IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

Enhancing Pharmaceutical Supply Chain Security: Blockchain and Smart Contracts for Counterfeit Drug Prevention

[1] Dr. Rohini Hanchate , [2] Aniket Kaygude, [3] Avadhut Kulkarni, [4] Vedant Gorule

[1] Professor, [2] Student, [3] Student, [4] Student
, [1] Computer Engineering Department,
[1] Nutan Maharashtra Institute of Engineering and Technology, Pune, Maharashtra, India

Abstract : The health of the public is, at risk due to medicines that not only endanger lives but also diminish trust in pharmaceutical companies. To enhance transparency and security while ensuring traceability in the pharmaceutical industry a proposed solution in this piece involves utilizing a blockchain powered system for managing the supply chain of medications, with the integration of contracts. In addition to automating compliance enforcement and using FSSAI license-based authentication to confirm medicine legitimacy, the system logs each transaction on an immutable ledger. Stakeholders may follow and authenticate pharmaceutical products using real-time monitoring and a consumer verification app, which lowers fraud and inefficiencies. This strategy guarantees supply chain integrity, increases pharmaceutical security, and promotes overall healthcare results by bolstering regulatory compliance and eliminating data manipulation.

IndexTerms **- Blockchain, Pharmaceutical Supply Chain, Counterfeit Drugs, Smart Contracts, QR-Code Authentication, Traceability, Regulatory Compliance.**

INTRODUCTION

The pharmaceutical sector is vital, for healthcare by providing efficient medications to people everywhere; however, the increasing prevalence of counterfeit medicines in supply chains has sparked serious worries about patient safety and regulatory adherence issues. Many current supply chain setups depend on centralized databases which are susceptible, to data tampering and unauthorized changes leading to inefficiencies. Furthermore, the absence of real time tracking systems hampers the capability to monitor a medicine's voyage from production to users. These limitations result in both monetary setbacks, for drug companies and potential health hazards arising from the circulation of counterfeit medicines demanding an open system to guarantee full drug tracking capabilities from start to finish.

With its decentralized and unchangeable record, blockchain technology presents a workable way to improve pharmaceutical supply chains' efficiency, security, and transparency. The system may automate regulatory approvals, compliance checks, and medicine authentication without requiring human participation by incorporating smart contracts. Throughout the supply chain process stakeholders can ensure the authenticity of a product by incorporating FSSAI license verification system in place. The likelihood of drugs spreading is minimized with the help of real time tracking features that ensure any discrepancies or abnormalities are quickly detected. Utilizing a blockchain powered solution enhances trust, among consumers manufacturers and healthcare professionals while also combating fraud and reinforcing adherence, to regulations.

NEED OF THE STUDY

The increasing presence of medicines, in pharmaceutical supply chains poses risks to patient safety and industry integrity while also undermining regulatory compliance efforts. Traceability of a drugs journey from production to consumers proves difficult using supply chain systems due to their dependence on centralized databases that are prone, to data tampering inefficiencies and illicit alterations. Implementing technology based on blockchain offers an tamper proof record that enhances traceability security and transparency thereby mitigating the perils associated with medications. By automating the process of obtaining approvals and conducting compliance checks through contract integration there is a reduction, in the need for manual intervention and an increase, in operational efficiency. Furthermore, using FSSAI license-based authentication guarantees accurate drug verification at every turn, enhancing stakeholder trust. For patient safety, pharmaceutical industry operating efficiency, and medication prevention and adherence. This research delves into the potential impact of blockchain technology, on managing medication supply chains. In addition to protecting public health, putting such a system in place aids pharmaceutical businesses in minimizing financial losses and preserving the integrity of their brands.

PROBLEM STATEMENT

The pharmaceutical sector encounters an issue, with medications entering the distribution network and jeopardizing patient safety and adherence to regulations. Conventional supply chain management methods depend on databases that're vulnerable to data tampering and unauthorized changes. The absence of visibility into operations, in time and strong verification measures hinders the ability to identify and stop the spread of counterfeit drugs. In the absence of an unchangeable system, for monitoring pharmaceutical items various parties such, as producers, distributors, pharmacies, and customers face difficulties in confirming the legitimacy of products and upholding regulatory standards. Resolving these issues requires an approach that offers tracking capabilities boosts security measures and streamlines compliance procedures to protect the pharmaceutical distribution network from counterfeit risks.

OBJECTIVE

The primary objectives of this research are as follows:

- To put in place a blockchain-based system for safe pharmaceutical product traceability from beginning to end.
- To use smart contracts and FSSAI license-based authentication to stop the distribution of fake medications.
- QR-code generation of prescription.
- To increase efficiency by automating transaction verification.
- To use blockchain's decentralized architecture to guarantee data security and privacy.

RELATED WORK

5.1 Traditional Supply Chain Management:

Conventional pharmaceutical supply chain management tracks and authenticates drugs using centralized systems. These systems contain information about drugs in databases which are kept up to date by producers, distributors and authorities. Nevertheless, centralized databases are vulnerable to hacks, data manipulation, and real-time tracking that is not effective. Furthermore, the manual record keeping procedures are prone to errors, delays and lack of transparency which makes it hard to detect fake drugs. The risk of counterfeits in the supply chain and their distribution is increased when stakeholders cannot guarantee drug authenticity and compliance with the regulations because there is no safe and unchangeable way to verify that.

5.2 Blockchain-Based Supply Chain Solutions:

Blockchain technology has quickly become an option, for boosting transparency and security within the pharmaceutical supply chain industry. Numerous models based on blockchain have been suggested to monitor and validate items with the help of ledgers and smart contracts. In comparison, to databases blockchain minimizes the chances of data tampering and unauthorized changes thus bolster the security of the supply chain. Smart contracts play a role, in automating processes such as handling payments efficiently and managing recalls and compliance checks seamlessly without the need, for intermediaries.

5.3 Gaps in Existing Solutions:

While there has been progress, in using technology for managing pharmaceutical supply chains end the widespread use is hindered by various challenges. Scalability poses a challenge, for networks as they struggle to manage high transaction volumes effectively resulting in network congestion and delays, in processing transactions. In the context of pharmaceutical supply chains that encompass parties and extensive transaction loads a scalable system is essential to enable real time tracking while maintaining optimal performance levels. Existing solutions often struggle to strike a balance between decentralization, speed, and efficiency this limits their effectiveness, in large scale operations.

One significant hurdle is ensuring interaction, with regulatory guidelines and outdated supply chain structures in the pharmaceutical sector and among regulatory bodies, which function on different platforms with diverse compliance rules in various regions. When incorporating blockchain into these systems it requires protocols. Effortless sharing of information mechanisms. Numerous blockchain driven solutions face challenges in aligning with databases, like the FDA Drug Supply Chain Security Act(DSCSA) or the European Medicines Verification System (EMVS) thereby impeding adoption. Ensuring these spaces are filled is essential, for the integration of technology, in managing pharmaceutical supply chains.

5.4 Literature Survey:

Paper Name	Author	Description
BLOCKCHAIN BASED DRUG TRACEABILITY IN HEALTHCARE SUP-PLYCHAIN	Dr. A Manjula, Associate Professor	Healthcare supply chains are critical backbone to services and vital for everyday life. The inherent complexity of such systems can introduce impurities including inaccurate information, lack of transparency and limited data provenance. A counterfeit drug is one consequence of such limitations within existing supply chains which not only has serious adverse impact on human health but also causes severe economic loss to the healthcare industry.
Drug Traceability In Supplies Of Healthcare Products Using Block Chain	SHAIK. AYESHA BEGUM	The goal of a drug traceability system is to track or trace where a drug has been and where it has gone along the drug supply chain, which is critical for public drug security and pharmaceutical company business. Traditional centralized server client technical solutions have failed to meet expectations in terms of data integrity, privacy, system resilience, and adaptability.
A review study of the blockchain-based healthcare supply chain	Jayendra S. Jadhav, Jyoti Deshmukh	Technological acclimatization in today's healthcare industry is a subject of new inventions. The worldwide Covid-19 epidemic has led to increase in the use of technology for healthcare supply chain, patient data management, and claims settlement. Data management in healthcare industry is a complex structure where multiple organizations provide proper supply chain services in day-to-day life.
A survey on Blockchain based pharmaceutical supply-chain management and drug distribution: The case of Morocco	Yassine Znaki, Wafaa Enneffah	The pharmaceutical supply chain management is facing numerous challenges that had led in the past and still today to issues in the distribution of drugs and their availability in the market. When interviewed, stakeholders affirm the issue does not involve the scarcity or lack of production, but indeed
Supply Chain Management, Between Resilience and Sustainability	A. Bouhaddou, A. Bentaleb, A. El Amrani	This paper explores the literature related to supply chain sustainability and resilience, aiming to build a theoretical framework that integrates both concepts.
Resilience and Sustainability in Supply Chains: A Systematic Review	M. A. Khan, M. R. Hasan, T. Wuest	This article provides a systematic review of contemporary literature, focusing on the exploration of supply chain resilience from two perspectives: resilience and sustainability.
Review on Supply Chain Resilience: Phenomena, Modelling Techniques, and Framework of Resilience Building Strategies with Future Research Directions	S. Rajesh	This study offers a systematic literature review of over 100 papers published between 2010 and 2020, identifying resilience strategies in supply chains and various methodologies used by academicians. It also develops a framework incorporating various strategies employed to enhance supply chain resilience.
A Conceptual Framework of Supply Chain Resilience Towards Sustainability	A. Ivanov, A. Dolgui, B. Sokolov	This paper proposes a conceptual framework for sustainable and resilient supply networks, discussing the overlaps and incompatibilities between sustainability and resilience principles, and emphasizing the need for flexible governance models and regulatory oversight.

PROPOSED SYSTEM

- **Drug Tracking & Individual Labelling** – Each batch of medication is given an ID code recorded on the system to allow for full tracking, from the producer, to the final user; this helps in thwarting counterfeit activities and guaranteeing genuine products.
- **Smart Contracts ,for Automation** – Smart contracts manage compliance checks and payments automatically while also triggering recalls based on preset conditions being fulfilled to enhance efficiency and minimize the need, for involvement.
- **Decentralization & Transparency**– Decentralized and transparent data access is facilitated through the tamper ledger that can be accessed by authorized parties such, as manufacturers, distributors, pharmacies, and regulators ensuring transparency and secure verification of any changes made.
- **Patient Control** – Patients are empowered with user data control over their information allowing them to manage who can access it – be it doctors or administrators – thereby safeguarding their privacy while enabling the secure and efficient sharing of prescription details.
- **Integration with the Blockchain Network** – The drug related information such, as manufacturing specifics and transportation records are securely added to the network to establish a record of transactions and minimize the likelihood of fraud.
- **Enhanced Security and Adherence**– The system guarantees that every medication in the distribution network adheres to requirements prior, to being shipped out; additionally, it employs cryptographic security features to prevent alterations and minimize the chances of counterfeit medicines entering the market.

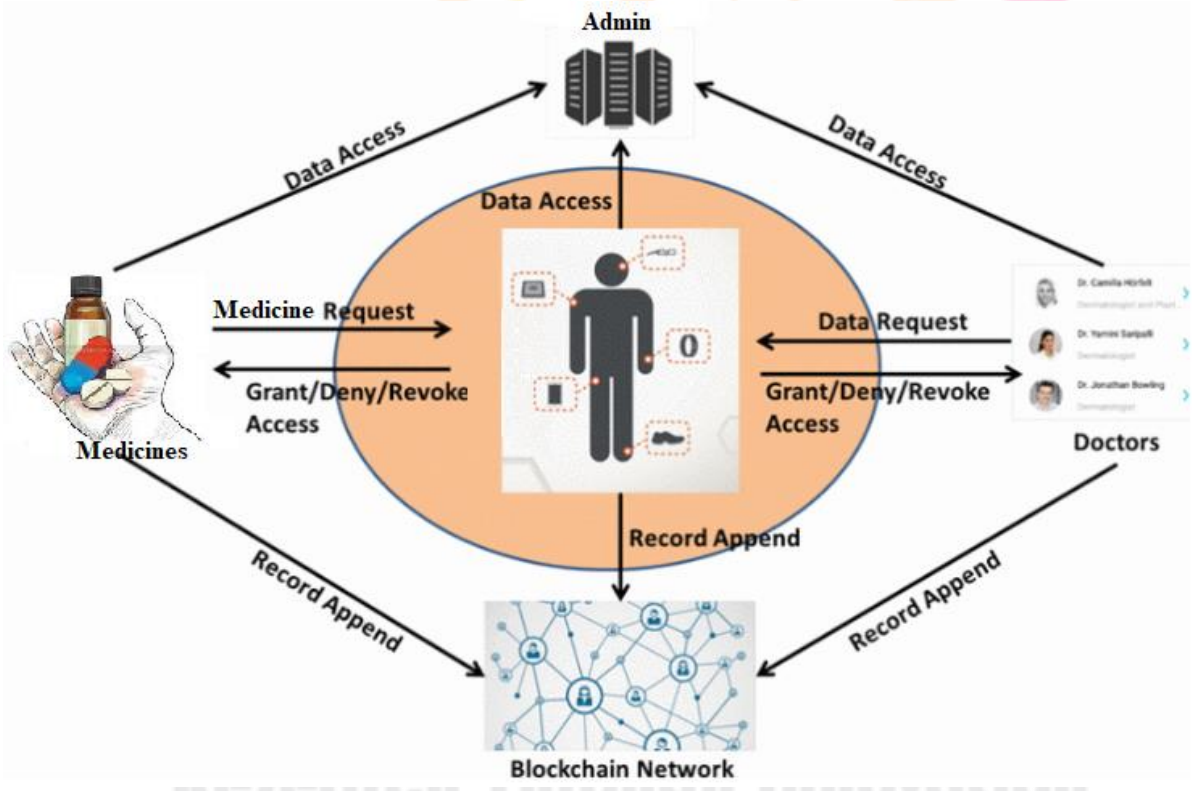

Fig1: System Design

ALGORITHM

Step 1: Initialization

We start the Tomcat and SQL server using XAMPP and configure **care_db** in phpMyAdmin as shown in Fig4. The database includes **tbladmin** for admin data, **tblblockchain** for blockchain-stored information, and **tbldealer** for dealer details. Blockchain network parameters are defined, including the consensus mechanism and smart contract rules. Stakeholders such as manufacturers, distributors, pharmacies, regulators, and consumers are registered with unique cryptographic identities. Smart contracts are deployed to automate compliance checks, payments, and recalls.

Step 2: Drug Manufacturing and Registration

Manufacturers record drug production details, including batch number, expiration date, ingredients, and compliance data, in **care_db**. Each drug batch is assigned a unique cryptographic hash to ensure authenticity and traceability, which is then stored on the blockchain.

Step 3: Drug Distribution and Tracking

Manufacturers transfer drug ownership to distributors through blockchain transactions, with each transfer being verified and recorded on the decentralized ledger. Distributors further transfer drug batches to pharmacies while maintaining traceability across all stages of the supply chain.

Step 4: Regulatory Compliance and Verification

Smart contracts validate drug authenticity and regulatory compliance at each transfer stage. Any unauthorized modifications or discrepancies trigger automatic alerts to stakeholders, ensuring data integrity and adherence to safety standards.

Step 5: Consumer Authentication

Consumers can verify drug authenticity using blockchain records. In case of a defective or non-compliant batch, a smart contract initiates an automatic recall and notifies all stakeholders. Regulators audit blockchain records stored in **tblblockchain** to verify compliance and generate reports for transparency.

Step 6: Recall Management and Auditing

Smart contracts facilitate recall management by enforcing compliance rules and notifying stakeholders of any issues. Regulators conduct audits to ensure that safety and quality standards are met, leveraging data stored in **care_db** and **tbblockchain** for verification.

Step 7: Finalization and Reporting

All completed transactions remain immutable on the blockchain for future verification. The system generates analytics on drug distribution, counterfeit detection, and regulatory adherence. Stakeholders review performance metrics to optimize supply chain operations, ensuring transparency and efficiency in the pharmaceutical industry.

FLOWCHART

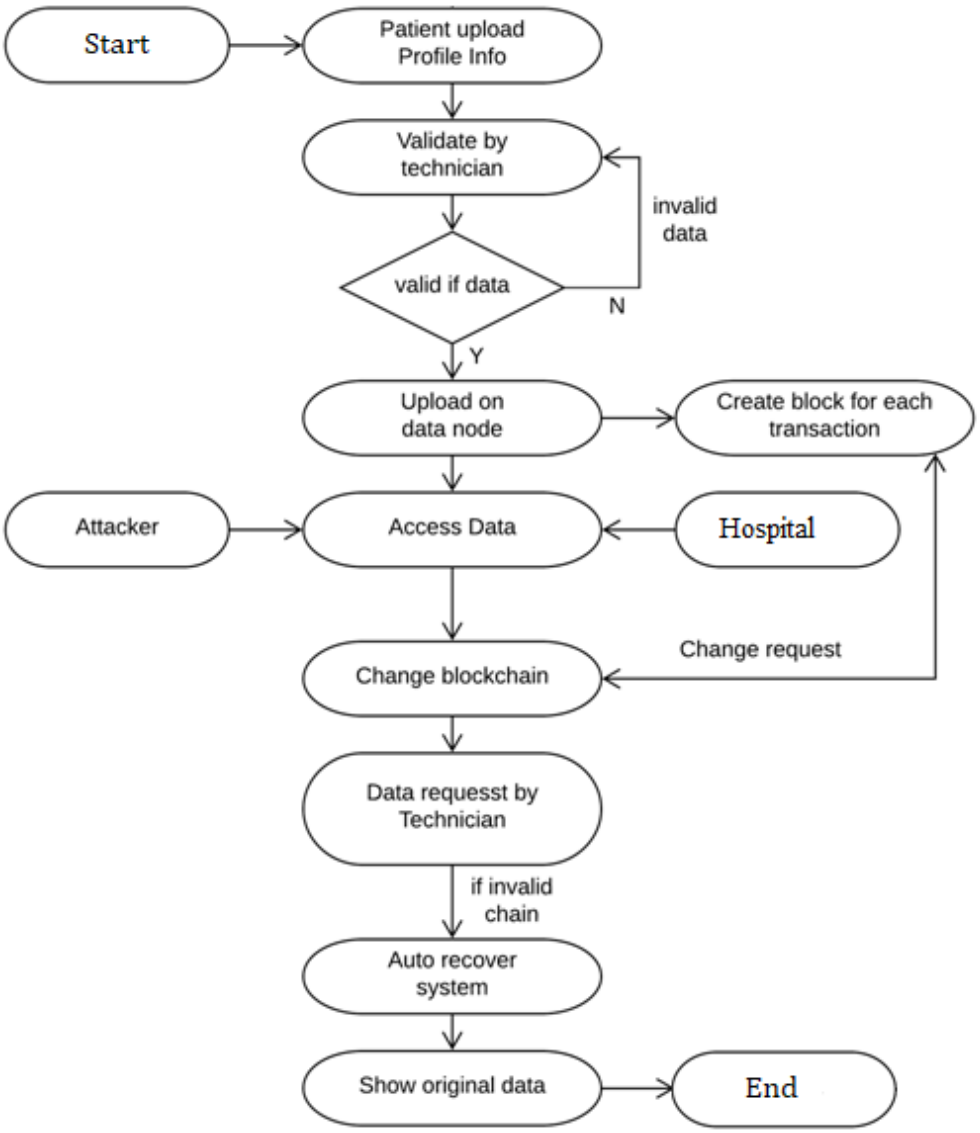

Fig2: Flowchart

METHODOLOGY

To develop a blockchain-based pharmaceutical supply chain system, the first step is designing a secure and scalable blockchain architecture. This involves selecting a suitable consensus mechanism, such as Proof of Stake, which offers efficiency and faster transaction processing. Smart contracts define the roles and permissions of supply chain participants, ensuring transparency and security. Additionally, a combination of on-chain and off-chain storage is implemented to manage large datasets efficiently while keeping critical records immutable and easily accessible on the blockchain.Conduct security audits to identify vulnerabilities.

To ensure seamless operation, the blockchain system must integrate with existing supply chain data sources. APIs play a crucial role in enabling communication between blockchain and legacy systems, allowing pharmaceutical companies to transition smoothly without overhauling their current infrastructure. Security is also a priority, with cryptographic techniques ensuring data integrity and user authentication. Compliance with regulations like GDPR and HIPAA is necessary to protect sensitive patient data, while governance policies define access control and modifications to maintain transparency.

Finally, the system undergoes rigorous testing and validation. Unit and integration testing help identify potential issues in the blockchain and smart contracts before deployment. Real-world supply chain scenarios are simulated to evaluate the system's performance under different conditions, ensuring it functions effectively across all supply chain stages. By addressing these key aspects, a blockchain-based solution can significantly improve pharmaceutical traceability, security, and compliance.

RESULT

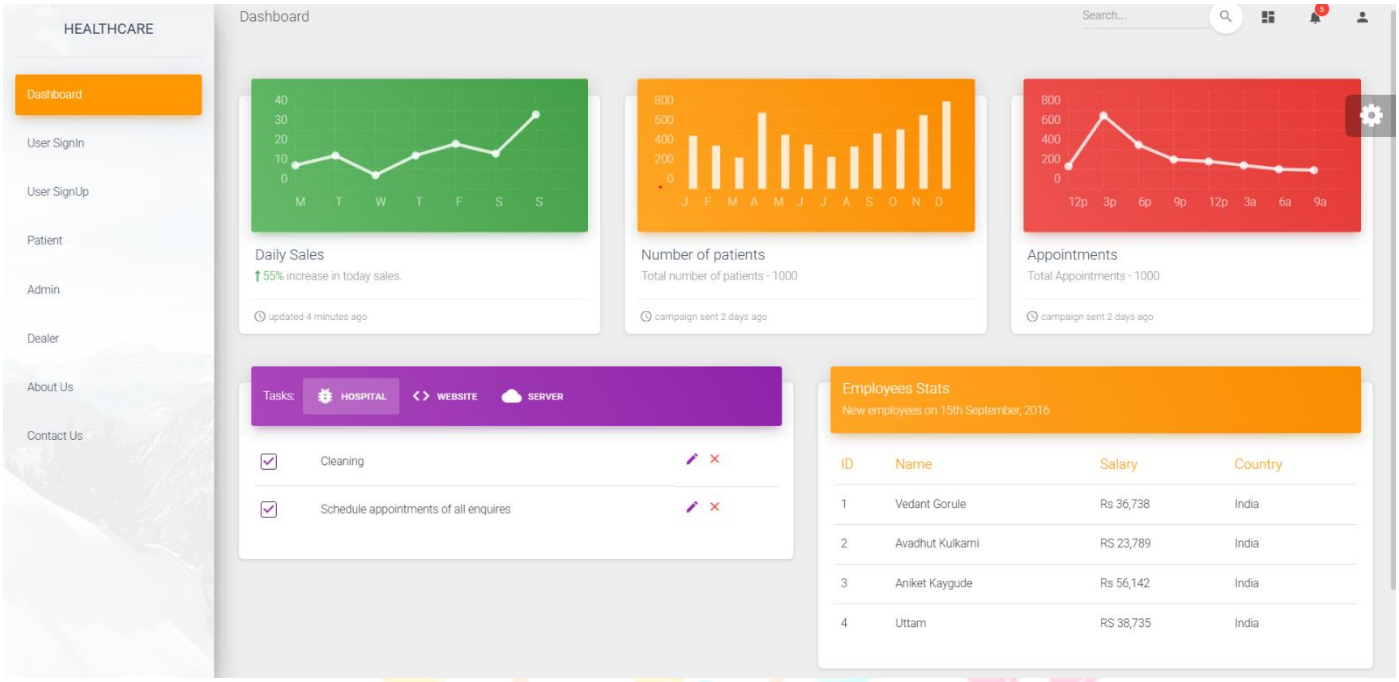

Fig3: Dashboard

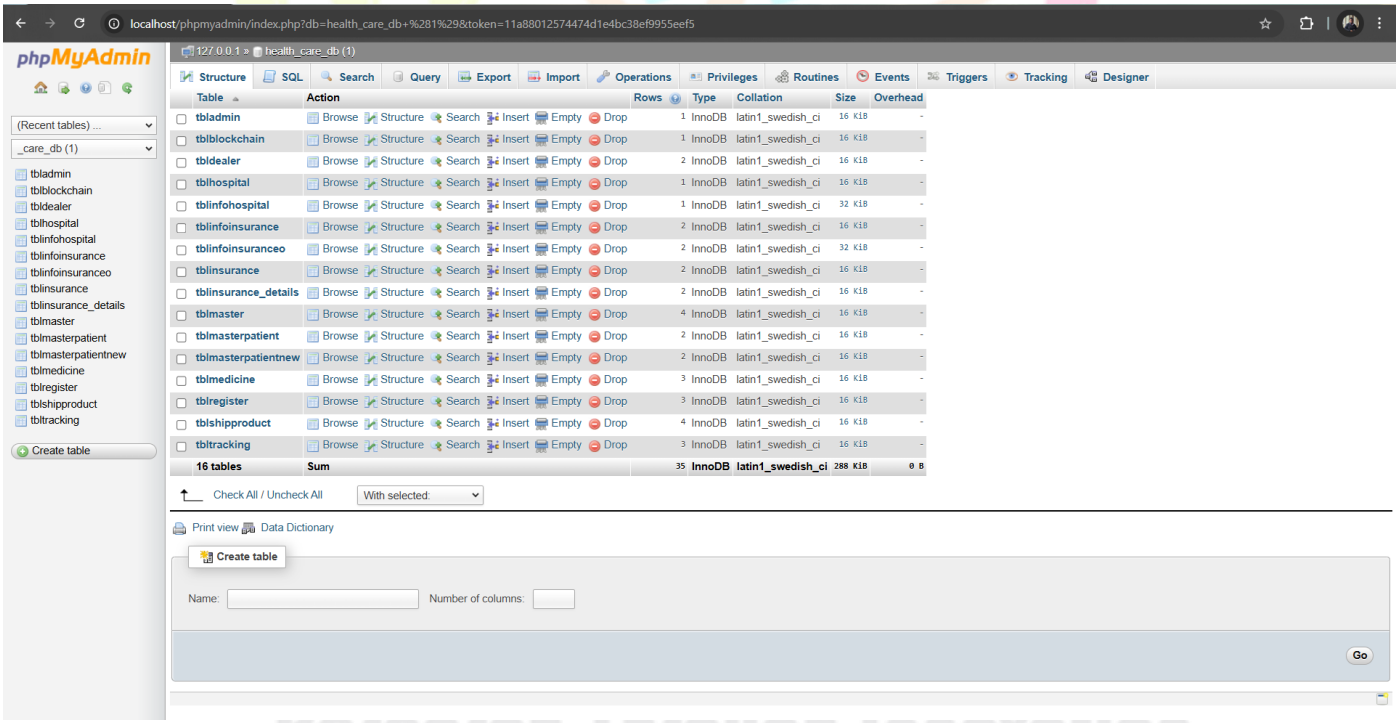

Fig4: Database

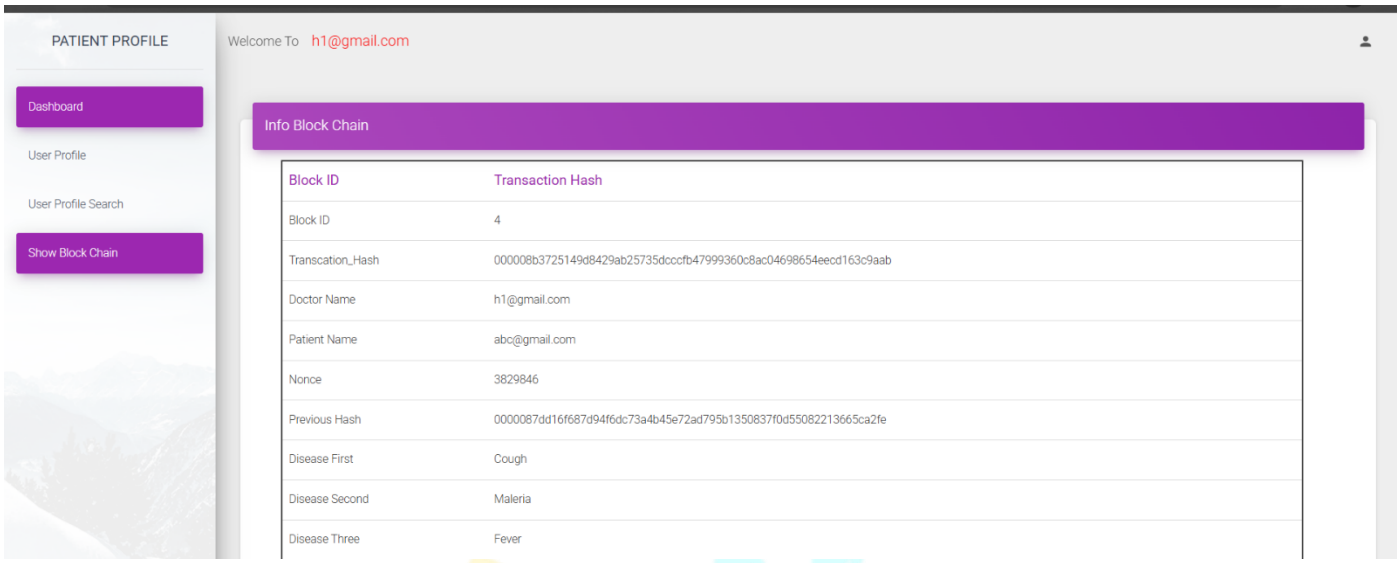

Fig5: Transaction Hash

BLOCKCHAIN IN PHARMACEUTICAL SUPPLY CHAIN

6.1 Exploring the Basics of Blockchain Technology, in Ensuring Drug Traceability:

Blockchain technology offers a distributed ledger system to monitor pharmaceutical products throughout the supply chain without interference or manipulation. Incorporating security and agreement mechanisms guarantees transparency and data integrity while providing verification of the authenticity of medications. Smart contracts streamline compliance procedures by minimizing input and enhancing efficiency. The incorporation of blockchain powered systems improves tracking capabilities. Reduces the presence of drugs while reinforcing adherence, to regulations. Thereby offering a robust solution, for safeguarding pharmaceutical supply chains. Furthermore, real time. Automatic notifications aid, in spotting abnormalities to stop behaviours. Moreover, blockchain technology facilitates teamwork, between involved parties building confidence and enhancing the efficiency of supply chain operations.

6.2 The Influence on Security and the Integrity of Data:

By integrating technology into pharmaceutical supply chains drug safety is improved through traceability from start, to finish. This helps in diminishing the circulation of medicines and ensures adherence, to standards. Utilizing solutions allows stakeholders to validate the authenticity of drugs instantly thereby boosting confidence levels and enhancing security and efficiency during the distribution phase. Moreover, the implementation of automated smart contracts simplifies inspections and financial transactions reducing mistakes and delays while promoting transparency and accountability in the supply chain.

DISCUSSION

In contrast, to systems w Blockchain based solutions enhance the traceability security and transparency of pharmaceutical supply chains. Challenging issues such as barriers to adoption scalability and meeting standards must be addressed Transaction congestion and steep computational expenses make Proof of Work (PoD} a concern for scalability so researchers are exploring Proof of Stake (PoA as a faster alternative that does not compromise security Flexible smart contracts and governance structures are vital, for complying with FDA and EMA regulations. Substantial financial support and educating stakeholders are crucial, for adoption as improving infrastructure development within the industry sector is vital too! The fight against products and enhancing global drug safety can be accomplished by addressing these challenges head on; moreover, employing innovative methods such, as Layer 2 scaling solutions can heighten effectiveness and widespread approval.

FUTURE INNOVATIONS

Advancements in blockchain-based pharmaceutical supply chains are set to enhance security, efficiency, and regulatory compliance. One key development is the integration of artificial intelligence (AI) with blockchain to enable predictive analysis and anomaly detection. AI-powered models can identify counterfeit drug patterns, detect supply chain inefficiencies, and automate decision-making, making the system more proactive and intelligent. Additionally, zero-knowledge proofs (ZKP) and advanced encryption techniques can enhance data privacy while maintaining transparency, allowing stakeholders to verify transactions and meet compliance requirements without exposing sensitive pharmaceutical data.

Another significant improvement is cross-chain interoperability, which facilitates seamless communication between different blockchain networks and traditional supply chain systems, enhancing data sharing and regulatory cooperation. Decentralized identity (DID) systems can further strengthen authentication, ensuring that only authorized parties can access or modify supply chain records. These innovations, along with continuous advancements in blockchain governance and automation, will contribute to a more secure, efficient, and transparent pharmaceutical supply chain, reducing counterfeit risks and improving global drug distribution.

CONCLUSION

Blockchain technology has the potential to transform pharmaceutical supply chains by enhancing drug traceability, security, and compliance. By utilizing decentralized ledgers and smart contracts, it ensures transparency, reduces counterfeit risks, and automates critical processes like compliance checks and recalls. However, challenges such as scalability, regulatory integration, and data privacy must be addressed for widespread adoption. Implementing hybrid blockchain models, ensuring interoperability with existing systems, and leveraging AI for predictive analytics can enhance efficiency and security. With continued innovation and collaboration, blockchain can significantly improve drug authentication, patient safety, and global pharmaceutical distribution.

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