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A Research of Knowledge and Technology Innovation on Business Model Innovation:

From the perspective of Chinese Pharmaceutical R&D Outsourcing Enterprises

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Abstract

In order to improve R & D efficiency and reduce R & D cost, pharmaceutical enterprises are willing to split up multiple stages of new drug R & D, and in the form of signing contracts, outsourcing part of pharmaceutical R & D business is carried out to professional organisations. These organisations undertaking R & D outsourcing services are called Contract Research Organization (CRO). Because of the rapid change of market, diversified demand and increasingly fierce competition, CRO is facing key problems such as enterprise development, service level and talent echelon. By adopting a flexible business model and adapting to the market demand quickly, enterprises can keep core competitiveness and realise sustainable development in the fierce market competition. Given this, this study focuses on the business model innovation of contract research organisation. Through literature, the paper analyses the important factors related to business model innovation and then use the research model of the actual enterprise questionnaire to complete the empirical research. Further reference to domestic and foreign literature, the corresponding questionnaire scale is formulated. After the preliminary verification of the reliability and validity of the pre-survey questionnaire, the legal issue of the questionnaire for empirical analysis. Then, the data of 213 effective questionnaires were collected by SAS software and excel. This study suggests that China's contract research organisation should attach great importance to the innovation of business model and increase investment in the whole process of knowledge management to increase the internal innovation source power of enterprises. China's contract research organisation should arrange the technical innovation in the direction of big data artificial intelligence in advance and formulate a complete risk management plan to significantly improve enterprise performance and enhance the core competitiveness of enterprises.

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INTRODUCTION

Background of Study

In May 2015, the State Council of the Chinese government issued the strategic document "made in China 2025" to deploy and comprehensively promote the implementation of manufacturing power. The document has designed a top-level plan and roadmap for the development of China's manufacturing industry in the next ten years. It is hoped that through efforts to realise the three major changes from made in China to created in China, from China's speed to China's quality, and from China's products to China's brand, China will realise industrialisation by 2025 and become one of the world's manufacturing powers. Therefore, it has become the action program of the first decade of China's implementation of the strategy of manufacturing power (notice of the State Council on Printing and Distributing "made in China 2025", 2015). With the implementation of the documents mentioned above, "made in China 2025", "healthy China", and "innovative China" strategies, the state has listed the pharmaceutical industry as a key development area in the strategic emerging industries, and a series of relevant policies have been issued one after another to support and encourage local and Chinese Pharmaceutical enterprises actively, pharmaceutical institutions and individuals to base their innovative research and development in China. For example, in the same year of 2015, the State Council issued the "opinions on the reform of drug and medical device review and approval system" (opinions of the State Council on the reform of drug and medical device review and approval system, 2015), which ushered in the spring of innovative drug development. Nowadays, R & D of innovative drugs have become the primary choice for the sustainable development of Chinese pharmaceutical enterprises. Most pharmaceutical enterprises continue to increase R & D investment and burst out great innovation vitality. Statistics show that during 2013-2019, the R & D investment of China's A-share listed pharmaceutical enterprises has increased from 9.7 billion yuan to 58.8 billion yuan (see Figure 1-1), with an average annual compound growth rate of 29%, showing a steady growth trend. Among them, the compound annual growth rates of R & D investment in chemical medicine, traditional Chinese medicine and biological medicine reached 20%, 38% and 34%, respectively. Especially since 2015, with the accelerated reform of the State Food and Drug Administration and the drug review and approval system, the upsurge of R & D of new drugs in pharmaceutical enterprises is booming and is entering the golden period of development (Bian Linglin).

New drug research and development has the theory of "two high and one long": high investment, high risk, and long cycle. New drug R & D is also a system engineering. We must rely on the effective integration of cross-domain engineering, technology, and knowledge to be competent in the whole process. We need to carry out the specialised fine division of labour from the perspective of the industrial chain and promote the development of new product R & D process with open innovation mode (Onetti & Zucchella). In this case, a new cooperation mode - "contract R & D" has emerged. Therefore, "contract research organisation" (CRO) emerges as the times require. CRO is an academic or commercial scientific institution that provides outsourcing services for pharmaceutical enterprises, medical device R & D enterprises, medical institutions and relevant government funds in basic medicine, translational research and clinical medicine R & D by signing contracts. Contract research organisation often provides professional and standardised services (parent, Fontana, Gimigliano, & Valentina, 2015) in a flexible and customised way to complete or assist in some key work in new drug research becoming an important part of pharmaceutical research and development.

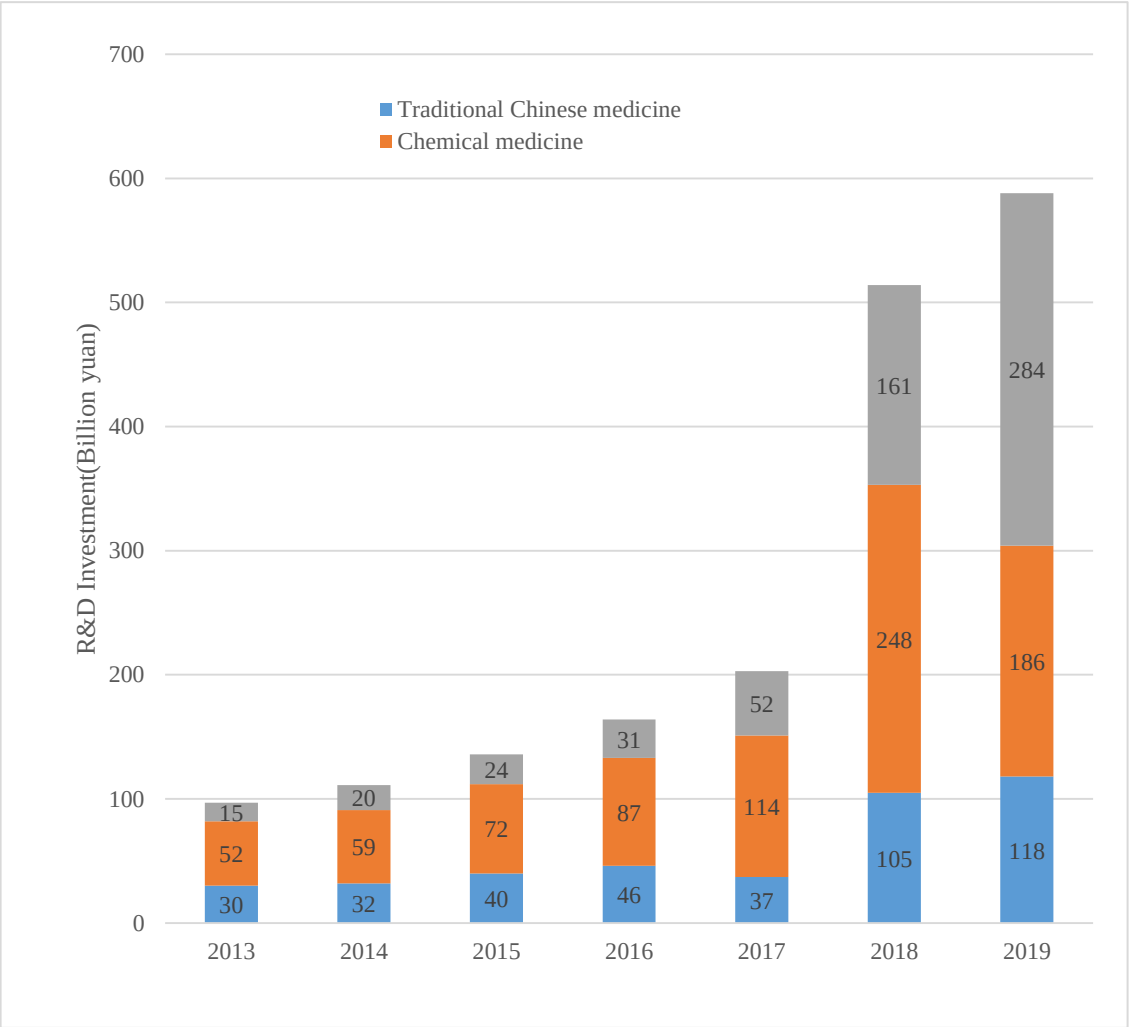

Figure 1-1 R & D investment of China's A-share listed companies (100 million yuan)

Problem Statement

Problems faced by contract research organisation

Cro industry, as the outsourcing service of drug R & D, is a service-oriented enterprise and a leading emerging industry in the world knowledge economy, which adapts to the future trend and strategic development direction of emerging industries and even the world economy (Zhang Rongbo & Huang Xiao, 2020). However, China's contract research organisation is generally faced with low industrial concentration, unable to break through the bottleneck of development scale. In recent years, with the leading companies of several CRO industries listed on the Chinese mainland or Hongkong stock market, the expansion and upstream and downstream businesses have been integrated through different modes such as investment, acquisition and expansion of the original business. However, there is still no enterprise with a market share of more than 10%. The main reason is that the demand for service outsourcing has been diversified and personalised, and the development of enterprises is restricted by the number and development of knowledge-based employees. It is difficult for the business model adopting traditional order service to adapt to the rapidly changing market environment. Therefore, business model innovation is imperative. Based on the classic business model innovation, most of them are based on the business model's constituent elements to study business model innovation from three aspects: customer value proposition

innovation, value creation and transfer innovation and enterprise value acquisition innovation. The urgent need of the CRO industry is to deeply explore the driving force for business model innovation to solve the development dilemma of enterprises.

Business model innovation factors of CRO

Although many studies have confirmed that different forms of business model innovation may positively impact enterprises, the question of "how can enterprises carry out business model innovation" is not clear enough. Previous studies on business model innovation are mostly ex-post oriented and extrapolated from the results, which can not effectively guide enterprises to actively and prospectively carry out business model innovation. Of course, business operators do not create new enterprises or new business models from scratch but first think about "what resources and advantages they have" and "what difficulties they are facing" (Doganova & Eyquem Renault, 2009).

Cro, as the upstream field of R & D in the pharmaceutical industry, its rise and development are usually driven by the outsourcing strategy of large and medium-sized pharmaceutical enterprises. Today, China's pharmaceutical industry has changed from emphasising imitation and neglecting innovation to the development of innovative drugs and clinical value generics. China's pharmaceutical outsourcing value chain is also gradually moving towards the high end, and the scope of outsourcing is also expanding from the small scale and single structure business scope to the whole life cycle outsourcing of drugs. It can be seen that the market and demand are also undergoing significant changes. A contract research organisation needs a constantly innovative business model to adapt to the rapid changes of the market, further expand the scale of the enterprise, and improve the enterprise's core competitiveness to seize the current development opportunities and cope with the industry pressure and fierce market competition. At present, the CRO industry has encountered many problems and bottlenecks in the development process. With the explosive growth of China's pharmaceutical R & D outsourcing industry, the age of employees in CRO companies is becoming younger and younger, and the industry turnover rate is high, resulting in the uneven quality control and delivery of responsible projects, which seriously affects the satisfaction of the sponsor (customer) and the company's reputation. Therefore, contract research organisation urgently needs a systematic knowledge training system, scientific management system and standardised operation process, and the reduction of R & D cost and improvement of R & D quality brought by technological innovation, such as medical technology, big data analysis and artificial intelligence.

Research Questions

Based on the background of the new wave of innovative drug development, this paper summarises, analyses and interprets the development status, industry pain points and customer needs of the traditional CRO industry, focusing on the analysis of why only continuous business model innovation is the foundation for the sustainable development of contract research organisation. This paper introduces the relationship model of business model innovation, technological innovation, and knowledge management of contract research organisation introduces the theoretical system of risk management, and deeply analyses the comprehensive relationship model of the risk control system of pharmaceutical R & D as technology and knowledge-intensive industry in the real innovation and development. To further improve the completeness of the research on the innovation business model of contract research organisation in China. The problems to be solved in this study are as follows

(1) What are the factors that affect the business model innovation of contract research organisation?
(2) What is the influence of knowledge management and technological innovation on the business model innovation of contract research organisation?

Research Objectives

(1) Determine the factors that affect the business model innovation of contract research organisation.
China has entered the macro background of vigorous development of innovative drug R & D, so it is necessary to carefully analyse the innovation evaluation dimension of China's contract research organisation business model. Although compared with European and American countries, China's CRO industry started relatively late, with the construction of "healthy China", the demand for R & D of innovative drugs is increasing, the ability of R & D innovation is strengthening, the requirements of laws and regulations are improving, and the division of professional labour is refining. It can be said that pharmaceutical enterprises and medical equipment enterprises are increasingly dependent on CRO company's services.
(2) Discusses the influence of knowledge management, technological innovation and enterprise risk management on the business model innovation of contract research organisation.

It is generally believed that the innovation of the business model mainly depends on the interaction of knowledge flow, information flow and value flow. These three organically combine to form a dynamic and evolving community, making the business model change from static to dynamic to adapt to the change of the external environment. Among them, knowledge is the main driving force (Li Changyun, 2012a). Knowledge can be divided into explicit knowledge and tacit knowledge whether the enterprise can internalise explicit knowledge into tacit knowledge through knowledge management to enhance the organisation members' innovation ability and support the continuous innovation of the enterprise business model. The support of Internet technology and digital technology will bring unprecedented changes to traditional clinical research. In order to ensure the quality and scientificity of data generated by clinical trials, fully protect the rights and interests of subjects, and finally apply to regulatory purposes.

The research goal of this study is China contract research organisation. It is necessary to explore how to improve business model innovation in order to maintain the competitiveness of enterprises under the background of the blowout development of pharmaceutical R & D. In the development of contract research organisation, the market demand is diversified, the research process and data are complex, highly dependent on knowledge workers, and the industry is highly mobile. To make the enterprise's business model innovation sustainable development, it is very important to sort out the important influencing factors of the enterprise's business model.

LITERATURE REVIEW

Business Model Innovation

Definition of business model. Bellman and others first put forward the business model concept in 1957 (Bellman, 1957). As soon as it came out, it was highly valued by the academic circles and gradually widely used. From a holistic perspective (Martins, Rindova, & Greenbaum, 2015; Venkatraman & Henderson, 1998), a business model is a structural system through which enterprises can provide customers with better product value or service value competitors and obtain profits. Amit & Zott (2001) believe that the business model, as a

popular enterprise operation mode or management system, crosses the boundary of core enterprise, is interdependent with it. Chesbrough (Chesbrough 2012) defines a business model as a kind of management process that transforms specific technological enterprise value into customer enterprise value. However, Teece (2010) believes that the business model is a series of ways and means to let enterprises transfer value to core customers and induce customers to pay to bring benefits to enterprises. Some scholars also regard the business model as a network to define the organisational value of enterprises and the source to enhance the value of enterprises (Afuah, 2003). Given the differences in the connotation of business model from different research fields, there is no consistent explanation of the concept of business model in academic circles (Jiang Jihai, 2014). Therefore, if an enterprise wants to gain a favourable position in the hands of competitors, it must build a business model that is in line with the development of the enterprise and is not easy to be imitated according to the characteristics of its internal resources and environment. Research on business model a mature business model should have four elements at the same time: value network element, core customer interface element, core strategy element and strategic resources element (Whitehurst, 2002). Amit & Zott (2001) believes that the composition of a business model can be interpreted as seven core levels, namely, product value creation, product/information/service flow, transaction system-related content, structure, system governance, business opportunity and capability (R. Amit & Zott, 2001). Stahler (2002) pointed out that the four core elements of the business model include value strategy proposition, product and service, value system and profit model (Yuanlei, 2007). Jonas Hedman & Kalling believes that the core elements of an enterprise's business model should be competitiveness, which is pluralistic and covers the competition level of enterprise products, business, enterprise resources, and the overall market management level (Hedman & Kalling, 2003).

Knowledge Management

Knowledge management is about acquiring, storing, transferring knowledge and ensuring knowledge workers share knowledge, which is an important content of enterprise management. Knowledge management is initially a process of acquiring, organizing, managing and disseminating knowledge through systematic methods, which can help people quickly achieve tasks, reuse and reduce duplication (Yang Xiaohong & Zhou Xiaozhang, 2017). Sheng Xiaoping and Zeng Cui (Sheng Xiaoping & Zeng Cui, 2010) pointed out that knowledge management theory is based on philosophical epistemology, knowledge capital of economics and management strategy theory. Chu Jiewang and Guo Chunxia (2007) summarized the development process of knowledge management theory. They divided it into the first and second generations. The first generation includes classic strategic management theory, competitive strategy theory and core competitiveness strategy theory, and the second generation includes human capital theory, life cycle theory and complexity theory. In addition, Qiu Junping (2006) established the discipline system of knowledge management from three aspects: theory, method and application. Anadona and Chan (2016) believe that knowledge is frequently transformed within the enterprise, and knowledge management is the management of knowledge transformation, which is an important factor that can affect the development of enterprises of all sizes (Laura et al., 2016).

In this study, knowledge management is defined as the knowledge management of enterprises. As a new development stage of applied knowledge, it must connect information, activities and enterprise development. In business activities, enterprises can obtain a competitive advantage through sharing information and knowledge, and finally through innovative thinking and innovative application.

Before the study of knowledge management, the first is to study the formation of knowledge. In the early stage, we studied the formation of knowledge in philosophy. The talent theorists believe that knowledge is born to us, and the human body is forgotten after being disturbed. The acquired training and learning are recalling their memory, and the acquired experience can not produce knowledge. The other is empiricism, which scholars accept. They believe that knowledge is acquired through experience and formed through stimulation. In the book knowledge management and organization design, knowledge management was first mentioned in China, translated by Jiang Huigong and edited by Paul S. Myers (Mayers & P. S., 1998). This book opens the door for Chinese scholars to study knowledge management.

Technological Innovation

For a long time, technical innovation has been regarded as an important way for enterprises to obtain a sustainable competitive advantage, which helps to improve the technical level of enterprises and increase performance. According to the classic theory, it includes a series of activities, such as related activities in science and technology, organization, business and Finance (Fujiaji, 1998). Liu Jintao (2017) believes that technological innovation is a kind of innovative behaviour in which entrepreneurs search for a promising target market by collecting relevant information. This kind of innovative behaviour has a commercial nature (Liu Jintao, 2017). By reorganizing the internal production conditions and factors, an enterprise can establish a more efficient and cheaper production management system, and then introduce new products and new production methods to the market, open up new markets with potential, obtain suppliers of new raw materials or new parts needed by the enterprise, or establish an organization again. The definition of technological innovation comes from practice, so its description involves the whole process of technological innovation. Technological innovation refers to a series of activities related to technological innovation, such as organizing and coordinating R & D, production and marketing departments, technological innovation, implementing R & D, planning production and performance evaluation.

In this study, the definition of technological innovation refers to the results of technological innovation and includes a series of business and social activities such as the promotion, dissemination, application, and external cooperation of the results. Technological innovation has long been regarded as an important way for enterprises to obtain a sustainable competitive advantage. The research of Nahm and Steinfeld (2014) suggests that technology-oriented innovation can achieve multi-directional learning and cross-border learning inside and outside the organization, increase the knowledge reserve of innovation and enhance the technological R & D capability of enterprises. As a kind of disruptive innovation, all the methods and processes of business model innovation are to obtain more economical premium, create higher enterprise value and improve the performance of new ventures. The unique knowledge management and management of contract research organization will bring the innovation of business model to the enterprise, which is conducive to the construction of the enterprise's core competitiveness and the enterprise's success. At the same time, it will have an important impact on the business model's innovation through the enterprise's comprehensive risk management.

METHODOLOGY

Research Design

Taking Chinese Contract Research Organization (CRO) enterprises as the research object, this paper explores the influence of knowledge management, technological innovation on enterprise business model innovation. Based on the concept of the proposed variables, the measurement dimensions and methods of the key research variables are determined, and the

corresponding questionnaire scale is designed. After the design of the questionnaire, the reliability and validity of the questionnaire and factor load test were analyzed to ensure the rationality and reliability of the data scale. Based on the current market situation of the Chinese mainland CRO, the study selected the appropriate research population and the high-reliability sample size. It ensured the credibility and the analysis of the research data, which provided a theoretical basis for the subsequent research hypothesis and the verification of the conceptual model. In the research process, special attention is paid to the comprehensive application of a variety of research methods and adopt the idea of combining theoretical research and empirical research, qualitative and quantitative research complement each other and make use of their different characteristics to complement each other, to obtain better research results. The specific research methods include literature research, interview and questionnaire survey. Through literature reading, combing the relevant literature, put forward the basic problems and preliminary ideas. Interview research is mainly to verify and adjust the idea and collect information for the next step of questionnaire design to lay the foundation for determining the measurement items.

Population, Sampling, and Unit of Analysis

The purpose of this study is to explore the relationship between business model innovation of contract research organization and technological innovation and knowledge management of enterprises. A contract research organization has special enterprise characteristics, which is essentially different from general R & D enterprises in business logic. Therefore, when selecting the respondents, we must choose the contract research organization in the traditional sense. In order to achieve the research goal of this study, we should strictly screen the target enterprises and questionnaire fillers in the process of questionnaire collection and try to eliminate the influence of interference factors.

Business model innovation scale design

The main way to realize business model innovation is to update and reshape the components of the business model. The evaluation of business model innovation should also focus on the ability evaluation of the components of the business model. Based on the scale compiled by Johnson (2008), this paper designs the scale from the perspectives of customer value proposition innovation, value creation and transfer innovation, and enterprise value acquisition. When formulating the evaluation items for business model innovation, we first conducted expert interviews with three founders of China's local contract research organization and two project management team leaders of a multinational contract research organization, One person in charge of the Commercial Department of the listed contract research organization and one director of human resource management of listed contract research organization. See table 3-6 for specific evaluation items.

Enterprise business model innovation scale

Reliability test

Enterprise Business Model Innovation contains 11 items. The total Cronbach's α value of the Enterprise Business Model Innovation scale is 0.9523, which is greater than 0.9; it proves that the Enterprise Risk Management questionnaire has high internal consistency and good reliability.

Table 3-1 Reliability measurement of enterprise business model innovation scale

The Cronbach's alpha value of the deleted item					
Item deleted variable	Original variable		Standardized variables		Cronbach α coefficient of the entire questionnaire
	Correlation coefficient with total	Alpha	Correlation coefficient with total	Alpha	
19. The competition in the industry is more intense	0.536006	0.955550	0.540105	0.956309	0.952309
20. Enterprises can achieve standardized service and service quality objectives	0.783193	0.948205	0.788232	0.947555	
21. Enterprises focus on identifying and serving market segments and customers	0.868492	0.944990	0.871343	0.944518	
22. Business scope covers upstream and downstream and can provide one-stop service	0.738456	0.949730	0.741344	0.949245	
23. Strong customized service capability	0.825290	0.946354	0.823618	0.946268	
24. Enterprises attach importance to customer value proposition, customer loyalty and high satisfaction	0.840737	0.945875	0.840469	0.945652	
25. Enterprises are using new technologies/developers are constantly updating (Research Technology/data, etc.)	0.825150	0.946375	0.822297	0.946316	
26. Enterprises have new sources of income growth	0.821141	0.946501	0.818134	0.946468	
27. Enterprises have a wide range of industry resources and networks and participate in the formulation of industry standards or consensus	0.799244	0.947372	0.797429	0.947221	
28. Flexible organizational structure adjustment	0.811772	0.946859	0.807008	0.946873	
29. Members of the organization have a high degree of participation in decision-making and strong interaction within the organization	0.764643	0.948760	0.758353	0.948634	

Source: Author

Table 3-2 Structural validity test of enterprise business model innovation

Item	Factor1	Factor2
19. The competition in the industry is more intense	0.1857	0.6511
20. Enterprises can achieve standardized service and service quality objectives	0.4043	0.7576
21. Enterprises focus on identifying and serving market segments and customers	0.3362	0.7435
22. Business scope covers upstream and downstream and can provide one-stop service	0.2637	0.6787
23. Strong customized service capability	0.3857	0.6545
24. Enterprises attach importance to customer value proposition, customer loyalty and high satisfaction	0.4168	0.6652
25. Enterprises are using new technologies/developers are constantly updating (Research Technology/data, etc.)	0.3192	0.7122
27. Enterprises have new sources of income growth	0.3369	0.6753
28. Enterprises have a wide range of industry resources and networks and participate in the formulation of industry standards or consensus	0.3999	0.6555
29. Flexible organizational structure adjustment	0.3281	0.7834
26. Members of the organization participate in decision-making with a high degree and strong interaction within the organization	0.2582	0.8463

Source: Author

Validity test

Factor analysis is used to evaluate the structural validity of the Business Model Innovation questionnaire. The chi-square value of Bartlett's sphere test is 976.46, P<0.001, which is statistically significant, indicating that this data can be used for factor analysis. The factor analysis extracts two common factors. After the maximum variance is orthogonally rotated, the factor 2 load is greater than 65%. It is believed that this scale can retain a principal component, as shown in Table 3-16.

Data Collection Process

The questionnaire is mainly distributed through the online electronic scale, filled in online by the respondents, and the questionnaire is investigated in the company by contacting the personnel manager (HR), senior management and manager of the target company. All key survey information is set as required in the design of the questionnaire to ensure the completeness of the filling. The survey data of the questionnaire is automatically saved on the online platform, and the time of the questionnaire collection is set for 20 days. The platform will automatically save the collected data for analysis.

FINDINGS AND DISCUSSIONS

Profile of Respondents

The samples of this study are mainly from enterprises in Shanghai, Jiangsu and Beijing, accounting for 78% of the total samples. These regions are also regions with the rapid development of the biomedical industry and strong industrial agglomeration. The other samples are mainly from Guangzhou and the capital cities in the central and eastern regions. Rich medical resources characterize these cities, many grade III class A hospitals, and the main institutions for drug clinical research and development.

The companies selected in this study not only covered contract research organizations listed in China, such as Wuxi Apptec, Pharmaron, Tiger Med, Medicilion and Boji, accounting for 26% of the total sample; it also includes the multinational Contract Research Organization, which is set up in China's independent operation companies, such as Parexel, Organization, PPD (Pharmaceutical Product Development) and Covance, accounting for 21% of the total research companies. The other research enterprises mainly come from Chinese mainland Contract Contract 52%. The sample proportion is between the intermediate value of international CRO market share and Chinese CRO market share (Xu Wen & Liu Yongjun, 2018); It can represent the current situation of China's CRO industry market and also refer to the international market development trend, so that the sample source can truly represent the situation of China's contract research organization, and reduce the sampling bias.

The influence of knowledge management on business model innovation

The four explanatory variables of knowledge management, knowledge acquisition, knowledge sharing, knowledge application and knowledge development are used to analyze business model innovation. Univariate analysis can preliminarily explore the relationship between predictive variables and response variables and delete some irrelevant predictive variables through univariate analysis. Through the multi-factor analysis, the variables in the model are brought into the multi-factor analysis to verify whether there is a significant correlation.

Based on the single factor analysis (knowledge management single factor analysis table), from the regression results, the overall correlation was 0.741, P < 0.0001, showing significance, passed the test. There was a positive correlation between knowledge acquisition and business model innovation ability, and the standard coefficient was 0.6773, P < 0.0001;

The standard coefficient of knowledge sharing was 0.6600, P < 0.0001; The standard coefficient was 0.6542, P < 0.0001; Knowledge development was positively correlated with business model innovation ability, the standard coefficient was 0.7059, P < 0.0001. Single-factor analysis shows that knowledge management and its four explanatory variables significantly affect business model innovation ability. The results showed that each item of a single factor had significance, which further confirmed the feasibility of the scale.

Table 4-1 Characteristics of questionnaire samples

Variable	Number (n)	Proportion (%)
Gender		
Male	82	38.86
Female	129	61.14
Age		
18~25	36	17.06
26~30	63	29.86
31~40	68	32.23
41~50	29	13.74
51~60	13	6.16
Above 60	2	0.95
Education		
College degree or below	22	10.43
Undergraduate	125	59.24
Postgraduate	52	24.64
PhD student	12	5.69
Working years		
Within 1 year	15	7.11
1~3 years	49	23.22
3~5 years	27	12.8
5~8 years	27	12.8
More than 8 years	93	44.08
Position		
Staff	104	49.29
Grassroots management	28	13.27
Middle management	33	15.64
Senior management	34	16.11
Founder/General Manager	12	5.69
Company size		
Large (>500 people)	83	39.34
Medium (100~500 people)	81	38.39
Small (<100 people)	47	22.27
In the field		
MC/CDMO	9	4.27
Animal Research/Central Labouratory	4	1.9
The clinical trial outsourcing organization	146	69.19
Hospital/Research Institute	6	2.84
Other	46	21.8

Source: Author

Table 4-2 The relationship between knowledge management and business model innovation

Dimension	Items	Correlation coefficient	P-value
Knowledge acquisition		**0.6773**	**<.0001**
	Enterprises have a multi-channel knowledge acquisition system.	0.5454	<.0001
	You and your team often receive external training.	0.5485	<.0001
	Enterprises have a complete curriculum training system and job training plan.	0.5681	<.0001
	The enterprise has full-time knowledge management personnel.	0.5117	<.0001
Knowledge sharing		**0.6600**	**<.0001**
	Enterprises have training courses and clear learning requirements.	0.5814	<.0001
	The enterprise has an inter departmental job rotation system.	0.3630	<.0001
	Regular training from cross-department / professional.	0.5069	<.0001
	The Department has a common internal learning sharing mechanism.	0.5649	<.0001
	Enterprises have a sharing platform for training or tools.	0.5185	<.0001
Knowledge application		**0.6542**	**<.0001**
	Always pay attention to the industry trends and apply them to work.	0.6308	<.0001
	The performance appraisal of enterprises has the requirement of knowledge and ability.	0.4839	<.0001
	The enterprise has a professional knowledge evaluation system.	0.4633	<.0001
	Enterprises will explore benchmarking management experience and promote the application.	0.6534	<.0001
Knowledge development		**0.7059**	**<.0001**
	Enterprise organizational culture is to develop a learning organization.	0.6297	<.0001
	Enterprises have an efficient information management system.	0.5596	<.0001
	We often organize to participate in "brainstorming".	0.5849	<.0001
	Enterprises will constantly update and revise business processes.	0.6386	<.0001
Total		**0.7411**	**<.0001**

Source: Author

The influence of technological innovation capability on business model innovation

The independent variables of technological innovation capability, including talent reserve and R & D investment, cooperation and innovation achievements and technology/service innovation level, were analyzed by single-factor analysis. Univariate analysis can preliminarily explore the relationship between predictive variables and response variables and delete some irrelevant predictive variables through univariate analysis. Through the multi-factor analysis, the variables in the model are brought into the multi-factor analysis to verify whether there is a significant correlation. Based on the univariate analysis (Table 4-7), from the regression results, the overall significant value $p < 0.0001$, showing significance, passed the test. There was a positive correlation between talent reserve and R & D investment and business model innovation ability, and the standard coefficient was 0.5608, $P < 0.0001$; The results of cooperation and innovation were positively correlated with the ability of business model innovation, and the standard coefficient was 0.6487, $P < 0.0001$; The level of Technology/service innovation was positively correlated with the ability of business model innovation, and the standard coefficient was 0.6090, $P < 0.0001$. Univariate analysis shows that knowledge management and its three explanatory variables significantly affect business model innovation ability.

Table 4-3 The relationship between technological innovation and business model innovation

Dimension	Items	Correlation coefficient	P-value
Talent reserve and R & D investment		0.5608	<.0001
	The proportion of full-time technical developers is more than 20%	0.4487	<.0001
	The annual R & D proportion of enterprises is more than 10%	0.4669	<.0001
	More than 30% of technical personnel in management	0.5142	<.0001
Cooperation and innovation results		0.6487	<.0001
	Cooperate with cross-industry experts to develop new technologies	0.5926	<.0001
	Working closely with top medical institutions / industry experts	0.5448	<.0001
	Enterprises receive technical awards from the government	0.5042	<.0001
Technology/service innovation level		0.6090	<.0001
	Enterprises have innovative patent technology	0.4622	<.0001
	A certain technical level of the enterprise and leading the industry	0.5043	<.0001
	AI technology applied to business service	0.4851	<.0001
	The high degree of digital application in Enterprises	0.5358	<.0001
total		0.6734	<.0001

Source: Author

In this study, 213 qualified samples of survey data were collected to explore the relationship and mechanism between knowledge management ability, technological innovation level and business model innovation. Through empirical test and statistical analysis, it is concluded that knowledge management positively impacts business model innovation. Knowledge management can effectively improve the work skills of the organization and its members and form the knowledge accumulation of the organization. At the same time, high-level knowledge-based talents can increase the external environment of the enterprise, such as the policy that will affect the strategic decision-making of the enterprise. Knowledge management has a positive impact on business model innovation. The stronger the ability of knowledge management, the more conducive to business model innovation.

Technological innovation has a positive effect on business model innovation. In business model innovation, technological innovation can provide technical help for enterprise business model innovation and help enterprises analyze the shortcomings of enterprises from the existing environment, which is conducive to business model innovation. The uncertainty brought by technological innovation will affect the effect in the whole model. Technological innovation can promote the efficiency and diversity of enterprise service amount, promoting business model innovation.

CONCLUSION

Based on the Chinese government's active encouragement of Chinese pharmaceutical innovation and the explosive growth of the pharmaceutical R & D industry, this study is based on the upstream industry of pharmaceutical R & D - pharmaceutical outsourcing industry (CRO). Through detailed analysis of the industry characteristics, market demand, and development trend of cro, this study believes that business model innovation is the key to maintaining enterprises' core competitiveness in the fierce competitive environment and rapid market change. This study takes business model innovation as the main research goal, sets it as the dependent variable, and discusses its influencing factors. Through many relevant literature searches, the CRO industry belongs to knowledge-intensive and technology-

intensive industries, so knowledge management and technological innovation are considered two independent variables. Learning from the maturity scale of China and foreign countries and previous relevant research, we measure knowledge management, technological innovation, and business model innovation. At present, there is no mature scale for business model innovation of pharmaceutical R & D service enterprises, so we conducted expert interviews before the survey, mainly for the founder, CEO and senior management of contract research organization, and formed the final questionnaire. In order to fully reflect the operation status of enterprises, this study takes the middle and high-level managers, grassroots managers who are familiar with the relevant information of enterprises and some front-line employees as the survey objects. This paper discusses the impact of three dimensions of technological innovation, namely talent reserve and R & D investment, cooperation and innovation achievements and technology/service innovation level on business model innovation; And the four dimensions of non-technological innovation, that is, the impact of knowledge acquisition, knowledge sharing, knowledge application and knowledge development on business model innovation. First, knowledge management has a significant positive impact on business model innovation. The research also verifies that knowledge acquisition, knowledge sharing, knowledge application, and knowledge development significantly positively impact business model innovation. If an organization can exist forever, the knowledge management process will never end. Enterprises can identify and acquire the knowledge they need, share the knowledge within the organization, internalize it into knowledge skills that can be applied by the organization, and create development in the continuous application and practice, thus forming a cyclic and rising dynamic cycle. In the era of the knowledge economy, the pharmaceutical R & D service industry, as a knowledge-intensive enterprise, is more dependent on knowledge workers, and knowledge value directly determines the enterprise value and innovation ability. In the multi-factor analysis, after the influence factors of technological innovation and risk management are brought in, they still show a significant impact. It also fully shows that enterprises need to continuously improve the level of knowledge management to enhance enterprises' business model innovation to make enterprises continuously active and obtain the core competitiveness of enterprises more effectively.

Secondly, the correlation between technological innovation and business model innovation is affected by many factors. In the single factor analysis, technological innovation and business model innovation are significant. The influence of three explanatory variables of technological innovation: talent reserve and R & D investment, cooperation and innovation achievements and technology/service innovation level are also significant. After knowledge management were introduced in multivariate analysis, the influence of technological innovation and business model innovation did not show statistical significance. The innovation of R & D outsourcing enterprises is more based on the optimization of service process and the improvement of service efficiency, which is different from the technological innovation of drug R & D enterprises. Under the influence of many factors, the technological innovation of contract research organization may not directly promote the business model innovation of enterprises in the short term. However, the author believes that since China's CRO industry started more than ten years later than that of European and American countries, the application of new technology AI and big data in research has become an irresistible trend. At the same time, due to the lack of qualified professionals in the industry, it needs advanced technology. Therefore, it is still an important strategic layout for a contract research organization to lay out the development and application of new technologies in advance.

REFERENCES

Ai Zhongzhou, Wu Panying, & Du Rong. (2016). The path to improving the innovation

capability of service outsourcing companies: the mediating role of knowledge sharing and absorptive capacity. *Science and Technology Management Research*, (1), 135-140.

Bian Linglin. (2020). Capital and talents resonate to promote the vigorous development of the CRO industry. *Chinese market, 000*(019), 1-4.

Cao Jiajun, & Wang Yuefen. (2018). Research on the Construction of Knowledge Innovation Service Application Model Based on Data Science. *Journal of Information, 037*(010), 971-978.

Cao Yuankun, & Wang Guangjun. (2011). A new understanding of the development process and research trend of enterprise risk management. *Contemporary Finance and Economics, 000*(001), 85-92.

Chen Guangren, & Jiang Xiaolong. (2017). Research on the innovation-driven development strategy of the business model of SMEs. *Business Economics Research, 16*(616), 102-105.

Chen Qingtai. (2006). Some thoughts on independent innovation. *Shanghai State-owned Assets Supervision and Administration, 000*(003), 64-66.

Cheng Wei. (2019). Review of business model innovation research. *Value engineering*, (23).

Ding Wei. (2000). From Information Management to Knowledge Management. *Journal of Information*, (02), 29-34.

Du Yeli. (2005). *Knowledge Service Model and Innovation*. Beijing Library Press.

Fu Jiaji. (1998). Technological Innovation Series. *Technological Innovation*.

Ge Qing. (2019). Analysis of influencing factors of business model innovation from the perspective of mergers and acquisitions. *Beijing University of Posts and Telecommunications*.

Guo Yifu. Business Model Innovation and Enterprise Competitive Advantage: Internal Mechanism and Empirical Research. *Donghua University.*

Han Jing. (2014). Risk Evaluation Method of Business Model Innovation Driven by IT——Taking the Online to Offline Model as an Example. *Technoeconomics, 033*(002), 15-20.

Liu Lina. (2000). A Glimpse of Knowledge Management. *Information Theory and Practice, 023*(005), 331-332.

Lu Jiayu. (2019). The relationship between employee loyalty and internal and external environments in knowledge-intensive enterprises. *Modern Economic Information, 000*(018), 131.

Lu Yang, & Cai Xiaohui. (2015). Research on Industrial Innovation of Synergy between Technology and Business Model. *Innovation Technology*, (08), 12-14.

Luo Min, & Li Liangyu. (2015). Business Model Innovation in the Internet Era: A Perspective of Value Creation. *China Industrial Economy, 57*(1), 95-107.

Ma Yibo. (2013). Research on the growth risk early warning system of knowledge-intensive startups. *Harbin Engineering University*.

Meng Diyun, Wang Yaozhong, & Xu Sha. (2016). Research on the influence mechanism of network embeddedness on business model innovation. *Science of Science and Management of Science and Technology, 37*(011), 152-165.

Pan Xuwei, Gu Xinjian, Cheng Yaodong, & Li Jianming. (2006). The knowledge management model of integrated context. *Computer Integrated Manufacturing System, 12*(2).

Qiu Junping, Wang Weijun, Fu Lihong, & Zhang Meijuan. (2000). On the knowledge economy and the development of my country's library and information industry. *Journal of Information, 019*(001), 54-63.

Qiu Junping. (2006). *Knowledge Management*. Science and Technology Literature Press.

Sheng Xiaoping, & Zeng Cui. (2010). The theoretical basis of knowledge management. *Journal of Library Science in China, 36*(005), 14-22.

Song Zhan, & Chen Yuhui. (2017). The mechanism of business model innovation on the technological innovation system: based on a rooted analysis of 20 leading enterprises in

the equipment manufacturing industry in Fujian Province. *Henan Science, 035*(004), 634-639.
Tong Lei. (2009). Research on the value of business model innovation. *Modern Commercial Industry, 21*(019), 19-20.
Wang Chongming. (2000). *Psychological research methods*. People's Education Press.
Wang Hui, & Zhao Yanzhi. (2017). Analysis and Design of Enterprise Knowledge Management System Based on Knowledge Flow. *Library and Information Guide, 2*(006), 55-59.
Wang Jingwei. (2010). Research on Organizational Performance Improvement Based on the Characteristics of Knowledge-intensive Enterprises. *Oriental Corporate Culture*, (15), 104.
Xie Kefan, Zhang Tao, & Gui Ping. (2002). Knowledge-based enterprise life cycle analysis. *Journal of Wuhan University of Technology*, (10), 99-102.
Xu Wen, & Liu Yongjun. (2018). China's pharmaceutical CRO industry development status and trend analysis. *Chinese market, 000*(019), 1-4.
Yang Feng. (2004). Discussion on the explicit incentive mechanism of tacit knowledge in knowledge management. *Modern Information*, (10), 36-37.
Yang Kaifeng. (2004). *Knowledge Management-The Essential Translation Collection of Harvard Business Review*. Renmin University of China Press.
Yang Lei, Shen Xiaohong, & Xiao Kaifeng. (2011). The risks of business model innovation and their prevention. *Times Economics and Trade, 000*(035), 110-110.
Zhao Shukun. (n.d.). *Research on the influencing factors of online retail enterprise business model innovation*. (Doctoral dissertation, Zhejiang Gongshang University).
Zhao Tian. (2015). NASA's knowledge management system and its application in risk management. *Aerodynamic Missile*, (10), 76-79.
Zhou Xinyi. (2016). *Research on the interaction mechanism between technological innovation and business model innovation of entrepreneurial technology enterprises*. (Doctoral dissertation, Southeast University).

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