Journal of Advanced Health Informatics Research (JAHIR)
Vol. 2, No. 1, April 2024, pp. 24-37
ISSN: 2985-6124, DOI: 10.59247/jahir.v2i1.288

Smart Contracts for Data Sharing in Drug Development a Systematic Review of Security and Transparent Measurement

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ARTICLE INFO

Article history:

Received January 18, 2024
Revised March 18, 2024
Published April 23, 2024

Keywords:

Blockchain,
Iot,
Data Security,
Drug Development,
Smart Contract

ABSTRACT

This systematic literature review explores the role of smart contracts in improving data sharing for drug development, with an emphasis on security and transparency. Using blockchain technology, smart contracts offer a decentralized tracking mechanism for pharmaceutical supply chains, addressing challenges related to drug authentication and supply chain optimization. The review examined 52 studies using the PRISMA methodology, highlighting the automation of data exchange, reduced reliance on external parties, and acceleration of operational processes. Advanced encryption and strict access controls in smart contracts strengthen data security, ensuring patient confidentiality and compliance with medical data regulations. Despite technical and regulatory barriers, smart contracts promise significant improvements in operational efficiency, transparency, and collaboration among stakeholders in drug development. This study emphasizes the need for standardized protocols, further empirical research, and strategic implementation to fully leverage the potential of smart contracts in the pharmaceutical industry. Integration of these technologies can accelerate clinical trials and improve data reliability, thereby enhancing the safety and effectiveness of the drug development process.

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1. INTRODUCTION

1.1 Background

Smart contracts have an important role to play in revolutionizing drug development and supply chain management by improving transparency, security, and efficiency [1]. Smart contracts, especially those using blockchain technology such as Ethereum, are increasingly being investigated in various aspects of the pharmaceutical sector. These smart contracts bring decentralized tracking and tracing mechanisms to the healthcare supply chain, guaranteeing transparency and uninterrupted data flow [2]. Capitalizing on blockchain technology and smart contracts, the pharmaceutical industry can address challenges associated with low-quality drugs, authentication, and supply chain optimization, ultimately improving the overall drug development process and patient safety [3].

The security and transparency in data sharing through smart contracts is an important element in the drug development process. Blockchain technology, as emphasized in several scientific articles, blockchain technology provides solutions to address issues such as data breaches, user confidentiality, and complying with rules in clinical testing [4]. Utilizing Blockchain and Smart Contracts, the authenticity of trial data can be guaranteed, facilitating transparent and secure information exchange among the parties involved [5].

Utilizes cryptographic Smart Contracts for authentication and access management, along with technologies such as IPFS for tamper-resistant data storage, increasing security in data sharing [6]. This strategy not only fosters trust and responsibility in the drug development environment but also reduces the risk of data tampering, thereby improving the reliability and efficiency of clinical trials [7].

1.2 Research Purposes

Smart contracts are essential in improving data sharing and security in various sectors, especially in the field of pharmaceutical development [8]. Research can provide important insights into the use of smart contracts in the pharmaceutical supply chain and the protection of health data through blockchain technology [9]. This research discusses the importance of smart contracts on blockchain platforms in countering the spread of counterfeit drugs and the need for decentralized monitoring and tracking systems to maintain transparency and data integrity in the healthcare supply chain. Blockchain technology also has the potential to address the complex issues of monitoring patient well-being, ensuring drug quality, and protecting data privacy in remote health monitoring [10].

1.3 Research Question (RQ)

This study aims to evaluate the application of smart contracts and blockchain technology in information exchange in pharmaceutical development. It describes the status and prospects of smart contracts in improving the confidentiality and transparency of medical data, identifies challenges, and prepares the ground for further research in this area. There were several research questions posed in this study.

RQ1: What are the smart contract implementations for data sharing in drug development that have been studied in the literature?

RQ2: How can blockchain technology improve data security in the drug development process?

RQ3: What are the key benefits of using smart contracts for transparency in health data sharing?

RQ4: What are the challenges in implementing blockchain for health data sharing, especially in drug development?

RQ5: How smart contracts can ensure compliance with protocols and regulations in clinical trials?

RQ6: What is the role of IPFS technology in improving data resilience and security in drug development?

RQ7: How can blockchain and smart contracts solve the problem of interoperability in health data sharing?

RQ8: What are the best recommendations for implementing smart contracts in health data sharing systems?

RQ9: How will the use of blockchain affect the efficiency and reliability of clinical trials in drug development?

RQ10: What are the latest innovations in the development of smart contracts for healthcare applications?

2. METHODS

2.1. Database Selection

Selection of databases that include reputable journals and literature sources is essential in SLR to ensure all relevant and high-quality literature is found [11]. Inclusion and exclusion criteria, defined prior to the literature search, ensure consistent selection of articles in systematic reviews [12]. Table 1 is a list of inclusion and exclusion criteria used.

Conducting a Systematic Literature Review on "Smart Contracts for Data Sharing in Drug Development" requires selecting relevant references and applying an effective search methodology. The references used included Pubmed, IEEE Xplore, Scopus, Web of Science, Google Scholar, Sciencedirect, Digital ACM, Springerlink, Arxiv, and Researchgate. Keywords such as "Smart contract," "Data Sharing," "Drug Development," "blockchain," "Security," and "Transparency" were used with Boolean operators to combine or expand search results. Filters were applied based on predefined inclusion and exclusion criteria. This search process was followed by a manual check of the titles and abstracts to ensure the relevance of the articles. Reference lists of relevant articles were also reviewed to find additional studies, so that the completeness of the SLR could be ensured.

Table 1. Inclusion and Exclusion Criteria

Inclusion	Exclusion
Articles directly related to the topic "Smart Contracts for Data Sharing in Drug Development"	Articles not directly related to the topic
Original research article, systematic review, or meta-analysis	Articles that appear more than once (duplication).
Studies written in English.	Inaccessible articles (for example, behind a paywall without access).
Peer-reviewed articles	Articles that are not peer-reviewed (e.g., opinion pieces, editorials, reader letters)
Articles published within 2010-2023	Articles written in languages other than English

2.2 Article Selection Process

Repeated searches with various keywords were conducted to thoroughly identify relevant literature. Article titles and abstracts were manually checked post-search, and duplicates were removed. Relevant articles were then carefully searched and assessed. Inclusion and exclusion criteria were applied to determine which articles would be included in the final review [13]. The reference lists of relevant articles were also scrutinized to uncover additional studies that may have been missed in the initial search, ensuring comprehensive identification and inclusion of relevant, high-quality literature. The article selection process was carefully documented, including the number of articles included and excluded and the rationale, allowing for review and validation by other researchers. This practice ensures a complete, transparent and reliable systematic review [14]. Figure 1 is a PRISMA flowchart showing the study selection process

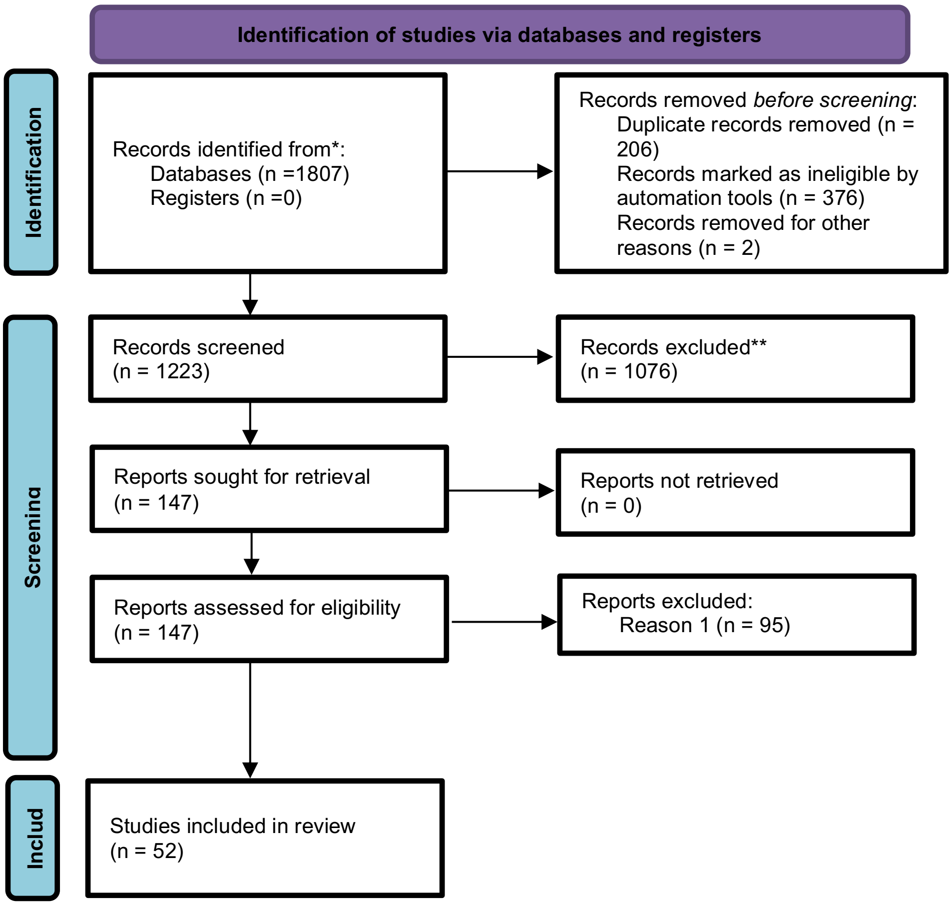

Fig. 1. PRISMA Flowchart

2.3 Data Extraction

The data extraction process involved retrieving variables from each selected article, including title, author, year of publication, journal, research objectives, methodology, type and sample size, key findings, conclusions, and recommendations. Other important variables include the type of data, smart contract technology used, security considerations, and the level of transparency in pharmaceutical development [15]. Systematic and structured data extraction ensured a thorough approach. Each eligible article was scrutinized and relevant variables documented, and the data was entered into a spreadsheet to maintain uniformity and facilitate analysis. Multiple researchers were involved in this process to reduce bias and improve data accuracy [16].

2.4 Article Quality Evaluation

He quality assessment of articles in a Systematic Literature Review (SLR) involves methodical techniques to ensure only high-quality studies are included [17]. Quality was measured based on internal and external validity, sample size, and data analysis approach. Assessment criteria included clarity of research objectives, validity of data collection methods, and accuracy of statistical analysis techniques. The clarity of the results report, discussion of limitations, and provision of raw or coded data for analysis were also evaluated. Biases such as selection bias, reporting bias, and potential conflicts of interest were assessed [18]. Two independent researchers evaluated each article and compared the results for consistency, involving a third rater in case of discrepancies [19]. Strict quality evaluation standards ensure that only articles with high validity and reliability are analyzed, guaranteeing reliable and relevant conclusions [20].

3. Research Findings

3.1 PRISMA Diagram

The PRISMA process incorporates important phases to ensure systematic and transparent selection of studies in the literature review [21]. During the identification phase, 1,807 records were found in the database, with 206 duplicates removed, 376 records ineligibles by automated tools, and 2 records excluded for other reasons, resulting in 584 records excluded before screening. In the screening phase, 1,223 records were screened, and 1,076 were excluded based on inclusion and exclusion criteria. A total of 147 reports were requested, with 95 reports excluded after assessment. Finally, 52 studies that met the inclusion criteria were included in the systematic review. This procedure demonstrates a meticulous approach in selecting pertinent studies, ensuring only studies that met the inclusion criteria were analyzed [22]. PRISMA diagram increases transparency and reproducibility in the systematic literature review process [23].

3.2 Characteristics of Inclusion Articles

3.2.1 Most Cited Publications

Table 2 shows each of the most cited documents. Global citations refer to the annual citation rate at the time the dataset used in this study was extracted. Based on Table 2, the article titled "Privacy-preserving generative deep neural networks support clinical Data Sharing" [24] is the article with the highest number of citations. This article contributes that machine learning-based predictors built on synthetic populations can be generalized to datasets generated by health clinics and that synthetic data can be shared for hypothesis-generating analysis. In the second position is the article with the title "Medchain: Efficient healthcare Data Sharing via blockchain" [25] received 395 citations. The article contributes to the creation of an efficient data sharing scheme, which overcomes efficiency issues and brings flexibility in sharing data, especially medical data. In the third position, the article titled "Biology-inspired microphysiological systems to advance patient benefit and animal welfare in drug development" [26] received 222 citations. The article contributes to the creation of Biology-inspired microphysiological systems (MPS) technology that aims to replace laboratory animals in drug development. The research also provided recommendations and a roadmap to overcome the challenges in MPS adoption. In the fourth position, the article with the title "Blockchain technology, improvement suggestions, Data Security challenges on smart grid and its application in healthcare for sustainable development" [27] received 217 citations. The article describes recent developments in non-financial applications of blockchain and the development of a mobile application model for medical records automation. At the fifth position, the article titled "Automating procurement contracts in the healthcare supply chain using blockchain Smart Contract" [28] received 186 citations. The article contributes to the integration of blockchain technology and decentralized storage to increase transparency, streamline communication, and minimize procurement time.

Table 2. Most Cited Publications

Title	Citation
Privacy-preserving generative deep neural networks support clinical Data Sharing	411
Medchain: Efficient healthcare Data Sharing via blockchain	395
Biology-inspired microphysiological systems to advance patient benefit and animal welfare in drug development	222
Blockchain technology, improvement suggestions, Data Security challenges on smart grid and its application in healthcare for sustainable development	217
Automating procurement contracts in the healthcare supply chain using blockchain Smart Contract	186
Precision health data: Requirements, challenges and existing techniques for Data Security and Data Privacy	176
Design of a secure medical Data Sharing scheme based on blockchain	144
Accelerating health Data Sharing: A solution based on the internet of things and distributed ledger technologies	127
Scalable blockchain model using off-chain IPFS storage for healthcare Data Security and Data Privacy	122
Digitization of healthcare sector: A study on Data Privacy and Data Security concerns	121

3.2.2 Most Productive Country

Table 3 shows data on the countries with the most cited publication productivity, as shown in Table 3. China ranks top with 769 citations, followed by Saudi Arabia with 477 citations as the second rank, and the United States with 467 citations as the third rank. Meanwhile, based on Table 4, India recorded the highest number of publications with 7 articles, followed by China with 6 articles as the second rank, and the United States with 5 articles as the third rank in terms of the number of publications published. Overall, China shows a strong dominance in the number of citations, while India has a significant contribution in the number of publications published.

Table 3. Most Productive Country by Citation

Country	Cited Article
China	769
Saudi Arabia	477
United States	467
India	405
United Kingdom	346
Australia	257
Germany	223
Pakistan	203
Malaysia	178
Spain	127

Table 4. Most Productive Country by Frequency

Country	Frequency
India	7
China	6
United States	5
United Kingdom	5
Saudi Arabia	3
Pakistan	3
Malaysia	2
Australia	2
Republic of Korea	2
Germany	2

3.2.3 Most Productive Institution

Table 5 represents data on institutions with high productivity of cited publications, as seen in Table 5. The University of Pennsylvania tops the list with 411 citations, followed by Tsinghua University with 395 citations.

In third place, King Saud University recorded 287 citations, while Technische Universität Berlin ranked fourth with 222 citations. Khalifa University finished fifth with 186 citations. The other articles in Table 5 also have citation counts above 100. Overall, these institutions demonstrate a valuable contribution to the academic literature which is reflected in the high number of citations their publications receive.

Table 5. Most Productive Institution by Citation

Institution	Citation
University of Pennsylvania	411
Tsinghua University	395
King Saud University	287
Technische Universität Berlin	222
Khalifa University	186
CSIRO Data61	176
Sindh Madressatul Islam University	151
Anhui Normal University	144
Universidad Politécnica de Madrid	127
Vellore Institute of Technology	122

3.2.4 Most Frequent Keywords

The occurrence and relevance of widely used keywords in the selected publications can be analyzed based on the inclusion criteria of this study. Table 6 lists the most searched keywords by researchers interested in the topic "Smart Contracts for Data Sharing in Drug Development". Based on Table 6, "blockchain" is the most frequently occurring keyword in the included articles with 24. Next, "Data Privacy" with 13, "Data Security" with 12, "Healthcare" with 8, "Smart Contract" with 5, "Transparency" with 4, "Data Sharing" with 4, "Ethereum" with 4, and the remaining keywords appear 3 times in all included articles.

Table 6. Top 10 Most Searched Keyword

Keyword	Frequency
Blockchain	24
Data Privacy	13
Data Security	12
Healthcare	8
Smart Contract	5
Transparency	4
Data Sharing	4
Ethereum	4
Data Security Analysis	3
Drug Development	3

3.3 Overview of Smart Contracts in Data Sharing for Drug Development

Smart contracts in blockchain technology improve the effectiveness, security, and transparency of data in pharmaceutical research [29]. With automation and self-validation, smart contracts guarantee the security and authenticity of data between researchers, pharmaceutical companies, and healthcare providers [30]. Transactions are recorded on the blockchain, creating a verifiable audit trail and reducing data tampering [31]. They also reduce reliance on intermediaries, speed up processes, and reduce costs [32]. Smart contracts enhance cooperation with instant access to critical information and speed up decision-making[33]. Using advanced encryption, they protect sensitive data [34], while decentralization increases resilience to cyber-attacks [35]. Smart contracts offer a holistic solution for pharmaceutical research data sharing, improving efficiency, security, transparency, and collaboration[35] [36].

3.4 Security Measures Associated with the Use of Smart Contracts

The utilization of smart contracts in sharing drug development data requires security protocols to maintain data integrity and confidentiality [37]. ata is encrypted end-to-end, ensuring access only for authorized entities and guaranteeing security during transmission [38] . Smart contracts regulate data access according to set permissions, restricting access only to authorized parties [39]. Validation procedures authenticate the accuracy of data before integration into the blockchain, reducing the risk of false data [40]. These measures enhance data security and ensure transactions and information exchange are carried out securely and reliably [41].

3.5 Transparency Measures Associated with the Use of Smart Contracts

Smart contracts in drug development data sharing include transparency and security protocols to ensure auditability and verification [42]. Each transaction is recorded on the blockchain, creating a permanent record that can be verified by outside parties [43], enforcing data integrity [44]. Decentralized identity verification authenticates each party, reducing unauthorized activities [45] [46]. Non-sensitive data is shared to increase transparency, allowing outsiders to verify information, thus increasing security, trust, and responsibility in pharmaceutical research and development [47].

3.6 Answers to Research Questions

Table 7. Answers to the Research Questions

Questions	Answer
RQ1 What are the smart contract implementations for data sharing in drug development that have been studied in the literature?	Smart contract implementations in the literature include the use of Ethereum and IPFS to automate information exchange and data management in clinical trials as well as applications for drug tracking in the medical supply chain.
RQ2 How can blockchain technology improve data security in the drug development process?	Blockchain can enhance data security through end-to-end encryption, decentralized data storage, and strict access management, ensuring that only authorized entities can access data.
RQ3 What are the key benefits of using smart contracts for transparency in health data sharing?	Key benefits of smart contracts include increased transparency through immutable audit trails, automation of administrative processes, and reduced risk of human error in data management
RQ4 What are the challenges in implementing blockchain for health data sharing, especially in drug development?	Key challenges include interoperability between different systems, data storage efficiency, the need for strong cryptographic algorithms, and regulatory barriers across different jurisdictions
RQ5 How can smart contracts ensure compliance with protocols and regulations in clinical trials?	Smart contracts can ensure compliance by automating protocol verification and data approval, so that every stage of a clinical trial complies with strict regulatory standards.
RQ6 What is the role of IPFS technology in improving data resilience and security in drug development?	IPFS plays a role in ensuring data resilience against corruption and manipulation by providing a distributed and secure data storage system, supporting data integrity in drug development.
RQ7 How can blockchain and smart contracts solve the problem of interoperability in health data sharing?	Blockchain and smart contracts can address interoperability issues by providing uniform data standards and decentralized communication protocols, enabling the integration of various health systems.
RQ8 What are the best recommendations for implementing smart contracts in health data sharing systems?	The best recommendations include the development of clear standards and protocols, training for human resources, and case studies for real-world impact evaluation, as well as increased cooperation between stakeholders.
RQ9 How will the use of blockchain affect the efficiency and reliability of clinical trials in drug development?	The use of blockchain can improve the efficiency of clinical trials by speeding up administrative processes, reducing costs, and increasing data reliability through transparency and automated verification

RQ10 What are the latest innovations in the development of smart contracts for healthcare applications?	Recent innovations include the use of artificial intelligence for medical data analysis combined with smart contracts, as well as the development of stronger cryptographic schemes to enhance data security.

4. Discussion

4.1 Implications of Smart Contracts for Drug Development

Research findings show that the use of smart contracts can accelerate drug development by automating administrative tasks, ensuring adherence to protocols, and encouraging cooperation among stakeholders [56]. The security and transparency measures implemented can reduce data breaches and increase confidence in research results [57]. Smart contracts transform drug development by improving operational efficiency through task automation, reducing research time and costs [58] [59]. esearchers can focus on important aspects with reduced administrative burden, and automation of logging and data verification processes reduces human error [60] [61] . Smart contracts ensure strict adherence to clinical research protocols, reducing the risk of non-compliance and regulatory issues [62] [63]. With automated compliance integration, the risk of non-compliance is minimized [64]. Secure and transparent data enables more efficient collaboration between entities involved in pharmaceutical development, accelerating research and clinical trials [65] [66]. Smart contracts provide quick access to critical information, improving coordination and reducing communication barriers [67]. The integration of smart contracts in pharmaceutical development improves efficiency, compliance, and collaboration, drives innovation, and accelerates the delivery of new therapies to patients [68].

4.2 Challenges and Opportunities in Implementing Smart Contracts in Data Sharing in Drug Development

The implementation of smart contracts in drug development data sharing faces technical challenges, regulations between countries, and industry inertia to change [69]. A high level of technical proficiency is required in the creation and maintenance of smart contracts [70], and expert resources are needed for their deployment [71]. Regulatory differences across different jurisdictions regarding medical data and blockchain technology may hinder global implementation, forcing companies to comply with multiple regulations [72]. Pharmaceutical companies may be reluctant to use new technologies such as smart contracts due to high start-up costs and changes in operational procedures [73], as well as uncertainty around long-term profitability and potential disruption of operations [74]. However, smart contracts offer great opportunities, including enhanced data security through strong encryption and careful access control [75], transparency through immutable audit trails, and strict identity governance [76]. Improved operational efficiency can reduce costs and accelerate drug marketing, increasing company revenue [77]. Critical factors for success include data security and confidentiality, the system's ability to handle big data, compatibility with existing IT systems, and compliance with local and international regulations [78].

5. Conclusion

5.1 Summary of Key Findings

Analysis of the literature shows that blockchain technology, particularly smart contracts, has great potential to improve security, efficiency, and transparency in drug development [79]. Smart contracts automate data exchange, reduce dependence on external entities, and accelerate operational processes. They facilitate self-verification and perpetual documentation of each transaction, guaranteeing data security and integrity [80]. Advanced encryption and strict access control protect confidential information from unauthorized intrusion, maintain patient confidentiality, and comply with medical data regulations [81] [82]. The decentralized structure of blockchain eliminates single points of vulnerability, strengthening the system's capacity against cyberattacks [83]. However, blockchain integration faces barriers such as system compatibility, data storage optimization, and the need for enhanced cryptographic protocols [84]. Solutions include more complex blockchain frameworks, advanced encryption techniques, and improved compatibility with healthcare frameworks [85]. Empirical case studies are needed to assess the efficacy and efficiency of blockchain-based solutions in real healthcare scenarios[86]. These insights build a solid foundation for pragmatic exploration and application, refining drug development procedures, strengthening data security, and increasing transparency in research and clinical operations [87] [88].

5.2 Implications of Smart Contracts for Data Sharing Practices in Drug Development

Research findings on the utilization of smart contracts in drug development data sharing have significant implications for the pharmaceutical industry [89]. Smart contracts have the potential to improve security, transparency, and efficiency in drug development [90]. Strong encryption technology and careful access management can enhance data security, essential for the privacy and security of medical data [91]. Transparency is enhanced by immutable audit trails and strict identity control, improving accountability and regulatory compliance[92]. In addition to advantages in security and transparency, smart contracts also promise operational efficiency, reduced administrative costs, and accelerated commercialization of drugs [93] [94]. Although there are technological and regulatory challenges that need to be overcome, the benefits of smart contract integration in drug development are encouraging [95]. For effectiveness, organizations must ensure seamless integration with IT frameworks, compliance with data regulations and medical research ethics, and substantial data management [96] [97]. The use of smart contracts offers a solution to the challenges of the pharmaceutical industry, improving efficiency, transparency and security in drug development [98].

5.3 Suggestions for the Use of Smart Contracts in Data Sharing in Drug Development

Optimizing the benefits of smart contracts in drug development data sharing requires comprehensive strategic actions [99]. The first step is to establish standards and protocols to ensure system interoperability and regulatory compliance [100]. These standards facilitate the use of smart contracts across different institutions and countries, reducing technical and legal issues [101]. Harmonizing regulations creates a uniform framework for all parties, easing integration and cooperation between countries [102]. Further research on the use of smart contracts in drug development offers practical insights, addresses challenges, and builds empirical evidence on the advantages of this technology [103] [104]. Data collection from real-world implementations enhances the understanding of smart contract adaptability in various scenario [105]. Long-term evaluation of financial, operational, and regulatory impacts is essential to ensure sustainable benefits [106] [107]. Human resource training and development ensures the workforce has expertise in the creation, implementation, and maintenance of smart contracts [108] [109]. This strategy enables smart contracts to improve efficiency, safety, and transparency in drug development [110]. Collaboration between researchers, pharmaceutical companies, and regulatory bodies is facilitated, accelerating innovation and the introduction of new therapies to the global health market [111].

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