Frontiers in Business, Economics and Management
ISSN: 2766-824X | Vol. 20, No. 3, 2025

Building a 'Three-Pronged Governance' Model for Cross-Border Data Compliance in the Biomedical Industry under the Dual Circulation Pattern

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Abstract: The development of the digital economy has accelerated the global flow of biomedical data, making cross-border governance a critical issue. This study innovatively constructs a 'regulation-enterprise-technology' tripartite dynamic balance governance model and proposes a systematic solution combining data classification and categorisation management, standardised compliance frameworks, and federated learning technologies. The study is based on the pilot practice in Shanghai Lingang, verifying the model's application value in reducing compliance costs and enhancing innovation efficiency. The research findings offer new insights into resolving the contradiction between data sovereignty security and global data flow, driving the digital transformation and innovative development of the biopharmaceutical industry.

Keywords: Biopharmaceutical data; Cross-border flow; Tripartite governance; Federated learning; Compliance framework.

1. Introduction

The global biopharmaceutical industry is accelerating its digital transformation, with cross-border R&D collaboration and data circulation becoming increasingly frequent. Major developed countries are formulating biopharmaceutical data governance rules, and China is also exploring a balanced path between data sovereignty and open innovation. Current research often focuses on single technologies or regulatory dimensions, lacking systematic solutions. This paper innovatively constructs a three-dimensional governance model, proposing a new paradigm of collaborative governance among regulators, enterprises, and technology. It validates the model's value through the Shanghai Lingang pilot programme, providing theoretical guidance and practical references for advancing cross-border governance of biopharmaceutical data.

2. Theoretical Foundation and Core Conceptual Definitions

2.1. Requirements of the 'Dual Circulation' Strategy for Biomedical Data Governance

Under the new development pattern, biomedical data governance must establish a development model where domestic and international dual circulation mutually promote and advance each other. The domestic circulation dimension is based on data sovereignty theory, emphasising the establishment of a localised data resource system, strengthening the construction of data element markets, improving biomedical data property rights systems, and ensuring data security and public health safety. The Shanghai Lingang Free Trade Zone is piloting new mechanisms for cross-border data flow, leveraging institutional innovation to attract global R&D resources and maximise data value [1]. The policy support system includes measures such as data classification and grading management, security assessment mechanisms, and data transaction rules, forming a institutional framework for cross-border data flow. The Free Trade Zone plays a hub role in cross-border biomedical data governance, establishing a platform for the market-based allocation of data elements to facilitate efficient data resource flow and value conversion, and driving the digital transformation and upgrading of the biomedical industry.

2.2. The Special Characteristics of Biomedical Data

Biomedical data is highly sensitive and complex, involving multi-dimensional data types such as clinical trial data, gene sequence information, and patient health records. This data has significant scientific research value and plays a key role in promoting new drug development and disease diagnosis and treatment, but it also faces ethical risks and privacy protection challenges. Domestic laws and regulations such as the Personal Information Protection Law and the Data Security Law impose strict requirements on local storage of data and security assessments for cross-border data transfers [2]. Meanwhile, international regulatory frameworks such as the EU's General Data Protection Regulation (GDPR) and the US's Health Insurance Portability and Accountability Act (HIPAA) establish adequacy standards for cross-border data transfers. Under the dual pressures of data sovereignty and globalisation, biomedical data governance must balance security protection with value utilisation, establishing a governance framework that aligns with international rules while incorporating Chinese characteristics, to achieve optimal allocation of data resources and compliant, orderly data flow.

2.3. Analysis of the Concept of 'Three-Dimensional Governance'

The 'Three-Dimensional Governance' model is based on multi-level governance theory and data governance theory, establishing a collaborative mechanism across three dimensions: regulatory governance, corporate self-governance, and technological governance. This model innovatively diversifies governance entities and introduces technology-enabled measures to form a systematic solution.

The three dimensions mutually support each other and maintain dynamic balance, forming a closed-loop governance system that drives the market-based allocation of data elements and industrial innovation and development [3]. As shown in Table 1, regulatory governance focuses on policy coordination and risk management, corporate self-governance focuses on compliance cost reduction and R&D efficiency, and technical governance emphasises the balance between data security and circulation efficiency.

Table 1. Analysis of the Dimensions of the 'Three-Dimensional Governance' Model

Governance Dimension	Core Objective	Key Contradiction
Regulatory Governance	Policy Synergy and Risk Control	Sovereign Regulation vs. Global Data Flow Demand
Corporate Autonomy	Compliance Cost Reduction and R&D Efficiency	Compliance Cost vs. Data Value Conversion
Technical Governance	Data Security and Circulation Efficiency	Encryption Protection vs. Research Collaboration Demand

This innovative governance framework breaks through the limitations of traditional single-mode regulation, organically combining regulatory constraints, market mechanisms, and technical means to provide a systematic solution for cross-border governance of biomedical data [4]. The various dimensions coordinate with each other and complement each other's strengths, effectively responding to the challenges of data governance in the context of globalisation and achieving a win-win situation for data security and industrial development.

3. Core Architecture Design of the Three-Tier Governance Model

3.1. Regulatory Governance Layer

The regulatory governance layer establishes a data classification and categorisation management system, implementing differentiated regulation based on the sensitivity of the data. Highly sensitive data such as genetic data is subject to strict outbound controls, with a unified storage and management system established domestically through the construction of a biomedical data centre. General data such as anonymised clinical statistics adopts a 'negative list' model, allowing cross-border flow within the scope of the free trade zone's white list. The Shanghai Lingang Free Trade Zone serves as a hub for cross-border data flow, establishing a 'domestic assessment-free trade zone transmission-overseas reception' full-chain linkage mechanism and setting up a fast-track for security assessments. This mechanism innovatively introduces supporting measures such as hierarchical authorization, risk early warning, and emergency response, enhancing regulatory efficiency [5]. The well-designed system and flexible regulatory mechanisms effectively balance data security and flow efficiency, providing institutional safeguards for cross-border governance of biomedical data.

3.2. Enterprise Self-Governance Layer

The enterprise self-governance layer emphasises the construction of a standardised compliance framework and the improvement of end-to-end management of cross-border data transmission. A standardised contract system clearly defines data transmission security responsibilities, including core elements such as confidentiality clauses and breach of contract liabilities, to standardise enterprise compliance behaviour. Intelligent compliance tools utilise artificial intelligence technology to automate data classification and risk assessment, with an error rate controlled within 5%, significantly reducing the cost of manual review. Enterprises establish internal control systems such as data asset inventories, risk assessment mechanisms, and emergency response plans to enhance compliance management efficiency [6]. The design of the compliance framework prioritises practicality and operability, helping enterprises improve R&D efficiency while ensuring compliance, thereby balancing compliance costs with data value.

3.3. Technical Governance Layer

The technical governance layer utilises emerging technologies such as federated learning, blockchain evidence storage, and TEE (Trusted Execution Environment) to build a data security protection system. The core technology combination shown in Table 2 provides comprehensive protection for the cross-border flow of biomedical data. Pilot enterprises in Shanghai Lingang have utilised blockchain-based evidence systems to reduce the cross-border data approval cycle to 14 days, fully demonstrating the enabling effects of technology [7]. Technological innovation reduces policy friction, enhances data circulation efficiency, provides a robust technological foundation for cross-border compliance of biomedical data, and drives the efficient flow and value creation of data elements.

Table 2. Core Technology Combination of the Technical Governance Layer

Technology	Function	Application Scenario
Federated Learning	Data available but invisible	Cross-national multi-center clinical trial collaboration
Blockchain-based Storage and Verification	Traceable transmission process	Customs/ Pharmaceutical Regulatory Agency audit and evidence
Trusted Execution Environment (TEE)	Ensures encrypted data processing	IP protection in genetic data analysis

This technology system achieves a dynamic balance between data security and efficiency, providing reliable protection for cross-border governance of biomedical data. The complementary and synergistic advantages of each technology effectively address security risks associated with cross-border data flows, supporting the digital transformation and innovative development of the biomedical industry. The continuous deepening of new technology applications is driving innovation in cross-border data governance models and laying the foundation for the construction of a secure and efficient data circulation ecosystem.

4. Implementation Pathways and Challenges

4.1. Pathways for Aligning Domestic and International Rules

The construction of a biomedical data governance rule

system requires strengthening international alignment and innovative integration. China actively adopts WHO clinical data standards and GDPR anonymisation norms to promote mutual recognition and interoperability between domestic standards and international rules. In the formulation of international rules, Chinese think tanks have played an active role. Commissioner Hao Haiping proposed the initiative of 'high-end think tanks leading international rules,' promoting China's participation in the formulation of international conventions on biomedical data. Rule alignment efforts focus on summarising domestic practical experience, combining China's unique regulatory model to explore institutional innovations with international influence [8]. Rule integration and innovation promote the global flow of data elements, helping China's biomedical industry deeply integrate into the global innovation network and achieve dual enhancements in rule-setting influence and industrial competitiveness.

4.2. Four-step Method for Enterprise Implementation

Enterprises implement cross-border governance of biomedical data using a systematic four-step method. In the data asset mapping stage, data categories and cross-border requirements are accurately identified in different scenarios, such as R&D collaboration, marketing authorisation applications, and production and logistics. In the compliance tool embedding stage, artificial intelligence classification engines and privacy computing platforms are deployed to improve compliance efficiency. contract template customisation designs transmission protocols tailored to specific scenarios, with R&D outsourcing emphasising intellectual property protection and regulatory submissions highlighting compliance requirements; and a dynamic monitoring and improvement mechanism conducts quarterly cross-border data flow audits to continuously optimise classification strategies [9]. This implementation methodology helps enterprises establish a systematic compliance management system, reduce compliance costs, and enhance the efficiency of data value conversion.

4.3. Risk Response Strategies

Cross-border governance of biomedical data faces multidimensional risk challenges, necessitating the establishment of a comprehensive risk prevention and control system. Geopolitical risk management utilises a 'dual backup' data centre architecture, synchronously deploying data storage facilities within the country and in neutral countries such as Singapore and Switzerland to ensure data security and controllability. Technical and ethical risk prevention involves establishing an independent ethics committee to formulate review standards and procedures for the use of sensitive data. Legal conflict risk resolution relies on arbitration mechanisms within free trade zones, such as the Lingang New Area International Arbitration Centre, to establish a cross-border compliance dispute resolution platform[10]. A multi-layered risk response strategy forms a systematic protective network to ensure the stable operation of the cross-border governance model for biomedical data and promote the industry's sustained healthy development.

5. Application Scenario Validation

As a pilot area for cross-border flow of biomedical data, the Shanghai Lingang New Area is actively exploring the practical application of the 'tripartite governance' model. Several companies in the pilot area have validated the effectiveness of the model in different application scenarios and achieved significant results. As shown in Table 3, in multinational pharmaceutical companies' multi-centre clinical trials, federated learning technology enables secure analysis of patient data, while blockchain-based evidence ensures traceability throughout the transmission process, helping companies reduce compliance costs by 30% and shorten R&D cycles by 25%. Overseas gene therapy projects utilise Trusted Execution Environments (TEEs) to process core gene data, combined with the special regulatory policies of the free trade zone, effectively reducing the risk of technology leakage by 90%. AI-assisted new drug R&D projects rely on the Lingang Data Centre for unified hosting of training data, with overseas institutions remotely accessing analysis results, improving data utilisation efficiency by 50%. Pilot practices have fully validated the significant effectiveness of the 'tripartite governance' model in reducing compliance costs, improving innovation efficiency, and ensuring data security, providing replicable and scalable experience for cross-border governance of biomedical data nationwide.

Table 3. Application Scenario Analysis of the 'Tripartite Governance' Model

Application Case	Solution based on the Three-Element Model	Outcome
Multi-center clinical trials by multinational pharmaceutical companies	Federated learning for patient data analysis, blockchain-based storage and verification for transmission records	30% reduction in compliance costs, 25% shorter R&D cycle
Gene therapy technology export	Processing core genetic data in a TEE environment, filing with the free trade zone before export	90% decrease in technology leakage risk
AI-assisted new drug development	Hosting training data in the Lingang Data Center, remote result retrieval by overseas institutions	50% increase in data utilization efficiency

6. Research Value and Policy Recommendations

6.1. Theoretical Innovation Value

This study innovatively constructs a 'regulation-enterprise-technology' triadic dynamic equilibrium model, breaking through the limitations of traditional data governance theory and achieving a theoretical breakthrough. This model systematically addresses the contradiction between data sovereignty security and global data flow, transcending the binary oppositional mindset and proposing a new paradigm of multi-dimensional collaborative governance. The triadic governance model provides practical, actionable system solutions at the operational level and enriches the theoretical framework of data governance at the theoretical level, enhancing the theoretical framework of the data element market. The research findings offer theoretical guidance for cross-border governance of biomedical data, promote interdisciplinary innovation, and contribute to the development of a data governance theoretical framework with Chinese characteristics.

6.2. Policy Recommendations

At the policy level, it is recommended to advance the establishment of cross-border governance systems for biomedical data in phases. In the short term, the focus should be on expanding the scope of pilot zones in free trade areas, incorporating regions with established industrial foundations such as Hainan Boao into the pilot programme, granting biomedical data the status of 'customs special supervision,' and exploring institutional innovations. In the long term, a 'Regulation on the Management of Cross-border Flow of Biomedical Data' should be formulated to clarify the legal status of the tripartite governance model and establish a systematic institutional framework. Policy design should prioritise operability and foresight, stimulating innovation while ensuring data security. Optimised institutional supply will promote the efficient allocation of data elements and unlock the innovative potential of the biomedical industry.

6.3. Industrial Value

The three-dimensional governance model creates significant economic value at the industrial level. At the enterprise level, standardised compliance toolkits reduce overseas expansion costs, with an estimated 15-25% reduction in cross-border compliance expenses, thereby enhancing international competitiveness. At the national level, a comprehensive data compliance system attracts global investment in biomedical research and development, strengthens industrial innovation capabilities, and helps China become a global centre for biomedical innovation. Industrial value is reflected in multiple aspects, including reducing corporate compliance costs, enhancing innovation efficiency, and strengthening international competitiveness, driving the high-quality development of China's biopharmaceutical industry and achieving a win-win outcome for both economic and social benefits.

7. Conclusion

This study constructs a tripartite governance model for the cross-border flow of biomedical data, providing systematic solutions across three dimensions: regulatory governance, corporate self-regulation, and technological governance. The research breaks away from traditional binary oppositional thinking and innovatively proposes a dynamic balance governance paradigm. The pilot practice in Shanghai Lingang has validated the model's significant effectiveness, providing valuable experience for national-level implementation. Future research will continue to track the application of new technologies and institutional innovations, refine the tripartite governance theoretical framework, promote the development of the biomedical data element market, and support the innovative growth of China's biomedical industry.

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