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RESEARCH ARTICLE

Adoption and Optimization of Blockchain Technology in the Regulation of Class II Vaccines

YI WAN[1], (Member, IEEE), AND HAILONG HUANG[2]

[1]Department of Computer Science and Engineering, and Institute of Artificial Intelligence, Shaoxing University, Shaoxing 312000, China
[2]College of Computer Science and Artificial Intelligence, Wenzhou University, Wenzhou 325000, China

Corresponding author: Hailong Huang (67337833@qq.com)

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ABSTRACT At present, there are many problems and challenges in the management of Class II vaccines, for example, regulatory regulations, the regulatory system and the quality supervision for second-class vaccines are not yet complete. Blockchain technology will play an increasingly important role in the safety supervision of Class II vaccines. Firstly, we have explored the vulnerabilities and causes of second-class vaccine safety supervision in this paper. Then we have studied the impacts of blockchain technology on second-class vaccine supervision and the potential drivers of adoption by reliability theory and fuzzy dynamic decision-making method. Finally, based on the study results, a modular and sustainable supply chain integration optimization design has be proposed for the second-class vaccine safety supervision system, the supervision system based on optimization design has deep traceability and disintermediation to track and monitor the quality of each stage of the entire supply chain, and has characteristics such as intelligence, scalability, and compatibility. This study provides theoretical basis and technical support for embedding blockchain ICT into the multi-agent collaborative supervision of class II vaccines.

INDEX TERMS Class-II vaccine traceability system, vaccine quality, blockchain technology, reliability theory, fuzzy dynamic decision-making, multi-collaborative supervision, supply chains.

I. INTRODUCTION

Class II vaccines refer to vaccines that are not included in the national immunization plan and are voluntarily administered by citizens at their own expense. From the ‘‘Shanxi Vaccine Event’’ to the ‘‘Shandong Vaccine Event’’ to the ‘‘Changsheng Vaccine Event’’, the frequent occurrence of Class II vaccine safety issues has caused extreme social panic and high attention from the government. The current situation and problems of Class II vaccine management are as follow:

(1) Regulatory regulations for second-class vaccines are not yet complete: The promulgation of the ‘‘Regulations on the Administration of Vaccine Circulation and Preventive Vaccination’’ provides legal protection for vaccine management, but its management of Class II vaccines is too careless. For example, the legal system specifications for the distribution channels, cold chain storage, transportation and other circulation links of second-class vaccines, as well as the full traceability system, are still unclear, and there are still many details that need to be improved. (2) The regulatory system for second-class vaccines is not yet complete: At present, administrative agencies have not fully grasped the dynamic information of vaccine production, circulation, vaccination, and often carry out passive supervision and disposal only after events occur and have a certain social impact, resulting in a passive regulatory behavior. Moreover, the number of provisions in the regulations on the circulation and supervision of vaccines that hold administrative entities legally responsible is limited, and the provisions are insufficient

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enforceability and deterrence against illegal behavior. (3) The quality supervision of second-class vaccines is not yet complete: the procurement circulation channels are chaotic, Class II vaccines exhibit a complex trend of multiple supply channels due to price factors and profit seeking behavior. Moreover, the cold chain system has poor responsiveness and adaptability to changes in market demand. The cold chain drug logistics system lags far behind market development in terms of quantity and service capacity, and cannot meet the market's demand for cold chain drugs. Insufficient support for the cold chain system can easily lead to difficulties in ensuring the circulation quality of second-class vaccines.

In order to solve many loopholes in the regulation of Class II vaccines, the State Council of China promulgated and implemented the ''Management regulations on vaccine circulation and vaccination (2016 Revision)'' in 2016, which incorporated all class II vaccines and class I vaccines into the centralized procurement on provincial public resource trading platforms [1]. However, the loopholes such as ''fragmentation'' of vaccine segmented regulation and ''information centralization'' in the production and circulation process have not been effectively eliminated, class II vaccine safety events still occur, such as the ''Jiangsu Jinhu Vaccine Event'' in 2019. Therefore, in order to fundamentally solve the vaccine safety problem, they are necessary to promote technological innovation and push forward behavioral norms, and improve the regulatory system for class II vaccines from the perspective of multi-agent collaboration [2], [3].

As an emerging internet technology, the blockchain with the features of distributed architecture, tamper-proof, high transparency, and traceability is able to eliminate the ''moral hazard'' and ''island'' phenomenon of information exchange or transfer, which has a natural coupling point with vaccine regulation in aspects such as multi-agent collaboration, information sharing, and data security. Literatures have shown that blockchain in the pharmaceutical and vaccine industries can improve process transparency and efficiency, enhance credibility, remove unnecessary intermediaries and distributors from supply chains, it can also enhance the trust of vaccination clinics and vaccination residents in the class II vaccine vaccination [4], and makes residents attach importance and actively participate in the vaccination of class II vaccines. Despite the potential role of blockchain technology integration (ICT) in class II vaccine supply chain, as an emerging technology, the general public lack the necessary knowledge and skills to develop and use blockchain technology (knowledge gap), moreover, the lack of attention and awareness of this technology also makes its large-scale adoption still a long way to go (awareness gap). Determining factors affecting participants' recognition, willingness, decisions, and adoption preferences for blockchain technology applications, as well as relative influence degree of each factor (driving degree) are of great significance for the application of blockchain integration technology (ICT) in the supervision of class II vaccine supply chain. At the same time, the evaluation of these important influencing factors provides a theoretical and practical basis for the optimal design and operation mechanism of the blockchain architecture of class II vaccine supply chain management [5].

In this work, we have explored the vulnerabilities and causes of second-class vaccine safety supervision. Then we have studied the impacts of blockchain technology on second-class vaccine supervision and the potential drivers of adoption by reliability theory and fuzzy dynamic decision-making method. Finally, based on the study results, a modular and sustainable supply chain integration optimization design has be proposed for the second-class vaccine safety supervision system, the supervision system based on optimization design has deep traceability and disintermediation to track and monitor the quality of each stage of the entire supply chain, and has characteristics such as intelligence, scalability, and compatibility. This study provides theoretical basis and technical support for embedding blockchain ICT into the multi-agent collaborative supervision of class II vaccines.

The organization of the paper is as follows: Section II presents a literature review; Section III presents the blockchain technology adoption and driving factors for collaborative supervision; Section IV elucidates optimal design for collaborative supervision of Class II vaccine supply chain; Section V presents discussion and conclusions.

II. LITERATURE REVIEW

A. THE ADOPTION OF BLOCKCHAIN TECHNOLOGY AND ITS DETERMINANTS

In information system research, the Technology Acceptance Model (TAM) is widely used, which is a model proposed by Davis when he uses rational behavior theory to study users' acceptance of information systems. The Technology Acceptance Model proposes two main determinants to affect users' willingness to adopt technology: (1) Perceived usefulness: it reflects the extent to which a person believes to improve their work performance by using a specific system; (2) Perceived ease of use: it reflects the degree to which a person believes it is easy to use a specific system [6]. Kamble et al. used the TAM model to analyze the adoption of blockchain technology and the tendency of supply chain managers to accept and use blockchain technology [7]. In addition, the UTAUT has been considered in the research on the adoption of blockchain technology, and UTAUT has four key structures, they are Performance Expectancy (PE),Effort Expectancy (EE), Social Impact (SI) and Facilitating Conditions (FC). Despite some achievements in research on technology adoption, TAM or UTAUT models have a low level of attention to adoption structures, which constrains other potential drivers or determinants of advanced technology adoption [8]. In addition, the TAM and UTAUT models only focus on user perceptions, without considering the differences in technology itself, so they have little inspiration for a robust information system design.

In pharmaceutical supply chains, Kamble et al. used interpretative structural modeling (ISM) and Decision-Making and Trial Evaluation Lab (DEMATEL) to evaluate and analyze the interrelationship between blockchain attributes in pharmaceutical supply chains. However, while considering price in the model, determining the level of each attribute and the optimal supply chain configuration is crucial to meeting user needs. In addition, the emerging ICT (such as the Internet of Things, RFID, sensor devices, cloud computing, and machine learning) should be integrated with blockchain to enhance and optimize the application of blockchain technology. At the same time, when designing information systems, decision makers need to fully consider the effectiveness of the system architecture, and also consider the impact of the key drivers and their level of technology adoption on sustainable supply chains [9].

B. BLOCKCHAIN INTEGRATED ICT ARCHITECTURE

Currently, the adoption rate of blockchain technology is very low, and some scholars have carried out relevant researches on the information system architecture of the pharmaceutical supply chain. Qi et al. explored the effectiveness and feasibility of a hybrid chain architecture platform for vaccine anti-counterfeiting tracking, inserting public and private chains into the design of the anti-counterfeiting tracking platform to achieve partial information privacy protection, enabling vaccine suppliers, the National Pharmaceutical Product Administration (NMPA), vaccine buyers, and vaccinators to access integrity information [10].

Due to the centralized trust mechanism, the selfish behavior of its members, the asymmetry of information in the production process, and testing costs have adverse effects on quality management, Eetansh Atrey et al. used blockchain-based records, QR (Quick Response) codes for vaccine safety, and BLE beacon networks to track and update vaccine information in real time, and built a complete vaccine supply chain system to solve these problems [11].

Humberto Jorge et al. proposed a unique identity and fog computing method based on blockchain with Ethereum blockchain and broken chain storage integration, the method provides solutions for issues such as global vaccination activities, privacy, and identification data sharing within hospitals, clinics, and research institutions [12], [13], [14]. In order to comprehensively track products on the blockchain, R Mythili et al. proposed an Ethereum smart contract with a multi-node collaborative consensus mechanism based on a two-layer blockchain structure to achieve vaccine supervision and detection, the smart contract ensures confidentiality and improves the privacy of chain participants [15]. The blockchain technology architecture has improved product tracking. For example, a ''vaccine blockchain'' system that integrates blockchain with collaborative consensus mechanisms and vaccine data cutting mechanisms has achieved space-time efficiency supervision of vaccine production [16], [17].

Considering the reality that vaccine manufacturers and vaccination units are implementing blockchain construction, R.H. Liu et al. constructed a VSC game model consisting of a vaccine manufacturer and a vaccination unit, analyzed the conditions for applying blockchain technology in the VSC, and discussed who undertakes the blockchain construction between the vaccine manufacturer and the vaccination unit, and further study the coordination of blockchain-based vaccine supply chain [18]. Ensuring integrity and confidentiality of information is critical, and reliable data is essential to both the government and its citizens. S. Shahbaz et al. proposed a service security architecture based on authentication and authorization for constrained environments during collaborative tasks for Software Defined Networking (SDN) and smart contract-enabled municipal smart cities [19]. To address unlimited scalability and unrestricted adaptivity, A. Buldas et al. delivered a sharded blockchain technology with unlimited scalability, and contributed the architecture of a universal tokenization platform that allows for universal asset tokenization, transfer and exchange as a global medium of exchange, called Alphabill platform [20]. Vaccination offers health, economic, and social benefits, however, three major issues—vaccine quality, demand forecasting, and trust among stakeholders-persist in the vaccine supply chain (VSC), leading to inefficiencies. H. Hu et al. established an intelligent VSC management system that provides decision support for VSC management during the COVID-19 pandemic. The system combines blockchain, internet of things (IoT), and machine learning that effectively address the three issues in the VSC [21]. To raise reliability of supply chains, Rajnish Kler, Thanh-Tuan Dang, Chia-Nan Wang et al. implemented the IoT based system for the traceability and demand-supply monitoring, and optimized the supply network to reduce the carbon emission from the transportation. This will result in significant cost and resource savings, as well as reduced environmental consequences and a long-term supply chain [22], [23], [24].

III. PROPOSED METHOD

According to the literature review, there are still three key issues to be addressed in blockchain technology for pharmaceutical and vaccine regulation: (1) What are the factors driving the adoption of blockchain technology by participants in the second class vaccine supply chain? How to embed these factors into the information system to make the architecture design of the system platform more reasonable and optimal to achieve higher availability and utility values; (2) How does the system architecture make the secondary vaccine supply chain compatible and enhance value creation support for participants? (3) How does the architecture ensure the safety and quality of class II vaccines and How to affect the sustainable operation of the supply chain for class II vaccines?

For further research, we conducted a mixed online and offline survey and questionnaire (as is shown in Figure 1 for the research process). A total of 420 questionnaires were distributed in this survey, with 380 valid questionnaires. The respondents were second-class vaccine production enter-

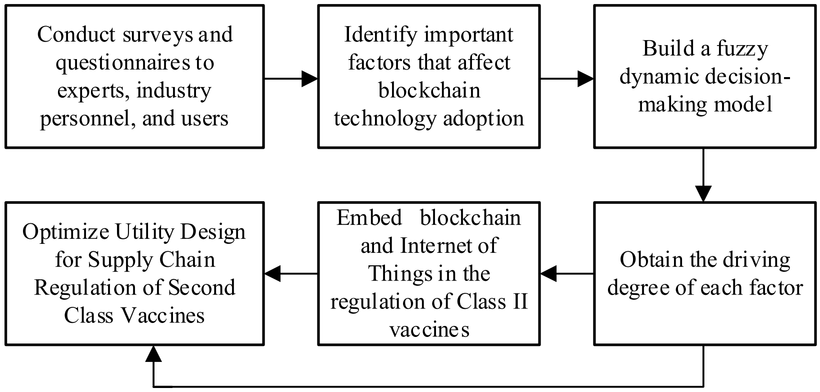

FIGURE 1. Technical roadmap of this study.

prises(manufacturers), distributors, disease control centers, and vaccination users. The second-class vaccine production enterprises accounted for 30% of the respondents, and the respondents were mainly managers, technicians, and quality testing staffs of the enterprises. Distributors accounted for 20% of the respondents, the respondents are mainly vaccine sales personnel with expertise in vaccine management. The Centers for Disease Control and Prevention accounted for 30% of the respondents, with the majority being managers and medical (technical) professionals. Vaccination users account for 20% of the surveyed respondents, mainly government staff, workers, teachers, students, etc. with a university or above education level. The contents of the survey include selecting important factors that affect the adoption of blockchain technology by Class II vaccine supply chain participants, the weight level of supply chain reliability attributes, and the degree of subordination of chain structure factors to reliability attributes to obtain what factors affect the preferences and willingness of participants in the secondary vaccine supply chain to adopt blockchain and emerging information technology, and the degree of impact (driving degree) of these factors, that is, the importance of these factors in the secondary vaccine supply chain architecture. For this, we use orthogonal design to generate a structured questionnaire with 20 testing factors, statistical analysis of the test results shows that traceability, disintermediation (disintermediation), compliance, credibility, co-control, and price are the main chain configuration factors that affect the acceptance, willingness decisions, and preferences of participants in the second class vaccine supply chain for blockchain technology adoption (as is shown in Figure 2).

Then, based on the reliability theory, a fuzzy dynamic decision-making method is used to determine the driving degrees of various factors on the blockchain of second-class vaccine supervision, and an optimal utility collaborative supervision system embedding blockchain for second-class vaccines is built.

Fuzzy comprehensive dynamic decision-making method is a decision-making method based on fuzzy mathematics theory. Compared to conventional methods, it can handle fuzzy and uncertain information, combine expert knowledge with mathematical models, improve the accuracy and efficiency of decision-making, and is widely used in industrial control.

(1) Determine important structural factor sets between the supply chain and blockchain adoption. Based on statistical analysis, the chain structure factor set is taken as: C=(C1, C2, C3, C4, C5, C6)=(traceability, disintermediation, credibility, co-control, compliance, price).

(2) Determine the set of reliability attributes that affect the class II vaccine supply chain. The purpose of embedding blockchain into the collaborative supervision of second-class vaccines is to improve the reliability of the second-class vaccine supply chain. The reliability attributes that affect the class II vaccine supply chain are: safety, transparency, shareability, and collaboration. Therefore, the reliability attribute set is taken as: B=(B1, B2, B3, B4)=(safety, transparency, shareability, and collaboration).

(3) Determine the weight sets of reliability attributes for the second class vaccine supply chain. The weights represent the proportion of each attribute in the reliability level of the second class vaccine supply chain system, and they reflect the role and importance of each attribute in the comprehensive supply chain reliability decision-making, and directly affect the results of fuzzy dynamic decision-making. The weight values for this study are determined based on a questionnaire. Table 1 shows some respondents giving weight levels (very low, low, medium, high, and very high) by grade way for the four reliability attributes. The weight values for each level are shown in Table 2.

The weight values given by all respondents are averaged by (1):

$$W_i = \frac{\sum_{j=1}^{n} W_{ij}}{n} \tag{1}$$

where, i=1,2,3,4. W_i is the grade value of the reliability attribute weight, W_{ij} is the rating value of the reliability attribute for the first respondent, and n is the total number

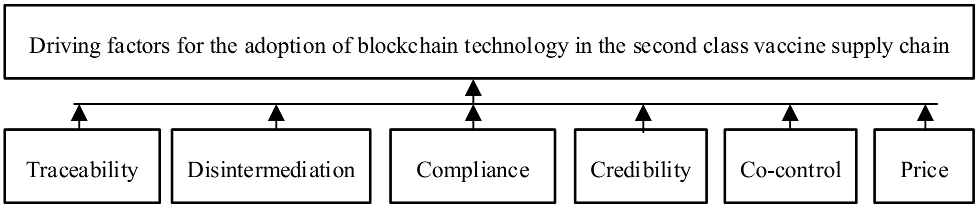

FIGURE 2. Important factors affecting the adoption of blockchain technology by participants in the second class vaccine supply chain.

TABLE 1. Weights of the reliability attributes of supply chain given by respondents.

NO.1	Security	Transparency	Shareability	Collaboration
Weight Levels	Very high	High	Low	Medium

NO.2	Security	Transparency	Shareability	Collaboration
Weight Levels	Very high	Medium	Low	High

NO.3	Security	Transparency	Shareability	Collaboration
Weight Levels	Very high	High	Low	Medium

NO.4	Security	Transparency	Shareability	Collaboration
Weight Levels	High	Very high	Medium	Low

TABLE 2. Weight values for each level.

Weight Levels	Very low	Low	Medium	High	Very high
Weight Values	0.1	0.3	0.5	0.7	1.0

of respondents. Then the grade values are calculated by a normalization:

$$WN_i = \frac{\mathrm{W_i}}{\sum_{i=1}^{4} \mathrm{Wi}} (i = 1, 2, 3, 4) \tag{2}$$

The weight set is obtained as follows:

$$WN = (WN_1, WN_2, WN_3, WN_4) = (0.37, 0.29, 0.20, 0.14) \tag{3}$$

where WN_i is corresponding weight of the i-th reliability attribute B_i, $(i = 1, 2, 3, 4)$, $\sum_{i=1}^{4} WN_i = 1$.

(4) Determine the degree of membership of chain structure factors to each supply chain reliability attribute. The closer the degree of membership M(C) approaches 1, the higher the degree to which C belongs to B. The closer M (C) approaches 0, the lower the degree to which C belongs to B. In order to more accurately determine the membership degree of various structural factors of blockchain adoption for security, transparency, sharing, and collaboration, a questionnaire survey is still used to obtain grade in a five grade way (very low, low, medium, high, and very high). The membership values of each level are shown in Table 3. The degree of membership of chain structural factors for each supply chain reliability attribute is shown in Table 4.

TABLE 3. Values of membership degrees for each level.

Grades of Membership	Very low	Low	Medium	High	Very high
Membership values	0.1	0.3	0.5	0.7	1.0

The average value is calculated and normalized based on the results of the questionnaire.

$$M_{ij} = \frac{\sum_{k=1}^{n} \mathrm{M_{ijk}}}{\mathrm{n}} \quad (i = 1, 2, 3, 4, 5, 6; j = 1, 2, 3, 4; k = 1, 2, \ldots, n) \tag{4}$$

where M_{ij} represents the grade value of the membership degree of the i-th factor of the j-th reliability attribute of the second class vaccine supply chain, $\mathrm{M_{ijk}}$ is the grade value of the membership degree of the i-th factor of the j-th reliability attribute that the k-th respondent is given. Thus, a fuzzy dynamic mapping of the supply chain structural factor set corresponding to the reliability attribute set is obtained:

$$\mathrm{c_i}| \rightarrow [\mathrm{a_{i1}\ a_{i2}\ a_{i3}\ a_{i4}\ a_{i5}\ a_{i6}}] \tag{5}$$

The fuzzy relationship matrix between B and C is built:

$$A = \begin{bmatrix} a11 & a21 & a31 & a41 & a51 & a61 \\ a12 & a22 & a32 & a42 & a52 & a62 \\ a13 & a23 & a33 & a43 & a53 & a63 \\ a14 & a24 & a34 & a44 & a54 & a64 \end{bmatrix}$$

From equations (4) and tables (3) - (4), A can be obtained:

$$A = \begin{bmatrix} 0.33 & 0.31 & 0.25 & 0.26 & 0.31 & 0.06 \\ 0.33 & 0.31 & 0.25 & 0.11 & 0.31 & 0.44 \\ 0.17 & 0.22 & 0.25 & 0.26 & 0.19 & 0.19 \\ 0.17 & 0.16 & 0.25 & 0.37 & 0.19 & 0.31 \end{bmatrix} \tag{6}$$

5) According to the fuzzy dynamic theory, fuzzy dynamic comprehensive evaluation and decision-making are made: A fuzzy dynamic comprehensive evaluation and analysis model

TABLE 4. Membership grade of chain structure factors to reliability attributes.

Important factors	Reliability attributes of the second-class vaccine supply chain			
Traceability	Security	Transparency	Shareability	Collaboration
Membership Degrees	Very high	Very high	Medium	Medium

Important factors	Reliability attributes of the second-class vaccine supply chain			
disintermediatio n	Securit y	Transparenc y	Shareabilit y	Collaboratio n
Membership Degrees	Very high	Very high	High	Medium

Important factors	Reliability attributes of the second-class vaccine supply chain			
credibility	Security	Transparency	Shareability	Collaboration
Membership Degrees	Medium	Medium	Medium	Medium

Important factors	Reliability attributes of the second-class vaccine supply chain			
co-control	Security	Transparency	Shareability	Collaboration
Membership Degrees	High	Low	High	Very high

Important factors	Reliability attributes of the second-class vaccine supply chain			
compliance	Security	Transparency	Shareability	Collaboration
Membership Degrees	Medium	Medium	Low	Low

Important factors	Reliability attributes of the second-class vaccine supply chain			
Price	Security	Transparency	Shareability	Collaboration
Membership Degrees	Low	High	Low	Medium

is constituted by a three-dimensional body (B, C, A), and a mapping fuzzy set H is obtained:

$$H = WN^{\circ}A = (WN1, WN2, WN3, WN4)^{\circ} \begin{vmatrix} a11 & a21 & a31 & a41 & a51 & a61 \\ a12 & a22 & a32 & a42 & a52 & a62 \\ a13 & a23 & a33 & a43 & a53 & a63 \\ a14 & a24 & a34 & a44 & a54 & a64 \end{vmatrix} = (h1, h2, h3, h4, h5, h6) \tag{7}$$

where $\circ$ is a fuzzy operator model M, including four calculation methods [17], they are follows as:

$$M(\wedge, \vee) = {}_{i=1}^{m}\vee(a_i \vee r_{ij}), M(\cdot, \vee) = {}_{i=1}^{m}\vee(a_i \cdot r_{ij})$$
$$M(\cdot, \oplus) = \sum\nolimits_{i=1}^{m} (a_i \cdot r_{ij}), M(\wedge, \oplus) = \sum\nolimits_{i=1}^{m} (a_i \wedge r_{ij})$$

In order to make the comprehensive decision-making results reasonable and reliable, we have adopted the fuzzy operator model: $M(\cdot, \oplus) = \sum_{i=1}^{m} (a_i \cdot r_{ij})$, A fuzzy dynamic decision is made by substituting data from (3) and (6) into (7).

$$H = WN \times A$$
$$H = (0.370.290.200.14) \times \begin{bmatrix} 0.33 & 0.31 & 0.25 & 0.26 & 0.31 & 0.06 \\ 0.33 & 0.31 & 0.25 & 0.11 & 0.31 & 0.44 \\ 0.17 & 0.22 & 0.25 & 0.26 & 0.19 & 0.19 \\ 0.17 & 0.16 & 0.25 & 0.37 & 0.19 & 0.31 \end{bmatrix} = (0.276, 0.271, 0.250, 0.232, 0.269, 0.231) \tag{8}$$

The decision result H reflects the relative level to which various structural factors affect the reliability of the supply chain by considering comprehensively each reliability attribute of the second-class vaccine supply chain, we call it the driving degree, and the decision result is shown in Figure 3.

Equation (8) and Figure 3 indicate that participants in the second type vaccine supply chain believe that traceability is the most important factor, with a driving degree of 0.276, followed by disintermediation (driving degree of 0.271), compliance (driving degree of 0.269), and credibility (driving degree of 0.250). The driving degree of co-control and price are 0.232 and 0.231, respectively. Figure 4 shows the impact of changes in the driving degree of structural factors adopted in the blockchain of the second class vaccine supply chain on system reliability. Based on the above findings, we need to fully reflect the characteristics of traceability, disintermediation, and compliance to design optimal blockchain architecture.

Traceability can be enhanced by integrating blockchain and other existing advanced technologies, such as the Internet of Things, RFID, image recognition, and other information technologies. Integrated blockchain technology has become a risk management tool to ensure the safety, quality, and chain integrity of drugs and second-class vaccines [25]; Disintermediation can be achieved through smart contracts running on peer-to-peer networks, disintermediation reduces transaction costs, ensures transactions, auditability, and data sources [26]; Credibility is a social and technological factor that can be enhanced or ensured through the invariance and synergy of transactions on blockchain distributed architectures [27]. Credibility and blockchain consensus algorithms are inseparable and can be achieved through intelligent identification, improving blockchain performance, and transaction reliability.

IV. RESULTS AND DISCUSSION

Based on comprehensive decision-making and analysis results, a management information system architecture for collaborative supervision of the second class vaccine supply chain based on blockchain and advanced technology integration is proposed. We integrated the important driving factors (traceability, disintermediation, and compliance) of

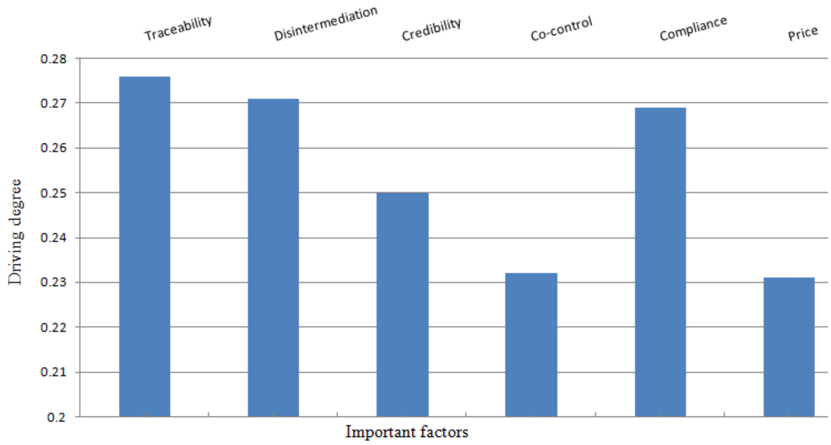

FIGURE 3. Driving degrees of structure Factors of the Second Class Vaccine Supply Chain.

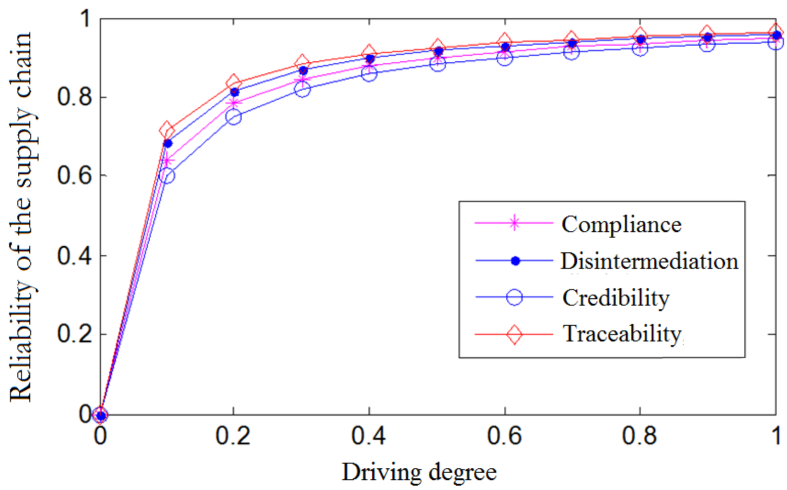

FIGURE 4. The impact of changes in driving factors on system reliability.

participants in the second class vaccine supply chain network into the optimization design of blockchain integration technology (as shown in Figures 5- 6).

In order to make the second-class vaccine supply chain system compatible and scalable, and enhance the value creation support for participants, we have constructed a modular and object-oriented reusable information system to help decision-makers configure and customize the supply chain based on their needs and other constraints, for the specific second-class vaccines such as rabies vaccines, influenza vaccines, hepatitis A vaccines, and haemophilus influenzae vaccines, live attenuated rubella vaccines, pneumococcal polysaccharide vaccines, and chickenpox vaccines. In order for production enterprises to comply with vaccine safety standards, it is not only necessary to track the antigen components and pathogenic microorganisms of the finished products, but also the quantity of bacteria and viruses in the vaccine, as well as vaccine adjuvants, preservatives, stabilizers, and emulsifiers. Moreover, it is necessary to track the quality of the entire supply chain process. So, we propose a mapper-based architecture, and utilize machine learning, image recognition, cloud computing, and blockchain integration to achieve full intelligence in transportation, logistics, and quality control, to achieve deep traceability, disintermediation and credibility.

A. NODE DISCOVERY AND MATCHING MODULE

The second class vaccine information system architecture enhances the trustworthiness and disintermediation of blockchains through peer-to-peer networks. P2P systems can provide digital interfaces through which different types of nodes can easily access, add, delete, modify, and search. This module helps to manage the complexity and diversity of supply chain functions, making the system more competitive, and improving products, services, and cash flow. Peer to peer network systems help to demediate, reduce transaction complexity by eliminating intermediate nodes, eliminate non complementary intermediaries, significantly reduce transaction costs, improve the value allocation of chain participants, achieve seamless transactions between participants in the second class vaccine supply chain, and further improve the competitiveness of quality [28]. Another significant feature of peer-to-peer network systems is the rating mechanism,

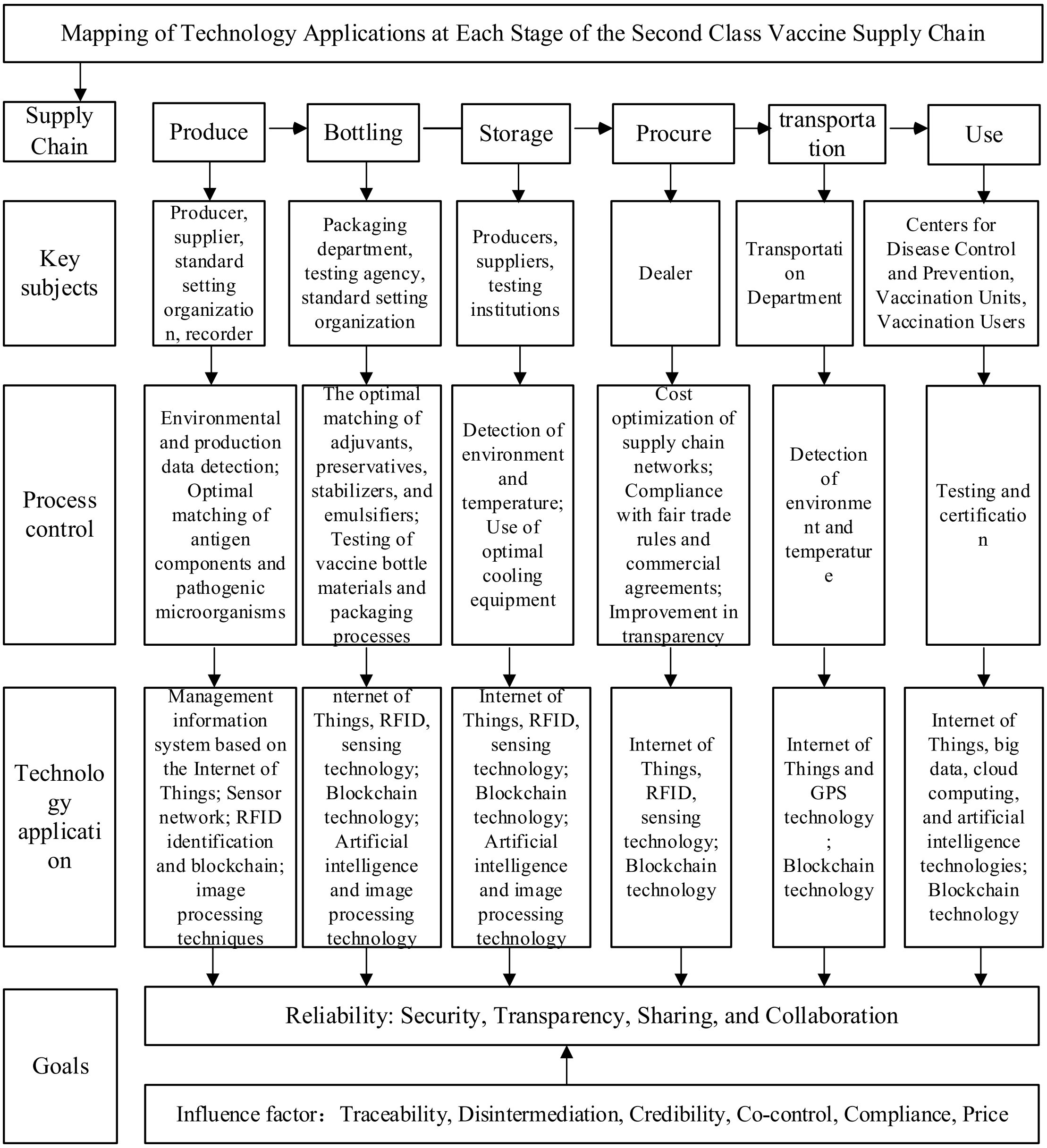

FIGURE 5. Each stage and corresponding technology application of the second class vaccine supply chain.

that the digital signatures of network nodes will facilitate rating and review, and cannot be forged or tampered with which helps restore credibility and protect the system [29]. Research has found that credibility is the third important factor perceived by respondents, and the peer-to-peer network system architecture of the second class vaccine supply chain is shown in Figure 7.

B. UNIQUE IDENTIFIER GENERATOR (REGISTRAR) MODULE

A registrar provides a unique identification number for each supply chain network participant, as well as a public and private key. It also provides a unique key for vaccines in the supply chain. Certification agencies certify vaccine containers or packaging to ensure safety and compliance. A unique identification code helps to monitor, track, and track vaccines for the second class vaccines.

C. RFID-EPC AND BLOCKCHAIN TRACKING MODULE

Each (batch) vaccine is labeled with an RFID-EPC code, as includes: (a) detailed information of the production location and enterprise; (b) The weight of the vaccine at the time of bottling; (c) Time and date (including factory and expiration date); (d) The types, specifications, and quality of vaccines; (e) Other important information. When executing a transaction, the information on the RFID

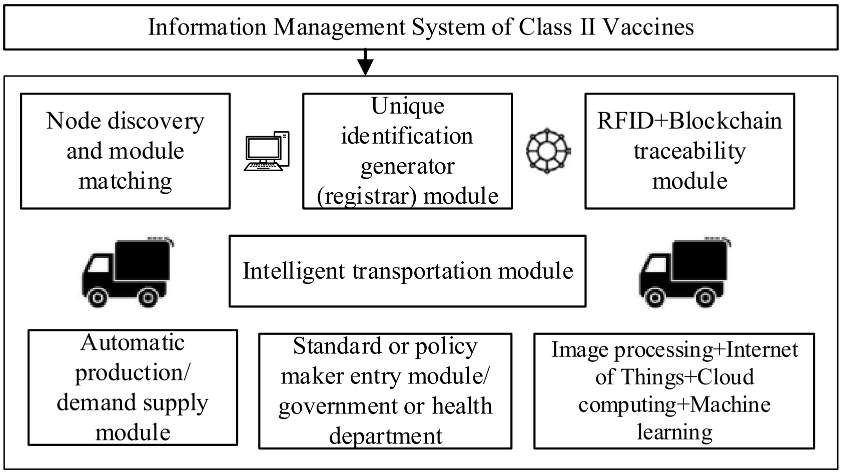

FIGURE 6. The Class II Vaccine Information Management System proposed in this study.

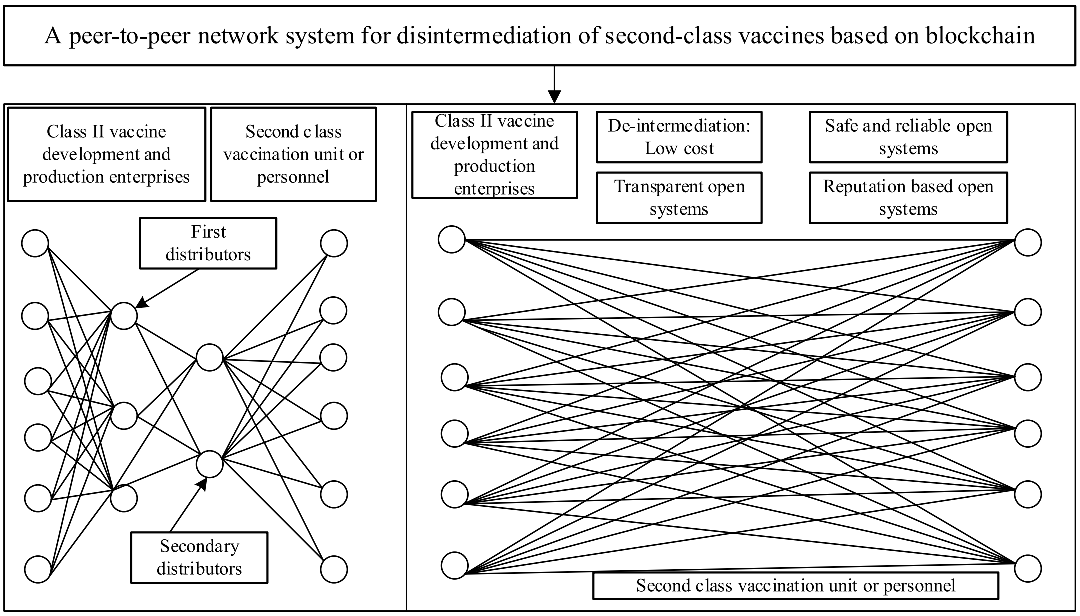

FIGURE 7. A peer to peer network system architecture for a Class II vaccine supply chain.

EPC tag will be included in the blockchain so that it will not be tampered with and permanently stored on a tamper proof and secure blockchain along with the time stamped transaction. We recommend using data redundancy, which means that information is stored on RFID-EPC tags and blockchains. During the traceability process, if the information on the blockchain does not match the RFID-EPC tags, the possibility of tampering or cloning the vaccine is inferred. Producers/processors can use public/private keys to transfer ownership to consumers. A series of transactions will be grouped and strung together in the Merkle tree to form a block. This will be added to the blockchain through the blockchain consensus algorithm, as shown in Figure 8. We have also constructed a relationship mapping that not only maps vaccines to their manufacturers, but also to raw material suppliers. The entire chain traceability process is shown in Figure 9. The key technology to be addressed is the standardization of interfaces and data models for the Internet of Things (RFID) technology.

D. EXCHANGE RIGHTS AND SECURITY MODULE

The ownership transfer of Class II vaccines can be realized by using the digital signature and public or private key of the blockchain. The collection of these transactions is grouped into a block stored in a Merkle tree to ensure the data source at the block level. Each block storage is connected to the blockchain through a hash function (as shown in Figure 8). Based on the blockchain consensus algorithm and game

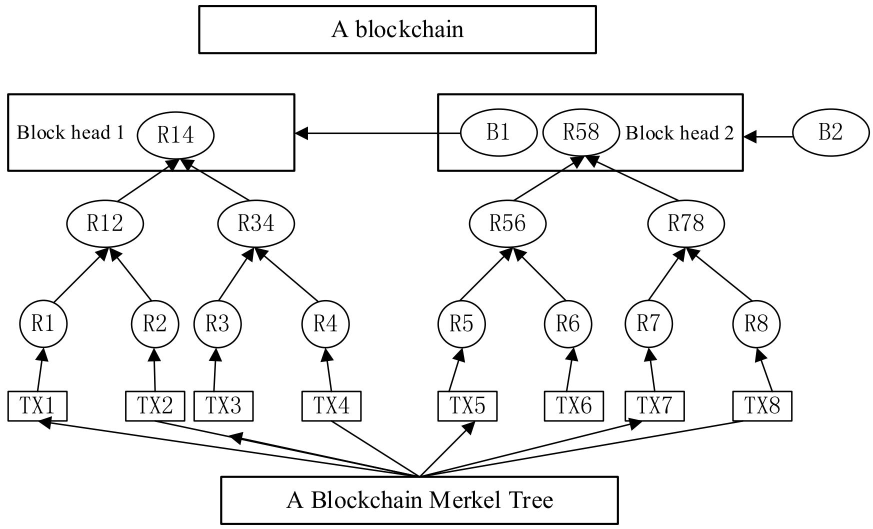

FIGURE 8. A blockchain merkel tree.

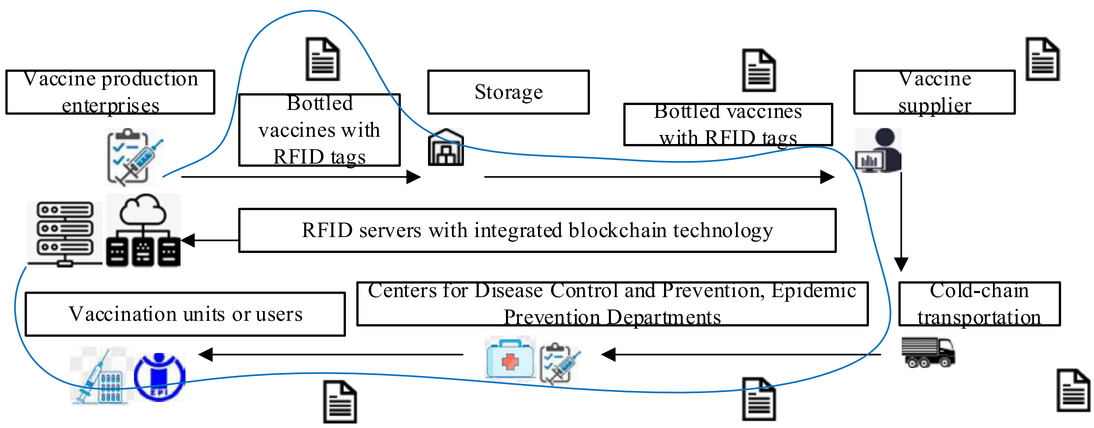

FIGURE 9. Deep traceability of the second class vaccine supply chain based on a integration technology.

theory, authorized participants can easily verify the stored data. Because all blocks are linked to each other through the hash function value of the previous block, the supply chain is a complete system that cannot be tampered with. The exchange empowerment and security module strengthen credibility-based supply chains, which is an important factor through adoption and preference research.

E. ELASTIC SMART CONTRACT MODULE

The proposed architecture is also equipped with an elastic smart contract module. Elastic smart contracts are a set of automatically executed codes that are computer protocols to propagate, validate, or execute contracts in an information-based manner. Elastic smart contracts allow for the most trusted transactions without a third party, which can be deeply tracked and irreversible. The elastic smart contract function of the second class vaccine supply chain can promote trust and security [30], allow blockchain technology to attract the attention of different new participants and boldly join the transaction, as shown in Figure 10. The elastic smart contract module embedded in the supply chain architecture is consistent with the respondents' perceived goals of traceability and credibility.

F. AUTOMATIC SUPPLY AND DEMAND, AND STANDARD ORGANIZATION MODULE

The automatic supply and demand module utilizes the Internet of Things to automatically replenish vaccine orders after transaction initiation. IoT sensors can detect stock keeping unit (SKU) on supplier shelves and automatically order from enterprise production points. It forms a fully automated, traceable, and trustworthy supply chain system with RFID-EPC and blockchain tracking modules, exchange authorization and security modules, and elastic smart contract modules.

The standard organization module involves government agencies issuing national technical standards for different vaccines, provides guidelines to ensure minimum technical

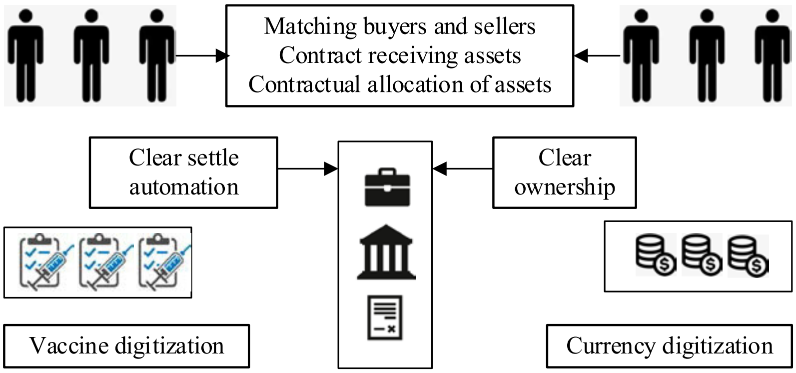

FIGURE 10. Elastic smart contracts in the second class vaccine supply chain.

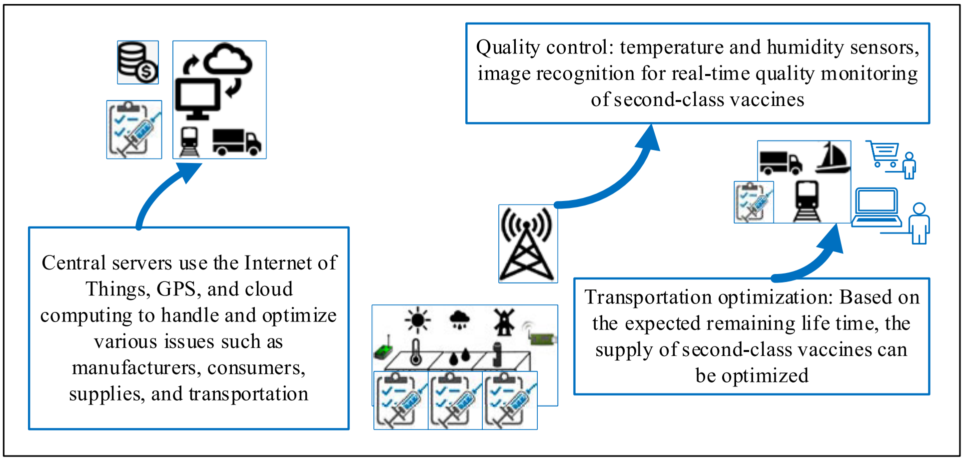

FIGURE 11. Quality control and blockchain optimization based on IoT, cloud computing, and big data analysis.

standards. This module can provide fair trade policies for sustainable supply chain operations.

G. QUALITY CERTIFICATION AND INTELLIGENT TRANSPORTATION MODULE

Quality authentication uses sensor devices, image processing and recognition technologies to track and monitor the quality of vaccines, capture various quality characteristic parameters of vaccines, then the collected data are transmitted to the cloud-based platform through wireless sensor network (WSN), and are analyzed and judged by machine learning (ML)/artificial intelligence algorithms [31].

GPS devices and RFID EPC tags can be used to track vaccine specific transport vehicles, from production to delivery points, and finally to vaccinators. Throughout the transportation process, sensor devices and image recognition technology are used to track and monitor the quality of vaccines, and the collected data and vehicle GPS positions are sent to the cloud platform to optimize the supply chain network. The quality control and intelligent transportation process are shown in Figure 11. The automatic supply and demand module and intelligent transportation module aim to strengthen the collaborative control mechanism and deep traceability among participants in the second class vaccine supply chain [18].

V. CONCLUSION

Based on reliability theory, this study uses fuzzy dynamic decision-making to obtain the key factors or determinants that affect the use of blockchain technology in the Class II vaccine supply chain, as well as the degree of adoption of these factors (described by driving degree), which are in turn traceability, disintermediation, compliance, trustworthiness, coordination and price. Traceability, disintermediation and compliance are the three most important technical and economic factors, which significantly affect the adoption willingness decision-making process of participants. Based on this research results, a modular information system for collaborative supervision of second-class vaccines with optimal and highest utility supply chain configurations was built using blockchain technology integration.

In the proposed architecture, the node discovery and matching module adopts a peer-to-peer network to eliminate non-complementary intermediaries in the supply chain, improve the system's search ability, and achieve rapid matching of potential producers and consumers; The automatic production and demand module is used to automatically replenish inventory to maintain supply and shorten delivery times. The transaction ownership module and smart contract module aim to promote transaction credibility and enhance system fault tolerance and auditing.

The proposed modular architecture and object-oriented design enhance the customization, competitiveness, and reuse of supply chain architecture. Therefore, our proposed architecture can support value creation, value capture, and value allocation.

The proposed blockchain-based architecture utilizes peer-to-peer network systems, the Internet of Things, and cloud-based system integration, as enabling each node in the supply chain to connect and coordinate with each other to form a collaborative system. Utilizing smart contracts and blockchain technology improve transaction compliance mechanisms and promote trust in the system. The architecture can introduce compatibility into the supply chain network through the authority and security module of the exchange and the node discovery and matching module, and form a security sharing platform with traceability, disintermediation and credibility.

Our research innovation has two points: (1) The study introduces reliability theory into supply chain research, and identifies six factors as potential driving factors for the adoption of second-class vaccine blockchain technology, and obtains the driving degree of adoption through fuzzy dynamic decision-making; (2) The study applies the fuzzy dynamic decision results to the multi-agent collaborative supervision of second-class vaccines, a optimal architecture of second-class vaccine supply chain system with the best utility value was constructed, and an information system with deep traceability and secure credibility was implemented.

The modular and sustainable supply chain integration optimization design method proposed in this study makes each stage of the entire supply chain has deep traceability and disintermediation, track and monitor the quality, and has characteristics such as intelligence, scalability, and compatibility, as is consistent with the research objectives.

Of course, currently blockchain technology has not yet formed a relatively unified standard, which poses certain challenges to the development and application of blockchain technology. Meanwhile, with the continuous development and expansion of blockchain technology, legal and regulatory issues are also becoming increasingly prominent. Therefore, we will promote the standardization process of blockchain technology, strengthen the formulation and research of blockchain technology standardization, and strengthen communication and cooperation with government departments, improve and implement legal and regulatory systems, in order to promote the development and application of blockchain technology in the regulation of second-class vaccines.

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YI WAN (Member, IEEE) was born in Shangrao, China, in 1971. He received the Ph.D. degree in intelligent systems from Southwest Jiaotong University, Chengdu, China. He was a Researcher with the Center for Advanced Life Cycle Engineering, University of Maryland, College Park, MD, USA. He is currently a Professor with the Department of Computer Science and Engineering, Shaoxing University, China. He has published more than 50 articles, authorized 18 invention patents, and published three monographs on intelligent algorithms and system reliability. He is responsible for ten provincial, ministerial, and national projects. He has been leading a research team in the area of the system reliability and artificial intelligence. He has now formed a new research institution. He is an expert Reviewer of the Natural Science Foundation and the Technology Plan Project of Zhejiang Province in China. He is a famous teachers and masters, training man of 551 Talent Project in Wenzhou, China.

HAILONG HUANG was born in Wenzhou, China, in 1979. He received the B.Tech. degree in automatic control systems from the Jiangxi University of Science and Technology, Ganzhou, China, and the M.S. degree in computer science and technology from Hangzhou Dianzi University, Hangzhou, China. He is currently a Senior Experimentalist with the Experimental Center, College of Computer Science and Artificial Intelligence, Wenzhou University, Wenzhou, Zhejiang, China. He has published more than ten articles on intelligent algorithms and network technology.