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Sustainable Innovation in the Biopharmaceutical Industry: An Analysis of the Impact of Policy Configuration

Xiao Xiao [1], Yue Cheng [1,*] and Yuling Zhang [2]

[1] School of Public Administration, Guangxi University, Nanning 530004, China
[2] Chengdu Education Technology Equipment Management Center, Chengdu 610036, China
* Correspondence: 20110003@gxu.edu.cn

Abstract: To achieve sustainable development, it is necessary to consider the business model adjustment of the industry in advance, from the development stage to the mature stage. In China, strategic emerging industries are industries that achieve technological breakthroughs, but such industries often have the characteristics of high investment, high technology, high risk, high returns, and long research and development times. This type of industry relies heavily on national resource support from the exploration period to the development period, but its high-profit characteristics also attract policy bias from the governments of other countries internationally. Therefore, understanding the resource requirements of such industries in different periods in advance will help the government to adjust resource allocation and strategic layout through policy means. This will facilitate the smooth transition of the entire industry from the development period to the mature period, and achieve its overall sustainable development. To assist the government in achieving reasonable predictions for policy adjustments, this study focuses on the biopharmaceutical industry, which is one of the representatives of the strategic emerging industries in China's Yangtze River Delta. Considering that policies are not used in a single manner, and that the observation period needs to span the development and platform periods of the industry, the traditional Qualitative Comparative Analysis method (QCA) does not consider the analysis of data from multiple periods. Therefore, this study innovatively uses the Multi-Time Qualitative Comparative Analysis method (mtQCA), adding the dimension of time change and exploring the policy configuration logic behind the differences in local industrial innovation performance. Extracting general rules from specific policy configuration patterns is meaningful for a better analysis and resolution of complex, dynamic management issues, which will promote the sustainable development of strategic emerging industries.

Keywords: sustainable innovation; policy configuration; urban agglomerations; multi-time qualitative comparative analysis

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1. Introduction

In recent years, global environmental and energy issues have become increasingly prominent. With the achievement of important international agreements, such as the 2030 Agenda for Sustainable Development and the Paris Agreement, promoting the green and low-carbon transformation of industry has become the trend in global development. The new concepts of green development and international planning have put forward new environmental and resource allocation requirements for the business models of global industries [1]. In the original business model, enterprises focused on their own interests to maximize demand. In order to achieve the sustainable development goal and maximize the enterprise value, enterprises need to prioritize policy orientation in the adjustment of their business models, and seek to be the new policy beneficiaries to maximize profits. This business model has given the government more market regulatory rights, especially for the strategic emerging industries, which are characterized by high investment, high technology, and high risk [2]. These industries are highly dependent on government resources, and the government's policy orientation directly affects the overall transformation direction of the industries. While the development of the industry itself is important, the demand gap also directly affects the transfer of government policy focus. For industries in different stages of development, the different periods correspond to different types of resource demands. From this perspective, the strategic emerging industries and the government have a collaborative and mutually supportive relationship. Under this cooperation model, the government relies on strategic emerging industries to achieve international environmental and technological strategic goals through innovative activities, while the industry relies on the government to achieve industry growth and sustainable development. In the context of this dependent model, the commercial practices of the strategic emerging industries increasingly emphasize innovation-oriented approaches, achieving sustained policy benefits for the industry through their continuous innovation activities.

Strategic emerging industries, at the deep integration of emerging technologies and industries, represent the direction of the next round of technological revolution and high-end industrial transformation. Scholars believe that it is a crucial area for cultivating and developing new technologies, new products, and new driving forces with which to gain future global competitive advantages [3,4]. As one of the representatives of the strategic emerging industries, the biopharmaceutical industry has received increasing attention in recent years regarding the sustainable development of research and development, especially due to the impact of the COVID-19 pandemic [5]. Scholars believe that sustainable innovation research in the biopharmaceutical industry is crucial for the advancement of global disease prevention and treatment technologies [6].

In China, the government attaches great importance to the exploration of the green and low-carbon transformation path of the biopharmaceutical industry. Plans, such as the "14th Five-Year Plan for the Development of the Circular Economy" and the "Situation Analysis and Development Suggestions for Strategic Emerging Industries in the 14th Five-Year Plan", have been introduced. These policies have pointed out the need to build iconic biopharmaceutical industry clusters, highlighted the leading role of high-quality cluster-based innovation forces, formed a cluster-based and complementary innovation momentum, promoted the green transformation within the biopharmaceutical industry, achieved the efficient use and recycling of resources, and promoted the peak and carbon neutrality targets for the industry. The biopharmaceutical industry in the Yangtze River Delta region of China is at the forefront of innovation, driven by its favorable political and economic location and leveraging the advantages of its being a pioneer and leader. From the rise of biotechnology in 1982 to the expansion of the biopharmaceutical industry in 2000, the biopharmaceutical industry has now entered a transitional phase, from a period of rapid development to a mature platform. An empirical analysis of the policy resource allocations to the biopharmaceutical industry in the Yangtze River Delta region of China during this transition, and identifying the optimal combination pattern of policy and innovation performance during this period are of great research significance for enhancing the forward-looking policy layout of resource-dependent future industries, and ensuring a smooth transition period under high innovation performance models for other industries in the future.

In the choice of research methods, a traditional multiple regression analysis assumes that the conditional variables act independently of each other, and adopts an atomic perspective to focus on the unique 'net effect' of analyzing the individual variables [7]. But, in reality, different policies are interrelated and interdependent, and the effect of a single policy depends on its configuration with other policies; the unique effects of a single policy may be obscured by other relevant variables, i.e., the uniform opposition between the conditional and outcome variables does not exist in management practice [7]. The configuration analysis method (QCA) does not analyze the impact of individual conditional variables on the outcome variable separately, but adopts a holistic and systematic analytical approach to identify the impact of different conditional combination relationships on the outcome [8]. This research paradigm, which investigates the causal relationship between overall configurations and dependent variables, serves as a new avenue for management studies, addressing the limitations of previous single-factor research [9].

However, the current configuration of research in management relies heavily on cross-sectional studies, lacking the consideration of temporal elements [10]. The study of static cross-sectional data has shaped the notion that the configuration path of cross-sectional data does not develop, adjust, or change over time. Under this influence, research conclusions obtained during a particular period are regarded as universally applicable, and are considered by other researchers to have a temporal blind spot [11].

Given the aforementioned analysis, this study aims to address the following issues: firstly, identifying an explanation for the policy causality behind the development of the high-performance path of industrial innovation; secondly, determining how to incorporate the time dimension into the configurational theory for dynamic research in order to reduce the temporal blind spots behind industrial policy innovation; and, thirdly, determining how to extract general rules from various configuration path features to better analyze complex, dynamic management problems. Regarding these issues, this paper takes the biopharmaceutical industry in the Yangtze River Delta region of China as the research object, and attempts to answer these questions through empirical data.

2. Literature Review

2.1. Concept and Impact of Sustainable Development

The UN 2030 Sustainable Development Agenda (2030 Agenda) sets out 17 sustainable development goals (SDGs) from the economic, social and environmental dimensions. This means that the concept of sustainable development will continue to guide global solutions to outstanding socio-economic and environmental problems for 15 years (2016–2030) [12–14]. Under the influence of the SDGs, governments around the world have incorporated the concept of sustainable development into the business sector, guiding industries towards a green and ecologically sustainable transformation through policy regulation. The new directive for this transformation has incorporated indicators such as carbon reduction, pollution reduction, energy efficiency, and green low carbon into the business decision making of enterprises. Under the influence of this concept, consumers are consciously pursuing more eco-friendly products. The change in market demand has driven enterprises to keep pace with the times and provide products that are more in line with sustainable principles. Nowadays, in the business field, adhering to the principle of sustainability has become one of the top priorities for corporate development. A business model for a sustainable development strategy (economic, social, and environmental) has also been created.

The sustainable business model updates the traditional business thinking of companies that focused only on the economic aspect while neglecting the environmental and social impacts. This model incorporates the concept of sustainability into the production, research, and development processes, emphasizing that companies should prioritize sustainable production and sustainable innovation. The process of sustainable production needs to balance environmental efficiency and production efficiency. The process of sustainable innovation emphasizes the innovation of recommended technologies, including clean technologies, energy technologies, and other innovative technologies that promote a sustainable interaction between the economy, society, and the environment [15]. The sustainable business model emphasizes the greening and low carbonization of the entire process of innovation and production, reducing the negative impact of industry production on the environment and increasing the positive impact of innovation on the environment, thereby enhancing economic benefits [16].

The emergence of sustainable business models has endowed the government with new policy inclinations, especially for emerging industries that are highly dependent on government resources and sensitive to policies. For emerging industries, the transition from technology to production, from the development to the mature stage, and innovation activities always run through the entire development process. This industry has created a new type of collaborative scenario between industry and government, where innovation results in the exchange of more resources. In this context, emerging industries have achieved the government's international environmental and technological strategic goals through their innovative activities, and the industries also rely on the government to grow in its sustainable development. It can be said that the government plays the roles of 'provider of innovation resources' and 'manager of innovation direction' in the developmental environment of emerging industries.

2.2. The Sustainable Innovation of the Biopharmaceutical Industry

The sustainable innovation of the biopharmaceutical industry is a composite concept, thus, requiring an understanding of the perspectives of its two core aspects. The first aspect is the biopharmaceutical industry. The biopharmaceutical industry is primarily composed of the biotechnology industry and the pharmaceutical industry. Meanwhile, it can also be seen as a combination of modern biotechnology, new drug research and development, drug production, disease diagnosis, disease prevention and control, and disease management [17]. The second aspect is sustainable innovation. The concept of sustainable innovation emerged at the beginning of the 21st century. Initially, sustainable innovation aimed to propose innovative optimization solutions from an environmental perspective, while reducing the impact of human activities on the environment through technological, social, and institutional means. Modern sustainable innovation takes the synergistic linkage of economic, resource, and environmental benefits as its goal for innovative development at the systemic level. It explores how to achieve high output, low energy consumption, minimal pollution, and maximal resource utilization with a relatively low innovation input. Sustainable innovation pursues the improvement of innovation efficiency, and innovation efficiency reflects the conversion relationship between innovation resource input and output.

Therefore, sustainable innovation in the biopharmaceutical industry refers to the concept of following sustainable development principles throughout the innovation process. The ultimate goal is to enhance the economic benefits of biotechnology and the pharmaceutical industry. Additionally, it enables a reduction in energy dependency and minimizes the environmental impact. Embracing this concept promotes the inclusive and sustainable development of the biopharmaceutical industry in both its environmental and economic aspects.

2.3. Research on Policies in the Biopharmaceutical Industry

Currently, there is a lack of research on policies in the biopharmaceutical industry, which represents a certain research gap. Specifically, the existing research directions of the global biopharmaceutical industry can be categorized into four dimensions: firstly, the technological innovation of industries; secondly, the perspective of industry clusters; thirdly, the layout of innovation networks; and, lastly, the perspective of biopharmaceutical industry policies. In the field of industrial technological innovation, scholars have focused on enhancing the efficiency of industrial innovation from various perspectives, such as human resources [18], technological gaps [19], patent conversion [20], and political behavior [21]. From the perspective of industrial clusters, scholars have attached importance to comparative studies of different diverse clusters [22], as well as evaluating and analyzing the learning, competition, and cooperation relationships within innovative clusters [23]. The innovation network layout refers to scholars utilizing Social Network Analysis (SNA) methods to study and analyze the spatial structure and operational mechanisms within an innovation network [24] in order to deeply explore the characteristic structure [25], evolutionary laws, and other internal features of the innovation network [26]. In the research related to biopharmaceutical industry policy, scholars have approached the subject from the perspective of industrial policy. By selecting different case study subjects and establishing various policy framework systems based on multiple research perspectives [27], they have analyzed the distribution characteristics of policies and dissected the use of policy tools [28,29].

Overall, the studies on the global biopharmaceutical industry are more focused on industry technological innovation, industry clusters, and the application of innovation networks. The studies in these three dimensions cover multiple perspectives and are relatively detailed and comprehensive. However, there are limited studies on biopharmaceutical industry policies, and the research direction is relatively narrow. There is a lack of new perspectives with which to broaden the research field of original industry policy, making it difficult to achieve the balanced development of the four dimensions of biopharmaceutical industry research.

2.4. Qualitative Comparative Analysis (QCA)

The traditional methodology of Qualitative Comparative Analysis (QCA) was widely utilized in the early stages to tackle political, diplomatic, and societal issues. Nevertheless, it has only been in recent years that it has gained considerable momentum within the field of management studies. Öz's utilization of the QCA method in management research marked a pioneering endeavor in this field [30]. In 2005, Takahashi and Nakamura further improved the QCA method based on this foundation [31]. In 2007 and 2011, Fiss published two articles that thoroughly integrated the QCA method with management studies, which officially gained recognition from the management community [8,32]. In subsequent years, the global management community acknowledged and commenced the widespread publication of articles on the utilization of QCA. Notably, over the last three years, the QCA approach has seen an extensive global application. At present, the QCA method has extensively infiltrated various domains within the realm of management studies, encompassing disciplines such as international business, human resource management, organizational design, and consumer behavior research.

However, there are still issues with the application of traditional QCA methods to the field of management studies, one of which is the insufficient quantity of applications. Using the data from applications within China as a reference, we conducted data retrieval for the keyword "QCA" in the China National Knowledge Infrastructure Database (CNKI). In total, we selected 1654 relevant Chinese articles up until March 2023, with 124 articles specifically in the field of management, accounting for 7.5% of the total. This indicates that the QCA method has been recognized in the field of management in China, but it also shows that its application is not extensive. The second issue is the neglect of temporal blind spots. Traditional QCA methods rely on cross-sectional data and often derive universal conclusions from a single point of observation, lacking the consideration of the temporal dimension and, thus, limiting the scope of the research.

Drawing upon the aforementioned deliberations, it is evident that a research lacuna exists in the utilization of the QCA methodology within the domain of policy research in Chinese management studies. Employing the QCA approach for scholarly inquiry not only serves as a complementary and expansive avenue for industrial policy research from a novel standpoint, but also ameliorates the inadequacies of QCA methodology implementation in the realm of policy research in modern-day Chinese management studies.

2.5. Policy Elements of Innovation Activities

Previous research has suggested that innovation activities should be composed of both innovative elements and innovative environments. The innovative element serves as the foundation for innovative activities, encompassing the convergence of the human, financial, and material resources invested in innovation to form distinct innovative entities. These entities play an interactive role in the entire innovation process, exhibiting a mutually reinforcing mechanism of interaction. Furthermore, innovative activities require favorable environmental factors, including a good institutional system for innovation, an innovative ecological environment, and an open international cultural environment [33–35]. Therefore, this paper attempts to divide the policy-influencing factors for innovation activities into two categories: subject elements and environmental elements. The subject elements consist of human resources, financial resources, and physical resources, while the environmental elements consist of the institutional environment, cultural environment, and ecological environment. Furthermore, a configuration analysis framework of the "subject–environment" relationship, as shown in Figure 1, is established.

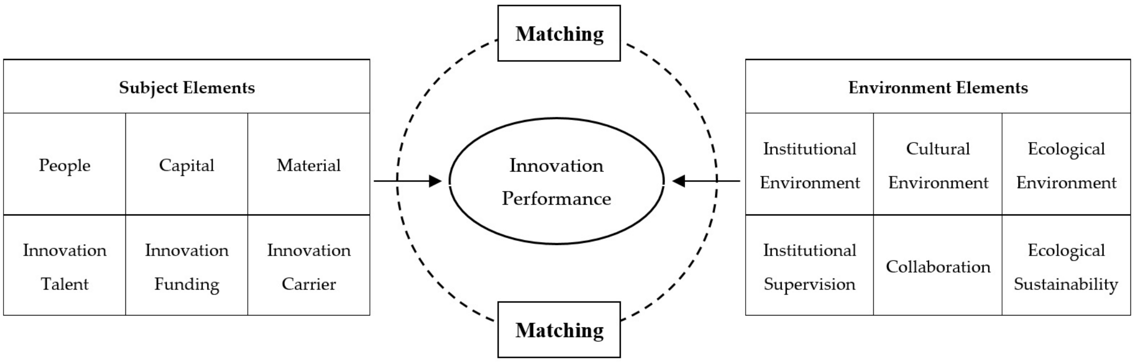

Figure 1. Research framework of the factors in the "subject–environment" relationship. Note: The framework includes two levels: the subject and the environment. The subject elements are represented by people, capital, and material, while the environment elements are represented by institutional environment, cultural environment, and ecological environment. The third level indicator represents six specific policy types.

2.5.1. Innovation Talent (IT)

Innovative talents refer to individuals with scientific and technological knowledge, creativity, and imagination, who can participate in the innovation process and propose original innovative concepts or new ideas, thereby identifying problems, solving them, and pioneering new frontiers in their field. These individuals make creative contributions to both the material and spiritual civilization of society by utilizing their innovative thinking and creative labor [36]. As a knowledge-intensive industry, the biopharmaceutical industry relies heavily on human capital for its innovative development. The individual element of "people", specifically "innovative talents", is often regarded as one of the key driving factors behind innovation [37]. Innovative talents, as the primary drivers of industrial innovation, play a critical role in improving the effectiveness of industrial innovation [38].

2.5.2. Innovation Funding (IF)

Innovation funds refer to the capital that enterprises use for innovative activities, including research and development innovation funds (investment in independent research and development by enterprises) and non-research and development innovation funds (such as the introduction of foreign technology, technology purchases, and technological transformation) [39]. The financial element plays a crucial supportive role in research and development innovation. The government's funding injection methods for innovation institutions can be classified into direct and indirect types. The main forms of direct approaches generally include fiscal appropriations, fiscal subsidies, innovation incentives, innovation activity funds, and research funding. The indirect means primarily encompass financial support, tax incentives, and government procurement. These generally include technology credits and guarantees, technology insurance, tax incentives for innovative products, tax reductions for research and development, and government-funded procurement [40]. Both the direct and indirect methods are crucial avenues through which the government can allocate financial resources to innovation institutions, and both have the potential to exert a substantial influence on innovation efficacy.

2.5.3. Innovation Carrier (IC)

Innovation carrier refers to a composite innovation platform or carrier organization that is formed by different functional and attribute parts, and that integrates different types of resources into a whole. The carrier, through coordinated organization and mobilization, shoulders the task of activating the stock of scientific research resources, building a bridge between scientific research and commercialization, and providing new intellectual support for economic development [41]. Scholars generally believe that the higher the support degree of the innovation carrier, the more it can promote innovation [42]. Common innovation carriers include incubators (collectively referred to as entrepreneurial nurseries or co-creation spaces and accelerators), university science parks, key laboratories, industry–university–research bases, public innovation service platforms, and technology research and development centers. Innovation carriers have the characteristics of multiple attributes and functions, and are regarded as important factors affecting the efficiency of innovation activities and enhancing technological competitiveness.

2.5.4. Innovation Supervision (IS)

Institutional supervision refers to the administrative legal system through which the administrative authority continuously monitors the acquisition of certain qualifications or rights by its administrative counterparts, as well as the entire process of implementing these rights [43]. The policy tool of institutional supervision enables the government to play a supervisory role in the innovation process from a legal perspective in order to establish a more fair, transparent, and efficient policy environment for innovation. It has a dynamic regulatory and control function for the overall innovation process [44]. The dimensions of supervision include not only rigid regulatory methods, such as administrative approval, market access, price regulation, and patent protection, but also flexible administrative adjustment modes, such as target planning, innovation culture construction, and science popularization policies. Both aspects are combined to exert the incentive and punitive effects of institutional supervision [45].

2.5.5. Collaboration with External Parties (CO)

Here, collaboration refers to innovative entities breaking through organizational boundaries and cooperating to obtain complementary innovative resources and reduce innovation risks and complexity. Collaboration emphasizes the cooperation between innovative entities and external organizations, promotes the flow of knowledge between organizations through the integration of complementary resources and, thus, affects organizational innovation performance [46]. Numerous studies by scholars have shown a significant positive correlation between open collaboration and corporate innovation performance, as well as research and development efficiency [47,48]. A good open collaboration atmosphere can help companies acquire more external knowledge and innovative resources, and it can establish good, cooperative, and sharing network relationships [49].

2.5.6. Ecological Sustainability (ES)

Ecological sustainability refers to the overall development strategy adopted by a country that integrates economic development, social inclusiveness, and environmental sustainability [50]. Through the long-term monitoring of the implementation progress of sustainable development goals, innovative activities are implemented to achieve ecological sustainability development goals [51]. Such policies should have innovative features, novelty, and value, and they should be able to effectively achieve resource conservation and environmental protection. Ecological sustainability has two policy classifications. The first is resource-saving green innovation, which includes promoting renewable energy and technology and supporting green public procurement. The second is related to industrial sustainable development, including building an innovative standard system, supporting innovative product standards, and standardizing industrial processes, among others. Scholars believe that these policy tools can affect environmental performance, drive resource conservation, improve the efficiency of the innovation chain cycle, and promote innovation performance [52].

3. Research Design

3.1. Research Methodology

Traditional static configuration theories and QCA approaches have faced several hurdles due to the ever-complex dynamics of management phenomena [10]. Scholars have criticized previous static QCA studies for failing to adequately consider the influence of time factors, thus, being unable to reflect the complex and dynamic configuration results of real life [53]. To address this issue, this paper draws on the Multi-Time Qualitative Comparative Analysis (mtQCA) method proposed by Vis [54]. This method introduces the concept of continuous time change based on traditional, static QCA research methods. The study period is divided into several segments, and configuration results are obtained for each period. These results are then compared across the periods to explore the changing patterns of different configurations over multiple periods and to investigate the reasons for configuration stability or change. By observing the changes in multiple sets of continuous time data, this method effectively reduces the time blind spot in traditional QCA research. This innovative improvement in the research methodology allows for an observation of the overall characteristics of the configuration conditions, as well as the patterns of configuration changes over time and space, thus, enabling the study of the dynamic evolution of policy configurations.

The mtQCA method has diverse application scenarios. It can be used for observing data at continuous time points, as well as for studying data in non-continuous time periods, for example: changes in the relationship between government and enterprises in different economic periods [55]; the relationship between the matching of national institutional contexts and organizational conditions and whether global corporate governance meets the standards in continuous time; etc. [56]. Scholars can fully obtain information on various possible time points by using the mtQCA method, and distinguish the appearance and absence of conditional configurations at different time points. By analyzing these differences, the evolutionary process of environmental relationships in different periods can be obtained. This can alleviate the bias in the sample time selection and the problem of non-robust configuration, ultimately enhancing the robustness of the analysis results.

3.2. Time Division and Data Sources

In 2015, the United Nations adopted the 2030 Agenda for Sustainable Development, which directed future industrial development towards sustainable development based on the economy, society, and environment. Since then, sustainable development has become the consensus of global enterprises [57]. However, the outbreak of the COVID-19 pandemic in 2019 disrupted the planned innovation pace of the biopharmaceutical industry, bringing significant disturbances to the research environment of the industry. Based on this perspective, the period from 2015 to 2019 was a stable stage for the sustainable development concept worldwide. By selecting this period, the impact of the rise of the concept of sustainable development on industrial innovation efficiency can be fully observed, while the disturbances caused by uncontrollable variables, such as the COVID-19 pandemic, can be excluded.

This study selected the innovation policy data of the biopharmaceutical industry in 41 cities in the Yangtze River Delta region in China from 2015 to 2019 for research, and it divided them into 5 time periods, namely, Stage 1 (2015), Stage 2 (2016), Stage 3 (2017), Stage 4 (2018), and Stage 5 (2019). The research sample included all prefecture-level cities in Shanghai, Jiangsu Province, Zhejiang Province, and Anhui Province, totaling 41 samples. According to the 2^{n-1} principle [58], which requires that the total number of research cases must cover all combinations of the conditional variables, six conditional variables and one outcome variable were determined for this study.

The conditional variable data all came from the policy texts publicly displayed on the government portal websites of the 41 prefecture-level cities in the Yangtze River Delta region, without involving internal confidential documents. To ensure the authenticity, comprehensiveness, and integrity of the policy text data sources, this study used the PKULaw database to conduct a secondary supplementary verification of the data [59]. The data collection period of 2015 to 2019 was selected. To collect the data more scientifically, the policy data collected had to follow the following standards: Firstly, the issuing unit of the policy had to be a municipal institution corresponding to the prefecture-level city, such as the people's government, municipal party committee, market supervision and administration bureau, intellectual property bureau, statistics bureau, finance bureau, or education bureau. Secondly, the policy content had to include the keyword "biopharmaceutical" or "biopharmaceutical industry". Thirdly, policies, such as plans and opinions, had to be retained while simultaneously excluding notification-type policies with lower relevance to the theme.

The dependent variable data were sourced from the Shanghai Intellectual Property (Patent Information) Public Service Platform. The platform's patent data retrieval database contains data from over 70 countries or relevant organizations, and its data update speed is at the forefront domestically. The data collection period of 2017–2022 was selected (with a policy lag of 2–3 years) [60]. Based on the conclusions of multiple research scholars, the selected patent search classification codes were A01H1/00, A01H4/00, A61K38/00, A61K39/00, A61K48/00, C02F3/34, C07G, C07K, C12M, C12N, C12P, C12Q, C12R, G01N27/327, and G01N33 [61,62].

3.3. Measurement and Calibration of Variables

3.3.1. Dependent Variable

The innovation performance (IP) of cities can be measured by the annual change rate of patent applications. The accessibility and universality of the patent data can represent the innovation level of a region [63].

The formula for calculating innovation performance is as follows:

$$Pcr_{in} = \frac{P_{in} - P_{im}}{P_{in}} \quad (1)$$

Among these, P_{in}, P_{im}, respectively, represent the number of patent applications of city i in the nth year and the $(n-1)$th year. The number of patents approved by the patent office is used to represent the patent application quantity of each city.

3.3.2. Conditional Variables

Based on the classification and description of the innovation policy factors in the previous section, this article selects six conditional variables, namely, "innovative talent policy", "innovation funding policy", "innovation carrier policy", "institutional supervision policy", "collaboration policy", and "ecological sustainability policy". Table 1 displays the tier 1 indicators and secondary indicators for the variables.

Table 1. Axial coding table for sustainable innovation in biopharmaceutical industry policy.

Tier 1 Indicators	Secondary Indicators	Conceptual Interpretation
Innovative Talent	Adjust formal educational curriculum (a1)	Innovative talents refer to individuals with scientific and technological knowledge, creativity, and imagination, who are capable of identifying and solving problems and pioneering new developments in their field. Policies aimed at protecting innovative talents have an impact on the aggregation of high-level innovative talents and the enhancement of the quality of talent services.
	Strengthen continuing education and on-the-job training (a2)	
	Training and introduction of high-level talents (a3)	
	Resettlement plans and staff movements (a4)	
	Support the human resources service industry (a5)	

Table 1. *Cont.*

Tier 1 Indicators	Secondary Indicators	Conceptual Interpretation
Innovation Funding	Financial investment (b6)	Innovation funding refers to the funds provided by the government or joint operating agencies to research institutions for innovative activities. It can be divided into direct fiscal investment and indirect preferential subsidies. The policy of innovation funds is a financial guarantee to promote scientific progress and enhance sustainable innovation capabilities.
	Innovation activity fund support (b7)	
	Research funding (b8)	
	Subsidies for supporting innovative activities (b9)	
	Introduction of foreign investment innovation policy (b10)	
	Enterprise R&D tax incentives (b11)	
	Tax incentives for venture capital (b12)	
	Tax incentives for innovation and entrepreneurship service institutions (b13)	
	Venture capital policy (b14)	
	Business and financial innovation policies (b15)	
	Technology credit and technology guarantee policies (b16)	
	Multi-level capital market policy (b17)	
	Technology insurance policy (b18)	
	Foreign exchange management policy (b19)	
	Technology innovation award (b20)	
	Government-funded procurement of innovative products and services (b21)	
	Prototype procurement and pre-commercial procurement (b22)	
	Government procurement policy favoring SMEs (b23)	
	Consumer subsidies and consumer education (b24)	
	Tax incentives for adopters of innovative technologies (b25)	
Innovation Carrier	Infrastructure construction (c26)	Innovation carrier refers to a composite innovation platform or organizational entity that is formed by the combination of different functional and attribute components, integrating various types of resources into a whole. Innovation carriers are considered material guarantees that influence the efficiency of innovation activities and enhance technological competitiveness.
	Construction of technological facilities (c27)	
	Technology information support (c28)	
	Market intelligence service (c29)	
	Business information service (c30)	
	Technology transfer and support (c31)	
	Entrepreneurship and project incubation policies (c32)	
	Cluster, technology park, and industrial park (c33)	
	Technology platform and network (c34)	

Table 1. *Cont.*

Tier 1 Indicators	Secondary Indicators	Conceptual Interpretation
Institutional Supervision	Innovation system policy (d35)	As a policy tool, institutional supervision plays a significant role in the innovation process from the perspective of laws and regulations, which helps to establish a more fair, transparent, and efficient innovation system environment. It has a dynamic regulatory and control function for the overall process of sustainable innovation.
	Bankruptcy law (d36)	
	Combating counterfeiting (d37)	
	Innovative environmental regulation (d38)	
	Administrative approval policy (d39)	
	Market access policy (d40)	
	Price policy (d41)	
	Intellectual property protection (d42)	
	Pharmaceutical patent linkage system (d43)	
	Government capacity building (d44)	
	Innovation culture construction (d45)	
	Popular science policy (d46)	
	Roadmap and technical outlook (d47)	
	National drug policy (d48)	
Collaboration with External Parties	Open shared resources (e49)	Collaboration refers to innovative entities breaking through organizational boundaries and engaging in cooperation to obtain complementary innovative resources. This policy can reduce the risks and complexities of innovation, promote the diffusion and dissemination of knowledge and information, and optimize the allocation of innovative resources and the construction of cultural systems.
	Overseas R&D collaboration policy (e50)	
	Regional cooperation (e51)	
	Outsourcing/contract R&D (e52)	
	Management of overseas institutions (e53)	
	Internationalization and innovation policy for enterprises (e54)	
	Trade agreements and trade tariffs (e55)	
Ecological Sustainability	Ecological environment and protection (f56)	Ecological sustainability refers to the overall development strategy adopted by a country that integrates economic development, social inclusiveness, and environmental sustainability (such as long-term monitoring and supervision) in order to achieve the full process of innovation, resource conservation, and environmental protection goals. Such policies play a crucial role in promoting the construction of a sound ecological system for sustainable innovation.
	Promotion and subsidies for sustainable energy/technology (f57)	
	Tax incentives for ecological environment (f58)	
	Eliminate tax breaks or subsidies for unsustainable activities (f59)	
	Green public procurement (f60)	
	Increase efficiency and save energy (f61)	
	Tradable licensing system (f62)	
	Construction of ecological civilization (f63)	
	Significant regional development policy (f64)	
	Industrial development policy (f65)	
	Enterprise development policy (f66)	
	Innovation incentive policy for SMEs (f67)	
	Product standardization and industrial process standardization (f68)	
	Commercialization of scientific and technological achievements (f69)	

Note: a1~a5 represent the secondary indicators of innovative talent; b6~b25 represent the secondary indicators of innovative funding; c26~c34 represent the secondary indicators of an innovative carrier; d35~d48 represent the secondary indicators of institutional supervision; e49~e55 represent the secondary indicators of collaboration with external parties; f56~f69 represent the secondary indicators of ecological sustainability.

The coding is based on whether key information appears in the policy text. The measurement standard is the content of the policy text, where the occurrence of any type of policy in a text is recorded once, and the cumulative record count is summed. The policy coding process uses qualitative analysis software NVivo12plus (12.6.0.959) and is coded using a three-level coding method of "policy text number–policy tool–specific policy tool", which converts the policy content into quantifiable text analysis units. First, an operational coding table is established. Referring to the research on the policy system framework for sustainable innovation in the biopharmaceutical industry that has been conducted by multiple scholars [64–66], this study subdivides the six conditional variables and establishes a coding table consisting of 69 policy tools, including fiscal investment and infrastructure construction. Second, an open coding of the text analysis unit is conducted word by word and sentence by sentence, and coding nodes are obtained through text induction and matching. Third, each code is classified and summarized based on the corresponding policy tool type of the coding node. In this classification, "01, 02, 03. . ." represents the policy text number, and "A, B, C. . ." represents the policy tool type (primary category). "a, b, c. . ." represents the sub-tools (secondary category) of specific policies. Finally, the occurrences of different types of policy tools are counted and recorded in the conditional variable data. The coding results are shown in Table 2.

Table 2. Policy coding statistical analysis.

Elements	Variables	Code Example	Total	Proportion (%)
Subject Element	IT	2-A-a52,14-A-a53. . .1192-A-a53,1193-A-a53	819	8.23%
	IF	2-B-b01,2-B-b61. . .1192-B-b10,1193-B-b01	2809	28.22%
	IC	22-C-c23,23-C-c23. . .1194-C-c18,1194-C-c22	2360	23.71%
	Subtotal		5988	60.16%
Environment Element	IS	22-D-d33,22-D-d36. . .1193-D-d64,1194-D-d34	1779	17.87%
	CO	2-E-e25,2-E-e26. . .1192-E-e25,1193-E-e27	1192	11.98%
	ES	2-F-f43,4-F-f43. . .1192-F-f50,1193-F-f48	995	10.00%
	Subtotal		3966	39.84%
	Total		9954	100%

Note: For example, the code "22-C-c23" means that "Clusters, science and technology parks, and industrial parks" is a sub-tool of the "Innovation carrier" policy tool under the "Principal elements" category of the "Shanghai Municipal People's Government opinions on promoting the sustained, healthy and high-quality development of venture capital in Shanghai", and the content of the policy is "To create a cluster area for venture capital and incubators in Shanghai, and to explore the construction of a demonstration area for venture capital cluster in mature areas. . .".

3.3.3. Data Calibration

Two main calibration methods have been used in the existing research for the calibration of fuzzy sets. The first is the indirect calibration method, where researchers assign multiple values between '0' and '1' for each condition based on their judgment [67]. The second is the direct calibration method, where researchers propose three qualitative anchor points: complete subordination, complete non-subordination, and intersection. Then, the data with different numerical values are mapped onto the range of [0, 1] using fs/QCA (2.5) software [8]. The fsQCA method allows for the case data to be calibrated into a set subordination score ranging from 0.0 to 1.0. The direct calibration method, which applies statistical models, is most commonly used [68]. Common calibration standards include the 95%, 50%, and 5% quantiles, and the 75%, 50%, and 25% quantiles. In the original coding of this study, the number of encoded variables for some urban policy variables was 0. Under this constraint, when using the second calibration method, there could be situations where the 25% and 50% quantiles are 0, making effective calibration impossible. Therefore, the first method is adopted for calibration to ensure the integrity of the calibration results.

This article sets six conditional variables and one dependent variable as completely subordinate, crossover, and completely non-subordinate to the three anchor points of 95%, 50%, and 5% quantiles of the case data [7]. The calibration of all the variables at each stage is conducted using a unified standard, and the calibration results are shown in Table 3.

Table 3. Calibration and descriptive statistics of fuzzy set.

Year	Variables	Average Value	Standard Deviation	Maximum Value	Minimum Value	Full Affiliation Point	Intersection Point	Fully Unaffiliated Points
2015	IC	5.54	6.21	27	0	16	3	0
	IF	6.66	9.04	39	0	22	3	0
	IS	5.73	7.50	37	0	18	3	0
	ES	3.00	4.64	17	0	15	1	0
	CO	2.59	4.09	21	0	10	1	0
	IT	2.24	3.96	25	0	6	1	0
	IP	0.27	0.39	1.88	−0.19	0.71	0.19	−0.17
2016	IC	17.66	18.89	63	0	56	8	0
	IF	11.27	12.65	46	0	41	5	0
	IS	11.49	11.77	38	0	36	8	0
	ES	11.90	13.01	51	0	39	8	0
	CO	9.27	10.47	35	0	31	6	0
	IT	5.20	5.93	22	0	16	3	0
	IP	0.01	0.26	0.55	−0.58	0.40	0.02	−0.52
2017	IC	11.41	18.54	95	0	46	6	0
	IF	8.90	12.17	64	0	19	7	0
	IS	10.05	12.82	60	0	27	7	0
	ES	6.10	8.80	54	0	17	4	0
	CO	5.59	9.21	54	0	15	3	0
	IT	3.63	5.92	33	0	8	2	0
	IP	0.34	0.41	2.11	−0.44	1.18	0.24	−0.15
2018	IC	10.56	13.73	67	0	36	5	0
	IF	9.12	12.56	61	0	35	4	0
	IS	8.17	12.83	78	0	24	5	0
	ES	6.68	13.28	83	0	18	2	0
	CO	5.27	8.09	42	0	20	3	0
	IT	3.66	5.30	28	0	13	2	0
	IP	−0.03	0.23	0.55	−0.57	0.46	−0.04	−0.31
2019	IC	7.17	12.02	71	0	21	3	0
	IF	12.63	25.57	153	0	46	4	0
	IS	5.68	10.54	67	0	15	3	0
	ES	3.78	7.50	44	0	13	1	0
	CO	5.54	10.26	64	0	13	2	0
	IT	3.78	10.90	70	0	11	1	0
	IP	−0.48	0.13	−0.08	−0.70	−0.20	−0.50	−0.65

Note: After coding the policy text using Table 2, obtain the initial coding result and the summary table for each year. For the annual summary table, use Microsoft Excel to obtain the quantities corresponding to the 5%, 50%, and 95% quantiles.

4. Empirical Findings and Analysis

4.1. Single-Factor Necessity Analysis

The criterion for judging a necessary condition analysis is as follows: if the level of consistency is higher than 0.9, then the conditional variable can be regarded as a necessary condition for the dependent variable [69].

The calculation method for the consistency of necessary conditions is as follows:

$$\text{Consistency}(Y_i \ll X_i) = \sum[\min(X_i, Y_i)] / \sum Y_i \quad (2)$$

In Table 4, the consistency of the individual conditional variables with high-performance paths and non-high-performance paths is below 0.9. This indicates that none of the six conditional variables can individually serve as a necessary condition for high innovative performance or non-high innovative performance in the biopharmaceutical industry. Based on this, it can be concluded that the level of innovative performance in the biopharmaceutical industry in the Yangtze River Delta region is not triggered by a single factor.

Therefore, it is necessary to conduct a subsequent analysis and study the impact of the biopharmaceutical industry policy configuration on innovative performance.

Table 4. QCA necessary condition analysis results.

Variables	High Performance					Not High Performance				
	2015	**2016**	**2017**	**2018**	**2019**	**2015**	**2016**	**2017**	**2018**	**2019**
IC	0.55	0.73	0.71	0.62	0.62	0.53	0.54	0.62	0.54	0.60
~IC	0.65	0.57	0.73	0.68	0.69	0.72	0.79	0.80	0.70	0.66
IF	0.58	0.74	0.68	0.62	0.61	0.57	0.52	0.59	0.53	0.59
~IF	0.65	0.60	0.71	0.68	0.73	0.76	0.85	0.79	0.72	0.69
IS	0.57	0.66	0.71	0.65	0.64	0.58	0.50	0.58	0.54	0.59
~IS	0.66	0.62	0.68	0.68	0.70	0.74	0.80	0.79	0.73	0.70
ES	0.48	0.66	0.73	0.62	0.67	0.48	0.51	0.62	0.43	0.43
~ES	0.65	0.63	0.69	0.64	0.62	0.79	0.80	0.78	0.78	0.82
CO	0.52	0.66	0.67	0.68	0.63	0.62	0.49	0.59	0.51	0.61
~CO	0.67	0.62	0.67	0.70	0.66	0.70	0.81	0.75	0.80	0.63
IT	0.58	0.67	0.63	0.65	0.58	0.64	0.52	0.59	0.49	0.52
~IT	0.65	0.61	0.67	0.68	0.70	0.68	0.79	0.69	0.77	0.71

Note: The values in the table are all at consistent levels. ~ denotes the absence of the condition.

4.2. Multi-Time Configuration Analysis

After completing the single-factor necessity analysis, a combination analysis of multiple conditional variables was conducted. The consistency threshold was set to 0.8, and the sample frequency threshold was set to 1 by using the software fs/QCA(3.0). Three types of solutions were obtained: a simple solution, an intermediate solution, and a complex solution [8]. This paper focuses on the intermediate solution, with the simple solution as a supplementary analysis, to identify the core and marginal conditions of this study. Du et al. argued that core conditions are factors strongly causally related to the outcome, and their presence has a significant impact on the outcome [9]. Therefore, the core conditions were used as the criteria for determining the independent configurations. A total of nine independent configurations were identified in each stage of this study. Based on this, the configurations of the conditions were classified and named according to the distribution of conditional variables in the dimensions of "subject" and "environment". They were further refined into four models: the "multi-subject–single-environment" model, the "subject-driven" model, the "collaborative linkage" model, and the "environment-driven" model.

In Figure 2, the overall consistency levels of each stage are 0.85, 0.85, 0.87, 0.86, and 0.89. This indicates that, among the cities that met all the conditions for each stage, the proportions of high innovative performance cities are 85%, 85%, 87%, 86%, and 89%, respectively. The overall coverage rates for each stage are 0.54, 0.60, 0.73, 0.57, and 0.58, respectively, indicating that the complete configurations in each stage can explain approximately 54%, 60%, 73%, 57%, and 58% of the cases. The consistency levels of the individual configurations in each stage are all above 0.8, indicating the effectiveness of this empirical analysis.

4.2.1. Configuration Analysis for Stage 1 (2015)

Configuration 1 can be classified as a "multi-subject–single-environment" model. Configuration 1 indicates that an innovative ecosystem characterized by high innovation carriers, high innovation funds, and high institutional regulation as the core conditions can lead to the development of a path with high innovation performance. During this period, innovation carriers, innovation funds, and institutional regulation exhibit a symbiotic or mutually beneficial coexistence. This also suggests that, under a favorable institutional environment (characterized by high institutional regulation), the government can enhance the innovation performance of innovation institutions by simultaneously increasing the deployment of policy tools related to high agent elements (funds and carriers). High institutional regulation standardizes the innovation environment by regulating the market's innovative behavior at the level of laws and regulations. In this environment, the investment and utilization of innovation carriers and innovation funds positively influence the innovation passion of the biopharmaceutical industry's innovation institutions, thereby transforming innovation intentions into innovative actions.

Variables	Paths																							
	2015		2016								2017				2018		2019							
	1a	1b	2a	3a	4a	5a	2b	3b	4b	5b	3c	6a	3d	6b	6c	7a	8a	6b	9a	7b	8b	6d	9b	7c
IC	●	●	●	●	●	•	●	●	●	•	●	⊗	●	•			●	•	•	•	●	•	•	⊗
IF	●	●	●	•	•	●	•	•	•	●	⊗	●	•	●	●	•	•	●	•	•	•	●	•	⊗
IS	●	●	•	●	•	•	●	●	•	•	●	⊗	●	•	•	•	•	•	●	•	•	•	●	⊗
ES	⊗	•	•	•	•	•					⊗	●	•	●	●	●	●	●	●	●	●	●	●	●
CO	•	•	•	•	●	●	•	•	●	●	⊗	⊗	•	•	•	●	•	•	•	●	⊗	⊗	⊗	●
IT	⊗	•					•	•	•	•	⊗	⊗	•	•	•	•	•	•	•	•	⊗	⊗	⊗	•
Original coverage	0.29	0.47	0.59				0.59				0.37	0.38	0.52		0.57		0.51				0.29			0.29
Unique coverage	0.07	0.26	0.01				0.01				0.10	0.09	0.23		0.57		0.24				0.03			0.04
Consistency	0.95	0.86	0.88				0.86				0.92	0.92	0.88		0.86		0.89				0.98			0.97
Coverage of solution	0.54		0.60								0.73				0.57		0.58							
Consistency of solution	0.85		0.85								0.87				0.86		0.89							

Figure 2. Configurations for high innovative performance. Note: ● denotes the presence of a core condition, • denotes the presence of a marginal condition, and ⊗ denotes the absence of a marginal condition.

4.2.2. Configuration Analysis for Stage 2 (2016)

(1) Configuration 2 can be classified as a "subject-driven" model. High innovation carriers and high innovation funds are the core conditions of this configuration. The coexistence or mutually beneficial symbiotic relationship between innovation carriers and innovation funds is evident during this period. This also suggests that the presence of environmental factors does not affect the development of high-performance pathways in this configuration. The improvement of innovation funds and innovation carriers can bring more material reserves to innovative institutions, mobilize the enthusiasm and creativity of scientific and technological workers and innovative institutions, and promote scientific and technological progress.

(2) Configurations 3, 4, and 5 can be classified as "collaborative linkage" models. High innovation carriers and strong institutional regulation are the core conditions of Configuration 3. The coexistence or mutually beneficial symbiosis between innovation carriers and institutional regulation is evident during this period. This also suggests that a favorable institutional environment and robust innovation carriers play an important role in enhancing innovation performance. In Configuration 4, compared to Configuration 3, the core condition of innovation carriers remains unchanged, but open collaboration replaces institutional regulation as the core influencing factor. This indicates that increasing the investment and utilization of innovation carrier policy tools in an open and collaborative cultural environment can drive the improvement of industrial innovation performance. Furthermore, in Configuration 5, compared to Configuration 3, the environmental element (open collaboration) remains a core condition, but innovation funding replaces innovation carriers as the core driver.

4.2.3. Configuration Analysis for Stage 3 (2017)

Configurations 3 and 6 can be classified as "collaborative linkage" models. Configuration 3, with high innovation carriers and high institutional supervision as the core conditions, appears for the second time in this stage. Unlike the Configuration 3 path in Stage 2 (2016), innovation funds, ecological sustainability, open cooperation, and innovative talents are all auxiliary conditions that do not appear in this stage. In Configuration 6, innovation funds and ecological sustainability exhibit a symbiotic or completely mutually beneficial coexistence during this period. This also indicates that increasing the deployment and use of policy tools for innovation funds in a good ecological environment can positively stimulate the improvement of innovation performance in the biopharmaceutical industry.

4.2.4. Configuration Analysis for Stage 4 (2018)

(1) Configuration 6 can be classified as a "collaborative linkage" model. During this period, Configuration 6, with innovation funds and ecological sustainability as its core conditions, appears for the second time. In contrast to Configuration 6 in Stage 3 (2017), during this stage, the innovation carrier no longer plays a supporting role.

(2) Configuration 7 can be classified as an "environment-driven" model. Configuration 7 indicates that there is a clear symbiotic relationship between ecological sustainability and open cooperation. In this model, the subject elements are no longer the core conditions, and their impact on innovation performance is not significant. Environmental elements play a crucial role, indicating that the government can stimulate innovation vitality by creating a favorable ecological and cultural environment and leveraging the stimulating effect of the "environment" element.

4.2.5. Configuration Analysis for Stage 5 (2019)

(1) Configurations 8 and 6 can both be classified as "collaborative linkage" models. Innovation carriers and ecological sustainability are the core conditions of Configuration 8. Innovation carriers and ecological sustainability exhibit a symbiotic or mutually beneficial coexistence during this period. This also indicates the symbiotic and mutually supportive characteristics of the subject elements and environmental elements in the collaborative linkage model. In addition, during this period, Configuration 6, which is centered on innovation funds and ecological sustainability, appears for the third time.

(2) Both Configurations 9 and 7 are considered "environment-driven" models. Regulatory governance and ecological sustainability are the core conditions of Configuration 9. During this period, Configuration 7 also appears for the second time. Under these two configuration paths, environmental factors play a central role in driving the development of high-performance industrial paths. Therefore, it is named as an environment-driven type. In the environment-driven model, the subject elements no longer appear in a way that complements the core conditions, and only environmental factors play a core role.

4.3. Robustness Test

In QCA research, it is essential to check the robustness of the research results. There are several methods to test the robustness of QCA, with the commonly used method being to set relevant parameters. For instance, one can adjust the minimum case frequency and consistency threshold of the truth table, and then analyze the adjusted truth table again. By comparing the changes in the configuration results, one can evaluate the reliability of the results [70]. If the adjustments to the parameters do not result in substantial changes in the number, components, consistency, and coverage of the configurations, the results of the analysis can be considered reliable [71].

This article focuses on the robustness test, examining whether there are significant changes in the intermediate and simple solutions under different operation selections. Due to this article's small sample size (41 cases), it is not convenient to use the increase–decrease case method, which is suitable only for large sample studies. Therefore, under a process of increasing consistency and a minimum case number threshold, if the results have the same or similar conditional configurations as the original results and at the same times, and the consistency and coverage rates do not decrease significantly, then it can be considered that the conditional configuration is robust. Here, 'similar' means having clear subset relationships and parameters in the solution, thus, not requiring different substantial explanations.

Robustness testing is an essential step in a QCA analysis. When conducting robustness testing for QCA, if the differences in the truth tables resulting from different operations do not substantially affect the interpretation of the results, the analysis results can be deemed robust. Referring to the methods of other research scholars, the thresholds of the truth tables for each year are adjusted [72] as follows: (1) the original consistency threshold of the truth table is adjusted from 0.80 to 0.85; (2) the case number threshold of the truth table is adjusted from 1 to 2; and (3) the original consistency and case number thresholds of the truth table are simultaneously adjusted to the first two items.

The above operation may reduce the number of high-performance cities in innovation, which will reduce the number of high-performance configurations and lower the overall coverage and consistency. The overall solution will be more concise, which helps to check whether the original intermediate and simple solutions still exist in the remaining high-performance innovation cases. If the simple solution and the intermediate solution are the same or similar, it indicates that the fsQCA analysis in this article is robust. The robustness test results are shown in Figure 3.

Treatment	2015		2016								2017				2018		2019							
	1a	1b	2a	3a	4a	5a	2b	3b	4b	5b	3c	6a	3d	6b	6c	7a	8a	6b	9a	7b	8b	6d	9b	7c
Consistency 0.85	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Frequency 2	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	✓	✓	✓	✓	✓	✓	(✓)	(✓)	(✓)	(✓)				(✓)
Consistency 0.85 and Frequency 2	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	✓	✓	✓	✓	✓	✓	(✓)	(✓)	(✓)	(✓)				(✓)

Figure 3. Robustness test results. Note: A ✔ indicates that the simple solution and the intermediate solution are the same, and (✔) indicates that the adjusted intermediate solution is the same.

5. Discussion

It should be noted that the above analysis is a longitudinal observation of Figure 2, showing the policy combination patterns, and the symbiotic or competitive relationships among policy elements for high innovation performance in the Yangtze River Delta region biopharmaceutical industry. However, from the cross-sectional observations in Figure 2, we can also obtain the individual or configuration evolution patterns for the Yangtze River Delta region. This is a further expansion of the results, so that our research can help other emerging industries in the future through the industrial transition, to achieve a forward-looking policy layout, and ultimately achieve sustainable development.

5.1. Trends in Individual Variables

(1) Innovation funds appeared in all five stages of the configuration. Specifically, innovation funds existed in one configuration in Stage 1; two configurations in Stage 2; and one configuration in Stages 3, 4, and 5. Furthermore, it existed as a core condition in each configuration. This indicates that, regardless of how the stages change, high innovation funds have a universal effect on generating high innovation performance and impact the effectiveness of the other factors.

(2) The significance of ecological sustainability emerged in the middle and later stages of the research period. Initially, in Stage 1 (2015) and Stage 2 (2016), high ecological sustainability was not identified as a fundamental requirement. Nevertheless, in Stage 3 (2017), one configuration emerged, followed by two configurations in Stage 4 (2018), and four configurations in Stage 5 (2019). This suggests that the favorable influence of ecological environmental factors on innovation performance intensifies with each period, and its significance grows annually.

(3) The impact of innovation carriers on innovation performance was strong in the early and middle stages of the research period, but slightly decreased in the later stage. In the three stages from Stage 1 (2015) to Stage 3 (2017), innovation carriers appeared frequently, mostly as a core condition. In Stage 4 (2018) and Stage 5 (2019), their frequency

was low, and mostly auxiliary and unrelated conditions were present. This indicates that the influence of carrier element resources on promoting the improvement of innovation performance gradually decreases year by year.

To summarize, this study highlights the significance of tracking the evolving patterns of individual conditional variables or configurations over time to forecast the future trajectory of sustainable innovation within the biopharmaceutical industry. Specifically, when examining the individual conditional variables, this study found that the importance of innovation funding remained consistently significant throughout the industry's transitional phase, whereas environmental policies gradually shifted from being peripheral auxiliary factors to becoming fundamental conditions. Consequently, it is reasonable to expect that funding policies will continue to play a central role in driving innovation activities, while the influence of green and sustainable environmental policies will further intensify.

5.2. The Relationship and Evolution of Configuration Paths

(1) In the context of the "collaborative linkage" model, innovation carriers and institutional regulation formed a frequently observed configuration that demonstrated a pattern of symbiosis or complete mutual coexistence. Throughout the evolutionary process, this configuration remained relatively stable and did not display a mutually exclusive relationship. This suggests that innovation carriers and institutional regulation, serving as the primary pillars for fostering innovation activities and providing an enabling environment, have generated mutually reinforcing and augmenting effects.

(2) Among multiple stages, the configuration of the "collaborative linkage" model (including Configurations 3, 4, 5, 6, and 8) had the highest number of configurations, followed by the "environment-driven" model (Configurations 7 and 9), while the "subject-driven" model (Configuration 2) and the "multi-subject–single-environment" model (Configuration 1) had the fewest number of configurations. Some of the configurations in the "collaborative linkage" model frequently appeared over multiple years. In particular, Configuration 6 appeared three times in the analyzed five-year period, while Configuration 3 appeared twice, and the other configurations only appeared once. Therefore, Configuration 6, which combines innovation funds and ecological sustainability, can be regarded as the dominant mode in the "collaborative linkage" model.

(3) The trinary development model (Stage 1) gradually transitioned to a binary development model (Stages 2–5). In Stage 1 (2015), its dominant path was singular, consisting of the trinary development model composed of innovation carriers, innovation funds, and innovation supervision. This model evolved into a binary development model, specifically the configuration of innovation carriers and institutional supervision, denoted as Configuration 3, which appeared stable over the long term. Innovation funds, in conjunction with other environmental elements, formed a "collaborative drive" model. During Stage 2, the coupling degree between innovation funds and collaboration was relatively high, which subsequently decreased. Ecological sustainability evolved from originally being an auxiliary condition to being a core condition, and its coupling degree with innovation funds gradually strengthened, indicating a certain incomplete "competitive" relationship between the open cooperation and ecological sustainability elements in this configuration. A possible reason for this is that the patent data collection year corresponding to Stage 3 was 2020, a period affected by the global pandemic. It was difficult for the elements of open cooperation to exert a strong core influence during this period and, correspondingly, the societal demand for ecological assets.

(4) The dominant model gradually shifted from a "subject-driven" model to an "environment-driven" model. The core proportion of subject elements decreased, while the core proportion of environmental elements increased. The "multi-subject–single-environment" model consists of two subject elements and one environmental element, while the "subject-driven" model consists of only two subject elements. The "collaborative

linkage" model consists of one subject element and one environmental element, and the "environment-driven" model consists of only two environmental elements. By observing the changes in the quantity of each element from Stage 1 (2015) to Stage 5 (2019), it was found that the quantity of subject elements showed a stable declining trend, while the environmental elements showed a stable increase. This indicates that there is a crowding-out effect for the subject elements in the evolutionary process, as they appeared more often as auxiliary or irrelevant conditions in the later stages of the research period, while the importance of the environmental elements began to stand out, gradually transitioning from auxiliary or irrelevant conditions in the early stages of the research period into core conditions.

The composition and trend of policy configuration are shown in Figure 4. In conclusion, from the perspective of policy configuration, the configuration model shifted from a "multi-subject–single-environment" model to a "subject-driven" model. Throughout the entire period, the proportion of subject elements gradually decreased, while the proportion of environmental elements continued to strengthen. It can be predicted that the future configuration pattern will be dominated by the "environment-driven" model.

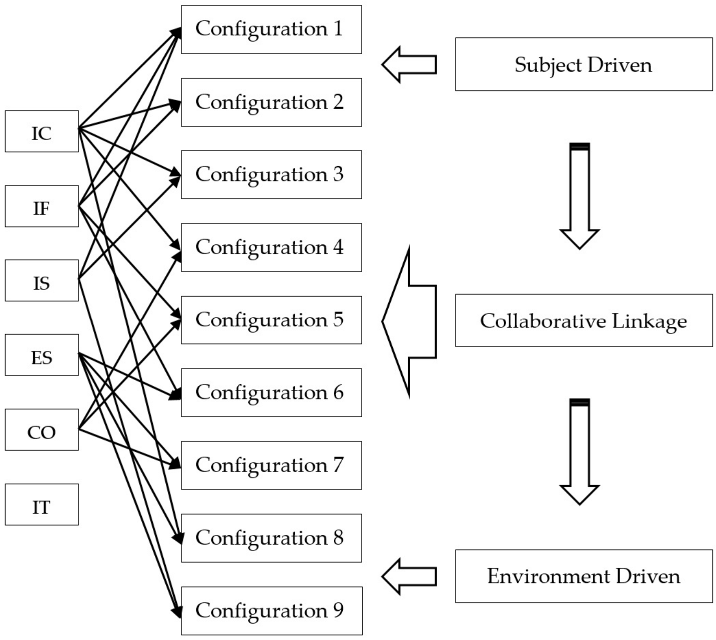

Figure 4. The composition and trend of policy configuration.

5.3. The Alternative to the Configuration

The analysis logic of Qualitative Comparative Analysis (QCA) is different from traditional regression analysis, mainly in terms of the understanding of causal relationships. Traditional quantitative analysis assumes a linear and one-to-one correspondence between causes and effects, which is irreplaceable. However, QCA assumes that the relationship between the variables and outcomes is interdependent, meaning that the occurrence of a social phenomenon may be caused by different combinations of factors, indicating substitutability between different configurations and high innovation performance. In this study, different configurations in the same year also produced the same results. For example, in 2016, Configuration 2, Configuration 3, Configuration 4, and Configuration 5 led to the same complex solution (IC $\times$ IF $\times$ IS $\times$ ES $\times$ CO); in 2018, Configuration 6 and Configuration 7 led to the same complex solution (IF $\times$ IS $\times$ ES $\times$ CO $\times$ IT). From a practical perspective, it can be considered that these configurations are alternatives, and each city can choose to operate based on its actual endowments to achieve high innovation performance in the industry.

6. Conclusions

This study utilized policy coding data and patent panel data collected from 41 cities in the Yangtze River Delta region of China as its foundation. Through the establishment of a configurational analysis framework that focused on the "subject–environment" policy impact factors, and the implementation of a Multi-Time Qualitative Comparative Analysis method, this study aimed to explore the evolving driving paths that exert influence on the innovation performance of the biopharmaceutical industry within these cities. The following conclusions were obtained. (1) The innovation performance of the biopharmaceutical industry in urban clusters is influenced by a multitude of policy factors that do not act in isolation but rather interact synergistically. (2) The policy-driven paths for high innovation performance in the biopharmaceutical industry are complex and diverse, consisting of four models: "multi-subject–single environment", "subject-driven", "collaborative linkage", and "environment-driven" models. (3) Over time, the dominant driving path for high innovation performance gradually shifts from a "multi-subject–single environment" model to an "environment-driven" model, with a decrease in the proportion of subject elements and an increase in the proportion of environmental elements. (4) The dominant model for high innovation performance in the biopharmaceutical industry is the "collaborative-driven" model, which consists of one subject element and one environmental element as the essential conditions. Different "collaborative-driven" models exhibit significant differences in their configurations, with innovation funding and ecological sustainability being the dominant configurations.

6.1. The Impact of This Research on Theory and Practice

On the theoretical level, this research expands the empirical literature on the innovation performance of the biopharmaceutical industry, particularly in the field of industrial policy. While the recent literature on the global biopharmaceutical industry has focused on industrial and technological innovation, industrial clusters, and innovation networks, research on biopharmaceutical industry policies is limited. This study introduces the innovative research perspective of policy configuration into biopharmaceutical industry policy research, achieving the balanced development of the four dimensions of biopharmaceutical industry research. Furthermore, this study employs the mtQCA method and applies it empirically in the Chinese region, increasing the application of the QCA method in China. The mtQCA method also integrates the time dimension into the research design, addressing the 'time blind spot' in traditional QCA methods in previous research, and reducing research limitations.

On the practical level, this study selects the biopharmaceutical industry as the reference point for observing strategic emerging industries and future industries. Through an empirical analysis, the policy causality logic behind the high-performance development path of the innovative biopharmaceutical industry in the Yangtze River Delta region in China, during its transitional period, is examined. It extracts the general patterns that generate high innovation performance from the configuration patterns of various policies. These conclusions can not only help the government to better analyze and solve the dynamic management problems of complex industrial transformation, but also provide forward-looking policy layouts for other strategic emerging industries and future industries with similar characteristics as those of the biopharmaceutical industry (like high investment, high technology, high risk, high return, and a long R&D time), ensuring that such resource-dependent industries smoothly pass through the industrial transformation period in a high innovation performance mode and achieve the sustainable development of the industry as a whole.

6.2. Limitations and Future Research

The data coding in this study employed qualitative research methods, which resulted in subjectivity in the selection and assignment of the conditional and dependent variables, making it difficult to test them using quantitative means. This requires researchers to have a comprehensive understanding of regional industrial policies and to be able to improve their research by combining the experiences of other scholars. This will be one of the key focuses of our subsequent research. Determining how to use more textual data to comprehensively grasp regional policies, how to apply theory and data to support a qualitative analysis, and how to make conclusions more convincing will all become key focuses of our subsequent research.

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