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EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA

GRIFFITH COLLEGE DUBLIN

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MSc in Pharmaceutical Business and Technology (QQI)

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May 2024

CANDIDATE DECLARATION

I hereby declare that the dissertation entitled "**EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA**" is submitted in partial fulfilment of MSc in Pharmaceutical Business and Technology is my original piece of work and due acknowledgment is given, where the reference is made to others work. I also affirm that I have not plagiarised anybody else's work, either partially or entirely, including other students.

Candidate Name: **LIGI ALEXANDER** Date: 16/05/2024

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Supervisor Signature:

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LIGI ALEXANDER

TABLE OF CONTENTS

TABLE OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

WHO	World Health Organization
RFID	Radio Frequency Identification
NFC	Near Field Communication
DSCSA	Drug Supply Chain Security Act
QR	Quick Response
DCA	Drug and Cosmetic Act
LMIC	Low- and Middle-Income Countries
DTAB	Drug Technical Advisory Board
CDSCO	Central Drugs Standard Control Organization
SLR	Systematic Literature Review
IoT	Internet of Things
API	Application Programming Interface
DSCMR	Drug Supply Chain Management and Recommendation
IP	Intellectual Property
CT	Clinical Trial
GCP	Good Clinical Practice
TRU	Traceable Resource Unit
WSN	Wireless Sensor Networks
PSCM	Pharmaceutical Supply Chain Management
EHR	Electronic Health Record
RBI	Reserve Bank of India
PDPB	Personal Data Protection Bill
GDPR	General Data Protection Regulation
FISM	Fuzzy Interpretive Structure Model
MICMAC	Cross-impact matrix Multiplication applied to classification
GAN	Generative Adversarial Network
PIL	Participant Information Leaflet (PIL)
ICF	Informed Consent Form
ERP	Enterprise Resource Planning

ABSTRACT

EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA

Ligi Alexander

The global pharmaceutical industry faces persistent challenges related to falsified and counterfeit medications and supply chain vulnerabilities, particularly in regions like India. This study explores the feasibility and implications of implementing blockchain-based digital identities in the Indian pharmaceutical supply chain to enhance traceability and security. The study sets out with a comprehensive introduction, highlighting the critical importance of addressing these issues and the transformative potential of blockchain technology. The research objectives encompassed assessing stakeholders' awareness, perceptions, and attitudes towards blockchain technology, identifying challenges and vulnerabilities in the existing supply chain, and providing strategic recommendations for implementation. The research questions are designed to investigate the current state of pharmaceutical traceability and security in India, the feasibility and perceived benefits of blockchain implementation, and the regulatory and technological hurdles hindering adoption.

Methodologically, a mixed-methods approach is employed, combining surveys and interviews to gather insights from Healthcare professionals working in the Indian Pharmaceutical industry. The methodology section details the data collection process, including the survey design and participant selection criteria. The research philosophy used for quantitative analysis was pragmatism and for qualitative analysis was Interpretivism. The deductive approach was used for quantitative analysis and the inductive approach was used for qualitative analysis. For quantitative analysis self-designed online survey questionnaire comprising of 24 questions was used. For qualitative analysis, a direct interview was done which was 20-30 minutes long. The study method was cross-sectional as the time was limited for data collection and analysis. The time limit was 1 month. Findings revealed a significant level of awareness and perceived benefits of blockchain technology among participants, with a majority recognizing its potential to prevent counterfeit drugs and improve supply chain transparency. However, regulatory hurdles, technological barriers, and supply chain vulnerabilities were identified as key challenges to implementation.

The analysis delves into the implications of these findings, highlighting the need for collaborative efforts, regulatory alignment, and strategic planning to overcome obstacles and realize the full potential of blockchain technology in the pharmaceutical sector. Recommendations emphasize the importance of regulatory compliance, education, and stakeholder collaboration to facilitate successful implementation.

In conclusion, while blockchain holds promise for mitigating supply chain risks and enhancing transparency, its successful integration into the pharmaceutical sector requires concerted efforts from all stakeholders. The study provides valuable insights into the current landscape and offers actionable recommendations for future initiatives. By advocating for strategic planning and regulatory alignment, this research aims to contribute to the advancement of pharmaceutical traceability and security in India, ultimately benefiting patients, healthcare providers, and society as a whole.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Blockchain-based digital identities have emerged as a promising solution to address the complex challenges surrounding pharmaceutical product traceability and security in India. With the healthcare supply chain being a labyrinthine network involving various stakeholders from raw material suppliers to pharmacies and patients, ensuring the authenticity and integrity of pharmaceutical products is paramount. Counterfeit drugs pose a significant threat to public health and safety, contributing to economic losses and even fatalities, particularly in developing countries like India *(Habiba, 2021)*.

Recent studies have highlighted the pervasive nature of counterfeit drugs within the pharmaceutical supply chain, with up to 30% of drugs in developing countries being counterfeit *(Uddin* et al., *2021)*. Leveraging blockchain technology offers a robust mechanism to combat this issue by providing a transparent, immutable, and decentralized ledger for tracking and tracing pharmaceutical products throughout their journey from manufacturer to end-user. Blockchain's inherent features, such as cryptographic validation and distributed ledger technology, make it exceptionally well-suited for establishing trust and accountability in the supply chain *(Habiba, 2021)*.

This paper aims to evaluate the impact of implementing blockchain-based digital identities for pharmaceutical product traceability and security in India. The study seeks to enhance traceability, minimize human intervention, and ensure real-time monitoring of drug movements. Furthermore, the paper intends to assess the effectiveness and feasibility of the proposed blockchain-based solution in the Indian pharmaceutical landscape.

1.2 PHARMACEUTICAL TRACEABILITY AND SECURITY IN INDIA: CURRENT SCENARIO

The Indian pharmaceutical industry stands as the third-largest in the world, contributing significantly to global healthcare. With a focus on generic drug production and vaccine manufacturing, India plays a crucial role in supplying essential medications to markets worldwide. However, despite its prominence, the industry faces persistent challenges in ensuring the traceability and security of pharmaceutical products. The complex pharmaceutical supply chain, coupled with regulatory gaps and the proliferation of

counterfeit and falsified drugs, poses significant risks to patient safety and industry reputation (Devmurari, 2023).

India's pharmaceutical export market, valued at approximately USD 18 billion in 2015-2016, underscores the industry's global reach and economic importance. However, concerns over the authenticity and quality of exported pharmaceuticals have prompted regulatory authorities and consumers worldwide to demand greater transparency and accountability from Indian manufacturers (Devmurari, 2023).

1.3 WHAT ARE FALSIFIED AND COUNTERFEIT DRUGS

Falsified and counterfeit drugs refer to medications that have been intentionally misrepresented to their identity or source. These drugs may contain incorrect ingredients, improper dosages, or may lack active ingredients altogether. They are produced and distributed to deceive consumers, often for financial gain (EMA, 2024).

Falsified drugs can pose significant risks to public health as they may not have undergone proper quality control measures or regulatory oversight. They can be ineffective in treating medical conditions, leading to treatment failure or worsening of symptoms. In some cases, they may contain harmful substances, posing serious health hazards to individuals who consume them (EMA, 2024).

Counterfeit drugs specifically refer to medications that are produced to imitate genuine pharmaceutical products. They may be packaged to closely resemble legitimate drugs, making it difficult for consumers to distinguish them from authentic medications (EMA, 2023).

Figure 1:Examples of Counterfeit drugs(Akhtar and Rizvi, 2021)

Figure 2:Falsified Medicine Authentication(PSI, 2023)

1.4 THE IMPACT OF FALSIFIED AND COUNTERFEIT DRUGS ON PUBLIC HEALTH

Counterfeit drugs represent a pervasive threat to public health and safety, causing harm to patients and undermining trust in healthcare systems. The World Health Organization defines counterfeit medicine as products deliberately mislabeled with respect to identity and source, posing serious risks to patients' health and well-being. The International Chamber of Commerce estimates that annual sales of counterfeit products amount to USD 650 billion globally, highlighting the scale of the problem and its implications for various industries, including pharmaceuticals (Kumar and Tripathi, 2019).

To address the challenge of counterfeit and falsified drugs, researchers and industry stakeholders have proposed various tracing and authentication mechanisms. These include Smart-Track systems with barcodes or RFID (Radio Frequency Identification) codes, Data-Matrix tracking systems, and NFC (Near Field Communication) tags for product authentication. While these solutions offer potential benefits, they often lack automatic verification of product authenticity and are susceptible to attacks such as replay and man-in-the-middle attacks. Thus, there is a pressing need for more robust and secure technologies to combat counterfeit drugs effectively (Kumar and Tripathi, 2019).

1.5 BLOCKCHAIN TECHNOLOGY AND BLOCKCHAIN-BASED DIGITAL IDENTITIES TO PREVENT FALSIFIED AND COUNTERFEIT DRUGS IN THE PHARMACEUTICAL INDUSTRY

Blockchain technology has araised as a promising solution for enhancing pharmaceutical traceability and security. Blockchain Technology is a decentralized, peer-to-peer database of information that enables transparent and secure transactions among involved parties. Whether public or private, blockchain networks provide tamper-resistant ledgers of transactions, ensuring data integrity and authenticity (Devmurari, 2023).

In the pharmaceutical context, blockchain-based digital identities offer a unique opportunity to establish verifiable credentials for each pharmaceutical product, enabling seamless tracking and authentication throughout the supply chain. By leveraging cryptographic techniques and consensus mechanisms, blockchain technology enables stakeholders to verify the authenticity and integrity of pharmaceutical products in real time, thereby mitigating the risks associated with counterfeit drugs and falsified medications (Devmurari, 2023).

The Drug Supply Chain Security Act (DSCSA) of 2023 mandates traceability at the unit level, emphasizing the importance of scalable and interoperable solutions for the pharmaceutical industry. Blockchain-based digital identities align with these requirements by providing a robust framework for tracking and tracing pharmaceutical products at the individual drug level. Through immutable records and cryptographic signatures, blockchain technology ensures transparency, accountability, and regulatory compliance within the pharmaceutical supply chain (Devmurari, 2023).

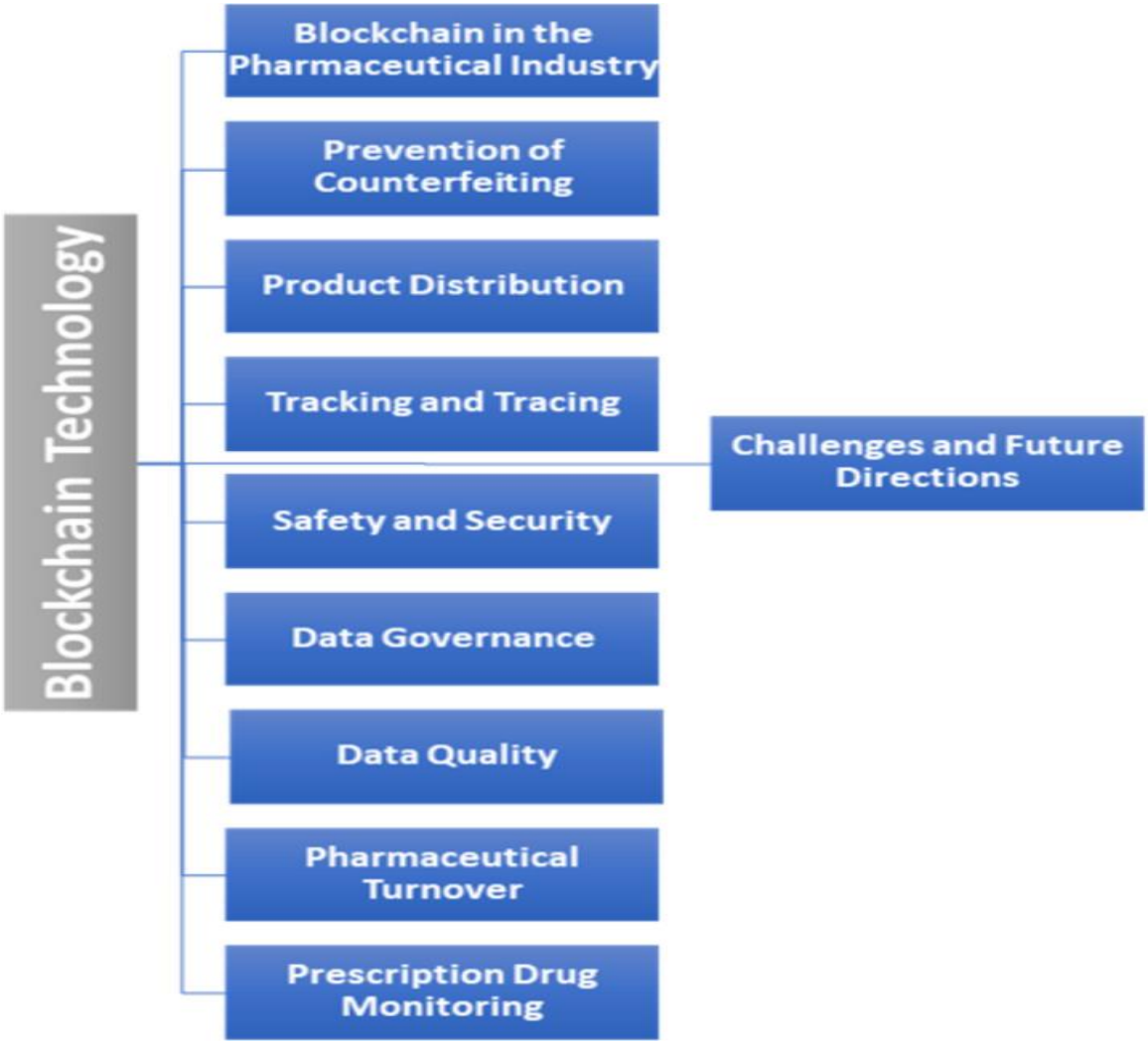

Figure 3:Taxonomy of Blockchain Technology(Zakari et al., *2022)*

1.6 THE BENEFITS OF IMPLEMENTING BLOCKCHAIN TECHNOLOGY IN PHARMA

The implementation of blockchain technology in the pharmaceutical industry offers numerous benefits, ranging from enhanced traceability and transparency to improved regulatory compliance and patient safety. By digitizing the provenance of pharmaceutical products, blockchain technology enables stakeholders to track the entire lifecycle of a medication, from production to distribution to consumption (Kumar, 2023).

This heightened visibility not only deters illicit activities but also streamlines regulatory reporting and quality assurance processes. Moreover, blockchain-based digital identities empower consumers to verify the authenticity and integrity of pharmaceutical products, fostering a culture of trust and accountability within the industry (Kumar, 2023).

The integration of blockchain technology with existing anti-counterfeiting solutions, such as RFID, NFC, and QR codes, enhances interoperability and strengthens the integrity of pharmaceutical supply chains. By creating an immutable and transparent ledger for recording transactions, blockchain technology provides a robust foundation for combating counterfeit drugs and falsified medications, thereby safeguarding patient safety and industry reputation (Kumar, 2023).

1.7 CHALLENGES AND REGULATORY CONSIDERATIONS

Despite its potential benefits, the widespread adoption of blockchain technology in the pharmaceutical industry faces several challenges and regulatory considerations. These include data privacy regulations, interoperability standards, and technological complexities. Moreover, the decentralized nature of blockchain networks requires stakeholders to collaborate effectively and align their interests to ensure the seamless integration of blockchain-based solutions into existing workflows (Uddin et al., 2021).

Regulatory compliance is another key aspect to consider, particularly in the context of pharmaceutical traceability and security. The Drug Supply Chain Security Act (DSCSA) of 2023 mandates stringent requirements for traceability and verification within the pharmaceutical supply chain, necessitating the adoption of scalable and interoperable technologies (Uddin et al., 2021).

Furthermore, technological advancements and regulatory frameworks evolve rapidly, requiring stakeholders to remain agile and adaptable in their approach to implementing blockchain-based solutions. Collaborative efforts among industry players, regulatory authorities, and technology providers are essential to overcoming these challenges and realizing the full potential of blockchain technology in enhancing pharmaceutical traceability and security (Uddin et al., 2021).

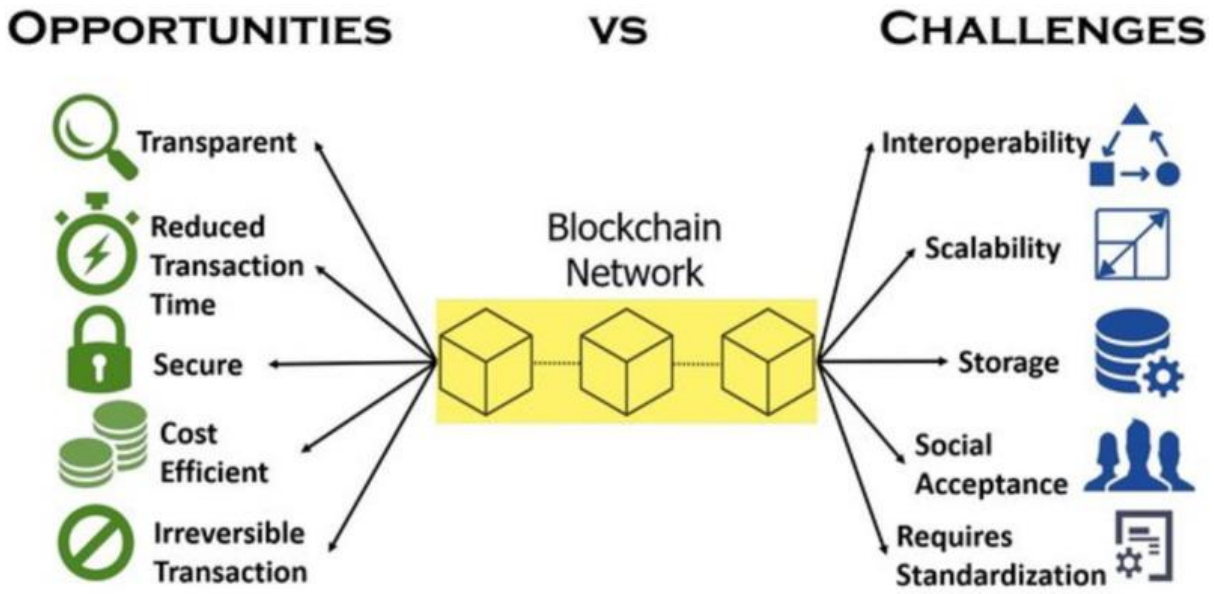

Figure 4:Advantages and Challenges of Blockchain Technology(Zakari et al.*, 2022)*

1.8 RESEARCH AIM

This research aims to underscore the vital role of blockchain-based digital identities in the Indian pharmaceutical industry, focusing on their necessity and practical implementation. By delving into associated benefits, challenges, and regulatory aspects, the study enhances pharmaceutical product traceability and security which are crucial in preventing falsified medications and counterfeit drugs.

1.9 RESEARCH OBJECTIVES

1. To investigate the current state of pharmaceutical product traceability and security in India.

2. To assess the necessity and feasibility of implementing blockchain-based digital identities in the Indian pharmaceutical industry.

3. Examine the potential benefits of blockchain-based digital identities in enhancing traceability and security within the pharmaceutical supply chain.

4. Analyse the challenges and regulatory considerations associated with the practical implementation of blockchain-based digital identities.

5. To propose strategic recommendations based on the findings to contribute to the effective prevention of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain.

1.10 RESEARCH PURPOSE

By investigating the current state, feasibility, benefits, challenges, and regulatory aspects of blockchain-based digital identities, the study seeks to provide valuable insights and strategic recommendations for enhancing the integrity of the Indian pharmaceutical sector. The study will provide insights into the potential benefits and challenges of considering blockchain-based digital identities for pharmaceutical product traceability and security. The consequences of patients taking falsified and counterfeit medications will also be discussed in the study. Apart from that, the regulatory considerations associated with the implementation of blockchain-based digital identities will also be discussed. The findings and conclusions from this study would help the researchers and healthcare professionals to use blockchain technologies to identify falsified and counterfeit drugs thereby increasing the traceability and security of these drugs. The current state of pharmaceutical product traceability and security in India and their advancements can be well identified and studied from this research study. The study can also help to create awareness in healthcare sectors regarding the implementation of blockchain technologies.

1.11 SIGNIFICANCE OF THE STUDY

The study was taken into consideration as it had a significant impact on the Healthcare sectors in India. This topic is highly relevant since after the COVID-19 pandemic, falsified and counterfeit medications are rapidly growing in the Indian Pharmaceutical industry. Falsified medications and counterfeit drugs pose serious threats to public health, potentially leading to

treatment failures, adverse reactions, and even fatalities. By enhancing traceability and

security in the pharmaceutical supply chain, the study aims to mitigate these risks and safeguard the well-being of consumers. By investigating the feasibility and benefits of blockchain-based digital identities, the study contributes to fostering transparency and accountability within the industry. Understanding the regulatory considerations associated with implementing blockchain-based solutions is vital for ensuring compliance with existing laws and regulations. The study can provide valuable insights into navigating these regulatory hurdles effectively. The security of patients and their personal data can be made secure by the implementation of Blockchain based digital identities. The potential advantages of blockchain technology can be explored and the ideas for solving the challenges for blockchain implementation can be obtained through the study.

1.12 RESEARCH QUESTIONS

1. How effective is the current traceability and security system for pharmaceutical products in India?

2. What are the existing challenges and vulnerabilities in the Indian pharmaceutical supply chain in terms of product traceability and security?

3. What specific benefits can be derived from the adoption of blockchain-based digital identities in improving traceability and security within the pharmaceutical supply chain in India?
4. What are the potential regulatory hurdles and considerations that need to be addressed when implementing blockchain-based digital identities for pharmaceutical products in India?

5. How can blockchain-based digital identities contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?

6. Based on the research findings, what strategic recommendations can be proposed to facilitate the successful implementation of blockchain-based digital identities and enhance traceability and security in the Indian pharmaceutical industry?

1.13 DISPOSITION OF THE STUDY

This dissertation comprises of five chapters and each chapter focuses to attain the research goal.

Chapter 1: Introduction

This section introduces the research topic, provides background information, states the research aim, objectives, research questions and outlines the significance of the study.

Chapter 2: Literature Review

The existing literature related to the research topic is reviewed and synthesized which mainly concise the findings and gaps. It explores the Traceability and Security of Pharmaceutical Products in India, necessity and feasibility of implementing blockchain-based digital identities in the Indian pharmaceutical industry, potential benefits of blockchain-based digital identities in enhancing traceability and security within the pharmaceutical supply chain, Challenges and regulatory considerations in the implementation of blockchain-based digital identities.

Chapter 3: Research Methodology

It outlines the study design, paradigm technique, conceptual framework, methods of data collection, ways to analyse the collected data along with ethical considerations and justifications.

Chapter 4: Findings and Analysis

The results obtained from the primary data sources are explained here. The findings of the study are often expressed using tables, charts, or graphs to illustrate quantitative data. In this section the results of qualitative and quantitative data are also included.

Chapter 5: Conclusions and Recommendations

The key findings and their implications for the research questions are discussed in this chapter. A nutshell of the differences in key findings from the literature and the study conducted is explained here. Details regarding limitations, recommendations, and suggestions for future research in this area are also included.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

The aim of literature review is multifaceted which include understanding the current state of knowledge, identifying gaps in knowledge, formulating research questions and hypothesis, providing methodological insights, decision making, and to contextualize research finding. It will help readers to comprehend properly before starting the research.

2.2 CONCEPT OF BLOCKCHAIN TECHNOLOGY

Blockchain technology, commonly linked with cryptocurrencies like Bitcoin, serves as a distributed ledger of transactions validated and maintained by a global network of computers. Unlike centralized databases, blockchain lacks a single controlling authority, instead of relying on a decentralized structure where records are supervised collectively, preventing alteration or deletion of transaction histories. Transactions are authenticated through computer algorithms, and upon verification, they are added to the blockchain as a linked chain of transactions. Originating from papers discussing distributed ledger concepts in cryptography, blockchain evolved with the introduction of electronic cash models by David Chaum and protocols like hashcash by Adam Back to combat spam emails. Satoshi Nakamoto's 2008 paper on Bitcoin marked a breakthrough, proposing a peer-to-peer electronic cash system, addressing the double spending issue through cryptography and a public ledger. The subsequent release of Bitcoin's open-source program in 2009 initiated the first bitcoins, leading to the proliferation of cryptocurrencies, with Bitcoin emerging as the dominant player due to its transparency and anonymity features. Ethereum, launched in 2015, expanded blockchain's utility by introducing smart contracts, facilitating secure and efficient transactions beyond currency exchange. This technological advancement led to widespread adoption, positioning blockchain as a transformative force in various sectors beyond finance (Sarmah, 2018). Block chain based digital identity encapsulates an individual's or entity's online representation, setting them apart. Identity theft involves unauthorized use of personal data, often for fraudulent purposes. Verification processes often demand supplementary identity details. Essentially, digital identity acts as a virtual document storage, facilitating easy access and sharing of official documents like government IDs and academic certificates across online platforms. This centralized repository serves both public and private needs, ensuring efficient document management and verification processes (Devi *et al.*, 2022).

Today, blockchain technology continues to evolve, with its third generation broadening its application areas beyond banking and finance to encompass sectors like healthcare, government, and science. This rapid evolution underscores blockchain's potential to revolutionize various industries by providing transparency, security, and decentralization in transactions and record-keeping processes (Tripathi et al., 2023).

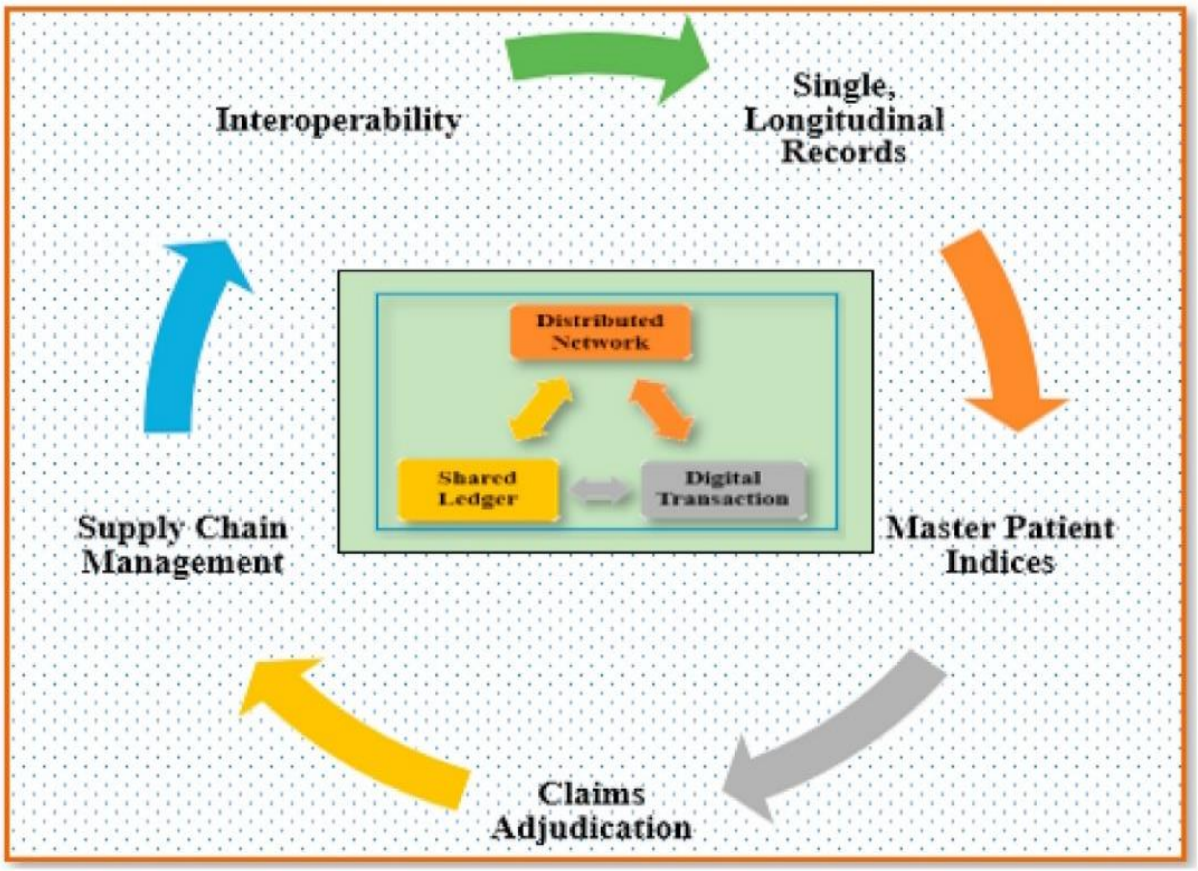

Figure 5: Integrated workflow process of Blockchain Technology (Habiba, 2021)

Blockchain ensures security, data integrity, and real-time access, crucial for personalized medicine and wearables. Implementation of Blockchain resolves safety concerns, providing a secure means for recording, transmitting, and accessing medical data, ultimately enhancing healthcare delivery and research efforts (Haleem *et al.*, 2021).

2.3 THE CURRENT INDIAN CONTEXT OF PHARMACEUTICAL TRACEABILITY AND SECURITY

Access to quality medicines is crucial for India's population of over 1.24 billion, with the right to health recognized in the national constitution and international laws. However, approximately one-third of the global population lacks access to essential medicines, posing significant challenges, particularly in low and middle-income countries like India. Despite the Indian government's efforts to provide free generic medicines to certain categories of patients, the prevalence of poor-quality drugs remains a serious concern. Poor quality drugs, including counterfeit and substandard products, pose a grave threat to public health, leading to treatment failure, antimicrobial resistance, and even death. India, being the largest manufacturer of generic drugs, faces challenges in accurately assessing the extent of the problem due to gaps in data and limited comprehensive studies. Regulatory measures have been implemented, such as amendments to the Drug and Cosmetic Act, strengthening of surveillance mechanisms, and public participation initiatives. However, there is a pressing need for stricter regulations, policies, and legal actions to effectively combat the issue. Promotion of generic medicines and initiatives like the Jan Aushadhi Campaign are steps in the right direction, but more research and action are required to safeguard public health and maintain trust in the healthcare system (Khan and Khar, 2015). Despite the growing awareness, up to 155,000 childhood deaths are annually attributed to falsified anti-malaria drugs and substandard antimicrobials. The economic impact of poor-quality medicines in Low- and Middle-Income Countries (LMICs) ranges from US$10 billion to US$200 billion, affecting approximately 10% of all medicines. Lifestyle drugs and antibiotics are also common targets for falsification due to high demand and market value. Online pharmacies exacerbate the issue by selling counterfeit and unregulated medicines, contributing to public health crises (Nayyar *et al.*, 2019).

2.4 COUNTERFEIT DRUGS

Counterfeit drugs come in various forms, each with its own set of consequences. These fraudulent medications may contain no active ingredient, insufficient active ingredient, a wrong active ingredient, or even potentially harmful substances. Some may also feature fake packaging to deceive consumers. Mislabeled medications, where drugs are sold under the guise of another brand, further exacerbate the problem. Counterfeit drugs containing the correct dose of the active ingredient, though constituting only a small percentage of fraudulent medicines, still pose risks due to their poor quality and lack of adherence to manufacturing standards. Variations in dissolution profiles and undocumented inactive ingredients can compromise the drug's efficacy and even pose health hazards. Mislabeled medications add another layer of complexity, as they deceive consumers with fraudulent

packaging and labelling information. Counterfeit drugs with incorrect doses of active ingredients can lead to serious health complications, particularly in the case of antibiotics, where low doses may foster the development of antibiotic-resistant strains (Gupta *et al.*, 2012). India ranks as one of the primary exporters of counterfeit medicines globally, with reports consistently identifying it as a major source, closely followed by China. A 2017 study by the World Health Organization (WHO) revealed that approximately 20 to 30% of medicines in India are counterfeit, based on the analysis of samples collected nationwide (Mamtashanti *et al.*, 2020). The business of drug counterfeiting is thriving in India due to several factors, including the rapid expansion of the pharmaceutical industry, inadequate regulation, high drug prices, value-added tax, prescription of unregistered drugs, and limited public awareness. The flexible legal framework and weak enforcement of regulations further exacerbate the issue. India's reputation as a low-cost manufacturing hub attracts counterfeiters who exploit the lack of heavy research and development costs incurred by genuine manufacturers, thus yielding significant profits. Detecting counterfeit drugs is challenging and expensive, as consumers and even prescribing physicians often struggle to distinguish between genuine and fake products. Counterfeiters continuously enhance their methods, utilizing advanced printing technologies like holograms to deceive consumers. Demand exceeding supply in the pharmaceutical industry incentivizes criminals to profit from manufacturing and distributing counterfeit drugs. Additionally, inappropriate use of medicines by consumers fuels demand for counterfeit products, such as weight supplements containing steroids. Illicit distribution channels and unauthorized markets contribute to the circulation of counterfeit drugs at inflated prices. Moreover, lax regulation of drug exports, especially through free trade zones, facilitates the entry of counterfeit drugs into distribution channels. Insufficient legislation and regulations create loopholes for counterfeiters to exploit, as a significant portion of countries lack robust drug regulatory authorities and effective control measures (Verma *et al.*, 2014).

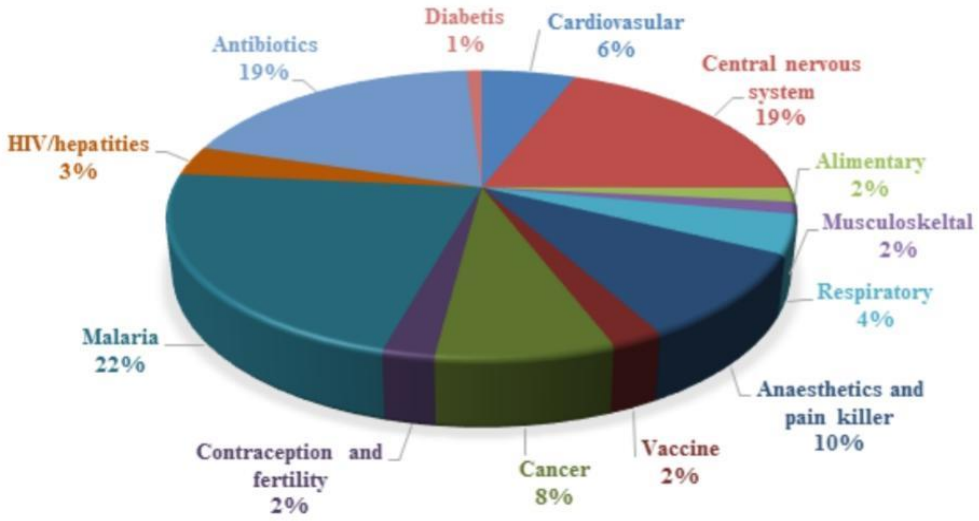

Figure 6: Counterfeit drugs with its therapeutic class (Mamtashanti et al.*, 2020)*

Pharmaceutical companies in India face substantial financial losses due to drug counterfeiting, with estimates suggesting losses of nearly $200 billion annually. The availability of counterfeit drugs undermines the integrity of the pharmaceutical industry and jeopardizes patient safety. Companies must focus on preventing counterfeiting at various stages of the supply chain and raising awareness among stakeholders. Regulatory bodies in India, like the Drug Technical Advisory Board (DTAB) and the Central Drugs Standard Control Organisation (CDSCO), have implemented measures to address counterfeit drugs. These include requiring unique identification numbers and barcodes on drug packaging to verify authenticity. Global regulatory authorities must collaborate and devise strategies to prevent drug counterfeiting internationally. Despite efforts to address counterfeit drugs, challenges remain. There are gaps in regulatory oversight and enforcement, particularly in developing countries like India. Limited resources and infrastructure hinder effective monitoring and surveillance of the pharmaceutical supply chain. Additionally, there is a need for further research to obtain accurate data on the prevalence of counterfeit medications in India. Mandating the use of newer technologies and active collaboration between stakeholders are crucial steps in preventing drug counterfeiting. Modern technologies, such as overt, covert, and track-and-trace technologies, are being employed to prevent drug counterfeiting. These technologies enhance packaging verification and supply chain transparency, making it easier to track and trace drugs. Blockchain technology shows promise in improving supply chain management and preventing counterfeiting. Its decentralized

nature ensures transparency and security, making it difficult for counterfeiters to tamper with records (Pathak *et al.*, 2023).

2.5 BLOCKCHAIN IMPLEMENTATION

Blockchain technology, characterized by decentralization and transparency, offers a controlled and secure approach to detect fake medicines in the pharmaceutical supply chain. This system empowers pharmaceutical companies to monitor and manage the distribution of drugs, mitigating the threat posed by counterfeit and unregistered medications, which endanger human lives and can lead to severe health complications or even death. By implementing blockchain alongside sensors and connected supply chain environments, cloud-based platforms enable real-time data sharing for drug traceability and security, enhancing patient safety and industry efficiency through collaborative information sharing and expert opinions (Kumar, 2023). It's undeniable that Blockchain technology has garnered significant attention as a potential solution to these challenges due to its ability to provide transparent, immutable, and secure data management across supply chains. However, despite the growing interest in blockchain technology, there remains a need for a comprehensive analysis of its application in the pharmaceutical sector. A systematic literature review (SLR) was conducted to identify relevant studies on blockchain technology in the pharmaceutical industry. Search criteria included keywords related to blockchain, pharmaceuticals, supply chain management, counterfeit drugs, and safety and security. Studies were screened based on relevance to the research objectives, resulting in the selection of 38 primary articles for analysis. The analysis revealed that counterfeit drug prevention is the most frequent category addressed in the literature, accounting for 45% of the included studies. Other prominent areas of blockchain application in the pharmaceutical sector include tracking and tracing, product distribution, safety and security. Various blockchain-based solutions have been proposed to address these challenges, ranging from drug supply chain management systems to smart contracts and Internet of Things (IoT) integration. Blockchain-based solutions for counterfeit drug prevention include drug supply chain management systems, decentralized applications for traceability, and simulation frameworks for biopharmaceutical supply chains. These solutions leverage blockchain's transparency and immutability to ensure the authenticity and integrity of drug data throughout the supply chain. The distribution of pharmaceutical products involves multiple parties and lacks comprehensive tracking mechanisms, leading to challenges such as counterfeit drug circulation. Blockchain technology offers solutions to improve product distribution through serialization, smart contracts, and distributed ledger systems (Zakari *et al.*, 2022).

To incorporate blockchain technology into the pharmaceutical supply chain system, it's imperative to grasp the underlying workings of a blockchain ledger. Blockchain inherently employs an identity mechanism through cryptographically secure key pairs, granting each participant specific activity permissions on the network. Participants, which can range from devices to individuals or entities, are

identified solely by these keys, concealing their original identities. Key pairs contain no inherent participant information, but additional details such as names or professional credentials can be associated with them. It's advisable to maintain this supplementary information off-chain and merge it with on-chain data using unique IDs. In the context of pharmaceutical supply chain management, participants like manufacturers, packagers, distributors, and doctors are identified by unique key pairs. Each drug is considered an asset, with a unique key or hash attached, often in the form of a QR code. With this foundational understanding, the proposed system's implementation can vary based on preferences, with numerous third-party Application Programming Interface (APIs) available for pushing data and transactions to blockchain networks. These APIs offer a range of services, but regardless of the chosen programming language or API, the system's basic architecture remains consistent. Selecting the appropriate blockchain network for storing transactions is critical, with two main types available: public and permissioned (or private) blockchains. In a permissioned blockchain, only participants with access can read or write to the blockchain, making it suitable for pharmaceutical supply chain management. Ethereum's permissioned blockchain is recommended for this purpose, although other options like Bitcoin, Hyperledger, or BigchainDB are available. Once a secure and trusted network is established, only trusted parties are granted permission to join, and a permissioned blockchain is utilized to store transactions securely. A user-friendly mobile app is provided for participants to interact with the blockchain, enabling seamless transaction management. When a factory produces a new product, a unique hash is created and assigned to it, registering the product on the blockchain. This product becomes a digital asset on the blockchain, tracked using its hash. Additional product information can be stored off-chain or on-chain, with off-chain data merged using identifiers. For instance, a hash digest of off-chain data is typically generated and linked to on-chain data. The mobile app facilitates easy ownership transfer of registered products between participants, with each transaction recorded on the blockchain. When a doctor or other participant seeks to purchase drugs, they can query the drug's ID through the mobile app to verify its journey from manufacturer to pharmacy. If genuine, the app displays the drug's complete history; otherwise, no record is shown, ensuring authenticity and transparency throughout the supply chain process (Haq and Muselemu, 2018). Another method is the Drug Supply Chain Management and Recommendation (DSCMR) mechanism, which involves various participants such as suppliers, manufacturers, distributors, pharmacies, hospitals, doctors, and patients. These participants interact within a blockchain-based system, where data related to users, suppliers, orders, and drug records are securely stored. Each user accesses the system through a client application, allowing them to perform transactions and communicate with the blockchain network. Throughout the DSCMR process, participants can track the status of drug delivery using the client application, while a separate data storage pool, known as stored-off blockchain, facilitates analytics, visualization, and machine learning model integration. The architecture ensures data consistency through peer nodes responsible for running the consensus algorithm, validating transactions, and maintaining a single transaction history.

For instance, when a manufacturer places an order for raw materials, any peer node can validate the transaction, ensuring its accuracy and authenticity. Similarly, doctors can securely place orders for medications through the blockchain system, with each step of the transaction process meticulously validated and recorded. The system's primary goal is to prevent counterfeit drugs and provide a secure supply chain management experience for users, leveraging blockchain's security and integrity features. Channels are introduced to establish separate private networks between nodes, ensuring data privacy and security (Haq and Muselemu, 2018).

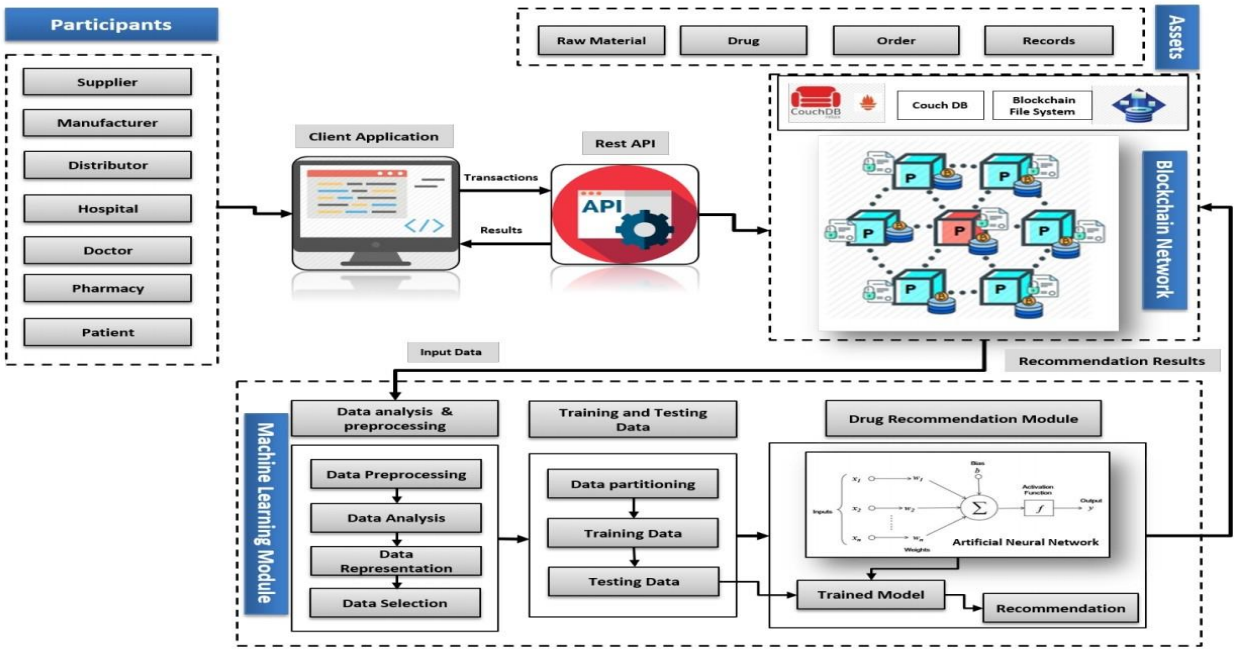

Figure 7: Architecture of DSCMR System (Abbas et al., 2020)

For example, patients can verify the authenticity of drugs they purchase by scanning the barcode, and accessing relevant information such as manufacturer details, manufacturing and expiry dates, and prices. The machine learning-based recommendation system further enhances the system's capabilities by recommending the best medicines to pharmaceutical company customers based on sentiment analysis and customer feedback. Notably, the proposed system stands out from existing solutions by offering both supply chain management and medication recommendation functionalities, all within a permissioned blockchain network. Users are validated and enrolled by user administrators, and the consensus algorithm ensures the integrity and consistency of transaction records stored in the distributed ledger (Abbas *et al.*, 2020).

2.6 APPLICATIONS OF BLOCKCHAIN IN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry faces significant costs in drug discovery and research, necessitating collaborative approaches among multiple companies to innovate faster and manage expenses. Blockchain technology offers a promising platform for facilitating trusted information exchange and collaboration. It can provide secure digital proof of Intellectual Property (IP) through immutable records and time-stamping, enhancing transparency and integrity in research. Moreover, blockchain enables competitive sharing of clinical trial data, accelerates research, and ensures proper outcome validation. Additionally, blockchain-based solutions address challenges in IP management, clinical trial management, and overall research collaboration. In IP management, blockchain solutions offer secure management of digital trails and prioritize safeguarding IP. In clinical trials, blockchain enhances patient recruitment, ensures data integrity, and expedites drug development (Katuwal *et al.*, 2018). Nearly 80% of medical studies lack reproducibility due to errors like fraud and data misrepresentation. Improving research quality not only ensures better reproducibility but also facilitates secure data sharing among research communities. Blockchain technology can address patient identity and privacy concerns by offering a decentralized data tracking system that fosters trust among stakeholders involved in clinical trials (CTs). It also enhances transparency between physicians and patients. Blockchain provides features like data traceability to enhance drug safety throughout a CT's lifecycle. It ensures compliance with Good Clinical Practice (GCP) and regulatory standards, thus improving competitiveness through transparency, accessibility, and trackability.

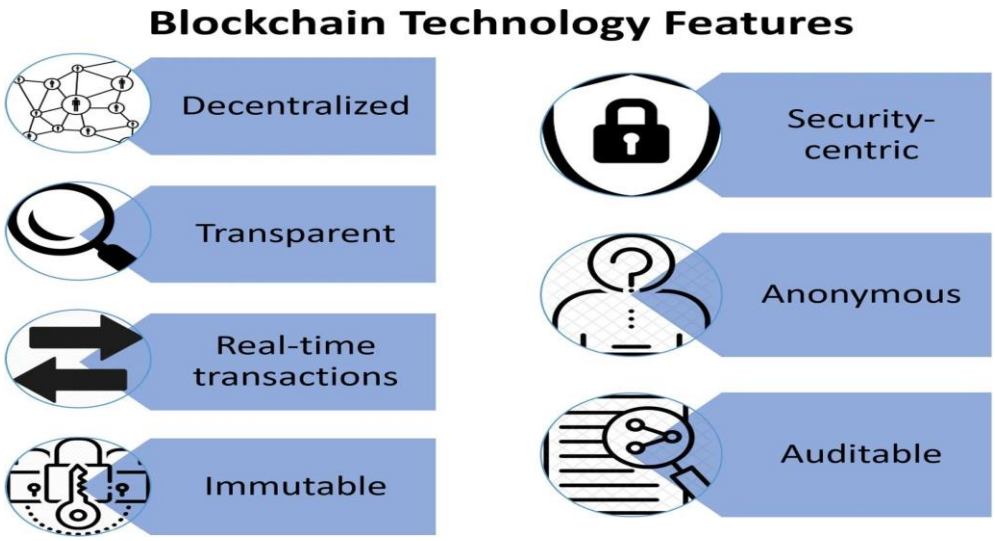

Figure 8: Applications of Blockchain Technology in Pharma (Omar et al.*, 2021)*

Patient recruitment, often a laborious process consuming up to 30% of the clinical timeline, can be significantly expedited with blockchain. Distributed ledgers connect patients and trial sites anonymously, streamlining participant selection based on protocol criteria. Medical data sharing faces challenges, with approximately 90% of trials failing to produce desired results. Blockchain solutions offer secure tracking systems, enabling participants to access real-time CT status updates. Patient identity protection is enhanced through encrypted addresses linked to their identity, accessible only with consent or through physician oversight during the CT (Omar *et al.*, 2021). Traceability refers to the ability to access all information pertaining to an object throughout its lifecycle using recorded identifications. The object, known as a Traceable Resource Unit (TRU), can be any traceable item within the supply chain. The objectives of traceability are to monitor transaction history and track the real-time location of TRUs. Traditional methods in supply chain management, such as barcodes, RFID tags, and Wireless Sensor Networks (WSN), have been used to capture data and facilitate product tracking. Smart-Track, for instance, employs GS1 standard barcodes with unique serialized product identifiers and lot production and expiration dates. Conventional approaches to traceability in the pharmaceutical supply chain are typically centralized and lack transparency among participants, allowing the central authority to modify information without informing others. In contrast, blockchain-based solutions offer data security, provenance, and authenticated transaction records (Musamih *et al.*, 2021)**.** The adoption of blockchain technology in Pharmaceutical Supply Chain Management (PSCM) heralds a paradigm shift from traditional methods, offering a plethora of advantages over conventional systems. Blockchain-infused PSCM revolutionizes transparency by enabling all stakeholders to monitor network changes, thereby enhancing supply chain efficiency and expediting issue identification. This heightened transparency fosters trust among participants, obviating the need for mutual trust and reliance on intermediaries. Furthermore, the adaptability of blockchain systems ensures swift responses to emerging challenges without incurring additional operational costs, thereby promoting market sustainability. By governing rules and monitoring channels, blockchain systems instill a sense of control and accountability, further bolstering trust in the system. Looking ahead, the future of blockchain in Procurement and Supply Chain Management is promising, with potential applications across various industries including food, automotive, and pharmaceutical supply chains. Particularly in pharmaceutical Supply Chain Management, blockchain holds immense potential in combating the proliferation of counterfeit drugs, safeguarding human lives, and bolstering the integrity of the supply chain. Through enhanced traceability and security measures, blockchain

technology offers a beacon of hope in addressing the pressing challenges faced by the pharmaceutical industry, propelling it towards a future of transparency, efficiency, and trustworthiness (Dwivedi *et al.*, 2020). The Traditional patient billing systems have also faced fraud and inefficiencies, often due to complex coding leading to billing errors. Integrating blockchain with computer-assisted coding can streamline this process. Blockchain ensures secure and efficient payment processing, contrasting with slow traditional methods, especially in insurance claims. By storing data immutably, blockchain expedites insurance claim payments, reducing resource usage, time, and costs (Yaqoob *et al.*, 2022).

2.7 REGULATORY CONSIDERATIONS AND CHALLENGES IN IMPLEMENTATION OF BLOCKCHAIN TECHNOLOGY

The transition from the current electronic health system to blockchain technology entails evaluating the volume and size of transactions processed through the network. However, several factors need assessment before implementation, including hardware and software setup, as well as ongoing support requirements. A notable drawback of blockchain is its inefficiency in handling data with high temporal resolution and multi-dimensional data such as complex text, images, and graphs. On an organizational level, the existing Electronic Health Record (EHR) system contains comprehensive health information gathered from various healthcare providers, fueled by substantial investments from academic institutions and government incentives. The significant financial and logistical investment in HER makes it economically unfeasible to expect hospitals and clinics to entirely replace their current record systems with blockchain technology. Instead, blockchain could complement the existing system by serving as a framework for connected data blocks, albeit not as a complete replacement. While most healthcare data would remain off the blockchain, each block could contain essential information about specific patients or procedures. However, the challenge lies in determining how to store current record data on the blockchain and establishing a universally recognized standard format for demographic information. Moreover, organizations must align on defining the data, size, and format acceptable for submission. Additionally, the implementation of blockchain technology necessitates addressing organizational issues, particularly managing the transition for employees involved in the change process. Regulatory and privacy concerns pose significant barriers to blockchain adoption in healthcare. Government institutions have yet to resolve regulatory uncertainties surrounding blockchain, and widespread adoption depends on substantial buy-in from global healthcare stakeholders. The culture shift required for embracing blockchain technology in

healthcare necessitates overcoming regulatory hurdles and fostering acceptance among industry participants (Attaran, 2020).

In India, exploring the potential of blockchain technology in healthcare requires understanding the legal framework governing healthcare. The Reserve Bank of India (RBI) has expressed concerns about cryptocurrency, a prominent application of blockchain, citing issues like financial stability and money laundering. Despite its popularity, cryptocurrency faces legal hurdles in India. Healthcare, a burgeoning sector, poses challenges due to diverse stakeholders and data privacy concerns. Unlike European states, India lags in collective data security efforts. Present laws, initially designed for cryptocurrencies, inadequately address healthcare issues. The Personal Data Protection Bill (PDPB) aims to regulate data handling, mirroring aspects of the EU's General Data Protection Regulation (GDPR) but with broader scope and government disclosure provisions. Health data receives special protection under the PDPB. Implementing the PDPB poses challenges amidst India's socio-economic landscape. Introducing blockchain 4.0 in Indian healthcare faces strategic hurdles within the traditional ecosystem. Adoption requires stakeholders' acceptance and integration into existing technical infrastructure. Blockchain promises benefits like data portability, interoperability, and cost-effective administration. Adopting blockchain could improve healthcare and treatment. However, India's legal landscape, rooted in conventional laws, may hinder large-scale blockchain integration. The effectiveness of blockchain in India hinges on overcoming regulatory and infrastructural challenges (Chakrabarty and Mukherjee, 2022).

Interoperability issues arise when standards are disregarded, hindering seamless data sharing among users. Uncertainty surrounds blockchain's nascent state, requiring clear specifications for successful initiatives. Storage capacity strain arises due to the vast volume of medical data, potentially overwhelming current blockchain systems. Cost considerations, including establishment and maintenance expenses, remain unclear, impeding widespread adoption until organizations grasp the technology's financial implications. Addressing these challenges is crucial for the successful integration of blockchain in uncertain healthcare scenarios (Sami Ullah *et al.*, 2020). Major pharmaceutical companies often avoid investing in and establishing production units in developing countries due to geopolitical factors, market inaccessibility, and government instabilities. Instead, they prioritize manufacturing and distributing branded medicines in developed countries like the USA and Europe, leveraging higher per capita incomes and pricing monopolies. Challenges faced by developing countries in attracting

pharmaceutical industry investments include poor infrastructure and insufficient government funding for research and infrastructure improvements. Existing pharmaceutical units struggle to meet global standards due to the need for significant investments in new production and packaging machinery. Implementing digital pharmaceutical product traceability requires additional space in manufacturing units for specialized packaging equipment, barcode printers, and vision systems, necessitating substantial financial investment. Furthermore, technology advancement poses challenges in developing countries for authenticating and tracing pharmaceutical products digitally. Serialization regulations adopted by developed countries, like the US and Europe, mandate drug manufacturers to print unique identifiers, such as 2D barcodes, on individual drug units for authentication and traceability. However, implementing serialization requires substantial investment in secure networks, high-speed internet, skilled resources, and fully digital warehouses. Limited technical capabilities and inconsistent regulatory standards hinder drug manufacturers in developing countries, like India, from complying with serialization requirements, leading to operational challenges and disruptions in pharmaceutical distribution.

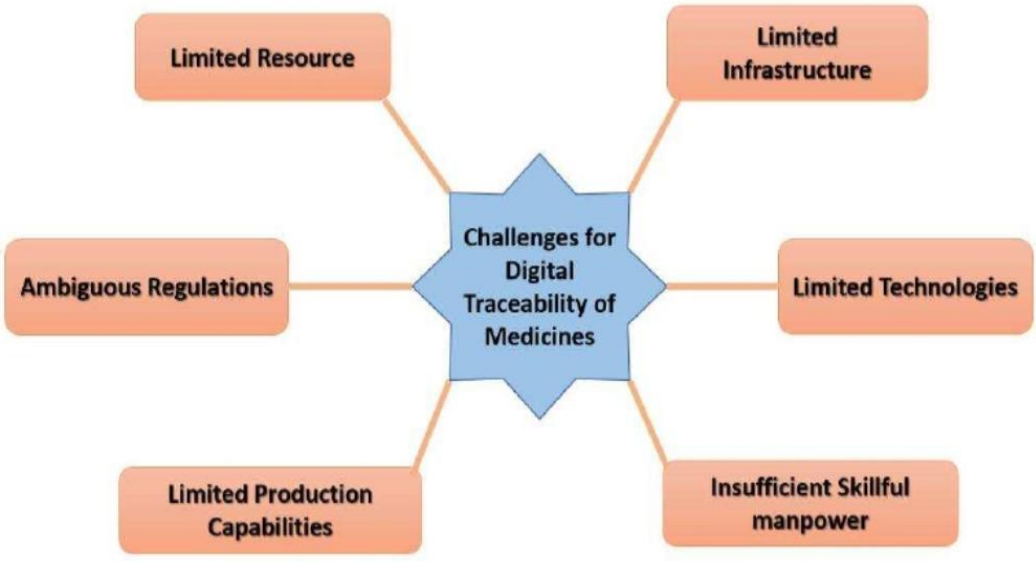

Figure 9: Challenges for Implementing Digital Drug Traceability in Developing Countries (Chakrabarty and Mukherjee, 2022).

Regulatory obligations also play a crucial role in implementing track and trace systems for drug traceability. Developed countries conduct pilot programs with the collaboration of stakeholders to understand industry status, challenges, and improvement requirements before

enforcing regulations. However, developing countries often lack focus on pilot programs and conduct policies without adequate due diligence, resulting in confusion and inefficiencies in compliance. Additionally, insufficient techno-functional resources pose a challenge to implementing and sustaining drug traceability systems, particularly in combating drug counterfeiting. The low technical literacy rate in developing countries further exacerbates this issue, hindering the effective implementation of serialization and drug traceability processes. Ultimately, addressing these challenges requires concerted efforts from stakeholders to ensure the safety and authenticity of pharmaceutical products in supply chains (Sarkar, 2022).

The integration of blockchain technology across various sectors has led companies to incorporate it into their operations, driven by its numerous benefits. While existing literature has examined challenges associated with blockchain adoption in various industries, there's a gap regarding specific challenges in the pharmaceutical sector. The study conducted by Riedel and Velamuri (2024) investigates the obstacles hindering blockchain adoption in the pharmaceutical industry to improve sustainability performance. The Fuzzy Interpretive Structure Model (FISM) analysis method was utilized to create a hierarchical model and establish relationships among these factors. A MICMAC (Cross-impact matrix Multiplication applied to classification) analysis was then applied to categorize factors into four clusters based on their driving and dependence power. This study lays the foundation for future research and provides a comprehensive overview of blockchain adoption challenges in the pharmaceutical industry through the integrated FISM-MICMAC approach. The findings offer valuable insights for industry practitioners and government policymakers, aiding in the selection of effective solutions to overcome challenges and ensuring long-term success and competitiveness. Additionally, the proposed FISM model assists business managers in devising operational strategies to tackle blockchain adoption challenges, providing clarity on the hierarchy of factors and enabling the formulation of competitive strategies based on their driving and dependence power. This approach allows organizations to gain a clear understanding of factors before adopting blockchain into their operations and empowers them to develop effective strategies accordingly.

Governance issues arise from the need for interoperability across both public and private blockchain networks, emphasizing the importance of globally coordinated standards and agreements spanning international borders and jurisdictions. However, the lack of legislation poses difficulties in establishing appropriate regulations governing ownership rights and

governance for medical transactions. Addressing ownership concerns, data access rights, and the distributed storage structure of blockchain within the existing regulatory framework presents a complex task, especially given the evolving nature of digital governance objectives. Transparency and privacy concerns emerge due to blockchain's inherent transparency, which may conflict with the privacy requirements of healthcare data. While encryption provides security, the availability of encrypted databases raises apprehensions among healthcare stakeholders. Hence, ensuring proper access control mechanisms within the blockchain context becomes crucial to maintaining privacy standards. Sustainability is another critical challenge, particularly concerning the management of encryption keys. In healthcare, the irrevocable nature of private encryption keys poses durability issues, as the loss or theft of keys can compromise the integrity and reliability of patient health records. Furthermore, scalability challenges arise as the blockchain expands with added data, increasing storage and computational demands. Failure to meet these demands could lead to centralization and slower data processing, undermining the decentralized nature and efficiency of the blockchain network. Continuous resource availability for maintenance, troubleshooting, and updates remains essential for the sustained operation of integrated blockchain-based healthcare systems (Gökalp *et al.*, 2018). The intricate nature of the blockchain due to the complex use of cryptography as its operational mechanism poses difficulties in implementation. Additionally, to fully leverage its anti-fragility benefits, a substantial network of users with widely distributed nodes is required, posing challenges in achieving complete advantage and resilience against attacks. As the healthcare blockchain network expands, transaction costs and network speed become increasingly problematic. Each node in the blockchain maintains consensus across its structure, ensuring fault tolerance, zero downtime, and immutable and censorship-resistant data storage. However, this comes at the expense of slower and costlier computation compared to traditional systems. The utilization of blockchain as a healthcare database demands high-quality, trustworthy, and accurate data recording systems. Continuous monitoring is essential to prevent security flaws resulting from the possibility of incorrect information being accepted as accurate. Transaction throughput is constrained by the need for verification of each participating node, leading to extended transaction times and scalability challenges. Interoperability issues arise, hindering effective data sharing among different service providers and seamless communication between them. Despite its immutability, blockchain data remains vulnerable to potential privacy breaches. Moreover, blockchain faces threats from selfish miners colluding to manipulate data. These drawbacks underscore the need for careful consideration and

continuous improvement in the implementation and utilization of blockchain technology, particularly in healthcare settings where data integrity and security are paramount concerns (Aithal *et al.*, 2021).

2.8 LITERATURE GAP

The literature review on blockchain technology and its potential to enhance pharmaceutical security and traceability in the Indian context sheds light on various aspects of the Indian pharmaceutical sector, including counterfeit medications, blockchain adoption, and implementation challenges. However, several gaps in existing research merit further exploration.

Firstly, there is a noticeable lack of information concerning the current status of traceability and security measures for pharmaceuticals in India. Despite the prevalence of counterfeit drugs in the market, research addressing the specific challenges and potential solutions for enhancing traceability and security remains limited.

Furthermore, while challenges related to the adoption of blockchain technology in India have been identified, there is a dearth of research examining the regulatory and legal landscape governing blockchain within the pharmaceutical industry. Given the novelty of blockchain technology in the Indian context, there is a need for research that investigates how existing regulations influence the implementation of blockchain solutions and identifies the regulatory frameworks necessary for their successful adoption.

2.9 FUTURE PERSPECTIVES

Blockchain technology has the potential to revolutionize health information sharing, offering enhanced data privacy, improved patient care, higher healthcare quality, and more robust medical research. However, before widespread adoption, critical concerns must be addressed to ensure security and functionality. Healthcare organizations need to assess blockchain's suitability for their specific needs and equip clinicians with the necessary skills to effectively utilize these tools. While blockchain facilitates superior knowledge sharing, it's unrealistic to expect instant benefits post-deployment. Moreover, blockchain can safeguard the confidentiality of medical records, making them unalterable, thereby enhancing the documentation of medical errors and facilitating the monitoring of treatment effects through clinical trials (Singh *et al.,* 2022). To some extent, blockchain technology addresses the

challenge of fragmented data and isolated parties by creating a unified and immutable database, overcoming past legal constraints on medical information. The accumulation of valid data on the blockchain enhances the quality of the database, aligning with the emerging paradigm of data-driven AI medicine research and development fueled by advancements in big data and AI technologies. This paradigm involves autonomous learning from vast amounts of machine-generated data, enabling the optimization of drug development based on expert experience. By leveraging large-scale medical data, AI techniques like recurrent deep learning and algorithm optimization facilitate progress across various medical domains, including cases, images, and genes, while establishing standardized and reproducible medical protocols. Additionally, AI advancements in medicine have led to notable achievements, such as Insilico Medicine's development of a candidate drug system using Generative Adversarial Network (GAN) technology, which significantly shortened the drug development timeline compared to traditional methods (Hang *et al.*, 2022).

CHAPTER 3: RESEARCH METHODOLOGY

3.1 OVERVIEW

Research methodology is the backbone of the dissertation, providing the framework for how to gather, analyze, and interpret data to answer research questions and objectives. It provides a structured approach to identify the exact aim to explore. The chosen methodology determines the reliability and validity of the research (Abuhamda *et al.*, 2021). It helps in selecting the most suitable methods for data collection, such as surveys, and interviews.

Research methodology guides on selecting the sample size and sampling technique. It outlines the techniques and tools that can be used to analyze the collected data. Quantitative studies involve statistical methods, while qualitative studies use thematic analysis, content analysis, or grounded theory. It addresses issues of validity and reliability to ensure the credibility of findings. This includes strategies for ensuring the accuracy, consistency, and trustworthiness of the data and the interpretations drawn from it. Ethical considerations related to research participants, data collection, and data storage are also discussed. Research methodology outlines the timeframe and resources required to conduct the study effectively. It helps in planning and managing the research process efficiently within the available constraints. Finally, the research methodology justifies the chosen approach and acknowledges any limitations or constraints of the study. This enhances the transparency and rigor of the research process (Abuhamda *et al.*, 2021).

SERIAL NUMBER	PRIMARY DATA	QUANTITATIVE ANALYSIS	QUALITATIVE ANALYSIS
1	PHILOSOPHY	Pragmatism	Interpretivism
2	APPROACH	Deductive	Inductive
3	STRATEGY	Questionnaire: Designed via Microsoft Forms and distributed online	Direct and Zoom Interview
4	STRUCTURE	6 Sections comprising of 24 questions	20-30 minutes interview
5	SUBJECT	Qualified personnel working in Indian Pharmaceutical Industries	Doctors, Pharmacists, Nurses, Production and Supply Chain Managers

Table 1: Overview of Research Methodology

The Research Onion, proposed by Saunders et al., (2019) is a comprehensive framework that helps researchers understand the various layers involved in conducting research. Each layer namely philosophies, approaches, strategies, choices, time horizons, techniques and procedures represent different aspects of the research process, and understanding these layers can guide researchers in designing, conducting, and analyzing their studies effectively.

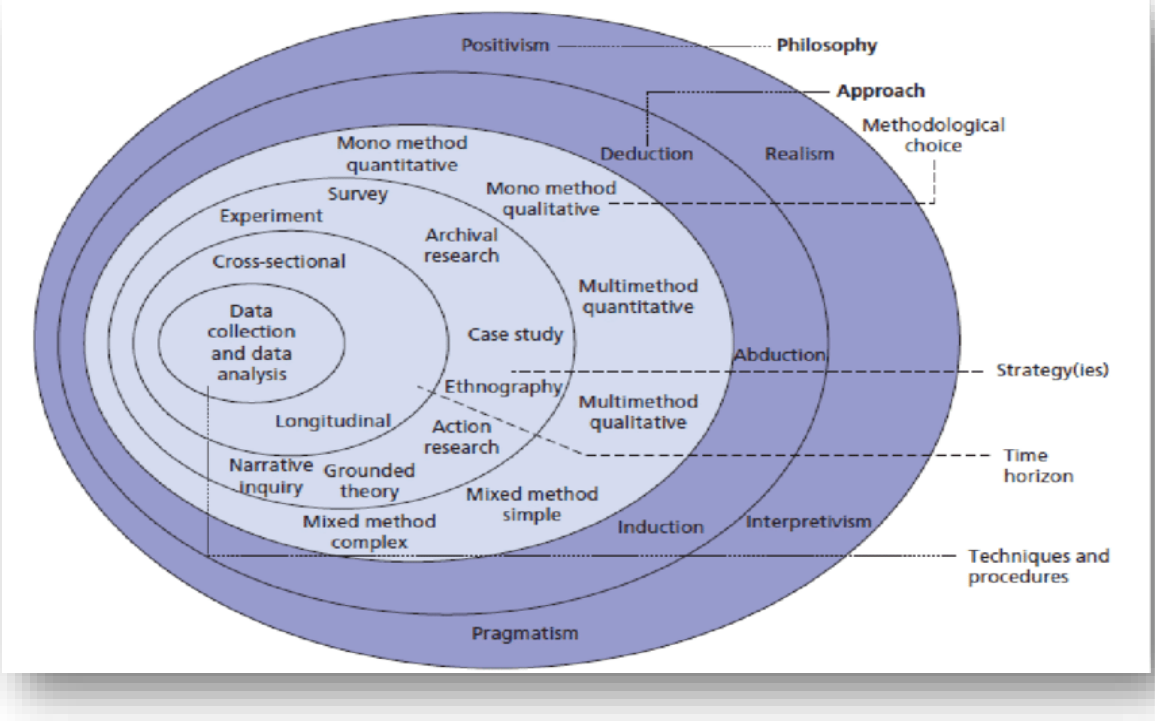

Figure 10: Research Onion (Saunders et al., 2019)

3.2 RESEARCH PHILOSOPHY

Research Philosophy refers to the set of beliefs concerning the nature of the reality being investigated. It is generally examined in terms of

- Ontology: Constitution of reality and understanding their existence
- Epistemology: It constitutes valid knowledge and measures to obtain it

The classification of research philosophy is tabulated below

RESEARCH PHILOSOPHY	DEFINITION
POSITIVISM	Positivism is based on the belief that knowledge should be derived from observable facts and phenomena. It emphasizes the use of scientific methods, such as experimentation and quantification, to uncover objective truths. It is mainly related to quantitative research.
REALISM	Uncovers both the objective structures of reality and the subjective interpretations of those structures. Realism influences choices regarding the level of abstraction in research questions, the balance between quantitative and qualitative data, and the integration of multiple perspectives in analysis.
INTERPRETIVISM	Represents an alternative philosophical perspective that emphasizes the subjective nature of reality and human experiences. Researchers focus on understanding social phenomena from the perspectives of the individuals involved, emphasizing context, meaning, and interpretation. They often employ qualitative research methods, such as interviews, focus groups, and ethnographic observation, to explore complex social processes and meanings.
PRAGMATISM	Researchers prioritize the usefulness and applicability of research findings, focusing on problem-solving and addressing real-world concerns. They are open to utilizing a variety of research methods and techniques, selecting those best suited to the research context and objectives. It encourages researchers to adopt a mixed methods approach, combining quantitative and qualitative data collection and analysis methods to gain comprehensive insights.

Table 2: Research Philosophy and Definitions (Dudovskiy, 2012)

For qualitative analysis, interpretivism allows to explore the subjective interpretations and meanings that individuals attach to phenomena. In this case, investigating the effectiveness of the current traceability and security system, understanding challenges and vulnerabilities, assessing the benefits of blockchain technology, analyzing regulatory hurdles, and proposing recommendations all involve understanding the perspectives and interpretations of various stakeholders within the pharmaceutical industry in India. Interpretivism enables to delve deeply into stakeholders' perceptions, experiences, and attitudes, providing valuable insights

into the complex social and cultural factors influencing the pharmaceutical supply chain.

Pragmatism is well-suited for quantitative data analysis in this study due to its emphasis on practical outcomes and problem-solving. By adopting a pragmatic approach, researcher can utilize quantitative methods to gather empirical data on the effectiveness of the current traceability and security system, assess the feasibility of implementing blockchain-based digital identities, and analyze regulatory hurdles associated with this technology. This quantitative approach ensures that research findings are grounded in empirical evidence, providing a solid foundation for developing strategic recommendations to enhance traceability and security in the Indian pharmaceutical industry.

3.3 RESEARCH APPROACH

The research approach refers to the overarching strategy or methodology employed to address the research questions or objectives. Deductive and inductive methods are two distinct approaches within the realm of research methodologies, each with its own set of characteristics and procedures (Woiceshyn and Daellenbach, 2018).

1. **Deductive Approach**

The deductive method involves the formulation of a hypothesis or theory based on existing knowledge, which is then tested through empirical observation and data collection. It starts small and gets bigger. It starts with a specific hypothesis that has been developed based on the information or patterns that have been observed by the researcher. Then this hypothesis is tested and a broader theory is developed from it. Associated with quantitative research method (Woiceshyn and Daellenbach, 2018).

2. **Inductive Approach**

The inductive method involves the generation of new theories or hypotheses based on observations and patterns identified in empirical data. Just opposite to deductive theory it starts with a broad theory and then it focuses later on a more specific detail. Also referred to as moving from general to specific. Associated with qualitative research (Woiceshyn and Daellenbach, 2018).

According to the research objectives:

1. Investigating the current state of pharmaceutical product traceability and security in

India

Deductive reasoning is applied here to test hypotheses derived from existing theories or models about the effectiveness of traceability and security systems.

2. Assessing the challenges and vulnerabilities in the Indian pharmaceutical supply chain

Inductive reasoning is suitable as it involves exploring new insights and patterns based on empirical observations.

3. Examining the potential benefits of blockchain-based digital identities

Deductive reasoning is employed to test hypotheses derived from existing literature or theoretical frameworks about the benefits of blockchain technology.

4. Analyzing the challenges and regulatory considerations associated with implementing blockchain-based digital identities

Inductive reasoning is appropriate here to explore new insights and patterns related to regulatory hurdles and considerations.

5. Proposing strategic recommendations for preventing the circulation of falsified medications and counterfeit drugs

A mixed-methods approach is suitable here, combining deductive reasoning to test hypotheses derived from existing theories with inductive reasoning to explore new insights and patterns.

3.4 RESEARCH STRATEGY AND COLLECTION OF PRIMARY DATA

Research Strategy refers to how the research work is being carried out and what method of data collection will be used. A Gantt chart is used to establish the research timeline.

Quantitative analysis is done via survey questionnaire and Qualitative analysis is done via in-depth interviews. To gather information, the questionnaire developed in Microsoft Forms was distributed electronically to pharmacists, nurses, doctors, and other healthcare professionals in the Indian Pharmaceutical Industry. The responses given are recorded and stored as databases in Microsoft Excel so that the results can be easily accessed. There are open-ended questions, closed-ended questions, multiple-choice questions, and questions using Likert Scale. It will take approximately 6 minutes to complete the survey. The confidentiality of the respondents are highly maintained throughout the study. Their consent to participate in the study was taken and the aim and purpose of the study were clearly explained to them. Graphs, pie charts, and other statistical tools were used to draw the results.

Sl. No.	HEADING OF THE SECTION	NUMBER OF QUESTIONS
1	Introductory part, Participant consent and Purpose of the study	2
2	Demographic questions	2
3	Current State of Pharmaceutical Product Traceability and Security	5
4	Blockchain Technology and its benefits	5
5	Challenges and Vulnerabilities in the Indian Pharmaceutical Supply Chain	4
6	Regulatory Hurdles and Considerations	2
7	Strategic Recommendations	3

Table 3: Summary of Survey Questionnaire

For qualitative analysis, Interviews with experts in the Indian pharmaceutical industry were conducted directly, via Zoom meetings and phone calls within a certain time frame. Thematic analysis was done to draw the conclusion after the interview. Participant Information Leaflet (PIL) and Informed Consent Form (ICF) were provided. The interview process was designed in a manner that was standardized and adaptable. The participants were made aware that all the data collected will be handled confidentially and according to the General Data Protection Regulation (GDPR).

Sl. No.	HEADING OF THE SECTION	NUMBER OF QUESTIONS
1	Demographic questions	2
2	Current State of Pharmaceutical Product Traceability and Security	3
3	Necessity and Feasibility of Implementing Blockchain-based Digital Identities	3
4	Benefits of Blockchain-based Digital Identities	3
5	Challenges and Regulatory Considerations	3
6	Contribution to Preventing Falsified Medications and Counterfeit Drugs	3
7	Strategic Recommendations for Implementation	3

Table 4: Summary of Interview Questionnaire

3.5 RESEARCH CHOICE

This mainly comprises of three methods

1. Mono method- Uses one research approach for the study
2. Mixed method- Uses two or more methods of research like Qualitative and Quantitative method
3. Multi-method- a wide selection of methods can be used (Vale, 2023)

In this study, Mixed method was used which comprises of both quantitative and qualitative data collection and their analysis. The quantitative approach used here is an online survey questionnaire (comprising of 24 questions) whereas the qualitative method used here is Interviews (comprising of 20 questions). All the data were collected from healthcare professionals working in the Indian Pharmaceutical Industry.

3.6 TIME HORIZONS

It refers to the time frame within which the study is intended for completion.

There are mainly 2 types of time horizons:

1. Cross-sectional: There will be a pre-set time established for the collection of data that is there will be a deadline.
2. Longitudinal: Collection of data repeatedly over an extended period of time.

In this study, cross-sectional method was used because of the shorter time frame for the research. So, the data collection and analysis occur within a certain time limit (Saunders *et al.*, 2019). In this study, the time limit for data collection and analysis was 1 month.

3.7 TECHNIQUES AND PROCEDURES

3.7.1 VALIDITY OF THE RESEARCH

The quality of the study is determined by the validity of the research. It is very important to investigate the effectiveness of the current traceability and security system for pharmaceutical products in India, as well as explore the potential benefits and challenges associated with implementing blockchain-based digital identities in the pharmaceutical industry. The objectives directly address the issues of traceability and security within the Indian pharmaceutical supply chain, which are significant concerns for public health and regulatory authorities. Investigating the current state and potential improvements aligns well with addressing these problems.

3.7.2 DATA ANALYSIS

Data analysis is a crucial step in research. It is the process of converting the information collected into a comprehensible data form.

QUANTITATIVE ANALYSIS

The responses from all respondents were collected and recorded in Ms Excel spreadsheet. Graphical representations like pie charts, bar charts were used to visually present the findings. The result from closed-ended questions were obtained through descriptive statistics and frequency distribution will also be obtained.

QUALITATIVE ANALYSIS

Thematic analysis was used to identify and analyse themes and patterns in participant responses. The interview questionnaire has mainly 6 themes namely Current State of Pharmaceutical Product Traceability and Security, Necessity and Feasibility of Implementing Blockchain-based Digital Identities, Benefits of Blockchain-based Digital Identities, Challenges and Regulatory Considerations, Contribution to Preventing Falsified Medications and Counterfeit Drugs, Strategic Recommendations for Implementation.

3.8 SAMPLE SIZE

The sample size was calculated using the formula;

$$\text{Sample size} = \frac{\frac{z^2 \times p\,(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p\,(1-p)}{e^2 N}\right)}$$

Figure 11: Sample size formula using Survey Monkey

Where, N = Population size

e = Margin of error (10%)

z (z-score) = **1.96** for a Confidence Interval of 95%

p (Standard deviation) = **0.5** to ensure the sample size is large enough

There are nearly 6 million healthcare professionals in India. So, the sample size obtained by using this equation and substituting the value is **97.** The number of responses obtained from the online survey was **74.**

3.9 PARTICIPANT SELECTION

Healthcare professionals like pharmacists, doctors, nurses, and individuals working in the Indian Pharmaceutical Industry were chosen for the study.

Inclusion criteria are only participants who have thorough knowledge regarding blockchain technology, its potential benefits and challenges, and regulatory hurdles are included in the study. Exclusion criteria are participants who opted not to participate in the survey and who lost interest and did not attempt to answer the questionnaire after receiving it. The healthcare professionals who are not working in the Indian Pharmaceutical Industry and who don't have a thorough knowledge of blockchain technology were excluded from the study.

3.10 ETHICAL CONSIDERATIONS

The ethical guidelines of the study were strictly followed by the researcher. Healthcare professionals who have knowledge in blockchain technology from India were selected as the participants in the research study. An introductory paragraph explaining the research aim and purpose was attached at the beginning of the survey. They were made aware that it is their right to decide whether or not to take part in the research. The interview and survey questionnaire were designed in such a way that they did not have to disclose their organizational or personal information. The questions parallelly aligned with the research objectives. The participants were also made aware that at any time if they lose interest in taking part in the survey or due to any circumstances, they have the right to withdraw from the research without facing any consequences. The responses given by the participants were kept highly confidential and the data collection will only be done according to GDPR. All activities during the research strictly adhere to the guidelines set forth by Griffith College, Dublin. The Ethics form was approved by the Supervisor without consulting the need of Griffith College Ethics Committee.

3.11 CONCEPTUAL FRAMEWORK

The conceptual framework revolves around evaluating the current state of pharmaceutical traceability and security in India, identifying challenges and vulnerabilities, exploring the necessity and feasibility of blockchain-based digital identities, assessing potential benefits, analyzing challenges and regulatory considerations, understanding the role in preventing falsified medications, and proposing strategic recommendations. This framework encompasses key factors such as existing systems, challenges, feasibility, regulatory

landscape, and the potential impact of blockchain technology on pharmaceutical supply chain security.

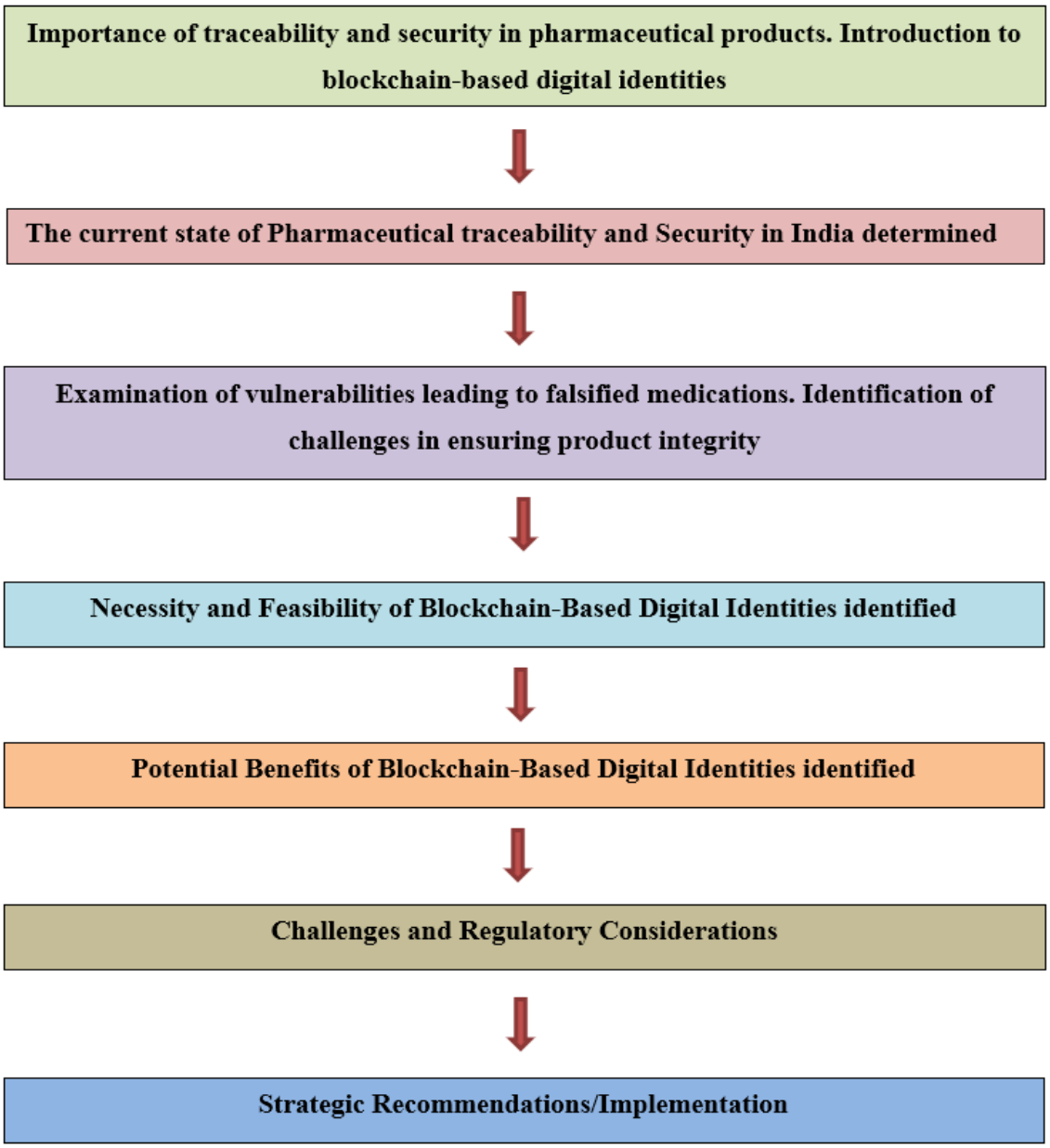

Figure 12: Conceptual Framework of the research cited by Ligi Alexander

3.12 CONCLUSION

Research methodology provides the framework for how to gather, analyze, and interpret data to answer research questions and objectives. A combination of qualitative and quantitative methods was used for data collection and analysis. The research philosophy used for quantitative analysis was pragmatism and for qualitative analysis was Interpretivism. The deductive approach was used for quantitative analysis and the inductive approach was used

for qualitative analysis. For quantitative analysis self-designed online survey questionnaire comprising of 24 questions divided into 6 sections was used. For qualitative analysis, a direct interview was done which was 20-30 minutes long. It consisted of both open-ended and closed-ended questions. Healthcare professionals working in the Indian Pharmaceutical industry were selected as participants in the study. The responses from the participants were carefully collected, analyzed and conclusions were drawn. The results of quantitative data were expressed in graphs, pie charts, and other graphical representations by using Ms Excel. The study method was cross-sectional as the time was limited for data collection and analysis. The time limit was 1 month. The findings and analysis of the research are thoroughly discussed in the next chapter.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 INTRODUCTION

This section analyses and interprets the data obtained from primary research (Online survey questionnaires and interviews) to reach the conclusion of the study. To answer the research questions about the impact of blockchain-based digital identities for pharmaceutical product traceability and security in India, the quantitative data was analyzed using descriptive statistics, and the qualitative data was analyzed using a thematic approach from open-ended questions.

4.2 QUANTITATIVE AND QUALITATIVE DATA ANALYSIS

4.2.1 PART 1- QUANTITATIVE ANALYSIS

An introductory paragraph regarding the survey and two introductory questions were added to the first part to ensure the participants fully understood the need and significance of the research and to ensure their consent for participation in the study. There is no point in conducting the survey if the participants are unaware of blockchain technology, and the purpose of the study. Also, it is very important to seek the approval of participants and they were made aware that they could withdraw from the study at any point. The sample size obtained was 97 but the total number of responses obtained in this short period from the survey was 74.

The responses obtained from the first two questions were:

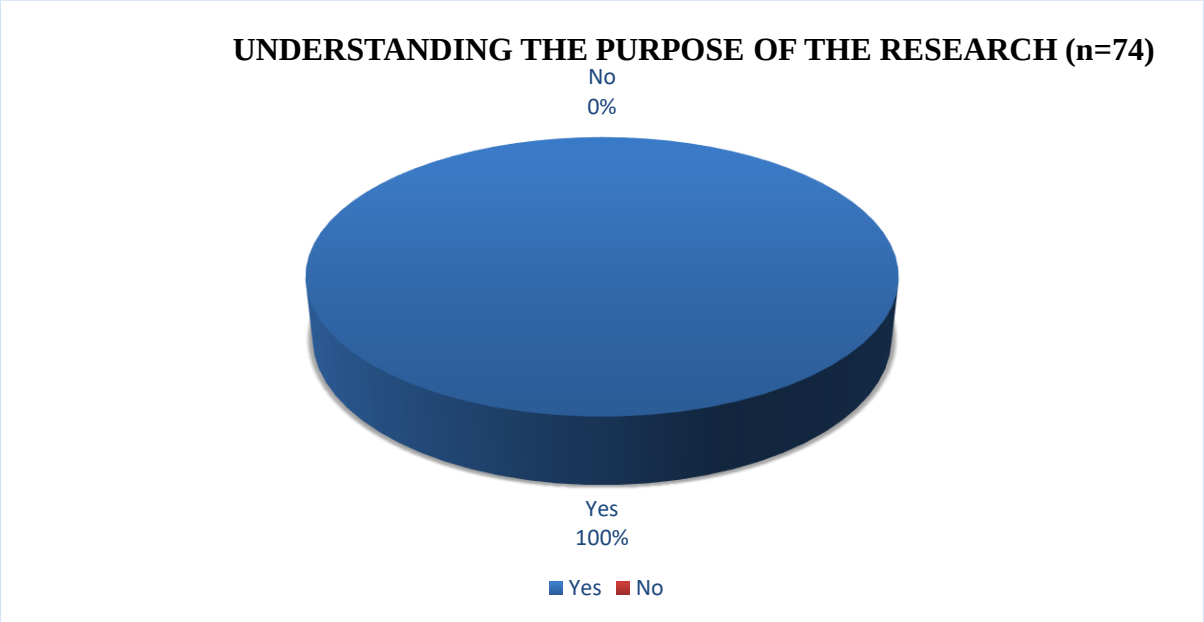

Figure 13: Pie chart representing the understanding of the purpose of the research by the participants

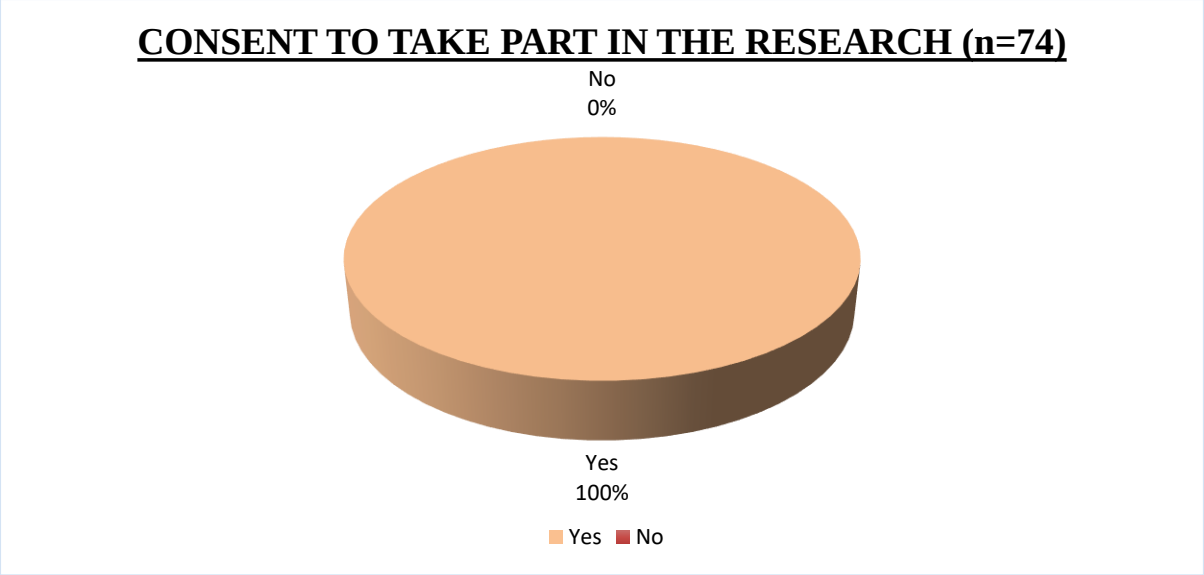

Figure 14: Pie chart representing the consent of participants to take part in the research

When looking at both the data above, it is clear that all participants (100%) fully understood the purpose of the research and they were willing to participate in the study. The number of participants was 74.

Demographic Questions (Question 3&4)

The participants who were working in the Indian Pharmaceutical Industry and who have a thorough knowledge of Blockchain technology were selected for the survey. The third question was to make sure that all participants in the survey were working in the Indian Pharmaceutical Industry. From the response given below in the graph, it was evident that all the participants (100%) were working in the Indian Pharmaceutical Industry.

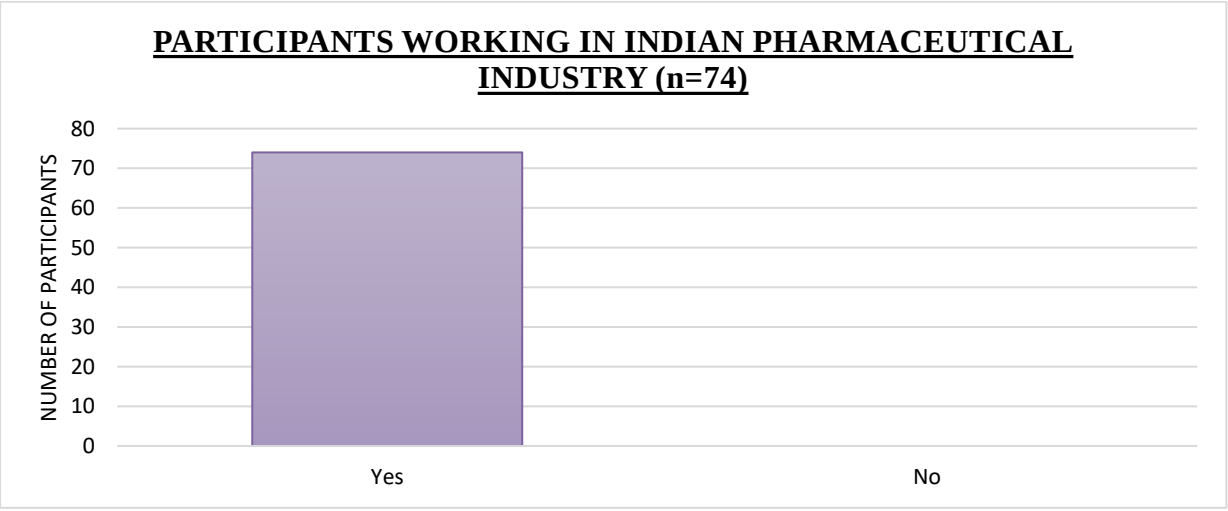

Figure 15: Bar graph representing participants working in the Indian Pharmaceutical Industry

The purpose of the next question was to analyze the work experience of the participants. This question ensures that participants who have enough work experience only took part in the study.

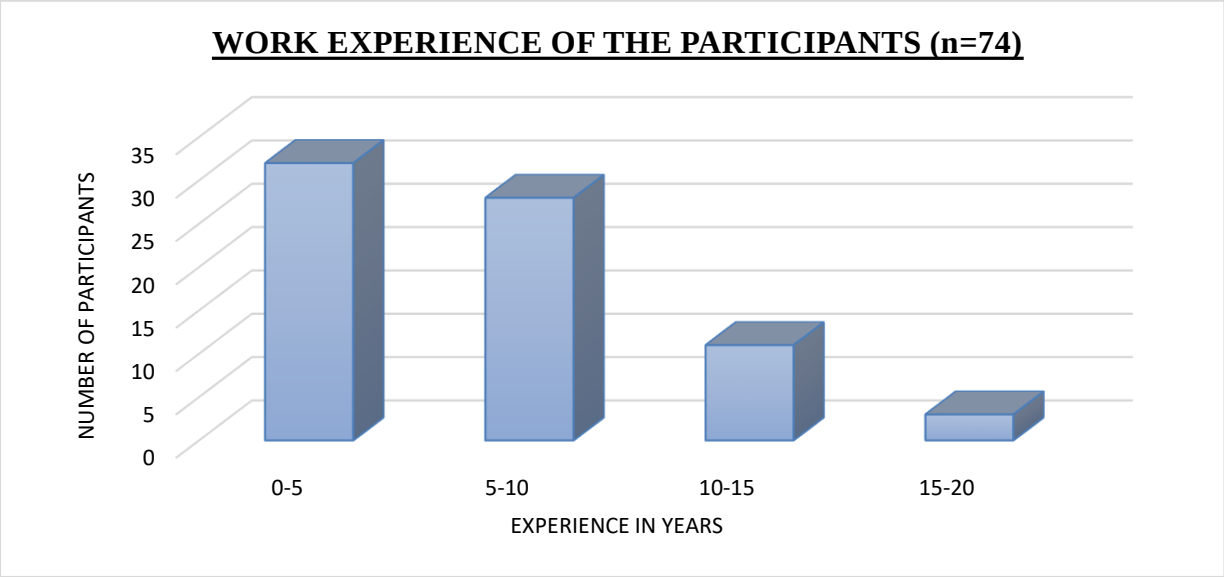

Figure 16: Bar graph representing the experience of participants in years

Work Experience (in years)	Number of participants (n=74)	Percentage of response
0-5	32	43.24 %
5-10	28	37.84%
10-15	11	14.86%
15-20	3	4.05%

Table 5: Table representing the experience of participants in years

When analyzing the data obtained from the fourth question, it was seen that the majority of the participants have work experience between 0-5 years (43.24%). 28 participants have experience between 5-10 years (37.84%) followed by 11 participants having experience between 10-15 years (14.86%). Only a very small number of participants (4.05%) have 15+ years of work experience.

Current State of Pharmaceutical Product Traceability and Security (Questions 5,6,7,8,9)

This section aims to examine the current state of pharmaceutical product traceability and security in India and methods to enhance the system.

The fifth question was to rate the effectiveness of the current traceability and security system

for pharmaceutical products in India.

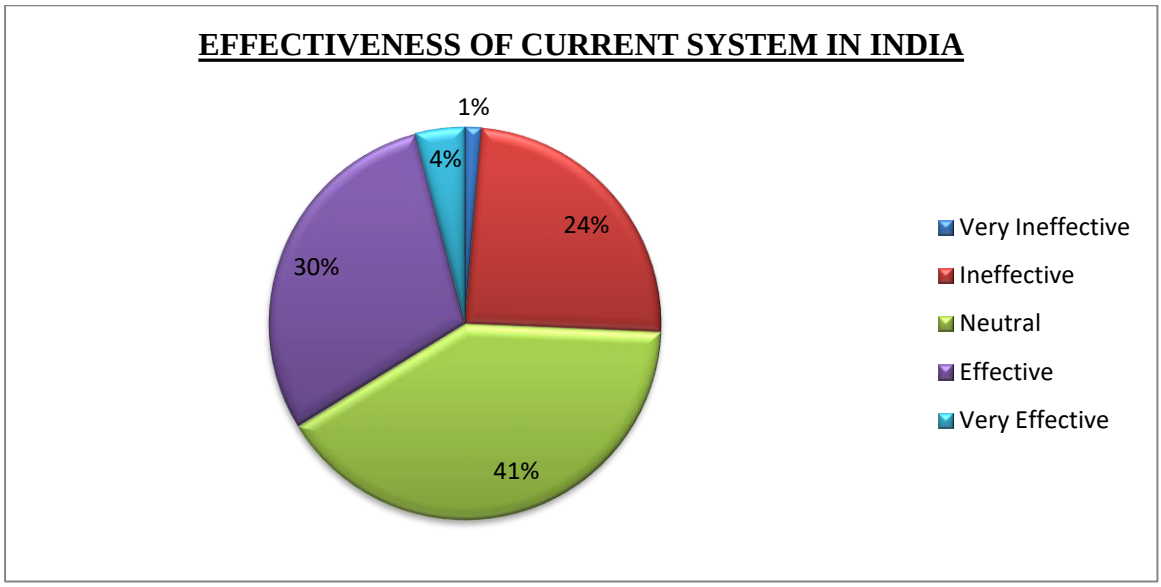

Figure 17: Piet chart representing the effectiveness of current traceability and security system for pharmaceutical products in India

Effectiveness rating	Number of participants (n=74)	Percentage of response
Very Ineffective	1	1%
Ineffective	18	24%
Neutral	30	41%
Effective	22	30%
Very Effective	3	4%

Table 6: Table representing the percentage of effectiveness of current traceability and security systems for pharmaceutical products in India

Out of the 74 responses obtained, the majority of the participants (41%) had a neutral approach regarding the effectiveness of the current system in India. 30% of the participants marked that the current system was effective. 24% of the participants said that the current system was ineffective. 1% of the participants strongly believed that the system was very ineffective. There was a follow-up question asked to the participants who marked the system as ineffective. Lastly, 4% of the participants indicated that the system was very effective in achieving traceability and security of pharmaceutical products in India.

The sixth question was to the participants who said the current system of traceability and security was ineffective in India, regarding the methods to improve it. It was a short answer type question. The responses provided by the participants were as follows:

1. Implement Comprehensive Track-and-Trace Systems: Mandate the use of advanced track-and-trace systems such as barcodes, RFID tags, or blockchain technology to monitor the movement of drugs throughout the supply chain. This ensures transparency and accountability at every stage.
2. Strict Regulatory Oversight: Strengthen regulatory agencies like the Central Drugs Standard Control Organization (CDSCO) to enforce compliance with drug traceability standards. Regular inspections and audits should be conducted to ensure adherence to regulations.
3. Enhanced Serialization Requirements: Require pharmaceutical manufacturers to serialize individual units of drugs, enabling unique identification and tracking of each product from production to consumption.
4. Public Awareness Campaigns: Educate healthcare professionals, pharmacists, and consumers about the importance of verifying drug authenticity and the risks associated with counterfeit drugs. Encourage reporting of suspicious activities.
5. International Cooperation: Collaborate with other countries and international organizations to share best practices, intelligence, and resources for combating drug counterfeiting and smuggling across borders.
6. Supplier Verification Programs: Implement supplier verification programs to ensure that pharmaceutical ingredients and products are sourced from reputable and licensed suppliers who adhere to quality standards.
7. Penalties for Non-Compliance: Enforce strict penalties, including fines and license revocation, for entities found guilty of non-compliance with drug traceability regulations. This serves as a deterrent to illicit activities.
8. Continuous Monitoring and Evaluation: Establish mechanisms for continuous monitoring and evaluation of the effectiveness of drug traceability measures, with regular updates and improvements based on feedback and emerging threats.
9. Capacity Building: Invest in training programs for stakeholders involved in the drug supply chain to enhance their understanding of traceability requirements and techniques for detecting counterfeit drugs (Aithal *et al.*, 2021).

The next question was to check the beliefs of participants regarding sufficient measures to ensure the security of pharmaceutical products within the Indian market.

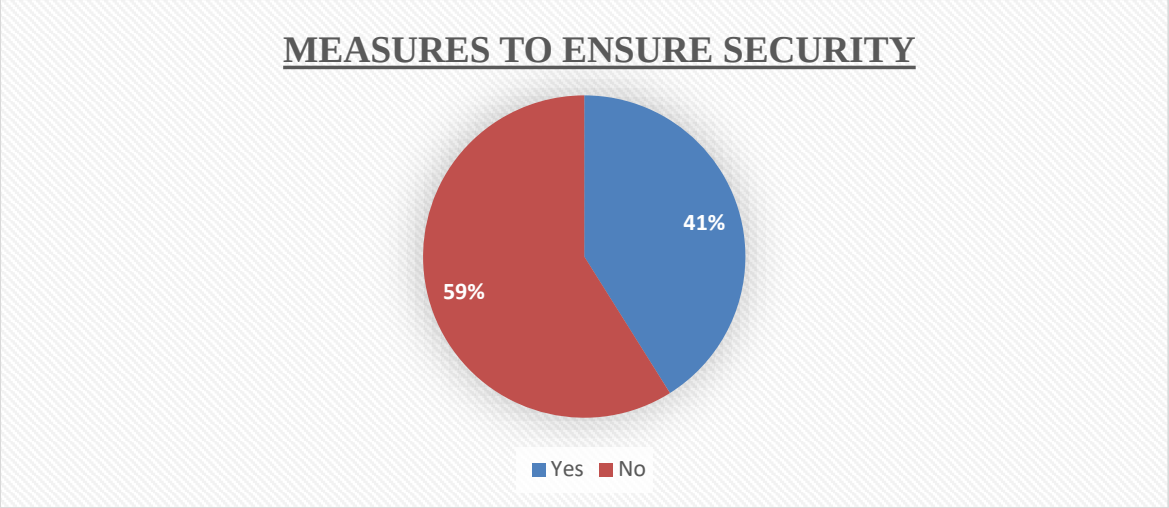

Figure 18: Pie chart representing the belief of the participants that sufficient measures are in place to ensure the security of pharmaceutical products in India

From the responses obtained from the participants, 41% of the participants (30 participants) believe that there are sufficient measures in place to ensure the security of pharmaceutical products in India but 59% (44 participants) of the participants believe there are no sufficient measures.

The eighth question was an open-ended question on technologies or systems currently utilized for tracking and authenticating pharmaceutical products in the Indian market. The responses were as follows:

1. Barcoding: Barcodes are widely used for product identification and tracking in the pharmaceutical supply chain. They provide a cost-effective way to encode product information and can be easily scanned at various points along the distribution process.
2. QR Codes: Quick Response (QR) codes are increasingly being used on pharmaceutical packaging to provide additional information and enable authentication through smartphone scanning. QR codes can contain encrypted data that can be verified by authorized stakeholders.
3. Serialization: Serialization involves assigning a unique serial number to each unit of a pharmaceutical product, enabling traceability throughout the supply chain. Serialized data can be stored in centralized databases and accessed for verification purposes.
4. RFID (Radio-Frequency Identification): RFID tags use radio waves to transmit data wirelessly, allowing for real-time tracking and monitoring of pharmaceutical products. RFID technology offers advantages such as increased automation, greater visibility, and faster data capture compared to traditional barcode systems.

5. Tamper-Evident Packaging: Tamper-evident packaging is designed to reveal if a product has been tampered with or compromised during transit or storage. Features such as seals, labels, or indicators are used to visually signal the integrity of the packaging.
6. Mobile Authentication Solutions: Mobile authentication solutions enable consumers to verify the authenticity of pharmaceutical products using their smartphones. These solutions may involve scanning QR codes, entering serial numbers, or accessing secure databases to confirm product legitimacy (Habiba, 2021).

The ninth question was closed-ended. The importance of this question lies in understanding the extent of counterfeit drugs or falsified medications within the Indian pharmaceutical supply chain. Such instances can have severe consequences on public health, including ineffective treatment, adverse reactions, and even fatalities.

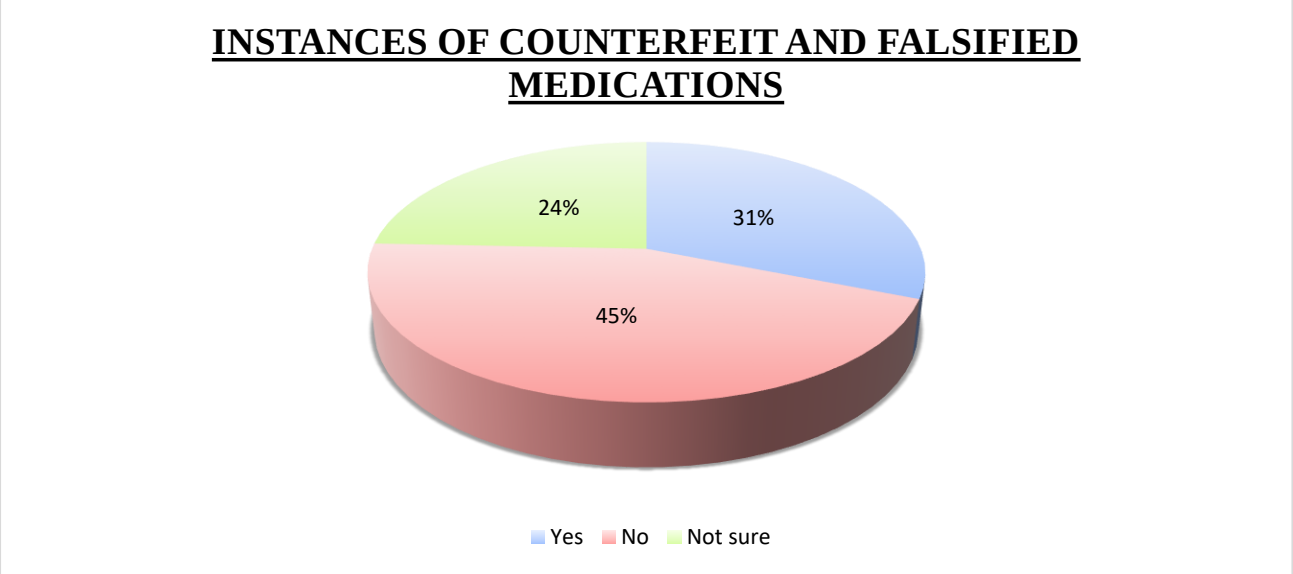

Figure 19: Pie chart representing the instances of counterfeit and falsified medications by them or their company

From the pie chart, it is clear that 45% of the participants (n=33) haven't experienced any instance of counterfeit or falsified medicines. 31% of the population (n=23) have experienced instances of counterfeit or falsified medicines and 24% (n=18 participants) were quite unsure.

Blockchain Technology and its Benefits (Questions 10,11,12,13,14)

The section aims to provide an overview of what blockchain technology is, how it works, and its potential advantages, such as transparency, security, immutability, and efficiency. Additionally, it delves into specific cases or examples where blockchain is being successfully implemented to solve real-world problems and improve processes.

The tenth question was to confirm awareness of blockchain technology targeting the Indian pharmaceutical industry, tailor the survey content, identify educational needs, and gauge readiness for adopting innovative solutions to industry challenges.

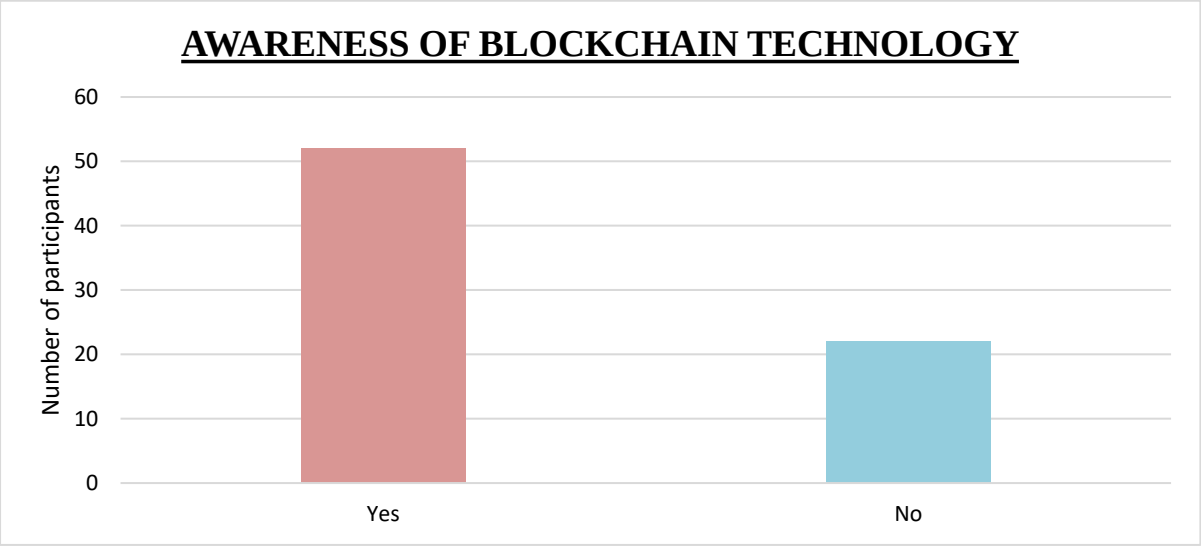

Figure 20: Bar graph representing the awareness of Blockchain technology.

Out of 74 participants, 60 (81.08%) were aware of the blockchain technology, but 14 (18.91%) participants were unaware of the Blockchain technology concept.

The eleventh question confirms whether industry professionals believe in the necessity of implementation of blockchain-based digital identities to help assess their perception of its potential benefits. If respondents indicate "Yes," it suggests recognition of the advantages such as enhanced transparency, security, and traceability in the pharmaceutical supply chain. Conversely, a "No" response indicates skepticism or a lack of perceived benefits.

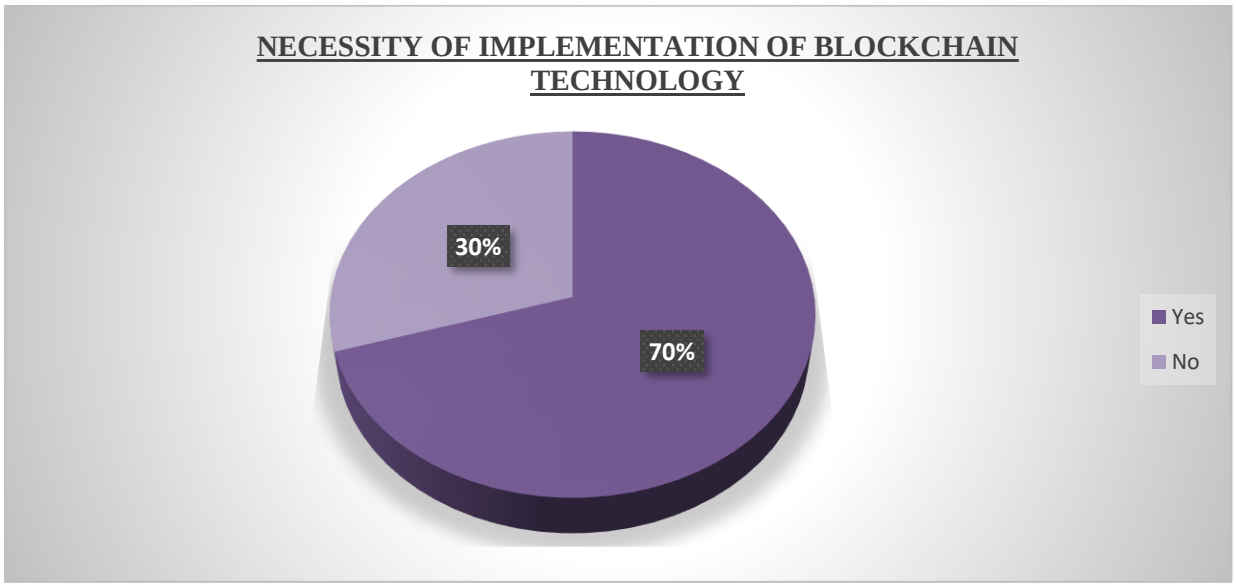

Figure 21: Pie chart representing the necessity of implementation of blockchain technology

It is clear from the above pie chart that more than half (n=52) of the participants (70%) know the importance and ease of their work after the implementation of blockchain technology, while 30% of the participants (n=22) think the implementation of blockchain technology is not necessary in the Indian Pharmaceutical Industry.

The twelfth question was a Likert Scale-based question. The survey targeting participants from the Indian pharmaceutical industry, asked about the feasibility of implementing blockchain-based digital identities and whether it is crucial for several reasons like assessment of the industry perception, identification of potential challenges, opportunity for strategic planning, guiding research and development efforts.

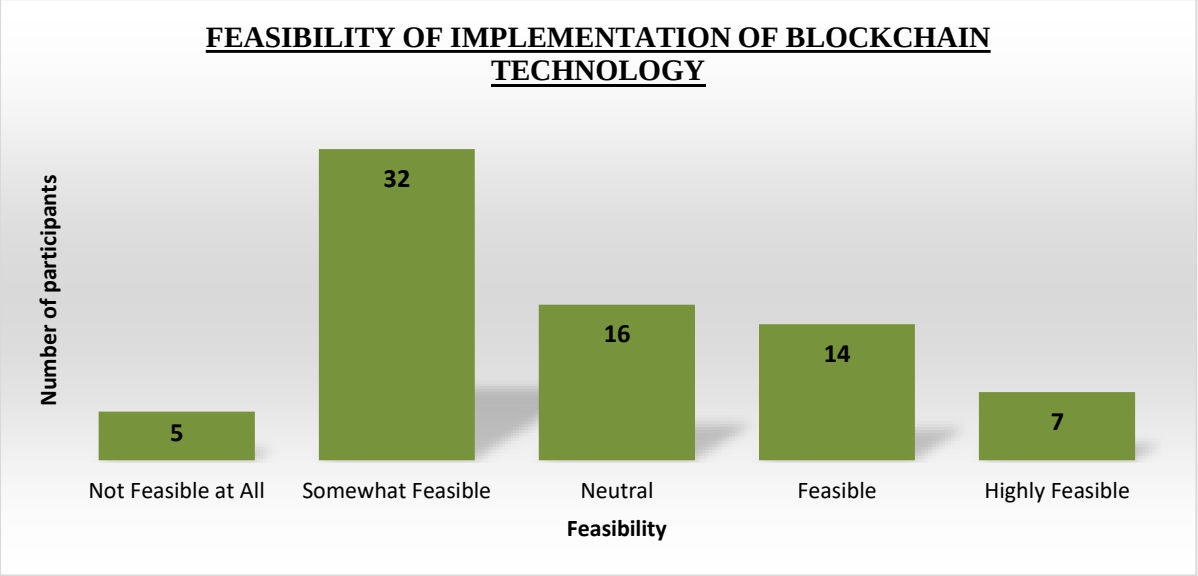

Figure 22: Bar graph representing the feasibility of implementation of blockchain technology

In the above bar graph out of 74 participants, 32 (43.24%) marked it as somewhat feasible was the implementation of blockchain technology. 16 (21.62%) participants had a neutral opinion followed by 14 (18.92%) stating it was feasible. 7 (9.46%) participants said that it was highly feasible whereas 5 (6.76%) participants said it was not feasible at all.

The thirteenth question was also a Likert-type question that asked the participants to rate the potential benefits of adopting blockchain-based digital identities in the pharmaceutical supply chain in India. It helps in strategic planning, resource allocation, risk mitigation, competitive positioning, and making policies and regulations.

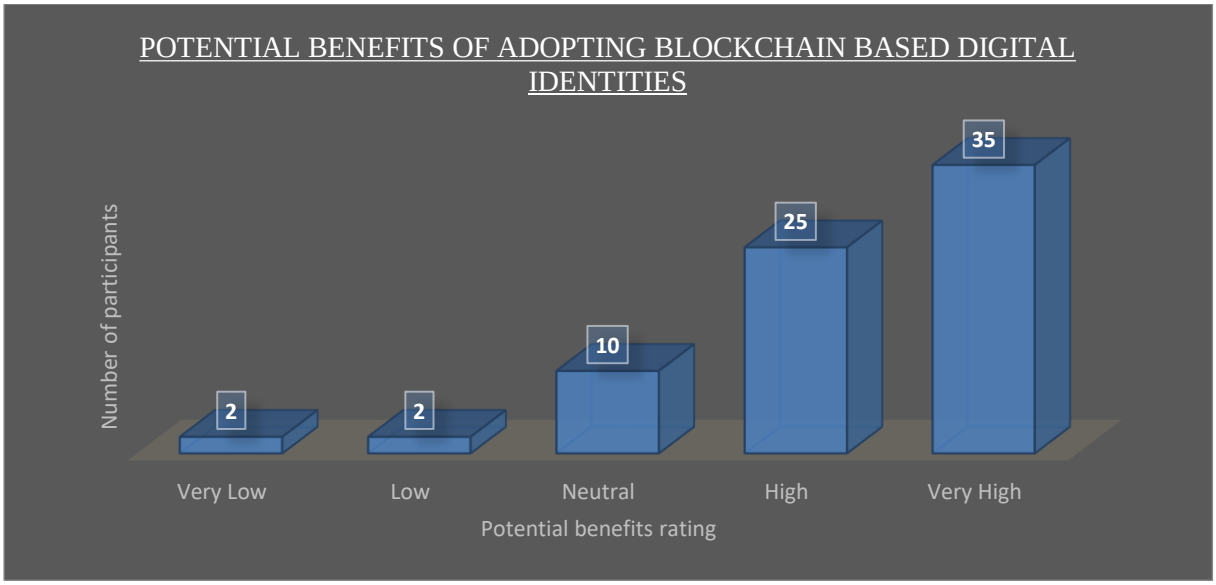

Figure 23: Bar graph representing the potential benefits of adopting blockchain-based digital identities

Out of 74 participants, 35 (47.3%) and 25 (33.78%) participants suggested that the implementation of blockchain-based digital identities had very high and high potential benefits. 10 (13.51%) participants had a neutral approach. Very low and low ratings were given by 2 (2.7%) participants in each category.

The fourteenth question was an open-ended question to know the opinion regarding the specific benefits that blockchain-based digital identities could offer in improving traceability and security within the pharmaceutical supply chain. The responses were as follows:

1. Immutable Record-Keeping: Blockchain technology provides an immutable ledger where transactions, such as the movement of pharmaceutical products, are recorded in a secure and tamper-proof manner. This ensures the integrity and authenticity of the data, reducing the risk of fraudulent activities such as counterfeiting or tampering.
2. Enhanced Transparency: Every transaction recorded on the blockchain is transparent and visible to all authorized participants in the network. This transparency fosters trust among stakeholders by providing a clear audit trail of product movements and ensuring that everyone has access to the same information, thereby reducing discrepancies and disputes.
3. Real-Time Tracking and Monitoring: Blockchain enables real-time tracking and monitoring of pharmaceutical products as they move through the supply chain. This visibility allows stakeholders to identify bottlenecks, track shipment statuses, and respond promptly to any issues or delays, improving overall efficiency and reducing the risk of supply chain disruptions.

4. Improved Authentication: Blockchain-based digital identities provide a unique and tamper-proof identity for each pharmaceutical product. These digital identities can include information such as batch numbers, expiration dates, and manufacturing details, which can be verified by scanning a QR code or accessing a blockchain-based database. This enables healthcare professionals and consumers to easily authenticate the legitimacy of pharmaceutical products, reducing the prevalence of counterfeit drugs in the market.
5. Supply Chain Efficiency: By streamlining data sharing and communication between supply chain partners, blockchain reduces paperwork, manual processes, and administrative overhead. This improves operational efficiency, reduces errors, and accelerates the flow of goods through the supply chain, ultimately lowering costs and improving profitability for pharmaceutical companies.
6. Data Security and Privacy: Blockchain technology uses advanced cryptographic techniques to ensure the security and privacy of sensitive information stored on the blockchain. Access controls, encryption, and consensus mechanisms safeguard data integrity and protect against unauthorized access or tampering, mitigating the risk of data breaches and cyberattacks (Gökalp *et al.*, 2018).

Challenges and Vulnerabilities in the Indian Pharmaceutical Supply Chain (Questions 15,16,17,18)

This section aimed to focus on challenges and vulnerabilities in the Indian pharmaceutical supply chain to provide a comprehensive understanding of the obstacles and weaknesses existing within the industry. Identifying and analyzing these challenges helps to raise awareness, inform decision-making, and to guide policy and industry development.

The fifteenth question was an MCQ-type question that mainly focused on the biggest challenges in implementing blockchain-based digital identities for pharmaceutical products in India.

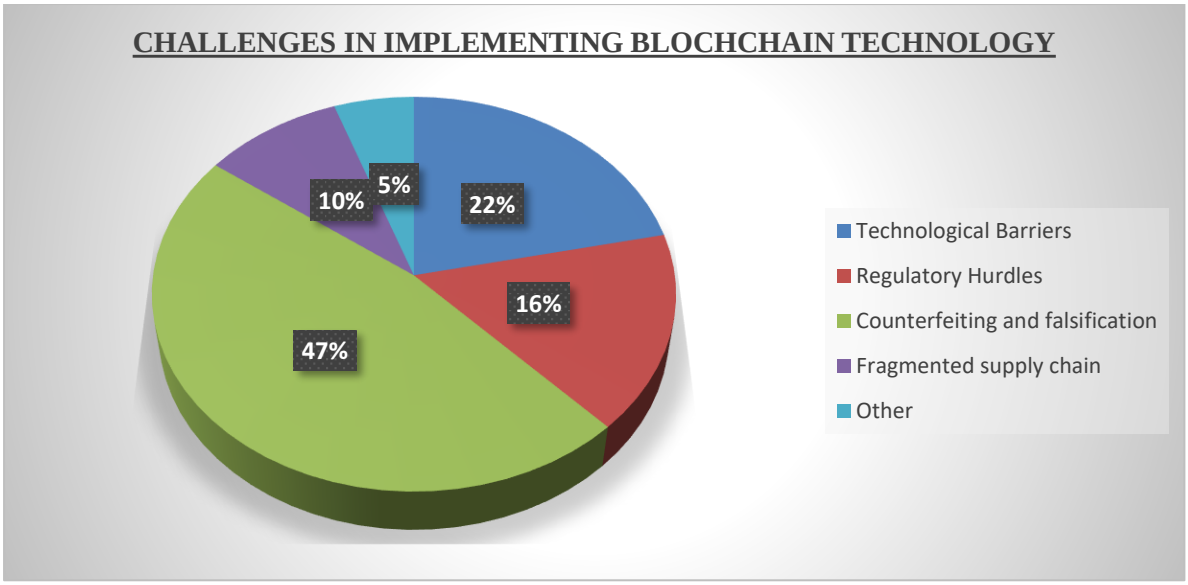

Figure 24: Pie chart representing the challenges in implementing blockchain-based digital identities

From the above pie chart, nearly half (47%- n=35 participants) had an opinion that counterfeiting and falsification were the biggest challenges in implementing blockchain technology. 22% of the participants (n=16) suggested technological barriers were the challenge. Regulatory hurdles and fragmented supply chains contributed 16% (n=12) and 10% (n=7) respectively. 5% (n=4) had other opinions like costs and resource requirements, environmental impact, interoperability, and scalability.

The next question was to analyze whether the participants were aware of the counterfeit and falsified medication distribution in India. As there are lots of companies and brands selling falsified and counterfeit drugs, this question is of great importance among healthcare professionals.

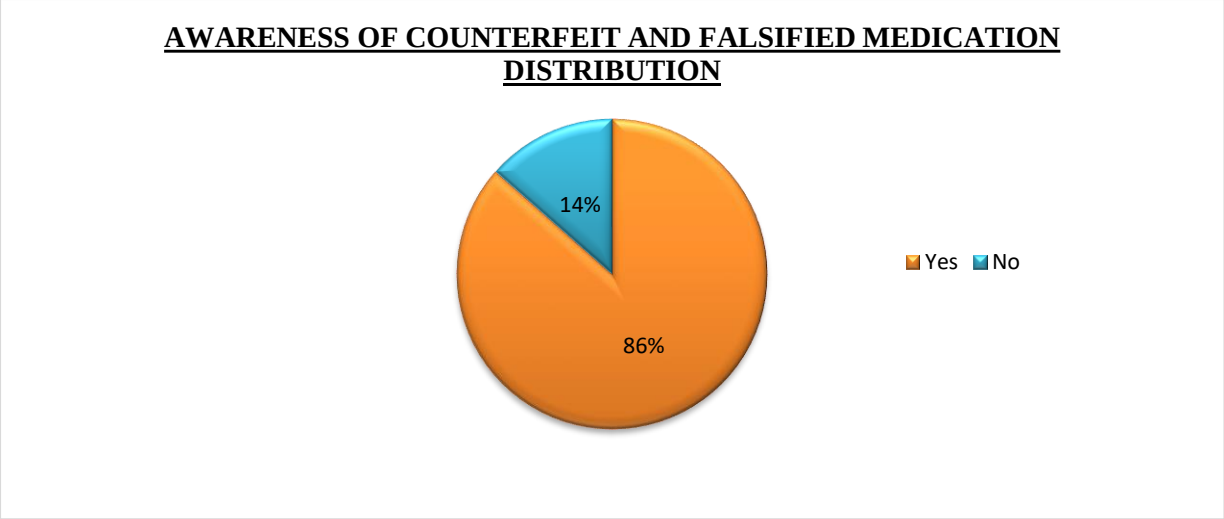

Figure 25: Pie chart representing awareness of counterfeit and falsified medication distribution in India

The pie chart illustrates that 86% (n=64) of the total participants were aware of the distribution of counterfeit and falsified medication whereas 14% (10) were unaware of the same.

In the seventeenth question, participants could show agreement or disagreement with the statement "Blockchain-based digital identities can significantly contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?". They were allowed to select options on a Likert scale from strongly agree to strongly disagree.

Likert Scale	**Number of participants (n=74)**	**Percentage of response**
Strongly Disagree	2	2.70%
Disagree	4	5.40%
Neutral	10	13.51%
Agree	26	35.13%
Strongly Agree	32	43.24%

Table 7: Agreement to the above question

From the above table, 43.24% of the participants strongly agree to the statement and 35.13% agree to the statement. 13.51% had neutral agreement. 5.40% and 2.70% disagree and strongly disagree to the above statement.

The next question was to assess the vulnerability of the Indian pharmaceutical supply chain to security breaches and counterfeit products. It is important for risk assessment, public health protection, regulatory compliance, business continuity, and improving consumer confidence within the industry. This question was assessed on a Likert scale ranging from highly vulnerable to not at all vulnerable.

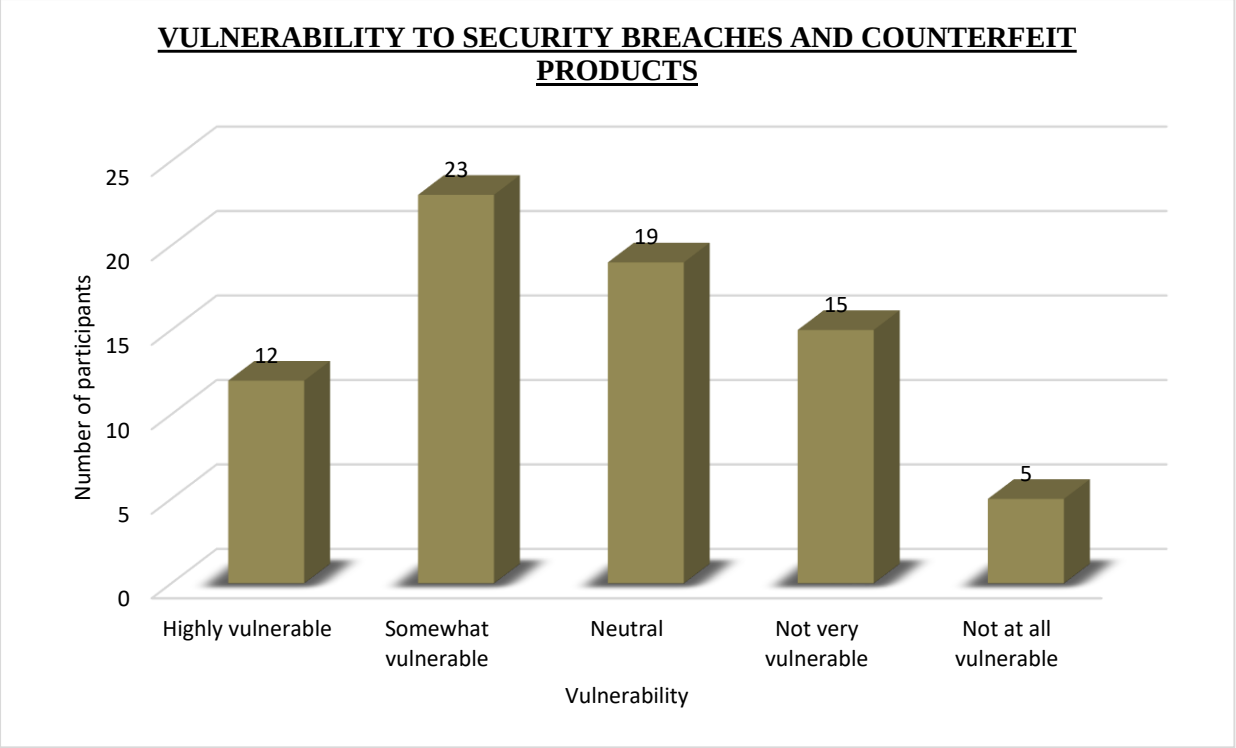

Figure 26: Bar graph representing the vulnerability of the Indian pharmaceutical industry to security breaches and counterfeit products

From the above bar graph, 12 (16.22%) participants said that the Indian pharmaceutical industry is highly vulnerable to security breaches and counterfeit products. 23 (31.08%) participants stated it is somewhat vulnerable and 19 (25.67%) had neutral opinions. Not very vulnerable and not at all vulnerable were marked by 15 (20.27%) and 5 (6.76%) participants, respectively.

Regulatory Hurdles and Considerations (Questions 19 & 20)

The aim of exploring regulatory hurdles and considerations in the pharmaceutical industry is to facilitate compliance, identify challenges, ensure patient safety, promote access to medicines, and guide policy development for the benefit of all stakeholders involved.

The nineteenth question was closed-ended to know whether the participants involved in the study were aware of any regulatory hurdles that might hinder the implementation of blockchain-based digital identities for pharmaceutical products in India.

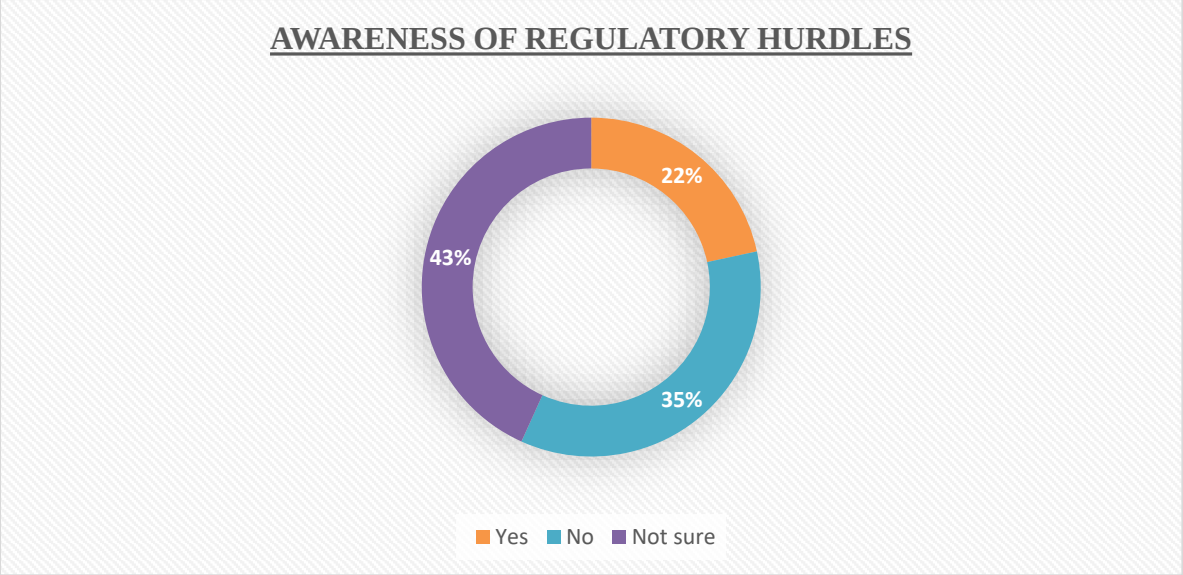

Figure 27: Doughnut graph representing the awareness of regulatory hurdles

From the above doughnut graph, it is clear that the majority of the population, 43% (n=32) was unsure about the regulatory hurdles. 22% (n=16) and 35% (n=26) answered "yes" and "no" to the question, respectively.

The next question was for the participants who answered "Yes" to the previous question. The question was regarding the regulatory considerations crucial for the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry.

1. Data Privacy and Security Regulations: Ensure compliance with data privacy and security regulations such as the Personal Data Protection Bill (PDPB) in India. Blockchain platforms should adhere to strict data protection standards, including encryption, access controls, and anonymization techniques, to safeguard sensitive information stored on the blockchain.
2. Regulatory Approval and Certification: Seek regulatory approval and certification from relevant authorities, such as the Central Drugs Standard Control Organization (CDSCO) in India, for blockchain-based systems used in pharmaceutical supply chains. Regulatory agencies may require validation of blockchain technology to ensure its reliability, accuracy, and compliance with industry standards.
3. Standardization and Interoperability: Promote the adoption of standardized data formats, protocols, and interfaces to ensure interoperability between different blockchain networks and platforms used by various stakeholders in the pharmaceutical supply chain. Collaborate with industry associations, standardization

bodies, and regulatory agencies to develop common standards and guidelines for blockchain implementation.

4. Auditability and Transparency: Design blockchain-based systems to enable auditability and transparency of transactions recorded on the blockchain. Ensure that regulatory authorities have access to relevant data and analytics for monitoring compliance, conducting audits, and enforcing regulations within the pharmaceutical supply chain.
5. Regulatory Reporting and Documentation: Develop mechanisms for regulatory reporting and documentation on the blockchain, enabling stakeholders to generate, store, and share regulatory documents, certificates, and audit reports in a secure and tamper-proof manner. Ensure that blockchain-based systems support compliance with regulatory reporting requirements, including submission deadlines and data formats specified by regulatory authorities.
6. Risk Management and Contingency Planning: Assess potential risks and vulnerabilities associated with blockchain implementation in the pharmaceutical supply chain, such as data breaches, system failures, and regulatory non-compliance. Develop contingency plans and risk mitigation strategies to address these challenges and ensure business continuity in case of unforeseen events.
7. Education and Awareness: Educate stakeholders, including pharmaceutical companies, healthcare professionals, regulators, and consumers, about the regulatory considerations and implications of blockchain-based digital identities in the pharmaceutical industry. Raise awareness about the benefits, risks, and best practices associated with blockchain adoption to facilitate informed decision-making and regulatory compliance (Kumar and Tripathi, 2019).

Strategic Recommendations (Questions 21,22,23)

The "Strategic Recommendations" section aimed to provide actionable insights and guidance to stakeholders within the pharmaceutical industry based on the findings and analysis presented in the preceding sections. It also enhances resilience, and fosters innovation within the pharmaceutical supply chain, ultimately benefiting patients, healthcare providers, and society as a whole.

The twenty-first question was an open-ended question asking the participants to provide any

additional thoughts or comments on how blockchain-based digital identities could help in preventing falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain. The responses were as follows:

1. Immutable Product Records: By recording every transaction and movement of pharmaceutical products on a blockchain ledger, digital identities create an immutable record of product provenance and authenticity. This transparency makes it extremely difficult for counterfeiters to introduce fake drugs into the supply chain without detection, as each product's history can be easily verified.
2. Tamper-Proof Authentication: Blockchain-based digital identities enable tamper-proof authentication of pharmaceutical products through unique identifiers and cryptographic signatures. These digital identities are securely stored on the blockchain and can be accessed and verified by authorized stakeholders, such as pharmacists, distributors, and regulatory authorities, using QR code scanning or other authentication methods.
3. Real-Time Verification: Blockchain allows for real-time verification of pharmaceutical products at various checkpoints along the supply chain. This enables stakeholders to quickly verify the authenticity of drugs before distribution, dispensing, or administration, reducing the risk of counterfeit products reaching consumers.
4. Supply Chain Transparency: Blockchain enhances transparency in the pharmaceutical supply chain by providing visibility into the entire lifecycle of a drug, from manufacturing to distribution to consumption. This transparency enables stakeholders to identify and address vulnerabilities in the supply chain, such as unauthorized diversions or parallel imports, that could facilitate the entry of counterfeit drugs.
5. Recall Management: In the event of a product recall or quality issue, blockchain-based digital identities facilitate rapid and precise identification of affected products. By accessing the blockchain ledger, stakeholders can quickly trace the origin and distribution path of recalled drugs, minimizing the impact on public health and safety.
6. Consumer Empowerment: Blockchain-based digital identities empower consumers to verify the authenticity of pharmaceutical products independently. By scanning a QR code or accessing a blockchain-based database, consumers can verify the legitimacy of a product before purchase or consumption, making informed decisions and avoiding counterfeit drugs.
7. Regulatory Compliance: Blockchain-based digital identities support compliance with regulatory requirements and standards for pharmaceutical traceability and

authentication. By providing a transparent and auditable record of transactions, blockchain helps pharmaceutical companies demonstrate compliance with regulations such as serialization mandates and track-and-trace requirements (Omar *et al.*, 2021).

The next question was an opinion-based question, regarding the key strategic recommendations that should be considered to facilitate the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry. The responses were as follows:

1. Collaborate with Industry Stakeholders: Foster collaboration between pharmaceutical companies, regulatory authorities, technology providers, and other stakeholders to develop common standards, guidelines, and best practices for blockchain implementation. Engage with industry associations, research institutions, and government agencies to leverage collective expertise and resources.
2. Invest in Education and Training: Invest in education and training programs to build awareness and capacity among stakeholders regarding blockchain technology, its applications in the pharmaceutical industry, and the regulatory considerations involved. Provide training sessions, workshops, and resources to empower personnel with the knowledge and skills needed for successful implementation.
3. Address Regulatory and Compliance Challenges: Proactively address regulatory and compliance challenges associated with blockchain implementation, such as data privacy, security, and interoperability requirements. Engage with regulatory authorities to seek clarity on regulatory expectations, obtain approvals, and ensure alignment with existing regulations and standards.
4. Select Suitable Blockchain Platforms: Evaluate and select suitable blockchain platforms based on factors such as scalability, security, interoperability, and regulatory compliance. Choose platforms that meet the specific needs and requirements of the pharmaceutical industry while ensuring compatibility with existing IT infrastructure and systems.
5. Ensure Data Integrity and Security: Implement robust data integrity and security measures to safeguard sensitive information stored on the blockchain. Utilize encryption, access controls, and other cryptographic techniques to protect against unauthorized access, tampering, and data breaches. Conduct regular audits and assessments to verify compliance with security standards.
6. Promote Interoperability and Integration: Promote interoperability and integration

between blockchain-based systems and existing IT systems used in the pharmaceutical supply chain. Ensure seamless data exchange and interoperability with Enterprise Resource Planning (ERP) systems, Electronic Health Records (EHRs), supply chain management software, and other relevant platforms to maximize efficiency and effectiveness (Pathak *et al.*, 2023).

The last question aimed to assess stakeholder readiness, willingness, and support for initiatives aimed at leveraging blockchain technology to enhance traceability and security in the Indian pharmaceutical industry, ultimately contributing to the industry's growth, resilience, and competitiveness. It was a Likert-scale type question ranging from very unlikely to very likely.

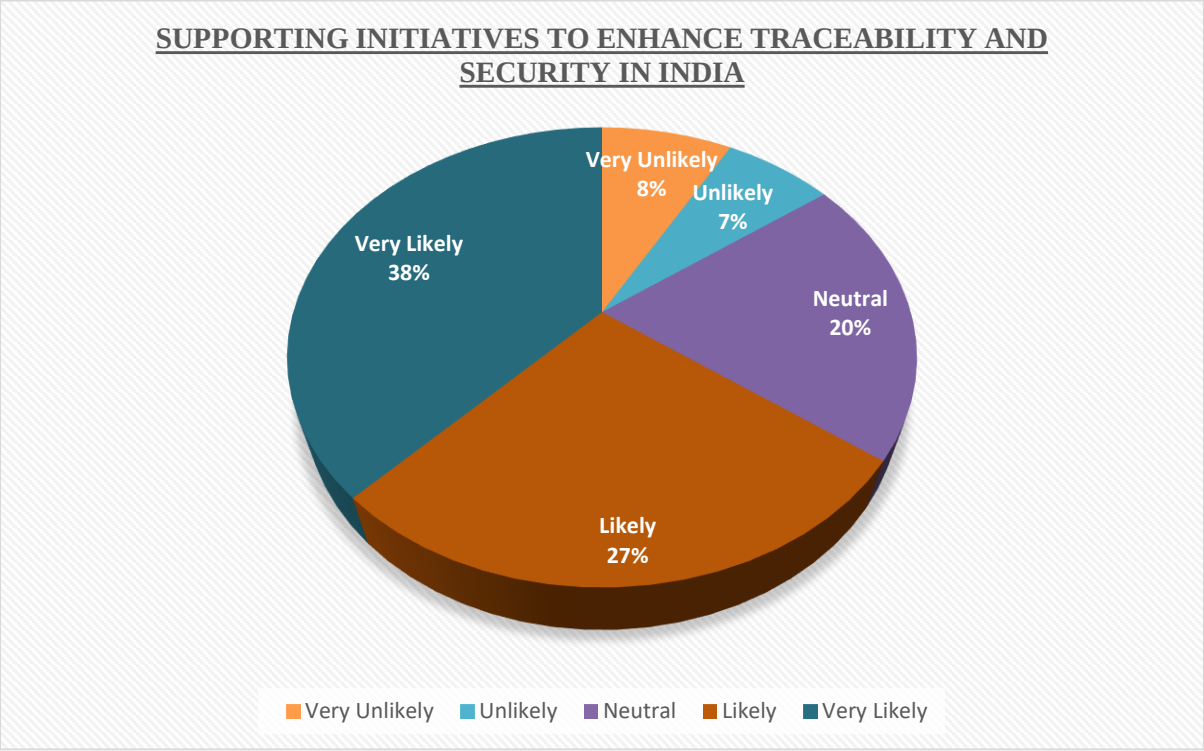

Figure 28: Pie chart to show supporting initiatives to enhance traceability and security in India

From the pie chart, 38% (n=28) were very likely to support initiatives to enhance traceability and security in India. 27% (n=20) likely supported and 20% (n=15) had a neutral approach. 7% (n=5) unlikely and 8% (n=6) very unlikely supported initiatives at enhancing traceability and security in the Indian pharmaceutical industry through the adoption of blockchain technology.

4.2.2 PART 2: QUALITATIVE ANALYSIS

A face-to-face interview was conducted with four healthcare professionals in the pharmaceutical industry. The goal of conducting this interview was to gather information and perspectives on the implementation of blockchain-based digital identities in the Indian pharmaceutical industry. The goal involved understanding the current state of pharmaceutical product traceability and security, exploring the necessity and feasibility of implementing blockchain technology, assessing potential benefits and challenges, considering regulatory considerations, and formulating strategic recommendations for implementation.

The first section was an introductory portion to ensure that the participants are currently working in the Indian Pharmaceutical industry. Their current position in the company and their work experience were asked before beginning the interview as the responses from well-experienced and professional participants were required for the study.

	Job title	**Work experience**
Respondent 1	Clinical Pharmacist	7 years
Respondent 2	Registered Pharmacist	5 years
Respondent 3	Supply Chain Manager	9 years
Respondent 4	Healthcare Practitioner	4 years

Table 8: Job title of the interviewees

Current State of Pharmaceutical Product Traceability and Security

In India, the existing traceability and security measures for pharmaceutical products vary in effectiveness and implementation across different regions and companies. While some organizations may have robust systems in place, others may face challenges such as counterfeiting and supply chain vulnerabilities. Technologies like barcoding, RFID (Radio-Frequency Identification), and serialization are commonly used to track and authenticate pharmaceutical products throughout the supply chain. Recent incidents in the pharmaceutical industry have highlighted challenges such as counterfeit drugs entering the market, theft, and diversion of medications, emphasizing the need for stronger traceability and security measures.

This section was divided into 3 questions. The response obtained to each question were as follows:

Question 1	How would you describe the existing traceability and security measures for pharmaceutical products in India
Respondent 1	The current state of traceability and security measures for pharmaceutical products in India is a mixed bag. While some companies have invested heavily in advanced serialization and track-and-trace technologies, others are still grappling with traditional methods like barcoding, resulting in a fragmented landscape of varying effectiveness.
Respondent 2	From a regulatory perspective, there are definite guidelines in place aimed at ensuring traceability, including requirements for unique identifiers and standardized packaging. However, the challenge lies in consistent enforcement across the industry, leading to gaps in product traceability and security.
Respondent 3	Technological advancements such as RFID and blockchain offer promising solutions to enhance traceability and security. However, the adoption rate among pharmaceutical companies in India remains relatively low, primarily due to cost constraints and the perceived complexities associated with implementing these technologies.
Respondent 4	Despite efforts to strengthen traceability measures, the persistent threat of counterfeit pharmaceuticals looms large. Weak supply chain controls and inadequate regulatory oversight create vulnerabilities, allowing counterfeit drugs to infiltrate the market, posing significant risks to public health and safety.
Question 2	What technologies or systems are currently used to track and authenticate pharmaceutical products throughout the supply chain?
Respondents 1 and 3	In our company, we primarily utilize barcoding and serialization technologies to track pharmaceutical products from manufacturing to distribution. Each product is assigned a unique barcode or serial number, which allows us to monitor its movement and authenticity throughout the supply chain.
Respondent 2	RFID (Radio-Frequency Identification) technology is gaining traction in the

	pharmaceutical industry for its ability to provide real-time tracking and authentication capabilities. By embedding RFID tags into product packaging, we can accurately monitor inventory levels and detect instances of tampering or counterfeiting.
Respondent 4	Blockchain technology is increasingly being explored as a means to enhance traceability and security in the pharmaceutical supply chain. By creating an immutable ledger of transactions, blockchain enables transparent and auditable tracking of product movements, reducing the risk of counterfeit products entering the market.
Question 3	Can you provide examples of recent incidents or challenges related to traceability or security in the pharmaceutical industry?
Respondent 1	We encountered a case of counterfeit drugs entering the market despite our traceability efforts, highlighting gaps in our security measures.
Respondent 2	Expired medications were discovered in circulation due to traceability issues, prompting concerns over product integrity.
Respondent 3	Illicit diversion of pharmaceutical products from authorized channels exposed vulnerabilities in our supply chain traceability.
Respondent 4	Contamination concerns led to a product recall, underscoring the importance of robust traceability systems for swift response.

Table 9: Response of participants to first section questions

Necessity and Feasibility of Implementing Blockchain-based Digital Identities

Blockchain-based digital identities could enhance traceability and security in the Indian pharmaceutical industry by providing a tamper-proof record of transactions and product movement. Blockchain has the potential to address challenges faced by current systems by enabling transparent and immutable tracking of pharmaceutical products from manufacturing to distribution. Barriers to adopting blockchain-based solutions may include regulatory uncertainty, technological complexity, interoperability issues, and concerns regarding data privacy and governance.

This section has three questions. The responses were as follows:

On the necessity of implementing blockchain-based digital identities

1. Blockchain-based digital identities are crucial for enhancing transparency and trust in the pharmaceutical supply chain, mitigating the risks associated with counterfeit

drugs.

2. The implementation of blockchain technology can revolutionize traceability in the Indian pharmaceutical industry, offering immutable records of product provenance and authenticity.
3. With the growing complexity of global supply chains, blockchain-based digital identities provide a standardized and decentralized solution to ensure product integrity and safety.
4. Blockchain-based digital identities are indispensable for meeting regulatory compliance requirements and safeguarding public health against the proliferation of falsified medications.

On addressing challenges faced by current traceability and security systems:

1. Blockchain technology has the potential to address the shortcomings of traditional traceability systems by providing a tamper-proof and transparent ledger of product transactions.
2. By leveraging blockchain, we can streamline supply chain processes, minimize counterfeit risks, and enhance the security and authenticity of pharmaceutical products.
3. Blockchain's decentralized nature ensures data integrity and immutability, offering a robust solution to combat the challenges faced by existing traceability and security systems.
4. The adoption of blockchain technology enables real-time tracking and authentication of pharmaceutical products, empowering stakeholders with actionable insights to prevent security breaches and ensure regulatory compliance.

On potential barriers or obstacles in adopting blockchain-based solutions:

1. One potential barrier is the upfront investment required for implementing blockchain technology, which may pose financial challenges for some pharmaceutical companies.
2. Interoperability issues between existing IT systems and blockchain platforms could hinder seamless integration and adoption across the pharmaceutical sector.
3. Regulatory uncertainties and compliance requirements may create barriers to the widespread adoption of blockchain-based solutions in the Indian pharmaceutical industry.
4. Concerns over data privacy and governance could impede the adoption of blockchain

technology, necessitating clear frameworks and standards to address these challenges.

Benefits of Blockchain-based Digital Identities

Adopting blockchain-based digital identities could offer benefits such as enhanced traceability, reduced counterfeiting, improved supply chain efficiency, and increased trust among stakeholders. Blockchain technology can enhance traceability, security, and authenticity by creating an auditable and decentralized ledger of transactions, making it difficult for unauthorized parties to manipulate data.

This section has 3 questions. The responses were as follows:

Question 1	In your opinion, what specific benefits can be derived from adopting blockchain-based digital identities in the pharmaceutical supply chain?
Respondent 1	Blockchain-based digital identities offer unparalleled transparency and immutability, ensuring accurate tracking of pharmaceutical products throughout the supply chain.
Respondent 2	The adoption of blockchain enhances trust among stakeholders by providing verifiable and tamper-proof records of product provenance and authenticity.
Respondent 3	Blockchain reduces the risk of fraud, counterfeiting, and diversion in the pharmaceutical supply chain.
Respondent 4	Blockchain-based digital identities enable swift and efficient recalls, minimizing the impact of counterfeit or unsafe medications on public health.
Question 2	How do you think blockchain technology could enhance the traceability, security, and authenticity of pharmaceutical products?
Respondent 1	Blockchain technology enhances traceability by creating an immutable ledger of transactions, enabling real-time monitoring and verification of pharmaceutical products' movements.
Respondent 2	Through cryptographic mechanisms, blockchain ensures data security and integrity, reducing the risk of unauthorized access, tampering, or data breaches.
Respondent 3	Blockchain enables seamless authentication of pharmaceutical products, allowing consumers and regulators to verify their origin, quality, and compliance with regulatory standards.
Respondent 4	The decentralized nature of blockchain ensures trust among stakeholders by

	providing a transparent and auditable record of every transaction, enhancing the overall security and authenticity of the pharmaceutical supply chain.
Question 3	Are there any case studies or examples that demonstrate the effectiveness of blockchain in improving traceability and security in the pharmaceutical industry?
Respondent 2	A blockchain-based platform enabled pharmaceutical manufacturers to monitor temperature-sensitive medications throughout the distribution process, ensuring product quality and compliance with regulatory requirements.
Respondent 3	A pilot project demonstrated how blockchain technology improved traceability and transparency in the distribution of controlled substances, minimizing the risk of diversion and unauthorized access.

Table 10: Response of participants to third section questions

Challenges and Regulatory Considerations

Regulatory hurdles in implementing blockchain-based digital identities may include uncertainty about compliance standards, jurisdictional issues, and the need for industry-wide consensus on governance frameworks. Existing regulations and standards may need to be adapted to accommodate blockchain technology, ensuring compatibility and adherence to legal requirements. Concerns related to data privacy, interoperability, and governance must be addressed to ensure the successful implementation of blockchain-based solutions.

This section has 3 questions. The responses were as follows:

On regulatory hurdles in implementing blockchain-based digital identities:

1. Anticipated regulatory hurdles include uncertainty around how existing laws will apply to blockchain-based systems, especially concerning data ownership, liability, and jurisdiction.
2. Obtaining regulatory approval for blockchain-based systems may require extensive validation and certification processes to ensure compliance with industry standards and patient safety regulations.
3. Interpreting existing regulations to accommodate the unique features of blockchain technology, such as decentralized governance and data immutability, presents a challenge for pharmaceutical companies seeking regulatory approval.

On adaptations to existing regulations and standards for blockchain technology:

1. Existing regulations and standards may need to be updated to provide clear guidance on how blockchain technology can be used to ensure compliance with pharmaceutical industry requirements.
2. Regulatory frameworks should incorporate provisions for verifying the integrity and authenticity of data recorded on blockchain platforms, establishing trust in the accuracy of information.
3. Collaboration between regulatory agencies, industry stakeholders, and technology providers is essential to develop standardized guidelines for implementing blockchain-based solutions in the pharmaceutical sector.
4. Regulations may need to address the interoperability of blockchain systems with existing IT infrastructure, ensuring seamless integration and data exchange across the pharmaceutical supply chain.

On challenges related to data privacy, interoperability, and governance:

1. Data privacy concerns revolve around ensuring the confidentiality and security of patient information stored on blockchain networks, requiring robust encryption and access control mechanisms.
2. Interoperability challenges arise when integrating blockchain solutions with legacy systems, necessitating the development of standards and protocols for seamless data exchange.
3. Governance issues, such as defining roles and responsibilities within decentralized blockchain networks, require careful consideration to ensure transparency, accountability, and compliance with regulatory requirements.
4. Addressing concerns related to data privacy, interoperability, and governance is critical to building trust and confidence in blockchain-based solutions for pharmaceutical product traceability and security.

Contribution to Preventing Falsified Medications and Counterfeit Drugs

Blockchain-based digital identities can help prevent the circulation of falsified medications and counterfeit drugs by providing an immutable record of product provenance and authenticity. Blockchain enhances transparency and trust among stakeholders by enabling

real-time tracking of pharmaceutical products and verifying their integrity throughout the supply chain. Potential drawbacks of implementing blockchain technology include scalability issues and the need for careful consideration of data management practices.

This section has 3 questions. The responses were as follows:

Question 1	How do you think blockchain-based digital identities could contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?
Respondent 1	Blockchain-based digital identities provide a tamper-proof record of each pharmaceutical product's journey from manufacturer to consumer, making it extremely difficult for counterfeiters to introduce falsified medications into the supply chain.
Respondent 2	By enabling real-time tracking and verification of product authenticity, blockchain technology acts as a deterrent to counterfeiters, reducing the risk of counterfeit drugs entering the market and safeguarding public health.
Respondent 3	The transparency and immutability of blockchain ensure that each step in the supply chain is verifiable, allowing stakeholders to quickly identify and quarantine any suspicious or counterfeit medications before they reach consumers.
Respondent 4	Blockchain-based digital identities empower consumers to verify the authenticity of pharmaceutical products using decentralized applications, fostering greater trust and confidence in the medications they purchase.
Question 2	What role do you see blockchain playing in improving transparency and trust among stakeholders in the pharmaceutical industry?
Respondents 1 and 2	Blockchain enhances transparency by providing a decentralized and immutable ledger of transactions, enabling stakeholders to access real-time information on product provenance, authenticity, and compliance.
Respondent 3	Through transparent and auditable records, blockchain builds trust among stakeholders by reducing the risk of fraudulent activities such as counterfeit drugs, diversion, and unauthorized tampering.
Respondent 4	Blockchain facilitates data sharing and collaboration among stakeholders while ensuring data integrity and confidentiality, fostering greater transparency and accountability throughout the pharmaceutical supply

	chain.
Question 3	Can you envision any potential drawbacks or unintended consequences of implementing blockchain technology for product authentication?
Respondent 1	One potential drawback is the scalability of blockchain networks, as increasing transaction volume may lead to slower processing times and higher costs, especially in large-scale pharmaceutical supply chains.
Respondent 2	Interoperability issues between different blockchain platforms and legacy systems may hinder seamless integration and data exchange, limiting the effectiveness of blockchain-based solutions for product authentication.
Respondents 3 and 4	Concerns over data privacy and security may arise, particularly regarding the exposure of sensitive information stored on blockchain networks, requiring careful consideration of encryption and access control measures.

Table 11: Response of participants to fifth section questions

Strategic Recommendations for Implementation

Stakeholders should collaborate to establish industry-wide standards and regulatory frameworks for blockchain implementation in the pharmaceutical sector.
Education and training programs can help stakeholders understand the benefits and challenges of blockchain technology and how to integrate it into existing supply chain processes.

This section consists of 3 questions. The first 2 questions were combined and the results were thematically analyzed.
On strategic recommendations for implementing blockchain-based digital identities and to maximize its benefits

1. Establishing industry-wide standards and guidelines for blockchain implementation is crucial to ensure interoperability, data consistency, and regulatory compliance across the pharmaceutical supply chain.
2. Investing in education and training programs to enhance stakeholders' understanding of blockchain technology and its applications in pharmaceutical traceability and security is essential for successful implementation.
3. Collaborating with technology providers and regulatory agencies to develop pilot projects and proof-of-concept initiatives can help demonstrate the feasibility and

effectiveness of blockchain-based digital identities in real-world scenarios.

4. Encouraging collaboration between pharmaceutical companies, distributors, regulators, and technology experts to address common challenges and share best practices can accelerate the adoption and implementation of blockchain solutions in the industry.

On necessary steps to ensure smooth adoption and integration of blockchain solutions:

1. Conducting thorough assessments of existing supply chain processes, IT infrastructure, and data management systems to identify areas for integration and optimization is essential for ensuring the seamless adoption of blockchain solutions.
2. Engaging with key stakeholders early in the planning and implementation process to gather input, address concerns, and align objectives is critical for fostering buy-in and ensuring the successful adoption of blockchain technology.
3. Developing clear implementation roadmaps, timelines, and milestones, along with dedicated resources and budget allocations, can help streamline the adoption process and mitigate risks associated with deploying blockchain solutions.
4. Continuously monitoring and evaluating the performance and effectiveness of blockchain solutions post-implementation and iteratively refining processes and strategies based on feedback and lessons learned, is essential for ensuring long-term success and sustainability.

4.3 CONCLUSION

From the inferences obtained from Qualitative and quantitative data analysis, the implementation of blockchain-based digital identities holds immense promise for enhancing traceability, security, and authenticity within the Indian pharmaceutical industry. Despite regulatory hurdles and technical challenges, strategic recommendations such as establishing industry-wide standards, fostering collaboration among stakeholders, and conducting thorough assessments can facilitate successful adoption. Effective collaboration among pharmaceutical companies, regulators, technology providers, and other stakeholders is crucial for maximizing the benefits of blockchain technology and overcoming common challenges. By addressing concerns related to data privacy, interoperability, and governance while ensuring smooth integration into existing supply chain processes, the industry can harness the transformative potential of blockchain to combat counterfeit drugs, enhance transparency, and safeguard public health. Through ongoing dialogue, education, and iterative refinement,

the Indian pharmaceutical industry can navigate the complexities of blockchain implementation and pave the way for a more secure and transparent future. The next section discusses further the conclusion of the study and provides recommendations for future studies and research.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

In conclusion, this research underscores the critical role of blockchain-based digital identities in revolutionizing the Indian pharmaceutical industry's approach towards traceability and security. The study has delved into the current state of pharmaceutical product traceability and security, revealing existing challenges and vulnerabilities within the Indian pharmaceutical supply chain. By examining the necessity and feasibility of implementing blockchain-based digital identities, the research has highlighted the potential benefits such as enhanced transparency, accountability, and security.

Moreover, the study has shed light on the regulatory considerations and hurdles associated with the practical implementation of blockchain-based solutions. Understanding these regulatory aspects is crucial for ensuring compliance and fostering trust within the industry. Importantly, blockchain-based digital identities offer promising avenues for preventing the circulation of falsified medications and counterfeit drugs, thereby safeguarding public health and well-being.

Based on the research findings, strategic recommendations have been proposed to facilitate the successful implementation of blockchain-based digital identities in the Indian pharmaceutical sector. These recommendations aim to address the identified challenges, leverage the potential benefits, and navigate regulatory complexities effectively.

Overall, this study contributes valuable insights and recommendations for stakeholders in the Indian pharmaceutical industry, enabling them to enhance traceability, security, and integrity within the supply chain, ultimately safeguarding the health and safety of consumers.

5.2 ANSWERING THE RESEARCH QUESTIONS

1. Current State of Pharmaceutical Product Traceability and Security

From the survey responses, it can be concluded that:

The current state of pharmaceutical product traceability and security in India reflects a mixed perception among stakeholders. While a majority (54%) of participants consider the existing system effective, there remains a notable proportion with neutral (27%) or

negative (19%) opinions. Suggestions for improvement include implementing comprehensive track-and-trace systems, strengthening regulatory oversight, enhancing serialization requirements, and conducting public awareness campaigns. Despite these recommendations, 59% of participants believe that there are insufficient measures in place to ensure the security of pharmaceutical products in India. Technologies currently utilized for tracking and authenticating pharmaceutical products include barcoding, QR codes, serialization, RFID, tamper-evident packaging, and mobile authentication solutions. Concerningly, 31% of respondents have experienced instances of counterfeit or falsified medicines, highlighting the urgent need for enhanced measures to combat this issue. Collaborative efforts, including industry-wide standards, regulatory frameworks, and education programs, are essential to bolstering pharmaceutical product traceability and security in India and safeguarding public health.

From the 4 interview responses, the whole idea can be concluded as follows:

The existing traceability and security measures for pharmaceutical products in India present a complex scenario, characterized by a mix of advanced technologies and traditional methods. While some companies have invested in serialization and track-and-trace technologies, others struggle with enforcement and adoption due to cost constraints and perceived complexities. Regulatory guidelines exist, emphasizing unique identifiers and standardized packaging, but consistency in enforcement remains a challenge. Technologies such as barcoding, RFID, and blockchain offer promising solutions for tracking and authenticating products throughout the supply chain, but adoption rates vary. Recent incidents, including counterfeit drugs infiltrating the market and concerns over product integrity and diversion, underscore the ongoing challenges in ensuring robust traceability and security within the pharmaceutical industry. Despite efforts to strengthen measures, the persistent threat of counterfeit pharmaceuticals highlights the need for continuous improvement and collaboration among stakeholders to safeguard public health and safety.

2. Necessity and Feasibility of Implementing Blockchain-based Digital Identities

From the 4 interview responses, the whole idea can be concluded as follows:

Implementing blockchain-based digital identities holds immense potential for revolutionizing traceability and security within the Indian pharmaceutical industry. By providing tamper-proof records of transactions and product movement, blockchain

technology addresses the critical need for transparency and trust in the supply chain, particularly in combating counterfeit drugs. Its decentralized nature offers standardized and immutable solutions to enhance product integrity and safety amid the complexities of global supply chains. However, challenges such as regulatory uncertainties, technological complexity, interoperability issues, and concerns regarding data privacy and governance must be addressed to facilitate widespread adoption. Despite these obstacles, leveraging blockchain holds promise in streamlining supply chain processes, minimizing counterfeit risks, and empowering stakeholders with real-time insights to ensure regulatory compliance and safeguard public health against falsified medications.

3. Benefits of Blockchain-based Digital Identities

From the survey responses, it can be concluded that:

The section provides an insightful overview of blockchain technology, its potential advantages, and real-world applications within the Indian pharmaceutical industry. A significant majority of participants (81.08%) demonstrate awareness of blockchain technology, with 70% acknowledging its necessity for improving transparency, security, and traceability in the pharmaceutical supply chain. While feasibility opinions vary, with 43.24% indicating some feasibility and 21.62% remaining neutral, the potential benefits of blockchain-based digital identities are widely recognized. The majority of respondents (80.08%) anticipate significant benefits, including immutable record-keeping, enhanced transparency, real-time tracking, improved authentication, supply chain efficiency, and heightened data security and privacy. Notably, participants highlight the importance of blockchain in addressing critical challenges such as counterfeit drugs and supply chain disruptions, underscoring its potential to revolutionize pharmaceutical traceability and security in India.

From the 4 interview responses, the whole idea can be concluded as follows:

Adopting blockchain-based digital identities holds immense promise for transforming the pharmaceutical supply chain, offering benefits such as enhanced traceability, reduced counterfeiting, improved efficiency, and increased stakeholder trust. Through its decentralized and immutable ledger of transactions, blockchain technology ensures unparalleled transparency, accuracy, and security in tracking pharmaceutical products from manufacturing to distribution. By providing tamper-proof records of product

provenance and authenticity, blockchain enhances trust among stakeholders and minimizes the risk of fraud, counterfeiting, and diversion. Furthermore, blockchain enables swift recalls and authentication of products, mitigating the impact of counterfeit or unsafe medications on public health. Case studies and examples further illustrate the effectiveness of blockchain in improving traceability and security within the pharmaceutical industry, demonstrating its potential to revolutionize processes and safeguard product integrity.

4. Challenges, vulnerabilities and Regulatory Consideration

From the survey responses, it can be concluded that:

This section provides a comprehensive analysis of challenges and vulnerabilities within the Indian pharmaceutical supply chain, offering valuable insights for industry stakeholders, policymakers, and regulators. While a significant proportion of participants identify counterfeiting and falsification as the most pressing challenge in implementing blockchain-based digital identities, technological barriers, regulatory hurdles, and fragmented supply chains also pose considerable obstacles. Awareness of counterfeit and falsified medication distribution is high among participants, highlighting the urgency of addressing this issue to protect public health. Moreover, a substantial majority recognize the potential of blockchain-based digital identities in combating counterfeit drugs, with over 78% expressing agreement or strong agreement with its efficacy. However, concerns regarding the vulnerability of the Indian pharmaceutical industry to security breaches and counterfeit products underscore the need for robust regulatory frameworks and strategic interventions to enhance supply chain resilience and protect consumer safety. Regulatory considerations, including data privacy and security regulations, standardization, interoperability, auditability, and risk management, are paramount for the successful implementation of blockchain technology in the pharmaceutical sector. Addressing these challenges and regulatory considerations requires collaborative efforts from industry stakeholders, policymakers, and regulatory agencies to foster innovation, ensure compliance, and promote patient safety within the pharmaceutical supply chain.

From the 4 interview responses, the whole idea can be concluded as follows:

Implementing blockchain-based digital identities in the pharmaceutical sector faces significant regulatory hurdles, including uncertainty surrounding compliance standards,

jurisdictional issues, and the need for industry-wide consensus on governance frameworks. Adapting existing regulations and standards to accommodate blockchain technology is crucial, requiring clear guidance on data ownership, liability, and jurisdiction, as well as provisions for verifying data integrity and authenticity. Collaboration between regulatory agencies, industry stakeholders, and technology providers is essential to develop standardized guidelines and address challenges related to data privacy, interoperability, and governance. Overcoming these hurdles is paramount to building trust and confidence in blockchain-based solutions, ensuring their successful implementation for pharmaceutical product traceability and security.

5. Contribution to Preventing Falsified Medications and Counterfeit Drugs

From the 4 interview responses, the whole idea can be concluded as follows:

Blockchain-based digital identities offer a potent solution to combat the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain by providing an immutable record of product provenance and authenticity. Through real-time tracking and verification, blockchain technology acts as a formidable deterrent to counterfeiters, ensuring that each step in the supply chain is transparent and verifiable. This transparency not only enhances trust among stakeholders but also empowers consumers to authenticate pharmaceutical products, fostering greater confidence in the medications they purchase. However, potential drawbacks such as scalability issues, interoperability challenges, and concerns over data privacy and security must be carefully addressed to ensure the effective implementation of blockchain technology for product authentication in the pharmaceutical industry.

6. Strategic Recommendations for Implementation

From the survey responses, it can be concluded that:

The "Strategic Recommendations" section offers actionable insights and guidance for stakeholders in the Indian pharmaceutical industry based on the findings from the preceding sections. It underscores the importance of collaboration among industry players, regulatory bodies, and technology providers to develop common standards and guidelines for blockchain implementation. Additionally, investing in education and training programs is emphasized to enhance stakeholders' understanding of blockchain technology and its applications, addressing regulatory challenges, selecting suitable blockchain platforms, ensuring data integrity and security, promoting interoperability, and

integration with existing IT systems. Stakeholder readiness and support for initiatives leveraging blockchain technology are crucial for enhancing traceability and security in the pharmaceutical industry, as demonstrated by a significant proportion expressing willingness to support such initiatives. By implementing these strategic recommendations, the Indian pharmaceutical industry can foster innovation, resilience, and competitiveness while safeguarding public health and ensuring regulatory compliance.

From the 4 interview responses, the whole idea can be concluded as follows:

To effectively implement blockchain-based digital identities in the pharmaceutical sector and maximize their benefits, stakeholders must collaborate to establish industry-wide standards, guidelines, and regulatory frameworks. This collaborative effort should include investing in education and training programs to enhance stakeholders' understanding of blockchain technology and its applications, as well as developing pilot projects to demonstrate feasibility. Additionally, engaging with key stakeholders early in the planning process, conducting thorough assessments of existing processes, and developing clear implementation roadmaps are crucial steps to ensure the smooth adoption and integration of blockchain solutions. Continuous monitoring and evaluation post-implementation will allow for iterative refinement, ensuring long-term success and sustainability in enhancing traceability and security across the pharmaceutical supply chain.

5.3 IMPLICATIONS OF THE STUDY

- Increased Awareness: Participants demonstrated a heightened awareness of blockchain technology and its potential applications in the pharmaceutical industry.
- Recognition of Importance: There's a clear recognition of the significance of blockchain-based digital identities in combating counterfeit drugs and enhancing traceability within the supply chain.
- Identification of Challenges: Key challenges such as counterfeiting, technological barriers, regulatory hurdles, and fragmented supply chains have been identified as obstacles to blockchain implementation.
- Acknowledgment of Vulnerabilities: Participants acknowledged vulnerabilities in the Indian pharmaceutical supply chain, particularly concerning security breaches and counterfeit products.

- Awareness of Regulatory Considerations: There's an understanding of regulatory considerations essential for successful blockchain implementation, encompassing data privacy, regulatory approval, standardization, and compliance.
- Strategic Recommendations: The study provides actionable insights and strategic recommendations emphasizing collaboration, education, regulatory compliance, platform selection, data security, interoperability, and stakeholder support for blockchain initiatives.
- Varied Stakeholder Readiness: Stakeholder readiness and support vary, with a significant proportion expressing willingness to support initiatives aimed at enhancing traceability and security through blockchain adoption

5.4 CONTRIBUTIONS OF THE RESEARCH

- The study contributes to a deeper understanding of blockchain technology and its potential applications in addressing challenges within the pharmaceutical supply chain.
- Findings reveal stakeholders' perceptions regarding the necessity of blockchain-based digital identities, offering insights into the perceived benefits and challenges of adoption.
- The study offers actionable strategic recommendations tailored to the Indian pharmaceutical industry, facilitating informed decision-making and guiding future initiatives.
- By assessing awareness levels and educational needs, the study underscores the importance of education and training programs to foster blockchain adoption and enhance stakeholder capabilities.
- It sheds light on regulatory considerations crucial for blockchain implementation, emphasizing the need for compliance with data privacy, security regulations, and collaboration with regulatory agencies.
- Likert-scale questions gauge stakeholders' readiness and support for initiatives aimed at leveraging blockchain technology, providing valuable feedback for industry-led efforts to enhance traceability and security.
- Overall, the study's findings have the potential to drive positive change, improve traceability, security, and efficiency within the pharmaceutical supply chain, ultimately benefiting patients, healthcare providers, and society as a whole.

5.5 LIMITATIONS OF THE STUDY

1. Sample Size: The study's findings may be limited by the sample size, potentially impacting the generalizability of the results to the broader pharmaceutical industry. The initial sample size for online survey was 97 but the number of responses obtained within the time limit was only 74.
2. Scope: The study's focus on the Indian pharmaceutical industry may limit its applicability to other regions or global contexts, warranting further research for broader insights.
3. Subjectivity: Interpretation of open-ended responses and Likert-scale questions may be subjective, leading to varying interpretations and potential biases in the analysis.
4. Temporal Context: The study's findings may be subject to changes in technology, regulations, or industry dynamics over time, necessitating ongoing monitoring and updates to remain relevant.
5. Lack of Longitudinal Data: The study may lack longitudinal data, making it challenging to assess changes in stakeholders' perceptions and attitudes towards blockchain technology over time.
6. Enough responses were not obtained for qualitative analysis when requests were sent through LinkedIn. So direct interviews had to be taken.
7. There were only a limited number of articles when considering the research objectives and questions.

5.6 RECOMMENDATIONS FOR FUTURE RESEARCH

- Conduct longitudinal studies to track the evolution of stakeholders' perceptions and attitudes toward blockchain technology in the Indian pharmaceutical industry over time.
- Supplement quantitative data with qualitative investigations, such as interviews or focus groups, to gain deeper insights into stakeholders' experiences, challenges, and perspectives.
- Explore the regulatory landscape surrounding blockchain technology in the Indian pharmaceutical industry, including legal frameworks, compliance requirements, and implications for data privacy and security.
- Evaluate the cost-effectiveness and return on investment of implementing blockchain-

based solutions for pharmaceutical traceability and security, considering factors such as implementation costs, operational efficiencies, and risk mitigation.

- Investigate emerging technologies and innovations that could complement or enhance blockchain-based solutions for pharmaceutical product traceability and security.
- Assess the role of blockchain technology in enhancing supply chain resilience and agility, particularly in response to external disruptions such as pandemics, natural disasters, or regulatory changes.

5.7 FINAL CONCLUSION

The study provides valuable insights into the current state, challenges, and opportunities related to the implementation of blockchain-based digital identities in the Indian pharmaceutical industry. Through a comprehensive analysis of stakeholders' perceptions, awareness, and attitudes towards blockchain technology, as well as the existing regulatory landscape and supply chain vulnerabilities, the study highlights the potential of blockchain to enhance traceability and security within the pharmaceutical supply chain. The findings underscore the importance of collaborative efforts among industry stakeholders, regulatory agencies, and technology providers to address challenges, foster innovation, and facilitate the successful implementation of blockchain solutions. Despite some skepticism and regulatory uncertainties, there is a clear recognition of the benefits of blockchain technology in preventing counterfeit drugs, improving transparency, and enhancing supply chain efficiency. Moving forward, it is imperative to prioritize education, regulatory compliance, and strategic planning to unlock the full potential of blockchain in ensuring the integrity and safety of pharmaceutical products in India.

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APPENDICES

APPENDIX A: SURVEY QUESTIONNAIRE

Available at: https://forms.office.com/r/Dre1kYFVnH

Assessing the Effect of Blockchain IDs on Pharmaceutical Product Traceability and Security in India

Dear Respondent,
I'm Ligi Alexander, pursuing my Master's in Pharmaceutical Business and Technology at Griffith College, Dublin. I intend to conduct an online survey to evaluate the impact of blockchain-based digital identities for pharmaceutical product traceability and security in India. It would be highly appreciated if you show interest in taking part in my research study. By investigating the current state, feasibility, benefits, challenges, and regulatory aspects of the blockchain-based digital identities, the study seeks to provide valuable insights and strategic recommendations for enhancing the integrity of the Indian pharmaceutical sector. Please take time to read the information attached to this form carefully. The survey comprises of multiple-choice questions and short-answer ones. By filling this survey, you are voluntarily agreeing to take part in the research study and I assure you that confidentiality of the responses will be highly maintained. The data generated will be handled as per General Data Protection Regulation (GDPR). If you have any queries concerning this survey, do not hesitate to contact me at the following email id - ligialexander09@gmail.com.

Section 1

1. Do you consent to take part in this research? *

- ◯ Yes
- ◯ No

2. Is the need and significance of the research fully understood by you? *

- ◯ Yes
- ◯ No

Section 2

Demographic Questions

3. Are you currently employed in a Pharmaceutical Company in India? *

- ◯ Yes
- ◯ No

4. What is your profession? *

Enter your answer

5. How many years of work experience do you have in the Pharmaceutical industry? *

- ◯ 0 - 5
- ◯ 5 - 10
- ◯ 10 - 15
- ◯ 15 - 20

Section 3

Current State of Pharmaceutical Product Traceability and Security

6. How would you rate the effectiveness of the current traceability and security system for pharmaceutical products in India? *

	Very Ineffective	Ineffective	Neutral	Effective	Very Effective
	◯	◯	◯	◯	◯

7. If ineffective, what all measures do you think can be adopted to increase the effectiveness of the current state in India? *

Enter your answer

8. Do you believe there are sufficient measures in place to ensure the security of pharmaceutical products within the Indian market? *

- ◯ Yes
- ◯ No

9. Which technologies or systems do you think are currently utilized for tracking and authenticating pharmaceutical products in the Indian market? *

Enter your answer

10. Have you or your organization experienced any instances of counterfeit drugs or falsified medications in the Indian pharmaceutical supply chain? *

- ◯ Yes
- ◯ No
- ◯ Not sure

Section 4

Blockchain Technology and its benefits

11. Are you aware of the Blockchain Technology concept? *

- ◯ Yes
- ◯ No

12. Do you believe it is necessary to implement blockchain-based digital identities in the Indian pharmaceutical industry? *

- ◯ Yes
- ◯ No

13. If you have answered 'Yes' or 'No' to the above question, please explain why? *

Enter your answer

14. How feasible do you think it is to implement blockchain-based digital identities in the Indian pharmaceutical sector within the next five years? *

	Not Feasible at All	Somewhat Feasible	Neutral	Feasible	Highly Feasible
	◯	◯	◯	◯	◯

15. How will you rate the potential benefits of adopting blockchain-based digital identities in the pharmaceutical supply chain in India? *

	Very Low	Low	Neutral	High	Very High
	◯	◯	◯	◯	◯

16. In your opinion, what are the specific benefits that blockchain-based digital identities could offer in improving traceability and security within the pharmaceutical supply chain? *

Enter your answer

Section 5

Challenges and Vulnerabilities in the Indian Pharmaceutical Supply Chain

17. What do you perceive as the biggest challenges in implementing blockchain-based digital identities for pharmaceutical products in India? *

- ◯ Technological Barriers
- ◯ Regulatory Hurdles
- ◯ Counterfeiting and falsification
- ◯ Fragmented supply chain
- ◯ Other

18. Are you aware of the counterfeit and falsified medication distribution in India? *

- ◯ Yes
- ◯ No

19. How much do you agree or disagree with the statement: "Blockchain-based digital identities can significantly contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?" *

	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
	◯	◯	◯	◯	◯

20. How vulnerable do you think the Indian pharmaceutical supply chain is to security breaches and counterfeit products? *

	Highly vulnerable	Somewhat vulnerable	Neutral	Not very vulnerable	Not at all vulnerable
	◯	◯	◯	◯	◯

Section 6

Regulatory Hurdles and Considerations

21. Are you aware of any regulatory hurdles that might hinder the implementation of blockchain-based digital identities for pharmaceutical products in India? *

- ◯ Yes
- ◯ No
- ◯ Not sure

22. If yes, what regulatory considerations do you think are crucial for the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry? *

Enter your answer

Section 7

Strategic Recommendations

23. Please provide any additional thoughts or comments on how blockchain-based digital identities could help in preventing falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain. *

Enter your answer

24. In your opinion, what are the key strategic recommendations that should be considered to facilitate the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry? *

Enter your answer

25. How likely are you to support initiatives aimed at enhancing traceability and security in the Indian pharmaceutical industry through the adoption of blockchain technology? *

	Very unlikely	Unlikely	Neutral	Likely	Very likely
	○	○	○	○	○

APPENDIX B: ETHICS FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA

RESEARCHER'S NAME: LIGI ALEXANDER

PROGRAMME OF STUDY: MSc PHARMACEUTICAL BUSINESS AND TECHNOLOGY

SUPERVISOR'S NAME: GANIRU PRISCILLA UGWU

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE:

DATE: 31/03/2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE:

DATE: 08 Apr 2024

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research *[300 words maximum/ use literature review findings to guide]*

Purpose of Research

By investigating the current state, feasibility, benefits, challenges, and regulatory aspects of the blockchain-based digital identities, the study seeks to provide valuable insights and strategic recommendations for enhancing the integrity of the Indian pharmaceutical sector. The study will provide insights of the potential benefits and challenges of considering blockchain based digital identities for pharmaceutical product traceability and security. The consequences of patients taking falsified and counterfeit medications will also be discussed in the study. Apart from that the regulatory considerations associated with implementation of blockchain-based digital identities will also be discussed. The findings and conclusions from this study would help the researchers and healthcare professionals to use blockchain technologies to identify falsified and counterfeit drugs thereby increasing the traceability and security of these drugs. The current state of pharmaceutical product traceability and security in India and their advancements can be well identified and studied from this research study. The study can also help to create an awareness in healthcare sectors regarding the implementation of blockchain technologies.

Objectives of Research

1. To investigate the current state of pharmaceutical product traceability and security in India.
2. To assess the necessity and feasibility of implementing blockchain-based digital identities in the Indian pharmaceutical industry.
3. Examine the potential benefits of blockchain-based digital identities in enhancing traceability and security within the pharmaceutical supply chain.
4. Analyse the challenges and regulatory considerations associated with the practical implementation of blockchain-based digital identities.
5. To propose strategic recommendations based on the findings to contribute to the effective prevention of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain.

1.2 Research methodology: *[300 words maximum/ detail how you will acquire your primary data (focus groups/interviews/online surveys etc). Proposed questions for questionnaires and/or interviews must be included in the appendix].*

This study will utilize a mixed-methods approach, combining both quantitative and qualitative techniques to gather comprehensive data and insights. Surveys will be distributed to stakeholders involved in the Indian pharmaceutical industry, including manufacturers, distributors, and healthcare providers. The survey will incorporate Likert scale questions and closed-ended questions to assess perceptions and opinions regarding traceability, security, blockchain technology, regulatory issues, and strategic recommendations. In-depth interviews will be conducted with key industry experts, and regulatory authorities to gain deeper insights into challenges, benefits, regulatory considerations, and strategic recommendations. Open-ended questions will be used to explore nuanced perspectives and gather qualitative data. Sample size determination will be based on the population size of each sector. Survey data will be analyzed using descriptive statistics to measure the effectiveness of the current traceability

and security system, assess challenges and vulnerabilities, evaluate perceived benefits of blockchain-based digital identities, and identify regulatory hurdles. Statistical software such as Excel will be utilized for analysis. Thematic analysis will be employed to analyze interview transcripts.

Informed consent will be obtained from all participants prior to data collection. Participant confidentiality and anonymity will be ensured throughout the study. Ethical approval will be sought from ethics committee. The research process is estimated to be completed within 2 months, including data collection, analysis, and report writing. Research findings will be disseminated through academic publications, to facilitate knowledge sharing in the pharmaceutical sector.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	~~Yes~~ No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	~~Yes~~ No
Sensitive, personal, professional or corporate issues	~~Yes~~ No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	~~Yes~~ No
Research that may negatively affect the reputation of Griffith College/Innopharma	~~Yes~~ No
Use of personal records without consent	~~Yes~~ No
Use of company data without consent	~~Yes~~ No
The offer of any inducements to participate	~~Yes~~ No
Audio or visual recording without consent	~~Yes~~ No
Using a language other than English	~~Yes~~ No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	~~Yes~~ No
Does your research group include any of the following vulnerable groups	~~Yes~~ No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study *[Do not provide names except where it is deemed impossible to conceal identity].*

Pharmaceutical Manufacturers: This group includes individuals involved in the manufacturing of pharmaceutical products in India. They possess insights into the current traceability and security measures implemented within their facilities and can provide first-hand information on the challenges faced in maintaining product integrity.

Pharmaceutical Distributors: Individuals engaged in the distribution of pharmaceutical products across various regions of India. They are key players in the supply chain and can shed light on the vulnerabilities and bottlenecks that exist in the distribution process, impacting traceability and security.

Regulatory Authorities: Representatives from regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO). Their perspectives are vital in understanding the regulatory landscape, existing frameworks, and potential hurdles in implementing blockchain-based digital identities.

Healthcare Providers: This category includes doctors, pharmacists, and healthcare administrators who interact directly with pharmaceutical products. Their input is valuable in assessing the impact of counterfeit drugs on patient health and safety and the potential benefits of improved traceability and security measures.

Blockchain Technology Experts: Professionals with expertise in blockchain technology and its applications. Their insights are crucial in evaluating the feasibility and benefits of implementing blockchain-based digital identities in the pharmaceutical industry, as well as addressing technical challenges.

4.2 How do you plan to gain access to/contact/approach your participant(s).

Pharmaceutical Manufacturers and Distributors: Utilizing industry databases and directories to identify pharmaceutical companies and distributors operating in India. Reaching out to these organizations via email, Zoom meetings or phone calls, introducing the research study and requesting participation.

Regulatory Authorities: Initiating contact through official channels, such as LinkedIn, email, Zoom meetings outlining the research objectives and seeking collaboration or participation.

Healthcare Providers: Approaching hospitals, clinics, and pharmacies across different regions of India to engage with healthcare professionals.

Blockchain Technology Experts: Identifying and contacting academic institutions, research centers, and technology companies with expertise in blockchain technology and its applications via phone calls or email.

Common platform for all the categories is contacting through LinkedIn.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes No
Details of what participation will involve	Yes No

Rights to anonymity	Yes ~~No~~
Confidentiality	Yes ~~No~~
Rights to withdraw from the research	Yes ~~No~~
The contact details of the researcher and supervisor (if necessary)	Yes ~~No~~

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.
~~No: my research study involves an online survey only and/or does not require signed consent~~

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data as long as it is still useful and there is an intention to use it further for research so if this is not the case then this can be stipulated here and a shorter retention period given.]

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Data Storage: The research data will be securely stored in digital format using password-protected files and encrypted storage solutions to prevent unauthorized access. A centralized repository or cloud-based storage platform with robust security measures will be utilized for data storage.

Retention Period: The research data will be retained for a specified period in accordance with ethical guidelines and institutional policies. Data retention periods range from 3 to 7 years after the completion of the research project.

Data Management Plan: Data will be organized and labelled systematically to ensure ease of retrieval and analysis. Access to research data will be restricted to authorized personnel involved in the research project. Data sharing protocols will be established to facilitate collaboration and dissemination of research findings while ensuring data confidentiality and integrity.

Data Protection Measures: Personal identifiable information of participants will be anonymized to protect their privacy. Informed consent forms will be obtained from participants, clearly outlining the purpose of data collection, how their data will be used, and their rights regarding data protection. Data encryption techniques will be employed during data transmission and storage to safeguard against unauthorized interception or access. Compliance with relevant data protection regulations such as the General Data Protection Regulation (GDPR) and applicable national laws will be ensured throughout the research process.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

~~Yes~~ No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes ~~No~~

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	~~Yes~~ N/A
9.2 Informed Consent Form (ICF) for participant	~~Yes~~ N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	~~Yes~~ N/A
9.4 Any other documents e.g. Non-Disclosure Agreement	~~Yes~~ N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE:31//03/2024

SECTION 10: APPENDIX

INTERVIEW QUESTIONNAIRE

What is your position in the company?

How many years of experience do you have in this field?

Current State of Pharmaceutical Product Traceability and Security

- How would you describe the existing traceability and security measures for pharmaceutical products in India?
- What technologies or systems are currently used to track and authenticate pharmaceutical products throughout the supply chain?
- Can you provide examples of recent incidents or challenges related to traceability or security in the pharmaceutical industry?

Necessity and Feasibility of Implementing Blockchain-based Digital Identities

- What are your thoughts on the necessity of implementing blockchain-based digital identities in the Indian pharmaceutical industry?
- Do you believe that blockchain technology could address the challenges faced by the current traceability and security systems?
- What potential barriers or obstacles do you foresee in adopting blockchain-based solutions in the pharmaceutical sector?

Benefits of Blockchain-based Digital Identities

- In your opinion, what specific benefits can be derived from adopting blockchain-based digital identities in the pharmaceutical supply chain?
- How do you think blockchain technology could enhance the traceability, security, and authenticity of pharmaceutical products?
- Are there any case studies or examples that demonstrate the effectiveness of blockchain in improving traceability and security in the pharmaceutical industry?

Challenges and Regulatory Considerations

- What regulatory hurdles do you anticipate in implementing blockchain-based digital identities for pharmaceutical products in India?
- How do you think existing regulations and standards may need to be adapted to accommodate blockchain technology in the pharmaceutical sector?
- What are the key challenges or concerns related to data privacy, interoperability, and governance when implementing blockchain-based solutions?

Contribution to Preventing Falsified Medications and Counterfeit Drugs

- How do you think blockchain-based digital identities could contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?
- What role do you see blockchain playing in improving transparency and trust among stakeholders in the pharmaceutical industry?
- Can you envision any potential drawbacks or unintended consequences of implementing blockchain technology for product authentication?

Strategic Recommendations for Implementation

- Based on your experience and insights, what strategic recommendations would you propose to facilitate the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry?
- How can stakeholders collaborate effectively to overcome challenges and maximize the benefits of blockchain technology?
- What steps do you think are necessary to ensure the smooth adoption and integration of blockchain solutions into existing supply chain processes?

QUESTIONNAIRE FOR ONLINE SURVEY

Dear Respondent,
I'm Ligi Alexander, pursuing my Master's in Pharmaceutical Business and Technology at Griffith College, Dublin. I intend to conduct an online survey to evaluate the impact of blockchain-based digital identities for pharmaceutical product traceability and security in India. It would be highly appreciated if you show interest in taking part in my research study. Please take time to read the information attached to this form carefully. The survey comprises of multiple-choice questions and short answer ones. By filling this survey, you are voluntarily agreeing to take part in the research study and I assure you that confidentiality of the response will be highly maintained. The data generated will be handled as per General Data Protection Regulation (GDPR). If you have any queries concerning this survey, do not hesitate to contact me at the following email id ligialexander09@gmail.com.

1. Do you consent to take part in this research?
    - Yes
    - No

2. Is the need and significance of the research fully understood by you?
    - Yes
    - No

Demographic Questions

3. Are you currently employed in a Pharmaceutical Company in India?
    - Yes
    - No

4. How many years of work experience do you have in the Pharmaceutical industry?
    - 0-5
    - 5-10
    - 10-15

- 15-20

Current State of Pharmaceutical Product Traceability and Security

5. How would you rate the effectiveness of the current traceability and security system for pharmaceutical products in India?
   - Very Ineffective
   - Ineffective
   - Neutral
   - Effective
   - Very Effective
6. If ineffective, what all measures do you think can be adopted to increase the effectiveness of the current state in India?

(Short answer)

7. Do you believe there are sufficient measures in place to ensure the security of pharmaceutical products within the Indian market?
   - Yes
   - No

8. Which technologies or systems do you think are currently utilized for tracking and authenticating pharmaceutical products in the Indian market?

(Short answer)

9. Have you or your organization experienced any instances of counterfeit drugs or falsified medications in the Indian pharmaceutical supply chain?
   - Yes
   - No
   - Not sure

Blockchain Technology and its benefits

10. Are you aware of the Blockchain Technology concept?
    - Yes
    - No

11. Do you believe it is necessary to implement blockchain-based digital identities in the Indian pharmaceutical industry?
    - Yes
    - No

If yes, why? If no, why?

12. How feasible do you think it is to implement blockchain-based digital identities in the Indian pharmaceutical sector within the next five years?
    - Not Feasible at All
    - Somewhat Feasible
    - Neutral
    - Feasible
    - Highly Feasible

13. How will you rate the potential benefits of adopting blockchain-based digital identities in the pharmaceutical supply chain in India?
    - Very Low

- Low
- Neutral
- High
- Very High

14. In your opinion, what are the specific benefits that blockchain-based digital identities could offer in improving traceability and security within the pharmaceutical supply chain? (Short answer)

Challenges and Vulnerabilities in the Indian Pharmaceutical Supply Chain

15. What do you perceive as the biggest challenges in implementing blockchain-based digital identities for pharmaceutical products in India?
    - Technological Barriers
    - Regulatory Hurdles
    - Counterfeiting and falsification
    - Fragmented supply chain
    - Other (please specify)

16. Are you aware of the counterfeit and falsified medication distribution in India?
    - Yes
    - No

17. How much do you agree or disagree with the statement: "Blockchain-based digital identities can significantly contribute to preventing the circulation of falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain?"
    - Strongly Disagree
    - Disagree
    - Neutral
    - Agree
    - Strongly Agree

18. How vulnerable do you think the Indian pharmaceutical supply chain is to security breaches and counterfeit products?
    - Highly vulnerable
    - Somewhat vulnerable
    - Neutral
    - Not very vulnerable
    - Not at all vulnerable

Regulatory Hurdles and Considerations

19. Are you aware of any regulatory hurdles that might hinder the implementation of blockchain-based digital identities for pharmaceutical products in India?
    - Yes
    - No
    - Not sure

20. If yes, what regulatory considerations do you think are crucial for the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry? (Open-ended)

Strategic Recommendations

21. Please provide any additional thoughts or comments on how blockchain-based digital identities could help in preventing falsified medications and counterfeit drugs in the Indian pharmaceutical supply chain.
    (Short answer)

22. In your opinion, what are the key strategic recommendations that should be considered to facilitate the successful implementation of blockchain-based digital identities in the Indian pharmaceutical industry?
    (Short answer)

23. How likely are you to support initiatives aimed at enhancing traceability and security in the Indian pharmaceutical industry through the adoption of blockchain technology?
    - Very Unlikely
    - Unlikely
    - Neutral
    - Likely
    - Very Likely

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Consent to take part in Research

EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA

- I [*insert participant name*] voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves actively sharing my knowledge, experiences, and perspectives related to pharmaceutical product traceability and security in India, as well as providing input on the feasibility and potential impact of implementing blockchain-based digital identities in the pharmaceutical industry.
- I understand that I will not benefit directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about. I agree to my interview being audio-recorded if it is online through Zoom.
- I understand that disguised extracts from my interview may be quoted in the dissertation conducted by Ligi Alexander followed by her publication in relevant journals.
- I understand that I will adhere to all of the codes of conduct and employee confidentiality for the company I'm working in and there is no expectation to breach these by partaking in this research.

- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained in encrypted password protected files for about 1 year.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for 3-7 years.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details
Name: Ligi Alexander
Degree Programme: MSc in Pharmaceutical Business and Technology
College Details: Griffith College, Dublin
Contact number: 0892441046
Contact mail: ligialexander09@gmail.com

Signature of participant
[Full Name – Printed]
Signature of research participant

---------- Date:

Signature of researcher
I believe the participant is giving informed consent to participate in this study

Ligi Alexander Date: 31/03/2024
Signature of researcher

GRIFFITH COLLEGE

Participant Information Letter

EVALUATING THE IMPACT OF BLOCKCHAIN-BASED DIGITAL IDENTITIES FOR PHARMACEUTICAL PRODUCT TRACEABILITY AND SECURITY IN INDIA

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take enough time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT?

I'm Ligi Alexander, pursuing my Master's in Pharmaceutical Business and Technology at Griffith College, Dublin. I intend to conduct a Research to evaluate the impact of blockchain-based digital identities for pharmaceutical product traceability and security in India. The purpose of my study is to investigate the current state, feasibility, benefits, challenges, and regulatory aspects of the blockchain-based digital identities. The study seeks to provide valuable insights and strategic recommendations for enhancing the integrity of the Indian pharmaceutical sector. The study will provide insights of the potential benefits and challenges of considering blockchain based digital identities for pharmaceutical product traceability and security. The consequences of patients taking falsified and counterfeit medications will also be discussed in the study. Apart from that the regulatory considerations associated with implementation of blockchain-based digital identities will also be discussed. The findings and conclusions from this study would help the researchers and healthcare professionals to use blockchain technologies to identify falsified and counterfeit drugs thereby increasing the traceability and security of these drugs. The current state of pharmaceutical product traceability and security in India and their advancements can be well identified and studied from this research study. The study can also help to create an awareness in healthcare sectors regarding the implementation of blockchain technologies. This topic is highly relevant to the course I'm doing and after successful completion of this dissertation I can achieve my Master's Degree which is my biggest dream.

WHAT WOULD TAKING PART INVOLVE?

It involves actively sharing knowledge, experiences, and perspectives related to pharmaceutical product traceability and security in India, as well as providing input on the feasibility and potential impact of implementing blockchain-based digital identities in the pharmaceutical industry. The data will be collected through surveys and interviews. The interviews taken online would be audio recorded and the survey responses will be protected in password protected files.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in the research because of your expertise, knowledge, and involvement in the pharmaceutical industry in India. Your insights and perspectives are valuable for understanding the current state of pharmaceutical product traceability and security, as well as assessing the feasibility and potential benefits of implementing blockchain-based digital identities. Your participation will contribute to identifying existing challenges and vulnerabilities in the pharmaceutical supply chain, analyzing regulatory considerations, and proposing strategic recommendations to enhance traceability and security, ultimately aiming to prevent the circulation of falsified medications and counterfeit drugs. Your expertise and experiences make you a crucial participant in generating valuable insights and recommendations for improving the integrity of the Indian pharmaceutical supply chain.

DO YOU HAVE TO TAKE PART?

Participation in the research is completely voluntary. You are not obligated to take part in the study. However, your insights and perspectives as a stakeholder in the pharmaceutical industry would be valuable for addressing the research objectives and contributing to the development of strategic recommendations aimed at enhancing traceability, security, and the integrity of the pharmaceutical supply chain in India. If you choose to participate, your input will help generate valuable data and insights that can inform potential solutions to tackle challenges related to pharmaceutical product traceability and security. You have the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever. If you need to withdraw please contact the undersigned.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Risks:

Confidentiality Concerns: There may be concerns about the confidentiality of your responses, especially if sensitive information about your organization or practices is disclosed during the research process.

Time Commitment: Participating in surveys or interviews may require a significant time commitment, potentially impacting your daily schedule or workload.

Perceived Bias: There is a possibility that your responses could be influenced by biases or preconceptions, leading to potential inaccuracies in the data collected.

Data Security: There may be concerns about the security of your data, particularly if it is stored or transmitted electronically, leading to potential risks of data breaches or unauthorized access.

Benefits:

Contribution to Knowledge: Participating in the research allows you to contribute valuable insights and perspectives to a study aimed at addressing critical issues in the pharmaceutical industry, potentially leading to advancements in traceability and security measures.

Professional Development: Involvement in research activities can enhance your professional development by increasing your understanding of current industry trends, challenges, and potential solutions.

Impact on Policy and Practice: Your input may inform the development of strategic recommendations aimed at enhancing traceability and security in the pharmaceutical supply chain, potentially influencing policy decisions and industry practices.

WILL TAKING PART BE CONFIDENTIAL?

Yes, taking part in the research will be confidential. Your responses and any information you provide during surveys or interviews will be treated with the utmost confidentiality. Only authorized researchers will have access to the data collected, and your identity will be kept anonymous to the extent possible. Any data shared will be aggregated and reported in a way that ensures individual participants cannot be identified. Additionally, strict data protection measures will be implemented to safeguard your privacy and confidentiality throughout the research process.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All data collected during the research, including survey responses, interview transcripts, and any other relevant documents, will be stored in secure digital formats until after my degree has been conferred. This may involve using password-protected files or encrypted storage solutions to prevent unauthorized access. Your identity and any personally identifiable information will be kept confidential. Responses will be anonymized to ensure your privacy is protected. Only authorized researchers involved in the study will have access to the data, and strict confidentiality protocols will be followed. The retention period for collected data will be 3-7 years.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be analyzed and synthesized to generate insights and conclusions regarding the current state of pharmaceutical product traceability and security in India, as well as the feasibility and potential benefits of implementing blockchain-based digital identities in

the pharmaceutical industry. The results will be made accessible in the college library and could potentially be made available in online e-journals or repositories, subject to the policies and guidelines of the institution.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Ligi Alexander

MSc Pharmaceutical Business and Technology, Griffith College Dublin

Mob: 0892441046

Email: ligialexander09@gmail.com

THANK YOU