its effects on Innovativeness and Relational Performance and had the least effect on Innovativeness. The results suggest that Operational (Routine) Capabilities were most related to and important to the routine project performance outcomes.

#### **6.1.1.3 Relationship between Dynamic Capabilities and Outcome-Innovativeness, Project Performance Outcomes, Relational Performance**

Dynamic Capabilities had positive effects on Innovativeness, Project Performance Outcome and Relational Performance. Dynamic Capabilities had the greatest impact on Innovativeness and play a leading role, followed by Relational Performance, and has the least impact on Project Performance Outcome, which was less than the impact of Operational (Routine) Capabilities on Project Performance Outcome. The results illustrated that the impact of Dynamic Capabilities on Innovativeness was particularly important.

#### **6.1.2 Mediating effects of Operational (Routine) and Dynamic Capabilities**

Among the second-order variables, CRO Engagement and Pharmaceutical Client Engagement significantly and positively affected Operational (Routine) Capabilities and Dynamic Capabilities, and through these two mediators, significantly and positively affected Innovativeness, Project Performance Outcomes, and Relational Performance. Operational (Routine) Capabilities and Dynamic Capabilities partially mediated the effects of CRO Engagement on Innovativeness, Project Performance Outcomes, and Relational Performance, and these mediating effects complementary in nature. Operational (Routine) Capabilities and Dynamic Capabilities fully mediated the effects of Pharmaceutical Client Engagement on Innovativeness, Project Performance Outcomes, and Relational Performance. The direct effects of Pharmaceutical Client Engagement on Innovativeness, Project Performance Outcomes and Relational Performance were not significant, indicating that in the Pharmaceutical R&D projects collaborated with CROs, the Pharmaceutical Client Engagement did not directly affect Innovativeness and project outcomes, but had positive and indirect impacts on Innovativeness

and project outcomes through the mediating variables of Operational (Routine) Capabilities and Dynamic Capabilities.

Among the First-order variables, Operational (Routine) Capabilities and Dynamic Capabilities fully mediated the effects of (1) CRO Employee Engagement, CRO Communication Strategies on Innovativeness, Project Performance Outcomes and Relational Performance; (2) CRO Organizational Relationship on Innovativeness and Project Performance Outcomes; (3) Pharmaceutical Client Employee Engagement, Pharmaceutical Client Communication Strategies and Pharmaceutical Organizational Relationship on Innovativeness and Project Performance Outcomes; and (4) Pharmaceutical Communication Strategies on Relational Performance. The effects of CRO Organizational Relationship, Pharmaceutical Employee Engagement, and Pharmaceutical Organizational Relationship on Relational Performance were partially mediated by first-order variables of Operational (Routine) Capabilities and Dynamic Capabilities, indicating that Relational Performance was not only affected directly by cooperative learning and the process of problem solving, good contract sign experience, satisfaction building, formulation of the mutual trust and the sustainable strategic partnerships of both teams, but also indirectly affected by those factors through team operational and dynamic capabilities. At the same time, the higher the Pharmaceutical Employee Engagement, the more positive impact the pharmaceutical client, as the project client and sponsor, had on the relationship between the two teams.

## **6.2 Theoretical contributions**

### **6.2.1 Measurement Model Contributions**

Establishing clear construct definitions and operationalizations is an important step in scientific research (Bernardes & Hanna, 2009). This study established the conceptualization and measurement of key Stakeholders' Engagement and Dynamic Capabilities in the field of pharmaceutical R&D collaboration projects, and Operational (Routine) Capabilities from the perspective of project management by Project Management Institution (PMI), which has important theoretical significance.

#### **6.2.1.1 Stakeholder Engagement**

Previous literature on the concept and measurement of engagement had been described as "conceptually tortuous", and "widely considered important, but there was no consensus on what its meaning or characteristics were", and the definition of engagement was ambiguous due to

its many definitions, operationalizations, forms, and treatments (Morehouse & Saffer, 2019, 2023). It had been argued in the literature that the concept of engagement was often defined and measured in context-specific ways, such as Employee Engagement, Company Society Relationship Engagement (Dhanesh, 2017). The literature had argued that Engagement was a dynamic interaction of stakeholders and organizational actions (Coombs & Holladay, 2018; Morehouse & Saffer, 2023). In other words, Engagement was social, relational, multi-dimensional, and was achieved through interaction, communication, and collaboration between entities, and was the ultimate relational decision-making tension between individuals, groups, organizations, businesses/industries, communities, and societies (Dhanesh, 2017; Johnston & Taylor, 2018). Kim (2018) mentioned the term "Engagement" was used to refer to the relationship between stakeholders, and Stakeholder Engagement was the process of building relationships through communication and shared decision-making. Stakeholders connect with others in a variety of ways. Relationship engagement remained at the individual level but emphasized the connection and relationship of stakeholders with others (Morehouse & Saffer, 2023).

This study combines the understanding of the concept of engagement in the previous literature and the way in which it was measured, including both the dimensions of employees, project team members engagement within the organization (Yong, 2018), and the dimensions of communication and relationship between stakeholder organizations and project teams. Moroni (2022) categorized the measurement of Stakeholder Engagement into dimensions of communication strategies and inter-organizational relationships. The empirical results of this study showed that in the field of pharmaceutical R&D cooperated projects, the measurement of Stakeholder Engagement can be categorized into three dimensions, Employee Engagement, Communication Strategies, and Organizational Relationship. The measures used in this study were shown to be reliable and valid by the test results.

#### **6.2.1.2 Operational (Routine) Capabilities**

Although strategic management researchers used a variety of terms to define capabilities, there was general agreement that capabilities were not the same as resources, but rather a unique and superior way of allocating, coordinating, and deploying resources (Flynn et al., 2010). The capability of an enterprise refers to the ability of an enterprise to deploy a range of resources to achieve a set goal (Story et al., 2017). Capabilities were further divided into Operational Capabilities and Dynamic Capabilities, with the former focusing on the daily operation and survival of the company, and the latter focusing on the change ability of operational capabilities

in the change environment (Markovich et al., 2021; Story et al., 2017).

Previous literatures, such as Wu et al. (2010) defined Operational Capabilities as a set of skills, processes, and routines specific to an organization, which were often used to solve problems faced by a unit and to allocate resources for the unit to meet the needs of the company. Mikalef (2020) and Winter (2003) defined Operational Capabilities as abilities to operate and survive in a short term, and was used for the business to make a living in the present. He-Boong (2022) indicated Operational Capabilities (OC) as a core competency of efficiency-driven best practices that enables organizations to pursue continuous improvement through excellence in routine operations and business processes. At the core of the Operational Capabilities was management's proficiency in controlling the existing resource to achieve better performance outcomes through benchmarking practices and incremental improvements (Krasnikov & Jayachandran, 2008; Yu et al., 2018). Operational Capabilities allow a company to leverage its resource to achieve operational continuity, which is an essential capability for an organization's short-term success.

In this study, the concept and measurement of Operational Capabilities of collaborated projects were considered from the perspective of project management practice. We referred to the structure and content of the Project Management Body of Knowledge (PMBOK) Guide, which was developed and continuously updated by the Project Management Institution (PMI), an international project management institute that contained globally accepted industry standards and best practices in the field of project management. The PMBOK guide divided project management into five basic process groups, namely: Initiating, Planning, Executing, Monitoring and Controlling, and Closing, and 10 knowledge areas, including integration management, scope management, time management, cost management, quality management, resource management, communication management, risk management, procurement management (PMI, 2021). This study referred to the PMBOK to divide the project Operational Capabilities into four dimensions, Planning capabilities, Execution capabilities, Monitoring capabilities, and Adjusting capabilities. The corresponding measurement scales covered five objectives and performance perspectives: task content, schedule, cost, quality, satisfaction, and eight operational plans perspectives: established standards and procedures, planned objectives, Integration plan, Human resources plan, Communication plan, Risk management plan, Procurement plan, and Change management plan. The empirical results of this study showed that in the field of pharmaceutical R&D cooperation projects, the measurement of Operational Capabilities base on the perspective of project management was reliable and valid.

### **6.2.1.3 Dynamic Capabilities**

Schilke et al. (2018) systematic reviews and summarizes the dimensions of Dynamic Capabilities into procedure, convention, function, hierarchy, or unit of analysis. Dynamic Capabilities were originally defined as an organization's ability to consolidate, build, and reconfigure internal and external resources and capabilities to respond to rapidly changing customers and environments (Guo et al., 2022; Kazadi et al., 2016; Teece et al., 1997). Dynamic Capabilities was a multidimensional concept (Teece, 2007, 2018), the value of which depends on the need to reallocate resources in different situations (Schilke et al., 2018). Dynamic Capabilities were defined as the capabilities used to expand, modify, change, and/or create combat capabilities. Unlike Operational Capabilities which allow businesses to make a living in the present, Dynamic Capabilities allow businesses to adapt to changing external environments. Therefore, Dynamic Capabilities were particularly important for companies to compete and survive in today's dynamic and globalized markets (Mikalef et al., 2020). Guo et al. (2022) and Schmidt et al. (2020) categorized Dynamic Capabilities into Sensing Capability, Learning capability, Integrating capability and Coordinating capability.

This study used Guo et al. (2022) measure Dynamic Capabilities with the following dimensions: Sensing capabilities, responding capabilities, transforming capabilities, integrating capabilities and coordinating capabilities. The empirical results of this study showed that in the field of pharmaceutical R&D cooperated project, it was reliable and valid to measure Dynamic Capabilities using these five dimensions.

## **6.2.2 Research Model Contributions**

### **6.2.2.1 Impacts of Dynamic Capabilities on Innovativeness**

Previous studies have illustrated the relationship between Dynamic Capabilities and Innovativeness. Teece (2018) noted that companies with strong Dynamic Capabilities would be able to profitably build and renew resources, assets, and general capabilities, and reconfigure them as needed to innovate and respond to market changes. Schmidt and Scaringella (2020) explored and demonstrated the relationship between Dynamic Capabilities and Innovativeness. Heideret et al. (2021) found that small and middle enterprises can innovate better their business models through Dynamic Capabilities. Some studies had found that Dynamic Capabilities can amplify the potential value of resources obtained from stakeholders, thereby driving Innovation activities (Zhao et al., 2021). In industry-university-research cooperation, enterprises with strong Dynamic Capabilities can gain more knowledge from universities and research institutes

and obtain higher innovation performance (De Silva & Rossi, 2018; Kafouros et al., 2020). Guo et al. (2022) suggested that Dynamic Capabilities can promote the innovative activities of stakeholders, and explored how Dynamic Capabilities generated Innovativeness, and further elaborated on the different roles of sensing, learning, integrating, and coordinating capabilities in Innovativeness development. This study further supported the empirical research in the field of pharmaceutical R&D collaborated project, that Dynamic Capabilities had the greatest positive impact on Innovativeness, which was consistent with the previous literatures.

#### **6.2.2.2 Impacts of Operational (Routine) Capabilities on performance outcomes**

This study, conducted in the field of in pharmaceutical R&D collaborated projects, produced results that were consistent with those obtained in the previous literatures. Operational (Routine) Capabilities were more related to effect on Project Performance Outcomes. The relationship between Operational (Routine) Capabilities and performance outcomes has been researched in previous literatures. For example, He-Boong (2022) noted that the difference between Operational (Routine) Capabilities and Dynamic Capabilities were from two distinct sources – the former was efficiency-driven best-practice operations and the later was change-driven learning and updating. In contrast, Operations (Routine) Capabilities allow businesses to improve their management proficiency in clearly defined tasks and operations. From this point of view, unlike Dynamic Capabilities, Operations (Routine) Capabilities was the essence of competency to maintain the stability of ongoing operations and the proficiency in managing static resources (Laaksonen & Peltoniemi, 2016; Schilke et al., 2018; Yu et al., 2018). Ahmed et al. (2014) noted that Operational (Routine) Capabilities form the necessary foundation of an organization's ecosystem, regardless of economic conditions, Operational (Routine) Capabilities could greatly impact short-term performance. Song and Liao (2019), Laaksonen and Peltoniemi (2016) pointed out that the impact of Operational (Routine) Capabilities on short-term performance was more pronounced, especially in the short-term performance based on returns. Mikalefet al. (2020) demonstrated that Operational (Routine) Capabilities had a positive impact on performance. He-Boong (2022) showed that Operational (Routine) Capabilities had a significant positive impacted on firm performance.

#### **6.2.2.3. Capabilities mediating the effects of Stakeholder Engagement on Innovativeness and Project Outcomes**

Previous research had shown that in the process of Stakeholder Engagement in co-innovation, inter-enterprise cooperation was an important driving force for enterprise Innovativeness, and

multi-faceted resources could be obtained. Previous literatures had examined the link between Stakeholder Engagement and Open Innovation from different perspectives (Vargo & Lusch, 2016). However, access to resources did not guarantee that synergies would be achieved. For example, Lowman et al. (2012) mentioned that CRO played an increasing role in innovation development, but in the long run, there would be potential risks for innovation, which might cause pharmaceutical company clients to lose control and creativity opportunities, which would lead to problems in the innovation and new product development process.

Cui and O'Connor (2012) argued that achieving synergies from different stakeholders resources required effective information and resource sharing across alliances, which was a daunting task that might be hindered or facilitated by a variety of factors. Managing a highly diverse portfolio of stakeholders requires significant coordination costs. The benefits of resource diversity might not be realized if organizations were unable to effectively share information and resources across alliances. Cui and O'Connor (2012) based on the argument of absorptive capacity, pointed out that the high degree of functional heterogeneity increased the difficulty of information and resource sharing, and reduced the contribution of resource diversity to innovativeness. The contribution of multiple parties to corporate innovation was not always beneficial in itself, but depended on various conditions.

Although Stakeholder Engagement introduced a variety of different perspectives to Innovativeness in the process of Stakeholder Engagement in co-innovation, diversity could also create conflicts in the project team if different participants had conflicting goals or values. Conflict required the special capabilities of the leader of the company to manage (Driessen & Hillebrand, 2013). While this stakeholder co-creation brought benefits to the focus company, it also presented new challenges due to the different stakeholders involved with different characteristics, interests, and goals. Bringing multiple stakeholders together can lead to increased differences in communication styles and goals and interests.

The diversity of stakeholders involved in these projects also creates conflict over the expected outcomes. As a result, to successfully manage these types of collaborations, companies may have to develop a different set of capabilities (Driessen & Hillebrand, 2013). Kazadi et al. (2016) noted that after identifying the specific challenges that exist in such cooperation, the focus of the analysis was to identify the capabilities to address these challenges and to strengthen the co-creative activities and Innovativeness of the firm. However, the previous literatures had not systematically studied and summarized the specific capabilities required and the relationship between them. Loureir et al. (2020) noted that the previous literature lacked a systematic and integrated concept of Stakeholder Engagement and Open



Innovation, which hindered the identification of relevant assumptions and limited the understanding of how stakeholders could be leveraged in Innovativeness development.

Based on the previous literatures, in this study, we conducted the empirical study based on the collaborated project between CROs and pharmaceutical client in the field of pharmaceutical R&D. The research model was constructed that clearly illustrated Stakeholder Engagement, Capabilities, and Innovativeness. The Engagement of both parties can be mediated by Operational (Routine) Capabilities and Dynamic Capabilities, which can significantly and positively affect project Innovativeness, Project Performance Outcomes and Relational Performance. The results of this study also suggested that Operational (Routine) Capabilities and Dynamic Capabilities had complementary mediating effects on Innovativeness, Project Performance Outcomes and Relational Performance. The results were consistent with the previous literatures. For example, He-Boong (2022) reported that Operational (Routine) Capabilities and Dynamic Capabilities had positive impacts on firm performance. While Operational Capabilities affected the short-term competitive advantage of the enterprise, and had a greater impact on short-term performance, Dynamic Capabilities helped to form a sustainable competitive advantage and had a greater impact on long-term performance. These two capabilities complemented each other to promote the development of the company and play a synergistic effect. Overall, in terms of theory, this study bridged literature gaps, and provided a theoretical basis for the collaborated project management of CROs and Pharmaceutical clients in the field of pharmaceutical R&D.

### **6.3 Practical Contributions**

Today's pharmaceutical industry faces declining R&D productivity, rising commercialization costs, legal disputes, pricing pressures, and shortened patent terms (Hughes & Wareham, 2010). Due to the volatile and changing environment created by these factors, companies must collaborate with external partners (Kazadi et al., 2016). "Open Innovations in the pharmaceutical industry" had gradually become the focus of research, enriching the field of open Innovation. In addition to theoretical contributions, this study contributes to practice by providing important insights and guidelines for cooperated projects in the field of pharmaceutical R&D and Innovativeness.

The empirical results in this study tested and supported the relationships among the variables as specified by our research model. These relationships would help managers to understand how the performance of collaborative R&D projects can be improved by



appropriately engage different stakeholders, and by effectively managing the project team's operational and dynamic capabilities. Specifically, improving the Operational (Routine) Capabilities was more inclined to improve the daily operation management level and efficiency, and improve the project performance results, and by improving the Dynamic Capabilities, it was more inclined to improve the Innovativeness. The research model built in this study could be used as a management measurement tool to guide the planning and practice of open collaborative innovation projects in pharmaceutical R&D in the future.

To achieve the set goal of improving project performance outcome, the project team can plan, execute, monitor and adjust the project through the development of capabilities, especially Operational (Routine) Capabilities. In the initial stage of the project, the project team can timely and effectively set task content objectives, schedule objectives, cost objectives, quality objectives, and satisfaction objectives. During the project execution phase, the project team was able to follow the management standards and processes determined by the implementation project, plan objectives, coordination and integration plans, human resources plans, communication plan, risk management plan, procurement plan, change management plan; In the process of project implementation, the project team can track and analyze the actual task content performance gap, the actual progress performance gap, the actual cost performance gap, the actual quality performance gap, and the actual satisfaction performance gap according to the set goals in a timely and effective manner, and can timely and effectively adjust the task content plan according to the actual task performance gap, the schedule according to the actual schedule performance gap, the project quality according to the actual quality performance gap, and the project activities according to the actual satisfaction gap, to supervise and regulate each aspect of the project.

To achieve the goal of improving Innovativeness, we can develop capabilities, especially Dynamic Capabilities, including the capabilities to sensing, responding, transforming, integrating, and coordinating. Companies and project team members can frequently scan the environment to identify and perceive new business opportunities, regularly evaluate the possible impact of changes in the perceived industry environment on the project, frequently assess whether the perceived actual work meets the needs of the project and invest time to evaluate the idea that perception can generate new business opportunities. Dynamic capabilities enable the project team to respond quickly to changes in customer and patient needs; frequently transform and apply the new perceived and recognized information and knowledge into the project, transform the existing information into new knowledge that was beneficial to project development, and effectively apply the new knowledge to the research and development of new

products, and effectively develop new knowledge for project product development; make the project team members have a full understanding of who has the professional skills and knowledge required by the project inside and outside the project team, and can actively coordinate and integrate the actions between the project team members and members outside the team to adapt to the changing situation when changes occur, ensure that the coordination resources were appropriately allocated within the project team, match the tasks with knowledge and skills, and ensure that the expertise and workflow of the project team members were coordinated smoothly; evaluate and absorb new ideas from internal and external sources, create a culture of innovativeness and innovation processes that contribute to the transformation of internal and external information into knowledge for new product development, and generate new methods and solutions through active cross-departmental collaboration.

To achieve the purpose of improving capabilities, it was possible to increase the engagement of internal and external resources of the team, such as improving the engagement of employees and team members, to take the initiative to propose new ideas or new solutions to solve problems in the process of cooperation, actively seek opportunities to improve the project, actively promote new ideas of employees to colleagues or leaders, seek support and recognition from relevant colleagues and leaders, actively participate in the decision-making and implementation of project needs, actively listen to new information and new ideas from internal and external, enhance communication strategies between teams, and actively use modern information technology such as network and digitalization, sharing platforms, artificial intelligence and other new technologies to facilitate communication, regularly communicate with internal and external teams through on-site meetings, conference calls, video conferences, etc. in accordance with the communication plan, use training and lectures as a communication strategy to unite and motivate the team, and regularly and timely communicate with relevant parties to show the performance report on operation, finance, quality, strengthen the inter-organizational relationship between teams, take the initiative to establish close contact with internal and external teams through the project cooperation learning process, actively assist customers and supplier teams to solve problems together, maintain good relationships, maintain good contract signing experience, effectively complete customer needs, and improve the trust and satisfaction of both parties.

Our study found that the effects of CRO Engagement on Innovativeness, Project Performance Outcomes and Relational Performance through Operational (Routine) Capabilities and Dynamic Capabilities was greater than those of Pharmaceutical Client Engagement through Operational (Routine) Capabilities and Dynamic Capabilities on Innovativeness and Project

Performance Outcomes and Relational Performance. This finding indicates that in the pharmaceutical R&D projects cooperated with CROs, relatively speaking, CRO Engagement had a greater impact on project outcomes than that of pharmaceutical companies. As such, managers should understand that CRO initiative and engagement in the collaborated projects were particularly important. In pharmaceutical R&D projects, it was important to choose a suitable and experienced CRO to undertake the cooperated project of the pharmaceutical sponsor.

Our results suggest that Operational (Routine) Capabilities and Dynamic Capabilities played a complementary mediating role between CRO Engagement and Innovativeness, Project Performance Outcomes and Relational Performance. In practice, managers can synergistically promote Innovativeness and Project Performance Outcomes by co-developing Operational (Routine) Capabilities and Dynamic Capabilities. Whereas, the direct impact of Pharmaceutical Client Engagement on Innovativeness, Project Performance Outcomes and Relational Performance was not significant, relying on the complete mediating effect of Operational (Routine) Capabilities and Dynamic Capabilities, so in pharmaceutical R&D projects collaborated with CROs, pharmaceutical companies could have a positive impact on Innovativeness and project outcomes by developing more Operational (Routine) Capabilities and Dynamic Capabilities, such as Planning, Execution, Monitoring and Adjusting capabilities, and the capabilities to respond to changing environments and policies. The first-order variables of CRO Organizational Relationship, Pharmaceutical Client Employee Engagement and Pharmaceutical Organizational Relationship also had some direct effects on the Relational Performance, which inspired managers to increase the interaction between CROs and pharmaceutical companies, increase the engagement and attention of pharmaceutical companies team members, in order to help improve the trust and satisfaction of both groups and finally develop into a long-term sustainable strategic relationship.

## **6.4 Limitations and Future Directions**

Since all the data in this study were collected in a relatively short period of time, the continuous longitudinal changes in the questionnaire survey on Innovativeness and project performance outcomes of pharmaceutical R&D cooperated projects with CROs could not be observed, so the data used were cross-sectional data in nature. Appropriate caution should be maintained in the verification and interpretation of causality. If use longitudinal data, we can better observe how variables change over time and describe them more accurately. Therefore, future studies can further consider designing longitudinal studies to identify and assess changes in the impact

of stakeholder engagement and competence on Innovativeness and outcomes over time.

This study selected the two most important stakeholders in the field of pharmaceutical R&D cooperated projects with CROs, who were also the vertical stakeholders in the value chain, as the research objects of this quantitative study. Future research on pharmaceutical R&D cooperated projects should also consider adding other stakeholders related to pharmaceutical R&D cooperated projects, such as the research sites-hospitals, investigators, vendors, and governmental regulatory authorities, to perform the case study and qualitative study of multiple stakeholders to explore and evaluate the engagement of other stakeholders, the relationship and impact of innovativeness and project performance and relational outcomes.

## 6.5 Conclusion

In this study, the definition and measurement Stakeholder Engagement, Operational (routine) Capabilities and Dynamic Capabilities, Innovativeness, Project Performance Outcome, and Relational Performance in the field of pharmaceutical R&D collaborated projects with CROs were validated. The relationships and effect mechanism among Stakeholder Engagement, Operational (routine) Capabilities and Dynamic Capabilities, Innovativeness, Project Performance Outcome, and Relational Performance were tested. The research questions raised at the beginning of the study were answered. 1). In the field of Pharmaceutical R&D collaborated projects with CROs, the CROs and the Pharmaceutical client sponsor were the main stakeholders and vertical stakeholders in the value chain. 2). The Engagement of CRO as the service provider and pharmaceutical company as the client had positive and significant impacts on the Operational (routine) Capabilities and Dynamic Capabilities. 3). Operational (routine) Capabilities and Dynamic Capabilities had a positive and significant impact on Innovativeness, Project Performance Outcomes, and Relational Performance. Operational (routine) Capabilities and Dynamic Capabilities mediated effects of Stakeholder Engagement on Innovativeness and project outcomes. This study not only enriched the existing management research in the field of Stakeholder Engagement, Organizational Capabilities and Collaborative Open Innovation, but also provided a theoretical basis and new tools for the management of collaborated Innovativeness projects in the field of pharmaceutical R&D. While, in general, the research purpose of this study had been achieved, but it was just a beginning and a steppingstone for future research to create more systematic theories and practical guidelines in the field of pharmaceutical R&D collaborated projects and innovation.

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## **Annex: Study Questionnaire**

### **Contract Research Organization (CRO) and Pharmaceutical R&D collaborated project Innovativeness Study Questionnaire**

Thank you for taking the time to fill out the questionnaire. This is the part of a doctoral dissertation in healthcare management, which mainly studies the relationship between the Stakeholder Engagement, Capabilities, Innovativeness, and Project Performance in the Contract Research Organization (CRO) and pharmaceutical client collaborated projects in pharmaceutical research and development (R&D). Your support and cooperation will enable us to gain valuable insights from the actual organizational environment and facilitate the generation of targeted management recommendations.

This questionnaire will be used purely for academic research purposes. The questionnaire data will be kept completely confidential and will not be disclosed to the public, nor will any records be left in your institution. When writing academic achievements, we only report overall trends and will not expose any personal data.

There are five parts in the questionnaire, the time required to fill out the answers is approximately 15-20 minutes. Please answer all questions.

If you are interested in the results of this study, please provide your contact information and we will provide you with the feedback after obtaining specific results. In case of doubt, please use the following contacts: email: \_\_\_\_\_ or mobile: \_\_\_\_\_.

### **Part 1 Project background information**

1.1 Please select one of the project in which CRO collaborated with the pharmaceutical company that you have participated in the past 5 years. Please answer all the following questions based on this project.

The project name is \_\_\_\_\_.

1.2 As a team member, which team did you participate in this project? [Single Choice]

(1) CRO

(2) Pharmaceutical company sponsor

(3) Other (please specify): \_\_\_\_\_

1.3 What are the research phase of the collaborated project you involved in?  
[Single Choice]

- (1) Phase I clinical trial project
- (2) Phase II clinical trial project
- (3) Phase III clinical trial project
- (4) Phase IV clinical trial project

1.4 The total duration of the collaborated project you participated in is about (how many)\_\_\_\_\_ Month. [Fill the number in the blank]

1.5 The total number of both team members in the collaborated project that you participated in is about (how many)\_\_\_\_\_ people? [Fill the number in the blank]

(Note: The total number of people refers to all the number of people participated in the whole project, not limited to any certain stage.) Among them,

(1) the CRO team members of the project is about (how many)\_\_\_\_\_ People. [Fill the number in the blank ];

(2) the pharmaceutical company client team members for the project is about (how many)\_\_\_\_\_ People. [Fill the number in the blank ]\

(3) if have, the other kind of team members include about (how many)\_\_\_\_\_ People? (Please specify\_\_\_\_\_ ) [Fill in the blank]

1.6 In the collaborated project that you participated in,

(1) the total number of employees of the CRO company is about (How many)\_\_\_\_\_ people?  
[Fill the number in the blank ]

(2) the total number of employees of the Pharmaceutical company is about (How many)\_\_\_\_\_ people? [Fill the number in the blank ]

1.7 Is the collaborated project that you participated in a local clinical trial or a global multi-site clinical trial project? [Single Choice]

- (1) Local clinical trial project
- (2) Global multi-site clinical trial project

## Part 2 Project Team Engagement

Please mark "√" in the corresponding positions 1-7 based on personal feelings and experiences (1= Completely disagree; 2=Disagree; 3=Somewhat disagree; 4=Either agree or disagree; 5=Somewhat agree; 6=Agree; 7= Completely agree).

### 2.1 CRO Employee Engagement

		Completely disagree				Completely agree			
CRO team members...		1	2	3	4	5	6	7	
a	contributed new ideas or solutions to solve problems during this project	1	2	3	4	5	6	7	
b	actively sought opportunities to improve project	1	2	3	4	5	6	7	
c	actively promoted their new ideas to colleagues or leaders to seek support and recognition	1	2	3	4	5	6	7	
d	actively participated in the decision-making and implementation of this project	1	2	3	4	5	6	7	
e	proactively interacted with Pharmaceutical clients team to	1	2	3	4	5	6	7	

obtain demand information or new ideas							
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## 2.2 CRO Communication Strategies

CRO team in the project...								
a	actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with Pharmaceutical client team	1	2	3	4	5	6	7
b	regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with Pharmaceutical client team	1	2	3	4	5	6	7
c	adopted the practice of education/training as a communication strategy with Pharmaceutical client team	1	2	3	4	5	6	7
d	disclosed its project performance reports (eg. operational, financial) to Pharmaceutical client team	1	2	3	4	5	6	7

## 2.3 CRO Organizational Relationship

The CRO Organizational Relationship									
CRO team in the project...									
a	adopted project collaborated learning to engage the pharmaceutical client	1	2	3	4	5	6	7	
b	actively sought to solve problems together with the pharmaceutical client	1	2	3	4	5	6	7	
c	actively had good relationship with the pharmaceutical client	1	2	3	4	5	6	7	
d	had good contracting experience with the pharmaceutical client	1	2	3	4	5	6	7	
e	is trustworthy	1	2	3	4	5	6	7	
f	was able to do what the pharmaceutical client need to do	1	2	3	4	5	6	7	

## 2.4 Pharmaceutical Client Employee Engagement

Pharmaceutical client team members...									
a	contributed new ideas or solutions to solve problems during this project	1	2	3	4	5	6	7	
b	actively sought opportunities to improve project	1	2	3	4	5	6	7	
c	actively promoted their new ideas to colleagues or leaders to seek support and recognition	1	2	3	4	5	6	7	
d	actively participated in the decision-making and implementation of this project	1	2	3	4	5	6	7	
e	proactively interacted with CRO team to obtain demand information or new ideas	1	2	3	4	5	6	7	

## 2.5 Pharmaceutical Client Communication Strategies

Pharmaceutical client team in the project...								
a	actively utilized web-based data sharing technology (e.g., SharePoint) to communicate with CRO team	1	2	3	4	5	6	7
b	regularly conducted, as the communication strategy plan, on site, telephone and video conferences actively with CRO team	1	2	3	4	5	6	7
c	adopted the practice of education/training as a communication strategy with CRO team	1	2	3	4	5	6	7
d	disclosed its project performance reports (eg. operational, financial) to CRO team	1	2	3	4	5	6	7

## 2.6 Pharmaceutical Client Organizational Relationship

Pharmaceutical client team in the project...		1	2	3	4	5	6	7
a	adopted project collaborated learning to engage CRO team	1	2	3	4	5	6	7
b	actively sought to solve problems together with the CRO team	1	2	3	4	5	6	7
c	actively had good relationship with CRO team	1	2	3	4	5	6	7
d	had good contracting experience with CRO team	1	2	3	4	5	6	7
e	is trustworthy	1	2	3	4	5	6	7
f	was able to do what CRO team need to do	1	2	3	4	5	6	7

## 2.7 Project Team Characteristics

a	Many of the project members of the two sides had worked together before	1	2	3	4	5	6	7
b	The location of the project manager of the two sides were based very close to each other	1	2	3	4	5	6	7
c	The project team had the autonomy on project task, schedule, budget, and change	1	2	3	4	5	6	7
d	The project team members had diverse experience and education background	1	2	3	4	5	6	7
e	There was a standard operating procedure for the operation of the project	1	2	3	4	5	6	7
f	The operation and communication process between the project team members of two sides was formal and planned	1	2	3	4	5	6	7

## Part 3 Project Team Operational and Dynamic Capabilities

Please mark "√" in the corresponding positions 1-7 based on personal feelings and experiences (1= Completely disagree; 2=Disagree; 3=Somewhat disagree; 4=Either agree or disagree; 5=Somewhat agree; 6=Agree; 7= Completely agree).

### 3.1 Planning capabilities

		Completely disagree				Completely agree		
In each stage, project team was able to timely and effectively set clear...								
a	task content objectives	1	2	3	4	5	6	7
b	schedule performance objectives	1	2	3	4	5	6	7
c	cost performance objectives	1	2	3	4	5	6	7
d	quality performance objectives	1	2	3	4	5	6	7
f	satisfaction performance objectives	1	2	3	4	5	6	7

### 3.2 Execution capabilities

In each stage, project team was able to consistently execute...		1	2	3	4	5	6	7
a	established standards and procedures	1	2	3	4	5	6	7
b	planned objectives	1	2	3	4	5	6	7
c	integration plans	1	2	3	4	5	6	7
d	human resources plans	1	2	3	4	5	6	7
e	communication plans	1	2	3	4	5	6	7
f	risk management plans	1	2	3	4	5	6	7
g	procurement plans	1	2	3	4	5	6	7

i	change management plans	1	2	3	4	5	6	7
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### 3.3 Monitoring capabilities

In each stage, project team was able to timely and effectively, according to set objectives, to track and analyze...

a	task content performance gaps	1	2	3	4	5	6	7
b	schedule performance gaps	1	2	3	4	5	6	7
c	cost performance gaps	1	2	3	4	5	6	7
d	quality performance gaps	1	2	3	4	5	6	7
e	satisfaction performance gaps	1	2	3	4	5	6	7

### 3.4 Adjusting capabilities

In each stage, project team was able to continuously make necessary changes to...

a	task content objectives based on task content performance gaps	1	2	3	4	5	6	7
b	schedule performance objectives based on schedule performance gaps	1	2	3	4	5	6	7
c	cost performance objectives based on cost performance gaps	1	2	3	4	5	6	7
d	project quality based on quality performance gaps	1	2	3	4	5	6	7
e	project activities based on satisfaction performance gaps	1	2	3	4	5	6	7

### 3.5 Sensing capabilities

Project team...

a	frequently scanned the industry environment to identify new business opportunities	1	2	3	4	5	6	7
b	periodically reviewed the likely effect of changes in our industry environment on the project	1	2	3	4	5	6	7
c	often reviewed our product/service development efforts to ensure they were in line with what the project wanted	1	2	3	4	5	6	7
d	devoted time implementing ideas for new business	1	2	3	4	5	6	7

### 3.6 Responding capabilities

Project team was able to react quickly to changes in...

a	policy and industry environment	1	2	3	4	5	6	7
b	vendors service	1	2	3	4	5	6	7
c	client requirements	1	2	3	4	5	6	7
d	consumer market	1	2	3	4	5	6	7

### 3.7 Transforming capabilities

Project team...

a	had effective routines to identify, value, and import new information and knowledge	1	2	3	4	5	6	7
b	had adequate routines to assimilate new information and knowledge	1	2	3	4	5	6	7
c	was effective in transforming existing information into new knowledge	1	2	3	4	5	6	7
d	was effective in utilizing knowledge into new products development	1	2	3	4	5	6	7



e	was effective in developing new knowledge that has the potential to influence product development	1	2	3	4	5	6	7
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### 3.8 Integrating capabilities

Project team...								
a	was forthcoming in contributing their individual input to the group	1	2	3	4	5	6	7
b	was fully aware who inside the team has specialized skills and knowledge relevant to our work	1	2	3	4	5	6	7
c	was fully aware who outside the team has specialized skills and knowledge relevant to our work	1	2	3	4	5	6	7
d	actively interrelated and interconnect our actions to members inside the team to meet changing conditions	1	2	3	4	5	6	7
e	actively interrelated and interconnect our actions between members inside and outside the team to meet changing conditions	1	2	3	4	5	6	7

### 3.9 Coordinating capabilities

Project team...								
a	ensured an appropriate allocation of resources (e.g., information, time, reports) within our group	1	2	3	4	5	6	7
b	were assigned to tasks commensurate with their task relevant knowledge and skills	1	2	3	4	5	6	7
c	ensured that there was compatibility between group members expertise and work processes	1	2	3	4	5	6	7
d	Overall, our project team was well coordinated	1	2	3	4	5	6	7

## Part 4 Project Outcome

Please mark "√" in the corresponding positions 1-7 based on personal feelings and experiences (1= Completely disagree; 2=Disagree; 3=Somewhat disagree; 4=Either agree or disagree; 5=Somewhat agree; 6=Agree; 7= Completely agree).

### 4.1 Innovativeness

		Completely disagree				Completely agree		
The final deliverable by the project...								
a	was new on the market	1	2	3	4	5	6	7
b	offered unique benefits superior to those of competitors	1	2	3	4	5	6	7
c	offered unique benefits superior to existing products on the market	1	2	3	4	5	6	7
Through the project, ...								
d	the CRO organization was enabled to become better in the management of developing new product	1	2	3	4	5	6	7
e	the pharmaceutical client organization was enabled to become better in the management of developing new product	1	2	3	4	5	6	7
f	the CRO evaluated and incorporated new ideas that come from the pharmaceutical client	1	2	3	4	5	6	7
g	the pharmaceutical client evaluated and incorporated new ideas that come from the CRO	1	2	3	4	5	6	7

h	the project members were enabled to develop a new innovative culture of cleverly transforming information from internal and external sources into valuable knowledge for new product development	1	2	3	4	5	6	7
i	the project members were enabled to develop a new innovative culture of collaborating and exchanging ideas between the departments in order to produce new approaches and solutions	1	2	3	4	5	6	7
j	the project members were enabled to develop new process benefit to innovation	1	2	3	4	5	6	7

## 4.2 Project Performance Outcome

		Completely disagree				Completely agree		
The project....								
a	was completed on schedule	1	2	3	4	5	6	7
b	was completed within budget	1	2	3	4	5	6	7
c	met quality goals	1	2	3	4	5	6	7
d	deliverable met planned task content scope	1	2	3	4	5	6	7
e	was satisfied as CRO expected	1	2	3	4	5	6	7
f	was satisfied as pharmaceutical client expected	1	2	3	4	5	6	7

## 4.3 Relational Performance

		Completely disagree			Completely agree			
After the project, CRO team....								
a	were more confident in the pharmaceutical client team than before.	1	2	3	4	5	6	7
b	were satisfactory with the relationship with the pharmaceutical client team.	1	2	3	4	5	6	7
c	were more committed to the relationship and collaboration with the pharmaceutical client team.	1	2	3	4	5	6	7
d	believed that the relationship with the pharmaceutical client team is strategic sustainable.	1	2	3	4	5	6	7
After the project, the pharmaceutical client team....								
e	were more confident in the CRO team than before.	1	2	3	4	5	6	7
f	were satisfactory with the relationship with the CRO team.	1	2	3	4	5	6	7
g	were more committed to the relationship and collaboration with the CRO team.	1	2	3	4	5	6	7
h	believed that the relationship with the CRO team is strategic sustainable.	1	2	3	4	5	6	7

## Part 5 Personal background information

The following is your basic personal information, please select or fill in.

5.1 Age: \_\_\_\_ (years old) [fill in the blank]

5.2 Gender: [Single choice]

(1) Male

(2) Female

5.3 Educational background: [Single choice]

- (1) Undergraduate or below
- (2) Bachelor's degree
- (3) Master's degree
- (4) Doctor's degree

5.4 How long have you worked in this industry?\_about \_\_\_\_\_ (Years) [Fill the number in the blank ]

5.5 How long have you been worked in your current company? about \_\_\_\_\_(Years) [Fill the number in the blank]

5.6 What is your current company?[Single choice]

- (1) CRO
- (2) Pharmaceutical/ BioPharma/ Biotech company

5.7 What is the ownership structure of your company? [Single choice]

- (1) Global/Foreign Company
- (2) Local Company

5.8 What is your department/function? [Single choice]

- (1) Clinical Operations Department (Clinical Research Associate/Manager, CRA/CRM)
- (2) Clinical Operations Department (Clinical Assistant, CTA)
- (3) Clinical Start-up Department (Clinical Start-up Specialist/Manager)
- (4) Project Management Department (Project Manager, Project Director)
- (5) Regulatory Registration Affairs Department (Registration Affairs, RA)
- (6) Data Management and Statistics Department (DM, Bios manager)
- (7) Medical department (Medical Sciences, Medical Monitoring, Physician, and Medical Writing)
- (8) Quality Assurance Department (QA, QC)
- (9) Pharmacovigilance Department (PV)
- (10) Other, please fill in \_\_\_\_\_

5.9 What is your position level/title? [Single choice]

- (1) Ordinary employees
- (2) Manager/Senior Manager
- (3) Director/Senior Director
- (4) Function Head
- (5) Company Head (CEO, Vice President/President)
- (6) Other, please fill in \_\_\_\_\_

**This is the end of the questionnaire. Thanks very much for your support for this research!**