Chapter

Investigating Knowledge Management Activities and Influential Factors of Contract Research Organizations (CRO)

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Abstract

The pharmaceutical industry is critical to a nation's economic development and welfare. However, most pharmaceutical companies do not have the capabilities to complete clinical trials by themselves and need assistance from the contract/clinical research organization (CRO). Clinical trials are highly knowledge-intensive and include several fields, such as toxicology, statistics, production, biology, health care, pharmacology, trial protocol design, and legal regulation. In academic research, few studies have focused on studying this important area from the perspective of knowledge management. Consequently, this research aims to fill this research gap by investigating knowledge management activities and influencing factors of CRO. A holistic framework was designed for this research, with the former (knowledge management activities) including four major constructs: knowledge creation and absorption, knowledge accumulation and storage, knowledge flow and diffusion, and knowledge protection, and the latter (influencing factors) including strategy and leadership, organizational culture, people, and information technology. Four CROs in Taiwan were selected for in-depth case studies. The research results are expected to contribute to both academia and industry.

Keywords: knowledge management, knowledge management activities, key influential factors, Contract Research Organization, clinical trial, CRO

1. Introduction

According to the 2020 biotechnology industry white paper, the global pharmaceutical market in 2019 reached approximately US $1.25 trillion, an increase of 4% compared to 2018. It takes an average of 10–15 years and the US $300–800 million to develop a new drug. Under increasingly strict global supervision, drug development has become more complicated, requiring numerous resources and equipment support. Therefore, reducing development and time costs, and ensuring compliance with strict regulations and standards at the same time, has become a common problem faced by global biotechnology and pharmaceutical companies.

In the entire drug development process, the clinical trial phase requires one-half to two-thirds of the development cost and time. Due to this, clinical trials have been outsourced to the Contract Research Organization (CRO) in recent years. According to Frost & Sullivan estimates, the global CRO turnover in 2019 reached

approximately US $49.74 billion, an increase of 8.5% compared to 2018. It can be seen that the clinical trial service industry is very important for biotechnology and medicine. Furthermore, the CRO industry is a knowledge-intensive industry. Professional knowledge and skills are its main requirements, which are also key to the competitiveness of enterprises. Additionally, the accumulation of experience and knowledge, and the maintenance of external relations are both important assets for an enterprise in the clinical trial industry. Therefore, improving the competitiveness of an organization through effective knowledge management has become one of the most important issues in business management.

Previous research on CRO mainly focused on its strategy, business, and operations model, and seldom discussed the knowledge management of CRO. Therefore, this research will focus on the CRO industry and select companies that provide clinical trial services in Taiwan to study their knowledge management practices and the impact of influencing factors on knowledge management activities.

The issues to be discussed in this research are as follows:

i. What are the main factors affecting the knowledge management of CROs?

ii. What are the main knowledge management activities of CROs?

iii. What is the impact of influencing factors of knowledge management on CROs' knowledge management activities?

In the following section, an overview of the CRO industry is introduced, as well as related literature on influential factors of knowledge management and knowledge management activities. The research framework is then introduced in the third section based on the research purpose and the literature review results. Besides, in this section, the research method, research objects, and data collection methods of this study are further explained. The fourth section describes the research cases. In the fifth section, seven research propositions are proposed and are followed by discussions. Finally, conclusions are drawn and the theoretical implications are depicted in the last section.

2. Literature review

This section discusses the current situation of the clinical trial service industry, the related literature on possible influencing factors of knowledge management, and knowledge management activities.

2.1 Contract Research Organization industry

The Contract Research Organization (CRO) is part of the biotechnology service industry. From the drug development stage to the market launch stage, it works closely with biotechnology and pharmaceutical companies or research institutes to provide services, such as drug discovery, clinical trial planning, assistance in monitoring clinical research, data analysis and management, application review, and post-marketing monitoring, to accelerate product development or launch.

The development of new drugs in global pharmaceutical companies is becoming increasingly complex owing to increasingly stringent regulations. Therefore, along with equipment support, more resources are required, which has increased the demand for entrusted R&D and clinical trial services in the biotechnology and pharmaceutical industries.

According to Frost & Sullivan estimates, the global CRO turnover is expected to grow to US$ 72.54 billion in 2024, with an average annual compound growth rate of 7.8%. North America (the United States and Canada) accounted for the largest proportion of the global CRO market in 2019, accounting for approximately 36.5%, followed by Europe (the United Kingdom, Germany, France, Spain, Italy, Finland, Denmark, Sweden, Norway, Iceland, Netherlands, Belgium, Luxembourg, and other countries in Eastern Europe), accounting for approximately 34.4%. In third place is the Asia-Pacific region (Mainland China, Japan, South Korea, and Southeast Asian countries), accounting for approximately 22.4%. However, in recent years, the number of clinical trial applications in the United States has gradually decreased, while the number of clinical trials in the Asia-Pacific region has increased annually. Combining the benefits of government support for clinical trials and lower trial costs, the future market growth rate of CRO in the Asia-Pacific region is estimated to be the highest among all regions, with an average annual compound growth rate of approximately 10.9%.

The process of drug development is divided into three stages: drug discovery, preclinical trials, and clinical trials. After the pre-clinical trial is completed, the experimental results of R&D, literature, and other data are collected, and the Investigational New Drug (IND) is applied to the drug management agency. After completing the first three phases of clinical trials and confirming the safety and effectiveness of the drug in the human body, New Drug Application Registration (NDA) is applied to the responsible agency to obtain the new drug marketing authorization, although it still needs to continue monitoring medication safety after approval.

To complete the aforementioned drug development process, the average time from laboratory to product launch is 10–15 years, which costs approximately US$ 300–800 million. This is a high price for pharmaceutical companies or biotech medical companies. However, if the development is successful and the patent is obtained, the new drug can achieve high-profit recovery through the umbrella of patents. Therefore, drug development must be done timely, and this reflects the importance of CRO. With help from the CRO's professional services, effective executions of important and complicated clinical trials can be done in reduced time and cost of development. This also helps pharmaceutical companies or biotech medical companies seize opportunities and make early profits.

2.2 Influential factors of knowledge management

Knowledge management (KM) refers to the continuous process of giving the right information to members of the organization in a timely manner to help them take correct actions to improve organizational performance [1, 2]. Besides, refining and developing knowledge-based processes can lead the entire organization to higher innovation performance [3, 4].

Four major motivating factors of knowledge management are identified: (1) Strategy and Leadership: Setting up useful strategies and obtaining the support of the top management will help the implementation of KM, (2) Organizational Culture: Creating an organizational atmosphere where employees are willing to share knowledge with each other, (3) People: The employees in the organization must receive relevant training courses on a regular basis, and a good incentive mechanism should be provided to encourage contributions to KM, and (4) Information Technology: In addition to digitizing the information in the organization, the most important purpose is to speed up employees' search for required knowledge, to increase the frequency of knowledge reuse [5].

2.3 Knowledge management activities

From the perspective of knowledge management procedures, this research firstly integrates and categorizes the literature proposed by scholars in the past, and summarizes the three knowledge management activities that this research intends to explore: (1) knowledge acquisition and absorption, (2) knowledge accumulation and storage, and (3) knowledge diffusion and exchange.

After considering the industrial characteristics of CRO, it is understood that it belongs to a knowledge-intensive industry, and its competitiveness lies in how to help client's complete clinical trials faster and seize the opportunity to launch. Therefore, this research also adds the activity of "knowledge protection" to examine how the CRO protects its knowledge in the process of knowledge management to avoid the leakage of internal and external knowledge.

2.3.1 Knowledge acquisition and absorption

Organizations create unique organizational knowledge through absorbing, imitating, digesting, and applying that knowledge, and that knowledge assets in organizations can be obtained by integrating existing or new knowledge through learning, integration, rearrangement, etc. [6–8]. Additionally, organizations assist internal development by acquiring external knowledge resources [9]. The acquisition methods are divided into five types: (1) complete internal self-development, (2) external assistance for internal development, (3) acquisition from the open market, (4) inter-firm development, and (5) mergers and acquisitions [9]. It is argued, however, that only a small number of companies can fully develop their core capabilities on their own, and most companies still need external knowledge [10]. The same scholar further stated that external sources of technical knowledge include consultants, consumers, national laboratories, suppliers, universities, competitors, and noncompetitive companies [10].

2.3.2 Knowledge accumulation and storage

After the organization absorbs knowledge, it needs to accumulate and store knowledge to facilitate its re-diffusion and re-absorption. The purpose is to form an "organizational memory" so that members of the organization can easily obtain and use it at any time. Knowledge accumulation also determines how the organization integrates, applies, and develops the basis of its core capabilities [6].

Knowledge carriers can be classified into two categories: people-oriented and object-oriented. The former means that knowledge can be accumulated in people's brains through training or mentor-disciple systems. The latter indicates that the knowledge and information can be stored in an information system, a document folder, a product, or a database so that people can access it directly.

It was also proposed that there are four major types of knowledge accumulation carriers: (1) Employee knowledge and skill: Whether the organization has members with high quality, high learning ability and motivation, and diverse knowledge and experience to create and accumulate new knowledge. (2) Physical technical systems: Whether information technology in the organization can effectively support knowledge management. If a member is transferred or leaves the department or job, whether the physical system can retain the member's assets, such as software programs, databases, hardware equipment, etc. (3) Managerial systems: The accumulation of knowledge among members of the organization is encouraged and supervised through the company's education, remuneration, and reward systems. These management systems create channels for knowledge acquisition

and circulation, and also set up barriers to inappropriate knowledge activities. (4) Values and norms: Values and norms determine what kind of knowledge the organization should create and accumulate, and can also be used as a mechanism for knowledge screening and control [10].

2.3.3 Knowledge diffusion and exchange

The knowledge accumulated by the organization needs to be diffused and exchanged so that it can be continuously re-absorbed, created, and accumulated, after which, organizational knowledge can continue to develop and grow. Knowledge diffusion is the transferring and sharing of knowledge to the entire organization through various channels, which may occur among individuals, teams, and organizations [11, 12]. Other scholars divided knowledge transfer into five different types, including formal and informal channels: (1) commissioners and face-to-face meetings; (2) pantry and conversation rooms; (3) knowledge exhibition and openness forum; (4) partner cooperation or master-apprentice inheritance, and (5) electronic technology [13, 14].

It was pointed out that five factors that hinder knowledge transfer: (1) a culture of silo mentality, (2) a culture that emphasizes personal expertise and knowledge creation more than knowledge sharing, (3) lack of communication, relationship connections, and common views among members, (4) a culture that relies too much on explicit knowledge but neglects tacit knowledge, and (5) not encouraging or allowing time to learn, share, or assist each other [2].

This research proposes five ways of knowledge transfer in organizations, mainly based on Davenport and Prusak's research, including formal and informal channels, and discusses the CRO's knowledge diffusion and exchange actions [13, 14]. This research will further check whether there are factors that hinder the diffusion of knowledge.

2.3.4 Knowledge protection

Knowledge is a resource that creates competitive advantages. Therefore, to maintain their competitive advantage, companies must make efforts to protect their knowledge. Many companies believe that their knowledge can be protected through patents, trademarks, copyrights, etc. However, not all knowledge can be defined through intellectual property rights. It also needs to be assisted by the employee code of conduct, adjustment of incentives, and job design [15]. Although knowledge protection is inherently difficult, and the existent literature rarely discusses the topic of knowledge protection, it is very important for knowledge-intensive companies.

Scholars proposed that knowledge-intensive service industries usually require employees or knowledge workers to sign confidentiality agreements, competition clauses, or other legally effective formalized contracts to restrict internal company secrets and direct or indirect outflow of customer information to third parties or competitors, while avoiding the possibility of employees changing jobs or malicious talent poaching by competitors [16]. In addition, the knowledge-intensive service industry also incorporates informal mechanisms such as education and training, incentive measures, shaping corporate culture, or establishing relationship connections to enhance employees' loyalty to the organization, and reduce the risk of professional knowledge leak.

The implementation of knowledge protection may not be as smooth as expected, with possibilities of increased workload for members of the organization, or hindered knowledge sharing or cultural learning, but it is a very important process for

the organization. Since the knowledge-intensive service industry relies on expertise in products or services, and knowledge assets are also a source of competitive advantage, organizational knowledge needs to be protected to achieve scarcity and prevent imitation. This research incorporates knowledge protection into knowledge management activities and explores the organization's activities in knowledge management activity.

2.4 Summary of literature review

In the era of the knowledge economy, knowledge is the most important production resource for organizations and is also the key for organizations to establish their competitive advantage. Knowledge management scholars have always valued issues ranging from acquisition, storage, and sharing for the effective application of knowledge. More companies have gradually realized the importance of knowledge management, which is both a strategy and a process. In this process, there must be factors that promote knowledge management, including organizational structure, organizational culture, personnel factors, and information technology. Therefore, this research analyzes the factors influencing knowledge management and knowledge management activities to understand the relevant actions of enterprises.

In the past, most scholars who conducted research on knowledge management discussed the knowledge management situation of enterprises from the perspective of process, and seldom used and described how knowledge management influences affect knowledge management activities. Therefore, this research analyzes the relationship between the influential factors of knowledge management and knowledge management activities to explore practices of case companies. Based on the literature discussed, this research integrates the elements proposed by previous scholars into four influential factors of knowledge management to explore the activities of case companies, namely "strategy and leadership," "organizational culture," "personnel factors," and "information technology." For knowledge management activities, this research summarizes the views of knowledge management procedures proposed by previous scholars. After considering the industrial characteristics of CROs, it will be divided into four major activities: "knowledge acquisition and absorption," "knowledge accumulation and "storage," "knowledge diffusion and exchange," and "knowledge protection," which will be used to study the activities of case companies. In addition, the research focuses on the "execution" phase of clinical trials in the CRO industry. Finally, this research analyzes the relationship between the influential factors of knowledge management and management activities. The research results are expected to contribute to both academia and industry.

3. Research methods

3.1 Research framework

The research framework is drawn as shown in **Figure 1**. This research examines the knowledge management practices of CROs from the perspectives of "influential factors of knowledge management" and "knowledge management activities," and explores how CROs in Taiwan perform knowledge management activities during the "execution" phase of assisting clinical trials. It then discusses the actual situation regarding the relationship between influential factors of knowledge management and knowledge management activities.

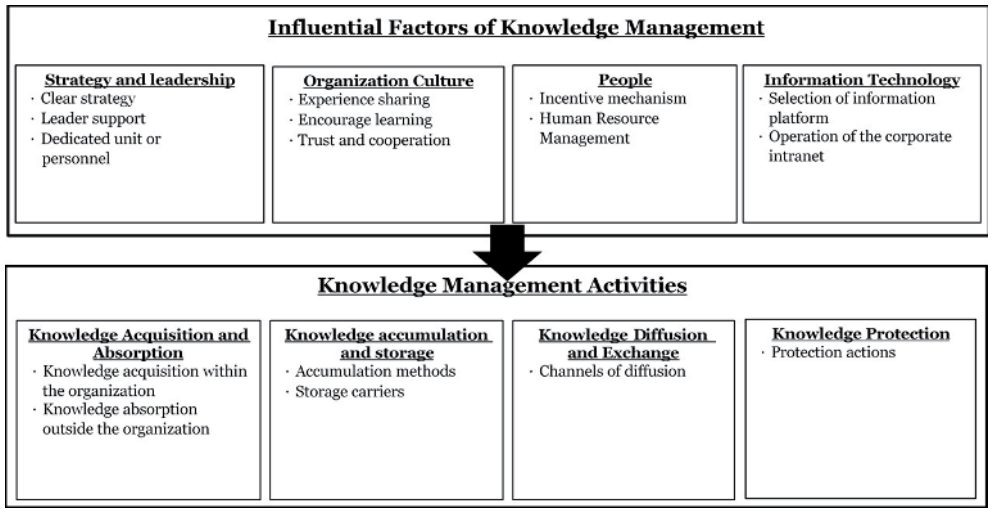

Figure 1.
Research framework.

3.2 Research method

The case study method is regarded as suitable and is proposed for this research to explore the required questions [17]. It focuses on phenomena that occur in real life. Therefore, the experience of researchers is important [17].

Since the research mainly explores the "influential factors of knowledge management" and "knowledge management activities" of CROs in Taiwan, this research adopts the case study method to conduct in-depth interviews for primary information and collect secondary data. After analysis of the real situation of knowledge management in CROs, the research findings, conclusions, and recommendations are derived. This research adopts the multiple cases method with the intention to explore how CROs implement knowledge management and provide suggestions and reference values to other CROs interested in knowledge management.

3.3 Research objects

This research chose two American companies with a branch in Taiwan, a Taiwanese company, and a Japanese company with a branch in Taiwan, as the research objects. The main purpose is to use the heterogeneous background of the CROs to make the analysis and discussion in this research more comprehensive. After comparing the sizes and backgrounds of different CROs, the similarities and differences in their knowledge management practices can be understood. Brief information regarding the four CROs is provided as follows.

IQVIA is a U.S. CRO and one of the top five CROs in the world. The IQVIA has a branch in Taiwan.

PRA Health Science is an American CRO, and it is also one of the top five CROs in the world. It has a branch in Taiwan.

The Formosa Biomedical Technology Corporation (FBTC) is a local Taiwanese biotechnology company. A clinical trial division was formally established in July 1995 to perform CRO-related services. It is one of the most famous CROs in Taiwan and is still actively growing and developing.

A2 Healthcare Corporation (A2HC) in Taiwan is a CRO owned by a Japanese business group. It is currently working hard to deepen its business in Taiwan. Compared to the first three companies, it is a small CRO company.

Research objects	Interviewees	Job title	Times interviewed	Total hours interviewed
IQVIA	Mr. Lin	CRA	3	6
PRA	Ms. Yu	CRA	3	6
FBTC	Ms. Chen	PM	3	6
A2HC	Ms. Chang	CRA	2	4

Table 1.
Interview information.

Table 1 illustrates the interviewees who participated in this research and other related information about the interviews.

3.4 Methods of data collection

There are two sources of data collection in this research, with primary data as the main source and secondary data as the supplement. Primary data include in-depth interviews with the internal personnel of the case companies and serve as the basis for deriving results. The interviewees chosen work in roles more relevant to the "execution" phase of the clinical trial: clinical research associate (CRA) and project manager (PM). In addition, the interviews were recorded to increase the accuracy of the records and subsequent data collation. Most of the interview questions were open-ended to avoid restricting the respondents' answers.

Secondary data was collected to help researchers understand the background, current status, development history, and related operational overview of the case companies. The main sources include official website information, annual reports, public brochures, and public announcements. In addition, industry analysis reports of market research companies and the public sector are also used as reference materials.

4. Research cases

4.1 IQVIA

IQVIA is a CRO founded in 1982 and headquartered in North Carolina, USA. It was originally named Quintiles. In 2016, it merged with IMS Health to form the Quintiles IMS. In 2017, it was renamed IQVIA. It mainly provides biopharmaceutical development and commercial outsourcing services, including phase I to IV clinical trials, related laboratories, analysis, and consultation. IQVIA is currently one of the top three companies in the global clinical trial service industry. Its global service base exceeds 100 countries, with nearly 70,000 employees. IQVIA provides professional services for many medical fields, including tumor treatment, central nervous system, cardiovascular diseases, autoimmune diseases, urinary system diseases, endocrine diseases, respiratory diseases, and various infectious diseases. So far, IQVIA has helped complete the R&D or commercialization of many best-selling drugs and biologics around the world. It has also helped customers reduce R&D costs and the timetable for R&D, contributing to improving the health of people.

4.2 PRA health sciences

PRA Health Sciences originated from the University of Virginia in Charlotteville, USA in 1976, and established a CRO to assist in data management in 1982. Until 1991,

it extended services to clinical trial management, drug safety, etc. Today, it has more than 15,000 employees, more than 75 offices around the world, and provides services in more than 90 countries. As one of the world's leading CROs, PRA continues to cooperate with biotechnology and pharmaceutical companies, and, like IQVIA, improves the R&D process, conducts drug development, and assists in clinical trials through mergers and acquisitions. At present, PRA provides services for multiple medical fields, including tumors, central nervous system diseases, inflammation, and infectious diseases. Its comprehensive service items include data management, statistical analysis, clinical trial management, supervision, and drug development consulting.

4.3 Formosa biomedical technology corporation

The Formosa Biomedical Technology Corporation (FBTC) was established in 2003. Its purpose is to combine the three major resources of the company in manufacturing, research in universities, and clinical trials. Through cross-field and cross-departmental cooperation, it jointly develops and produces high-quality and high-tech products that are beneficial to human health. In 2006, a clinical trial division was established. With the assistance of medical resources of the Chang Gung Memorial Medical System and the academic resources of Chang Gung University, it received medical materials and commissioned research services from domestic and foreign pharmaceutical companies. It is focusing on contracting at various stages of clinical trial cases and actively looking for partners worldwide. Through clinical experience in progress or completed assistance, it attracts more multinational clinical trials to Taiwan, promotes its business in Europe and the United States, and deploys globally. Currently, Formosa Biomedical Technology Corporation provides the following professional services: (1) clinical research monitoring; (2) test organization management; (3) regulatory services; (4) trial design; (5) data processing; (6) statistical analysis; and (7) trial report writing.

4.4 A2 Healthcare Corporation in Taiwan

A2 Healthcare Corporation (A2HC) in Taiwan was established in 2012. It performs clinical research services under the Japanese ITOCHU Group and is positioned as a CRO that provides comprehensive clinical research services for customers in Taiwan and overseas. So far, it has executed and accumulated services for 45 clients and more than 60 clinical trial cases worldwide. The service scope ranges from strategic planning, trial planning and execution, data collection and analysis, and research report writing to a closed GCP audit. The detailed items are as follows: (1) clinical research execution; (2) data processing and statistics; (3) medical writing; and (4) overseas clinical trial services.

5. Research propositions and discussions

According to the case study results, several research propositions are raised, illustrated with a case brief, and discussed as follows:

Proposition 1:

When CROs implement knowledge management, they tend to integrate the knowledge management concept into the standard of procedures (SOP) and educational training programs.

Case illustration:

The standard of procedures (SOP) of IQVIA includes some rules of knowledge management practices that employees have to follow. In addition, the company assigns specific staff for designing corresponding training programs and continuously adjusts the rules. PRA not only integrates knowledge management practice requirements into SOP, but also into general clinical practice (GCP), particularly in the areas of knowledge accumulation and protection. They also pay attention to whether employees comply with the regulations. Both FBTC and A2HC integrate the rules of knowledge management accumulation and protection into their training programs and SOPs. In FBTC, the quality assurance (QA) personnel are in charge of the monitoring process, in A2HC, both QA and the heads of divisions are responsible for checking KM implementation.

Discussion:

For the CROs, the accumulation and protection of clinical trial knowledge and results are critical information and are important documents to conduct further analysis and for later authority checks. It is believed that once the rules and processes of knowledge management can be integrated into the SOP, training programs, and daily working life, the concept and importance of knowledge management can be better realized by employees. Thus, a higher performance by CRO firms is expected. Although a few studies have tried to connect knowledge management with operations management, such as [18], very few have addressed how the knowledge management practices are transformed into the SOP.

Proposition 2:

When CROs implement knowledge management, they tend to emphasize the organizational culture of knowledge sharing to stimulate effective learning and inheritance of experiences among employees.

Case illustration:

Both IQVIA and PRA have an obvious knowledge-sharing atmosphere. They organize different groups from different divisions, with group heads in charge of promoting knowledge sharing. These heads monitor the situations of colleagues implementing knowledge management and suggest a change in KM rules to their supervisors when necessary. FBTC and A2HC emphasize knowledge sharing in formal meetings, through which a few cases are discussed. The latter firm also relies heavily on its internal intranet for knowledge sharing, learning, and recording.

Discussion:

A large amount of tacit knowledge exists in the brains of individual employees. This knowledge can be shared with others, and can create values for the organization [9, 19]. Thus, the degree of employees' willingness to share their knowledge and experiences, usually determined by the organizational culture, is a key factor in knowledge sharing. As for the CROs, many projects are quite similar with only differences in external partners and contractors that may require different working methods. Therefore, if employees working for different groups can share knowledge and techniques with one another, they can improve their knowledge base, capabilities, and work efficiency.

Proposition 3:

The CROs tend to emphasize the institutions and rules of transition during employment status shifts to enhance the retention of employees' experiences and knowledge.

Case illustration:

All four case firms have transition SOPs as guidance when employees either shift to new positions, leave offices, or retire. Their transition SOPs include detailed

rules, checklists, and procedures. The people in charge of the transition will check if the leaving employee passes on their professional knowledge, experiences, and the required documents. Meanwhile, they need to ensure that the followers can come on track quickly and smoothly.

Discussion:

Research in knowledge management has indicated that individuals drive knowledge processes and are the true source and creator of knowledge [20–22]. If industrial firms can develop a KM-based human resource management system, then their employees will be in a better position to fuse old and new knowledge. Thus, we can conclude that the top managers of these four firms pay high attention to human resource management, with a particular focus on managing people exchange.

Proposition 4:

While relying on information systems for knowledge management, CROs tend to focus on a few major functions: information archiving, classifying, sharing, and searching.

Case illustration:

All four case firms rely on the information system to collect and archive the magnanimous data of clinical trials. In addition, the information system serves as an important channel for employees' communication. They can either share or ask questions to their colleagues through the system. Furthermore, employees can learn from the information system, which stores necessary information for training. Among these cases, IQVIA and FBTC establish a specific information system for dealing with only clinical trial-related data with concerns of data complexity and fear of knowledge leak.

Discussion:

The utilization of information technology or information systems to facilitate knowledge management has been recognized for a long time [23, 24]. The information system possesses the capacity to accumulate large quantities of various types of data useful for new or junior employees to learn, and for project team members to share project-executing experiences. While information systems can be used to facilitate knowledge management, as the knowledge involved is explicit, there still exist limitations when knowledge involved is tacit in nature. Companies need to find other ways, besides information systems, to implement knowledge management.

Proposition 5:

CROs tend to rely on experience sharing as a major approach for implementing knowledge flow and acquisition.

Case illustration:

The project team members of IQVIA organize monthly meetings for experience sharing and learning from one another. The company also builds "buddy" and "mentor" systems, with junior employees as the former and senior employees as the latter, to facilitate knowledge diffusion. PRA employees rely more on informal channels for consultation with experienced colleagues for knowledge learning. Through the knowledge exchange process, new knowledge can be created. Both FBTC and A2HC emphasize "on-job-training" for training new employees and those in new positions to be equipped with the necessary knowledge and skills for new jobs as soon as possible. A2HC also holds workshops for new employee training and quick learning.

Discussion:

From the case study results, we can conclude that CROs use mentoring systems to assist new and junior employees to learn from senior and experienced employees.

The major experiences of CROs' employees may include communication skills with hospitals (mainly medical doctors and nurses) and contractors (biotechnological and pharmaceutical companies), accumulated knowledge about clinical trials, and analytical skills from the clinical trial data check. The characteristics of this type of tacit knowledge are regarded as different from those based on information systems and databases [20].

Proposition 6:

CROs tend to adopt both formal and informal mechanisms for their knowledge protection.

Case illustration:

All four case firms take three major knowledge protection actions: signing confidentiality agreements with clients and employees, establishing the codes of conduct in the SOP for knowledge protection, and setting the information access limit to authority. The first action belongs to formal and legal mechanisms, while the second and third actions belong to informal mechanisms.

Discussion:

Knowledge of intellectual property, particularly in the manufacturing sector, is usually protected in legal terms, such as patents, copyrights, trademarks, and trade secrets. However, it is argued that the protection mechanisms in the service sector need to be broadened to include other mechanisms [25]. Scholars claimed that knowledge-intensive business services (KIBS) firms can include other mechanisms for protection, such as complexity of design, lead-time advantages on competitors, education and training, codes of conduct, and incentive measures in addition to legal methods [16, 26]. As the CROs' data and results of clinical trials are very important to their pharmaceutical clients, they must strive to protect them.

Proposition 7:

Once the CROs establish a performance appraisal and incentive system for KM, more support from top management would lead to higher performance in knowledge sharing and accumulation.

Case illustration:

All four case firms are found to support KM activities of knowledge management. However, different firms may have different incentive systems. For example, PRA has an incentive mechanism called "star system." Once employees have particular achievements in KM-related activities, they would be credited with a certain number of stars, which later becomes one of the major criteria for salary raises and promotion. A2HC designed an evaluation form with a checklist to check how knowledge sharing and exchange is implemented when people change with new positions.

Discussion:

It is indicated that more support for knowledge sharing by top management makes it easier for employees to implement knowledge-sharing activities [27]. Other studies have also indicated the crucial role of leadership in knowledge sharing [28]. With enough support from top management, employees would be encouraged to put efforts into keeping important data safe, storing, and sharing knowledge. Consequently, firms will have a higher performance in knowledge exchange and accumulation.

6. Conclusions and implications

6.1 Conclusions

The study draws several conclusions. When an organization implements knowledge management, if it can integrate the concepts and objectives of knowledge management into the staff's standard procedures of daily work by matching education and training courses, it can become deeply rooted in the staff's daily work. Even if knowledge management is not clear by definition, employees can still improve their participation in knowledge management activities through daily work processes. Therefore, companies would construct a set of suitable norms for employees to follow so that knowledge management becomes a part of daily work norms and knowledge accumulation and knowledge protection activities can be carried out more reliably.

Furthermore, due to the nature of CRO employees' work, they rely heavily on the absorption of empirical knowledge, including communication skills with the hospitals and the clients, familiarity with the clinical trial process, clinical trial data recording, and review skills, etc. Such knowledge acquisition is necessary for experience sharing in the organization to allow employees to communicate with each other through the mentoring system, or experience and knowledge sharing activities similar to the mentoring system, to achieve the purpose of imparting and spreading experience and knowledge. In addition, the establishment of information technology can provide a systematic platform for employees of the company to record, integrate, and transfer knowledge to improve the efficiency of knowledge diffusion and exchange.

Additionally, when CROs implement knowledge management, they emphasize the support of the leadership and the coordination of the improved human resource management system for knowledge diffusion and accumulation. The higher the support of the organization's leadership for knowledge management, the higher the willingness of employees to participate in knowledge management activities. A robust human resource management system, including the design of rewards or performance evaluation systems, can increase employees' motivation for knowledge diffusion and communication. Clear handover specifications can avoid loss of experience and knowledge during the movement of personnel. Thus, it can promote the easier implementation of accumulation and storage of knowledge.

Whether it comes from the internal norms of the organization, the content of clinical trial books, the acquisition of relevant prior knowledge, or the absorption of updated knowledge from outside the organization on regulatory and implementation aspects, knowledge management can improve the efficiency of the organization members in the implementation of the clinical trial. With this knowledge, when faced with the needs and questions of the clients and the hospital staff, they can quickly answer and carry out diffusion and exchange of knowledge.

6.2 Theoretical implications

According to the above conclusions, this research provides two major academic contributions. First of all, the study takes CROs as the objects to explore the "integrity" of knowledge management. The CRO industry is a knowledge-intensive industry. Although several prior researches have been conducted on its strategic aspects, business, and operating models, the knowledge management of CROs have seldom been discussed. Therefore, this research focuses on the CRO industry and

selects institutions that provide clinical trial services to explore their knowledge management practices and the impact of influential factors on knowledge management activities.

In past empirical research on knowledge management, there have been more discussions on the influential factors of knowledge management or knowledge management activities in a single dimension. The results of these studies may have several limitations. Based on the perspective of "integrity," this research explores four aspects of knowledge management: strategy and leadership, organizational culture, human factors, and information technology; and four aspects of knowledge management activities: knowledge creation and absorption, knowledge accumulation and storage, knowledge diffusion and exchange, and knowledge protection. This is expected to contribute to a holistic approach to knowledge management studies.

Second, this research takes the organizational level as the unit of analysis to conduct empirical research on knowledge management. Past empirical studies on knowledge management mostly focused on the "project level" or "individual tintegrated research, especially with the "organization level" as the unit of analysis. Knowledge management of CROs is expected to be helpful in the research field of knowledge management at the organizational level.

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