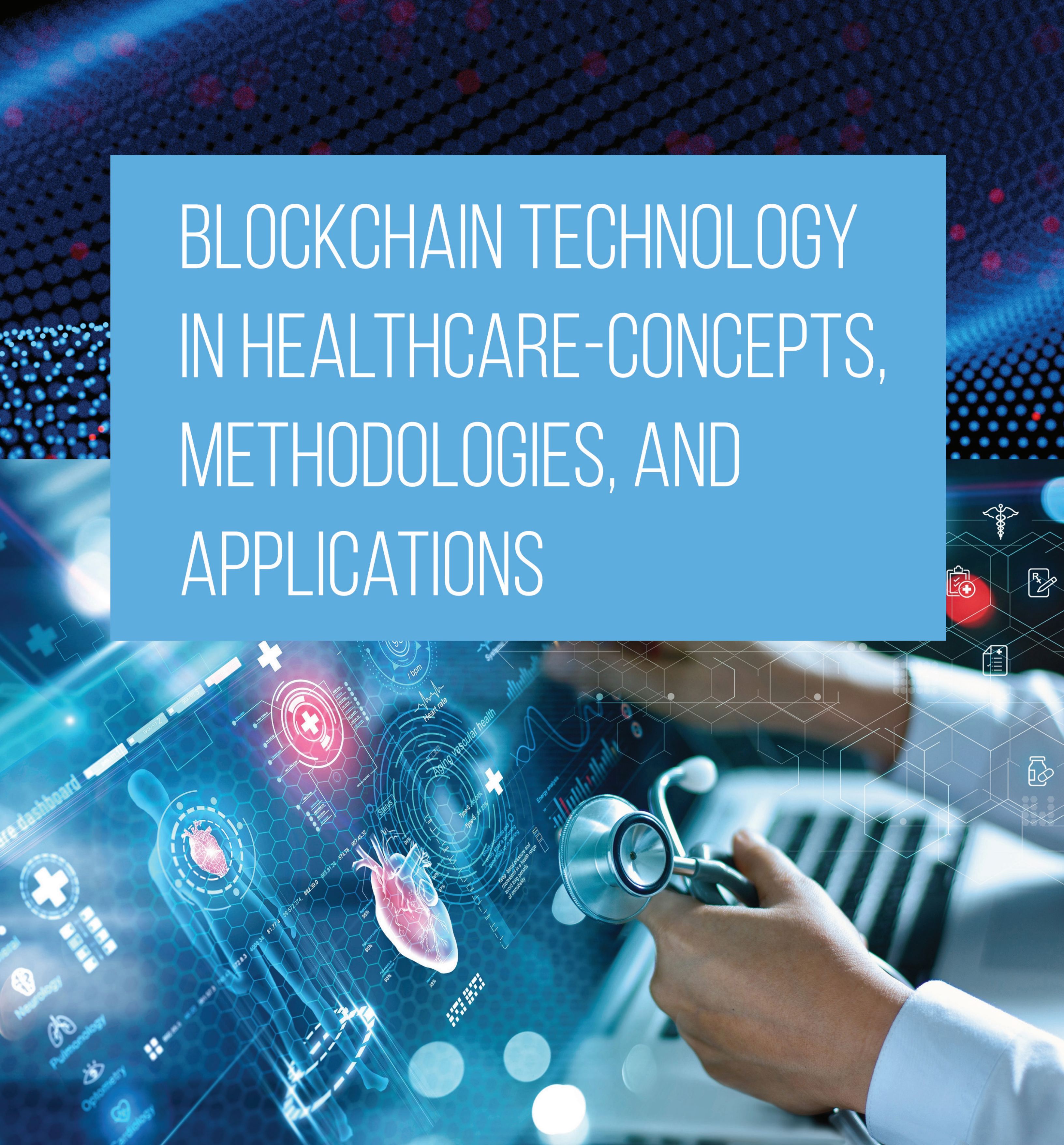

BLOCKCHAIN TECHNOLOGY IN HEALTHCARE-CONCEPTS, METHODOLOGIES, AND APPLICATIONS

Editors:
Nilayam Kumar Kamila
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Applied Artificial Intelligence in Data Science, Cloud Computing and IoT Frameworks

(Volume 1)

Blockchain Technology in Healthcare-Concepts, Methodologies, and Applications

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FOREWORD

Blockchain technology has successfully revolutionized cryptocurrencies by creating a new form of money transactions without relying on having trust in a centralized/third-party service to function. The blockchain is a special distributed ledger technology with tremendous potential to revolutionize how we change value, transfer ownership, and verify transactions in many industrial sectors. A blockchain system is a shared, immutable, distributed digital ledger system that stores linked blocks of peer-to-peer transactions, agreements, and control records, in which the data stored cannot be tampered with. Relying on established cryptographic algorithms, the blockchain allows each participant in the system to interact without pre-existing trust between each other. Unlike traditional centralized systems, a blockchain system does not have a central authority, and all transactional information is stored in blocks and distributed across all participants in the network. Restrict verification is required before adding any information to the chain, which allows trustless participants to share data without losing control and ownership while maintaining an immutable audit trail of all interactions. The decentralized nature of blockchain allows blockchain to help enterprises build processes and solutions, reducing costs, increasing traceability, verifying ownership and proving identity, improving customer experience, and enhancing security. This book provides a good exploration of e-blockchain technology and details on how it can be used to solve business problems. It also explores what they can achieve in various industrial sectors, specifically in medicine and healthcare. In the healthcare sector, a typical use case of blockchain technology is blockchain-enabled supply chain governance, which integrates blockchain technology into the supply chain management system to create a more traceable, secure, transparent, and reliable supply chain system. Using self-executing smart contracts, the blockchain pharmaceutical supply chain takes into account the requirements and interests of all stakeholders. It offers immutability from lab to bedside and secure data management. Blockchain has a broad field of applications in the medicine and healthcare industry, which can facilitate the immutable and secure exchange of medical records and personal data, manage the pharmaceutical supply chain and maintain the traceability of all information involved. On the other hand, the blockchain is capable of keeping an immutable, traceable, secure, transparent, and decentralized database of all patient data and medical records. The restricted verification using cryptographic algorithms in blockchain technology also allows patients, clinics, healthcare organizations, and healthcare providers to share medical information without privacy leakage concerns. This book brings new insights and opportunities that can make medicine and healthcare sectors secure, efficient, and interoperable by using blockchain technology. The insights and solutions of blockchain highlighted in this work can also be easily ported to other industry sections to address challenges related to transparency, immutability, traceability, and full ecosystem interoperability. This work is expected to prompt the realization of the full potential of blockchain technology in medicine and healthcare and illustrate how to build blockchain application ecosystems.

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PREFACE

Overview

The blockchain revolution has profoundly altered global economics and industry-specific strategic practices. The novel uses of blockchain technology can be viewed as a developing sector in anything from data management, financial services, cyber security, IoT, and food science, to the healthcare business and brain research. While innovative blockchain technology and its applications are still being built and developed, it is crucial that academics and industry professionals gain a more excellent knowledge of this universal phenomenon. An emerging area of study is blockchain in medicine and healthcare. The blockchain combines cryptography, critical public infrastructure and economic modelling with peer-t--peer networking and decentralised consensus to synchronise dispersed databases. Although cutting-edge blockchain technology and its applications are still being created and developed, thus academics and business experts must have a deeper understanding of this global phenomenon. The use of blockchain in healthcare and medicine is a new area of research. The blockchain coordinates scattered databases using peer-to-peer networking, decentralised consensus, critical public infrastructure, economic modelling, and cryptography.

Regarding accurate diagnosis and treatment through safe and secure data sharing, blockchain is also rebuilding conventional healthcare practices more dependably. By integrating all the real-time clinical data about a patient's health and presenting it in an advanced secure healthcare setting, blockchain technology can help us soon provide personalised, authentic, and safe healthcare. Additionally, security, privacy, trust, and scalability considerations are necessary.

Objective

The book "Blockchain Technology in Medicine and Healthcare - Concepts, Methodologies, Tools, and Applications" is intended to report on the most recent advancements and innovations in blockchain in medicine and healthcare. The book will be essential in greatly improving human lives. The blockchain, health informatics, and security fields will significantly help researchers and practitioners. This book would be an excellent compendium of cutting-edge methods for using blockchain in healthcare and medical applications. Knowing the top-performing techniques fast will be incredibly helpful for new researchers and practitioners working in the field.

They could contrast various strategies and continue their research in the most crucial area directly affecting improving human life and health. This book would be beneficial because there is yet to be one on the market that offers a comprehensive compilation of cutting-edge blockchain applications in healthcare. The use of blockchain in biomedical and healthcare research is a relatively new development with few established applications.

This book aims to report on the most recent advancements and breakthroughs in security, health informatics, and blockchain. The book's material is divided into three sections; the following three sections go into greater detail on the coverage and topics of each chapter:

• Blockchain and Clinical Trials for Health Informatics.

• Blockchain for Medical Data Analysis.

• Blockchain for Security and Health Information Exchange.

Organisation

The book, **"Blockchain Technology in Medicine and Healthcare: Concepts, Methodologies, Tools, and Applications"** consists of 13 edited chapters, and the full contents of the book are organised into the following three sections:

• *Part I: Blockchain and Clinical Trials for Health Informatics.*

The application of blockchain to clinical trials in health informatics has been the main emphasis of this section. This section consists of three chapters. The first chapter explains how to use blockchain to gather and store patient data, analyse outcomes in a distributed but secure manner, an exchange that data transparently while maintaining its immutability, and overcome the difficulties associated with conducting clinical trials. The second chapter discusses the difficulties in maintaining the confidentiality, accuracy, and integrity of clinical data while conducting clinical trials. Specifics about the data collection techniques used during the clinical trial's operation and the problems they caused. Additionally, it suggests a secure cloud-based clinical data management system that is blockchain-enabled.

The final chapter thoroughly analyses how revolutionary and disruptive blockchain technology is being applied to the healthcare sector to address the problems mentioned above. In a peer-to-peer (P2P) network, a blockchain ledger that is cryptographically immutable, time-stamped, distributed, and tamper-proof can be created to preserve Electronic Health Records (EHRs) in the healthcare system. With the help of this technology, any transaction in a blockchain network has no intermediaries between the source and destination points. The substance of every transaction in a blockchain network cannot be changed because all transactions are cryptographically lither.

The fourth chapter will provide a broad review of guiding principles, applications of blockchain in the healthcare industry, and potential problems and solutions.

• *Part II: Blockchain for Medical Data Analysis.*

There are six chapters in the second portion. The first contribution looked at numerous cutting-edge blockchain applications in the healthcare industry. The blockchain has more reviews than ever before, but they are constrained. The exoteric study offered in this chapter reveals that, when compared to other applications, this disruptive technology offers clear advantages in the healthcare industry.

The second chapter investigates the current application methods, obstacles faced, open questions, data standards, and compliance issues fundamental to adopting a blockchain-based solution in the healthcare business through a systematic study of the literature on blockchain and healthcare data. The current research also investigates the worries and perspectives of blockchain professionals working in the healthcare sector. The third chapter emphasises blockchain's decentralisation feature and how it will resolve problems. By developing a broad mechanism that connects various personal records, blockchain can help the electronic health records sector by lowering data sharing and interoperability. It can also simulate data sharing by immediately bridging the gap between owners and customers. As a result, this chapter aims to give comprehensive information on using blockchains to advance health research data analysis.

Businesses and governments are looking for solutions as the coronavirus illness (COVID-19) continues to spread worldwide to lessen its impact. In chapter four, a structured literature review of peer-reviewed articles on blockchain's implementation and adoption in the supply chain management, education, logistics, and finance sectors was carried out to evaluate the effectiveness of blockchain technology in its efforts to lessen the impact of the pandemic and clearly define the challenges and prospects of blockchain.

It is advised that blockchain be used and adopted in all industries since it offers a decentralised network where information is available, and individual privacy and security are ensured, not just in the banking industry. Therefore, blockchain can be used by businesses, governments, and health professionals in the fight against the virus by transforming the challenges into opportunities combined with prominent essential enablers, which would speed up its wider adoption. Blockchain has been widely accepted and implemented in a few sectors of the economy, especially in finance and supply chain management.

The work carried out by numerous researchers over the previous 11 years is methodically reviewed in chapter four. A projection of a new use of the same technology is proposed, specifically the application and influence of blockchain technology in numerous industries, such as crypto-currencies, the health sector, e-governance, banking, and finance. The final chapter covers distributed ledger technology in the healthcare industry, which has been cited as crucial for producing patient data for research, medication adherence, managing multiple patient bedside data, pharmaceutical supply chain, and quality of care. This chapter will outline how Blockchain distributed ledger technologies are applied to the biomedical and healthcare industries.

• *Part III: Blockchain for Security and Health Information Exchange.*

This section consists of three chapters. Blockchain technology is the cure that enables medical service units that are based on various platforms to share electronic health record data. However, given the cost and size of the blockchain, Chapter 2 has emphasised that one of the main issues with this strategy is the difficulty in storing all the electronic health record data on the blockchain. Cloud computing was selected as a potential exit strategy. A unique possibility provided by cloud computing includes storage of scalability and availability. However, because sensitive data is exchanged through a public route, the cloud computing-advantaged electronic health records may be vulnerable to attacks. To effectively manage and combine medical care, it is necessary to share and disseminate medical information and data electronically. Unfortunately, it is challenging to share data securely using the outdated cloud-based electronic medical record storage infrastructure. Due to blockchain technology's tamper resistance and traceability, sharing extremely private health information is possible. As a result, this chapter aims to give comprehensive information on the use of blockchain in medical imaging systems.

The construction of the blockchain, its framework, the advantages and disadvantages of combining these technologies, and the function and significance of machine and deep learning algorithms in fraud detection and prevention in the blockchain are covered in the first section of the second chapter. The reported work is the main topic of the next part, which also highlights the work of other researchers who use Blockchain technology to detect and prevent fraud. The chapter's last section compares numerous performance metrics for each sort of fraud detection utilising blockchain technology, including accuracy, the area under the curve, confidence, true negative, false positive, and genuinely positive results.

The final contribution showcases a cutting-edge healthcare framework that uses the blockchain idea. This article mainly aims to use Blockchain to construct electronic health records (EHR). Its decentralised design eliminates the possibility of a single point of failure and strengthens the system. The proposed method uses an off-chain data source to address the extensibility issue that blockchains all share. The findings show that computers are far safer and fraud-free compared to the conventional health record system. Finally, the suggested technique highlights situations where the new approach should work well, like in an EHR.

Target Audiences

The current volume serves as a reference book for a variety of audiences, including the following:

• Researchers working in this area who want to be aware of the most recent advancements in theory, methodology, and research.

• Biomedical and informatics students and academics interested in deepening their understanding of recent advancements.

• Business and professionals from technical institutes, research and development firms, and fields relating to machine learning, blockchain, the internet of things, cloud computing, biomedical engineering, and health informatics.

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CHAPTER 1

Utilizing Blockchain Technology to Improve Clinical Trials

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Abstract: The development of new drugs by pharmaceutical companies becomes a challenging task as it takes longer timelines, and the clinical trial process involved before the introduction of any new drug is risky and highly unpredictable. The patient data available for the clinical trial process is distributed across several databases, and the data are stored in different formats; hence it becomes difficult to perform clinical trials. Many stakeholders (pharmaceutical companies, research labs, patients, participants, government authorities, and many more) across geography are involved in the clinical trial process. Cooperation among these stakeholders is necessary to conduct a clinical trial. A Clinical trial is a complex and time-consuming procedure that faces a constant challenge of data management, data sharing, and data security, resulting in being an expensive affair.

Blockchain technology can be used to augment the entire workflow of clinical trials and overcome the mentioned challenges. It uses consensus protocol for efficient transmission and communication of data between nodes. Patient recruitment for clinical trials can be easily managed through “Smart contracts”. Any computational problem related to patient recruitment for a clinical trial, checking the validity of clinical trials, can be coded with smart contracts. This paper describes the utilization of blockchain to collect and store patient data and analysis results in a distributed yet secured manner, which can be shared in a transparent way and remain immutable as well as allows to tackle the challenges involved in the clinical trial process.

Keywords: Blockchain, Clinical trial, Consensus protocol, Smart contracts, Stakeholders.

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1. INTRODUCTION

1.1. Background

Scientific studies conducted to treat, diagnose, screen, or find better ways to treat disease is called clinical trial (CT). CT is also a primary method to test and validate new drugs and therapies. Trials involve multiple sites all over the world, with different trial protocols and government regulations. Due to these reasons, CT process involves a high cost and also consumes a lot of time to complete the entire process. Research institutions and pharma companies involved in clinical trials try hard to reduce the time and cost involved in conducting the CT process. The high cost is incurred by pharma companies due to the unpredictable and risky nature of the CT process. Several factors are involved in the clinical trial process, like patient involvement, laboratory investigation, patient investigation, approval from regulatory bodies, *etc*. Due to these processes, the CT process takes long development timelines, which reduces the chances of introduction of a successful process to zero, which is evident in the COVID-19 pandemic.

1.2. The Problem

The COVID-19 pandemic has discontinuous clinical trials worldwide, with long-lived effects on medical science. Worldwide Disruption in the clinical trial process has occurred due to this pandemic situation. The virus has led to the situation that the flexibility to conduct trials safely and effectively is completely not possible, as the trials have to be conducted to vulnerable patients (subjects) who are exposed to covid-19 [1]. Moreover, several trials are stopped due to the difficulties to conduct trials under the lockdown situation. Even after relaxing the lockdown in some sites, there were great challenges in conducting trials.

In the Indian scenario, the trial process is likely to be conducted in private hospitals as severe covid-19 patients will require intensive care support. This would deprive economically backward people to get the benefit of participating in the trial process. So, the challenge here is the Indian government should set up a supervised trial by the government agency which should allow all covid-19 patients to register for their trial process irrespective of their economic background.

Participants selected for Clinical trials of covid-19 are selective as it requires in-depth attention. This is because it affects the efficiency of therapeutic intervention and evaluation. Following the scientific and ethical principles into practice during the clinical trials of covid-19, is a huge challenge [2].

Due to covid-19, there were huge disruptions in clinical trials [3]. These disruptions were due to the slow or suspension of enrollment and delay in the trial initiation process. Based on the data source provided by global data, it is evident that the delay in the initiation process was steady, and there was an increase in the slow enrollment process. One of the main reasons for subjects not to enroll in a clinical trial was because the chances of contracting covid-19 are high with them due to their previous health issues [4].

The uncertainty created by the covid-19 pandemic poses many glitches to investigators/researchers. The challenges faced by the investigator include producing accurate data, maintaining clinical data privacy, on-time patient enrolment methods, and efficiently sharing personal data across the various stakeholders involved in the clinical trial process. Luckily, there's a new technology that is attracting the attention of investigators and researchers that may help find solutions to all of the problems, which is Blockchain technology. With this technology, many researchers find a lot of highly effective and efficient processes that may help address the challenges faced nowadays. It took nearly two years to help recognize the viability of this technology in addressing the challenges present today in clinical trials, like patient enlisting, auditing the clinical supply chain, restoring integrity to trial information, and helping research institutions to reduce the time and cost to conduct trials [5].

1.3. The Proposed Solution

Blockchain is a time-stamped data structure where it has the 'append-only' option of data. Blockchain works in a distributed environment with a peer-to-peer network. The primary functionality of blockchain is transaction processing. When any new transaction arises in a blockchain, it is verified by the participating node in the network using a consensus algorithm. Blockchain processes transactions in a transparent and secure manner. Due to the digital immutability feature possessed by blockchain, information, once entered into the blockchain can never be altered or changed. Because of these reasons, blockchain has applications in various sectors like Banking, Education, Medical, and electronic health record. Bitcoin is one of the most popular applications of blockchain that helps to transfer money without the need for a third party.

Another important feature of blockchain is smart contracts; with smart contracts, the blockchain can keep track of interactions among nodes in the network without the involvement of any intermediary or third parties. It enables the execution of contracts between parties in a neutral and unbiased way. Hence, a smart contract helps in achieving ethical practices in business. This same technique, if applied in the clinical trial process, will benefit the various stakeholders like Investigators, patients, and sponsors. The central theme of this chapter is to bring in a smart contract-enabled private network for various processes involved in Clinical trials. As blockchain enables storing a huge amount of information in an encrypted form on a distributed network, the cost involved in cloud storage is minimized.

The remaining chapter is organized as follows: This chapter attempts to bring in the efficacy of implementing blockchain for clinical trial purposes. Section 2 focuses on the current research status with a state-of-art review, and highlights a systematic literature review on the adoption of smart contract-enabled private blockchain for the clinical trial process. The detailed process of the clinical trial is illustrated in Section 3 to enable readers to have an understanding of the clinical trial process before the details of blockchain implementation are discussed. Section 4 discusses clinical data management, and Section 5 presents various blockchain architectures with a main focus on private blockchain architecture. Consensus protocols that are used in the hyper-ledge platform are mentioned in Section 6. Blockchain platforms on which the clinical trial process can be carried out are highlighted in Section 7. Section 8 explains the challenges in implementing blockchain in Clinical Trials, and this chapter is concluded in Section 9.

2. LITERATURE SURVEY

The success of clinical trials lies in several factors, like patient enrolment, patient and principal investigator perspective, trial protocols, and trial sites [6]. Due to insufficient patient enrolment, 19% of registered clinical trials were either closed or terminated [7]. Every clinical trial should meet its recruitment goal. Delay in Patient recruitment and failure to meet recruitment goals lead to inaccurate statistical results and waste of time and cost. Data generated through clinical trials are published in journal and newspaper articles. Regulatory bodies use these data as the basis for the approval of new drugs. So, the integrity of clinical trial data is essential for the various stakeholders involved in the process [8]. Data can be altered or lost, published analysis may not be a true representation of data, and data can be duplicated or manipulated by the researchers [8]. Several threats to the data collected in the clinical trial process exist [9] which has to be tackled. Blockchain is one of the emerging technologies that has its successful application in Bitcoin, provides an opportunity to solve the threat associated with the integrity of data collected in clinical trials, and also ensures that statistical analysis made out of this data meet the requirements of trial plans [10]. Ilhaam A. Omar *et al*. mentioned in their work that blockchain technology is a promising disruptive technology that reduces the emphasis on traditional data management [11]. Even though blockchain is considered to be an evolving technology, Kuo T *et al*. realize its maturity as its applications are being explored in many areas like education, banking, finance, and the healthcare sector [12].

Blockchain creates a decentralized environment that shares encrypted data between ledgers in a secure manner without the involvement of any third party. The main function of blockchain technology is digital immutability, that is, the information entered in the blockchain can never be altered or erased. These functionalities make information transfer between stakeholders transparent, fully trustworthy, and immutable [13]. The data immutability feature of blockchain brings greater confidence among the public, and their trust in biomedical research also increases. Siyal *et al*. [14] highlighted the benefits of using blockchain and smart contracts for the healthcare sector. In their work, they have mentioned that blockchain has the potential to reduce data loss by securing the information on the ledger.

To enhance patient involvement in the clinical trial, and make them more active in the clinical trial, David M Maslova *et al*. proposed a block trial, a system that makes use of a web-based interface, to enable users to run trials using a smart contract on an Ethereum network [15]. As the patients' medical data are stored electronically using blockchain methodology, it enables patients to show greater ownership [16] towards their data, and also data transformation between platforms is made possible [17, 18].

Zheng *et al*. recommended private blockchain, also called permissioned blockchain, for healthcare organizations to ensure the safety and suitability of trial data. Private blockchain allows only authorized participants to read and write in the network [19]. Asma Khatoon used Ethereum-based smart contract for Clinical Trials to store medical records in the network [20]. Ethereum-based smart contract functionality in a blockchain network is described as a future-generation cryptocurrency and decentralized application platform [21, 22]. The benefit of using Smart Contract is that it does not involve a third party; it is a piece of program code, also called chain code. It is an algorithmically written contract between the stakeholders in the clinical trial. It executes according to the terms and conditions provided in the trial protocol [23].

Nugent *et al*. proposed a private, permissioned blockchain network in the Ethereum platform. The network is maintained by regulatory bodies like MHRA, FDA, pharma companies, and research organizations in parallel with clinical data management systems [24]. The authors used two core types of smart contracts: regulator contract and trial contract. The regulator contract is owned and updated by regulators and it holds a data structure that contains a clinical trial authorization. It also contains functionality to deploy a trial contract by CROs.

The trial contract contains a data structure to store the trial protocol [24]. Nugent *et al*. demonstrated in their work that smart contracts that run on the Ethereum blockchain platform help to improve the transparency of data in clinical trials. In this chapter, we have described that the private, permissioned blockchain in a hyper-ledge platform helps to maintain data privacy and security in a trustless blockchain environment.

Hyperledger, Ethereum is the most popular private blockchain implementation [25]. Olivia Choudhury *et al*. presented a novel framework that creates a private channel in a private blockchain network to improve data privacy and integrity. In their work, they demonstrated how to create a private channel for segregating sensitive data and, at the same time, leveraging smart contracts to regulate the activities of study protocol [26].

3. UNDERSTANDING CLINICAL TRIAL

3.1. Introduction to Clinical Research

Clinical research is research conducted by pharmaceutical scientists and drug researchers with the help of humans to test newly developed medicines, therapies, and other health services. It is of two types:

• Observational studies:

Observational studies are an important part of clinical research where the researcher has no control over the individual or drug and hence cannot manipulate the results. It is classified as:

– Retrospective studies- the data is collected before the objectives are set.

– Prospective studies- the data is collected after the objectives are set.

– Cohort studies- the subjects are followed over time.

– Cross-sectional studies- at one point in time, the subjects are examined.

• Clinical Trials:

Research studies that are aimed at evaluating surgical, medical, and behavioral interference with the involvement of a small set of people are called clinical trials. Clinical trial plays an inevitable role in the release of a new drug because 1) It is the basic way pharmaceutical scientists and researchers find out if a new treatment, drug, or diet is harmless and suitable for humans. 2) It helps to analyze the new treatment's harmfulness, effectiveness, and side effects as compared to the standards set for that treatment.

Apart from these primary reasons, clinical trials are used to find an illness, ailment, or disorder early, even before they start showing symptoms. It especially benefits people suffering from chronic health problems with no cure.

Clinical trials must be fair and unbiased, which is achieved by three kinds of trials: blind, double-blind, and triple-blind. Clinical trial participants are mostly unaware of which product they are sampling to make the results accurate. The comparison is made between a standard medication or a placebo against the trial medication. These types of trials are regarded as “Blind.”

A double-blind trial is where both the participants and the specialist governing the tests are unaware of the products and drugs given to the participants. This is more effective in producing accurate results than “blind” clinical trials since it removes the manipulation of results by doctors who are too eager to bring those drugs into the market. In a triple-blinded study, even the evaluator is unaware of the process and the product. In many clinical trials, especially when the drug is being developed for an extreme disease, there is a pre-clinical phase where it is tested on animals to make sure it is safe and can be further tested on humans.

3.2. Stakeholders in Clinical Trails

The clinical research industry works in collaboration with different organizations. Fig. (**1**) shows the stakeholders in the clinical trial. They are:

Fig. (1). Stakeholders in Clinical Trial.

• Patients(subjects)

• Sponsors

• Government agencies like Data security and monitory team

• Investigating team

• Regulatory authorities like FDA

• Analyst

All the stakeholders come under either of these responsibilities- administrative, ethical, and scientific responsibilities. Participants are the main component of a clinical trial, along with the drug or product to be tested. A set of participants from various backgrounds with suitable health conditions for the clinical trial help in getting accurate results.

Sponsors are important stakeholders who are the reason to initialize clinical research by financing it. Sponsors can be a company, organization, or an individual, and most biotech companies, pharmaceutical companies, and academic institutions are sponsors.

Sponsors hire the investigator or the supervisory team. Usually, the investigating team comprises of co-investigator, sub-investigator, study nurse, pharmacist, lab assistant, research coordinator, and subject recruiter. They must be qualified and have had the proper training to conduct the duties assigned to them during clinical research. The investigator and his team must keep all records and reports of various details in the trial.

Regulatory authorities are responsible for granting permission to conduct clinical research in the country. The sponsors submit the new drug application for review and approval by regulatory authorities. Upon the sponsors, continue the research. The Regulatory authorities conduct an inspection when there are serious and major violations as they are responsible for the protection of public health and the subjects in the clinical trial.

Some important regulatory boards in India are [27]:

• Ministry of Health and family welfare.

• Central drug standards control organization.

• Indian Council of medical research.

The independent ethics committee or institutional review board is a stakeholder who is at the site of clinical research. The trial starts only after the approval of the ethics committee. It is accountable for the well-being of trial subjects, review of clinical trials in process, payments, and compensation to trial subjects [28].

3.3. Clinical Drug Development Phases

Developing a drug doesn't happen overnight. To let a medicine available to the public as a product, it has to pass several stages to assure it safe, effective and satisfies all regulatory requirements. The detailed stages of drug development are:

• Discovery and development

• Preclinical research

• Clinical development

• Regulatory approval

• Post-market monitoring

3.3.1. Phase 1: Discovery and Development

Discovery starts by choosing a biochemical mechanism of a disease. Usually, a lot of money is spent on research and development of new medicine for the targeted disease or ailment, which may come from the government, non-repayable funds, *etc*. The drug is gradually developed in laboratories with the help of scientists observing the drug's properties, effects, and level of vigor.

3.3.2. Phase 2: Pre- Clinical Research

The preclinical phase is one inevitable phase since the drug is tested on some living organisms. This is a preliminary phase where the drug's safety is ensured by testing it on animals. Each process in a test is reported carefully. Any kind of ignorance or manipulation of the results of this phase may cause harm to subjects who will be participants in the clinical trial.

3.3.3. Phase 3: Clinical Development

When the drug passes pre-clinical research, it is further trialed on a small set of people, and this is called a “clinical trial.” Though the drug is said to be safe after testing on animals, it should pass the parameters set by a regulatory authority to be tested on humans. The clinical trial is a very crucial phase since it is the final step of testing and finding its whole set of properties before approval and release in the market. Therefore, manipulation of results in a clinical trial is highly prevented by making the technical and non-technical people of a clinical trial unaware of the drug and its different dosages.

3.3.4. Phase 4: Regulatory Approval

In India National Regulatory Authority (NRA) is the central drugs standard control organization (CDSCO). It is responsible for regulating the market and imposing several rules. Approval to conduct different tests and trials in drug development is given by CDSCO. All phases of clinical trials have to be conducted mandatorily for the drug substances which are discovered in India as per the rules given by the drugs and cosmetics act 1940. After conducting clinical trials, the exploratory results are submitted by the conducting team for drug approval. When the reports comply with the regulations, it is further approved for release in the market (Note: initially for a limited supply).

3.3.5. Phase 5: Post-Market Monitoring

After regulatory approval, the drug is released into the market and available to the public. But initially, its supply is limited to lesser people. The effect of the drug is still monitored just in case of abnormal activity of the medicine. In case of such odd reactions, the reason is found out either from dosage or an unknown effect of the drug. Then accordingly, medicine is manufactured and gradually made available in masses.

3.4. Steps in Clinical Trail

A clinical trial is usually parted into five stages. Let us look at them in detail.

3.4.1. Stage 0:

This is the first phase of a clinical trial done with very few subjects. Research specialists medicate a very small dose of the drug to make sure that the drug doesn't harm humans in the upcoming phases of the clinical trial. In the case of the drug giving different effects on the human body than expected, the clinical research team steps back a little and does more preclinical research before resuming the clinical trial.

3.4.2. Stage 1:

In phase 1 of the clinical trial, researchers spent much more time than in phase zero (several months) to study the subjects and observe the formulated medication's effect. The participants of this phase of the clinical trial must have no underlying health conditions. Phase 1 is important as it finds the highest dosage of the drug that humans can ever take. Since the highest dosage is to be found in this phase, the monitors closely observe how the participant's bodies react to the medication. The best way to administer the drug to the human body is also determined, *i.e*., orally, intravenously, or topically.

3.4.3. Stage 2:

The number of participants in phase 2 ranges from a few hundred to a thousand with the condition that the new drug is meant to cure. The same dosage as in the previous phase is given and the subjects are examined for several months or years to know any new side effects or harm caused due to long-term usage of the medication. To know better the effects of the drug on humans' people from different backgrounds are encouraged to participate in phase 2 of the clinical trial.

3.4.4. Stage 3:

The third phase involves at most 3,000 participants with the respective condition that new medication is meant to treat. The drug's effect is compared to existing medications for the same health condition. To achieve these random participants are chosen, some receive the new medication and some receive the existing medication. The double-blind method is used in this phase where neither the participant nor the investigator is informed about the type of medication and its dosage [29].

3.4.5. Stage 4:

After all the approval in previous trials, the medication is given to thousands of people and the trial can last for several years. This phase aims to reap any unknown details, or effects of the drug which has not been found in previous phases [30].

3.5. Approval from the Regulatory Authority

After the clinical trial is completed and the drug is tested safe for usage on humans, it is to be manufactured. To do so, the company which is to produce the medicine needs the approval of the regulatory authority. In India, permission must be granted by the licensing authority (DCGI) to import or manufacture a medicine. The appropriate data as in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945, should be submitted.

Rules & guidelines mentioned under the various acts like the Drugs and Cosmetics Act, Consumer protection act, ICMR guidelines, *etc*, has to be followed for the regulation of drugs in India.

Stages in approval of drugs to be manufactured in India are given below:

• Submission of reports and details of all stages of the clinical trial for evaluating safety and efficiency.

• General information regarding the clinical trial team and the location.

• Stages in which the drug was corrected and strained.

• Papers seeking permission and approval for the manufacture of new drugs.

• Administrative and legal information.

• Summary of the nature and origin of the drug.

• Scrutinizing and approval of the drug to be manufactured.

• Post-approval changes in the safety, quality, and success of a product.

• Submission of clinical and non-clinical information about the drug for new approval.

If the company doesn't satisfy with any of the conditions and parameters for approval, the regulatory board may point out the reason for not approving the particular drug and offer another opportunity [31, 32].

3.6. Efficacy of Blockchain in Clinical Trials

The main purpose of blockchain is to store digital information on a distributed peer-to-peer network. It provides a shared and reconciled database. One of the important features is that it ensures the correctness of transactions by recording every change across the entire distributed network. As the data stored in a blockchain is encrypted and the transactions are processed in a secure manner, it provides a good fit for data security and patient privacy in the clinical trial process.

Clinical trial demands a fast, transparent, and easy way to share large quantities of patient’s data that are spread over a vast geographical area. A good trial process requires transparency in data as to 4 Ws, that is where, when, by whom data was entered, and who has access to data. The audit trail provides answers for these 4 Ws, and blockchain can help to improve the clinical trial process in terms of privacy and security.

Fig. (**2**) depicts the flow of work involved in the clinical trial process. Initially, the Trial protocol is set, and registration is carried out. Next, patient enrollment takes place, followed by data collection. At this point, various data about the patient are collected, and analysis is carried out. Finally, reports are generated, and the results of the clinical trial process are published to the stakeholders. A blockchain solution could be used at various stages in the clinical trial process. Through smart contracts, blockchain allows for securely automating the clinical trial process. A smart contract helps to set protocol, ensuring that preconditions are met before any action is executed, and carries out permissions for action. Blockchain could be used at various stages by providing data integrity and reliability through the creation of an in-depth, time-stamped ledger of information transfer and question events.

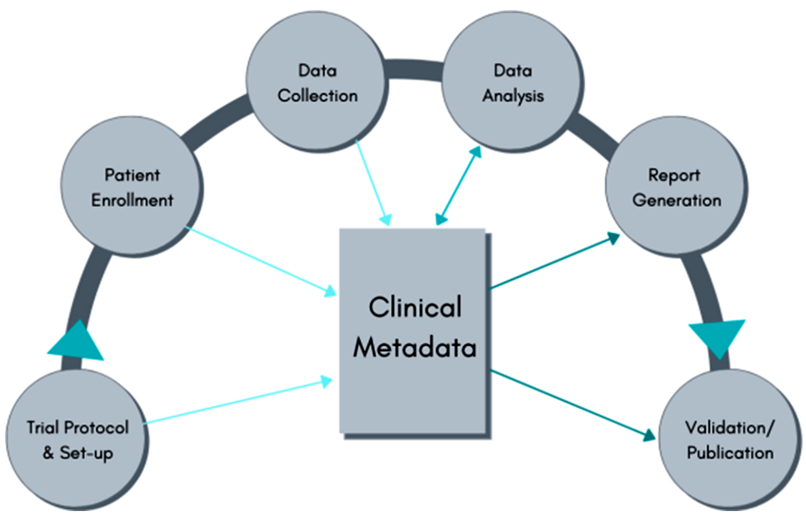

Fig. (2). Clinical Trial Workflow.

4. CLINICAL DATA MANAGEMENT (CDM)

4.1. Introduction to Clinical Data Management

Clinical Data Management (CDM) has a very important role to play in managing all aspects of the clinical trial process. The role and responsibilities of CDM include:

• To obtain high-quality clinical data that is reliable. It ensures the integrity of data while the data is being transferred from trial subjects to database systems.

• To collect correct and complete data, so that the analysis results become reliable.

• Ensures the trial database reflects the true representation of data that was collected during the trial.

• Takes care of data cleaning, facilitates data analysis, and finally produces data reports.

Several key personnel like the Project manager, Database Administrator (DBA), Statistician, and Clinical data associate are involved in taking care of activities under CDM. Project managers are utilized to supervise the overall conduct of the trial. The task of DBA is to handle data and check the validity of data. A well-qualified Biostatistician is involved to conduct the statistical analysis. The service of clinical data associates is required to prepare study reports [33, 34].

The largest Pharmaceutical companies are finding ways to utilize blockchain technology to store patient data in a secure manner, speed up the trial process, and reduce the cost involved in drug development. These pharma companies feel that several challenges faced in the clinical trial process can be easily sorted out using blockchain technology.

4.2. Mechanism

Blockchain presents a network of computers that has identical data. The system has controlled access, and also the same data is accessible to any or all the parties. It's a huge central library/ledger wherever every transaction, transfer, transcription, and transformation of information is registered. The data listing is time sealed, immutable, and maintained with an audit path. Any unauthorized access to an equivalent, with the negative significance of manipulation or modification, isn't attainable. Data on the blockchain cannot be erased or modified. The information owner has the right to determine who will access the knowledge. Thus, for the clinical trial method, it is the patient who is the owner of the data.

Fig. (**3**) depicts the mechanism of blockchain in a clinical trial. Blockchain technology works on the principle that an algorithmic hash program is run over the transaction data to form a secure hash. Individual blocks are related to the previous one to form a chain. Hash is generated for every individual block and sent to the blockchain. Patient health information is collected by the principal investigator, a hash is created for patient information, and it is relayed in the blockchain. After Patient authorization, health reports can be retrieved. The study team can now query the blockchain and retrieve the patient information securely.

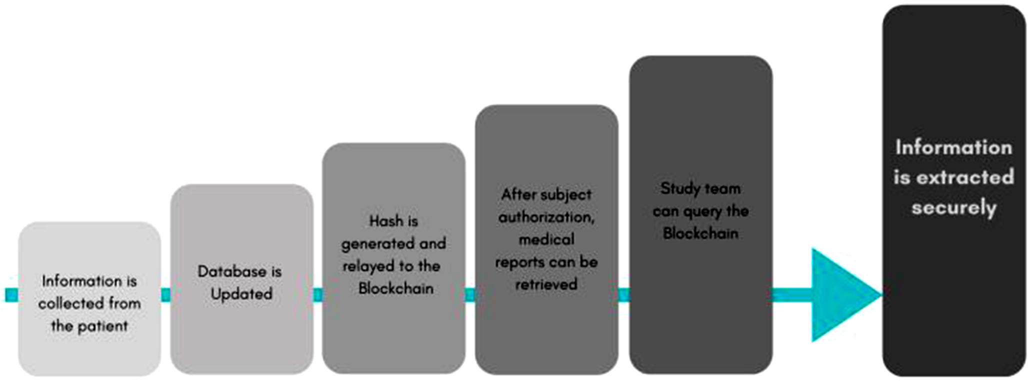

Fig. (3). Mechanism of Blockchain in a clinical trial.

4.3. Data Management in Blockchain

Blockchain-powered, time-stamped and immutable information will address key challenges within the healthcare sector. A clinical trial is a field where "Trust" is more important. Stakeholders involved in the CT process, like investigators, sponsors, and patients have high confidence in the information and its analysis that are carried out through the clinical trial process. Hence, carrying out the clinical trial process using blockchain technology is considered a trust-enabler. Its digital immutable feature prevents any alteration or modification by any intermediate body or any third party. Also, the organizations are asked to publicly disclose clinical trials' results by regulatory bodies like the FDA and NGOs. Implementation of the clinical trial process using blockchain brings in data traceability, trustworthiness, and integrity.

4.3.1. Data Traceability with Security

Although data storage on the blockchain is feasible, storing massive data chunks generated throughout a trial might incur enlarged storage prices and lower performance. Heavy prices are due to numerous transaction processing, creating a new block, and querying huge data sets in the blockchain. However, any data generated during a trial is stored separately on a database system (Sidechain) and hashed through a secured cryptographic algorithm [35]. It will offer a unique and tamper-proof low-weight signature for every document. These signatures are going to be kept on the blockchain to supply secure data traceability for all stakeholders.

4.3.2. Patients' Engagement and Consent Management

Patients have become more attentive and willing than ever to involve within the healthcare industry. As a result, patient engagement is additionally turning into a vital success factor in clinical trials. Once permitting consent to participate in a trial, the patient could rest assured regarding agreed protocols encoded through blockchain sensible contracts. Sensible contracts make sure that patient's consent is received when there is any protocol modification. Patients who have enrolled in the trial process should share any past or current medical conditions with the investigators.

However, during a recent instance in Estonia, nearly 1.3 million citizens benefited from a blockchain-enabled secure e-Health record system. Now, we can say that such a system will automatically grant investigators access to patients' medical records at the same time adhering to the digital consent signature of patients. In a nutshell, it is believed that continuous updates of patients' information on the blockchain will foster transparency and enforce patients' trust in trial investigators.

4.3.4. Reporting to Regulators

Governments and other stakeholders involved in the process are needed to determine the advantages and risks related to an investigated drug as per the proof submitted by the trial investigators. For that, it needs stakeholders to form all trial-related documents accessible to regulators upon request. Implementation of Consortium blockchain's architecture is ideal in this case as the records have to be shared with regulators, trial sponsors, Clinical Research Organizations (CROs), and alternative healthcare organizations. It will enable them to endlessly share clinical information among themselves at the same time ease regulatory bodies to directly place queries on the blockchain. Although information related to a clinical trial is going to be accessible by all or any interested stakeholders, this sort of blockchain developed with platforms like Hyperledger can make it confidential because it contains patients' personal information.

5. BLOCKCHAIN ARCHITECTURE

There are three types of blockchain architecture, namely public, private, and consortium. Depending on the type of application, any one of these architectures can be used. In public blockchain architecture, anyone who is keen to participate in the network has access to the data, nobody has full control over the network, but everybody can read or write. The control on the blockchain is equally distributed among each node in the network and hence is known as a thoroughly distributed and fully decentralized network.

Private blockchains are also referred to as permission blockchain. In this type, there is a restriction as to who can access the data and participate in the network for transaction processing. Only an authorized user with a unique non-public identity will be a part of the network, browse the ledger, propose transactions, and participate in consensus. The network is controlled by selective participants from a specific organization. Once any stakeholder joins the network, the blockchain continues to function in a localized manner. They handle and control reading and writing operations into the blockchain. Such a sort of blockchain is principally utilized by financial or healthcare organizations to confirm efficiency and auditability. Moreover, mining isn't necessary within the private blockchain, as one private entity has sole possession of making and verifying blocks. Hyperledger cloth is one of the common samples of private blockchains. These kinds of networks are used in a private company to efficiently manage the confidential data that should be accessible or available only to the authorized person in the organization.

A consortium blockchain is a type of private blockchain and is governed by a group rather than a single entity. It is a collaborative model that brings a group of organizations that work and compete with each other. This type of blockchain can be more efficient as some rights can be kept restricted to the individual, like data access rights, to keep it secure from public access, whereas groups can collaborate on some common aspects of the business.

A hybrid blockchain draws its feature from the public as well as private blockchains. The permission-based structure of a private blockchain system is combined with the security and transparency of a public permission-less system. This makes the hybrid blockchain very flexible for the users, who can effortlessly join multiple public blockchains from the private blockchain. Usually, in a hybrid blockchain, the transaction of a private network is verified within that network [36].

5.1. Permissioned Blockchain Architecture for Clinical Trial

Private blockchains will facilitate to resolve 4 basic issues associated with CT information, like information privacy, compliance, price, and speed. In contrast to the public blockchain, solely authorized or selected organizations/entities will be a part of the network, thereby guaranteeing information privacy. In permissioned blockchain, the transactions are often verified through mechanisms, like Proof of elapsed time (PoET) and practical Byzantine Fault Tolerance (PBFT). Smart contracts play an important role in a private blockchain. To control transactions inside the network, smart contract frames a set of rules and implements functionalities to enforce these rules defined during business processes. It is the responsibility of the smart contract to automatically invoke the execution of rules during transaction processing. Fig. (**4**) represents a private blockchain network.

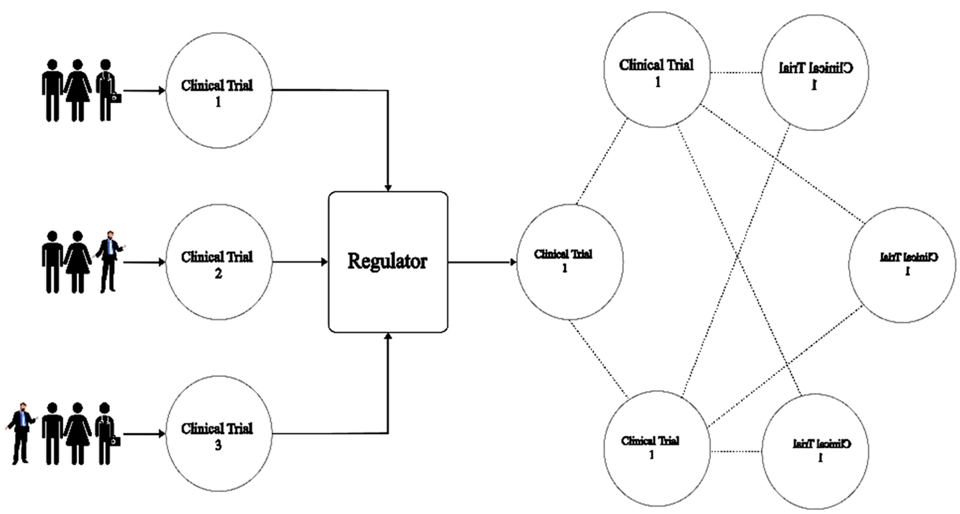

Fig. (4). A Private Blockchain network.

Clinical trials conducted at multiple sites are regulated by regulatory authorities. Upon approval by the regulator, the clinical trial study report is distributed to CRO and other stakeholders like the Data security and monitoring team (DSMT) and supervisory team (ST) for further verification and validation of clinical data. Finally, the study results are distributed to pharma companies. A separate private channel is maintained for the transformation of information across various stakeholders.

6. CONSENSUS PROTOCOL

6.1. Proof of Elapsed Time (PoET)

The consensus mechanism, Proof of Elapsed Time (PoET), is a random process to decide the miner who will create the next block based on waiting time. In this process, a random wait time is assigned to each node, and the opportunity to create the new block is given to the node which completes its wait time first. PoET can work effectively if there exists a system to authenticate that multiple nodes are not run simultaneously and the assignment of the wait time is genuinely random.

6.2. Practical Byzantine Fault Tolerance (PBFT)

Byzantine Fault Tolerance is the feature of a distributed network. It is used as one of the consensus algorithms in the blockchain. It works effectively on an asynchronous system. The main feature of this consensus algorithm is that it reaches consensus even when some of the nodes in the network fail to respond with correct information. It safeguards against system failure by employing collective decision making both correct and faulty nodes. It also aims to reduce the influence of faulty nodes. This consensus mechanism is used in a Hyperledger blockchain platform

7. BLOCKCHAIN PLATFORM

Permissioned and permissionless blockchains can be used to develop different interesting applications in different platforms like:

• *Hyperledger:* Hyperledger is an open-source project that aims to create a suite of tools for enterprises to deploy Blockchain technologies quickly and effectively.

• *Ethereum:* It is an open-source and distributed computing platform, mainly used for executing smart contracts.

• *Ripple:* It is an open-source distributed consensus ledger that uses the native currency called Ripple or XRP that achieves the consensus between nodes using probabilistic voting.

• *Chain Core:* Chain core is a blockchain infrastructure that uses a chain protocol to implement a permissioned network.

• *Corda:* It is a blockchain platform that uses a smart contract protocol to record, supervise, and synchronize financial agreements between regulated financial institutions by removing costly frictions in business transactions.

7.1. Hyperledger Platform

To facilitate enterprise to deploy blockchain technologies effectively, an open-source project called Hyperledger is created. Hyperledger has a set of pluggable components that helps to speed up the development. It is strongly supported by the Linux foundation, and therefore, it is designed to work effectively on Linux servers. Linux supplied expertise to accelerate the creation of the protocol. In the Hyperledger platform, the network consists of several nodes, a chain program, or a smart contract, a distributed ledger consisting of a state database, and a transaction log. A node in a hyper ledger network is maintained by a single or group of users. The nodes at various levels have the following functionalities:

Level 1 (L1) node which includes patient (subject) and patient explorer. It invokes transactions,

Level 2 (L2) node, which maintains and updates the ledger. It consists of stakeholders like the Data security and monitoring team (DSMT) and Supervisory team (ST)

Level 3 (L3) node, which supports communication and maintains the order of transactions. After verifying the endorsement message, it sends transactions to the level 2 nodes. It includes Regulator authority. The working of Hyperledger is shown in Fig. (**5**).

7.1.1. Hyperledger Characteristics:

One of the characteristics of Hyperledger is modularity, it allows different plug and plays components like membership functions and consensus. A chain program or smart contract is one such function that consists of a set of logical functions that creates a set of rules, which helps to administer transactions in a blockchain network. All transactions invoke the relevant chain program functions for accessing the ledger. Hyperledger validates the proposed transactions by implementing endorsement policies. As illustrated in Fig. (**6**), when a client from any one of the sites (L1) initiates any transaction, it has to be endorsed by the nodes at Level 2, and then the endorsement signature is sent to the L3 node. The L3 node upon verification of the endorsed message from all endorsers, is sent as a new block to all peers. Another important characteristic of Hyperledger is confidentiality. This is achieved by Membership Service Provider (MSP). A verifiable digital identity is made to nodes at various level by a trusted MSP. The function carried out by MSP, like issuing a cryptographic certificate and user authentication, are abstract, hence all information related to a channel is accessible only by the nodes of that channel, thereby bringing in the level of confidentiality.

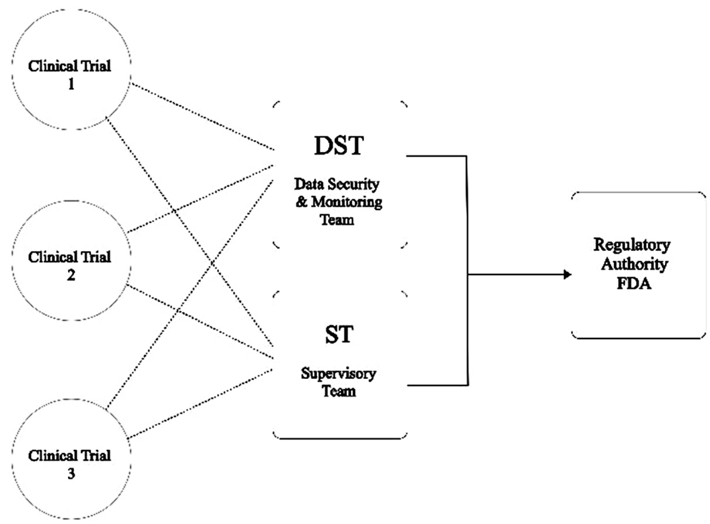

Fig. (5). Hyper Ledger platform for Clinical Trial.

7.2. Stakeholders in Clinical Trial Blockchain Network

Following stakeholders are involved in Clinical Trial Blockchain Network:

• *Patient* –A patient is any individual who participates in the clinical trial process. The patient is called the subject. The researcher/investigator needs to collect data from the subject to research. Data can be collected in several ways, like intervention or by just interacting with the subject.

• *Patient Explorer (PE)* –Patient Explorer is key personnel who is responsible for organizing and monitoring the site where the clinical trial takes place. PE has access to subject data, analysis results, and exceptional or adverse events that may happen during research. PE must take care of subjects/patients enrolled in the trial process at the same time they should maintain ethical conduct of the study.

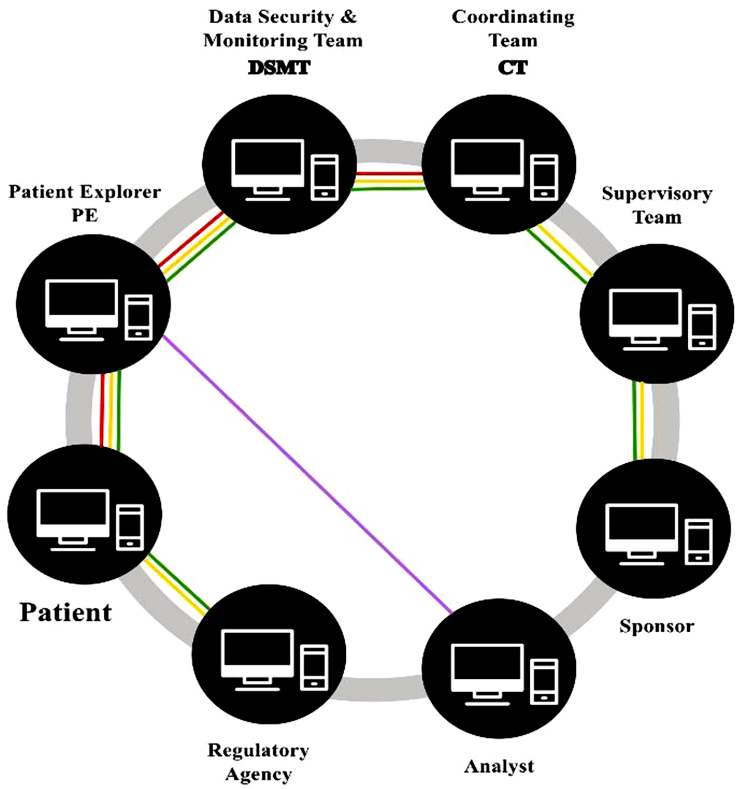

Fig. (6). Network partition and its associated smart contracts.

• *Centralized database Center (CC)* –This centralized database center is responsible for coordinating the various activities during the trial process. They maintain a centralized database that stores details related to the schedule of activities that might have been planned for subjects and also communicate them to the relevant stakeholders.

• *Data Security and Monitoring Team (DSMT)* –An expert team that reviews and checks the correctness of the study data for the safety of patients. A decision regarding the continuation, modification, or termination of the trial will be recommended by this team.

• *Governing agencies* –Governing agencies are also called regulatory agencies. The prime duty of these agencies is to inspect the study sites and to ensure the quality of the data collected during the trial process. These agencies also need to maintain the security and integrity of data. Also, they ensure that medical treatments given to the patient are safe and effective without any side effects.

• *Sponsors*–Sponsors can be any individual, institution, or organization that accepts to completely fund a clinical trial process.

• *Analysts* –Analysts are any person who analyzes the data collected from the trial process. Data collection, integration, cleaning of data will be done by analysts. They produce trial results and publish them to the other stakeholders.

Each of the above-mentioned stakeholders will be a participating node within the blockchain network. A node may represent a patient, sponsor, or analyst, as shown in Fig. (**6**). In this CT blockchain network, every node operates on a smart contract and maintains a ledge to store information. A smart contract is a piece of code that checks the validity of trial data for the intended study (*i.e*) it checks whether the data is as per the predefined protocol. Once the data is verified, the trial data is stored on the ledger.

7.3. Partition Network Channels and Smart Contract

Hyperledger enables partitioning network channels into multiple channels, each of the individual channels maintains a ledger and a separate smart contract. These multiple channels are private and are created to establish a relationship between a subset of members in the network. Several benefits that can be realized out of this light-weight channel include:

• Confidentiality: Access to all data, transaction, ledger, and channel information is not granted explicitly.

• Reduced storage space.

• Reduced energy consumption.

• Improve transaction throughput as the transactions are executed in parallel.

• Limit data access and data flow.

• Implementation of smart contract to check the validity of activities in each channel.

The following steps describe the various network partition and their associated smart contracts implemented in each private channel.

7.3.1. Smart Contract Enabled Roster Channel (SCERC)

There is a need for a private channel for handling information related to patient enrollment. In Fig. (**6**), the blue channel denotes the patient enrollment process, which involves stakeholders like PEs, CC, and DSMT. When the patient becomes eligible for participation in the trial process, the patient's data, including the patient's health information, are collected by PEs.

Before a patient participates in the clinical trial process, a set of criteria needs to be satisfied to determine whether he or she is eligible for the process. A smart contract that is implemented in this roster channel verifies whether the candidate satisfies the set of criteria before registering the patients and storing data in the ledger. PEs can invoke smart contract to do the intended job. Further, the smart contract can check if the patients can view the data provided by them in the ledger. Members of DSMT can also have read or write access to the data. Restricting the access of patient's sensitive information to designated members of the network improves data privacy. Once approved by both the candidate and DSMT the patient's record will be included in the ledger.

7.3.2. Smart Contract Enabled Trial Tracking Channel (SCETTC)

The trial tracking channel collects and monitors different types of activities and data during the trial. The activities may include collecting questionnaires or samples from candidates, running laboratory tests, and reporting cases of adverse events. Samples are collected from the candidates at regular intervals at the trial sites. A separate channel involving various stakeholders in the clinical trial is created for monitoring and controlling the activities involved in the trial process. The channel members have access to the study data gathered from the candidates, test results, and abnormal events experienced during the trial. This is shown by the green channel in Fig. (**6**).

During the trial process, each trial site or clinic conducts a given set of activities based on a schedule of activities defined in the protocol. A smart contract specific to this channel can verify the following:

- If the prerequisites are met before data entry.

- If the data collected during the scheduled activities were recorded in the system within the prescribed timeline.

Generally, PEs experience difficulty in recording, tracking, and updating abnormal events during laboratory tests. Smart contracts can record and track and update such events in real-time. Moreover, smart contracts can flag the transaction if there are any attempts made to tamper with the recorded data. This ensures the quality of data collected from different sites. Implementation of a single smart contract across all sites guarantees a consistent data framework.

7.3.3. Smart Contract Enabled Analysis Channel (SCEAC)

An analysis channel is created between PEs and data analysts to share secondary data (data collected from candidates) for analysis. The analysts will carry out various analyses of data to know the effectiveness of the clinical trial. A smart contract created for this channel can do the following:

• Limit Unauthorized data access.

• Checks the consent information stored on the ledger to ensure the validity of the request.

The smart contract confirms the validity of the request and transfers the data to the analyst in SAS format (Format that enables data analysis). Various kinds of analysis that can be carried out by analysts include meta-analysis, latitude and longitudinal data analysis, *etc*. Smart contracts in this channel can automatically invoke the relevant code for analysis

7.3.4. Smart Contract Enabled Reporting Channel (SCERC)

Smart contracts enable the private channel for reporting the results of the clinical trial process is essential. This channel integrates statistical data analysis and produces presentations and reports. This channel includes various stakeholders listed above for managing and sharing of study documents.

This is indicated by the pink channel in Fig. (**6**). Hence, in this framework, each node maintains a ledger corresponding to each of its member channels, rather than a single ledger containing the entire trial data. Transactions within each channel are further governed by its smart contract.

8. CHALLENGES IN IMPLEMENTING BLOCKCHAIN IN CLINICAL TRIAL

The quality of blockchain technology to record transactions on distributed ledgers offers a variety of opportunities in the field of clinical trials and healthcare to improve transparency, maintain a database, and prevent fraud. Since blockchain is a growing technology, it is facing multiple challenges and issues which are discussed below.

8.1. Security

The most important and critical challenge of blockchains is the security and privacy of data. As we all know, the data is growing at an enormous speed in almost all fields, the same is the case with health records. For conducting a clinical trial, patient data is of utmost importance. Basic patient data like their personal information and data on their previous health issues are required during the CT process. There is a possibility of data being sold or leaked out unethically for commercial purposes. Care should be taken to safeguard the patient data so that no intermediary or third party that might misuse the data.

Several countries have introduced regulatory standards and regulatory bodies are appointed for medical and health care systems which can prevent data leakage and ensure security and privacy of data. These standards help to boost the confidence level of the patient when they disclose the data to investigators. Traditionally, health care records were managed in a centralized system that follows a client-server architecture. In these kinds of systems, there is a fear of data being leaked out as it is managed by the central authority. With the implementation of blockchain technology in maintaining patient data, the need for a third party is eliminated to carry out a transaction. As the data is exposed to all nodes in the network, data privacy may be harmed. But the nodes which are authorized to transmit information in blockchain can prevent data breach by not providing consent.

Blockchain works as a public ledger. However, there is a pressing need to ensure several different aspects:

• Consensus: Has to be made sure that the local copies are consistent and updated.

• Security: The data which is fed needs to be tamper-proof as some of the nodes may act maliciously or can be compromised.

• Privacy and Authenticity: The data belong to different nodes on the blockchain, so privacy and authenticity need to be checked.

8.1.1. Selfish Mining

Nodes that have more than 51% computing power can alter the transaction content and reverse the transaction. Eyal *et al*. mentioned in their work that the blockchain is vulnerable even if a small portion of hashing power is used to cheat. The selfish miners keep their mined blocks themselves without releasing them [37].

If someone has more than 51% computing power, then the person can find the Nonce value faster than the rest of them, which means that the person has the authority to decide which block is permissible. It can:

1. Modify the data, providing the doctors with false information.

2. Stop a miner from mining any of the available blocks.

In 2014, Ph.D. candidate Ethan Heilman proposed a defense mechanism against selfish miners. In this scheme, the profitability would be reduced for every selfish miner by using unforgettable timestamps to penalize the ones who withhold blocks.

8.2. Scalability

One of the major challenges in Blockchain implementations is scalability. As the usage of Blockchain is increasing day by day, the data is becoming bigger and bigger, giving rise to big data. The loading and synchronization of data are also becoming harder since the size is growing on a linear scale every day. During the CT process, a database has to be maintained, which will consist of the various drugs which have been developed, which are in the developing stage, the various requirements for each of these drugs, and the reason for the failure of the tests (if any). Apart from this, it also has to store the patient database which is used for these trials. The scalability limits of the blockchain are based on the number of servers used in the chain, the rate at which the transactions are processed, and the latency time (time taken for a data packet to travel from the source to the destination) of the transaction. The latency between the transaction submission and the arrival on the destination node is affected by the consensus protocol. A consensus algorithm is a procedure through which all the peers of the Blockchain network reach a common agreement about the present state of the distributed ledger.

Scalability can be divided into three other sub-categories: throughput, cost, and capacity and networking.

8.2.1. Throughput

Transaction throughput is the rate at which valid transactions are committed by the blockchain in a defined time. The number of transactions that a blockchain carries out is much lesser when compared to the other technologies. With the growing data size, the number of transactions per second reduces.

8.2.2. Cost and Capacity

Huge storage is required in Blockchain to store the enormous number of growing transitions. Storage is required not only to store current transactions as well as for storing data archives. A node in a blockchain has a certain predetermined capacity to store the data beyond which it cannot store data. The participating nodes in the blockchain have to pay for the usage of Blockchain and to carry out transactions. During the CT process, as the number of patients enrolled for the process grows, which is evident in the case of covid-19, Blockchain should have the capacity to accommodate all the patient data for the results of the analysis to be effective.

8.2.3. Networking

Whenever any process in a Blockchain is carried out, it is first broadcasted to all the nodes in the chain. A more efficient data transmission algorithm is required as there is a necessity to transmit information to all nodes whenever a block is a miner. Also, network latency time should be low for effective communication between nodes. In the CT process, there should be proper networking between all the participating nodes, including sponsors, subjects, regulatory bodies, *etc*. Only then CT process can be carried out effectively.

8.2.4. Ways to Solve the Problem of Scalability

Following are some of the methods that help to solve the scalability problem.

8.2.4.1. On-Chain

Increasing block size: An average size of any block in the blockchain is 1 MB. Increasing block size results in higher maintenance costs due to propagation delay. So, the better option is to either reduce the number of bytes stored in each block or compress the data stored in a blockchain.

Frequency of block addition: The frequency of a block addition also impacts the transaction rate. Reducing this block addition time would mean more transactions going through at a faster rate. The number of transactions taking place in a block multiplied by the frequency of block addition gives the upper-limit for the transaction rate. This method also has a few issues. It increases the orphan rate (mined blocks that do not make it to the main chain due to competition), and hence more wastage of computations. It also results in a greater centralization pressure, reduced effective hash rate, and hence the reduced security of the network.

8.2.4.2. Off-Chain

The main concept of off-chain solutions is to process the transaction outside the Blockchain.

Sharding: This is an effective method to enhance the scalability of Blockchain. It follows the technique of database partitioning that can be used to scale Ethereum's blockchain and enables it to process more transactions per second. The nodes are split into different shards, each shard contains a part of the data and there is parallel processing of data. The information contained in a shard can still be shared and viewed among other nodes. This keeps the ledger secure and decentralized because everyone can still see all the ledger entries, they just don't process and store all the data. The disadvantage of this technique is that the data would be harder for the public to verify, and it could also create compliance issues.

8.2.4.3. Inter-Chain

Connecting two sub-chains is called an interchain. It gives the flexibility of changing from one platform to another. It helps to connect private and public blockchain. Interchain can be used to reap the benefit of both public and private blockchain

8.3. Transparency

In the healthcare sector, the data need to be transparent since there's a huge amount of data present in the database. The data is present in the form of old medical records, patients' records, doctors' records, prescription records, information systems at hospitals, *etc*. In the area of clinical trials, there is a need for the data to be transparent so that the communication between doctors and patients is more streamlined. Blockchain has the tools to provide smart contracts that can increase the traceability and transparency of clinical trial sequences and can also provide financial incentives for a patient's participation and sharing of their data. Smart contracts are computer protocols that embed the terms and conditions of a contract.

As discussed in the first part, the need for a middle party to carry out a process is eliminated in a blockchain. If any third party is allowed to intrude on behalf of patients, it leads to the issue of transparency of data. If the data is accessible by someone who isn't supposed to, then there are chances that confidential/personal information can be sold in the market without the patients' consent. Apart from this, the data can be manipulated to produce false results and this data can be falsely sent to the public, which can be alarming. So there has to be a system that needs to be devised by which the data can be transparent to a few users, but at the same time, not many people can view the data. There can be a role-based authentication that can be devised, where the patient plays the primary role, and all the data is visible to him. The other representatives which are chosen by the patient, can play a secondary role where only restricted information is displayed.

CONCLUSION

Utilizing blockchain in clinical trials proves to be beneficial as it enforces data integrity through transparency, and gains trust among all stakeholders in a CT process. This chapter gives an overview of the clinical trial process and describes how blockchain will help build transparent, highly trustable trials. Key functionalities of blockchain in clinical data management are highlighted. The importance of clinical data management and the implementation of blockchain in CDM is discussed in this chapter. The chapter also describes various blockchain architecture and protocols involved in blockchain implementation. Permissioned blockchain is appropriate for the CT process as the process should be highly transparent, and at the same time, it should be trustable trials. Implementation of Hyperledger fabric in permissioned blockchain for CT process is described in this chapter. Hyperledger enables partitioning network channels into multiple channels, each of the individual channels executes a separate smart contract to validate the activities of the CT process and maintains a ledger of its own. This technology enables the maintenance of trusted electronic health records in multiple sites and also bridges the gap between clinical researchers and patients. By implementing Blockchain in CT, patients can now share their medical reports with doctors freely and, at the same time, maintain full control over the privacy of their medical data. Finally, challenges in implementing blockchain in terms of security, scalability, and throughput are discussed in this chapter.

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CHAPTER 2

Securing Clinical Trials Data with Blockchain

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Abstract: Discovering and developing new drugs/ medicines is very crucial for the pharmaceutical industry. The increasing number of drugs approved in recent years demonstrates the impact of modern drug discovery approaches, digital technologies, and automated drug development methodologies. Drug development is a systematic and methodological process of developing a new pharmaceutical drug once the process of Drug discovery has identified the prime pharmacological component. The structured sequence of steps followed for drug development aims to ensure the safety and efficacy of the drug being developed. It includes pre-clinical research on microorganisms and animals, preparation of detailed data with respect to pharmacology, pharmacokinetics and toxicology details, application and approval by regulatory authorities and conduction of clinical trials. The conduction of clinical trials is an expensive affair as it needs a collaborative effort by multiple stakeholders along with a high level of monitoring and regulation. The data generated during the lifecycle of clinical trials is very critical for pharmacological scientific publications, regulatory approval for the target drug and post-marketing surveillance that ultimately leads to the development of better decision support systems for drug development. Hence, the data integrity of such data is of prime importance. Several Clinical data management (CDM) systems have been developed to ensure seamless collection and management of clinical trial data. These CDM systems enable useful analysis and decisions supported by authentic data. However, such systems face several security challenges with respect to privacy, integrity and authenticity of the clinical data. Another major challenge in conducting the clinical trials is finding the appropriate willing candidate who is physically and clinically suitable for the study. In view of the above, it is highly desirable to have a technology component that can address the above-mentioned issues. In this chapter, the technologies like blockchain and cloud computing have been introduced to address the challenges posed by clinical trial data management. The paper also proposes a blockchain based secure clinical data management system. The proposed system intends to help the data security issues like data integrity, privacy, ease and quick access to immutable clinical trial data with thorough access control enabling greater transparency and accountability.

Keywords: Blockchain, Clinical trials, Clinical data management, Cloud computing, Drug development, Data integrity, Security, Smart contracts.

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1. INTRODUCTION

Drug development [1] is a long, step-by-step expensive process that has three basic stages: Drug discovery, Drug development and clinical trials. This process needs interdisciplinary knowledge and expertise like pharmaceutical related in-depth knowledge and scientific & technological skills. This also needs a collaborative ecosystem that will enable multidisciplinary professionals to work together, including the pharmaceutical industry, research organizations, government regulators and healthcare professionals. A new drug is a pharmaceutical terminology used to indicate medication or therapy that has not been in clinical practice to treat a disease or health condition. It takes approximately twelve years and an average of $1.8 billion to launch a new drug and make it usable in the market [1]. Fig. (**1**) depicts the lifecycle of any new drug that needs to be brought to market for human use.

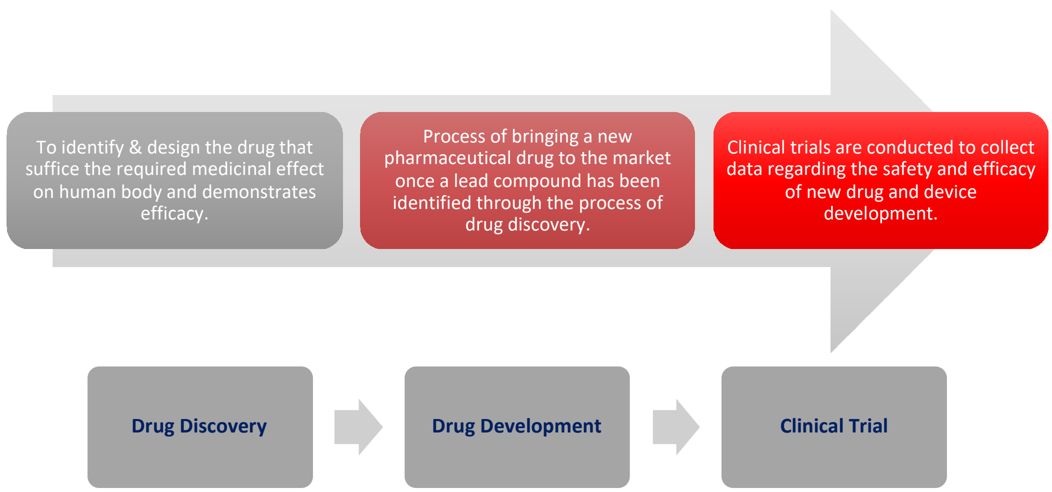

Fig. (1). Lifecycle of Drug Development.

Drug discovery [2] is a complex process of identifying a synthetic molecule or a biomolecule as a potential drug candidate for treating a disease or health condition. This process includes subprocesses like identification of the disease & its unmet need, identification of the best compound to target the disease, finding out the prime components that exhibit potency and optimization to attain efficacy of the identified molecule. Drug development is a systematic and methodological process of developing a new pharmaceutical drug once the prime pharmacological component has been identified by the process of Drug discovery. Clinical trials [3] are research studies performed in humans that aim to evaluate a medical therapy to treat a disease or medical condition through surgical, or behavioural intervention. These studies are the primary mechanism to validate the safety and efficacy of the new pharmaceutical product like a drug or vaccine, or medical device. It can only be conducted if pre-clinical data demonstrate the usefulness of the drug in treating a disease and is proven to be reasonably safe for testing in humans. Clinical Trials have several phases, and at every stage, important data is generated that is useful for various stakeholders of clinical trial. Fig. (**2**) depicts an overview of clinical trial phases with details of data generated at each stage.

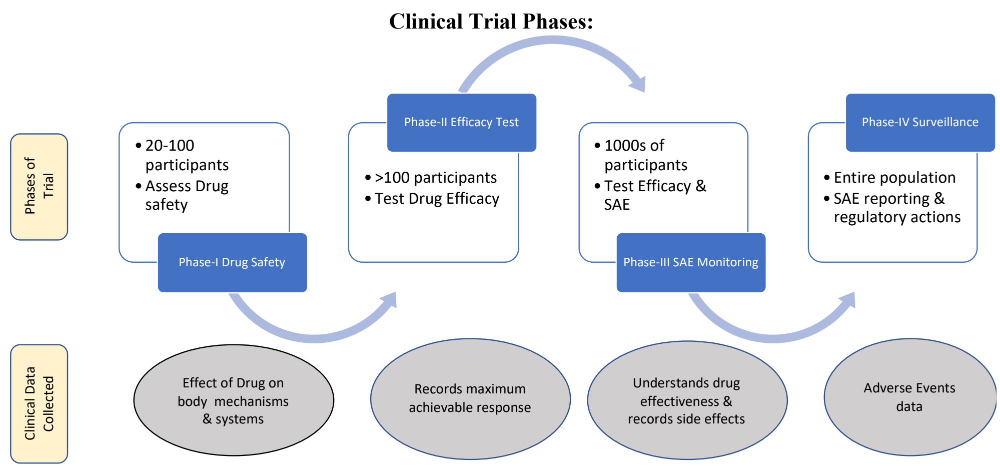

Fig. (2). Phases of Clinical Trial with details of data generated.

As indicated above, a clinical trial is a time taking process and hence, has to be properly designed and planned to provide reliable efficacy and safety data. Standard operating procedures & protocols, along with revision histories, needs to be documented and maintained. This data provides end to end audit trail of the clinical trial. The same needs to be intimated to regulatory authorities, and approval must be secured. The trial is also monitored by the ethics committee. Clinical trials must adhere to rules and guidelines, including the Code of Federal Regulations [4], the Good Clinical Practices (GCPs) [5, 6] guidelines from the International Conference on Harmonization (ICH), state laws, Sponsor Standard Operating Procedures (SOPs), and institutional SOPs.

2. CONDUCTING CLINICAL TRIALS

Clinical trials are conducted to collect data regarding the safety and efficacy of new drugs and device development. There are several steps and stages of approval in the clinical trials process before a drug or device can be sold in the consumer market. The pharmaceutical product is extensively tested in the research laboratory, which can involve years of experiments in animals and human cells.

• If the results of the initial laboratory test are positive, the research organizations request permission from regulatory authorities to further continue research in humans by submitting the required data produced during initial trials.

• On approval, human testing of drugs and devices under consideration can begin in phase wise manner. There are typically four phases of the conduction of a clinical trial, as indicated in Fig. (**2**).

• Each phase is considered a separate trial, and after completion of a phase, investigators are required to submit their data for approval from the regulators as a pre-requisite to the approval and continue to the next phase.

• Any sort of amendments during the conduct of the trial needs to be reported to regulatory authorities, and approval for the same needs to be taken.

2.1. Stakeholders of Clinical Trials

The organization of a clinical trial is particularly complex as it needs the involvement of many stakeholders [7], as depicted in Fig. (**3**). Apart from the subjects on whom the clinical studies are conducted following are the stakeholders in the process of conducting the complete clinical trial:

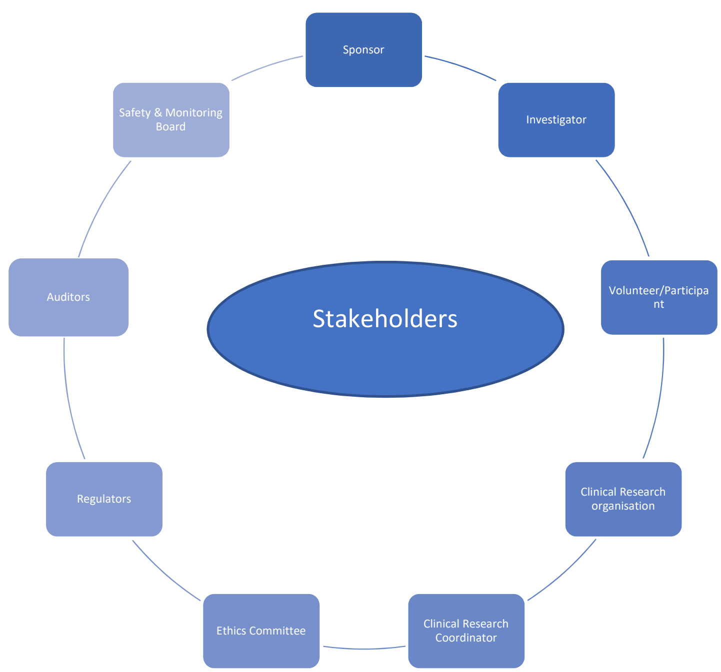

Fig. (3). Stakeholders of Clinical Trial.

• **Sponsor:** Sponsor is an individual or an organization who is responsible for initializing, funding and managing the conduct of a clinical trial. This could be a pharmaceutical company or clinical research organization. The financing of a clinical trial may come from the sponsor but can also come from a third-party.

• **Ethics Committee:** Ethics Committee (EC) is responsible for ensuring the rights, safety, and well-being of trial participants. EC conducts time to time review of clinical trials following the approved SOPs and protocols. The data like Trial protocol(s)/amendment(s), written informed consent form(s)of participants, investigator's brochure (IB), subject recruitment procedures (*e.g*., advertisements), written information to be provided to subjects, information about payments and compensation available to subjects, the investigator's current curriculum vitae, *etc*. is reviewed, and trial is monitored accordingly.

• Principal Investigator (PI): The principal investigator is the site project leader who is responsible for the conduct of a clinical trial at the site and has the prime responsibility for the generation and documentation of data during the study.

• Regulator: The regulatory authority (*e.g*., Central Drugs Standards Control Organization (CDSCO), is in charge of protecting public health by assuring safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. The regulator achieves this through an extensive review process of the data provided by the sponsor/ PI in case of clinical trials.

• Volunteer or participant: A participant is an individual who is found clinically suitable for participating in the trial and is personally willing to contribute in the trial process. He/she should meet the criteria of washout period and should be well aware of the information about payments and compensation.

• **Clinical Research Coordinator (CRC):** CRC plays the role of a project manager who manages and coordinates the smooth, timely progress of clinical study from the planning stage till study completion. CRC acts as a liaison to other stakeholders, including the investigator, the subject, the research site, and the sponsor.

• **Data Safety & Monitoring Board**: It is an independent data monitoring Committee formed by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints and recommends the sponsor for continuation or suggests the required modification or advises to stop the trial.

3. CLINICAL DATA MANAGEMENT SYSTEMS (CDM)

Clinical data management (CDM) is an important process in clinical research, that enables the generation of detailed, reliable, and auditable data that is collected during the conduct of clinical trial. The data is stored in such a way that it is statistically representable and analyzable. As the goal of a CDM system is to bring out analysis and meaningful conclusions from the clinical research, it enables the grant of marketing authorization and helps to protect public health. An efficient CDM tool leads to a drastic reduction in time from drug development to marketing authorization [8]. Data is generated at each stage of the clinical trial life cycle, from the initial protocol, approval of trial, and collection of baseline participant data at the time of participant enrolment that is useful for statistical analysis and audits in the future [9].

Five major stages of the clinical trial life cycle are discussed below, and data is collected at each step as per the guidelines in respective countries [10, 11, 12]. Data collected during clinical trials must conform to the regulatory requirements of different regions like:

a) India: Regulatory guidelines as per Third Schedule of Drugs & Cosmetics Act.

b) Europe: ICH GCP E-6.

c) US: FDA – 21CFR Part 11 and Guidance for Industry – Computerized Systems used in Clinical Trials.

3.1. Trial Design and Preliminary Trial Registration

The design of Clinical trials research & study is very well designed in advance, along with the details protocolfor conducting the trial and the statistical analysis plan (SAP) [13] detailing. The complete design of the trial and SOPs are well defined before the start of the participant enrollment. Important metadata is generated with the protocol details and the SAP that is used for reporting inspections and audits. During the trial, the protocols and the SAP generally undergo amendments that are explicitly documented within the protocol, and an approval has to be taken from regulatory authorities. World Health Organization's (WHO's) International Clinical Trials Registry Platform (ICTRP) [14] has recommended the structure of trial data that has to be provided for the complete registration of clinical trials. There are currently 24 items in the WHO Trial Registration Data Set, referred to as the TRDS.

3.2. Participant Enrollment

The first step towards clinical trial data collection is patient and volunteer registration. The volunteer registration is done using the basic personal details, and subsequently, the clinical research data is added to the same record. This data is added throughout the lifecycle of the trial.

3.3. Data Processing & Freezing

This is a very important step in the lifecycle of clinical trial as the conclusions drawn from the research work are used for analysis, presentations, data exploration, and hypothesis generation. Subsequent to participant enrollment, the raw data is abstracted, coded in medical standard terminology and transcribed for further analysis. The raw data is cleaned and processed into an analyzable data set. The data is cleansed post-study completion, and additional variables are derived to make data more analyzable and used in performance analysis using software tools that lead to useful conclusions. Further, based on the data & conclusions drawn, the researchers prepare manuscripts for publication. This is done once participant activities have ended. The raw and processed data both are stored and preserved as individual participant data. Also, it is very important to store an immutable copy of the data & the analytical code used in an analysis so the results can be reproduced.

3.4. Publication

Clinical Trial data is an analyzable dataset that is used to generate useful results and further conclusions.The results can be extracted at any point of the clinical trial life cycle, although it most often occurs after study completion leading to multiple publications from a single trial.

3.5. Regulatory Application

An approval from the regulatory authorities is required before a new indication, or finished product gets its marketing authorization. For making an application to the regulatory authority, the results of clinical trials are needed.

4. DATA COLLECTION DURING CLINICAL TRIALS

Data collection is a critical step for a good-quality study. Data is collected at each and every step during the course of clinical trial, the approved plan for which is prepared in advance. The data captured during the conduct of clinical trials at a site is collected & maintained by the site investigator and is required to be demonstrated at the time of any inspection or audits conducted by the regulatory authorities. Hence, the security & integrity of this data is of prime importance.

The various types of data that are collected during the conduction of clinical trials are:

• Case report form (CRF): CRF [15] is a clinical trial data collection tool that is prepared by the sponsor either in the form of paper or electronic form to collect data from each of the participating patients. CRF is carefully designed & developed based on the study protocol to collect the data that is needed to support the hypothesis or to answer the research questions related to the trial. Its prime objective is to collect, preserve and maintain the quality and integrity of the trial data.

CRF is designed to meet the requirements of all stakeholders, such as investigator, site coordinator, study monitor, data entry personnel, medical coder and statistician. It is designed to enable the creation of metadata, detailed reporting and thorough data analysis. Following are the types of CRFs adopted:

4.1. Paper CRF

Paper CRFs are handwritten clinical patient data in a fixed or standard format that enables technologies like optical character recognition (OCR) [16] to allow computers to read the handwritten data and automatically update the records into the database.

4.2. Electronic CRFs (eCRF)

eCRF are electronic forms that are developed to capture trial data directly in a computer. They are developed by following strict adherence to defined standards and metadata structures based on the respective country's regulations. The prime requirements of an e-CRF are:

• Strong software validations as per the requirement of quality data.

• Every correction or modification that is made to the data entered must be traceable.

• Strong authentication and access control mechanisms for access to program and data.

• Automated and regular Data backups.

• Availability of computers and internet at all investigator sites.

• Intensively training site staff for using the eCRF.

• Helpdesk facility to handhold & support stakeholders.

• PROs/ ePROs: Patient Reported Outcomes (PROs) and Electronic Captured PROs (ePROs).

The term PRO is used for the health data that is directly reported by patients. It is reported through various forms, including questionnaires that are easily understood by patients regardless of their level of literacy and digital skills. Several mobile applications have been developed and adopted by patients to communicate their direct experiences of their health condition. Patients can maintain their health records in the form of daily e-diary that can be accessed by health professionals for better treatment.

• **Direct Data Capture (DDC):** DDC is the term used where the clinical data of a patient is directly captured from the medical & diagnostic equipment.

Some examples of Direct Data Capture (DDC):

• Laboratory data.

• Electrocardiogram (ECG) data.

• Central image reading (Magnetic Resonance Imaging (MRI) results).

• Electronic patient questionnaires/diaries.

The following are the characteristics of high-quality data for clinical trials:.

• Data completeness and accuracy.

• Can be evaluated and analyzed.

• Allow valid conclusions to be drawn.

• Data consistency across all records.

• Complete in terms of mandatory fields.

• Clear and easy to understand.

• Clearly indicative of subjective clinical experiences.

5. REQUIREMENTS OF CDM

Good Clinical Practice (GCP) is an internationally accepted standard given by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for the quality conduction of clinical trials that involve humans. The guidelines defined in GPC ensure for rights, safety and well-being of the participants in the trial. GCP guidelines state that any change or correction made to CRF should be documented along with a timestamp, authenticated, and approved and should not hide the original entry of the record. Also, an audit trail of all the updations done in CRF should be maintained An Audit trail for CRF is an essential document that:

• Is stored in open-format files in a secure system.

• Details all modifications to a database.

• Documents data changes.

• Is subject to audit.

6. DATA SECURITY RELATED CHALLENGES OF CDM FOR CLINICAL TRIAL

6.1. Adherence to GCP

Clinical trial is designed by the sponsor as per the standard guidelines of GCP. The clinical trial is approved & registered by regulatory authorities after verifying its adherence to GCP guidelines. However, its quite challenging for regulatory authorities like CDSCO to ensure that CTs abide by GCP guidelines during the conduction of the trial. Frequent audits and inspections by regulators are required for the monitoring of clinical trials. Many clinical trails are being conducted in multiple geographically spread sites, and their data is maintained by the site investigator respectively. Regulators encounter several challenges wrt to detailed data auditing, lack of easy access to geographically spread data & transactions with timestamps. There is a high possibility of delay in accessing even patient's serious adverse events data for further necessary actions. In addition, real-time monitoring of CTs is both time-consuming and expensive.

6.2. Data Traceability

Traceability & transparency are the prime requirements of GCP. Traditional CDM systems have high risk of data manipulation as well as data entry errors going undetected in real-time. Infact, data traceability and reaching back to the original source from the current record is quite challenging in case of any query in the audit process.

6.3. Traceability of Volunteer/ Patient Data for Enrollment

As the sponsor makes good payment & compensation to the trial participants, in many places, many participants either participate in multiple trials or take part before the washout period of the trial. This is due to the lack of centralized volunteer/patient registration system. Thus, there is a need for establishing network access to centralized database in the country that would maintain the details of the patient/volunteer patient populations. This would ease out the selection process of the participants that meet the inclusion and exclusion criteria accordingly, as defined in the study protocol.

Hence, the management of clinical trial data needs technology solutions that would not only manage the data but also provide more data security, traceability, controlled access, real-time data analysis as required by various stakeholders. One such technology solution is Cloud-based Blockchain platform that promises to address the issues of data accessibility & security, traceability, access control and, most importantly, data quality.

7. BLOCKCHAIN TECHNOLOGY

A blockchain is a distributed database that consists of a chain of blocks where each block contains hashed transaction data, timestamp, and the hash of the previous block. The previous block's hash links the blocks together and prevents any sort of modification in the block or insertion between the two blocks. In this way, each subsequent block secures the mutability of the previous block and hence the entire blockchain [17]. It also provides well immutability, traceability, transparency, audibility, and accountability of the data stored in it. Blockchain can be configured as a permissionless or permissioned chain [18], depending on the requirement. In permissionless blockchain, any user is allowed to join the network and is allowed to update the new transaction and hence also called the public blockchain. *e.g.*: Bitcoin [19] is a permissionless blockchain that uses the Proof of Work (PoW) algorithm in order to validate transactions using group consensus [20]. A permissioned network or private blockchain allows only specific participants to join the network and enables certain actions to be carried out by specific users in the network. *e.g.*, Ethereum enables the establishment of permissioned blockchain platforms by using algorithms like PoW and Proof of Stake.

The blockchain has been successfully applied in various domains like financial services, supply chain management, energy industries, clinical data management and pharmaceutical track & trace. Also in forensic applications, blockchain technology is promising to address the above-mentioned challenges. The advantage of blockchain technologies in Digital Forensics is that the examiner can provide self-verification for digital evidence, which can use hash functions to effectively establish verifiable evidence chain.

The important concerns of data management in clinical trials & research are data immutability, data access control and data auditability or investigation of clinical trials which can be very well addressed by imparting blockchain technology.

As we know, blockchains are decentralized and distributed in nature, where a consensus is made among the various nodes for any updation or modification. The consensus from all nodes enables data integrity and originality. Immutability strengthens the overall data auditing process and, makes it more efficient, cost-effective, and brings more trust and integrity to the data.

The hash value generated for each of the block is done by using SHA-256 algorithms, function of which are easily available in modern programming languages like python. For example, we can generate hash values in python using the hashlib library. As hashes are irreversible, it simply meets the requirement of data immutability as required by ICH-GCP guidelines for the clinical trial.

8. SMART CONTRACTS

Smart contracts are lines of code that are stored on a blockchain and are executed automatically when predetermined conditions are met. At the most basic level, they are programs that run as they've been set up to run some business logic. The benefits of smart contracts are most apparent in processes/businesses with many stakeholders and collaborations, where they are typically used to enforce some type of agreement so that all stakeholders can be certain of the outcome without an intermediary's involvement. Smart contracts are immutable, *i.e.,* no party will be able to change the contract once it is fixed and written to the ledger like blockchain. Next, they are distributed in nature as all steps of the smart contract are validated by every participating party so that no one can claim that it was not validated. The protocol of the clinical trial that is once approved could be very well managed and monitored by implementing smart contracts. "Smart Contract" is a programmable self-executing protocol that regulates blockchain transactions. The recruitment challenges in clinical trial can be addressed using smart contracts [21]. A blockchain supports multiple trial-based contracts for trial management and patient engagement and smart contract for automated subject matching, patient recruitment, and trial-based contracts management.

9. ROLE OF BLOCKCHAIN IN DATA MANAGEMENT OF CLINICAL TRIALS

Clinical data management is an important part of any clinical trial. As many stakeholders are involved in clinical trial, a lot of data is generated & is shared amongst them at different points of time. Fig. (**4**) depicts the role of various stakeholders during the conduct of the clinical trial. An important function of the principle investigator (PI) is to maintain trusted information about individuals participating in the clinical trials. It is the site PI who is responsible for maintaining the enrolment information of the participant, their clinical data, protocol details as approved and details of SAE. Managing this data and providing access control to the stakeholders at the right time is a complicated and challenging task. Some records exist only in paper CRF, and if changes need to be made in these records, approval must be taken, and a proper track detail must be maintained. And, of course, these data must be protected against unauthorized access or manipulation, with no room for error.

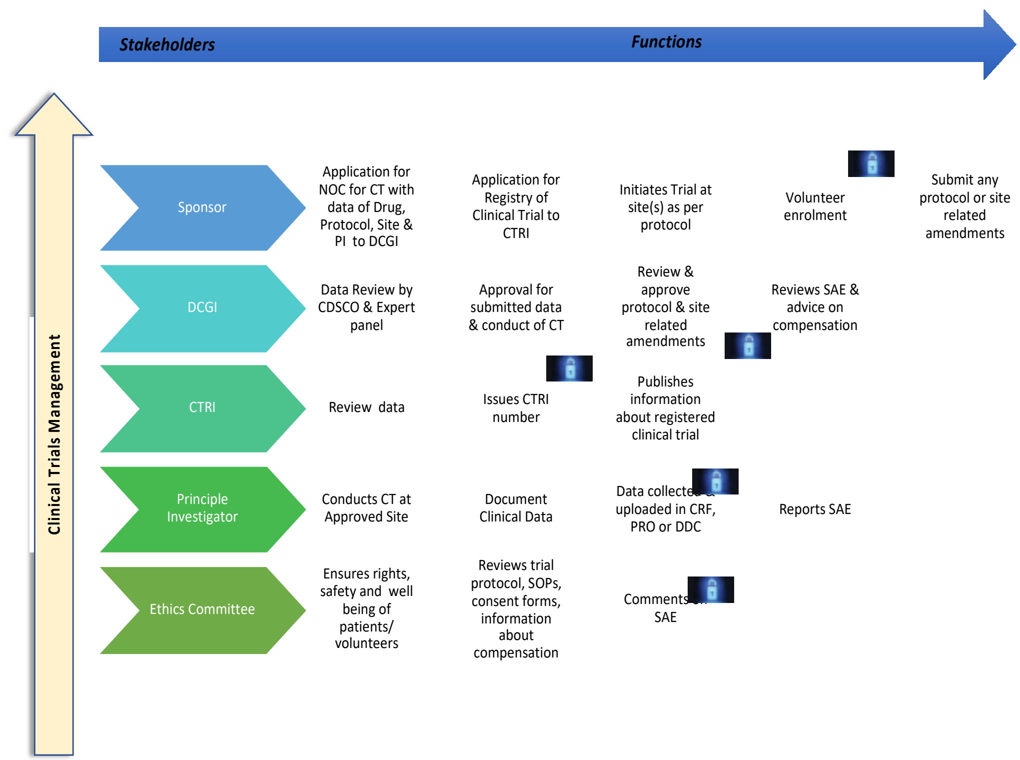

Fig. (4). Data management during the clinical Trial.

Blockchain technology could simplify the management of trusted information, making it easier for stakeholders to access and use critical CT data while maintaining the security of this information. A blockchain is an encoded digital ledger that is stored on multiple computers in a public or private network. It comprises data records, or "blocks." Once these blocks are collected in a chain, they cannot be changed or deleted by a single actor; instead, they are verified and managed using automation and shared governance protocols.

10. FOLLOWING ARE THE BENEFITS OF BLOCKCHAIN TECHNOLOGY FOR DATA MANAGEMENT

10.1. Data Security

Information security techniques prove useful against data breaches; however, they do not ensure end-to-end protection. Even the systems of organizations with the highest levels of security have been penetrated. Blockchain technology is a promising technology against data breaches in which hash values are created for data. These hash values represent data records but cannot reconstruct the information contained in files. They are stored on blockchain and distributed on a network. When files are changed, new hash values are appended to the blockchain, and they are then immutable. The system demonstrates transparency to all stakeholders, and the changes to records are closely monitored & recorded.

10.2. Data Quality

In the case of clinical trials, the quality of data is of utmost importance and must be ensured before committing to a digital ledger, where data can be kept on different nodes, whether private or public. This assurance of data quality is implemented in blockchain using the concept of smart contracts, although it adds up an extra layer of verification and check. Smart contracts are a way of ensuring that the terms of the agreement need to be met before the contract can be executed. Gartner has recently predicted that blockchain technology will improve the quality of data by 50 percent by 2023 [22]. Also, all transactions are recorded and cannot be altered. This means trusted and secure transactions or agreements can be held between anonymous parties without the need for an enforcement mechanism, a legal system, or a central authority.

10.3. Data Traceability

Data traceability is another aspect of clinical trials that are required in case of any or audits in terms of ownership, timestamps, and location. Blockchain allocates a token to each entity that uniquely identifies it and helps in secure data retrieval.

10.4. Data Sharing:

Government, Regulators, CROs, Sponsors and site principle investigators need to have controlled access to data being generated during the conduct of the trial. The data captured during the trial is located locally at individual sites in silos, it isn't as useful as it could be. This restricts the transparent information sharing with the stakeholders for inspection purposes. Centralised information repository containing the clinical trial data is a reasonable solution for information sharing;

however, it comes with the risk of data security. A large amount of sensitive data stored in one location would be a likely target for cyber-attacks. This is another area in which blockchain technology could provide a reasonable solution. The decentralized nature of blockchain allows data to be shared easily across organizations with proper access control. Information is stored on a dedicated ledger in a blockchain database that stakeholders can access online with restricted permissions at the field level.

10.5. Real-Time Data Analysis

Running data analysis in real-time, and monitoring changes as they happen is a great advantage. This is one of the most effective ways of safeguarding against fraud and theft in a data-driven industry. This kind of data analysis was not possible until relatively recently, and it can help to reduce these areas of vulnerability. As Blockchain is distributed and transparent by nature, businesses are able to notice any irregularities as they occur, and they can be viewed in spreadsheet documents. Blockchain technology also allows simultaneous collaboration on the same sets of data.

11. TRADITIONAL CLINICAL TRIAL SYSTEM

Traditionally, clinical data management systems were implemented using proprietary software that was installed at local trial sites where the data was captured and maintained by the site principal investigator. If any of the stakeholders needed data, the data would be shared explicitly by PI either through an email or shared physically in hardcopy. This process was very time-consuming and managing & maintaining several versions of data was quite cumbersome. Also, any changes related to any of the site, protocol, or technical team need to be initiated to regulators and approval of the same needs to be taken by submission of data to regulators. Fig. (**5**) explains the scenario where the internet (*via* email) is used to share information related to clinical trials among CT sites and other stakeholders. For better clinical data management, CROs /sponsors moved their systems to the cloud.

12. CLOUD-BASED CLINICAL DATA MANAGEMENT SYSTEM

Most of the Clinical Data management systems being used now use cloud storage to store the clinical & personal data of the participants, as it is more cost-effective with lower IT management costs and has better access to information generated during the conduct of clinical trial. Cloud computing [23] is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (*e.g*., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. There are several benefits of enabling clinical data management systems on the cloud. It enables real-time monitoring & quick access to trial data. This opens up new opportunities for CT monitoring, from identifying underperforming sites to flagging potential data quality issues. Additionally, cloud computing enables data aggregation across trials and sponsors. The data that is anonymized and aggregated — can be used to create benchmarks so data managers can see how their trial matches up against others in the same therapeutic area. Fig. (**6**) depicts the way clinical data management utilizes cloud storage for real time information sharing:

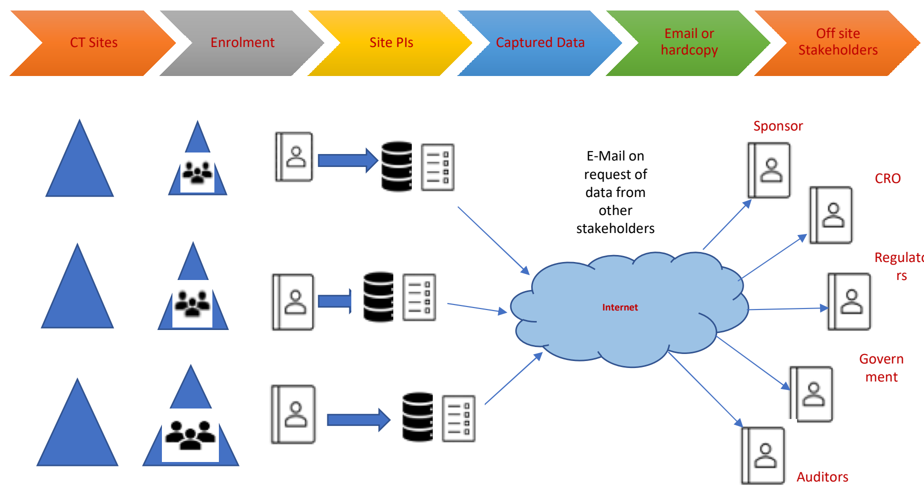

Fig. (5). Traditional Clinical Data Management.

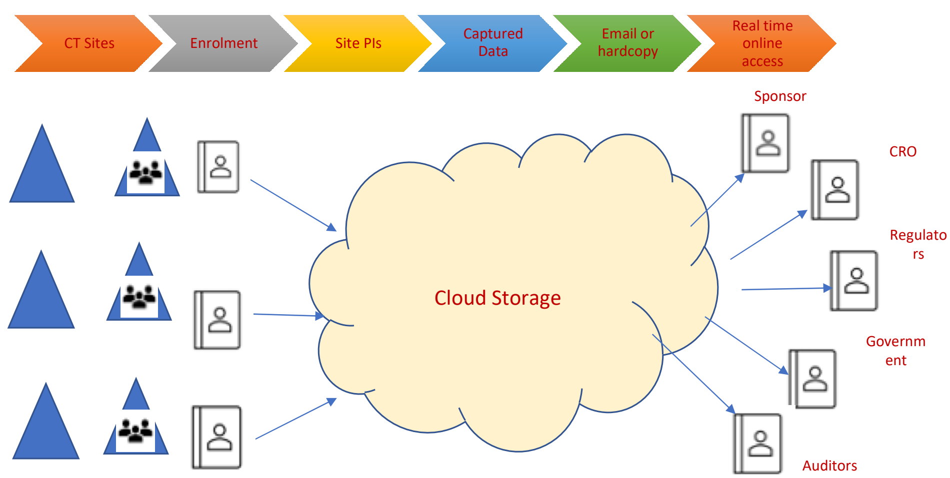

Fig. (6). Clinical Data management using Cloud Storage.

The clinical data collected during the trial is uploaded to cloud storage that is accessed in real-time by the permitted stakeholders. However, sponsors or CROs, as consumers, rely on cloud providers to store the application data, and hence, they relinquish direct control over that data and are unaware of where the data is geographically located and who has access to it apart from the stakeholders. The sponsor /PI would potentially have control over access to these data streams, but would rely on the cloud storage to enforce data access rights.

As per HIPPA standards [24], the CIA properties of the health-related data need to be protected. Although the use of cloud storage provides easy access to stored data, there are many risks that a consumer undertakes by using cloud storage for storing health-related personal data of the participants of clinical trial. In cloud-based architecture, data is replicated to ensure high availability and moved frequently, so the risks of unauthorized access to data increase. Additionally, multiple individuals apartment from target stakeholders have potential access to the data, such as administrators, network engineers, and technical experts that perform services on, or for, the servers that host this data. This also increases the risk of unauthorized access and use.

13. PROPOSED BLOCKCHAIN-BASED CLINICAL DATA MANAGEMENT SYSTEM

This study [25] discusses a blockchain based architecture for managing blood banks. Similarly, implementing Blockchain technology in clinical trial data management provides a secure & immutable database by enabling the cryptographic hash link between blocks and transactions. It also provides well immutability, traceability, transparency, audibility, and accountability of the data stored in it, enhancing data security. Fig. (**7**) shows the architecture of the system implementing blockchain smart contracts for clinical data management on the cloud.

CONCLUSION

Clinical trials play a key role in drug development and its final outreach to patients. They have a major impact on the manufacturer's interests and efforts and the treatment of disease. Thus, clinical trials are not only important to a pharmaceutical company and patients but also to the government, regulators, and future consumers of the drug. The data collected during a clinical trial forms the basis of research and subsequent safety and efficacy analysis of drugs, which in turn drive decision-making on product development in the pharmaceutical industry. The security & integrity of the generated data is important to numerous stakeholders. Clinical data management (CDM) is a critical process in clinical research, whose ultimate goal is to ensure that outcomes from clinical research are well supported by authenticated & quality data. Enforcing Good Clinical Practice (GCP) guidelines at CT sites is the responsibility of regulatory authorities. The regulatory authorities encounter several challenges, such as data auditing and the lack of a secure and easy method of viewing data transactions as and when they occur in real-time. Monitoring of CTs is both time-consuming and expensive as it is common practice to conduct frequent site visits for inspections to verify that trials are being conducted as per approved protocol and the data source is trustworthy. The lack of traceability and transparency of data leads to a high risk of modifying, manipulating and deleting data as well as a high probability of data entry errors going undetected in real-time. Another challenge faced during the initial stages of CT is patient enrolment as there is no integrated database that can provide the participation history of the patients willing participants. Hence, there is a need for technology solution that addresses the issues of data security, integrity, quality, and traceability. Incorporating blockchain technology into the CT process is highly beneficial. The smart contract ensures that there is transparency by triggering events whenever a certain activity is completed, such as the approval or rejection of a new drug application, CT protocol, amendments in the protocol, *etc*. Moreover, patient enrolment is simplified with blockchain as time is consumed in verifying whether patients meet the criteria and if they have submitted their informed consent. Using blockchain-enabled cloud storage is further proposed and useful for better reaching out of the CT information to stakeholders while addressing the data security & integrity issues.

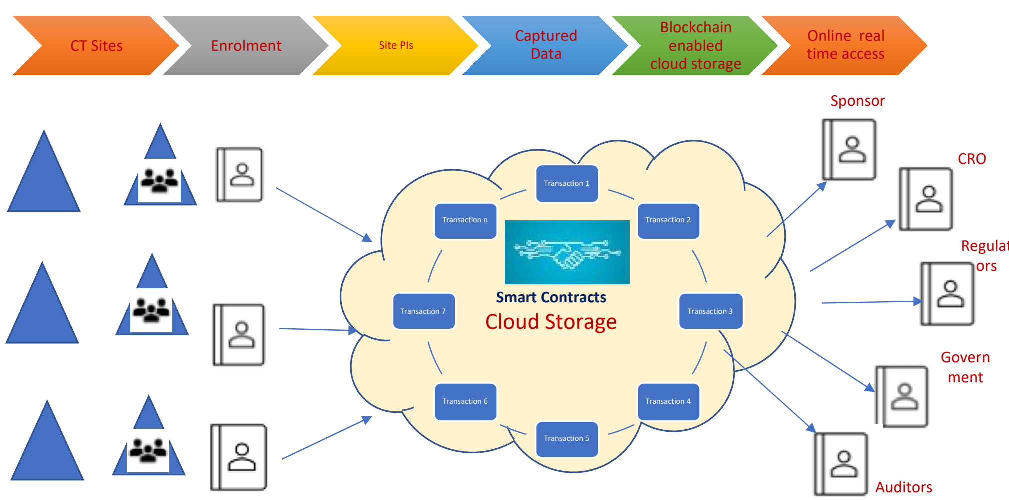

Fig. (7). Blockchain enabled Cloud Storage for Clinical Data management.

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CHAPTER 3

A Complete Review of Block Chain Technology in the Health Sector

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Abstract: The health sector has been a huge market in recent times. It is drawing minute attention regarding pathological tests, drug manufacturing and supply, clinical trials and diagnosis by doctors and finally, recovery of patients quickly. The technologies used in health care for the last decades are redundant. Clinical trials and diagnoses by doctors can be made more accurate, better and faster with a past medical history of the patient in hand. Drug manufacturing and distribution can be made tampered proof and monitored properly by designing a transparent supply management system for medicine and medical goods. Attempts were made in the past to record the medical history of patients in a centralized database server, which lacks security, immutability and consistency of the records. This paper reports a systematic review of the application of revolutionary and disruptive Blockchain technology in healthcare systems to address the above issues. Blockchain technology can be used to create cryptographically immutable, time-stamped, distributed and tamper-proof ledger in a distributed P2P network to maintain Electronic Health Records (EHR) in the health care system. This technology removes all intermediaries between the source and destination point of any transaction. In a Blockchain network, transactions are cryptographically connected and hence merely difficult to modify the content of any transaction. This review shows that a number of studies in the past have proposed the application of Blockchain in health care. However, many of these used cases lack detailed prototypes and consensus algorithms from an implementation point of view. The review also highlights and depicts in detail the application of Blockchain in EHR and medicine supply management systems. The review further highlights the bottleneck of Blockchain and the area of its research in the near future.

Keywords: Blockchain, Consensus, Distributed ledger, Mining, P2P Network, Supply chain.

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1. INTRODUCTION

In recent years, the digitization of health & patient data is undergoing a radical shift for efficient clinical diagnosis. Patient's past medical history in prior will definitely accelerate & precise the diagnosis process by the doctors. Storing patient's data in centralized servers at different stakeholders may sometimes lack privacy, security, consistency, integrity, isolation & accessibility.

Distributed databases [1 - 3] can utilize the benefits of a centralized database, particularly in data sharing. If any breakdown occurs, distributed systems are less affected than a centralized system. If a node breaks down in a distributed system, the system may not halt its functioning due to the presence of other nodes. The topology of the network, communications software and nature of the distributed data are the major parameters that affect the operations and efficiency of a distributed system. Complex data management techniques are introduced in distributed database system to handle issues and problems pertaining to data integrity and concurrency. As data are located and replicated at different locations, it may lead to data inconsistency whenever data is modified [2] at a particular location. Significant challenges are there to implement a distributed system. Data communication can be controlled by advanced networking software that can also address the overhead associated with the system. Fig. (**1**) depicts centralized, decentralized and distributed system.

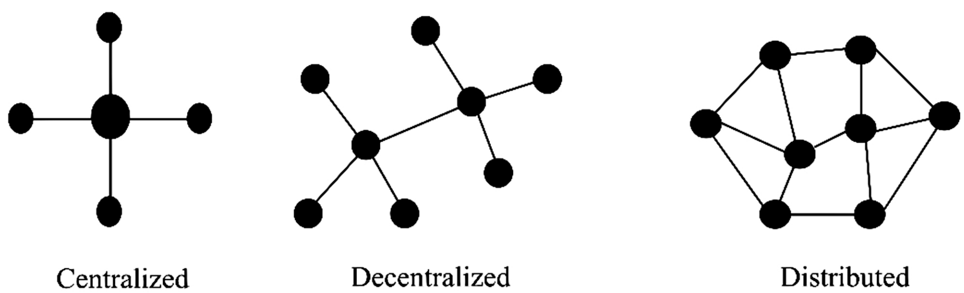

Fig. (1). Centralized, Decentralized & Distributed System.

Moreover, centralized systems are based on some trust-based models, and hence any transaction will involve the intervention of a third party. In decentralized systems, the decision is made by individual nodes. The final result of the system is obtained by the decisions of the individual nodes. Blockchain [4] seems a promising technology in the near future to cater to the above challenges to store patients and other medical data in decentralized manner. The transactions in a blockchain network are not verified by any third-party entity, but rather driven by some consensus mechanism [5].

Blockchain, the technology behind the first cryptocurrency Bitcoin [6, 7], was first proposed by an anonymous person aliasing Satoshi Nakamato [8] in the year 2008. Blockchain-based bitcoin network [7] was meant for transacting cryptocurrencies robustly in a P2P network without the intervention of any third party. Since then, the technology has been buzzing a lot in the market to revolutionize data storage & transactions over a P2P network. The technology is based on distributed Ledger Technology [9], where transactions are time-stamped and added to the network without involving any intermediaries. Transactions are stored in blocks and are added to the network owing to some consensus mechanism. Advantages of this technology include immutable ledger, decentralization, anonymity, transparency, integrity, and security through cryptographic mechanisms [10]. Initially, the scope of blockchain technology was limited to Bitcoin cryptocurrencies [7] which is often termed blockchain 1.0 [11]. Later on, the ethereum [12] network was developed, which uses blockchain technology to implement programming *smart contract* [13], also called blockchain 2.0. Nowadays, researchers are applying blockchain technology to develop decentralized applications (DApps) [14] usable for industry, which are termed as blockchain 3.0 & 4.0. Fig. (**2**) depicts the evolution of Blockchain technology. In spite of many challenges & constraints [15], it is expected that this technology is going to envisage the current infrastructure of internet & communication.

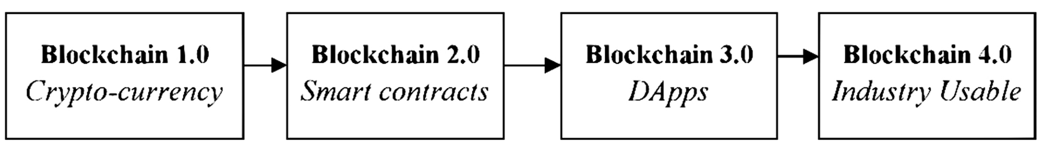

Fig. (2). Evolution of Blockchain Technology.

In the past few years, many researchers have proposed the use cases of Blockchain technology in several areas like cryptocurrencies [16 - 20], Internet of Things (IoT) [21 - 25] and health sectors [26 - 35]. But this potential technology could address many vital areas of the healthcare industry to a great extent. Researchers are emphasizing blockchain technology which can yield industry-usable products. But health sector is trending a lot for the evolution of this technology to a great extent. Few areas where Blockchain can impact the health sector are maintaining patient's database [27], drugs supply chain management systems [28], health insurance [29], *etc*.

This paper systematically reviews the application of *revolutionary* and *disruptive* Blockchain technology in the healthcare industry. It also explains various use cases for healthcare management and applications using blockchain. This paper also aims to discuss the potential challenges of Blockchain technology in the health sector. Also, a consortium-based blockchain network design & operation is proposed for the health insurance sector.

This paper is organized as follows: Section 1 introduces the review work of blockchain technology, Section 2 presents the background of blockchain technology & its cryptographic aspects, and Section 3 presents the review of the technology specific to Electronics Health Records (EHR) & Medical Goods Supply Chain. Section 4 explains the proposed application of blockchain technology in health insurance. Section 5 depicts the open challenges & future scope of blockchain technology, followed by a conclusion in Section 6.

2. BACKGROUND

In earlier days of communication over the internet, most of the web architectures used client-server networks [37]. In a client-server network, a system or a group of systems acts as a server managed by some administrator, whereas other systems act as clients. Here the server keeps all the information in a centralized database [38] from where the clients can access the information. Centralized database at server's end is managed by a group of administrators assigned with some access control rule. The central server has the power to make changes to the database if intended. Clients can access the database with rules assigned by the central server. In contrast, a distributed system involves all the participants of the network to arrive at some decision or consensus. Record keeping, updating or any other operation is done by all the nodes of a distributed system. Blockchain is a technology that uses distributed network where a transaction is broadcasted to all its neighbors when it is created. With the help of mining, transactions get a permanent position in the blockchain network, whose copy exists at all the systems in the network. In this section, detailed blockchain architecture and cryptography aspects used in blockchain are discussed.

2.1. Blockchain Overview

Blockchain is like a linked data structure where several blocks are linked together cryptographically. In a blockchain networks, blocks are immutable, *i.e.*, once a block is added permanently to a blockchain network, and then it is impossible to make changes to the content of that block. Blocks are appended to the network with the help of miners and confirm some consensus mechanism. This process is known as mining. Initially, blockchain network was meant for transacting cryptocurrencies only, often hailed as Blockchain 1.0. But with evolve of ethereum network, whose underlying architecture is blockchain technology, decentralized applications can be deployed by using smart contract. Ethereum network added much flexibility to develop decentralized applications using blockchain. Solidity is a popular contract-based programming language [39, 40].

2.1.1. Blockchain Architecture

Blockchain is considered a linked list of blocks, where successive blocks are connected cryptographically, where each block contains a set of one or more transactions. Two vital data structures used in a blockchain network are:

▪ **Pointers –** This is a field in a block that stores the address of its preceding block in the blockchain. The address of the block is computed by the hash function applied to the whole content of a particular block. If some changes are made to the content of a block, its corresponding hash will also change and ultimately, its link with other blocks will be detached. Therefore, it is very difficult to change the transaction in a block.

▪ **Linked lists –** It is the collection of one or more blocks where each block possesses some data and is linked to other blocks with the help of pointer. Fig. (**3**) shows a LinkedList of blocks in a blockchain network.

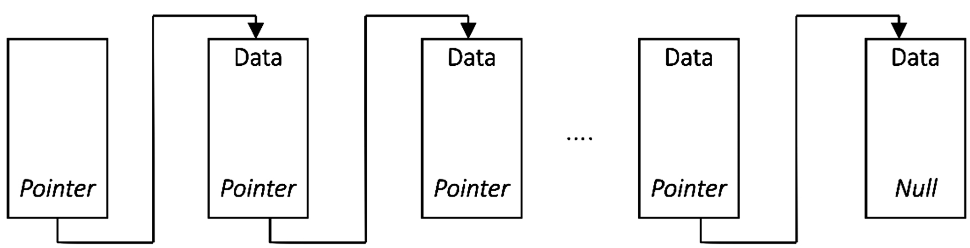

Fig. (3). Linked list of blocks.

The genesis block is the first block in a blockchain network that does not contain a pointer. Except for genesis block, all other block holds the address of its previous block through a pointer. Fig. (**4**) shows a blockchain, which is a sequence of blocks that are linked cryptographically.

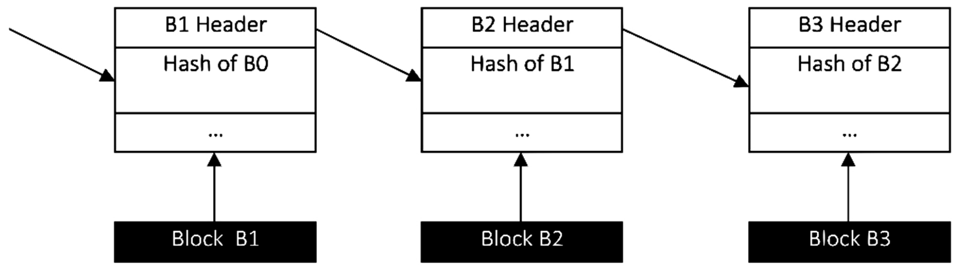

Fig. (4). Blockchain as linked blocks.

There are mainly four components in an individual block, which is shown in Fig. (**5**).

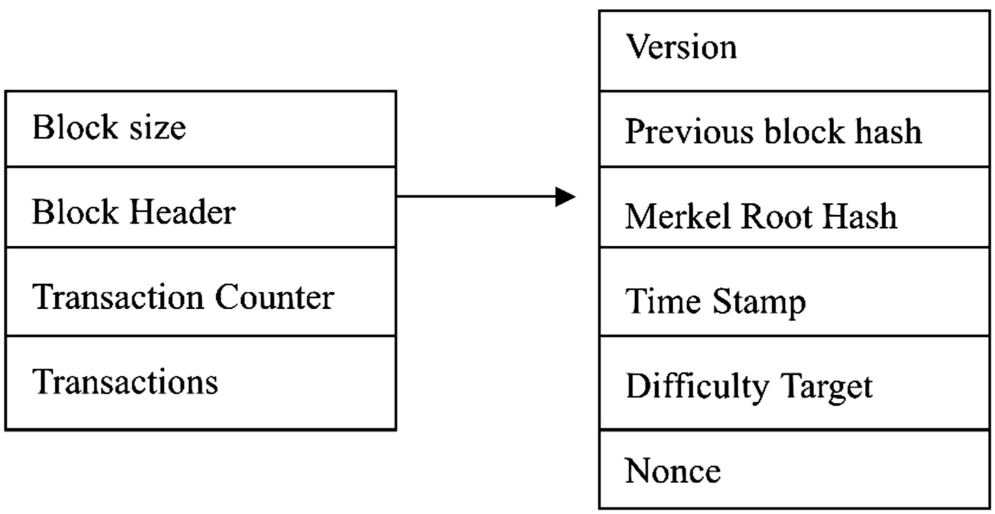

Fig. (5). Structure of blocks in blockchain.

1) *Block size*- It defines the size of the block.

2) *Block header*-Block header contains the information for the identification of the block. It is further divided into many fields shown in Fig. (**5**).

3) *Transaction counter*- Transaction counter is a counter variable that indicates the number of transactions done.

4) *Transaction*- It contains information about the transaction.

2.1.1.1. Types of Blockchain Architecture

Depending upon the user control, blockchain networks are classified into three categories:

▪ **Public blockchain:** In a public blockchain network [41], the system is open to all, which means anyone can participate in a public blockchain network. Also, all the participants in the blockchain network may act as miners. Cryptocurrencies like Bitcoin, Ethereum, and Litecoin follow a public blockchain system.

▪ **Private blockchain:** In a private blockchain network [42], only some specific users or organizations control the network. As a specific node control the network, all the participants in the networks cannot act as a miner and play a role in achieving consensus.

▪ **Consortium blockchain:** In this type of blockchain network [43], a number of organization controls the network. It's an intermediary version of the private blockchain network and public blockchain network.

Table **1** provides a comparison of different blockchain systems.

Table 1. Comparison of various Blockchain architecture.

Parameter	Private Blockchain	Public Blockchain	Consortium Blockchain
Consensus authority	Within one organization	All miners	Selected set of nodes
Consensus process	Permissioned	Permission-less	Permissioned
Read Accessibility	Public or restricted	Public	Public or restricted
Degree of Centralization	Maximum	Minimum	Intermediate
Immutable	No	Yes	No
Efficiency (in terms of use)	High	Low	High

Blockchain is a distributed ledger where all participants of the network hold the entire copy of blockchain transactions. Regarding consensus authority, all the miners have the rights in a public blockchain; only selected nodes in a consortium blockchain network remain within one organization in a private blockchain network. In terms of the consensus process, public blockchain is permissionless, whereas consortium and private blockchain are permissioned. As cited in Table **1**, degree of centralization is maximum in the case of private blockchain networks and minimum in the case of public blockchain networks. Fig. (**6**) depicts the working of a blockchain network [44].

Records are merely impossible to change in a public blockchain network but can be tampered with in a private or consortium blockchain network.

Public blockchain networks are less efficient as compared to private blockchain networks due to more transaction time and a huge amount of computation power.

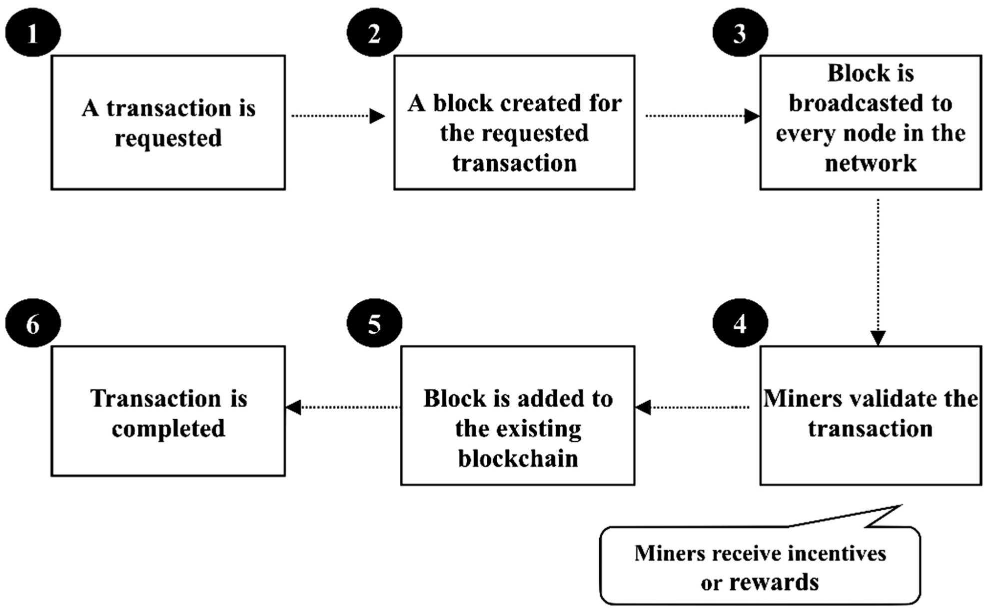

Fig. (6). Working of the blockchain network.

Blockchain is used in organizations and enterprises to cater following purposes [45]:

▪ **Reduction of cost –** Huge money is spent to hold and maintain a centrally held database. With the help of blockchain, this cost can be minimized. Also, data can be made more secure and tampered with proof with the help of blockchain technology.

▪ **Easy and Transparent access to the history of data –** Using blockchain, it is very easy to check the history of transactions at any point in time. In a blockchain network, a transaction cannot be backdated. Hence transparent & actual history of data can be obtained in a blockchain network.

▪ **Data validity & security** – Though performance is compromised in a blockchain network, only valid data are entered in a blockchain network. Also, the degree of security of data in a blockchain network is more.

Table **2** highlights the key characteristics of Blockchain Architecture.

Table 2. Important Characteristics of Blockchain.

Property	Public Blockchain
Cryptography	In a blockchain network, transactions are validated and secured through cryptographic techniques.
Immutability	Blocks in a blockchain cannot be deleted or modified.
Provenance	Origin of any transaction can be tracked easily
Decentralization	Every participant of the network owns a copy of blockchain data and performs a transaction without the help of any intermediaries. Transactions are validated through a consensus mechanism.
Anonymity	Users of a blockchain network remain anonymous to all other parties as their original identities are not disclosed. Users are identified by their unique address.
Transparency	The blockchain network is transparent as it can't be tampered with or corrupted by a third party. All the transactions are validated through a consensus mechanism.

2.1.2. Consensus, Mining & Incentives

After a block is created by a node, it is broadcasted to all other nodes in the blockchain network. The block is added to the blockchain network owing to some consensus. This technique of adding blocks to a blockchain network is known as mining. Miners are the nodes responsible for mining blocks in a blockchain network. Miners also earn some incentives after successful mining. This section describes consensus, mining & incentives in a blockchain network.

Through the consensus mechanism, all the nodes in the blockchain network achieve agreement on a single value. It is useful in record-keeping, among other things. Block validators or miners are the nodes that participate in the process of mining blocks for validating blocks. The miners are rewarded for mining blocks into the blockchain network (as they use their computational power and electric power). Different blockchain applications use different methodologies for selecting miners from the available pool of nodes. Few consensus mechanisms used in blockchain are discussed below:

2.1.2.1. PoW (Proof of Work)

In proof of work consensus, the task of mining remains open to all the participants of the blockchain network. Every participant competes with each other to validate the block. Practically, participants with more computation power win the challenge of proof of work. Some incentives in terms of cryptocoins are rewarded to the participants after successful mining. Bitcoin uses the Proof of Work algorithm.

2.1.2.2. PoS (Proof of Stake)

In proof of stake, participants with greater stakes (*i.e*., having a greater number of crypto coins) have a greater chance of mining blocks into the blockchain network. Here also, some rewards are earned by the miners after successful mining.

2.1.2.3. Proof of Capacity (POC)

In proof of capacity, a node with more memory space has the privilege and rights to maintain the public ledger.

2.1.2.4. Proof of Activity (PoA)

PoA is a hybrid approach that combines the feature of PoS and PoW. In this method, the mining switches between PoW and PoS.

2.1.3. Advantages & Disadvantages

Most blockchains are designed as a decentralized platform intending to remove the middleman in any transaction. In a blockchain network, records are immutable, and blocks are connected cryptographically, which ensures data integrity and security.

The advantages of blockchain technology are:

2.1.3.1. Decentralization

A blockchain network relies on the concept of decentralization, which ensures the elimination of an intermediary or any third party to verify the transactions. The consensus mechanism is used by a blockchain network to verify and validate the transactions.

2.1.3.2. Immutability

It is almost impossible to change the data in a blockchain network once they are successfully added to the network, as different blocks in the network are linked cryptographically. Hence a blockchain network can be useful to maintain a ledger of transactions that cannot be altered.

2.1.3.3. Transparency

A blockchain network guarantees transparency to all its users of it, as the copy of blockchain data is shared across all the nodes of the blockchain network. This enables trust among different nodes of the blockchain network.

2.1.3.4. Availability

When a block is successfully added to a blockchain in a network, the updated copy of blockchain is replicated across all the nodes of the network. The same copy of blockchain exists in all the nodes of the network. Therefore, data remains highly available in a blockchain network irrespective of individual node failures.

2.1.3.5. Security

The transactions in a blockchain network are highly secure as they confirm some consensus and are linked cryptographically.

2.1.3.6. Cost Minimization

No intermediaries or third parties are involved in transactions occurring in a blockchain network. Hence, intermediary costs towards commission or service charges can be eliminated.

In spite of many potential advantages, blockchain technology suffers from the following drawbacks now:

1. Scalability
2. Adaptability
3. Regulation
4. Relatively immature technology
5. Privacy

2.2. Cryptography in Blockchain

Blockchain mainly uses asymmetric-key algorithms and hash functions as cryptographic primitives for its growth and operation. These primitives constitute the foundation of security in blockchain and enable the blocks in the blockchain network to be connected securely without any tampering. Cryptography [46] plays an important role in designing a blockchain network.

2.2.1. Asymmetric key Cryptography

In asymmetric key cryptography [47], private keys and public keys are used by the sender and the receiver for encryption & decryption. The private key in an asymmetric key algorithm is generated randomly and its corresponding public key is generated by applying an irreversible algorithm. Various applications of asymmetric key cryptography are encryption, decryption, key exchange and digital signature. The main advantage of asymmetric key algorithm is that it uses two separate keys for encryption and decryption. Main challenges with asymmetric key cryptography are unsatisfactory encryption strength and slower operations speed of the algorithms. Digital signature [48] plays a crucial role in asymmetric key cryptography. Digital signatures ensure data integrity, verifiability and reliability. Digital signatures ensure the quality of non-repudiation as like signatures in the real-world. The digital signatures confirm that the transactions in a block are verified and correct, and the blockchain is valid.

2.2.2. Hash Functions

Hash functions [49] are used to produce the fixed-length hash code or message digest of input data of variable size. In blockchain, every block (except the genesis block) holds the hash of the content of their previous block. This ensures that data in a block are immutable and also maintains the integrity of data. Any changes made in the block data [50] can make that block invalid, as its hash will be recalculated and will not match the previous one. Many blockchain networks generally use the SHA-256 algorithm as a hash function. The advantages of these cryptographic hash functions [51] in a blockchain network are:

▪ **Avalanche Effect –** A small change in the input data will cause a significant change in the output data. For instance, applying the SHA-256 hash function to the input given below:

Input Message: North Orissa University Baripada

The output obtained for the above input message is:

Output:
8ccb122f5d3eb1734b1991846f63dbf704cef13b1167ef4e9cbf56516d7ab0bb

Now consider the message with a slight change, like changing the lower case letter ‘a’ to the upper case letter ‘A’ in the word Baripada.

Modified Input Message: North Orissa University Barip A da

Again applying SHA 256 algorithm to the above message, the output is:

Output:
105a721e2a7fdea3b454e03520e9e76577ef092c2264c7fb33ff18026444be83

By comparing both outputs, it can be noticed that there is a huge difference in the output by changing a single character of the input message from lowercase to uppercase. This property of the hash function makes the data secure and reliable in the blockchain network. Any changes in the block data will lead to a change in its hash value and will mark that block as invalid. Therefore, transactions in a blockchain network are immutable.

▪ **Uniqueness –** Every unique input data has a unique message digest or hash code.

▪ **Deterministic –** Any input message will produce the same hash code if passed through the same hash function any number of times.

▪ **Quickness –**Hash code, the output of the hash function, can be generated in a very quick time.

▪ **One-way property-** The hash function always satisfies the one-way property, *i.e.*, the input cannot be reverted back by having the output and hash function.

2.3. Smart Contract

Smart contact, a decentralized programming platform that can be implemented in a blockchain network. Due to the security aspect of blockchain technology, blockchain network has become a standard execution environment for smart contracts. A smart contract program is comprised of two units, *i.e.*, function and data. In the late 1990s, Smart contracts were first theorized by Nick Szabo in an article named Formalizing and Securing Relationships on Public Networks [52], but its potential became prominent with the invention of blockchain technology and bitcoin. Smart contracts are deterministic in nature that enables integrity. This property ensures to yield the same result when a smart program is run by any node in a network. Ethereum blockchain platform uses solidity, a programming language to implement smart contracts.

3. REVIEW OF THE APPLICATION OF BLOCKCHAIN IN HEALTHCARE

Centered with the features like decentralization, security, transparency & immutability, Blockchain seems a promising technology to address the challenges faced in the healthcare industry in the past few years related to electronic health records (EHR), medicine supply chain management systems *etc*. Many researches in the past few years pertained to the application of Blockchain in the healthcare industry. Khezr, *et al*. [25] studied & reviewed Blockchain technology in Health care. This study highlighted Blockchain-based healthcare management applications like EHR, supply chain management systems, Internet of medical things (IoMT) *etc*. In 2020, Hasselgren *et al*. [26] published a review paper to improve healthcare services using blockchain. This study highlighted that Electronic Health Records(EHR) are the most promising areas of application using blockchain technology, and Ethereum seems to be the most used platform in this area. Common challenges of the healthcare industry & its Blockchain opportunities are depicted in Table **3**.

Table 3. Difficulties in Healthcare & Blockchain Solution.

Difficulties in Healthcare	Blockchain Solution
Past medical records	Patient's records are maintained using immutable distributed ledger technology.
Security	Data is protected cryptographically and impossible to tamper.
Consistency	Data consistency is maintained using smart contracts.
Huge Cost	In blockchain technology, the cost is minimized by the elimination of intermediaries or third parties.

This section systematically reviews the application of blockchain, specifically in EHR and medicine supply chain management.

3.1. Electronic Health Records

Many attempts have been taken in the past by researchers to incorporate blockchain technology to maintain electronic health records. Shahnaz, *et al*. [24] discussed how the potential blockchain technology can be used in EHR systems and cater to issues like data integrity and security. This paper also highlighted a framework for EHR augmented with blockchain technology to ensure the security of the system. Tanwar, *et al*. [35] proposed solutions using blockchain that can address recent limitations in healthcare systems. Security & efficiency is enhanced in the proposed system that uses blockchain technology. Fig. (**7**) depicts the proposed architecture by Tanwar, *et al* [35].

There are four participants in the proposed system, as shown in Fig. (**7**): Patient, Clinician, Lab and System admin. Tanwar *et al*. also proposed an algorithm for working with admin, patient, lab, clinic, *etc*. Hasselgren, *et al*. [26] studied that the use of blockchain technology in the health domain is increasing exponentially. This study highlighted areas like EHR within the health domain that potentially could be deeply impacted by blockchain technology. Katuwal *et al* [28] studied Applications of Blockchain in Healthcare. In this study, it was found that most of the aspects of blockchain are limited to whitepapers, concepts only.

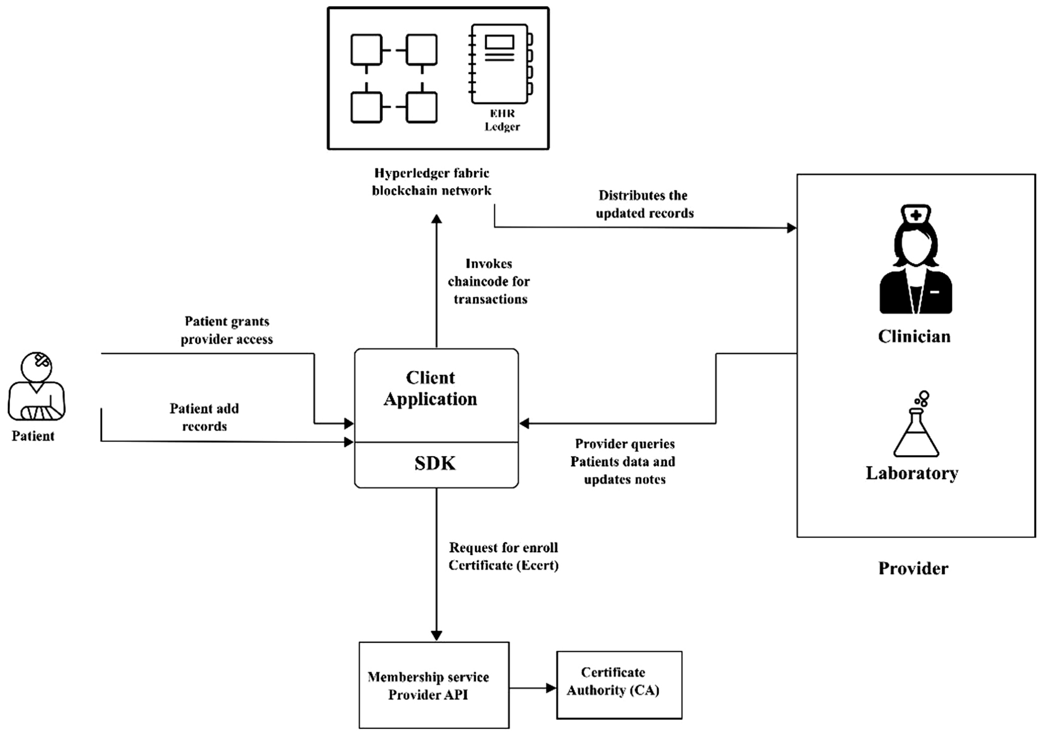

Fig. (7). System architecture of EHR.

3.2. Medicine Supply Chain Management

With globalization, the movement of pharmaceutical goods across borders and long distances involves a number of different parties. Blockchain technology can increase efficiency and reduce the costs of this supply chain system. It will transform supply chain management in many different ways, like transaction processing and settlement.

The pharmaceutical Supply chain involves the passing of medical goods starting from the manufacturing unit to end customers. In between, it has to pass through distributors, re-packagers, wholesalers and retailers. Pharmaceutical Supply chains using blockchain ensure transparency, quality, and traceability of medical units starting from the manufacturing unit to the end customers. Drugs can be tagged with barcodes or RFID's, and all their details can be fetched once scanned.

These records are immutable and hence bring transparency to all people sitting along the supply chain. Records pertaining to various goods are updated in realtime as they are shifted from one entity to another entity. The immutable nature of blockchain ensures drug traceability from manufacturer to customer. This also confirms if the system is compromised somewhere.

Tseng, *et al*. [36] studied the use of blockchain for the drug supply chain, which can prevent counterfeit drugs and protect public health, including patients. The lifecycle of drugs, from development to the final release in the market, includes basic research, non-clinical trials, and clinical trials, licensing, manufacturing, and distributing/selling. Every stage of the life cycle of drugs requires good control and inspection to yield goods at the final end. Fig. (**8**) shows the Medicinal product lifecycle management framework & Fig. (**9**) shows Medicine Supply Chain Management System.

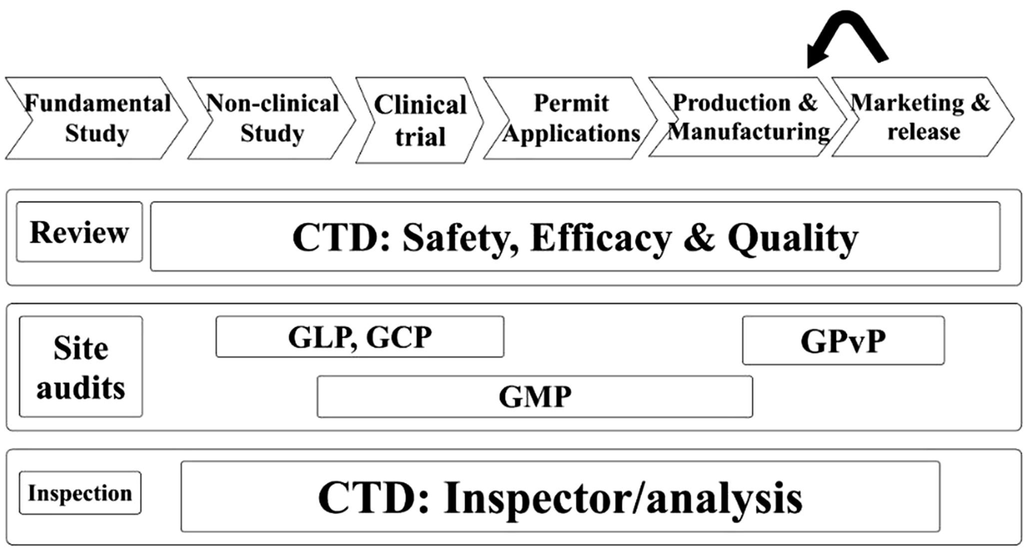

Fig. (8). Medicinal product lifecycle management framework.

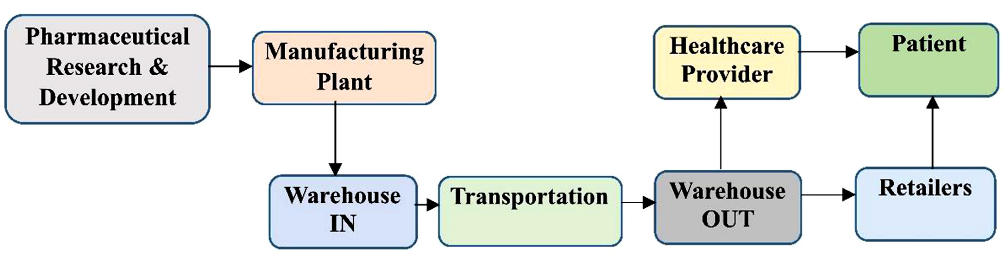

Fig. (9). Medicine Supply Chain Management System.

Abbreviations: CTD: Common Technical Document, GLP: Good Laboratory Practice, GCP: Good Clinical Practice, GPvP: Good Pharmacovigilance Practice, GMP: Good Manufacturing Practice.

4. PROPOSED BLOCKCHAIN MODEL FOR HEALTH INSURANCE

Traditionally, as compared to other industries in the financial sector, insurance has been slower to respond to technological advancement due to the nature of the industry, and also due to the mammoth amounts of data involved in the same. However, despite this, there seems to be a growing awareness about the capabilities of blockchain among health insurers which may disrupt the existing infrastructure of health insurance industries.

Therefore, blockchain technologies in the future can impact the healthcare industry to a huge extent. Patients, doctors, hospitals, nurses, and pathologists can be connected to a blockchain network to store and maintain medical records. Whenever a patient visits a doctor for consultation, the impression inferred and all diagnoses made or proposed by the doctor will be added to that centralized Blockchain network by the doctor against the unique id number of the patient. The results of pathological tests prescribed by the doctor will also be added to the blockchain by the pathologist in the same blockchain network. Likewise, all medicines, hospital details, *etc*., will be added to the same blockchain network using the unique id number of the patient. In this way, all aspects of a particular patient can be integrated into a tampered proof and secure blockchain network. Now the patient need not have to go with all his past medical records to every hospital or doctor whenever he goes for a consultation. Doctors and all medical staff can login to the blockchain network to get all the medical history of the patients in a quick time. This will facilitate faster medical services to critically ill patients.

The blockchain network discussed in the above paragraph may lead to faster claims of health insurance policies, as insurance companies will also remain a part of the blockchain network. Also, this will benefit the insurance company to get rid of insurance forgery and misuse.

Here, a model is proposed for the application of blockchain networks in the health insurance industry. A consortium-type blockchain network is proposed here, which can be designed to which patients, doctors, hospitals, drug stores, and health insurance agents will be connected. Through smart contracts, records can be added to the blockchain network by various entities participating in the blockchain network.

Various participants of the proposed blockchain network, shown in Fig. (**10**), are:

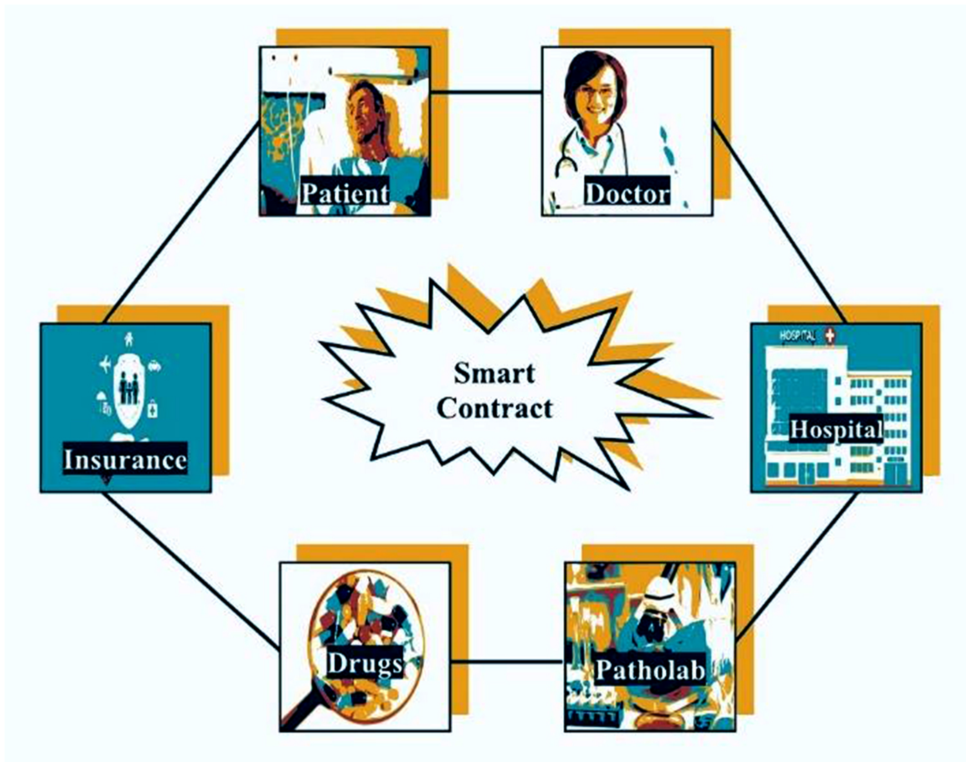

Fig. (10). Blockchain network for Healthcare insurance.

1) Health insurance agents

2) Doctors & Hospitals

3) Patients

4) Drug Stores

5) Patholab agents

Different participants have different access labels and use different smart contracts in the blockchain network. Patients, doctors, hospitals & health insurance companies can be connected to a government-backed consortium-type blockchain. They can connect to the blockchain network using some proper identification number like an Aadhar number or other valid document. Once they become part of the blockchain network, they can write data into it through a smart contract. For example, doctors can write data related to the diagnosis of the disease; hospitals can write all data related to patient, starting from the day of admission to the date of discharge, including all bills. Patholab's representative can write all pathological test reports of the patients into the blockchain network. These data present in the blockchain can be used by health insurance companies for insurance management, claims & benefits to new customers. Also, the insurance company can reduce the premium amounts after going through the past medical history of any person who is part of this blockchain network. Fig. (**11**) shows a use case of health insurance.

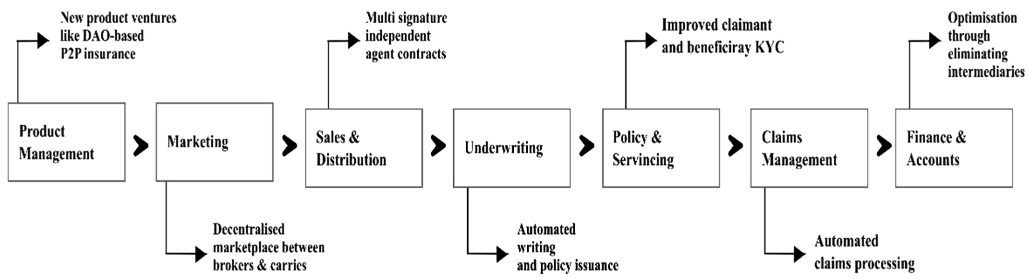

Fig. (11). Industry use case of insurance.

The main advantages of the use of blockchain networks in Healthcare insurance are:

1) Lower operational cost

2) Increased automation

3) Secured Transaction

4) Reduced risks

5) Easy claim of insurance

5. OPEN ISSUES & FUTURE SCOPE

Despite the potential benefits of blockchain technology, it has few limitations. Lack of scalability and storage at individual blockchain network users seems to be a major constraint. A transaction in a blockchain network requires validation of the block through consensus and the entire blockchain data. This leads to the demand for high storage space at individual nodes. The restriction of the block size contributes to the scalability issue in a major way. Limited block size (1 MB) and slow consensus process resulted in very slow transaction processing in a blockchain network. Increasing the block size can result in more delay in block propagation. Energy consumption is another con of this technology. The energy required for a Bitcoin transaction is 80,000 times the energy required for processing a credit card. At present limited scalability, storage issue, unsustainable consensus mechanisms, lack of formal contract verification, lack of governance & standards, and quantum computing threat seems challenging metrics of blockchain technology before it acquires its full identity in terms of end uses. But following the fact that every problem has a solution, it is expected that this particular blockchain technology will revolutionize the infrastructure of data communication, data storage in the near future.

CONCLUSION

The primitives of potential blockchain technology are discussed in this paper. The technology mainly focuses on decentralized applications in a P2P, ensuring data security and integrity. Smart contract eliminate the intermediaries in a transaction using blockchain, and Ethereum seems the ideal platform at present to write smart contracts. The areas of the health sector where the application of blockchain seems promising are Electronic Health Records, Medical Goods Supply Chain Systems, Health Insurance, *etc*. Here in this study, we have proposed a theoretical approach for applying blockchain in the healthcare system to bring more transparency & remove intermediaries in healthcare insurance. At present, blockchain technology seems to be at its infant stage to replace the current infrastructure of data communication & storage. It is expected to bring revolution in the coming years.

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CHAPTER 4

Blockchain and Clinical Trials for Health Informatics

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Abstract: Blockchain is part of the disruptive novel technology stemming from the cryptocurrency and bitcoin, which became large-scale around the year 2011. Subsequently, these technologies have triggered much need attention through the development and growth of more novel cryptocurrencies resulting in transactions, elections, peer reviews, democratic decision-making, identification and audit trails. The health sector has benefited immensely from the rapid advancement in blockchain, such as growth in biomedical research, drug traceability in the pharmaceutical sector, clinical trials, biological testing, patient's data management, health informatics, data sharing, supply chain management of medical goods, legal medicine, telemedicine, health record, remote patient monitoring, payment services and security. Thus, this chapter will give a general overview of the principles, and applications of blockchain in healthcare industries and possible challenges with ways to resolve them.

Keywords: Bitcoin, Blockchain, Cryptocurrency, Health sector, Technology.

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Nilayam Kumar Kamila, Sujata Dash & Subhendu Kumar Pani (Eds.)

1. INTRODUCTION

Studies have revealed that blockchain, as part of the disruptive novel technology, stems from cryptocurrency and bitcoin, which became large-scale around the year 2011. Subsequently, these technologies have triggered much need attention through the development and growth of more novel cryptocurrencies resulting in transactions, elections, peer reviews, democratic decision-making, identification and audit trails [1 - 9]. In particular, the health sector has benefited immensely from the rapid advancement in blockchain, such as growth in biomedical research, drug traceability in the pharmaceutical sector, clinical trials, biological testing, patient's data management, health informatics, data sharing, supply chain management of medical goods, legal medicine, telemedicine, health record, Remote Patient Monitoring, payment services and security [10]. Blockchain in the medical and healthcare sector has the advantage of preserving data from corruption to make it secure. The decentralization healthcare management using blockchain can be the backbone where stakeholders can utilize patient's data or records without any hindrance or obstacle. Blockchain data cannot be altered, corrupted and retrieved due to encryption appended in chronological pattern and time stamped using cryptographic key. Esmaeilzadeh *et al*. [11], in their study examined the perceptions of patients toward the utilization of blockchain mediated health information exchange networks and the arch significance of blockchain knowledge from the perspectives of consumers in the healthcare industry. The authors created seventeen knowledge-based exchange situations for regulated Web-based trials. The results indicated that the views of patients varied concerning various information exchanges as far as patients' privacy was concerned. The work showed both the promising roles of health information exchange and the limitations. Blockchain helps patients to detect any misuse emanating from any stakeholder, thereby providing data ownership and privacy with cryptographic protocols and smart contracts. Even though so many beneficial properties have been presented about blockchain in healthcare industries, there are still contending challenges, such as storage issues and large amounts of computational power [12]. Thus, this chapter will give a general overview, principles, and applications of blockchain in healthcare industries and their possible challenges with ways to resolve them.

2. PRINCIPLES OF BLOCKCHAIN

Blockchain, a public ledger of transactions, has operational principles. For instance, in blockchain, there is no need for a central regulator or a third party. There is no need for any hardware. Instead all participants are involved in data authentication. In fact, blockchain technology utilizes no central server, and the network is *i.e* P2P protocol. All nodes in the P2P network exhibit identical network power. Crossby *et al*. [13], reported that blockchain is a system where dispersed consensus in the arithmetical world is created to enable individual entities to understand that a digital activity happened by creating a correct score in a public blockchain ledger. It creates room for the development of a scalable and open arithmetical economy from a central one. Another important concept is transparency and openness.

In the blockchain approach, data is accessible to everyone. It is, therefore, possible for anyone to critique or question blockchain data. Applications can also be created *via* a shared interface. In blockchain, all data properties are grouped into the nodes linking every blockchain arrangement. Data external to the blockchain arrangement are inhibited. All information and activities within the arrangement are open and apparent to all the nodes that are in the system. Through the integration of hash encryption and asymmetric encryption, the blockchain provides high transparency of data [14, 15]. Apart from openness and transparency, another concept is independence. The blockchain is managed by its own node. No manual intervention is involved in the implementation of its data proof mechanism [14].

Like the works of Zheng *et al*. [15], Crosby *et al*. [13], Lin and Liao [14], Lansiti and Lakhani [16], reviewed principles underlying blockchain technology. In the blockchain, there is data distribution, openness and transparency. This implies that no one regulates blockchain data and it is possible for anecdotal data to be checked by every partner directly. Blockchain is decentralized, and as such, no communication involves a central node, but partners communicate directly. Another important concept of blockchain is that once records have been updated, alterations cannot be affected. There are many computational algorithms which made transactions permanent. Lastly, blockchain transactions are programmed. This means that participants can put forth algorithms between nodes that instigate transactions automatically.

3. TYPES OF BLOCKCHAIN

Studies have revealed the existence of three kinds of blockchain-based permission levels federated blockchain, public blockchain and private blockchain. Concerning public blockchain, it is permissionless transaction validity anonymity, easy to operate by the public community such as Bitcoin, Waves, Ethereum, Bit shares, and Dash. The federate blockchain is based on permission with group operating protocols like consortiums like EWF, B3i and R3 Corda. The private blockchain is also a permission centralized blockchain which is faster but highly vulnerable to security issues such as private Ethereum, Hyper Ledger with Sawtooth, and Monax.

4. APPLICATIONS IN HEALTH CARE

Zyskind and Nathan [17], looked at the decentralized form of personal data management system, which enables operators to possess and regulate data. The authors also conducted a scheme that turned a blockchain into an automated access-control supervisor, which was independent of third-party trust. As an alternative, this system enables users to regulate and control the security and data services in personalized ways without necessarily affecting the integrity of the security architecture. They identified no need for confidential data to be entrusted in the hands of a third party, and this was achieved courtesy of blockchain combination with off-blockage storage capacity, repurposed as access control moderator. Annual Report [18] remarked that blockchain technology, due to its traceability, has a tendency to provide provenance and transaction transparency.

Yue *et al*. [19], developed a technology referred to as Healthcare Data Gateway architecture on the basis of blockchain, enabling patients to control, share and own their personal data devoid of privacy violation securely and easily. With this, a new promising way of improving healthcare intelligence was created without violating the privacy of patients' data. Zheng *et al*. [20], purported that using consensus-driven and decentralized environment, distributed ledger technologies will facilitate reliable results like IOTA Tangle, Ethereum, and blockchain, to enhance healthcare system data networks.

Zhang and Lin [21], created an innovation on personalized healthcare information based on privacy and a secured platform utilizing blockchain technology to enhance prognosis, diagnosis and treatment, particularly for e-Health systems. Based on the study, private blockchain and consortium blockchain were designed by employing their consensus mechanisms and data structures. Though, the consortium blockchain functioned in the record-keeping of secure data of personal health information, the private blockchain functioned in storing personal health information. The authors ensured that data such as personal health information, keywords, patient's identity and description are encrypted with code search so as to attain access control, security, data privacy protection and search. Also the block generators were expected to show proof of conformance in order to facilitate the addition of novel blocks to the blockchains to guarantee system availability.

Dubovitskaya *et al*. [22], published a report on the management of healthcare data, specifically medical electronic records, on the basis of blockchain. The authors designed a scheme for sharing and handling electronic medical records for cancer patients. The model was shown to greatly enhance judgment, decrease the rate and time for medical electronic record distribution and facilitate quick decision-making for healthcare, thus reducing the general cost.

European Society of Radiology [23] reported the uses of blockchain in medical imaging. These include improved access to electronic medical records, traceability of image data, and image distribution and data annotation through enhanced traceability for artificial intelligence training. With blockchain, patients can control accessing their data. It enhances fairness and security and makes imaging records for artificial intelligence available in sufficient quantities.

Just as a way of addressing security, privacy and interoperability challenges of the internet of medical things, Li *et al*. [24], presented a blockchain-enhanced Internet of health things platform by adding blockchain to current Internet of health things systems. The roles with other opportunities attributed to these novel models were equally illustrated. The model demonstrates a tendency of being utilized in managing the COVID-19 pandemic, particularly in the aspect of contact tracing, disease prevention, provision of injectable therapeutics and location sharing.

Several studies have enumerated the global impact of the COVID-19 pandemic, particularly the general disruption of the global healthcare system and lifestyles, thereby negatively causing global economic instability. Several approaches have been suggested with minimal impact, but the internet of Health of Things has been revealed to have huge advantages to combat and fight emerging health challenges such as infectious diseases, particularly COVID-19 raving the entire globe. These platforms can be deployed to various health centers, hospitals, and laboratories, thereby enhancing the health sector through reduced diagnostic time, contact tracing, secured location sharing, medical supplies distribution, waste management and efficient data processing and record-keeping methods. The internet of health things enabled blockchain can be incorporated as a healthcare system beneficial architecture, particularly in the fight against infectious diseases like COVID-19.

Ismail *et al*. [25], discussed a thorough analysis of a novel integrated blockchain-cloud for the medical system to unveil the roles of integrated blockchain-cloud for improved healthcare. The authors highlighted, among others, the challenges of the integrated blockchain-cloud architecture, including the possible solutions and research prospects.

Studies have revealed that blockchain, as a disruptive innovation in health care management, represents a major next-generation technology for effective and efficient patient's management and care due to its unique characteristics liversuske transparency, secured nature, cloud computation, cost-effectiveness, elasticity and peer-to-peer approach. Blockchain is known to offer adequate solutions to healthcare challenges like the provision of sustainable ways of privacy, security of data, scalability, and managing diverse multifactorial challenges in the health sector through a blockchain-cloud integrative approach.

Vangipuram *et al*. [26], utilized an off-chain distributed storage solution for the purpose of loading large health record sets. This scheme was also used for implementing blockchain for transmitting information from COVID-19 infected person to medical center through an edge infrastructure called CoviChain. The authors also loaded the COVID-19 data on edge, and later transferred it to the InterPlanetary File network storage system to collect the mess of the data folder. The retrieved hash data is transferred to the blockchain through smart contracts. While attaining bigger data storage systems on the blockchain at lower time and cost, CoviChain is capable of managing privacy and security challenges and avoiding the exposure of patients' data.

The current COVID-19 pandemic has forced the whole world to adopt many approaches that are linked to internet, algorithms and applications across various sectors like education, agriculture and health, particularly in contact tracing of infected individuals due to the infectious nature of the virus. This approach is classified under the internet of health things for collation, collection, processing and analysis of health data by scientists and healthcare providers. The blockchain has the ability to accommodate large data samples, transfer through various platforms and secure them for easy retriever through the utilization of edge infrastructure, InterPlanetary File Systems, smart contracts and CoviChain.

Dubovitskaya *et al*. [22], discussed, among others, the advantages of blockchain technology in oncology. In the study, a permissioned-system based on blockchain was reported for electronic health record integration and data sharing. In the study, ACTION-electronic health record, patient-centric system, electronic health record data transfer and sharing and radio-therapeutic treatment of cancer patient based on blockchain was created. Ji *et al*. [27], reported the blockchain-based location allocation for the purpose of telehealth information systems. The result of the work indicated that the model can be employed for realizing secure blockchains based-location allocation for telehealth information systems.

Sun *et al*. [28], reported that medical or health information, which is generally searchable through the utilization of a smart contract approach or blockchain technology, has generated much attention, particularly in the healthcare system. In their study, they conducted a hash calculation concerning electronic health data and value system which was stored on the blockchain system for maintaining authenticity, elasticity and integrity. Thereafter, electronic health data was coded or encrypted, then stored in a distributed storage protocol known as an interplanetary file system. The operations were shown to resolve the central data store of several health organizations. It can reduce pressure or strain from data and other access or storage challenges to the blockchain. Furthermore, the authors stored the encrypted or coded index data of electronic health records on the Ethereum blockchain. The result of the work indicated that the scheme is highly efficient, secure and cost-effective.

Fu *et al*. [29], reported a lightweight, secure principle for healthcare blockchain platforms. The authors applied the inter-leaving encoder to encrypt real electronic medical records. A (t, n)-threshold lightweight communication transfer system was then used, and thereafter, the catalogues of the stored electronic medical records transferred were utilized for generating blocks which were joined to form a blockchain. These results indicated that the platform was highly efficient, effective and with a similar structure in terms of energy utilization, storage and space consumption. The healthcare blockchain network was much more highly stable, together with the projected information sharing and transfer scheme.

Hylock *et al*. [30], reported a novel patient-based blockchain platform, the HealthChain, to improve data security, patient involvement, management and regulated transfer of stored information in a background that is secure and interoperable. They developed a mixed-block blockchain for supporting retractable patient blocks and immutable logging. The work showed and supported the fact that blockchain represents a very viable platform for the patient-based exchange and transfer of healthcare data. The work solved issues relating to interoperability, data security, block storage, patient-based data access and distribution.

5. BLOCKCHAIN IN ANALYTICS: DATA, MODEL, AND COMPUTATION

As far as blockchain technology is concerned, it continues to be a fascinating and innovative tool in software and data security. Using the Ethereum platform, Maslove *et al*. [31], developed blockchain smart contracts in a bid to determine the contribution of blockchain in support of the management of clinical trial data. The authors were able to create a novel BlockTrial, which permits patients to give the researcher access to their data. It also permits researchers to submit queries for off-chain stored data. BlockTrial is useful in increasing data trustworthiness retrieved during medical research offering a beneficial advantage to regulators, researchers, industries and academia. Furthermore, the network system tends to empower patients so that they can be more active and enable informed partners in research activity.

Omar *et al*. [32], designed a framework approach on blockchain for research in clinical trial data health care management utilizing Ethereum smart contracts utilizing IPFS as a storage system for the automation of information, processes and exchange among relevant stakeholders of clinical trials. It was hard to tamper with clinical trial documents that were stored in the IPFS because they exhibit unique cryptographic hashes. The authors noted that the model benefitted all stakeholders as it elicited data transparency, integrity and compliance. In spite of that, the intended framework, which was investigated on the blockchain Ethereum system, if it is capable of being mobilized in a private blockchain system courtesy of their original smart contract approaches. One of the benefits of the model was that it assured data security and integrity and promoted traceability, transparency and transfer of data information among relevant stakeholders. In the study, the authors made smart contract codes accessible on Github publicly.

Ethereum is a blockchain system. Blockchain-based Ethereum smart contracts are a potential alternative for availing very secure high-integrity data storage, sharing and transfer. On the virtual achiness of blockchain, the platform is immutable-running smart contracts. Based on the 2019 Integrated data analysis, sharing and anonymization exercise for Secure Genome Analysis, participating members were stimulated to create a real-time space-efficient Ethereum smart contracts system purposely for drug-gene interactive information. Gursoy *et al*. [33], created a particular smart contract for the storage and querying of gene-drug interactions in Ethereum through a multi-mapping approach that is based on an index. The authors went the extra mile to enhance the “challenge solution” and design an option called fastQuery smart contract, a platform that integrates different identical drug- gene-variant mixtures to form a distinct storage platform with resultant production of better query efficiency and scalability. The authors reported that the model and fastQuery solutions showed time usage and linear memory for the insertion into and for the querying of small databases, especially greater than 1,000 entries. FastQuery was able to maintain scaling even for databases larger and between1000 and 10,000 entries. The solutions were also shown to query by a combination of fields “1- or 2-AND” or by a single field “0-AND”. Using 0.1 MB of memory, the challenge solution is capable of completing a 2- AND query obtained from a small database of 100 entries in thirty- five milliseconds. FastQuery was shown to exhibit a two-fold enhancement in real-time and a ten-fold enhancement in the memory for the same query.

Marbouh *et al*. [34], reported that several scientists had utilized different blockchains in fighting against the current SARS-CoV2 virus infection causing the COVID-19 pandemic, thus they designed a monitoring and tracking mechanism for the detection of the SARS-CoV2 virus and subsequent generation of data, collection from different external links. The author suggested that blockchain-network system through Ethereum smart contracts, oracles enables monitoring and adequate data processing involving a number of deaths, and infected and recovered cases; the authors present detailed algorithms that are capable of capturing the involvement between different stakeholders in the network.

Esmaeilzadeh *et al*. [11], in their study examined the perceptions of patients toward the utilization of blockchain-mediated health information exchange networks and the arch significance of blockchain tools from the perspectives of consumers in the health industry. The authors created seventeen data exchange information situations for regulated Web and internet-based tests. The results indicated that the views of patients varied concerning various information exchanges as far as patients' privacy was concerned. The work showed both the promising roles of health information exchange and the limitations.

Over 2 billion dollars is lost due to health abuse and fraud. Blockchain technology in view of its transparency, could help in curtailing fraud. Mackey *et al*. [35], constructed a platform courtesy of blockchain in an immutable format for recording claims data and transactions and for enabling the patients to function as a validation node to assist in detecting and preventing abuse and fraud in health sector. The authors created a healthcare blockchain abuse and fraud platform through blockchain tools. Based on digital identity, they created application sheets of consensus algorithms, tokens, smart contracts, and the Ethereum platform. In the study, the authors design a model through the blockchain Ethereum platform, coupled with its design characteristics, system architecture, smart contract utilities, workflow, software implementation and data outlined. The pile of software utilized for building the entire system is made up of a blockchain network, a front-end user interface framework and a processing server back-end. While solidity was designed as the smart contract communication and language utilized for interacting with a local blockchain Ethereum network, was utilized for the user-friendly interface network or platform, NodeJS and an Express server were utilized for the processing server back-end. Thus, the study summarily demonstrated that the model and the initial prototype could enhance the healthcare claims process through the use of blockchain technology for the purpose of securing consensus mechanisms and data storage, which made the claims adjudication process better for patient-centric prevention and identification of healthcare abuse and fraud.

Currently, there has been a transition from old healthcare systems to modern healthcare systems such as Mobile health (telecommunications, wearable sensors and the Internet of Things (IoT) for healthcare delivery. Major shortcomings have always been security, transparency and privacy of medical data. Blockchain technology is one plausible way out due to its decentralization and mmutability.

Taralunga *et al*. [36], suggested a mobile Health platform that utilizes a private blockchain that works on the basis of the Ethereum platform.

Griggs *et al*. [37], suggested smart contracts coupled with blockchain for the enhancement of secure management and analysis of medical sensors. The authors designed a platform where interaction can occur between a smart device and the sensors that can call be referred to as smart contracts, which can write records or information about different activities on the blockchain using an Ethereum protocol that is centered on private blockchain. The authors reported that this platform can support real-time disease or patient tracking, monitoring and health service interventions by disseminating notifications to healthcare providers and patients without compromising secure records.

6. CURRENT LANDSCAPE AND CHALLENGES

Blockchain technology has gained several advantages in solving healthcare problems healthcare data management, pharmaceutical industry, supply chain management, medication adherence, data provenance, consent management, counterfeit drugs identification, analytics, and billing/claims management [38 - 66]. Even though several advantages have been enumerated by several authors in the healthcare sector, the field is rapidly evolving and many issues needs to be addressed urgently, such as interoperability, integrative system, cost uncertainty, adoption and technological barrier, regulation compliance, and scaling processes in the healthcare industry.

CONCLUSION

From this review, the major shortcomings have always been security, transparency and privacy of medical data. Blockchain technology is one plausible way out due to its decentralization and immutability. Though several authors have enumerated numerous advantages about the application, benefits and importance of blockchain in the healthcare sector, the field is rapidly evolving, and many issues need to be addressed urgently through research like interoperability, integrative system, cost uncertainty, adoption, a technological barrier, regulation compliance, and scaling processes in the healthcare industry.

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CHAPTER 5

Blockchain Technology: A Vehicle for Efficient and Comprehensive Medical Application Solutions

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Abstract: Blockchain technology is the technology of the twenty-first century. Web 3.0 is the name given to the next digital revolution. It was first developed to provide a secure payment mechanism, but it was later adapted and utilized in various industries. Healthcare is one of the domains where this technology has been deployed in the last few years and has yielded considerable results. The fast adoption of digital technology in the clinical sector has led to the construction of massive health records. As a result of this growth, there are never-before-seen requirements for clinical information security throughout usage and exchange. This adoption of the blockchain method as a reasonable and effective data storage and handling platform is opening up new opportunities in healthcare for tackling key data privacy, security, and integrity issues. Patients and healthcare providers have difficulty accessing, storing, integrating, and transmitting health information. Individuals are likely to access and control their medical information from everywhere on the planet, process and report their clinical findings, grant permissions, and even securely exchange that data with certain medical professionals. Straightforward health information access and an even more complete digital information architecture might help the medical industry better prepare for public health threats like COVID-19. We will examine several of the numerous ways that blockchain methodology has been employed in the clinical area, as well as its prospective scopes and possibilities for a better tomorrow, in this research.

Keywords: Blockchain, Healthcare, Health records, Medical applications.

1. INTRODUCTION

R. Vidhyuth and Dr.T. Manoranjitham [1] explained Blockchain is a decentralized network that was first introduced as part of the Bitcoin movement. This is a p2p infrastructure system that runs *via* the internet and is initially represented in a

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research work done by Satoshi Nakamoto (pseudo name), a Japanese (proclaimed) researcher, in October 2008. The author introduced the world to Bitcoin, the digital money that will be used as a secure online payment mechanism. This Cryptocurrency system was designed to cope with the complexity of peer-to-peer (P2P) duplicate spending. This digital currency was built on the blockchain database approach, and this virtual currency system could issue currency, transfer ownership, and validate transactions without using a central authority. Abu-elezz and coworkers [2] have explained, in a public blockchain, a block consists of four main components: the content, the hash of the continuing block (classifying identifier), the hash of the previous block, along with the date-time when every new block is chained toward the prior block. Fekih and Lahami [3] have explained that, as a consequence, these blocks form a chain or data set, with every block constructed on the former ones. As per Zhang and coworkers [4], whenever a block gets added to the network, the historical record of its transactions is encrypted to protect against tampering.

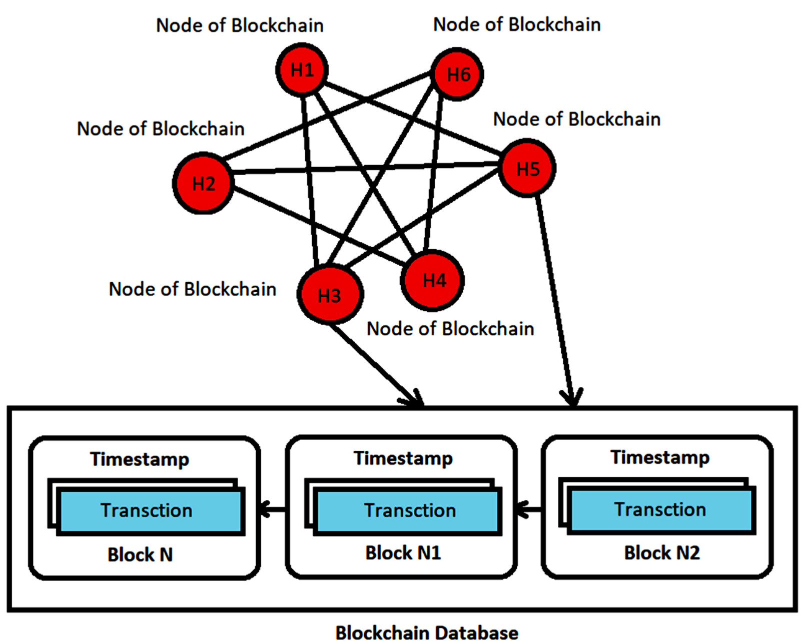

Fig. (1). A Typical Blockchain Network Architecture.

Currently, Blockchain is being divided into four categories: (i) Public, (ii) Private, (iii) Consortium, and (iv) Hybrid. The public blockchain network is quite open. Every user has access to the consensus process and can participate in it. One-story solutions leverage private blockchain to track data transfers between agencies and individuals. Each user must agree to join the network, and the user will be informed when the network has been consolidated. The Blockchain Conglomerate is indeed a reliable and established initiative. To record data transactions between members, it's being utilized as a highly coordinated decentralized platform that can be audited. Public and private cryptographic protocols are merged in hybrid blockchain systems. The database is publicly disclosed by utilizing a decentralized backend system that limits access to the ledger's updates explained in Fig. (**1**).

Bitcoin technology was deployed one year after the publication, and its technology was made open source. Because of the publicly available data, many academics and technologists have stepped forward to understand and apply this technology to other applications. Other digital currencies, such as Litecoin, Name coin, Peercoin, Dogecoin, and others, were created in response to Bitcoin's flexibility and acceptability. This was the initial generation of the blockchain implementation, or version 1.0. “Smart Contracts” are a set of digitally declared commitments and mechanisms for the signatories to serve upon those commitments. According to the authors [5], these contracts are commonly used to authenticate contracts among multiple signatories. Smart contracts and their properties are related to blockchain technology's second generation or 2.0 version. As per Zhuang and coworkers [6], these contracts are computer programs that specify the regulations for governing and administering intelligent properties. For example, smart contracts may be used to manage transactions by enforcing the interoperability standard of sent data. Durneva and coworkers [7] have explained that interoperability is indeed the capacity of diverse gadgets, data systems, and implementations (systems) to acquire, interchange, incorporate, and constructively utilize information in a synchronized way, both inside and beyond operational, territorial, and governmental borders, to offer faster and more reliable data adaptability. JinYoon [8] has stated that the transformation beyond organization piloted into consumer-focused interoperability will be aided by blockchain methodology.

According to Tanesh and coworkers [9], when compared to previous contracts, a smart contract is not only quicker, but it also reduces the time it takes to execute and disseminate patient data. As per the authors [10], QTUM, Ethereum Classic, Ethereum, and NEO are a few examples of blockchain 2.0. Non-Fungible Tokens, or NFTs as they are currently known, are an example of these smart contracts and may be conceived as a bridge between Web 2.0 and Web 3.0. As a result of the preceding, non-monetary blockchain implementations are the primary goal of the new era of blockchain systems (blockchain 3.0). In order to help other businesses and use cases, attempts have been undertaken to redesign blockchain methods outside of banks. As a result, blockchain is gaining traction as a general-purpose technology with utilization in various industries and implementations, including conflict management, identity authentication, logistics operation, contract administration, security claims, and wellness, among others.

Due to the rising interest in blockchain as well as its acceptance in numerous organizations and sectors, many biomedical and healthcare informatics researchers, on the other hand, are interested in learning more about this technology, its capabilities, limits, application techniques, and implementations in the biomedical and healthcare domains.

2. BLOCKCHAIN TECHNOLOGY VS. TRADITIONAL METHODS

Attaran [11] have explained in their research work how clinical documents are stored securely inside a centralized Information systems infrastructure and cannot be shared. Obtaining, providing, collecting, and analysing individual information takes time with money. A blockchain is, by definition, a database. It's a one-tim--only information directory which means that these advanced information directories are created just once, and they are never changed or deleted, as per Dimitrov [12]. In the current era, blockchain is the preferred choice for ensuring information security, which has yet to be compromised, according to Ijazul and Olivier [13]. It's a collection of related data of data blocks linking inside a decentralized system by identifiers that are identified through a sequence that distinctively defines each block. Every information block also contains a reference to the data block before it is in the chain. Every chain of blocks, and every P2P access point serves as a collector of information blocks and an inspector of appropriate content rights and authorization. Every interaction gives every unit the ability to introduce the latest blocks to the collection as well as execute inspection criteria. A common consent gets established whenever such trials are conducted through collaboration with another endpoint. Whenever either of these operations inside a block is changed, maybe just marginally, the hash value would change drastically, potentially breaking the network to afterward structures. As a result, a piece of modification towards such block's information inside the blockchain network can be promptly detected. As a result, whenever an event is included in such a block as well as connected well to the blockchain, it could no longer be modified nor reversed. As a result of A, blockchain data is thought to be immutable.

Anthem, the nation's second-biggest health insurance, said in 2019 that they will use blockchain methodology to preserve the healthcare information of their 40 million customers. The European Commission's unique drug experimental model, “Blockchain Enabled Healthcare,” dominated by Novartis, also delves into the possibilities of these distributed systems. Its objective is to produce modern excellence, like Ethereum, and establish new ones as found necessary. Its concentration would be on permitting services that potentially put to good use individuals. Furthermore, because the data inside the chain of blocks is repeated among every network node, it fosters an environment of openness that empowers medical organizations, especially individuals, to comprehend when, from whom, where, and how their information is being used.

Kuo and coworkers [14] have described in their research, to better comprehend how blockchain's wide-spread-record methodology could be reasonable to clinical implementations, anyone can correlate this to conventional distributed database management systems (DDBMS), such as Oracle as well as non-SQ--based systems such as Apache Cassandra. Decentralization, transparency, immutability, autonomy, anonymity feature, and open-source nature are the six key components of blockchain technology as shown in Table **1**, as stated in the research work of Siyal and coworkers [15]. So, the following are the most significant benefits of employing blockchain-based methods in the biomedical as well as healthcare systems: (1) privacy, (2) robustness, (3) decentralized administration, (4) data provenance, and (5) immutable audit trail are all major considerations.

Table 1. Blockchain technology's key features.

Key Elements	Functionality Description
Decentralization	Anyone connecting to the network has open access to a database system. On numerous platforms, the data may be accessed, monitored, saved and updated.
Transparency	The data that has been gathered and stored on blockchain may be viewed by potential users, and it can be updated fast. The transparency nature of blockchains will make it difficult for information to be tampered with or stolen.
immutability	The information is maintained permanently and cannot be modified until more than 51 percent of a certain node is under command around the exact time.
Autonomy	Because the blockchain network is self-contained as well as independent, every node can securely retrieve, exchange, preserve, as well as update data, making this dependable and free of exterior interference.
Open Source	As per the blockchain's design, everybody connected to the network has open-source access to it. This unrivalled flexibility allows anybody to not only verify the information openly but also to construct a variety of new applications.
Anonymity	As data is sent from node to node, the individual's identity stays anonymous, making the system safer and more dependable.

The first big benefit of blockchain is decentralized administration. Users assume they're working with a centralized database; however, the foundational computers could be mechanically scattered, while blockchain is a p2p, decentralized database management. Numerous attempts have been made to implement blockchain in medical fields, like as HIE, biomedical research operations, and pharmaceutical supply chains, since these characteristics of decentralized distributed transaction validation guaranteed information traceability, information exchange, information blending, and cryptographic protocol versatility accommodate so well with requirements of several biomedical applications. The majority of blockchain-based health applications, on the other hand, seem to be in their experimental stages as shown in Fig. (**2**).

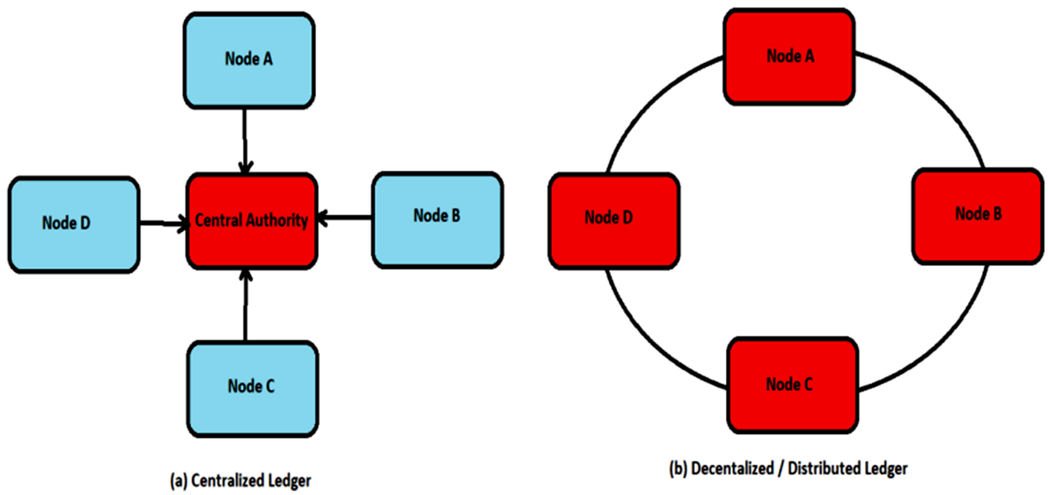

Fig. (2). Centralized Ledger (Traditional Method) vs. Decentralized Ledger (Blockchain Method).

The next key advantage is the unchangeable audit report. DDBMSs, like certain other database management systems, generate, retrieve, modify, and remove items, whereas blockchain simply allows users to generate and retrieve information. As a result, this technology is best suited for storing critical data like an immutable registry *(e.g.,* insurance claim records).

The authenticity of the information is the next item to evaluate. A system administrator could alter the possession of digital commodities in this Distributed database, although, on the blockchain, the individual possessor can only alter the possession using cryptographic encryption. Furthermore, any provenance of a property may be tracked (that is, the origins of documents and information could be confirmed), increasing the recyclability of security breaches (For example, insurance management).

Its next positive consequence is it is durable as well as readily available. Even though both DDBMS, as well as blockchain, is constructed upon distributed architecture and therefore do not include a primary breakdown spot, DDBMS is very high priced to acquire considerably reliability dismissal that blockchain obtains (That is, every node has a complete replica of the entire documented information reports).

The greater privacy and safety afforded *via* encryption operations is the final significant benefit of this technology. As in the Blockchain network, for instance, a 256-bit Secure Hash Algorithm (SHA256) is employed as a cryptographic algorithm inside the hash-chain upon which concrete evidence algorithm executes. The NIST produced the FIPS 186-4, which defines SHA256. In addition, blockchain technology employs ECDSA, a 256-bit encryption method described inside the FIPS, for producing as well as authenticating confidential secret keys as authentications, making sure the possession of digital resources in a manner homogeneous towards how individual information is safeguarded.

3. BLOCK CHAIN IN HEALTHCARE APPLICATIONS

Medical services are indeed an information-concentrated industry that generates, retrieves, as well as exchanges massive volumes of information on a regular intervals. Due to the delicate character of information as well as constraints like confidentiality and protection, preserving and disseminating, a huge amount of information is also essential as well as problematic. The authors [16] have stated that a health information administration that is stable and secure assists in the growth of digital wellness, which has several good outcomes. Sharing healthcare and clinical notes is among the most significant and crucial aspects of improving the effectiveness of medical practitioners and keeping the current healthcare intelligent. Shen and coworkers [17] have explained that considering sustainability, versatility, as well as affordability constraints, certain virtualized medical information exchange approaches are proposed that use information encryption as well as acquisition identity management; valetudinarians are commonly wary about exchanging their own personal and confidential information to the server due to the inevitable potential risks. Amongst all clinical implementations, the most frequently addressed is indeed the utilization of blockchain as a fundamental architecture for Ehealth (HIE), as well as clinical exchanges connecting individuals, physicians, insurers, as well as other interested stakeholders. As per a subsequent BIS study, implementing blockchain solutions inside the medical sector could defend the entire division up to $100 billion annually by 2025.

Suppose Sam visits a hospital for a routine physical examination and is diagnosed with several health problems or illnesses. Now the doctor inquiries about his previous health, meals, allergies, and meditations to propose a remedy for his current problem. As a result, Sam must submit all of the necessary details. In this situation, Sam may either have all of the necessary, correct data, or he could have to go to the medical office and gather all of the previous documents and prescriptions. Sam's therapy will be affected if he supplies all the information yet part of the data is incorrect. On the other side, if medical fails to supply data or if the data they do have is altered for any reason, the therapy will also fall short of expectations.

As a result, when Sam visits other doctors, he has to re-inform his medical history, repeat laboratory tests, and even conduct unneeded examinations. Repeating the same laboratory test will not only raise the expense, but it may also be unsafe to repeat some tests with high radiation levels. In such scenarios, only data provided by health organizations are integrated, regardless of Sam's healthcare data, diet, information gathered *via* wearables, or data obtained *via* home surveillance systems.

There are other circumstances when Sam goes outside of his nation for tourism or other reasons. He may also need to seek medical assistance for the treatment of an ailment at times. In such cases, doctors and hospitals in other countries should be aware of Sam's medical information to provide effective medical coverage. Using blockchain-based technologies, health data may be quickly exchanged with appropriate authorities in another nation, and Sam will have consent and control over that data.

Omar and coworkers [18] have explained blockchain could be utilized to ensure individual information as well as give data owners control over it. Telecommunication Corporation (Du), for example, is experimenting with the use of health data to transmit data across service providers. As per the authors [19], Guard Time, a Dutch information protection business, teamed up with the Estonian administration authority to establish a blockchain architecture for authenticating individuals and transferring health records. Yue and colleagues suggested a healthcare data gateway on a private blockchain that could enable individuals to handle their personal clinical information, as explained in the research work of Gordon and Catalini [20]. Ivan also suggested a universal blockchain application that encrypts healthcare data and stores it openly, resulting in a cryptographic personal private medical report. Another two blockchain-based EMR systems are MedBlock and BlockHIE.

The Health Information Exchange (HIE) is critical in overcoming data requirements or record issues. Clinical data interchange is the electronic interchange of clinical data between institutions inside a territory, neighbourhood, or medical system. It allows physicians, caregivers, chemists, various clinical personnel, as well as sick people to authenticate as well as communicate a person's critical medical records, improving the timeliness, efficiency, security, and efficiency of care. These sections on better health care record administration, faster insurance settlement procedure, and faster clinical trials additionally categorise these implementations depending on their respective main goals for leveraging blockchain-preserved information.

3.1. Management of Medical Records

Medical data has its own set of characteristics. All the required data should be accurate as well as absolute. Also, all the information should be identifiable and impenetrable to modification, falsification, or termination. Due to statutory obligations to preserve individual confidentiality and safeguard sensitive health data, healthcare records must be stored private and confidential. This information should be provided available. However, identifying the individuals to the one who pertains should persist concealed to allow for biomedical research. The authors [21] have stated that as per the HHS Office of Civil Rights, assaults in 2017 may have affected slightly less than 2.6 million people. After a breach at the insurance company Anthem in 2015, 78.8 million patients' information was stolen, accounting for more than a quarter of the US population. To protect the safety of patients' private information, a dependable storage and sharing solution is required when a vast volume of individual health information accumulates. Clinical information admittance, Gem Health Network, BitHealth, MedVault, Fatcom and additional current efforts are concentrating on transferring clinical data utilizing blockchain technology to improve patient information management. Several well-known companies are also experimenting with blockchain-based methods to preserve and manage health information and clinical reports, including Deloitte and Accenture. Even though all efforts leverage blockchain technology, mainly FHIRChain, Patientory, Healthbitt, and MedRec implemented a minimum single healthcare information standard dedicated to offering access to both physicians and sick people. Ekblaw and coworkers [22] explained that MedRec takes use of the Ethereum network and provides individuals access to their medical information and analysis about someone who has access to them. It provides patients with a complete, accessible, dependable written document of clinical findings.

Health professionals and individuals will benefit from the PHR and EHR since they will have better access to their medical information. The private blockchain stores essential operations, including (1) individuals as well as clinical establishments granting, canceling, and denying authentication to own EHR information; (2) individuals and clinical provider authentication to obtain EHR information; and (3) medical institutions maintaining statistics for treatment sessions of an individual. Health Wizz, for example, is beta-testing a blockchain based as well as FHIR-authorized EHR collector smartphone application that tokenizes data and lets users confidentially gather, organize, exchange, gift, as well as trade their own personal clinical information.

Research released in 2019 described the construction and evaluation of a PHR architecture that integrates decentralized medical information using the blockchain method and the common EHR compatibility benchmark. The purpose of this research was to discuss the development and evaluation of an OmniPHR-based PHR (Personal Health Record) architecture that integrates decentralized medical files with the openEHR compliance protocol. The authors studied 60 papers and analysed articles on OmniPHR, a health-records platform incorporating blockchain technology. This method included developing a working model and evaluating the interoperability and effectiveness of patient history from multiple manufacturing sources. To evaluate the model's implementation, they used a statistical model of approximately 40 thousand elderly individuals anonymized across two clinical repositories. To give an actual view of medical files, they experimented with data dispersion and reintegration. They also put their approach to the trial in a setup that involved 10 super peers and thousands of competing transactions, all performing operations on clinical information in real-time, with an average latency of fewer than 500 milliseconds. The blockchain in this prototype has a 98 percent availability rate. This performance revealed that information transferred across a chain of blocks could be restored with such a short average processing time and good durability under the conditions they tested. Their study also demonstrated how the OmniPHR framework could combine different information into a cohesive picture of clinical information.

3.2. Internet of Medical Things

Chronic disease is a major cause of sickness as well as death globally. The price of medication for common persistent disorders like CVD in the US was $555 billion in 2014, as well as it’s anticipated to reach $1.1 trillion by 2035. Due to the significant adoption of smart gadgets, cell phones, servers, and wireless connectivity, the integration of these technologies may be utilized to track the physiological state of chronically ill patients. Utilizing the conveyance and stockpiling methodology based on the blockchain, patient data can be consistently sent to the internet.

Blockchain is a fairly new concept that blends the principles and advances of the IoT and artificial intelligence revolutions. The progress of health and medical information systems is dependent on IoMT (Internet of Medical Things) technologies. As AI progresses, healthcare providers will be able to utilise the

IoMT paradigm to take a photo, discover malignant areas or even dangerous cells, and convey that information to individuals who have permission to see it. The precede parts are primarily concerned with AI breakthroughs in medical IoT and intelligent medical equipment.

As seen in Fig. (**3**), the individual is the provider of all information. These days, smart watches, smartphones, health monitors, and IoMT gadgets all obtain records of the user's information. All-important health data is regularly monitored by these devices' artificial intelligence, including pulse rate, daily walking distance, cardiac output, and skin temperature, and a large quantity of data is stored in their unique cloud servers. On these servers, blockchain will be implemented.

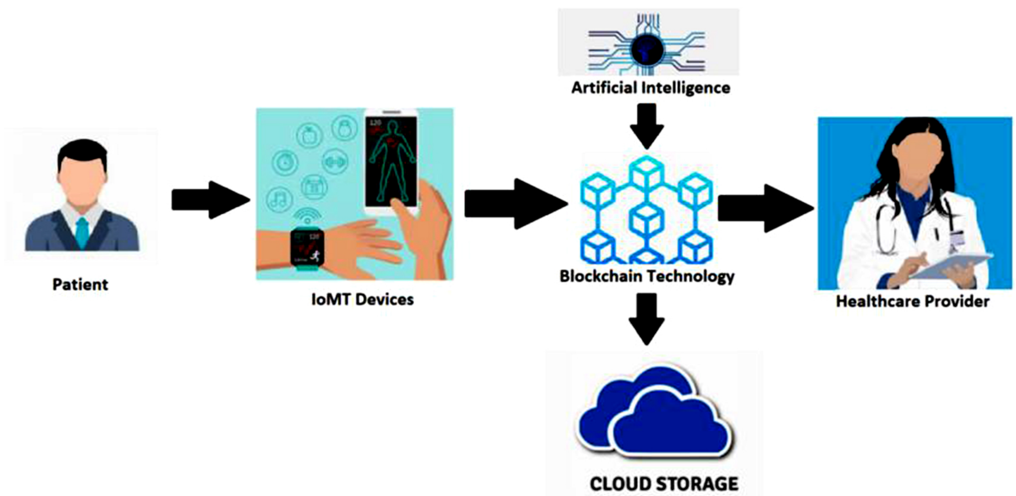

Fig. (3). A blockchain based visualization of IoMT.

IAI will assist the blockchain in the construction of intelligent virtual agents, who will be able to create new ledgers on their own. Healthcare providers are the final participant who wants authentication to a reliable and trustworthy healthcare provider authorized by the owner.

Griggs and coworkers [23] have stated that WBANs are indeed the abbreviation for wearable technology or devices, and a patient in a WBAN is fitted with a range of portable or implanted clinical devices which record actual data on key parameters such as pulse rate and sugar levels. This integration among both advancements is referred to as blockchain-based IoT (BIoT), as well as this has an extended implementation in each of the healthcare as well as non-health-care domains, as per Tiago and Paula [24].

3.3. Implementation in Billing and Insurance Claim

Medical billing is a crucial component of the healthcare sector. This is because appropriate service delivery cannot be guaranteed without accurate invoicing. Whenever a person gets hospitalized, this procedure begins as well as finishes whenever the patient is discharged. Checking in, verifying monetary liability, classifying invoicing conformity, forwarding any assertion, and getting compensation through health insurers are all pieces of the routine explained in Fig. (**4**). The entire billing system may be complicated since many of the expenditures are filled by that same person's medical insurer or have been reimbursed by the affected person. Excessive billing is a major issue in medical billing, owing to a sort of openness and assurance between physicians, individuals as well as insurers. Inside the clinical industry, claims and billing are frequently mishandled, but they may be controlled or minimized by adopting a transparent system that benefits all parties. As a result, validation assertion exchanges to endorse clinical activities like policing reimbursement, appropriate monetary mechanisms, involuntary assertions utilizing quick consolidated level assets as well as crypto algorithms, or even Patient Monitoring Characteristics to better handle public assistance recipients' continual outflow as well as re-entry due to approval adjustments, is just a central objective. MIStore is a health coverage retention platform implemented upon an Ethereum network and serving as a platform for insurance companies and hospitals; it was introduced by Zhou and colleagues. The solution increased the effectiveness of the data storage process, allowing insurers to clear up claims and preauthorization payments to patients more swiftly.

3.4. Pharmaceutical Uses

The pharmaceutical sector is one of the rapid growing industries in the world, and it is a key player in healthcare delivery. The pharmaceutical industry not only aids in bringing new and promising products to market, but it also helps to ensure the security and validity of medical items and drugs marketed to the general public. Pharmaceutical firms are always working to enhance the quality of medicine and develop novel treatments for a variety of disorders. This type of drug must go through a lengthy procedure to ensure the protection of the patient, their safety, effectiveness, statistical validity, and regulatory approval. In general, this activity requires a long period to complete, from invention to industrialization, with medical studies accounting for just a significant portion of that time. As a result of the lack of security and privacy, such a lengthy process is prone to medication recall and counterfeiting. This roadblock might be overcome by incorporating blockchain technology into the pharmaceutical procedure. Content from biopharmaceutical companies, like as manufacturing identification codes as well as package details, must be maintained only on blockchain as then pharmacists, healthcare companies, as well as buyers, can verify the content's authenticity by connecting to the blockchain. We could protect privacy and assure security by utilizing the blockchain's distributed ledger, which ensures each research is documented over tamper-proof blockchain networks. This may be accomplished through the use of an intelligent agreement that ensures authenticity, accountability, as well as accessibility.

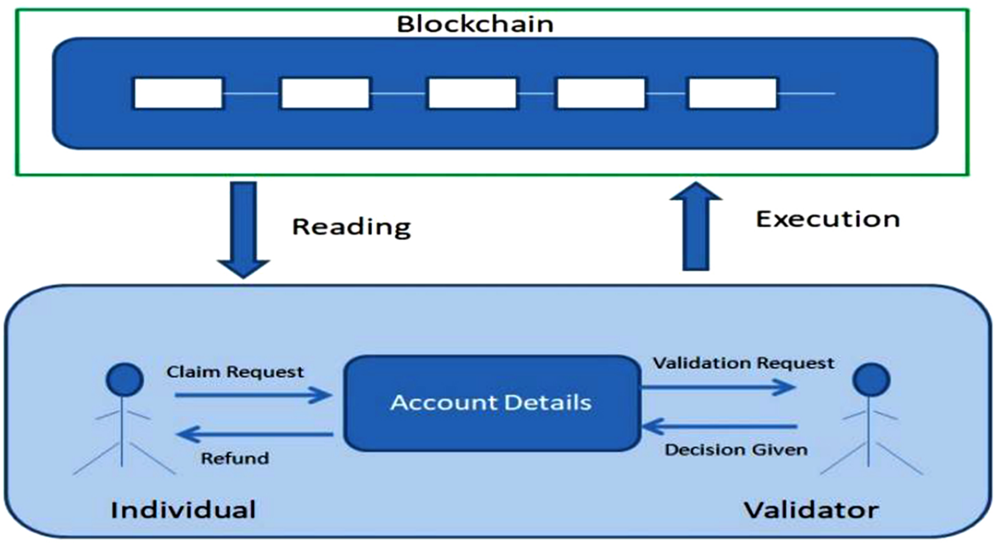

Fig. (4). Insurance Claim using Blockchain.

3.5. Supply Chain Management

Global counterfeit drug sales are likely to reach $75 billion this year, according to the CSPI in US, representing a 90 percent increase over the preceding five years. According to the WHO, counterfeit medications account for 10% of all medicines sold worldwide, with 30% of those identified in underdeveloped nations and in wealthy countries, counterfeit medications account for about 1%–2% of total drug use. The authors [25] have stated that counterfeit medications are especially prevalent in the Asia Pacific, African, and Latin American areas. Each tenth drug is entering distribution for less as well as medium countries being considered to just be fraudulent or even of dubious value. Thus, according to Bryatov and Borodinov [26], the use of certain substandard things does hurt incidence and mortality.

PSCs are much more complicated compared to conventional distribution networks. A fundamental cause for this is that ownership of pharmaceuticals changes often between the time they leave raw material suppliers and reach patients' hands. Haji and coworkers [27] have explained how manufacturers and distributors are unable to provide a consistent supply, and it poses a danger to businesses. This also puts the original pharmaceutical businesses' reputations in jeopardy, prompting medicine producers and distributors to spend a significant amount of money on countermeasures. Due to its direct influence on public health, this distribution system is a complex and sensitive biopharmaceutical cold chain that must be carefully controlled and maintained. Nonetheless, worries about vaccine expiration, the inclusion of counterfeit vaccines, and vaccination record fraud continue to impact vaccine supply chains, as per Yadav and coworkers [28].

By permitting p2p connectivity amongst IoT systems, blockchain technology allows the p2p trade and asset tracking along the supply chain *via* IoT depicted in Fig. (**5**). When each member of the supply chain shares similar data, irreversible and well-spread records with independently audited transactions are suitable for detecting all components inside a distribution network. The authors [29] have explained how blockchain technology's cryptographic properties are the foundation of pharmaceutical sector safety and security. And as per Khurshid [30], the secrecy of information on this network is guaranteed by an encryption technique. The preservation of information assures that no particular entity could implement adjustments independently besides an agreement. Modum.io is a firm that follows subsections as well as blockchain technologies to optimize biopharmaceutical supply chain operations. LifeCrypter is also an elegant blockchain system and prototype proposed, which delivers global medicine supply chain integrity, traceability, and transparency. This platform provides patients across the globe with user-friendly software that tracks every item of medicine during its trading history, thereby “dissuading” counterfeit drug distribution, according to Schöner and coworkers [31]. Additionally, Khezr and co-workers [32] describe why the blockchain's decentralized registry enables medical executives as well as clinicians to evaluate or confirm vendor identification. Throughout most of the COVID-19 outbreak, launched faster provider access to aid inside the regulation of health distribution networks, and everything was easily accessed by healthcare institutions as well as regulatory agencies to assist users in identifying suppliers for essential aid as well as personal protective equipment.

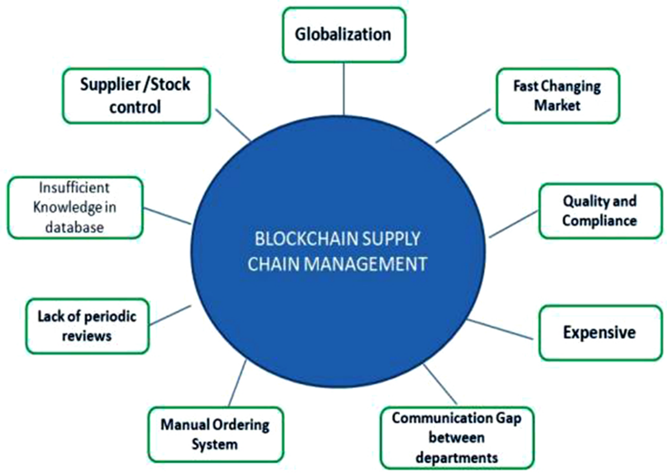

Fig. (5). Blockchain in Supply Chain Management.

3.6. Implementation in Clinical/Biomedical Research

Blockchain plus wellness usually remains a matter of minimal study. This academic work mainly includes a greater summary of such systems which has been designed, evaluated, as well as implemented. Numerous academics, notably MedRec, Healthbank, and Data Lake, as well as information exchanging systems, build upon blockchain, and recommend utilizing blockchain tools to facilitate tertiary trial information consumption *(i.e.,* clinical and as well as trials). Model Chain is indeed a blockchain-based platform that helps businesses enhance the safety as well as sustainability for decentralized confidential clinical parameter estimation. Rejeb and Belll [33] have described the study's existing concerns and challenges in Tunisia's healthcare industry, as well as contextualized the role of new technologies in improving patient care, financial management, and patient safety. The authors [34] presented a blockchain-based clinical research supplier network to ensure experiment data consistency as well as sustainable trial-related operations along a permission-based society, called Hyperledger Fabric. These outcomes indicate how and why the Hyperledger Fabric society's sprinting fulcrum agreements could be utilized to improve the reliability of information management within clinical science. Yan Zhuang and coworkers [35] proposed a blockchain architecture that included many experimented agreements enabling research delivery as well as individual contact, also a single consortium blockchain enabling computerized item pairing, individual recruitment, as well as experimented procurement of agreements. Those who are concentrating on using Blockchain Systems to improve Clinical Trial Recruitment. Tong Min Kim and coworkers [36] suggest building a clinical blockchain ecosystem built upon an adaptive consent mechanism. The proposed solution not only addresses security concerns by utilizing blockchain technology, but it also addresses the issue of privacy piracy by utilizing a novel dynamic consent mechanism. The blockchain model demonstrates elements that can address clinical trial recruiting concerns through a simulation procedure. Using a master smart contract to match patients with trial-based contracts to manage clinical trials can improve the recruiting process in terms of time savings, identifying any conceivable topics, and care coordination, including oversight by its administration.

3.7. Advanced Biomedical/health Care Data Ledger

COVID-19 has afflicted around 19 million people globally, as well as slain approximately 700,000 individuals over the course of July 2020. The United States of America is the globe's wealthiest nation, including $3.5 trillion annual clinical spending; it also has the largest number of individuals diagnosed with COVID-19 (around 5 million) as well as fatalities (>150,000). The COVID-19 disease outbreak has distinctly exemplified the inability of established organizations to safeguard individual health as well as prevent ubiquitous pain and misery because of the absence of accurate statistics, the absence of physicians as well as clinical platforms to conduct regular screening, unsatisfactory strategic planning, an absence of requisite clinical devices, contradictory knowledge from various inputs, as well as constrained techniques for inter-professional collaboration. Therefore, a blockchain-based autonomous, as well as a widespread collective registry platform, will be immensely useful in these situations and a precautionary measure against subsequent outbreaks.

In contrast, to the use of blockchains as healthcare information registers, numerous research findings, as well as initiatives, had also recommended collecting cytogenetic as well as highly accurate drug information, individual-focused statistics, supplier repositories as well as supervision lined up information, healthcare research information, individual authorised information, drug supply chain information, as well as genetic information over blockchains (that is, HIE).

4. POTENTIAL PROBLEMS AND CHALLENGES

Regardless of various benefits of blockchain technology, such as faster turnaround management as well as information exchange, there seem to be substantial challenges to surmount while blockchain technology gets embraced as well as utilised inside the clinical sector. The very first two issues are openness as well as reliability. Since everyone can monitor anything on a public blockchain, enhanced exposure and decreasing concealment, including the explicit reveal of data throughout the exchange, are always seen as blockchain restrictions. Additionally, although an individual becomes unidentified *via* utilizing hash codes like identifiers, that individual might be re-recognized *via* obtaining and interpreting readily obtainable user information upon that blockchain platform, concluding that the blockchain merely allows "anonymization." Individual information (protected health information, or PHI, as well as identifying details) is acutely susceptible, which makes such a problem crucial for clinical implementations. The GDPR plus blockchains have a thorny connection. On the one side, blockchains seem to comply with the General Data Protection Regulation (GDPR). On another side, a range of problems could be detected (In which pertains to the protection of privacy, for instance, and even when their analytical application of smart contracts could impede vast information management *via* the autonomous system, a smart contract is indeed a good alternative).

The second concern has been one of sustainability as well as efficiency. The sustainability of blockchain-based systems is distinguished by the pace of transactions, which generally relies upon those guidelines. Typically, Bitcoin generates roughly 288 000 occurrences daily (or 3.3 interactions per second) by utilizing a concrete evidence system, contrasted to around 150 million for something like a credit card such as Visa (or around 2000 interactions per second). Considering the architecture's 1 MB of data block length limitations, Bitcoin's peak value response time is 7 transactions every second, while Visa's potential limit response time is 4000 transactions every second. It is a critical challenge to produce new as well as sustainable blockchain-based clinical service applications.

5. PROPOSED SOLUTION

The aforesaid issues may indeed be addressed *via* correctly formulating as well as delivering clinical methods. Imagine ModelChain as such an instance. ModelChain is indeed a blockchain-based technique that provides medical groups to transmit anonymous computational methods safely as well as effectively (that is, a cluster of artificial intelligence frameworks or clumped inputs) as shown in Fig. (**6**). Since it shares forecasts yet not PHI, openness is never an issue. Besides that, it includes an artificial study experience which may require a lot of time to fully implement (minutes and perhaps even hours), decelerating blockchain transactions. Since it relies upon private blockchain, malevolent nodes are still not able to communicate with another node at whim, eliminating the chances of a 51 percent attack. Intercepting private information such as PHI or identifying details over the public blockchain, stockpiling critical information just to publicizing instructions such as cryptographic connections or authorization data over blockchain, as well as self-driving information handling guidelines utilizing smart contracts are a few execution methodologies to ameliorate the unfading nondisclosure concern. To resolve this concern of performance and flexibility, one possibility would be to use blockchain as little more than an eHealth information repository instead of a data warehouse for every kind of information, as well as to keep even the latest verified digital exchange instead of the entire sequence of occurrences. In addition, numerous emerging blockchain applications, including BigchainDB, provide far faster exchange rates compared to the public blockchain, possibly addressing the performance as well as sustainability concerns.

Through leveraging a VPN to transmit the information as well as placing certain modules onto secure HIPAA-compliant cloud computing systems, such as iDASH, the possibility of something like a 51 percent cyberattack upon that clinical public blockchain may indeed be greatly decreased.

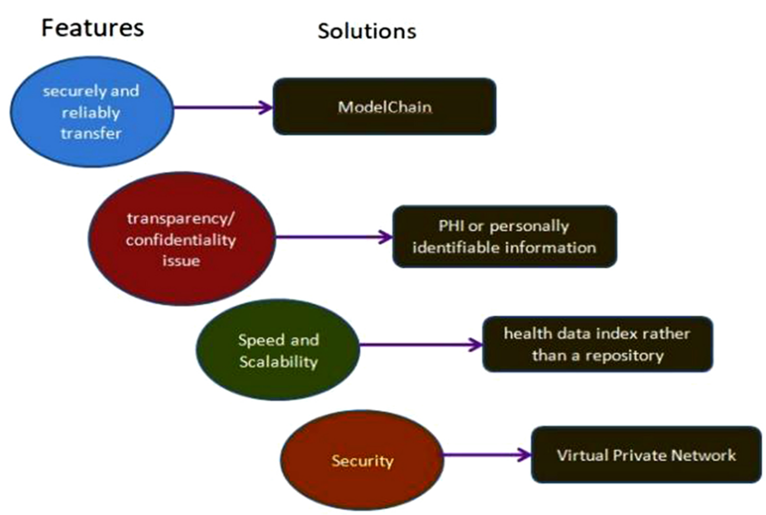

Fig. (6). Proposed Solutions for Blockchain.

CONCLUSION

Bitcoin, as well as the blockchain processes that underlie this, have been evaluated for distributed administration, fully unchangeable succession, information derivation, structural rigidity, safeguards, as well as controllability. In addition, the advantages of blockchain in clinical therapies-based implementations above conventional large-scale datasets have been acknowledged, as well as an overview of the most recent clinical administration blockchain systems was provided. The medical industry could benefit from distributed ledgers in a variety of ways, similar to how the internet revolutionised healthcare and introduced telemedicine. Modern research would be expected to advance in the future as blockchain technology lowers overall expenditures of tracking, installation, as well as maintenance, as well as healthcare information governance. This same direct implementation of blockchain applications in the clinical field could well assist physicians, professionals, R&D experts, medical organizations, as well as medical scientists as it will enable us all to even further effectually publicize voluminous information, openly discuss medical experience, as well as interact suggestions whereas managing higher security as well as confidentiality safeguards. This will also help common people to get proper and more trustworthy health treatment and information.

Blockchain's future in the healthcare industry appears to be bright and promising. However, the usefulness of a blockchain-based healthcare application has yet to be shown. However, the characteristics that blockchain promises to bring to current healthcare systems will allow for enhanced and higher-quality care. The healthcare ecosystem is predicted to be reshaped by blockchain technology. The right implementation of these technologies in healthcare situations would undoubtedly increase biomedical trial possibilities.

Additionally, since clinicians could observe all genuine, accurate, as well as elevated repository information efficiently, practitioners won't think twice concerning the affected person supplying them with appropriate health status, which will minimize the risk of previous clinical inaccuracies. Individuals need not think about picking up a new assessment through an outside physician since this information is open. This technique currently has a few issues and limits. However, by carefully designing and executing applications, these challenges may be avoided, which is why blockchain's use in health care is expanding. By combining every actual medical information upon the individual's condition as well as providing it more as a contemporary secured clinical arrangement, blockchain could be a system that will aid there in coming years, providing tailored, trustworthy, as well as comprehensive health coverage. The biomedical and healthcare areas may get an advantage from blockchain distributed ledger technology in numerous ways, and many new applications will be emerging shortly.

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CHAPTER 6

Blockchain: Blocking Hassles in Healthcare

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Abstract: Healthcare institutions around the world are increasingly reliant on digital databases for the storage of medical data. The unprecedented growth of healthcare data's scale and velocity has made it of paramount concern for the modern age. Digital databases are vulnerable and adversely affect both the patient and the healthcare industry as a whole. The risk of cyber threats can breach data and disrupt its integrity. Maintaining both data integrity and patient privacy is critical to healthcare organizations. Regulatory frameworks such as GDPR in the EU and HIPAA in the US are both bodies for compliance rules for maintaining healthcare data privacy. Unfortunately, the tendency of healthcare institutions to use proprietary systems creates isolated silos of data that become difficult to secure using traditional methods.

A blockchain-based method provides a novel way of securing electronic healthcare records using a decentralized peer-to-peer based network on top of these isolated silos. Each block contains information and links to the other, forming a collective chain. This chain enables it to regulate on its own to store and share information instead of relying on a centralized system. Blockchain has many potential use cases in healthcare applications and can help in patient monitoring, storage, securing data, health information exchange, and clinical trial management, among others. The principle of decentralization and cryptography, at its core, will help transform the Healthcare system by improving the accessibility and security of patient information for the modern age.

Through a systematic review of literature on Blockchain and healthcare data, this paper aims to explore the current application methods, challenges faced, open questions, data standards, and compliance issues that are core to implementing a Blockchain-based solution in the Healthcare industry. Further, the present study seeks to explore the concerns and scope of the blockchain experts operating in the healthcare industry.

Keywords: Blockchain, Cyberthreat, Data privacy, GDPR, HIPAA, Healthcare, Patients privacy.

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1. INTRODUCTION

Out of all the industries, healthcare is the most sensitive concern to human. Though artificial intelligence has hit human beings hard yet the blockchain that emanates from cryptocurrency has evolved itself in various modes and dimensions. The relevance of online mechanisms has been indisputably realized in the pandemic times. The applications of blockchain have been profoundly realized, especially in the healthcare sector, a brief of which is presented as follows:

1.1. Electronic Health Records

Medrec is among the most cited initiatives in the Blockchain-based patient record management domain. It is an open-source Blockchain platform that has been developed, specifically for EHR management. Health Suite Insights, developed by Philips' Healthcare division, is experimenting with Verifiable Data Exchange Process, that would allow members in a hospital to exchange medical data among themselves. Medshare, also similar to Health Suite Insights, enables data exchange processes based on Blockchain technology. The data can be shared between the untrusted parties utilizing auditing, trailing and data provenance that is developed using blockchain-based smart contracts and access control mechanisms. It enables administrators to track the data behaviors and revoke access if a violation occurs. Iryo [1] is developing a global repository of health information, and the format used is Open EHR. There are several other projects that are included under it, such as Gem Health [2], OMNI PHR [3], Patientory [4] and others.

Blockchain in EHR is plagued by challenges of interoperability among the several Blockchain-based solutions that have come up in the recent past. Interoperability itself springs forth because of missing standards within Blockchain EHRs. Scalability issues are yet another concern, and so is the maintenance and management of privacy and security, given the nature and volume of healthcare data.

1.2. Personal Health Records Management

These are patient-centric applications that have several similarities with EHRs. The development of these applications based on Blockchain will assist patients in handling their data in a secure manner. A Blockchain-based PHR management works best with a device like a modern smartphone with a 4G/5G enabled network. A system on such a modern smartphone can help provide access to all three layers, a storage layer that is secure and reliable, a data management layer and a data usage layer. Emergency Access Control Management System, EACMS, is one of the applications that are based on permissioned Blockchain Hyperledger fabric and composer. The PHR permissions are handled by the patients on the basis of the same. Healthcare Data Gateway, HDG, as proposed in [5], is also a patient-centric application developed using Blockchain technology. The prime use case being, that a patient can on-demand generate a token that would allow the practitioner limited or timed access to their health data. The provider's HDG will comprise the patient data replica, and the practitioner will be able to access only the authorized information as an outcome. Also, the HDGs will ensure that automated replica destruction is done once the authorized time period is expired.

1.3. Remote Patient Monitoring

Remote Patient Monitoring or RPM utilizes IoT-enabled devices or body area sensors to capture biomedical information of the patients. The captured data, helps in diagnosing the status and condition of the patient. The data generated is real-time and can be accessed by a practitioner, who may not necessarily be present in the same facility. Blockchain technology and networks can be used to manage and store the biomedical information that is gathered for the purpose of RPM [6]. The research conducted in [7] showcases the mechanisms by which smart contracts used on Ethereum-based Blockchain can be used to handle real-time patient information in a secure environment. Patient-Centric Agent, PCA has been developed to provide end-to-end security for continuous RPM applications [8]. Handheld devices are used to make sure that the exchange of data is done in a secure Blockchain-enabled technology [9]. The study [10] includes a Hyperledger-based Blockchain implementation for data gathering and transfers, especially in mobile healthcare applications [11]. SMEAD is one of the Blockchain-based mobile healthcare applications that are developed to monitor and manage diabetes patients and their information [12].

1.4. Clinical Trial Management

Patient recruitments for clinical trials are among the most challenging processes, and the inability to recruit them in a prescribed timeframe can have a negative outlook and be a waste of funds. Blockchain can be used to avoid such issues or challenges by helping in eliminating false data and avoiding underreporting in clinical trials [13]. Patient consent can be easily obtained as anonymity is guaranteed with the involvement of Blockchain. The research conducted in [14] proposes a Blockchain framework that makes use of the master smart contracts for matching the patients with the trial-based contracts. This can lead to significant time savings and can also lead to the identification of the potential subjects. Using Blockchain ensures that there are no violations of data security and privacy. The decryption of the data will be allowed for only a handful of users [15]. A proof-of-conceptual study undertaken by Wong *et al*., evaluated the process of clinical trial management using Blockchain. It showed that the use of the Blockchain technology can enhance security while data processing, data entry and even data storage. It gives a robust immunity at the infrastructural level as well as within the institution [16].

2. DISCUSSION

This systematic literature review presents the most relevant studies carried out on some of the most promising state-of-the-art healthcare applications that are using blockchain technology to highlight the on-going research trends. Traditionally, the patients' information is stored across several databases scattered across multiple services, which could lead to severe interoperability issues. The ability to work collaboratively on such data also is limited [17].

The use of Blockchain for EHR management transfers the control of Patient's own health information to themselves. There is increased transparency and consistency promised to all healthcare stakeholders [18]. The use of Blockchain for information storage can bring up the challenges around patient security and privacy. There are some of the organizations and research projects, for example, Phillips and MedRec have created the Blockchain-based EHR applications [19].

There are three different aspects of the literature that are identified on the basis of the literature review. These include the most popular Blockchain-based healthcare applications, concerns and compliance challenges that may be related to the use of the technology, and the recommendations to resolve the challenges.

2.1. Challenges Related to Security

There are multiple security issues in Blockchain, and they are usually associated with the traditional problems around consensus for transaction verification. Some of the primary security vulnerabilities include the Distributed Denial of Service, selfish mining, double-spending attacks, block discarding, and Sybil attacks [20]. Additionally, blockchain-based bugs further give route to the exploitation in smart contract implementation. This may lead to an increased probability of the attacks, such as identity theft and data exfiltration [21]. The involvement of Blockchain can also lead to the transaction flow, that can be traced to determine the physical identities and associated information publically available on the Blockchain networks [22].

2.2. Challenges Related to Privacy

Despite encryption being at the core of Blockchain, violation of privacy is still witnessed in the public Blockchain. Multiple seemingly related information about the patient available in the public domain can be put together to reveal the patient's identity [23]. The inclusion of the new patient information in the Blockchain includes several steps to make sure that the patient is genuine [24]. There may also be challenges and concerns around non-compliance with the GDPR regulations, which include the right to be forgotten. In other words, a patient in European Union can request authorities to completely erase, which the facilities must adhere to when received [25]. Similarly, the United States follows HIPAA guidelines wherein the user's change of mind is acknowledged in association with private health information. This is specifically significant for the data present within an immutable Blockchain [26]. The immutability aspect of Blockchain makes sure that there are no changes possible to the data, and it shall not be deleted. This may be in contradiction with the request of the patient to completely delete the medical records.

2.3. Challenges Related to Interoperability

These challenges are primarily witnessed due to the lack of the applicable standards. This results in adherence to different standards and practices by different vendors, which may lead to interoperability issues. For instance, two similar healthcare applications developed using Blockchain but developed on two different Blockchain platforms could make it impossible to have data exchanged between the two [27, 28].

2.4. Challenges Related to Storage Requirements

There is a considerable amount of storage that is required by Blockchain to store the information and the transactional records. This could be a major problem for the restrictive nodes that transmit the information over the network. Blockchain can make sure that there are no integrity issues involved; however, the storage of potentially large-scale distributed EHR information could be a matter of concern [29].

2.5. Challenges Related to Computing Power Limitations

IoT devices are increasingly being adopted in healthcare. However, to incorporate Blockchain within this would mean to incorporate cryptographic computations in these IoT-devices. IoT devices are generally low-powered and primarily deal with sensor and actuator protection, and have meagre computation capabilities [30, 31]. This poses a significant challenge to Blockchain wherever IoT is concerned [32].

2.6. Challenges Related to Scalability and Latency

Healthcare data can become massive and overwhelming since it's not viable to store such data locally and therefore offloaded to remote data-centers. Therefore, there is always a problem of speed and latency. If Blockchain-based processing overhead is added on top of this, it further worsens the situation. For instance, the validation process involved in the Ethereum Blockchain requires all the nodes present in the network to participate and is particularly challenging when the load is high.

2.7. Relevance of the Study

This paper is an attempt to explore the application of various dimensions of healthcare management in the form of medical record management, identity management, hospitals and doctors' record maintenance and third-party involvement such as insurance companies, *etc*.

This concept which is based on virtual networks, is yet to be explored and tested with the various perspectives from medical practitioners and drug specialists regarding the medical care prescribed and received.

3. LITERATURE REVIEW

The authors [33] mentioned in their research study the characteristics of blockchain, such as that data decentralization as well as security and privacy management. This technique is known to provide a smart solution to the existing problem of data mismanagement and the threat of being used by an unidentified and unknown source. The ease of sharing the data is known through the slicing of data into different packages and categories for the decision to share only that amount of data. Authority over data is controlled and facilitated through the mode of blockchain [34]. Proposed attribute-based signature for the patient to authorize his data sharing to a particular professional for a defined objective. Thus, only that segment of data and information is shared, which is significant. They [35] through their extensive work, reported the benefit of telemedicine. Telemedicine ensures a check on data integrity and diagnostics usability. The doctor diagnoses and prescribes medicines that are validated with the segment of trust for patients and act as an endorsement from healthcare experts. Any expert will like to maintain their reliability and, thereby, performance scores. The platform of international healthcare is maintained through the processes of artificial intelligence and provides the benefits of regulation by keeping processes under surveillance. The authors [36] found that the integration of various processes and records through blockchain has aided in the facile care and treatment of the patient. This is due to the fact of maintaining the ease of records with the patient, their concerned authority and third-party agents. Predictive analysis helps in precision management. Blockchain is an essential medium of transfer learning that extends an opportunity for deep learning that acts as a solution of harnessing and unlocking the potential of big data. The authors [37] proposed the deployment of the technology of blockchain as a measure of engaging patients into self-care where they manage their own records. Their identity is managed by themselves or their caretakers. They [38] cautioned the health insurers that the patients might register themselves with more than one insurance firm. Blockchain can act as an excellent supervisor on such smart moves of those who, due to human intervention, take undue advantage of the organizations that are established with the vision and mission of serving and supporting those in dire need of medical care.The authors [39] reported cloud storage as a safety mechanism for data storage. Identity-based encryption and attribute-based encryption define and prove the identity basis of the signature. The authors [40] shared the sociological as well as technical aspects of the application of blockchain in the healthcare segment.

Health is more or less characterized due to demographic and heredity factors. Both cognition and emotional processing are caused due to social ideologies. Authors [41] conveyed through their research that many times pharmacist returns some other medicine instead of that prescribed due to the non-availability of that particular brand. Electronic medical records are provided with a feature of ensuring privacy protection. Permission-based application is a paradox where individuals have the power to cross-validate for the correct and complete guidance of the ongoing medical department [42, 43].

3.1. Research Design

A survey of three hundred of such patients had been undertaken who had visited countries across the globe to offer the leverage of medical tourism. Doctors had been consulted through websites and their advice had been sought for. Not only had the availability of wards and ICU been confirmed to them before they reserved their flights. The healthcare managers need to take keen interest in knowing the gap and bridging the gap with the requisite skills and knowledge for providing medical solutions. The health experts undertook this for the essential exposure as a part of the growth trajectory of their career portfolio and for the hospitals to incur advantage of cross-national currencies. This is a new concept which had begun to reveal its significance. The concept can be extended to other industries such as aviation, banking, finance, insurance and telecommunications, *etc*. As the data is stored in e-parcels, the government finds it easy to practice e-governance over the scattered data. Also, the patient reserves a right to their identity and privacy. Thus, blockchain is a concept that is at its nascent stage. Its potential is unknown to the common man, and therefore they cannot harness it in the present times.

4. RESEARCH METHODOLOGY

Three hundred patients (caretakers) were approached, with one hundred respondents in public sector hospitals and a sample size of two hundred respondents from private hospitals. The study was conducted over a span of three months May, 2020-July, 2020. The respondents were from the age group of 15-70 years. Out of two hundred respondents, 158 were those who had received alternate treatment at some other hospital for the same ailment, while 42 cases reported the non-availability of medical amenities in their country. Among the rest of hundred respondents, they were oblivious to the concept. Along with the patients', doctors and other health workers were also interviewed to gauge the appreciation of advanced technology in the system and awareness of this new concept in supporting treatment and such healthcare maintenance and practices for patients. The research covered respondents in the geographical areas of Delhi only. Two private hospitals and two government hospitals were included.

5. FINDINGS

Out of the open-ended questions asked during the interview with experts, the answers assorted unfolded the little awareness of blockchain for the healthcare industry. Due to Covid 19, many doctors started with digital healthcare, that is, through video visits to rooms of patients or even monitoring at home through these digital waves. Out of 300 hundred patients surveyed as shown in Table **1**.

Table 1. Survey Data.

Type of Hospital	Number of Patients Surveyed	Number of Doctors Surveyed
Public	140	20
Private	160	25

5.1. Respondents' Profile

It was found that seventy-nine percent of the respondents in the category of patients did not know about the concept of blockchain. These were the patients who had been in the advanced age bracket and just wanted treatment.

6. RECOMMENDATIONS

6.1. Engagement Between Researchers and Regulators

It is recommended that the regulators and researchers shall get involved in an early and open dialogue so that the plans made by the researchers are shared with the regulators, and the aspect of compliance is involved early on. The regulators can come up with regulatory policies and norms for ensuring improvements in compliance.

6.2. Clinical Research Pilots

The developers and operators associated with Blockchain shall execute the clinical research pilots that shall be developed in the technology-regulatory sandbox environment. The early pilot project shall comprise various sites so that the application value can be increased and the promotion of cross-site research and regulation can also be done.

6.3. Privacy and Security Countermeasures

Health chain is one of the EMR applications that make use of IBM Blockchain's Hyperledger fabric and claims to be secure and offer enhanced scalability. It uses chain-codes that are based on smart contracts for the purpose of access control and authorization [44]. To manage the data privacy, the attribute-based signature scheme has been proposed. It includes multiple authorities wherein the sensitive information will be kept intact, and the information will be included as per the attributes of the patient message. This will promote overall security and privacy. Another approach is to use a hybrid scheme in which Blockchain shall be combined with the Public Key Infrastructure, PKI for advanced access control [45, 46].

6.4. Interoperability Standards

The interoperability issues are present due to the lack of defined standards. There shall be defined standards for data formatting and authentication along with structure, validations, and security. The development of these standards can take time. Meanwhile, the regulatory agencies shall take ownership to gather the Blockchain vendors and agree on the acceptable guidelines. The scalability issues can be handled by storing the patient information on the cloud databases. The Blockchain shall only have the data pointers and fingerprints. This will also resolve the issue of data deletion requests by the patient [47, 48]. The data present in the database will be deleted which will automatically dissolve all the data pointers and fingerprints present in the Blockchain. However, it may counter the redundancy developed on the Blockchain, which promotes overall availability [47]. To improve the overall system performance and increase the processing speed, there are certain nodes that have permission to get involved in the validation and consensus mechanisms. However, it is in contradiction with the protocols included in the public Blockchain, for instance, Bitcoin, in which any of the nodes can participate [48]. There are a few prerequisites that the public Blockchain in healthcare applications must include:

a. Transactional connections must not be publically accessible or visible.

b. Only the participants shall have access to the content of the transaction patterns.

CONCLUSION

Blockchain is one of the emerging technologies, and there is significant research that is already being done on the topic. It is essential that the research and development works in the field are carried on. The primary contribution of the research study conducted is to make sure that the Blockchain applications in the healthcare sector can be effectively determined. There are four such major areas that have been identified. The objectives that were set for the study included the determination of the Blockchain applications in the field of healthcare, understanding of the associated benefits and challenges, and to provide a set of recommendations that can be implemented for further improvements. Blockchain is a relatively new concept, and there will be a wider scope of research in the future. Future research can explore more use cases based on wider data sets. It will contribute to determining the associated patterns and trends for Blockchain applications in the healthcare sector. Future research is also required to resolve the present concerns around data security & privacy, GGDP scalability, interoperability, and latency with Blockchain-based healthcare applications. There are issues of non-compliance that are also identified in terms of the GDPR [11] and HIPAA [8] compliance that needs to be further researched as well. The majority of the research that has been done in the past is based on theoretical concepts that are still not in practice. There is also a limited user base that is associated with all of these studies. The adoption of Blockchain technology in commercial healthcare applications will be based on improved data security and privacy aspects. The mitigation of these issues will increase the opportunities to have commercial Blockchain-based healthcare applications in place.

FUTURE RESEARCH DIRECTIONS

This is a new concept which had begun to reveal its significance. The concept can be extended to other industries, such as aviation, banking, finance, insurance and telecommunications. As the data is stored in e-parcels, the government finds it easy to practice e-governance over the scattered data. Also, the patient reserves a right to their identity and privacy. Thus, blockchain is a concept that is at its nascent stage. Its potential is unknown to the common man, and therefore, the practical aspects and usability in multiple industries and domains are just beginning to rise. Further research can explore bigger data in different geographical contexts.

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CHAPTER 7

Advancing Health Research Data Analysis with Blockchain Technology

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Abstract: It has been discovered that the storage problem of complex health records and data has been addressed, but there were still several issues with data security sharing with cloud technology. The decentralization attribute of blockchain will help in solving the problem. In electronic health records, blockchain can assist in reducing data sharing and interoperability in the industry by creating an overarching mechanism connecting different personal forms. It can also mimic data sharing by directly bridging the gap between owners and buyers. Therefore, this chapter will provide detailed information on Advancing health research data analysis with blockchain.

Keywords: Blockchain, Cloud technology, Data, Health record, Security.

1. INTRODUCTION

There are several advancements in the application of Blockchain, especially in academicians and healthcare. One of the significant challenges encountered in healthcare literature is data management [1]. Therefore, several the utilization of blockchain technology has been identified as a sustainable means that could help several problems encountered in various sectors of healthcare systems, especially

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in the management of data [1]. Data management faces several challenges, such as failure to maintain security and confidentiality, lack of interoperability, and loss of diagnosis data, especially those containing patient health records.

Also, it has been documented that medical centres' governments have several roles to play in contributing to the development of the health sector through advancing technology that could maintain human health [2 - 9] and documentation of proper records [10]. Moreover, numerous challenges are associated with healthcare information systems [11]. But introducing blockchain technology will go a long way in mitigating several challenges in healthcare and provide opportunities that could help combat several challenges in the healthcare domain [12].

Moreover, public and private healthcare organisations have established various sharing techniques that could improve information exchange advantages [13]. Several investigations have shown the three significant exchange models that could be utilized using healthcare individuals to electronically communicate patient health information, such as patient-centred exchange, query-based, and direct. These modes can enhance communication and coordination, especially among healthcare organisations managing several illnesses by steadily substituting identifiable patient data. Also, these modes enhance the steady covering of identifiable data of patients. That enables the sender to recognize the recipient's details and records of the patient medical information, which can be substituted directly from one healthcare organization, primarily through extensively embraced email protocols [14 - 17]. This chapter provides comprehensive information on advancing health research data analysis using blockchain.

2. BITCOIN AND PRIVATE BLOCKCHAIN LIMITATIONS FOR HEALTH CARE APPLICATIONS

Bitcoin is an acephalic digital payment platform that employs blockchain technology. Although Bitcoin has many controversies, it has functioned flawlessly and has been applied in many fields, including medicine. Personal health record platforms could be converted to a decentralized network using Blockchain technology [18]. Blockchain is faced with many challenges. In their review, Kamel *et al*. [19] identified challenges associated with blockchain, including privacy, confidentiality and security. Privacy and protection of personal medical data are crucial and confidential. They must be handled cautiously, just like in the conventional medical record share in which, for example, the HIV laboratory test result of a patient is forwarded to the doctor's office without the awareness of the patient, and health reports are susceptible.

Unfortunately, with blockchain, leakage to a third party is not impossible. One of the sources of such leakage is cyber-attack, any unauthorized, offensive invasion targeting information communication systems, personal computers and networks. This occurs through stealing, modulation and alteration, or a particular target's destruction through hacking.

Another challenge that is associated with blockchain is scalability and performance issues. The scalability of blockchain is the tendency to support an increasing quantum of transactions and a rising number of nodes in the network [20]. Specifically, the Bitcoin blockchain scalability issue refers to the Bitcoin system's capability limitation to manage big data in the shortest time frame on its platform. This implies that the Bitcoin blockchain exhibits minor frequency and size. Consensus protocol or algorithm is one factor that can influence blockchain technology's scalability and performance. The consensus algorithm describes how a blockchain network's propagation, validation and finalization occur. Network latency is another determinant of blockchain scalability and performance. Blockchain nodes comprise a database and runtime engine hosted on the cloud or premise. When dedicated infrastructure resources are unavailable, node performance may be inhibited. A node can affect blockchain scalability and performance. The more the number of nodes, the longer it will take to propagate a transaction. The next factor is bright contract complexity. Concerning the number of reads and writes from or to the ledger and validation logic, the processing latency will also increase when smart contracts are more complex. The size of the transaction payload also affects blockchain scalability. The larger the loads, the longer it takes for replication across nodes. Database efficiency is another factor influencing blockchain network performance. The last is transaction queuing. The blockchain network comprises many nodes that work together to provide high availability. However, each node's handling capacity shows the number of transactions accepted for further processing from the client applications.

The reports of Hussein *et al.* [18] and Hussein *et al.* [12], even though blockchain applications are spreading over many fields, including agriculture, reputation system, the economic sphere and medicine, Zheng *et al.* [21] also reiterated a barrage of uphill concerns about blockchain technology, especially scalability and data security problems. In their study, Kuo *et al*. [22] highlighted the uphill associated with blockchain, such as privacy and data security. Sun *et al*. [23] posited that preserving electronic health information and record and synchronization have always posed a considerable challenge.

Blockchain applications and implementations are increasing, but the issue is variations in underlying technologies. Therefore, it may be difficult and impracticable for all of them to work together. Insidious intrigues are often obtained when smart contracts communicate across blockchain implementations without human interaction [24]. Hussien *et al*. [12] remarked that healthcare applications of blockchain need robust security and privacy platform to achieve optimal interoperability, validation and exchange of health records data to meet the stringent policies and regulations of the 'Health Insurance Portability and Accountability Act of 1996.

In Cloud, access to online data is possible. Blockchain can be viewed as an encrypted platform that devises different formats of encryption and hash to store data in protected databases. Both cloud computing and blockchain technologies are fast-growing mechanisms worldwide. However, one significant difference between the two is immutability. Blockchain is immutable, while cloud computing is mutable. While commenting on cloud computing, Ismail *et al*. [25] and Al-Issa *et al*. [26] noted that cloud computing got access to the healthcare system because it is elastic and cost-efficient, transparent, has energy savings, resource sharing, fast deployment and is secure. COVID-19 plague massively improved the number of investigations in areas related to healthcare and payment technology platform integration [27]. Ismail *et al*. [25] recalled the challenges associated with cloud computing, including its incapability of providing many healthcare givers with a protective and secure patient-centred cohesive approach. Blockchain has shortcomings, such as scalability and efficiency issues, but it has the advantage of decentralisation. This implies that cloud computing and blockchain need to be integrated. Against this background, Ismail *et al*. [25] developed a new model known as blockchain-cloud integration for medical applications.

Regarding solutions to blockchain challenges, Kamel *et al*. [19] highlighted some ways out. They emphasised the importance of the identity of health providers and health receivers as a way of tracking who has access to medical information and records. Another method is the integration of cloud computing with blockchain, according to the report of Ismail *et al.* [25]. Cloud computer is a flexible, energy-conserving, cost-effective and resource-sharing mechanism of security and fraud detection, management of medical and pharmaceutical device supply chains, data monetisation and public health surveillance, the use of autonomous devices such as drones with many internets of things, enabling of open tagged and public data.

Furthermore, blockchain challenges can be overcome by having a dedicated network bandwidth. Having a dedicated bandwidth helps in enhancing overall throughput and reduce network delays. The use of reliable infrastructure resources will improve node performance and blockchain scalability. The consensus mechanism's quality can influence the blockchain's performance and scalability. Schorr's signature is another way of improving the scalability and efficiency of blockchain technology. Schorr signature is a digital signature created by the Schnorr signature algorithm. Besides, a smart contract can be reduced by using mercerised abstract syntax trees.

Al Issa *et al*. [26] discussed how their proposed 'Blockchain and Distributed Ledger-based Improved Biomedical Security' system could improve data confidentiality and protection across medical spheres. The authors intended to improve patients' access to utilise data for supporting their care and providing consent platforms for data exchange within various groups. The study results showed that the new blockchain-based payment medium enables easy and rapid interactions between data suppliers to enhance data confidentiality and security among healthcare receivers.

3. BLOCKCHAIN TECHNOLOGIES FOR BIOMEDICAL AND HEALTHCARE APPLICATIONS

Telemedicine and telehealth are innovations in healthcare delivery with promising roles in offering Medicare services to curtain the transmission of COVID-19. Unfortunately, they are limited by their centralised and mutability attributes. Since blockchain is known to be decentralised and immutable, Ahmad *et al.* [27] attempted to examine the interventional contribution of blockchain technology in this regard. The authors showed that blockchain technology could enhance telemedicine and telehealth operations. It can provide remote Medicare in a decentralised, transparent, traceable, trustful, reliable and secure approach. Using blockchain can also assist in identifying fraud cases, especially those that have to be with the academic qualifications of healthcare providers and the status of testing kits.

Presently there is no single trusted infrastructure that can be used for exchanging and storing medical data and no medium for tracking patients in the scope of the healthcare cycle. This has therefore made communication hard, with procedural cost hiking significantly. This situation made communication hard and impaired how the traceability of patients can be achieved. It has also increased procedural costs. With the introduction of a decentralised healthcare mechanism called 'PatientDataChainblockChain', the traceability of patients has been improved. Cernian *et al.* [28] examined this approach's vision in its interoperability. In the study, system components were developed. Also, system components were validated courtesy of a proof of concept that utilised one hundred patients' data and more than one thousand transactions. The authors showed that the 'PatientDataChainblockChain' is feasible as far as the integration of individual health records from non-homogenous sources is concerned.

Personal health record security, protection and accuracy are essential in medical services. Blockchain is a platform where data retrieval can be achieved. The study by Lee *et al*. [29] aimed to design a blockchain-mediated scheme for an 'international health record exchange' platform to achieve health record integrity, privacy and availability for rapid Medicare interoperability and management. The blockchain platform designed by the authors was reported to be effective regarding the utilization of Personal Health Records. Through the Asia eHealth information network, the platform has been devised. In summary, the study indicated the possibility of combining diverse data storage modes to effectively proffer solutions to the problems associated with human record data storage, security and transmission. The work also indicated the possibility of having a mix of blockchain and data privacy and security platform to enhance the exchange of 'international Personal Health Records'.

With blockchain technology, personal health record systems can be converted into a decentralised network infrastructure. But privacy and storage capacity is the incapacitating factors. A study by Hussien *et al*. [18] addressed the hiccup between Personal Health Records and blockchain technology by simply transferring many health data into the Interplanetary File System storage as well as by creating an enforced cryptographic authorisation and access control platform which will be used for outsourced encrypted health record and data. The authors constructed the access control on the premise of a novel 'lightweight cryptographic' concept called 'smart contract-based attribute-based searchable encryption', which was also developed courtesy of searchable symmetric encryption, leverage of innovative contract technology and encryption extension on the premise of the ciphertext-policy attribute. Among others, data confidentiality was achieved by removing trusted private key generators, efficiently managing intelligent outsourced encrypted data and a searchable process with a multi-keyword feature. Security validation was confirmed through Automated Validation of Internet Security Protocol and Applications.

It is not unusual for patients' data to be lost or violated in the conventional platform. Electronic health record has several benefits but is limited by security and privacy issues. The mechanism of providing a secure solution to these issues is through blockchain. Blockchain technology addresses the problems because it transmits information in a decentralised manner. Abunadi *et al*. [30] constructed a blockchain security framework to store electronic health records effectively, protectively and securely. Through the platform, health information can be acquired for patients, healthcare providers and insurance agents, not at the expense of the patient's data.

Cheng *et al*. [31] discussed the benefits of blockchain technology, and a network model called blockchain Based-Medical Cyber-Physical System was constructed. The authors showed that the blockchain Based-Medical Cyber-Physical System did realise health management data exchange. Besides, it met various ideal security criteria in the security validation phase. The authors concluded that the model was more appropriate for securing sharing of big health data.

A study by Leeming *et al.* [32] discussed the existing blockchain-mediated health record platforms as well as the model architecture for a "Ledger of Me" platform, which devises personal health records to design a new approach that integrated the array and set of healthcare data and innovative contracts-induced digital interventions. The authors' target was to allow patients to utilise data to support their care and provide robust consent schemes to exchange data between different groups and applications. The reference architecture presented by the authors can serve as prospective blockchain-based healthcare application architecture.

Liu *et al*. [26] discussed how their proposed 'blockchain and Distributed Ledger-based Improved Biomedical Security system' can improve data security and data protection and security across medical applications. The authors intended to improve patients' access to utilise data for supporting their care and provide consent schemes for data exchange within various groups and applications. The study results showed that blockchain-related digital platforms enable easy and rapid communications within data suppliers for enhancing confidentiality and data security and protection.

A review conducted by Velmovitsky *et al*. [33] examined the possibility of using blockchain techniques in solving healthcare challenges. The authors identified five areas where blockchain technology can be used. In the drug and food supply chain, blockchain technology can avail products' provenance and transportation that will be auditable. In health insurance, it can enhance the process of claims management and assist in medical and pharmaceutical spheres calculation. In genomics, blockchain can directly help link data, buyers and owners. It can provide an auditable and secure way of sharing genomic data. In consent management, blockchain can offer a time-related and immutable log of consent, thereby increasing the transparency of the consent management process.

Fang *et al*. [34] investigated, among others, the recent landscape, design and applications of personal health records based on blockchain. The authors reported that off-chain storage and permissioned blockchains were the most common design choices for personal health records. Dubovitskaya *et al.* [35] discussed the advantages of blockchain technology in oncology. It enhances data-sharing health-related research. It helps attain an optimized pharmaceutical supply chain through its traceability, transparency and immutability to the applications [36 - 63].

CONCLUSION

This chapter has provided detailed information on advancing health research data analysis with blockchain. Detailed information on the relevance of Bitcoin and Private Blockchain Limitations for Health Care Application were supplied during the Blockchain technologies for biomedical and healthcare applications. Relevant details on Telemedicine and Telehealth are innovations in healthcare delivery with promising roles in offering Medicare services to prevent the transmission of COVID-19 were also provided.

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CHAPTER 8

Blockchain Technology as a Tool for Prediction and Prevention of the Spread of COVID-19

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Abstract: Blockchain is predicted to greatly transform the conventional methods of transacting between users, covering almost all sectors of the economy. While the expectations of blockchain technology are high, the actual impacts and benefits are still unclear, causing delays and skepticism in its adoption. As the coronavirus disease (COVID-19) continues to affect the world, businesses and governments scramble for answers in attempting to limit the impact of the pandemic. In order to assess the ability of blockchain technology in its efforts to minimize the impact of the pandemic and clearly define the challenges and prospects of blockchain, a structured literature review of peer-reviewed articles on block chain's implementation and adoption in supply chain management, education, logistics and finance sectors was conducted. It is recommended that block chain's implementation and adoption is not limited to the finance sector but can be applied in any sector, where it provides a decentralized network in which information is accessible and personal privacy and security are guaranteed. Therefore, the wider acceptance and implementation of blockchain in selected sectors of the economy, especially in finance and supply chain management, has proven that blockchain can be utilized by businesses, governments and health professionals in the fight against the virus by transforming the challenges into opportunities combined with the prominent essential enablers would fast track its wider adoption.

Keywords: Adoption, Blockchain, Challenges, COVID-19, Implementation, Prospects.

1. INTRODUCTION

Blockchain technology is a distributed network of historical transactions where transactions are stored in a database that is safe and protected by cryptography

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and reliable mechanisms [1]. The database contains smart contracts where records and programs run without interference and the risk of interruption, restriction or fraud [2]. Not only is blockchain regarded as the enabler of cryptocurrencies like Bitcoin, but is also more valuable in enabling certain economic and social activities such as asset tracking and digital recording of asset proprietorship. This happens due to the de-centralized nature of the information that enables tracking asset movements easier and limits tampering with the record of transactions.

The widespread organizational use of blockchain symbolizes the increase and tremendous impact that new trends in technology have on organizations and governments that cushion the drastic negative effects of environmental forces [3, 4]. Blockchain is regarded as one of the new trends in the vast array of technologies which has instigated extensive interest and discussion about its applications and facilitation amid many debates concerning security and trust issues. Blockchain is predicted to drastically transform the interactions and transactions that people have with each other paving the way for virtual business models with huge potential [5]. Therefore, the applications of blockchain transcend beyond the mere notion of buying and selling but branch out into governments, businesses and public domains, completely affecting and revolutionizing the way in which these important sectors operate [6].

The impact of coronavirus disease (COVID-19) on important sectors of the economy has affected key industries that generate huge revenues. A number of key sectors are shut down as a result of government interventions to control the spread of the virus combined with the public refusal to use services in fear of exposing themselves to COVID-19 [7, 8]. As a result, governments and economic bodies are trying to limit the impact of COVID-19 on important economic industries, including airlines, tourism and hospitality sectors like hotels, restaurants, clubs, entertainment and events venues and the retail industries. The ripple effect on these sectors trickles down to taxi and cab operators who commute between airports ferrying tourists and travelers to their destinations and *vice versa* because the airports are closed from international and domestic flights, and more and more people are working from home, resulting in significant losses of revenues. Furthermore, the withdrawal by parents from their jobs has drastically increased due to the suspension of schools and childcare facilities. The isolation of infected patients and those in hospitals and quarantine facilities has put massive pressure on the economy and health systems. On the contrary, some businesses like supermarkets, online retailers, and medical equipment manufacturers will continue to gain from the impacts of the virus. In contrast, most non-food businesses will recover in the near future because mobility is restricted, culminating in reduced spending [9].

Industry expectations on blockchain and its benefits are countless amid the chaos of COVID-19, reaching extravagant proportions where dis-similarities exist between the expectation and experience. Given the newness of the blockchain phenomenon and outbreak and elevation in status of COVID-19 to pandemic proportions, the expectations of blockchain far outweigh the experience acquired from the actual applications in businesses' skepticism about the genuineness and value creation attributes accorded to it in this uncertain business context continues to gain momentum. The lack of broader acceptance of its applications threatens its rise and universal use from already established systems. However, the benefits that blockchain endows businesses cannot be undermined in the face of COVID-19, including eliminating intermediaries by allowing suppliers and customers to interact and transact directly, and accessibility to a secure database whereby customers can easily access information and make purchases. Therefore, blockchain must be bestowed the prominence and recognition it deserves to nurture wider acceptance of this new technological trend, and the benefits users can derive from it [6] as governments and businesses scramble to answer the pandemic.

2. PROBLEM STATEMENT

In the last eight months, the impact of the deadly coronavirus disease pandemic has decimated businesses and heavily crippled the economy of countries around the world. According to reported news from media sources, the airline industry, tourism and hospitality sectors and the economy as a whole have absorbed the impact of the COVID-19 pandemic as countries scramble to mitigate its effects. As the world comes to terms with COVID-19 by providing medical assistance with the staunch support of the world health organization (WHO) and leading economic powers like the great eight (G8) and great twenty (G20) countries, reported cases to continue to rise to the hundreds of thousands despite their combined efforts. Thus, as a measure of controlling the infection rate of the virus, governments are instituting lockdowns and restricting human interactions and mobility aimed at containing and minimizing the rapid rates of infections. These restrictive measures have reformed the traditional business methods of business and client interactions. With the COVID-19 control protocols in place, human interactions have been restricted, engendering new economic practices where businesses are forced to interact through virtual platforms. As a result, the need for blockchain technology continues to gain popularity among organizations with substantial benefits such as reduction of intermediary involvement where the direct supplier and customer transaction is facilitated, nullifying the desire for reconciliations and updated system for tracking asset movements and guaranteed quality data [10] seem to be applicable in the current situation. Therefore, this review paper focuses on understanding blockchain technology and its ability to limit the pandemic with particular attention to challenges and prospects for effectively dealing with COVID-19.

3. LITERATURE REVIEW

Blockchain is described as the new technology driving force behind Bitcoin. Blockchain technology has garnered support and adaptation owing to cryptocurrency excitement [11]. Therefore, as defined by Angelis & Da Silva [11], this technology produces a safe list of previous dealings arranged into distinct blocks connected chronologically and readily available between servers for reliable applications. Blockchain is a new technology trend that is complex, yet provides state-of-the-art security measures guaranteeing honesty and trustworthiness within a connected network [10]. According to Hughes *et al*. [10], two essential features critical to the success of blockchain are (1) its ability to maintain high integrity and facilitate secure transactions from duplications and alterations and (2) the removal of intermediation aimed at reducing or even eliminating related costs and human errors.

Hughes, *et al*. [10] confirmed that blockchain gains in solving business problems are enormous because of the inherent attributes and the technological advantage expected to revolutionize business practices. This potential propels blockchain into a dynamic business proposition that enables interaction and facilitates transactions among individuals and businesses. Additionally, blockchain guarantees a secure, honest, and reliable platform that enables effective commerce between people and businesses. Familiarity and reliability with a particular system repeat interactions and transactions. However, as highlighted by Biswas & Gupta [12], people are skeptical about blockchain to a certain degree, fearing that the reluctance to adoption by businesses may disrupt their activities. Therefore, the ability to exceed customers' expectations emphasizes confidence and trust in the ability of the network to deliver on its promise.

Blockchain technology is both transformative and revolutionary in its applications, yet certain aspects remain docile, which could take years to rectify, rendering it ineffective. Business processes are changed as a prerequisite for implementing blockchain, and other business practices are tested as migration from old to new application infrastructures takes place [10]. According to Biswas & Gupta [12], a few issues of importance hinder the adoption of blockchain, like problems of scalability surface due to heavy reliance on block-size information transmission, the agility of transmission through the network, and verification of a vast array of information at every point. In terms of scalability, accomplishing business objectives within a reasonable time frame simply enhances block chain's capabilities for broader use. According to Fenech [13], sixty percent of executives expressed that the implementation of blockchain was complicated as first anticipated because of its scalability [14]. It concurred that the essence of blockchain's scalability issue was its ability to maximize output while minimizing delays in waiting for a component to perform its task fully.

The ability and willingness of payment dealers to successfully embrace blockchain in the future cast doubt and anxiety for users. According to Yadav *et al*. [15], adopting blockchain in India is a dilemma as it is in its experimental stage, citing the need for documentation and raising awareness for fast-tracking the adoption rate. There are also technological risks associated with blockchain technology severely affecting its rollout because upgrading and software installation exercises across mines of computers in the network are difficult to fathom. The costs of electricity and the internet to continuously operate a blockchain are so high in most developing countries, surpassing the financial gains that blockchain engenders. In line with that, substandard infrastructure problems cannot fully accommodate the magnitude of transactions that occur daily.

Despite the challenges of blockchain adoption and implementation, the prospects strongly validate its application by users. According to Chalmers *et al*. [3], one of the enablers of entrepreneurship that foster interaction, edition, and distribution is digital technologies susceptible to change in different environments. The multiplying effect of digital technologies has permeated all sectors across geographical boundaries resulting in broader adoption and usage of producing technologies like cloud computing, and 3D printing. Of course, blockchain enables new entrepreneurship behaviors like eliminating disintermediation and allowing direct interaction and transactions to develop between businesses and people.

The devastating impact of COVID-19 permeating society has affected countries, communities, and businesses in numerous ways, from forcing abrupt closure of schools to healthcare systems and insurance problems not undermining the toll of lives lost due to COVID-19 [16, 17]. This pandemonium has forced governments and businesses alike to scramble to provide answers to these issues as answers based on blockchain technologies are proposed to mitigate the setbacks related to COVID-19 [18]. In this case, blockchain is paramount in creating reliable and transparent healthcare models with higher degrees of accuracy and trust because of its tamper-resistant features creating rapid response through a network of connectivity alerting professionals on outbreaks. Alluding to Banafa *et al*. [18], blockchain as an enabler can be used for tracking health data surveillance, infection, and outbreaks, providing accurate reports and efficient responses to COVID-19.

Oluwatobi *et al*. [19], reiterated that many financial and human resources are poured into the fight against COVID-19, and topping that list is blockchain technology's integration into health care and supply chain sectors. Blockchain is applied in the areas of material distribution, donations, relief, distribution and other responses in a quick and reliable fashion in responding to the pandemic. Ledger Insights [20] commented that blockchain ensured that data was not tampered allowing US health sector officials to manipulate data attempts. In doing so, data is available in real time across the country in databases supporting the tracking and treatment of COVID-19.

4. THEORETICAL FRAMEWORK

The blockchain innovative framework of Hughes, *et al*. [10] in Fig. (**1**) highlights the critical elements of the [21] model, guaranteeing organizations reviewing of potential benefits and applications of blockchain, which ensures transparency where proper processes are followed in answering key questions in the process [20]. Sticking to the process within the models provides organizations with key decision points along the framework where organizations revisit their decisions as they progress from one stage to the next. The underlying purpose of the framework is to establish whether correct decisions are taken and necessary limitations clearly defined and applied. The framework focuses on blockchain benefits for organizations and critically overhauling the process for continuous improvements. The framework will form the basis for effective decision making where organizations identify certain barriers such as culture and technological advancements that restrict poor adoption. These crucial factors, significant when combined with innovations, will produce results when critical factors affecting strategic partners are clearly comprehended [22, 23, 24, 25].

5. RESEARCH METHODOLOGY

The research articles on blockchain for this project were sourced from international journals and Google search engine articles. Additionally, the search terms "Blockchain" and/or "COVID 19" were used within the Google search engine and also yielded twelve relevant results with references to the theme. These selected articles were reviewed for quality and appropriateness to the topic, eliminating irrelevant articles unrelated to Blockchain technology and COVID-19.

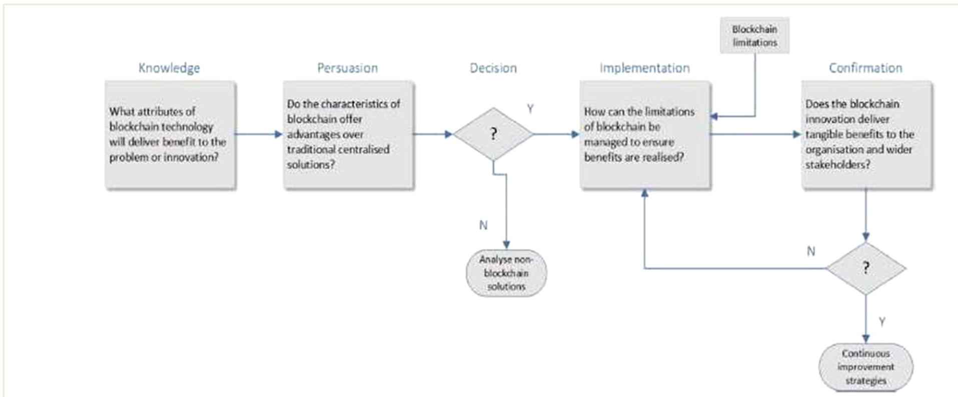

Fig. (1). *Modified Blockchain Innovative Framework* [10].

The evidence of the literature search process was a total of 37 publications and articles that were applicable to the study. These articles were considered because of their relevance to the key terms of the theme of the study focusing on the general blockchain and its applicability and its contributions to the limitation of COVID-19. The data reviewed develop a comprehensive argument and their relevance and applicability based on the content and context. The articles were considered individually, providing details between different studies specifically aligned to the theme developed for the study [26].

6. PRACTICAL APPLICATIONS OF BLOCK CHAIN TECHNOLOGY IN COMBATING COVID-19

This section looks at the practical application of blockchain in fighting the pandemic that has brought the world economy to a grinding halt. Predicting the spread of COVID-19 and instituting a preventative strategy, treating and containing COVID-19 has been elusive, making authorities' efforts incapable of dealing with the virus.

6.1. Prediction and Spread Prevention

Predicting the spread of COVID-19 and attempting to prevent it from spreading is a hassle for any regime. However, the integration of blockchain in combating the virus has made that possible through the sharing of information in real time between relevant authorities. Information sharing between important bodies, including WHO, health ministries and professionals through a common network accessing information in real-time enables the prediction and containment of the deadly virus [27].

The sudden outbreak of COVID-19 has brought to the fore the limitations of the health systems in establishing effective control measures for containing the virus. The lack of an untrusted data surveillance system denies relevant healthcare organizations and governments vital information about potential virus outbreaks. Therefore, blockchain technology is used to connect different nodes in the information spectrum to a reliable network that ensures relevant information is available for real-time decision-making, and instant actions are taken to contain and combat the spread of the virus.

6.2. Treatment

This section looks at how blockchain can effectively contribute to the treatment of deadly infectious diseases like COVID-19. According to Banafa *et al*. [18], the use of blockchain in effectively treating COVID-19 has four critical are: tracking infectious diseases, donations tracking, crisis management and securing medical supply chains.

6.3. Tracking Infectious Disease

Blockchain is used to track infectious disease outbreaks because of blockchain's transparent and accurate reporting systems and efficient responses to outbreaks. This reporting accuracy can empower relevant authorities to develop treatments swiftly by rapidly processing data, thus enabling early detection of COVID-19 before spreading to magnanimous proportions [27].

6.4. Donation Tracking

In the effort to treat COVID-19, issues of mismanagement of donations are prevalent where millions of financial resources are poured into combating and treating the virus are diverted to other areas. Blockchain becomes handy by allowing donors to track their donations to their full exhaustion by ensuring transparency in the application of funds [18].

6.5. Crisis Management

According to Banafa *et al*. [18], blockchain is efficient in managing crises by alerting the populace about COVID-19 through the concept of smart contracts.

Blockchain relays sensitive information from WHO to countries and medical professionals with recommendations for containing the virus. Blockchain technology provides a secure platform for relevant authorities to keep up to date with each other through united efforts to limit the spread of and contain COVID-19.

6.6. Securing Medical Supply Chains

Another treatment feature of blockchain, according to Banafa *et al*. [18], is the beneficial tracking and tracing of medical supply chains as the movement of critical medication takes effect. This technology streamlines medical supply chains by ensuring that health professionals and infected patients access medical supplies when needed and preventing contaminated supplies from being reused.

7. DIRECTION AND PROSPECT OF BLOCK CHAIN

This section purposely suggests the direction and prospect of blockchain and how it could be utilized to contain COVID-19. The containment of the virus is very complex, considering its impact on the economy in varying degrees from country to country. However, striking a balance between gathering and protecting privacy is crucial. Blockchain is more efficient in gathering and organizing patient data, patients' mobility compliance with social distancing protocols and protecting the identity of patients. Block chain permits the selective sharing of information that is consistent with COVID 19 containment efforts while the identity of patients and sensitivity of information is safeguarded [18].

As proposed by Dragov *et al*. [27] utilizing blockchain in the COVID-19 containment efforts focuses on minimizing contact of patients with the community. This is done through distributed network securing personal proximity tracking, which ensures user privacy and avoids data misuse. In addition, another blockchain solution is tracking the mobile phones of patients promising total privacy where authorities receive critical data and giving assurance to patients that their information is kept confidential. Blockchain platforms are paramount in decentralized biobanks necessary for biodata storage which allows them to undergo secret COVID-19 testing, where this data is passed on to government and health officials.

8. BLOCK CHAIN TECHNOLOGY TO REDUCE THE IMPACT OF COVID-19 IN VARIOUS SECTORS

This section attempts to recognize the adoption of blockchain technology aimed at minimizing the deadly impacts of the pandemic in key economic sectors that are being hard hit by COVID-19 and how these sectors can bounce back from the shadows of COVID-19 into prosperous turnarounds. The impact of the deadly virus on business has resulted in sanctioned lockdowns leading to reduced expected spending on technology. COVID-19 has virtually affected all sectors of the economy, however, the effects and magnitudes will be quite different from industry to industry in the near future. While the situation poses challenges for blockchain technology in the coming years, this technology will definitely create new options for blockchain in the long distant future [27]. The resurgence of the economy is vital for the continuation of business and life as this section delves into how different sectors emerge out of the wake of COVID-19.

8.1. Education

The repercussions of the COVID-19 pandemic outbreak primarily affected the public health systems, with spillover effects observed in education, stemming largely from extended school closures. As a result, over one billion students have been impacted across 150 countries since early 2020. The infection among school children is still low, yet schools are closed in order to educate the public on social distancing protocols for containing the virus and reduce the acceleration of new infections. The effectiveness of slowing down the spread of COVID-19 depends on the timing of closures, the age structure of the population and the length of the closure [28].

As the education sector rebounds from the impact of COVID-19 and moves to contend with the ‘new normal’, blockchain plays a vital role in ensuring that personal records and information consistently and continually maintain continuity as the recovery efforts of education systems intensify. According to Sharples *et al*. [29], it is important and necessary to provide resilient academic records that are accessible and widely available among institutions where academic bodies can store secure public records of the personal achievements of students. Blockchain can also assist in opening up systems of scholarly attributes now linked with academics. The application of blockchain has covered many other domains, including education, yet underlying problems persist. The notable advantage of digital certification being unequivocal certification by the issuing university is the non-transferability and inalterability by the university or recipients. In this way, academic credentials are securely stored in unalterable chains restricting duplication, proving difficult to fake. With the adaption of blockchain in the current and post-COVID-19 era, virtual learning modes will replace traditional classroom learning and produce digital certificates rather than conventional paper ones, which are constituent with blockchain's benefit, which is to reduce middlemen, in this case, the teachers.

8.2. Business

Since blockchain's entry into the market in 2009, it has gained widespread and rapid interest from both individuals and businesses alike, with the potential to generate values upwards of $176 billion by the year 2025 and $3.1 trillion by 2030 [30]. Realizing these windfall value streams will require navigating through the impact of COVID-19 and other impediments which have caused forced business leaders to hesitate or be cautious in the testing blockchain. Furthermore, the major benefits of blockchain in business, including transparency, immutability and autonomy, pose a threat to early adopters in its infancy stages because these promised benefits may not materialize or may take time to mature. The objective is to seriously contemplate blockchain technology in recuperating from the shocks of COVID-19 on business [31, 32, 33].

The pandemic has exposed underlying issues of businesses, making them vulnerable to winding up and other risks associated with the virus certain. Blockchain technology offers opportunities to increase trust & transparency as businesses recover from the negative impacts of the pandemic and adapt to the new normal where human interactions and transactions are eliminated, encouraging direct business-to-customer service [34, 35]. This is the best feature of blockchain in adhering to the protocols and precautionary measures instituted by the world health organization and customized versions by governments to negate COVID-19 by emphasizing social distancing. Responsible and holistic deployment of broader digitization strategies such as blockchain in business will ensure that the technology deployed is inclusive, interoperable, and have integrity [36, 37].

8.3. Agriculture

The outbreak of the COVID-19 at start of the year has affected entire food supply chains confirming that the world's food systems are interconnected and fragile, susceptible to external influences and that solutions must be developed together. Agriculture is considered the backbone of almost all countries and an essential economic activity, and farmers are urged to continue toiling harder to cope with the pandemic of worldly proportions. Countries' lockdowns prohibiting border movements have strongly denied farmers vital supplies, including seeds, pesticides, nutrition supplements and chemicals for agriculture. For instance, farmers in Uganda (UNFFE) are restricted from accessing seeds and other advisory services as countries act swiftly to close off their borders [34, 38]. Food intermediaries like distributors and retailers are also affected by the same concerns culminating in the closure of shops, restaurants and food marts as the impact of the virus weighs down heavily on them. Farmers and advocacy groups are lamenting the negative impacts of lockdown enforced by governments as they scramble to limit the spread of COVID-19; predictions for blockchain in agriculture and distribution are destined to increase by 87% annually and revenues from $45 million in 2018 to $3,314.6 million in 2023after rebounding from the impacts of COVID 19 [39].

8.4. Banking

This section derives the application of blockchain in the banking sector in reducing the impact of COVID-19 in the banking sector, focusing on the resurgence of this key industry post-COVID-19. Blockchain plays a significant role in the banking and finance industry by digitizing, stabilizing and widely distributing transactions that are chronologically recorded in real-time. Blockchain technology has the potential to totally and ultimately reform the universal banking and finance industry, offering businesses and humans many opportunities, and completely revolutionizing the way people transact and interact with money and values. The ledger combines subsequent transactions citing the consent of users connected through nodes. This maintains an ongoing system of checks and balances, eliminating information management and ensuring quality, control, and direction [40].

According to HIllsberg *et al*. [41], the banking and financial sector has experienced unprecedented changes as COVID-19 spreads its tentacles into all sectors of the economy, including the banking and finance sectors. The reason is that the same technology that powered Bitcoin contacts, pro- vides numerous benefits, including accessibility, greater transparency, lower fees, and faster transactions. Overlooking the advantages of blockchain technology, in light of the pandemic and its effect on the economy, is similar to operating a handheld pager for communication instead of a smartphone. Therefore, as alluded to by Sharma *et al*. [40], blockchain technology is a chain of interlinked blocks acting as information warehouses that reference transaction links to an earlier block in the same transaction. The interconnected blocks form a sequenced chain paving the way to simple transactions, whereas general information is shared on the network enabling participants to individually validate information without joint authority.

As a matter of fact, the failure of one node does not disrupt the operations and activities of other nodes because transactions are collectively approved by users.

8.5. Manufacturing

This section aims to highlight the impact of COVID-19 on the manufacturing industry and the intervention by blockchain in recovering process from the impacts of the pandemic, which has affected businesses and governments as they attempt to negate the undeniable impact of the virus on profit and citizens. Other sectors of the economy are also hit hard. Still, the focus here is on the manufacturing sector as people are struck by fear and anxiety in coming to terms with COVID-19 infections, with no end in sight. As a result of the virus, the need for personal protective equipment (PPE), sanitizers, and masks has increased astronomically since the outbreak of COVID-19. To satisfy the demand for this essential, many businesses have outsourced production to third-party businesses because of a shortage of sufficient production capabilities. This leads to severe problems of low-quality standards and falling short of guidelines for hygienic compliance [42].

According to Kalla *et al*. [42], there will be a huge demand for medical supplies and vaccines after the slowing down of infections will present opportunities for small and micro manufacturers to produce those vital supplies. The traditional slow and tedious business styles will give way to a decentralized integrative, vigorous monitoring network to regulate production. IoT ensures that quality measurements are obtained throughout the production process, including sourcing raw materials, production, storage, logistics and so on. The deployment of blockchain nodes in production sites is designed to link master production systems. Hence, this ensures a record of all product information that is secure and unchallengeable. Control audits and noncompliance monitoring are features of smart contracts as medicines and vaccines have the potential for universal production aided by blockchain-enabled cloud-controlled production ecosystems. These decentralized production environments prove that smart contracts may become handy in managing royalties and intellectual property rights.

8.6. Transportation

As the world contends with the impact of the recent outbreak of the pandemic, countries have acted swiftly in the face governments' control measures, consequently leading to a severe reduction of transportation of goods, *i.e.,* land, air and sea modes, affecting services that depend entirely on transports and migration of labour within the local and foreign markets. As a result of social distancing measures, less workers are available, disrupting transport services and restrictions to minimize virus transmission domestically and internationally. These factors cause disruptions in food supply chain logistics, straining the shipment of food and agricultural inputs, which threatens food security and nutrition, particularly for the vulnerable.

Transportation and supply chain administration are considered spheres where blockchain is a good fit for several reasons. From the outset, *i.e.,* the lifecycle of the product, through the value chain (from production to consumption), data produced is documented as a transaction, thus creating a permanent history of the particular product. Considering other things, blockchain technology effectively contributes to the (a) recovery of assets (from product to container) as it passes through the supply chain nodes, (b) tracking orders, receipts, invoices, payments and other necessary documents, and (c) tracking digital assets (such as warranties, certifications, copyrights, licenses, serial numbers, bar codes) parallel with physical as- sets. Moreover, blockchain's decentralized nature can contribute to information sharing about the production process, delivery, maintenance, and all defective products between producers and customers, ushering in exciting modalities of cooperation in a complex assembly line. The implementation of blockchain curtails encounters such as delays in delivery, loss of paperwork, unknown source of goods, errors, *etc* [43].

9. CHALLENGES OF IMPLEMENTING BLOCK CHAIN TECHNOLOGY

The goal of this section is to highlight the challenges of implementing blockchain technology in business as the COVID-19 pandemic continues to rage on despite spirited efforts by both governments and businesses to contain and limit its impact. Despite the vast potential of blockchain technology, there appear to be few barriers to its widespread adoption note mentioning. Blockchain has been instrumental in addressing security concerns, yet challenges still persist. Some of these challenges highlighted by Meva *et al*. [44] are described here;

9.1. Scalability

Block chain's tremendous development in size has been due to the increase in volume in terms of usage and the upsurge in daily transactions. As a result of the increase, the validation of these transactions is deposited into nodes acting as data warehouses. Thus, when a transaction occurs, the validation process for the source precedes that of the transactions. The limit of the block and waiting time necessary for creating a different block greatly affect the instantaneous dispensation of transactions in real-time for use. On a few occasions, the block size hampers the processing of transactions [45]. According to Fenech *et al*. [13], 60% of managers believe that complexities experienced in blockchain implementation are because of scalability problems. It has been [46] concurred that both known blockchain applications, Ethereum and Bitcoin, had 20 and 7 transactions per second, respectively, than Visa Inc's unrivaled efficiency of 4, 000 transactions per second [47].

9.2. Privacy Leakage

The major disadvantage of blockchain technology is the leaking of transaction privacy. Since users on the network have access to the balances and information of other users. This recommends anonymity and blending solutions to reduce privacy issues [48].

9.3. Selfish Mining

The major challenge of blockchain is the mining of blocks on the network resulting in cheating. Despite the attempts at tackling this issue, miners continue to mine in secret without being active on the network. As a result, legal miners of the blocks spend time and resources only for private miners to benefit from this blockchain mining [48].

9.4. Personal Identifiable Information (PII)

Blockchain accords users with an ideal distributed database used for users' identifiable information, which provides confirmation on the network pointing to offsite users' identifiable information bank where transaction details can be accessed. According to Elmaghraby *et al*. [49], the focus of maintaining the privacy of PII is to ensure secure communication and location perspectives.

9.5. Security

Security in blockchain refers to maintaining the integrity, availability and confidentiality of the network. However, integrity and confidentiality are difficult to maintain in distributed databases, while availability is encouraged by the replication feature of the network. Blockchain experiences almost 51% of attacks which poses a threat to the security and privacy of users giving full access and control of the network to a single miner. Preventing DDoS attacks, Trojans, and viruses is also a major struggle [35, 50].

9.6. Fork Problems

The common problem faced by distributed networks is fork problems. The two common types of fork problems are soft fork and hard fork. Hard fork problems surface when there are incompatibility issues between new and older versions of the network render the older version use-less, creating two chains. On the other hand, incompatibility issues remain, but the new and older versions operate independently in the chain called soft forks. Soft forks ignore all changes in version and rules and maintain high levels of constancy and success [49].

9.7. Time Confirmation

Delays in processing confirmation is a feature of blockchain technology where Bitcoin takes an hour while conventional transactions clock 3 hours maximum. However, this is very slow compared to the lightning network's imminent arrival.

9.8. Regulation Problems

Regulation policies and rules differ from country to country, making control of reserve banks feeble with respect to the country’s economic policy and the amounts transacted through blockchain. This calls for research and formulation of strategies and policies.

9.9. Integrated Cost

Migrating from an old system to blockchain technology incurs high costs in time and monetary terms. The infrastructural changes are necessary due to this new technology's anticipated monetary benefits.

9.10. Energy Consumption

The proof-of-work (PoW) system used to validate transactions entails extremely complicated mathematical calculations and energy to power up computers to perform this mandate. The rate of energy consumption of this magnitude causes businesses [36] to uncover new sources of energy or other sustainable business areas.

9.11. Public Perception

Blockchain is a revolutionary technology forecasted to transform the industry, however, the lack of awareness and knowledge in the public domain about its decentralized ledger system restricts its progress. All people know about blockchain is bitcoin and the cryptocurrencies, negatively associating currency with money laundering, the black market and other illicit activities. Greater awareness is paramount in dispelling negative connotations concerning Bitcoin and blockchain.

9.12. Technical Maturity

Due to blockchain's immaturity and newness to the market, coerces it to be prone to important issues, including capability, network breakdowns, new viruses and use by inexperienced publics, which pose a threat to its wider adoption.

9.13. Integration Barriers

Integrating different systems into a single system hinders blockchain from delivering viable solutions and requires overhauling designs to match this integration. Decisions have to be taken on which system is compatible with blockchain because different systems use varied templates of data and models for keeping information. This allows these systems to function independently and produce data for objectives.

10. FACTORS THAT ENCOURAGE ADOPTION OF BLOCK CHAIN TECHNOLOGY

This section identifies the summarized and synthesized key enablers of blockchain technology mentioned by Kamble *et al*. [51] that drive adoption of blockchain by organizations. The critical factors that drive the adoption of blockchain technology are discussed below;

10.1. Anonymity and Privacy

Blockchain's privacy-preserving structure ensures an impenetrable security system that allows information confidentiality and privacy through positioning of cryptographic individual key through ring signatures that provide confirmation, authorization and anonymity that guarantees usages. The signature acts as an authentication individual key that warrants individual key investor to match peculiar public keys privately. Blockchain ascertains the security of its users without revealing their identities.

10.2. Auditability

The blockchain as a system is auditable, trustworthy, and tamper-resistant and self-managed that eliminates human and machine errors and securing database of reviews making the network available for users in compliance with auditable and trustworthy standards. Accountability in supply chain greatly improves as blockchain becomes dependable and provides accurate data. Therefore, blockchain technology establishes authority for trading in- formation and records resulting in accountability and effectiveness.

10.3. Decentralized Database

The decentralized database provides an added advantage that allows communication within the distributed system. Data for communication is spread throughout the network in computer nodes which allows for trust among users to increase.

10.4. Immutability

Immutability alludes to the incredible idea that despite of innovation and change taking place, a thing remains constant or unchanged. This feature of blockchain technology creates a historical record of transaction easily traceable when required and reinforces network security protocols from manipulation, fraud and cyber-crimes.

10.5. Improved Risk Management

A large number of risks eventuate in business as a result of late payments, careless asset control and information exposure. With blockchain's decentralized network, payment is instantaneously made and delays caused by intermediaries and parties are eliminated completely resulting in reduced margin or collateral surpluses for new investment portfolios. Thus, deploying blockchain fast tracks investments avoiding longer process which will lead to delays.

10.6. Provenance

Provenance permits blockchain to get full value of goods from the source which creates a unique signature for individual products and tracing back to the source in the value network. This happens as digital indications such as tokens are attached on essential capital and in every stage of the value chain. As the essential assets travels from one client to the next, the asset's token is reallocated also in the blockchain. This paves way for connectivity and data accountability in tracking assets.

10.7. Reduced Transaction Costs

Blockchain's distributed ledger, cryptographic name protection and eradication of intermediation greatly contribute to reducing the costs of transactions. In comparison with traditional practices, overhead expenses are enormously reduced. As a result, smart contract drive transaction costs down significantly.

10.8. Reduced Settlement Lead Times

The significant reduction of delays and resolve lead-time issues narrow down the transactional lead times as blockchain is introduced with the aim to consolidate or delete duplicated steps in the post-trade settlement. Data stored in the network is used to improve efficiency and transaction lead times.

10.9. Secured Database

The distinctive characteristic of blockchain technology is secured database which deploys asymmetrical cryptography and exchange authentication like hash and blocks, known also as mining. This ensures that manipulating a chain in the database is tougher to implement.

10.10. Shared Database

Blockchain permits users to share information by repeating, reproducing information and unlimited access to appropriate data that is stored in the database. This decentralized aspect of the network reduces compromises from dangerous attacks.

10.11. Smart Contracts

The smart contracts comprise the terms and conditions of users that are necessary for electronic supply chain and data exchange. The secured nature and wider application of blockchain networks facilitates the transfer of currency in the context of smart contract.

10.12. Traceability

Blockchain endows businesses with ability to trace transactions by collecting, distributing and transmitting accurate information with timestamp on all transactions to users in the network. Blockchain's features like guaranteed security and distributed ledger boosts trust in tracing goods, information and monetary resources in a transparent manner.

10.13. Transparency

The added advantage of blockchain technology is its ability of generating similar duplicates of the database at every node allowing up to date audit and review of information that makes the network transparent. This transparency of the network and procedures allows for sharing and accessibility of information by users in the network. This provides a challenge for blockchain to improve its reputation and avoid fraudulent action paving the way for heightened authenticity and transparency compared to undistributed supply chain.

11. DISCUSSION

The following section outlines the broader context and assumptions about blockchain on limiting the impact of COVID 19 and identifies the challenges and enablers in the adoption of the blockchain technology in dealing with the impacts of COVID 19 and discussing a way forward as the world comes to terms with the disastrous realization of the deadly out- comes of the pandemic. COVID 19 has impacted and affected business, governments and people causing major chaos and confusion as governments seek to provide answers as the economy spirals downward.

The practical application of blockchain in fighting the pandemic focused on important areas used to predict and prevent the spread of COVID 19. Currently, the health system and government agencies lack the capacity of state-of-the-art surveillance systems capable of providing crucial information about the outbreak and the mobility of patients, However, block-chain offers the technology and application necessary to prevent the spread of the virus by using connected nodes through a reliable network availing information for real time decision making. As the cases of COVID 19 patients rise, authorities seek viable options that can effectively counter the rise of the pandemic. Therefore, blockchain enables treatment by tracking the patients as the live among communities, track donations to ensure that finance and resource are exhausted in the efforts of fighting COVID 19, manage the current perilous times by providing information and alerting authorities of cases and making recommendations on limiting the spread and securing supply chains so vital medical supplies reach health professionals and infected patients. Blockchain is paving a new direction on how it can contain the virus by finding a balance between selective information sharing and safeguarding sensitive patient's information heading into the future. This allows for mobile phone tracking while assuring privacy of patients.

The impact of COVID 19 on various sectors and economy has been extensive which brought previously lucrative industries to grinding halt as the virus reaped through important sectors. Consequently, schools were forced into closure, business were advised to downsize their operations, agricultural products were scarce on the market as seeds and farming chemicals could not reach farmers as countries began closing their borders, banking and finance sector was reduced to facilitating international wire transfers and electronic banking with no customers came in, manufacturing industries were reduced to half their size with small producer and micro manufacturers closing business and flow of transportation and logistical services dried up as international travels were banned affecting delivery of important commodities central the fight against the pandemic. In the midst of the uncertainty and anxiety, blockchain creates a system whereby students and teachers are connected through a decentralized system allowing students to access notes and education materials. Through blockchain businesses are required to form networks by seeking reliable partners in supply chain for better and added productive blockchain acceptance by persuading, encouraging and seeking new ways of attracting partners to join a co-operative of business so that the flow of goods and services is less disruptive. Two areas of concern which blockchain address is agriculture and food supply chain where producers and customers are brought together in a virtual reality where numerous trusted players are interlinked through a dependable and secure network focusing on the distribution of food and maintaining effective supply chain. With manufacturing industries blockchain aims to create a system that is integrative, robust, and collaborative to ease and manage the production process that ensures efficient system of sourcing materials, manufacturing, warehousing and logistics needs. Deploying blockchain nodes in the manufacturing process links the system to the master production line eliminating delays and stoppages.

Blockchain has gained tremendous support overtime due to vastly inherent potentials but certain hurdles are needed to be overcome in order for adoption and full realization. Business and governments are drawn to block-chain and to its guaranteed potentials but there are challenges that need to be reduced or to a certain extent eradicated before its widespread adoption. Of the many issues, few critical ones are discussed such as scalability is- sues need to be addressed by improving the processing times of transaction from seven per second to over thousand per second which increases productivity and eliminates delays and stoppages. In the current information age, privacy and security of identity and information are considered paramount. People are hesitant and sceptical in adopting blockchain in fear that their personal information will be publicly displayed since blockchain is a network of connected nodes in a decentralized system where data is accessible by users. Another reason is the time consume to confirm a transaction which puts blockchain on the downward scale. Blockchain still has the potential to reduce confirmation time from three to four days to a mere hour. Blockchain technology is improving by firstly addressing the challenges by converting them to opportunities for improvement.

12. IMPLICATION OF THIS STUDY FOR ACADEMICIANS, POLICY MAKERS

The advantage of providing a distributed network greatly benefits educational institutions in accessing and distributing educational achievement with other user institutions. Storing personal and institutional accomplishments in a secured network system is a feature of a secured educational blockchain database. A database of such reputation will connect scholars and academics allowing easy access and sharing of materials and data pertaining to their achievements and accomplishments. This involves commitment and deliberate preparations in order to accomplish a widely recognized and acceptable practice that wins over the trust of public. However, the already existing management setbacks will trade the reputation of educational achievements resulting in edition of new blocks in the system. Practical and ideological issues persist posing a challenge in converting academic credentials into an acceptable currency. The single most controversial issue in academic circles is establishing a rate of exchange of reputation into currency which will be used to trade.

The pivotal concern of the system is further embedded in commodifying education-where it allows students to browse, purchase and use academic products without consideration for the intellectual value associated with the materials. However, building a better and strong reputation in academia has been the cornerstone of blockchain technology. This reputational currency of blockchain downgrades knowledge in the marketplace, calling for research and innovation of better ideas to distribute in the network for accessibility.

CONCLUSION

This research sought to understand the use of blockchain in limiting the rapid spread of COVID-19 by highlighting challenges hindering effective adoption. For adoption to take place, the challenges need to be addressed so that the implementation of blockchain, with the intent of limiting the spread of the pandemic, may be achieved. The study highlighted the practical application of blockchain to minimize the potency of the virus. This suggested measures to predict and prevent the spread of the virus, the treatment aspect and the future direction and prospect of blockchain. Next, blockchain's ability to reduce the impact of COVID-19 and how industries affected by the virus revived into formidable economic sectors vital for business and people is crucial. Perhaps most significant are the challenges faced by businesses and people alike in the implementation process of blockchain. With the persistence of the challenges, implementation would be hard, so the organizations' task is to address these issues. Paramount to the concerns are privacy and security issues that require attention. Moreover, the enablers of adoption on a larger scale make blockchain attractive and overshadow the difficulties in all new technological trends. This enables quash of skepticism and enable blockchain to be adopted in different sectors and industry.

LIMITATIONS AND SCOPE OF FUTURE WORK

All studies abound by certain limitations, and this study is no exception. Firstly, through this study, certain key attributes of blockchain were identified in order to effectively fight the virus. However, the challenges are that the virus is active and continues to claim lives and affect businesses, so the enablers and challenges identified now may change in the future. Secondly, along with the process of discovering the abilities and benefits associated with blockchain to fight COVID-19, the lack of empirical study greatly clouded the discussion rendering the study potential bias. It is good to emphasize that this study did not intend to propose medically approved solutions to limit the virus but only proposes the benefits that are also proven in early literature. Furthermore, the ongoing rise of COVID-19 cases worldwide has put a strain on health systems and authorities to provide relief by tracking and tracing patients reintroduced into society. Finally, issues of implementation continue to associate with blockchain making early adoption a challenge as people become skeptical and hesitant in the adoption process. A future comprehensive study into the gaps in blockchain technology can be advocated in the future by studying the challenges for implementation and enablers of adoption separately or individually to understand their effects. Furthermore, blockchain impacts various sectors of the economy and can also be considered independently, focusing on an area chosen for study. Thus, the logistical and supply chain aspects can be used to directly examine the common link that blockchain technology and supply chain activities share and blockchain's efforts to predict and prevent the spread of the pandemic.

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CHAPTER 9

Blockchain Technology: The Future of Decentralized Applications

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Abstract: The advances in computer science & technology have gone to new levels. The process of computational technology and ubiquitous computing is expanding exponentially daily. The computer system & its related inventions have become an integral part of our lives. People & services are migrating towards clouds and decentralized platforms. Nowadays, commerce & finance on the Internet rely on trusted third parties like banks to process electronic online payments. Though it fits well with most transactions, it still suffers from the inherent weakness of trust-based models. Blockchain Technology- the technology behind the cryptocurrency Bitcoin is buzzing a lot nowadays to invent and witness the future of data storage & processing in an efficient, decentralized, tamper-proof, and peer-to-peer (P2P) network. Nowadays, the use of blockchain is not confined to crypto-currencies only. This revolutionary technology is drawing its impact & use in many fields and applications. Primarily, a blockchain network can be used for storing, sharing & transparently transferring data without the intervention of third parties and other intermediaries. In a blockchain network, blocks are added using a consensus algorithm & connected cryptographically. Hence it is merely impossible to delete and modify the content of blocks stored in a blockchain network. Other advantages of this technology include consistency, security, transparency, distributed ledger, decentralized network, *etc*. This paper systematically reviews the work accomplished by many researchers for the past 11 years. Specifically, the application & impact of blockchain technology in various fields like crypto-currencies, the health sector, e-governance, banking, finance, and food supply management systems have been discussed, and a projection of a novel application of the same technology has been proposed.

Keywords: Blockchain, P2P network, Distributed ledger, Decentralized, Consensus, Systematic review.

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1. INTRODUCTION

Most of today's transactions over the Internet are routed through third-party systems, which indeed are based upon some trust-based model, *i.e.*, centralized (Fig. (**1**) depicts a centralized and decentralized system). Blockchain technology eliminates all such intermediaries in a transaction. It was first used by researchers in 1991 to time stamp documents. But the emergence of Bitcoin [1, 2] in 2009, again revived by Satoshi Nakamoto [3], paved a new direction for the design of distributed ledger in a peer-to-peer(P2P) network which was cryptographic based and eliminated all intermediaries in a transaction involving bitcoin cryptocurrency. The foundation of bitcoin technology was laid through the revolutionary blockchain technology. The major credentials of blockchain technology are a miniaturization of third-party's involvement, blocks are cryptographically linked, which makes it almost impossible to delete or change the content of a block once it is added to the blockchain network, use of decentralized & distributed P2P network, *etc*. The development of Bitcoin in 2009 by Satoshi Nakamoto, an anonymous identity, laid down the foundation of blockchain technology with few limitations [4]. Firstly, the transaction time for adding a new block to the blockchain network is about 10 minutes. Secondly, it is not turning complete [5, 6]. And more often, huge computation power & electric energy is required for mining blocks, where mining is the process used to add a block to a blockchain network. In 2013, Ethereum Whitepaper [7] was published by Vitalik Buterin. Ethereum network's block time is about 20 seconds. In an Ethereum network that uses blockchain technology, developers can write a program using *smart contracts* [8]. Then blockchain technology was intended for *DApp, a* Decentralized application & making it usable for the industry. Fig. (**2**) depicts the evolution of blockchain technology, starting from its application to Bitcoin to industry-usable applications.

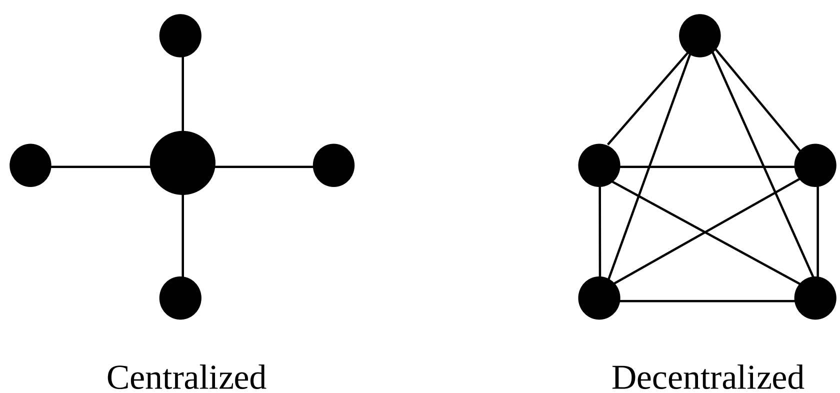

Fig. (1). Centralized & decentralized Network.

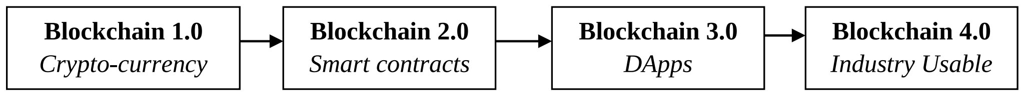

Fig. (2). Evolution of Blockchain.

The main focus of this technology is to decentralize the network applications by maintaining a distributed ledger and removing all trusted third parties, ensuring data integrity & security.

This paper highlights & discusses the primitives of blockchain technology with different dimensions of its applications & utilities, especially to cryptocurrency. Also, the areas like the health sector, IoT, and supply chain management where blockchain application looks significant are briefly introduced. Finally, a few possible areas where blockchain can be applied are listed.

2. BACKGROUND

In this section, the fundamentals & prerequisites of blockchain technology are discussed.

2.1. What is Blockchain?

Blockchain can be defined as a group of blocks that are linked together cryptographically, where each block holds the actual transactional data. The main motive of this technique is to create a growing list of records that are linked securely & immutable. It is intended to work in a decentralized manner, where any computer can add blocks to the blockchain network, confirming some consensus mechanism. It can be used for transferring items, like money, contracts, properties, *etc*., without the involvement of third-party intermediaries like banks or any other financial or non-financial institutions. It is very difficult to modify the data once they are recorded inside a blockchain network. Formally, a blockchain is a linked list of blocks, where each block is connected to its previous block as shown in Fig. (**3**) and maintains the following properties:

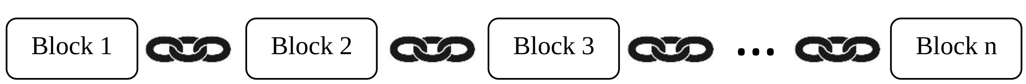

Fig. (3). Blockchain as Linked list.

(i) Replicated

(ii) Distributed

(iii) Consistency maintained by consensus algorithm

(iv) Blocks are cryptographically linked and immutable

(v) Integrity is maintained cryptographically

2.2. Blockchain Variants

Different variants of blockchain are:

2.2.1. Public

A public blockchain is a chain that anyone can access and participate in the mining process. This system rewards incentives to the miners after successful mining. The consensus algorithm is vital in a public blockchain system, as the network is open to all. Through consensus, requested transactions are added permanently to the blockchain network after successful mining.

2.2.2. Private

A private blockchain is a chain where participants are selected and given access to the chain by a central authority or organization that creates the blockchain. In this blockchain, no one can contribute and participate in mining transactions.

2.2.3. Consortium

A consortium blockchain is a chain where participants are selected and given access to the chain by restricted or selected groups. The network is controlled by some pre-authorized computers. Mainly this type of blockchain system is useful for handling transactions at the inter-organizational level.

Table. 1 depicts the comparison of the characteristics of different variants of blockchain.

Table 1. Comparison of the characteristics of different variants of blockchain.

Properties↓ Type →	**Public**	**Private**	**Consortium**
Access	Anyone	Single organization	Multiple selected organizations
Participants	Permission less Anonymous	Permissioned Known identities	Permissioned Known identities

(Table 1) cont.....

Properties↓ Type →	**Public**	**Private**	**Consortium**
Security	Consensus Mechanism Proof of Work/ Proof of stake	Pre-approved participants Voting/multi-party consensus	Pre-approved participants Voting/multi-party consensus
Transaction Speed	Slow	Lighter & Faster	Lighter & Faster

2.3. Blockchain Architecture

A Blockchain is a chain of blocks that are time-stamped & linked using the cryptographic hash value. Individual blocks block has mainly four components which are shown in Fig. (**4**).

1) *Block size-* which contains the size of the block.

2) *Block header contains* vital information about the identity of the block. The Block header is an important part of the block structure and is further divided into various fields.

3) *Transaction counter* is a simple incremental counter of several transactions in a particular block.

4) *Transaction-* contains the transaction information.

The first block in the chain is called the *Genesis block* [7]. Each new block in the chain is linked to the previous block.

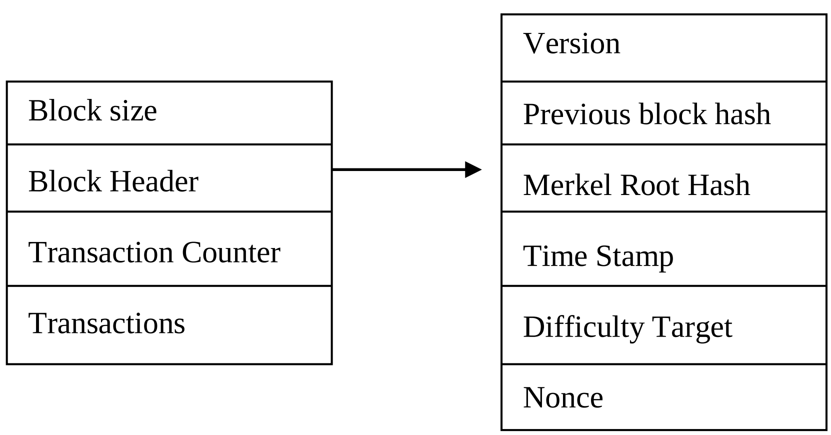

Fig. (4). A Block structure with fields of the block header.

A block also has a hash value. A hash is a one-way function which means the hash algorithm will take some data as input and give some random string of numbers as output. This is called a one-way function, which cannot be reversed like a normal cryptographic function. The Hash of a block is unique, and it identifies a block in a blockchain network. The use of the hash technique makes the content of blocks unchangeable once they are added to the blockchain list. It is because if a block changes its content, then the corresponding hash will change, which will make it difficult to find a position in the blockchain network. Each Block in a blockchain network has three components- *data*, *hash*, and *hash of the previous block*.

Also, a blockchain system does not rely on the rules of a centralized server or entity, where the central device has the power of deletion, addition, update, *etc*., if not handled or managed properly. A blockchain system is, therefore, secure in this regard by itself by following decentralized property. It uses a distributed network where anyone may join, considering a public blockchain system. A participant acquires the full copy of the blockchain once he enters the system (shown in Fig. (**5**)).

Fig. (5). Distributed P2P network.

2.4. Cryptographic Primitives

Cryptography plays a vital role in the blockchain network. In a blockchain network, blocks are linked cryptographically, which makes it impossible to change the content of a block in the blockchain network. Each block is connected to its previous block by holding the hash of its previous block. The hash function and public key cryptography play a very important role in the blockchain. A Hash function is a message digest function, which takes variable length data and produces an output of fixed length. The major credentials of the hash function are one-way property, unique, and the avalanche effect. The one-way property guarantees that it is impossible to get back the original data by knowing its hash value and function. Uniqueness confirms that, for every distinct message or data, the hash function will result in a unique output. The Avalanche effect states that a minor change in the input data will bring a huge change in the hash output. Various hash functions used in blockchain are SHA 256, SHA 512, SHA 3, *etc*. Therefore, the hash function acts as an important primitive in blockchain technology. Public key cryptography or asymmetric cryptography is also used in blockchain for digital signatures, message authentication, *etc*. In this cryptography, two keys (*private key* and *public key*) are used for the encryption and decryption process, which does not seek sharing of keys through insecure channels. ECDSA (*Elliptic Curve Cryptography Digital Signature Algorithm*) is an efficient public key digital signature algorithm used by many blockchain-based cryptocurrencies.

2.5. Merkle Tree

Merkle trees are a very important part of the blockchain and are related to the hashing algorithms. The Merkle tree helps in the validation of transactions. A Merkle tree takes a bunch of data input and confirms its validity. Let's understand it with the help of Fig. (**6**).

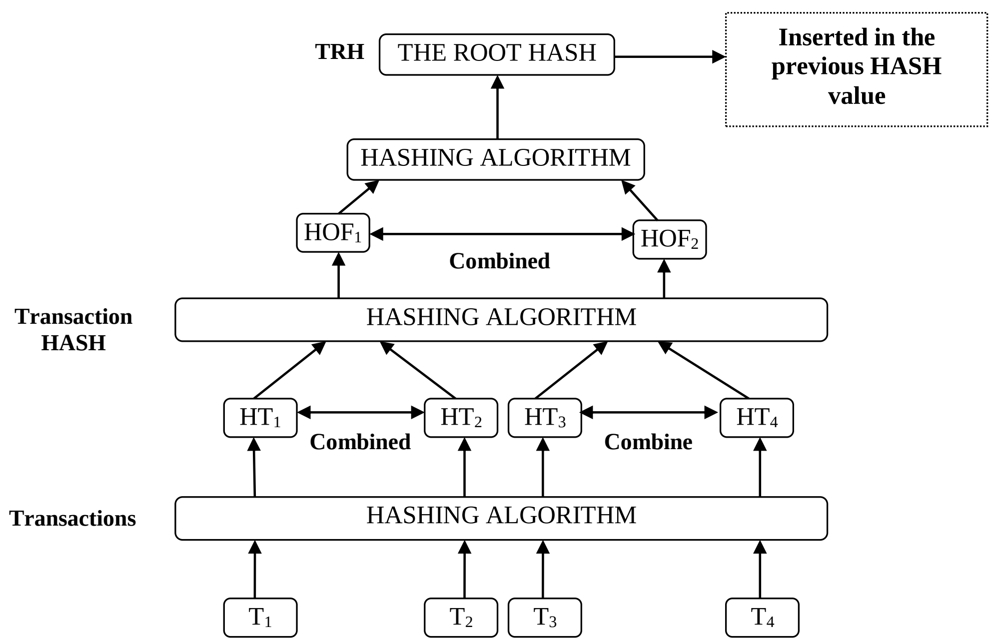

Fig. (6). Merkle Tree.

Imagine four transactions, T1, T2, T3 & T4, in a block. Note that although there are thousands of transactions that happen inside a block, we took four to understand the concept clearly. All these transactions are input into a hashing algorithm to get four individual transaction hashes HT1, HT2, HT3 & HT4. Hash HT1 is combined with HT_2 and HT_3 with HT_4 and finally again fed into the hashing algorithm.

The output from the second hashing algorithm, we get Hashes of Hashes, let us call it HOF1 & HOF2, are combined to pipe in for the last time to the hashing algorithm generating an output TRH which is the Root Hash. This root Hash value is inserted in the previous Hash value of the next block.

Every block has to go through this Merkle tree process to provide the previous value of the next block in the blockchain. In this way, this Merkle tree provides a secure and tamper-proof system for blockchain. If, at any stage, someone tampers or changes the data of a block, then the whole output will change, and a flag will be raised by the system for an invalid value.

3. CONSENSUS ALGORITHM

A consensus algorithm is a set of rules required to achieve a single data value or decision point in a distributed system, where anyone may initiate a transaction. After a transaction is initiated for its addition to the blockchain network, a block is created for the requested transaction; it is then validated by the miners using some consensus mechanism and finally added permanently to the blockchain network. Various consensus algorithms work on different principles, some of which are outlined below.

3.1. Proof of Work

In the Proof of Work (PoW) consensus, the mining challenge is open to all. All the miners compete with each other to add the next block to the blockchain network. A fixed reward (termed an incentive) is given to the miner who finds the solution first. The node with more computational power usually wins the race. Bitcoin uses the PoW algorithm. It was the first decentralized consensus protocol proposed by Nakamoto to ensure consistency and security in the Bitcoin network. For a given transaction, multiple valid blocks may be generated by the miners. In such circumstances, the nodes closer to the miners accept the block the forward the same to other neighbors. Finally, at a later stage, conflict can be avoided by acquiring the longest version of the chain, which is added permanently to the blockchain. In PoW, generally, nodes with higher computation power win the mining challenge. This leads to 51% of attacks on the bitcoin network. If a node acquires 51% control of the network, then the chances of integrity violation are there. Moreover, this mode of consensus leads to more electrical power consumption.

3.2. Proof of Stake

PoW suffers from excessive power consumption and seeks nodes with higher computation power. Proof of stake (PoS) was proposed to overcome this. It is a common alternative to PoW. Here, the validators are chosen based on the fraction of coins they own in the system. The nodes with more coins have more chance to be selected than the node with a lesser number of coins. In PoS the reward is a transaction fee; new coins are not created for paying the validators. Presently, Blackcoin, NXT, and Peercoin blockchains use the PoS algorithm. A 51% attack is generally considered more expensive in the case of a proof of stake chain. However, many oppose it ideologically as it gives the 'rich' control over the blockchain.

Also, there is a problem of 'nothing-at-stake' where a malicious miner loses nothing by betting on two different forks of the chain.

3.3. Byzantine Fault Tolerance Algorithm

The Byzantine fault tolerance (PBFT) algorithm was proposed to solve the Byzantine General's Problem, which was meant to conduct a successful attack on a rival city by the Byzantine army [9, 10]. According to this algorithm, all must work with the same plan and attack simultaneously on the rivalry to win the battle. As a small number of finks could damage the plan, the loyal generals should stick to the decided plan, no matter what the finks do. In the blockchain network, PBFT works to achieve consensus among all the participating nodes. All the nodes maintain their current state. When a new message is received, the current state and the message are fed together for computations to help the node to reach a decision. This decision is then broadcast to the network. A majority of the decisions determine the consensus for the network. Hyperledger [11], which is working on developing consortium blockchain systems for businesses, utilizes PBFT as its underlying consensus mechanism. It should be pointed out that many of the new developments in blockchain stem from prior work on distributed databases [12 - 14].

4. MINING & INCENTIVES

Mining and miners are very crucial ingredients of a blockchain network. Mining is the technique of validating and adding blocks in a blockchain network. The nodes responsible for mining blocks into the blockchain network are termed miners. Generally, miners are the nodes with greater computation power, stakes, *etc*. A miner receives some cryptocurrency as a reward when mining is successful. In contrast, miners may also get penalties when their blocks are not included in the blockchain.

5. REVIEW OF THE APPLICATION OF BLOCKCHAIN

Initially, blockchain technology was meant for time-stamping digital documents & transacting cryptocurrencies like bitcoins, Ethereum, *etc*. But nowadays horizon of its application is increasing. A few prominent application areas of blockchain are reviewed systematically in this section.

5.1. Cryptocurrency

The block chain technology evolved with the introduction of time stamp server by Stuart Haber and W. Scott Stornetta in the year 1991. They proposed a computationally practical procedure to design a trusted time-stamping service (TSS) [15] to time-stamp digital documents, which makes it infeasible to back-date or forward-date the documents. TSS mainly used hash functions & digital signatures to safeguard documents while transmitting them. According to Scott *et al.,* hash of the document has to be time-stamped instead of time-stamping the original document. Collision-free hash functions are a family of functions h: $\{0,1\}^* \rightarrow \{0,1\}^l$ which compress bit-strings of arbitrary length to bit-strings of a fixed length l, with the following properties:

1) The functions h are easy to compute.

2) It is computationally infeasible, given one of these functions h, to find a pair of distinct strings x, x' such that h(x) = h(x').

The use of the hash function was attributed to the reduction of bandwidth & storage requirements. TSS also used digital signatures proposed by Rabin [16] and by Diffie and Hellman [17] to ensure the security & validity of documents.

In 2009, an anonymous programmer under the alias Satoshi Nakamato [2] proposed a peer-to-peer version of an electronic cash system that allowed the transfer of the first cryptocurrency called Bitcoin [1] without the involvement of any financial institution. The underlying architecture of Bitcoin used by Satoshi Nakamoto was a Blockchain network. He used proof of work (poW) consensus to add blocks in a Blockchain network & avoid double spending problems. PoW also ensures it is computationally impractical for an attacker to change the content of a block if honest nodes control a majority of CPU power. However, Bitcoin suffered from these limitations. Firstly, mining blocks into a Blockchain network requires a long time. Secondly, computation power & electric power consumption was also very high. Nakamoto also solved the problem of double spending in the Bitcoin network. Fig. (**7**) depicts the real deal of a bit coin transaction. Figs. (**8**, **9**, and **10**) depict the transaction's metadata, inputs, and output, respectively.

Fig. (7). A Bitcoin transaction.

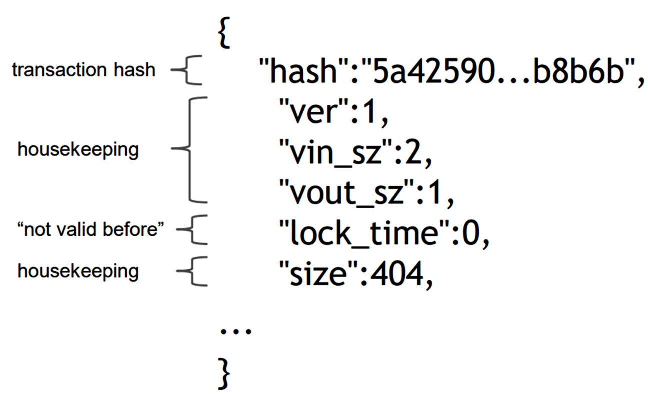

Fig. (8). Transaction metadata.

Fig. (9). Transaction inputs.

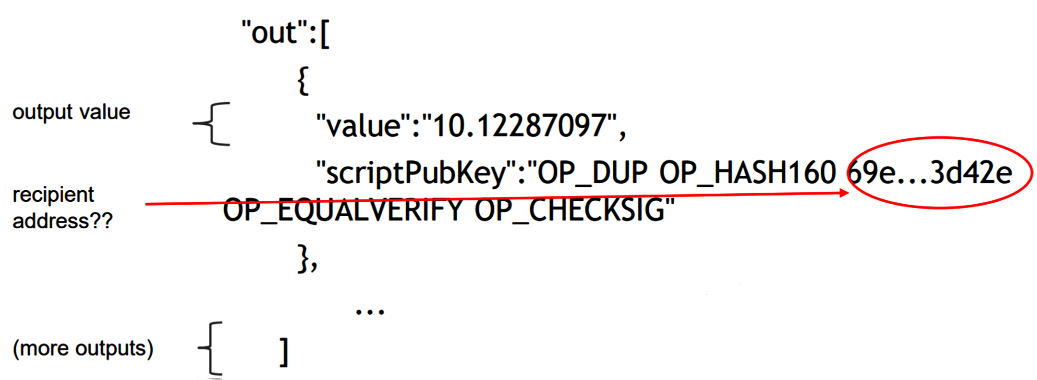

Fig. (10). Transaction outputs.

Lite coin [18] was developed by Charlie Lee, who developed this cryptocurrency in 2011 while working for Google. It is currently the fourth biggest cryptocurrency after Bitcoin, Ethereum, and DASH. Lite coin's primary focus is on adapting this coin by increasing exchanges, merchants, and users. Lite coin can be considered a lite and improved version of Bitcoin with improved performance. Lite coin transactions usually take 2.5 minutes to complete, much less than Bitcoin. This means block processing is very fast in Lite Coin, which helps in better processing. Also, the double spending attack is prominent in Bitcoin because of more processing time. Lite coin requires around 10 times less computation power than Bitcoin. Bitcoin uses SHA 256 for hashing, which means the development cost for the ASIC boards will be quite less compared to Lite coin, which uses a complicated script algorithm. Lite coins can be mined with the help of GPU or 3D cards.

Ripple [19] is another popular cryptocurrency that works on a different platform than blockchain technology. It has its ripple network in which mining is not possible. It is a consensus-based network developed to be used by big corporations, banks, and other financial institutions. Multinational corporations can use the ripple network for commodity trading or transfer funds or assets like gold, copper, diamond, *etc*. It is quite similar to a traditional monetary system. It is denoted by XRP.

In late 2013, Ethereum [20] was proposed by Vitalik Buterin through a white paper [4]. In the year 2016, hackers around the globe launched a month-long attack on the Ethereum network where hackers were able to access the 50-millio--dollar fund. After this incident, the core team of developers decided to change and modify its code, and in 2017 they hard-forked it to launch a new Ethereum. Simultaneously the developers have renamed the original Ethereum as "Ethereum classic" and the new hard-forked version as "Ethereum." The Ethereum classic is now "ETC," and Ethereum is "ETH." Fundamentally Ethereum classic is far superior in technology to primitive Bitcoin. The smart contracts in the Ethereum blocks can be implemented easily and provide a robust solution to various business problems. Another major advantage of the Ethereum blockchain is that it supports other applications to run on the blockchain platform other than cryptocurrencies. This essentially means that the developers can program a true decentralized, distributed application by using the Ethereum blockchain. Ethereum is coded in C++ and is a widely used and user-friendly programming language. Applications can be designed using faster time frames. Ethereum used proof of stake (PoS) consensus for mining blocks in the Blockchain network.

In 2018, a message circulated that Facebook, the social media giant, is developing its cryptocurrency. On June 18, 2019, Facebook released the white paper for the cryptocurrency Libra [21] to confirm the rumors. Table **2** depicts various cryptocurrencies with their consensus mechanism, advantages, disadvantages & values.

5.2. Blockchain in Health Sectors

The health industry is a huge market nowadays. The tools & techniques used in the health industry for past decades are quite redundant. Hospitals have adopted many automated smart machines for patient diagnosis. Patients are involved more nowadays in any medical diagnosis. Common challenges & Blockchain opportunities [22 - 25] are depicted in Table **3**.

Table 2. Major Cryptocurrencies.

Year	Crypto Currency	Consensus Mechanism	Advantage	Disadvantage	Value in Indian Currency (in Rs)
2009	Bitcoin	Proof of work	Solved double spending problem, security	Lack of scalability, slower block generation time, *etc*.	842978.26
2011	Litecoin	Proof of work	faster block generation & transaction confirmation time, security	absolute anonymity	3687.85
2012	Ripple	Method of confirmation	Reduction in the usage of computing power and minimizes network latency	Vulnerabilities, Capitalizes on a “Small World” Philosophy	18.67
2014	Ethereum	Proof of stake	The decentralized software platform, Smart Contracts	Many platforms	28206.62
2019	Libra	Byzantine Fault Tolerant	Scalability, flexibility, highly secure	Privacy and anonymity	3.773017

Table 3. Challenges in Healthcare & Blockchain Opportunities.

Challenges in Healthcare	Blockchain Opportunities
Access to the patient’s past medical history	Patient data can be maintained in a tampered proof & immutable distributed ledger.
Data security	Digital identity authorization to protect data.
Data consistency	Use of smart contacts with different permission labels to ensure data consistency.
Cost	Reduced transaction cost & time lag for data access by eliminating intermediaries.

A centralized government-owned Blockchain can be created and linked with an Aadhar number with medical records of each individual, including the prescriptions, tests conducted, and other vital details. Doctors, on the other hand, can update the outcome of their visit and diagnosis on the same blockchain ledger. Hospitals can update the admission status of the patients and the details of the treatment into the same blockchain. This blockchain can integrate all the health aspects of an individual. The patient will not have to carry his reports to every hospital during consolation. Doctors can log in to the system and can access all history and details of the patients easily. This will enable the first delivery of medical services to critical patients where entering an Aadhar card can give all information. One can move freely across the world and access all his reports whenever required. EHR (Electronic Health Record) and Medical Supply Chain Management Systems seem to be two promising areas of application of blockchain technology in the field of health care.

5.3. Supply Chain Management

The concept of blockchain can be used in supply chain operations [26]. It can help the warehouses track the location of the products in logistics operations and distributions. The sending and receiving nodes can update the status in the blockchain, which can be accessed by the end users or the consumers of the product. Consumers can access that blockchain over the network to find out the exact day and date of manufacturing of a particular product. In this way, more transparency and accountability could be enforced for the safety and awareness of the consumers.

5.4. Internet of Things (IoT)

IoT has stepped out from its infant stage in the past few years. Now it has become an indispensable ingredient of many macro & mini devices. But the access control is mostly centralized & hierarchical in many IoT devices. Blockchain-based IoT solutions [27 - 29] can be designed where data can be stored safely without any risk of modification.

6. CHALLENGES & FUTURE SCOPE

Despite much theoretical hype, blockchain suffers from many disadvantages. First is the scalability problem. When a transaction is initiated in a public blockchain network, the same has to be passed to all other nodes in the same network. The same copy of the blockchain will exist in every node in the blockchain network, which leads to greater storage at the individual node. Also, increasing the size of the block would delay the propagation of nodes. This can be reduced by decreasing the size of the block. Secondly, block generation time is more as compared to conventional database transactions. In a blockchain network, once a transaction is initiated, its corresponding block will be broadcasted to all other nodes. The block will be added permanently to the blockchain network if necessary consensus is achieved in the blockchain network. Another challenge faced in a blockchain network is energy and power consumption [30 - 33]. Nodes consume more electric power for the mining process. It is found that 1 bitcoin transaction would take 80,000 times the power consumed to process a credit card.

Starting with blockchain specific to cryptocurrencies only, the horizon of cryptocurrencies is increasing daily. Many robust decentralized applications can be developed using the basis of blockchain technology. It will work dominantly in the health sector, supply chain management system, and other decentralized applications. Smart contract programming code can transfer many assets digitally in a tampered-proof manner. The future of this technology seems promising, considering the inherent characteristics of the blockchain network.

7. PROPOSED AREA OF APPLICATION OF BLOCKCHAIN

7.1. Law and Order

All the court verdicts, judgments, and each session of the courts can be recorded and updated on a centralized law ministry blockchain. It can provide more streamlined governance. The uploaded judgments on the blockchain are foolproof systems that can reduce corruption and increase transparency.

7.2. Real Estate

Transactions are complex in a real estate business and operation. Many third parties, like brokers, institutions, and governments, are involved in the transfer of properties. Blockchain can be applied to maintain all historical transactions in the real estate business and operations. Middle man can be removed, and hence chances of threats to transactions can also be minimized. Blockchain technology binds every property of real estate digitally and transfers them securely without involving any middleman.

7.3. Refugee Database

In the case of refugee arrival, it has been observed that most of them arrive without proper documentation and academic credentials to the new countries. A centralized degree & certificate system based on the blockchain can ensure access to their education or academic credentials from anywhere in the world. It can help them get jobs based on their qualifications in the newly migrated country.

7.4. Education

Education is very important for our personal lives; the credentials earned are associated with us for a lifetime. We earned those credentials in elementary school, followed by high school, college, post-graduation, and in other various stages of our careers. We also get awards, recommendations, and certificates from various organizations for any kind of recognition and excellence in academics or at the workplace. These credentials or documents are very precious, and we often keep them in safe custody at our home or preferably in bank lockers. We can create a global network to track all these credentials of an individual worldwide powered by blockchain technology. As it is distributed, the major benefits of using this are availability, authentication, and validation. Also, this can stop the forgery of mark sheets and degrees.

7.5. Attendance Records

Similarly, attendance records can be updated on the blockchain automatically with device synchronization and can be accessed by organizations for a background check. For instance, employers can track punctuality at the office or institute.

CONCLUSION

In this paper, we have discussed the background of blockchain technology & different existing & proposed areas of application. The technology is mainly centered on a decentralized & immutable ledger maintained in a P2P network. Though technology is buzzing a lot in the industry, many more primitives of this technology are expected to come shortly. The main issue related to a blockchain network is mining cost, *i.e.*, the time required to add a block in a blockchain network.

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CHAPTER 10

Blockchain Distributed Ledger Technologies for Biomedical and Healthcare Applications

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Abstract: The distributed ledger technology in the healthcare sector has been reported to be very important in generating patient information for research, medication adherence, management of several bedside information about patients, pharmaceutical supply chain, and quality of care. Its application has been documented in the biomedical domain and blockchain technology such as custom, IOTA, NEM, Gcoin, JUICE, TenderMint, Multichain, Hyperledger Fabric, Ethereum, Bitcoin, as well as in data integrity, data auditing, data provenance, data versioning, access control and non-repudiation. Therefore, this chapter will give an overview based on the applications of Blockchain distributed ledger technologies for biomedical and healthcare systems.

Keywords: Blockchain, Biomedical, Distributed ledger, Healthcare sector, Patient.

1. INTRODUCTION

The advancement of technologies in healthcare sector has brought about several innovations in blockchain distributed ledger technology. Knowledge sharing

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about patient's information using technology can be useful in predictive models and advanced visualization of patients' conditions for diagnostic purposes. Blockchain distributed ledger technology serves as a complementary approach to digital medical platforms. Blockchain distributed ledger technology serves as a good platform for fast retrieval of patient's information due to the large amount of data generated from healthcare. Studies have revealed that many emerging applications from advanced technologies are beginning to form the basis of clinical trials, biomedical research and databases, medical insurance, and data protection. The potential benefits of distributed Ledger technology in the maintenance of health care data collection, medical transactions record for finance and clinical trials. Drosatos and Kaldoudi [1] reported that distributed ledger technology in the biomedical domain comprises of 1) blockchain technology like custom, IOTA, NEM, Gcoin, JUICE, TenderMint, Multichain, Hyperledger, Fabric, Ethereum, Bitcoin, 2) Maturity of the approach like evaluation, implementation, architecture, proposal, 3) Biomedical data like financial data, database queries, ambient temperature, transaction records, consent forms, persona records, clinical trial records, medical records, location and sensor data, 4) application areas such as biomedical database, clinical trials, health records, wearables, medicines insurance, mhealth and embedded, and 5) reason for using blockchain like data integrity, data auditing, data provenance, data versioning, access control and non-repudiation. Distributed Ledger Technology can utilize public and private identifiers *via* cryptography to protect patient's data, thereby suppressing non-compatibility. This system identifies and aggregates large amounts of data, like a data lake, to enhance decision-making, legislation, reporting, census and research. Distributed Ledger technology can be utilized for enhanced health records and management, provider directory, historical care data of patient ledgers, patient directory, improved insurance claim analysis, care plans, increased pharma/ health research, and ADT back office part. Also information such as global patient ID software, full-featured electronic health record systems, and public health data access cannot be operated with distributed ledger technology [2 - 9]. The chapter will give an overview of the applications of blockchain distributed ledger approaches for health care and biomedical systems.

2. ESSENTIAL ROLES OF BLOCKCHAIN DISTRIBUTED DATABASES FOR HEALTHCARE/ BIOMEDICAL APPLICATIONS

Currently, there has been a transition from an old healthcare system to modern healthcare systems such as Mobile health (telecommunications, wearable sensors and Internet of Things for healthcare delivery. Major shortcomings have always been security, transparency and privacy of medical data. Blockchain technology is one plausible way out due to its decentralization and immutability. Investments into blockchain tools were estimated to attain $400 million US in 2019. Roman-

Belmonte *et al*. [10], examined the advantage of blockchain technology in the medical field. It enables a secure and stable data set, which makes it possible for users to interact *via* transaction. It is also possible for clinical data to be operated without any compromise occurring to other data. Another major benefit of blockchain is decentralization and maintenance of the entire network. With blockchain technology, reliance on organizations for storage is required. Block code, apart from being open, can be used, modified and revised. The promising applications include research, electronic medical records, big medical data, medical service payment and legal medicine.

Zhang *et al*. [11], designed a background for evaluating the activity of blockchain enterprises holistically in the provision of value-added care through the extension of the balance scorecard evaluation. In the study, the balanced scorecard was extended. The framework evaluated the performance and appropriateness of blockchain initiatives in the medical system. Radanovic *et al*. [12], reported that the salutary advantage of blockchain technology lies in its decentralized database, which makes it capable of storing a registry of transactions and assets through a peer-to-peer computer system. Utilizations of blockchain technology include public and financial records, cryptocurrencies, digital contracts and technological ownership. The application includes science, medicine, scholarly property, and education and distribution chain management.

Kamel *et al*. [13], reviewed studies on blockchain technology. The specific advantage of blockchain technology includes cryptographic security, decentralization and immutability, and these features make the blockchain technology an influential contender in reconstructing the healthcare landscape worldwide. Blockchain technology is applied in the aspect of patient and healthcare givers' identities, handling health and pharmaceutical materials supply chains, research and data monetization, detection of health fraud, public health monitoring and surveillance, facilitation of open and public geo-tagged data, energization of multiple Internet of Things-connected autonomous technology such as drones, wearables, vehicles and augmentation of reality in the mapping of crisis and recovery scenarios. Despite its challenges, blockchain technologies are expected to become increasingly strong and powerful, especially when they are integrated with artificial intelligence in healthcare solutions.

Mackey *et al*. [14], reported that blockchain, shared transmitted digital ledger tools, offers better data security and management, demonstrating a tendency to improve healthcare. Blockchain is utilized in the optimization of stakeholders for the optimization of business processes, causing a reduction in costs, improvement in patient outcomes, enhancement of compliance, and enablement of better use of healthcare data.

The study conducted by Tan *et al*. [15], examined the relative relevance of blockchain tools to medical care. Blockchain tool is a means where patient data are shared. Promisingly, it functions as the basis for individualized patient treatment and precision. It helps strengthen the security of confidential patient data for cybercriminals. In the COVID-19 scenario, relative to telehealth, delivery of remote healthcare will be earned through blockchain platform. Smart contracts-borne blockchain systems may decrease international humanitarian support to low- and middle-income countries. In pharmaceutical companies, blockchain technology is devised to ensure supply chain provenance and improve service delivery to its members.

Petre *et al*. [16], noted that blockchain unites stakeholders with divergent interests and provides a great support mechanism for the authentication of confidential and sensitive data such as clinical trial consents. Dauda *et al*. [17], examined the importance of blockchain tools in healthcare, including healthcare information storage on accessible blocks with no unnecessary distress. Blockchain technology improves the effectiveness of healthcare provision.

A study by Leeming *et al*. [18], discussed the existing blockchain-mediated health record platforms as well as a reference link for a “Ledger of Me” platform that spreads personal health records to design a novel system that integrated the access, collection of health data and digital interferences with smart contracts. The actual target of the authors was to give patients the opportunity to utilize data for the support of their care and for the provision of robust consent pathways for data transfer between diverse institutions and applications. The reference architecture presented by the authors can serve as prospective blockchain-based healthcare application architecture.

3. BLOCKCHAIN TOOLS FOR HEALTH/ BIOMEDICAL CARE APPLICATIONS

Telemedicine and telehealth are innovations in healthcare delivery with promising roles in offering Medicare services to curtain the transmission of COVID-19. Unfortunately, they are limited by their centralized and mutability attributes. Since blockchain is known to be decentralized and immutable, Ahmad *et al*. [19], attempted to analyze the interventional importance of blockchain tools in this regard. The authors showed that blockchain technology can enhance telemedicine and telehealth operations. It can provide remote Medicare in a decentralized, transparent, traceable, trustful, reliable and secure approach. Using blockchain can also assist in identifying fraud cases, especially those that have to be with the academic qualifications of healthcare providers and the status of testing kits.

Presently there is no single trusted infrastructure that can be used for exchanging and storing medical data and no system for checking the traceability of patients within the scope of the health-care system. This has therefore made communication hard, with procedural cost hiking significantly. This situation may result in tough communication hard and impaired how traceability of patients can be achieved. It has also increased procedural costs. With the introduction of a decentralized healthcare mechanism called 'PatientDataChainblockChain', the traceability of patients has been improved. Cernian *et al*. [20], examined the vision of this novel tool on the basis of its interoperability. In the study, system components were developed. Also, system components were validated courtesy of a proof of concept that utilized a dataset of hundred patients and more than one thousand transactions. The proof of theory showed that the PatientDataChainblockChain is feasible as far as the integration of personal medical records from varied sources is concerned.

The security, protection and accuracy of Personal health records are important in medical services. Blockchain is a platform where data retrieval can be achieved. The aim of the study conducted by Lee *et al*. [21], was to design a blockchain-based design for an international medical record exchange system with the hope of achieving medical record integrity, availability and confidentiality for rapid Medicare interoperability and health management. The blockchain platform designed by the authors was reported to be effective as far as the utilization of Personal Health Records is concerned. Through the Asia eHealth information network, the platform has been devised. In summary, the study indicated the possibility of combining diverse types of data storage modes for the effective proffering of solutions to the problems associated with human record data storage, security and transmission. The work also indicated the possibility of a crossbreed of data and blockchain security platforms to enhance effective international Personal Health Record conversation.

Through blockchain technology, personal health record systems can be converted into a decentralized network infrastructure. But privacy and storage capacity are the incapacitating factors. A study by Hussien *et al*. [22], addressed the hiccup between Personal Health Records and blockchain technology by simply transferring many health data into the InterPlanetary File System storage as well as by creating an enforced cryptographic authorization and access control platform which will be used for outsourced encrypted health record and data. The authors constructed the access control on the premise of a novel lightweight cryptographic idea 'smart contract-based attribute-based searchable encryption, which was also developed courtesy of searchable symmetric encryption, leverage of smart contract technology and encryption extension on the premise of the ciphertext-policy attribute. Among others, data confidentiality was achieved through the removal of trusted private key generators, efficient management of smart outsourced encrypted data and a searchable process with a multi-keyword feature. Security validation was confirmed through Automated Validation of Internet Security Protocol and Applications.

It is not unusual in the conventional platform for patients' data to be lost or violated. Electronic health record has a number of benefits but is limited by security and privacy issues. Mechanism of providing a secure solution to these issues is through blockchain. Blockchain technology addressed the issues owing to the fact that it transmits information in a decentralized manner. Abunadi *et al*. [23], constructed a blockchain security framework aimed at storing electronic health records effectively, protectively and securely. Through the platform, health information can be acquired for patients, healthcare providers and insurance agents, not at the expense of the patient's data.

With cloud technology, the storage problem of complex health records and data is addressed, but there was an issue with data security sharing. The decentralization attribute of blockchain will help in solving the problem. In the study conducted by Cheng *et al*. [24], the advantage of blockchain tools was discussed, and a network model called blockchain Based-Medical Cyber-Physical System was constructed. The authors showed that the blockchain Based-Medical Cyber-Physical System did realize health management data transfer. It also met the different ideal safekeeping criteria in the security verification period. The authors concluded that the model was more appropriate for securing sharing of big health data.

A study by Leeming *et al*. [15], discussed the existing blockchain-mediated health record platforms as well as a reference design for a "Ledger of Me" platform that spreads personal health records to design a novel system that integrated the access, collection of health data and digital interventions with smart contracts. The actual target of the authors was to give patients the opportunity to utilize data for the support of their care and for the provision of tough consent pathways for data transfer between diverse institutions and applications. The reference architecture presented by the authors can serve as prospective blockchain-based healthcare application architecture.

Liu *et al*. [25], discussed how their suggested blockchain and Distributed Ledger-based enhanced biomedical security network can improve confidentiality and data protection and security through medical uses. The intention of the authors was to improve patients' access to utilize data for supporting their care and for the provision of consent systems for data sharing among various organizations and applications. The study results showed that the new blockchain-based digital platforms enable easy, fast and smooth connections between data providers for enhancing security, data privacy and healthcare receivers.

A review conducted by Velmovitsky *et al*. [26], examined the possibility of using blockchain tools in solving healthcare challenges. The authors identified five areas where blockchain technology can be used. In electronic health records, blockchain can assist in reducing data sharing and interoperability in the industry through the creation of an overarching mechanism that connects different personal records. It can also mimic data sharing by directly bridging the gap between owners and buyers. In the drug and food supply chain, blockchain technology can avail product's provenance and transportation that will be auditable. In medical insurance, blockchain can enhance claims management methods and assist operators in health, pharmaceutical and medical benefits calculation. In gene and genomics studies, blockchain can directly help link data, buyers and owners. It can provide an auditable and secure way of sharing genomic data. In consent management, blockchain can offer a time-related and immutable log of consent, thereby increasing how transparent the consent management process is.

Fang *et al*. [27], investigated, among others, the recent landscape, design and applications of personal health records based on blockchain. The authors reported that off-chain storage and permissioned blockchains were the most common design choices for personal health records. Dubovitskaya *et al*. [28], discussed, among others, the advantages of blockchain technology in oncology. It enhances data-sharing health-related research. It helps in attaining optimized medical, pharmaceutical and health supply links *via* its transparency, immutability and traceability to the uses.

4. CHALLENGES AND SOLUTIONS FOR ADOPTING BLOCKCHAIN TOOLS FOR HEALTH/ BIOMEDICAL CARE USES

Personal health record platforms could be converted to a decentralized network courtesy of Blockchain technology [22]. Blockchain is faced with many challenges. Kamel *et al*. [13], in their review, identified challenges associated with blockchain, such as challenges of security and privacy. Privacy and security of personal medical data is crucial and confidential and hence require to be handled with caution. Just like in the conventional or traditional medical record share in which, for example HIV laboratory test result of a patient is forwarded to doctor’s office without the awareness of the patient, health reports are very sensitive. Unfortunately, with blockchain, leakage to a third party is not impossible. One of the sources of such leakage is cyber-attack, any unauthorized, offensive invasion targeting information communication systems, personal computers and networks. This occurs through stealing, modulation and alteration, or destruction of a particular target through hacking.

Another challenge that is associated with blockchain is scalability and performance issue. Scalability of blockchain is the tendency to support increasing quantum of transactions and rising number of nodes in the network [29]. Specifically, bitcoin blockchain scalability issue refers to capability limitation of the Bitcoin system to manage huge quantities of contract data in the shortest time frame on its platform. This simply implies that bitcoin blockchain exhibits small frequency and size. Consensus protocol or algorithm is one of the factors that can influence the scalability and performance of blockchain technology. The consensus algorithm describes the process through which propagation, validation and finalization of a blockchain network occurs. Network latency is another determinant of blockchain scalability and performance. Blockchain nodes are made up of a database and runtime engine hosted on the cloud or premise. When dedicated infrastructure resources are not available, there is a possibility that the node performance might be inhibited. Node can affect blockchain scalability and performance. The more the number of nodes, the longer it is going to take for the propagation of a transaction. The next factor is smart contract complexity. With respect to the number of reads and writes from or to the ledger and validation logic, when the complexity of smart contracts is more, the processing latency will also increase. The size of the transaction payload also affects blockchain scalability. In fact, the larger the payloads, the longer it takes for replication across nodes. Database efficiency is another factor influencing blockchain network performance. The last is transaction queuing. Blockchain network is made up of many nodes which work together to provide high availability. However, the handling capacity of transactions of each node shows the number of transactions that will be accepted for further processing from the client applications.

Like the reports of Hussein *et al*. [22], and Hussein *et al*. [30], despite the fact that blockchain applications are spreading over many fields, including agriculture, reputation system, Internet of Things and economic services, medicine, among others. Zheng *et al*. [31], also reiterated several challenges attributed to blockchain tools, like security issues, and scalability requiring serious attention. Kuo *et al*. [32], highlighted the issues of blockchain, like privacy, security and protection of data. Sun *et al*. [33], posited that preservation of electronic health information and record and synchronization have always posed a huge challenge.

Blockchain applications and implementations are on the increase but the issue is variations in underlying technologies. Therefore, it may be difficult and impracticable for all of them to work together. Insidious intrigues are often obtained when smart contracts communicate across different blockchain implementations in the absence of any human interaction [34]. Hussien *et al*. [30], remarked that healthcare applications of blockchain need robust security and privacy platform to achieve a high-level interoperability, authentication and health records transfer in order to conform with the stringent ethical conditions of the Health Insurance Accountability and Portability Act of 1996.

Cloud can be described as a cyberspace in which data assessment can be carried out online. Whereas, blockchain is a coded or encrypted platform that devises several styles of codes and hash for the storage of data in a protected and secured databases. Both cloud computing and blockchain technologies are fast-growing mechanism worldwide. However, one major difference between the two is immutability. Blockchain is immutable while cloud computing is mutable. Ismail *et al*. [31], and Al-Issa *et al*. [32], while commenting on cloud computing noted that cloud computing got access into the healthcare system due to it is elastic and cost-efficient, transparent, energy savings, resource sharing, fast deployment and security. Wang *et al*. [35], stated that the COVID-19 pandemic massively improved research on integrating digital technologies and healthcare. According to Ismail *et al*. [36], the challenges associated with cloud computing include its incapability of providing a protective and secure patient-centered cohesive approach to many healthcare givers. Blockchain also has shortcomings, such as scalability and efficiency issues, but it has the advantage of decentralization. This implies that cloud computing and blockchain need to be integrated. Against this background, Ismail *et al*. [36], developed a new model known as blockchain-cloud integration for medical applications.

As far as solutions to blockchain challenges are concerned, Kamel *et al*. [13], highlighted some ways out. They emphasized the importance of the identity of health providers and health receivers as a way of tracking who has access to medical information and records. Another method is the integration of cloud computing with blockchain, according to the report of Ismail *et al*. [36]. Cloud computer is an elastic, energy-conserving, cost-effective, and resource-sharing mechanism of security and fraud detection, management of medical and pharmaceutical device supply chains, data monetization and public health surveillance, the use of autonomous devices such as drones with many internets of things, enabling of open tagged and public data.

Furthermore, blockchain challenges can be overcome by having a dedicated network bandwidth. Having a dedicated bandwidth helps in enhancing overall throughput and reducing network delays. Use of dedicated infrastructure resources will improve node performance and blockchain scalability. The consensus mechanism's quality can influence the blockchain's performance and scalability.

Schorr's signature is another way of improving the scalability and efficiency of blockchain technology. Schorr signature is a digital signature created by the Schnorr signature algorithm. Besides, intelligent contracts can be reduced by using mercerized abstract syntax trees.

Liu *et al*. [25], discussed how their Distributed Ledger-based blockchain can be enhanced effectively for biomedical data protection, and security systems can improve the security and privacy of data protection across medical uses. The authors intended to improve patients' access to and utilize data to support their care and to provide agreement systems for data transfer among various institutions and uses. The study results showed that the novel blockchain-based digital systems enable easy, seamless, and fast connections between data providers to enhance security, privacy, and data protection with healthcare receivers [37 - 65].

CONCLUSION

This chapter intends to provide detailed facts on blockchain distributed ledger technology. Detailed information on the key benefits of blockchain when compared to traditional distributed databases for biomedical/health care applications. The specific advantage of blockchain technology includes cryptographic security, decentralization, and immutability, and these features make the blockchain technology an influential contender in reconstructing the healthcare landscape worldwide. In contrast, its role in attaining an optimized pharmaceutical supply chain through its traceability, transparency, and immutability is highlighted. Relevant information on potential challenges and proposed solutions for adopting blockchain technology for biomedical/healthcare applications was provided.

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CHAPTER 11

Medical Imaging Systems Using Blockchain

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Abstract: It has been discovered that in the old electronic health record platform, each health service unit managed its health records, making sharing difficult on the different medical platforms. However, it has been discovered that blockchain technology is a panacea that makes it possible to enable medical service units that are based on different platforms to share electronic health record data. However, one major challenge with this approach is the difficulty in storing whole electronic health record data in the blockchain, given the price and size of the blockchain. As a way out, cloud computing was ticked as a potential solution. Cloud computing affords a unique opportunity, including storage of scalability and availability. But again, the electronic health record with cloud computing advantage may be susceptible to attacks because sensitive data is transferred through a public channel. The task of sharing and disseminating medical information and records electronically is inevitable as far as medical management and treatment combination are concerned. Unfortunately, the old cloud-based electronic medical record storage platform is hard to achieve data security sharing. Given the tamper resistance and traceability, blockchain technology makes it possible for highly sensitive health data to be shared. Therefore, this chapter intends to provide detailed information on the application of medical imaging systems using blockchain.

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1. INTRODUCTION

Blockchain has been recognized as a reliable technology which has become popular, especially in the prevalent accepted cryptocurrency markets. This has several uses in sectors, such as healthcare, industry most especially in medical imagining, where they are applied in the storage of data through distributed cryptographic databases where data associated with access, creation, and update could be kept in a proper way [1].

It has been discovered that numerous people that utilized blockchain, such as scientists, patients, radiologists, and physicians, could be applied in regulating how and through whom healthcare data could be applied. Moreover, it has been stated that Blockchain could be applied in several areas, such as image annotations, ownership and tracking of images, which all have numerous relationships with artificial intelligence [2, 3].

The application of Blockchain can be applied for the tracking of all alterations in the database. Also, it has been established that Blockchain applied cryptography for the authenticity of data, verifiability and immutability of data, and transparency. They also play a crucial role in making data to become mere reliable, especially through a distributed trust network, without using a central, trustworthy master copy. Also, their application in the tracking of radiological data has been established [4].

2. MEDICAL IMAGE SHARING AND IMAGE TRANSFER

In conventional settings, methods such as shipping, posting, vendors and the use of videos and many more have been utilized in the dissemination of medical information [5]. However, technology now enables information to be transferred through the clouds without any actual physical transit. Medical image sharing can be defined as the transfer and dissemination of medical images electronically from healthcare providers and healthcare receivers. A good example of medical image sharing is the 2009 'radiological society of North America's image share project'. Usually, the transferred images are usually in the form of 'digital imaging and communication in medicine' or 'portable document format'. Sharing of images between two quarters is regulated by a platform, an example of which is 'Enterprise Document Sharing'.

In the work conducted by Sandberg *et al*. [6], determined the experiences of healthcare providers and healthcare receivers concerning image sharing. One of the main intentions of the authors was to know if utilization of the urge to devise imaging depends on the location or the specialty of the providers and how healthcare providers and their staff were able to access medical imaging outside. Using semi-structured interviews for 85 health personnel, it was reported that physicians who were situated in pediatric and family medicine depended on written reports majorly instead of X-rays and hence claimed no difficulties. While subspecialists reported having hiccups and delay in getting imaging information on portable media, those of them that were situated in small towns, urban and sub-urban areas claimed to have received imaging studies *via* electronic communication.

In the work conducted by Jung *et al*. [7], looked at the discrepancy in accessing radiological images in comparison to text-only reports *via* information dissemination platforms. In the study, 1,670 medical doctors and non-medic were recruited. It was shown that the likelihood of accessing medical images was about 4% greater for those who were in specialty care when compared to primary care medics. Instead of text-only reports, specialty medics showed an 18% greater likelihood of getting real images.

Alvin *et al*. [8], hypothesized that specialists such as neurologists, otolaryngologists and neurosurgeons viewed neuroradiology images most often, while neuroradiology reports as the least common of all medical specialties. The authors collected ordering data on radiological studies for 4 weeks. 85.7% and 53.2% of studies were viewed, while 13.1% were not viewed. It was also gathered that neurosurgeons who attended to in-patients viewed both reports and images.

In the work conducted by Langer *et al*. [9], the need to create a successor technique that will eliminate the role of physical media was highlighted. This becomes necessary to view the barrage of difficulties that characterize the latest medical information dissemination paradigm. Such included hiccups that may occur when patients' information, such as reports and images, is transferred from one healthcare provider to another or healthcare provider to healthcare receiver.

Rosenkrantz *et al*. [10], looked at the assessment of the perception of emergency health providers and radiologists. 34 radiologists and 38 emergency health providers responded, with 32.4 percent of radiologists and 55.3 percent of emergency health providers showing a preference in image quality transferred from the exterior. 29.4% of emergency providers indicated that getting information from outside will diminish image repetition. 40.6% of radiologists believed that an outside report will halt extra image recommendation, 43.8% claimed confidence in new examination interpretation, and 15.6% believed that new examination interpretation will be altered by the report.

Vest *et al*. [11], briefed on the impact of medical image exchange on the utilization of imaging approach by patients. It was reported that medical image exchange was associated with a marked reduction in repeat imaging. It was also reported that image sharing led to a huge improvement in the utilization of imaging approach. Mendelson *et al*. [12], discussed the medical imaging approach and the associated virtues, being a replacement for conventional practice (the use of compact disc, VCD and DVD). This internet-based approach has its limitations. One of which is a common standard deficiency for information exchange. The provision of a common standard platform for information exchange will eliminate the need for locally restricted image stores such as Digital Imaging and Communications (used in radiology).

Wang and Song [13] designed a model with secure electronic health records that are built on block-chain technology principle and 'attribute-based cryptosystem' in supporting fine-grained access control and in attaining integrity, confidentiality and authentication of medical data. The authors used 'identity-based encryption' and 'attribute-based encryption' in encrypting health data. Identity-based signature was utilized in implementing and achieving digital signatures. The authors also invented a cryptographic primitive, called 'combined attribute-based/identity-based encryption and signature' in order to come by various actions of 'attribute-based encryption', 'identity-based encryption' and 'Identity-based signature in one cryptosystem'. Management of the system was enhanced by these without any need for the introduction of different 'cryptographic systems' for different security and privacy requirement components. The authors also utilized blockchain techniques to ensure the traceability and integrity of medical data with the hope that it can be applied for medical insurance.

Kim *et al*. [14], in their study, designed a secure scheme for a cloud-assisted electronic health record system courtesy of block-chain. With respect to the approach, the block-chain technique is devised to provide data security, credibility and access control courtesy of 'log transactions'. The authors utilized elliptic curve cryptosystems in providing secure medical data sharing with cloud computing. The electronic health record proposed by the authors is capable of preventing various attacks through analysis and evaluation of informal security and through a simulation platform known as 'automated validation of internet security protocols and applications (AVISPA) simulation'.

Kalia *et al*. [15], surveyed the recent practices for the use of light and transportable media, such as compact discs, for the purpose of medical imaging in the United States' Pathology department. It was reported that ninety-eight out of hundred percent of respondents claimed that their institutes had produced media that was compliant with Digital Imaging and Communications in Medicine, and only 2.0% of them were not sure. Just only 22.2 percent of respondents indicated that their institutes have produced media that was compliant with that of Integrating the Healthcare Enterprise Portable Data for Imaging' and 71.6% were not certain.

Qin *et al*. [16], designed a safe consortium-based blockchain scheme for sharing 'stroke electronic medical records'. The model makes use of an index of medical records that were saved on the block-chain, and the ciphertext of medical records was stored in the cloud and index of medical records. The privacy protection platform presented by the authors creatively integrates 'searchable encryption', which supports patient pseudo-identity search and proxy re-encryption. Unfortunately, the study results indicated that the model was incapable of ensuring the privacy of patients' identity information and important private data. It was incapable of resisting the interference and deletion attacks launched on internal and external malicious nodes on the medical record data.

3. APPLICATIONS OF BLOCKCHAIN IN MEDICAL IMAGING

Blockchain is well-known as a distributed ledger technology with immutable and encrypted properties. Apart from the aspect of cryptocurrencies, where it was initially and fondly used, there are many applications. McBee *et al*. [2], discussed the concepts and principles that underlie the blockchain technology and uses, especially with respect to medical imaging. The challenges associated with the technology as well as with implementations which include distributed ledger size constraints, public *versus* private key access, speed, complexity and security pitfalls, were enumerated. Applications of blockchain technology in medical lines, such as tracking of implanted medical devices, direct patient ownership of images, research, teleradiology and artificial intelligence, were highlighted.

Sultana *et al*. [17], claimed that blockchain technology is important for data integrity as it maintains an audit trail of every transaction. The task of data security has for years been a major flashpoint. The authors indicated that a system that is capable of combating medical/health data susceptibilities is available, which among others, deploys the immutability of blockchain and the scalability of off-chain data storage courtesy of 'Inter Planetary File Systems'. Therefore, utilization of this system is capable of improving the security and safety of health information transmission and dissemination.

Securing storage and holistic utilization of personal medical records has consistently proved to be an issue of concern for many. But with the advent of blockchain technology, a novel concept for finding a solution to the challenge was created. With its peculiarities such as verifiability, decentralization and immutability, blockchain technology can be utilized in saving 'personal medical data' with adequate protection. Chen *et al*. [18], created a storage platform that could handle personal health information on the premise of blockchain and cloud storage. The proposed platform was reported to be independent of a third-party without any single party having absolute power to influence the processing.

Personal health record platforms could be converted to a decentralized network courtesy of Blockchain technology. Privacy and storage have always drawn the concept back. Through the platform, health data become accessible to everyone in view of the transparent and decentralized attributes of the scheme. It was in this challenge that Hussien *et al*. [19], designed a study to bridge the gap existing between personal health records and blockchain technology through the transfer of data into interplanetary file system storage as well as the creation of access control and an enforced cryptographic authorization. The authors constructed the access control on the premise of a novel lightweight cryptographic concept called 'smart contract-based attribute-based searchable encryption which was also developed courtesy of searchable symmetric encryption, leverage of smart contract technology and encryption extension on the premise of a ciphertext-policy attribute. Among others, data confidentiality was achieved through the removal of trusted private key generators, efficient management of smart outsourced encrypted data and searchable process with a multikey word feature. Security validation was confirmed through 'Automated Validation of Internet Security Protocol and Applications.'

Chenthara *et al*. [20], looked at ways of ensuring patient privacy and data are secure during transmission of sensitive data across organizations and healthcare personnel in a distributed environment. The goal of the study was to create a basis for constructing a security solutions model against internet-related attacks by making use of natural features of the blockchain. A privacy-preservation paradigm was built through 'Healthchain' on the premise of blockchain technology that was able to maintain scalability, privacy and credibility of the e-health data. The Blockchain was created on 'Hyperledger fabric' means by using Hyperledger composer, and it can store electronic health records by making use of 'Interplanetary File System' to develop the health chain framework. Furthermore, the data stored in the Interplanetary File System was encrypted using a peculiar cryptographic public key encryption algorithm. The results showed that the health information records remained untraceable to unauthorized access.

The task of sharing and disseminating medical information and records electronically is inevitable as far as medical management and treatment combination are concerned. Unfortunately, the old cloud-predicated electronic medical record storage platform is hard to achieve data security exchange. Blockchain technology, in view of tamper resistance and traceability, it is possible for highly sensitive health data to be shared. Qin *et al*. [16], designed a safe consortium-based blockchain exchange platform for stroke electronic medical records. The model uses an index of health records that was saved on the block-chain and ciphertext of medical records that were stored in the cloud. The protection platform presented by the authors creatively integrates searchable encryption which was in support of patients' pseudo-identity search and proxy encryption. Unfortunately, the study results indicated that the model was incapable of ensuring the confidentiality of patients' identity information as well as important private data. It was incapable of resisting the interference and deletion attacks that can be launched against internal and external malicious nodes on the medical record data.

Since preservation of electronic health information and record and synchronization have always posed a huge challenge, Sun *et al*. [21], conducted an algorithmic calculation on the electronic medical data and got the corresponding value outcome which was stored on the block-chain in order to maintain its validity. Thereafter, the authors encrypted the electronic medical data and had it stored in the interplanetary file system. With these centralized data stores of servers of several medical institutions was solved, and stress from data stores and high-frequency access to blockchain was shown to reduce. Attribute-based encryption scheme was devised to ensure that only the features that match the access rules and regulations cause the decryption of the encrypted electronic health records [22 - 50].

CONCLUSION

This chapter has provided detailed information on the application of blockchain in medical image sharing and image transfer, as well as their applications of blockchain in medical imaging. Detailed information on the applications of blockchain technology in medical lines, such as tracking of implanted medical devices, direct patient ownership of images, research, teleradiology and artificial intelligence, were highlighted. The relevance of blockchain technology in finding solutions to the challenge is due to its peculiarities, such as verifiability, decentralization and immutability also, blockchain technology can be utilized to store personal medical data with adequate protection. Also, the significance of blockchain technology in the maintenance of scalability, security, privacy and integrity of the e-health data were also highlighted.

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CHAPTER 12

Effectiveness of Machine and Deep Learning for Blockchain Technology in Fraud Detection and Prevention

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Abstract: Blockchain was formerly originated to prevent fraud in digital currency exchanges. Blockchain refers to a collective decentralised ledger that is unaffected by tinkering. It provides the confirmed contributor access to the store, views, and shares the digital information in a situation that is rich in safety, which in turn supports the development of trust, liability, and transparent business associations. Identity theft and fraud safety are endless challenges for everyone in buying and selling. With each novelty in security technology, hackers and fraudsters learn how to outsmart the technology and breach these networks. The first section of the chapter describes the structure of the blockchain, its framework, the pros and cons of combining these technologies, and the role and importance of machine and deep learning algorithms in fraud detection and prevention in the blockchain. The next section focuses on the reported work, highlighting different researchers' work for fraud detection and prevention using Blockchain technology. The chapter's final section comprises a comparative analysis based on various performance parameters such as accuracy, the area under the curve, confidence, true negative, false positive, and truly positive for a different type of fraud detection using blockchain technology.

Keywords: Artificial intelligence, Blockchain technology, Deep learning, Fraud detection, Fraud prevention, Machine learning.

1. INTRODUCTION

The emergence of machine learning or deep learning algorithms in various domains is evident. These algorithms have provided immense power in analyzing and making decisions using the collected data. But, for the model to be efficient and accurate requires training with enormous data [1]. Data sharing within organi-

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zations can lead to various threats like tampering with data, attacks by various hackers, and decentralization of data. Another technology, Blockchain, possesses the capabilities which can overcome all the described shortcomings. The amalgamation of these technologies results in systems that are resistant to ticketing, robust, decentralized, and secure [2]. One such application of such systems has been studied in this chapter, fraud detection and prevention using blockchain and machine learning or deep learning algorithms. An unknown group, Satoshi Nakamoto, behind Bitcoin, described the importance of blockchain technology in solving the problem of maintaining the order of transactions. Bitcoins consist of blocks that are constrained-size structures containing transactions. These blocks relate to the help of hash values [3] present in the previous blocks. As described, Blockchain was formerly originated to prevent fraud in digital currency exchanges. Blockchain, unaffected by tinkering, gives the confirmed contributors access to store, view, and share digital material in a situation rich in safety, which supports the development of trust, liability, and transparency in business relations. To capitalize on this specified assistance, companies have now started exploring ways in which Blockchain technology could be used to prevent fraud in numerous industry verticals [4]. Fig. (**1**) describes the structure of blockchain technology. It is visible from Fig. (**1**) that each block is a collection of transactions occurring at the same timestamp. It also contains the hash value of the next block in a chain [5].

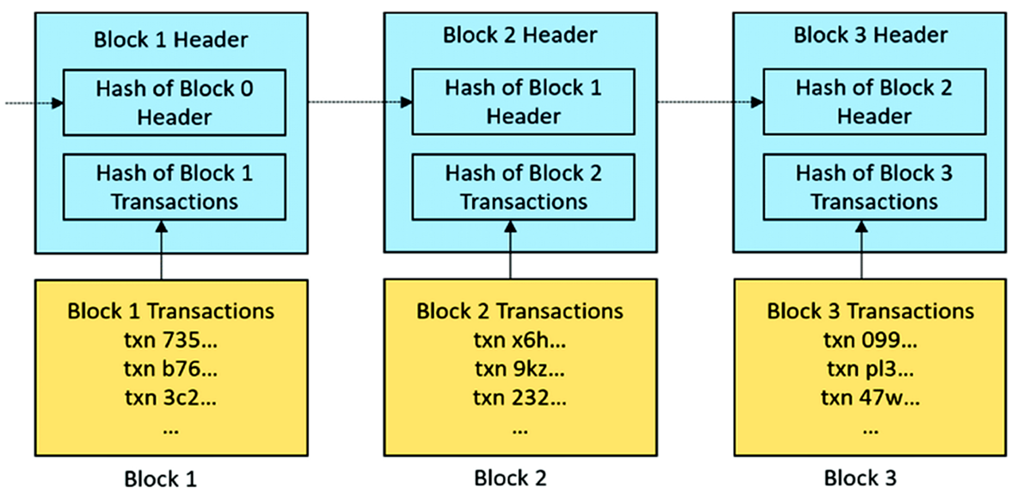

Fig. (1). Structure of Blockchain [6].

Protection from identity theft and fraud is an endless challenge for everyone to elaborate on buying and selling. Merchants, consumers, issuers, and acquirers know there are susceptibilities in how payments and data are secured. With each novelty in security technology, hackers and fraudsters learn how to outsmart the technology and breach these networks. Blockchain seems to possess capabilities that help to overcome the described problems [6].

Fig. (**2**) displays the various properties of blockchain:

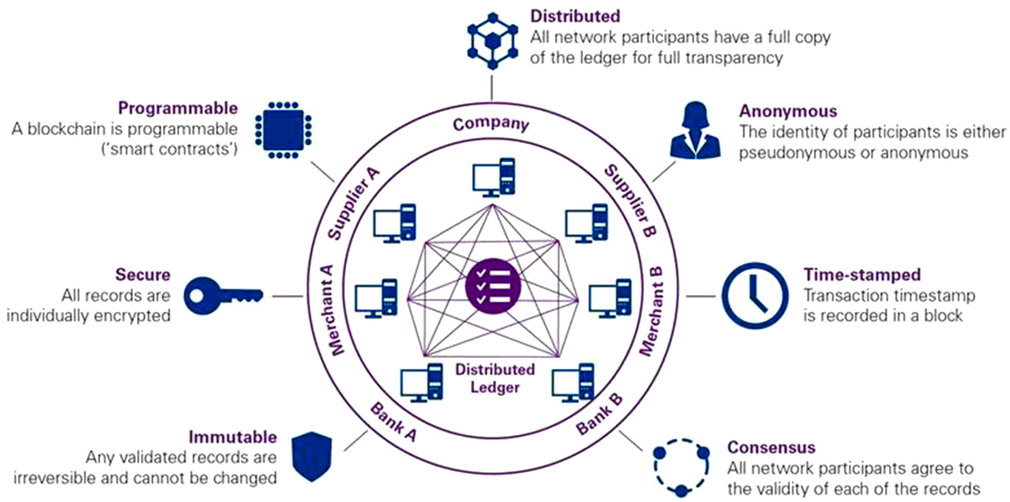

Fig. (2). Properties of Blockchain [11].

● **Programmable:** Blockchain uses the concept of smart contracts (SC). SCs can be defined as: "a computerized transaction protocol which helps in executing the terms of a contract", which minimizes external risks. In the context of blockchain, SCs can be defined as scripts that run in a decentralized manner [7] without relying on third parties.

● **Distributed:** This is one of the biggest strengths of blockchain. In this, all the computers (nodes) in a network have a copy of the full ledger to ensure transparency [8].

● **Immutable:** The data present in the ledger cannot tamper. Hence, making the blockchain robust.

● **Consensus:** Since the data present in the ledger is transparent and distributed so all the nodes in a network agree to the validity of the records.

● **Secure:** All the records present in the blockchain are encrypted individually.

● **Time-stamped:** All the records present in the ledger are time-stamped. These time-stamps are also stored in the ledger with their corresponding records.

● **Anonymous:** Blockchain doesn't reveal the information of the user, hence keeping them anonymous.

Sensing devices like IoT devices, web applications, *etc* have led to massive production of data [9]. The data produced can be effectively analyzed with the help of various algorithms of machine learning and deep learning [10]. But, such algorithms in application work on centralized models where various organization servers can access this model on their specific data, without sharing it [11]. But, this centralized nature of models leads to the problem of tampering with data [12]. Moreover, data authenticity cannot be verified [13]. So, the outcomes of these models cannot be trusted completely. We can say that,

Decentralized AI= Blockchain + Machine Learning/Deep Learning Algorithms

Such systems allow securely shared data and help in the better personal analysis of the data. This allows authentication of the source of data and also stores data in a highly secure manner.

The primary concern of the chapter is to highlight the various features in the blockchain which can prevent different types of fraud from occurring. Another focus is to highlight the different types of fraud, identify theft, and supply chain, which can be prevented and detected using blockchain technology. This chapter will also cover the various implementation challenges to prevent fraud and the importance of machine learning and deep learning for fraud detection in blockchain technology [14]. The machine learning models for blockchain include the anomaly transaction detection system, Bitcoin fraud detection, and other types of fraud detection. The structure of the chapter will comprise a framework for automatic fraud detection systems using blockchain, the motivation of the work, different benefits of fraud prevention, and detection using blockchain technology, applications, and role of learning models in blockchain for fraud prevention and detection. The chapter will also cover the work that has been done by different researchers in the analysis section.

2. BACKGROUND STUDY

This section of the article gives information about the framework of blockchain, the different types of frauds, the importance of machine and deep learning in blockchain, the benefits associated with the work, and most importantly, the research challenges associated with it.

2.1. Automatic Framework of Blockchain

This section of the chapter describes the framework of the blockchain for an automated transaction.

Fig. (**3**) explains the flow of transactions in a blockchain-based framework. Suppose, A requests B for the transaction, this request is broadcasted *via* peer-to peer. The algorithms are used for the validation of transactions and users by the nodes; nodes represent the computer systems in a network of multiple systems. Further, it awaits the verification of the transaction. Once the transaction is verified, it can involve cryptocurrencies, records, or confidential information. A new block is created in a ledger that is being added to the existing blockchain, which is immutable and permanent. This addition of the block to the blockchain marks the completion of the transaction.

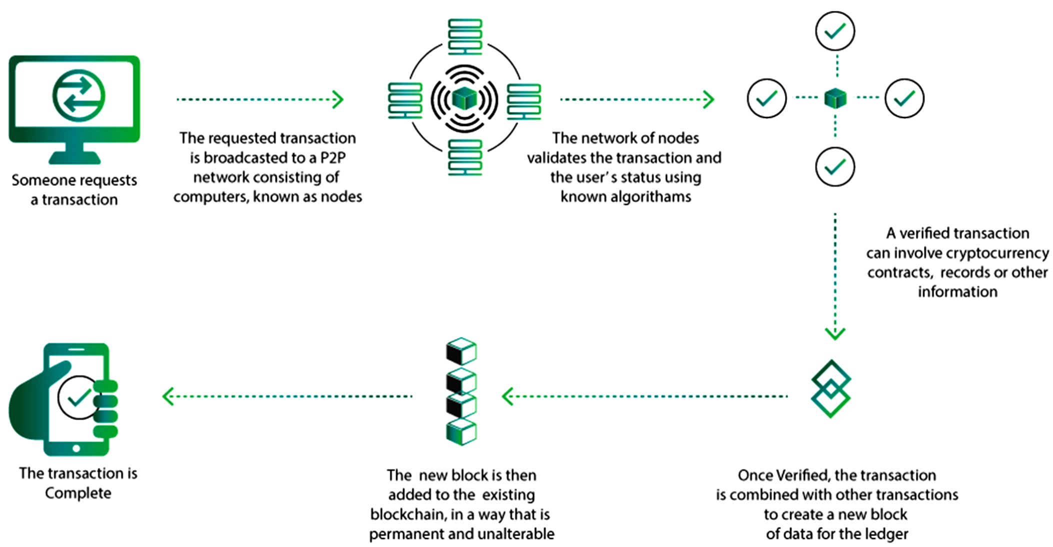

Fig. (3). Blockchain framework for automated transaction [14].

There are many industry-specific frameworks of blockchain. Some of them are [8, 16, 17]:

- **Exonum:** It's an open-source project given by the Bitfury group and developed in Rust. It has applications in fintech and legal tech.

- **Hyperledger:** It's an open-source project given by the Linux Foundation and developed in Python. It has applications in cross-industry.

● **Openchain:** It's an open-source project given by Coinprism and developed in Javascript. It has applications in cross-industry.

● **Graphene:** It's an open-source project given by Cryptonomex and developed in C++. It has applications in cross-industry.

● **Corda**: It's an open-source project given by R3 Consortium and developed in Kotlin, Java. It has applications in the financial services industry.

● **Multichain**: It's an open-source project given by Coin Science and developed in C++. It has applications in the financial services industry.

All of the above-mentioned frameworks allow smart contracts and are generally private. Only hyperledger and graphene are public. Most of them allow regular updates; only a few are inactive.

2.2. Types of Fraud

Technological advancements have also posed immense threats like phishing, malware, *etc*. Many threats that have been caused due to the misuse of technology are categorized into multiple types. Nine types of fraud are discussed below [5, 17, 18]:

● **Mail Fraud:** This kind of fraudulent activity revolves around postage mail. It involves a letter sent intending to scam money or steal a person's personal information. In simple words, mail fraud involves the use of mail.

● **Driver's License Fraud:** At first glance, this fraud doesn't seem to cause a lot of harm to anyone but has an immense capability to ruin someone's life. A driving license can help in fraudulent activities like opening a bank account in someone's name, boarding a plane, *etc*.

● **Health Care Fraud:** In this type of fraud, insurance information is used by any other individual for personal gain. To avoid such frauds, keeping updated on all medical bills, personal information, and insurance claims is necessary.

● **Debit and Credit Card Fraud:** It is one of the most common fraudulent activities we all encounter. It happens when a number present on the card or the card itself is stolen. Continuous monitoring of bank accounts every week is crucial to prevent this fraud. One should keep their cards safe and not display the number present on the card. These days, hackers are also using "skimmers" to tamper with information. Never save card numbers online. Instead, use e-wallets for the purpose.

● **Bank Account Takeover Fraud**: Getting account information is comparatively easy. Personal information required to access an account can be obtained by accessing the cheque in the cheque box, through an email scam, or maybe with the help of malware. It is necessary to keep a check on account statements. Never log in to the bank account using unsecured Wi-Fi.

● **Stolen Tax Refund Fraud:** It is one of the top scams encountered by the IRS. It happens when someone steals a Social Security number and fills in the taxes themselves, and this leads to receiving a refund from a thief. It is necessary to be vigilant to whom we provide our information.

● **Voter Fraud:** This broad term includes various malfunctions like voting under a false identity, buying votes, voting twice, and voting as a felon.

● **Internet Fraud:** As it sounds, it is the type of fraud that occurs *via* the Internet. It includes breaching of data, EAC (email account compromise), phishing, and malware. Every year, millions of dollars are stolen through the internet. It is necessary to keep an anti-virus update for your system to prevent malware and viruses from entering your system. Always read links to ensure that you are being directed to an official site.

● **Elder Fraud:** Senescence makes the person more susceptible, kind-hearted, and trusting. Scammers extort all these qualities of an elderly person and lead to illegal activities like phone scams offering lottery winnings and health care services. These activities help them to gain access to their personal information.

2.3. Importance of Machine Learning and Deep Learning-based Models for Blockchain in Fraud Prevention and Detection

Machine learning is a paradigm that learns automatically from the data fed to it. It gains knowledge by observing the data provided to it. Various patterns are analyzed, and inferences are made based on those observations. Machine learning-based models facilitate automatic learning in several fields. The model's efficiency depends on large volumes of data [19, 20]. There are two phases in the machine learning process: the training and validation phase. These models learn through the training cases in the training phase; labels of a large portion of the data are fed to the model as input (also known as the training set). Further, the constructed model trained using the training set is evaluated using the validation data. The validation phase involves testing trained models and is validated by cross-checking the predicted labels of the data [21, 22]. It helps the system understand complex perception tasks to achieve maximum performance. Learning can be classified into the following broad types:

● **Supervised learning:** It is a learning in which machines are taught or trained using data that is well labelled, which means some data is already tagged with the correct answer. Examples of majorly used supervised classification algorithms include Decision Trees, Support-vector machines, linear regression, Logistic regression, and Naive Bayes.

● **Unsupervised learning:** Unsupervised learning is the training of a machine that uses information that is neither classified nor labelled and allows the algorithm to act on that information without guidance. Unsupervised classification algorithms like the K-means algorithm, Neural Networks, and K-Nearest Neighbor algorithm have been widely employed.

● **Semi-supervised algorithm:** Semi-Supervised learning proves to be very useful when the cost of labelling the data set is too high to allow a fully labelled data set. Semi-supervised Learning methods include regression algorithms such as Ordinary Least, Cluster assumption, Manifold assumption, Generative models, Low-density separation, Graph-based methods, and Heuristic approaches.

● **Reinforcement learning:** This is reward-based learning, *i.e.,* for each correct prediction, the learning approach gets a positive reward. Popular reinforcement learning approaches are State–action–reward–state–action (SARSA-Lamda) and Deep Q Network (DQN).

Deep learning is a subsection of machine learning in artificial intelligence. Deep learning approaches are networks that can learn from complex/intrinsic data. Deep learning is also recognized as deep neural learning and deep neural networks. As the name indicates, deep neural networks imitate the functioning of the human brain, *i.e.,* the neurons in a neural network and those in the human brain work similarly. The deep learning model consists of various layers, including a non-linear processing unit for feature extraction. Also, deep learning models exhibit hidden layer processing that works like a human brain and performs classification more accurately. Popular deep learning models are Artificial Neural Networks, Convolutional Neural Networks, and Stacked Auto-encoders.

Applications of deep learning include Biological image classification (diagnosing images like x-ray, Computed Tomography (CT), Magnetic Resonance Imaging), Deep Vision Systems, Healthcare (disease identification, robotic surgery), Parking systems, Object Detection (moving object detection in videos), Medical Applications (drug targeting, personalized medicine, predictive analytics, personal care), Document analysis and recognition, Data flow graph, Remote Sensing, Stock market analysis (predicting the rise and downfall of shares in the stock market based on the patterns), semantic image segmentation, synthetic aperture radar, person re-identification, and many more.

Machine learning applications include image recognition, speech recognition, medical diagnosis, automatic language translation, online fraud detection, stock market trading, email spam and malware filtering, virtual personal assistance, self-driving cars, traffic prediction, product recommendation, and many more [11].

Some of the work of the various researchers using machine learning or deep learning for fraud detection has been discussed below:

● To control corruption in governmental bodies.

● Automatic digital signature during the transaction with the help of machine learning.

● It helps solve the access control problem of IoT.

● It is useful to protect customers from online fraud ratings.

● It helps remove the anonymity in the blockchain, which leads to illicit activities. A supervised machine learning technique is useful by providing 80.2% accuracy.

● It is useful in detecting suspicious activities by using various algorithms like XGBoosting, Support Vector Machines, Random Forests, and many more.

● It helps detect fraud with the help of various graphs with considerably high results.

● Various clustering techniques are also helpful in detecting suspicious activities and frauds.

● By detecting fraud, machine learning also helps an organization to increase profits. Frauds in telecommunication can be precisely detected with the help of fuzzy logic with an accuracy of 97.6%. It also helps organizations to divide customers into various categories.

● By analysing a series of transactions can successfully address the problem of high false-positive rates. Algorithms like SVM and LSTM-RNN are helpful by giving AUC 89.322% and 95%, respectively.

● Generative Adversarial Networks help increase the data available for the minority class. This helps reduce the overfitting problem and increase the model's performance.

Considering the above-provided results, we can considerably check that the results of deep learning and machine learning are significant in the field of fraud detection. They help detect fraud and also the associated problems with it. So, it is a brainer to avoid merging these two emergent techniques with blockchain [9].

Bringing AI and Blockchain together can result in a revolutionised paradigm. Blockchain, on the one hand, is a distributed ledger that is transparent and immutable, whereas AI (machine learning and deep learning) can result in the study of the enormous data gathered in the blockchain. Machine learning and deep learning can help analyze the data gathered more efficiently. It can be fruitful in enhancing the security feature of the chain. Since blockchain works on a decentralized ledger, so enormous data can be gathered for training the machine learning model, because of this, creating a robust model. Their amalgamation has resulted in various frameworks for fraud detection, like credit cards, insurance, and many more. The proposed work of many researchers in this field is demonstrated in the reported work section of the article, where we will come across the advantages their merger has posed [23].

2.4. Benefits of Blockchain

Blockchain has three main features that increase its robustness and make it suitable for fraud detection. Those three features are Distributed Networks, Immutable, and Permissible. As a result, the relevance of Blockchain technology increases exponentially [10]. According to a survey conducted by IBM in 2017, almost 33% of executives are engaged with blockchain. With the advancements, three generations of blockchain have been witnessed [24]. Blockchain has many advantages:

● It provides more efficient performance for security and transactions [25 - 30]. Since blockchains are transparent and transactions are digitally signed and encrypted, they are highly secured.

● It inhibits the involvement of third parties, so hidden fees are not involved. Blockchains have made the involvement of third parties or settlers zero because all the users in a network can check the ledger, all the activities are transparent, and blockchain also involves using smart contracts.

● It provides transparency. It means that all the network's associated nodes (computers) can see the ledger at any instant. All the transactions are known to everyone connected in a network.

● Since it is based on a distributed ledger, it creates a sense of trust among its participants or connected nodes in a network.

● Highly cost-effective. Since it expedited the involvement of third parties.

● Transactions are cryptographically signed and verified. All the transactions which are made in blockchains require users to sign them digitally, and all the transactions are encrypted thereafter.

● It provides security against hackers as the data present in the ledger cannot be tampered with.

● It provides high speed. Since blocks in the blockchain are connected *via* hash values, it is easy and faster to navigate between them.

● It helps to check fraudulent activities like corruption because of its transparent and distributed characteristics.

2.5. Research Challenges

This section discusses the challenges faced in bringing blockchain and AI together. Some of the main issues are listed below:

● **Privacy:** The data stored in ledgers of blockchain are publicly available. It can lead to harm to privacy. But making the data private can lead to inefficient performance of AI models.

● **Blockchain Security:** Blockchain is susceptible to cyber-attack by 51% [21, 31]. The decentralized characteristics of blockchain make it more prone to attacks. Issues related to security are more evident in public blockchains like Bitcoin and Ethereum.

● **Trusted Oracle:** Smart contacts cannot pull data from the outside world. It cannot trigger an event automatically. To overcome this problem, trusted oracles, commonly known as third parties, come into play [22].

● **Scalability and Side Chains:** Bitcoin can complete a total of 4 transactions in a second, whereas Ethereum can complete 12 transactions. Side chains enhance scalability [32, 33]. These days researchers are working significantly on improving the scalability of the blockchain [34].

● **Fog Computing:** It allows localised computation of the gathered data. It helps to prevent long delays which can be faced in cloud computing [35, 36, 37, 38].

● **Lack of Standards, Interoperability, and Regulations:** No standards have been devised. Many bodies are working towards it [25].

● **Smart Contracts Vulnerabilities and Deterministic Execution**: Smart contracts should be error-free and secured against various vulnerabilities. For instance, DAO was hacked in 2016, resulting in a loss of 3.6 million Ethers [26].

● **Governance:** Managing, deploying, and constructing blockchain effectively among its participants is crucial.

● **Quantum Computing:** Blockchain requires a digital signature that is cryptographically stored. It is estimated that by the year 2027 [28]. Subsequently, sound research which can solve blockchain scalability, security, and breakability issues using quantum computing should be worked on.

2.6. Various Features of Fraud Detection/Prevention Systems

Multiple systems detect fraud in advance and those that prevent fraud. A brief description of such systems is given below:

●**Real-time transaction screening and automated review:** Machine learnings help to monitor incoming data. This real-time processing of data helps employees in reviewing data [27].

●**Deep insights on user behaviour:** Machine learning or deep learning-based systems help to understand user behavior better and help analysts to work accordingly.

●**Reduction in False-positives:** It means the decline of legitimate transactions. Accuracy can be maintained by going beyond the transaction amount and the user's location.

●**Real-time operations tracking and reporting:** Customers can track their performance in real-time. They can also check information like location, channel, payment method, *etc*. Analysts use various fraud patterns using visualization software to find user behavior [28].

●**Automation Level:** Organizations have two choices: either completely rely on automated fraud detection models or consider taking an additional service of analysts to comply with the model results [29].

●**Comprehensiveness and self-learning capability:** Systems used for fraud detection must be versatile. The systems used by organizations must be comprehensive so that they can cover all the information systems. These systems should be able to automatically learn from the data gathered in the organization so that known and yet-to-be-discovered threats can be discovered [30].

●**Multiple protection layers:** Gartner group suggested a five-layer approach to detect and prevent fraud. Fig. (**4**) describes five layers:

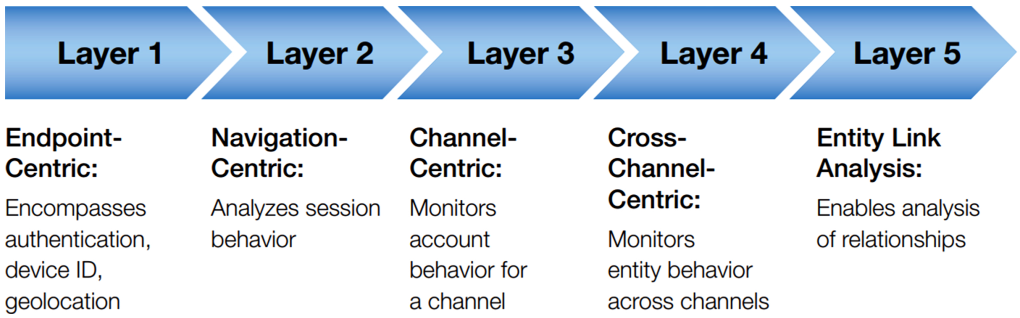

Fig. (4). Five-layer architecture for fraud detection or prevention [30].

●**Integration and deployment:** Organizations should encourage discussions and reviews of their products so that they can work on the pitfalls. They should also be focused on integrating current facilities in their software.

●**Compliance with security standards:** Organizations should maintain the document of their requirements handy. They must ensure that every customer complies with these pre-settled requirements of the organisation.

●**Cost:** The cost of fraud detection software varies according to the organisation's expectations. The choice is between having fixed subscription plans and flexible pricing according to the requirements. For example, Fraud screening tools are comparatively less expensive than full-service fraud tools.

●**Customer Support:** Organizations should provide robust and easily accessible customer support services. They should work on a document that describes the technical support customers can get from the service provider in case of difficulty, the response time, and the contact authority.

●**Approval rates and false-positive handling:** It is necessary to evaluate how the software handles cases of false declines which are originally legitimate.

3. REPORTED WORK

In this section, we explicate the finding of different researchers for fraud detection and prevention using blockchain technology. Many significant research works have been reported in this section that enhances the domain knowledge and resolve the issues using multiple advanced techniques. This section also highlights how deep and machine-learning techniques have been used in blockchain technology for fraud detection and prevention.

3.1. Fraud Detection Using Blockchain

Many researchers have documented significant achievements in the field of detecting fraud using blockchain concepts. In research by Joshi *et al*. [1], a framework was worked out to prevent fraud among various governmental organizations. The work was generic and developed a layered architecture for the disbursement of funds through various government bodies. They addressed the problems of corruption, which occur at various levels, leading to economic losses to the country. They employed blockchain because of its transparent, decentralized, and immutable characteristics. They used a complete graph to model cash flow across various levels of government. The information generated at any level is broadcasted on a network. The proposed model has four levels: sub-departments, district government, state government, and central government. Their model can be deployed on Ethereum. In their model, central authorities could deploy the smart contracts whereas other levels could only update about it. Their objectives were transparency, time complexity improvement, complete utilization of funds, immutability, security, promptness, and eco-friendly. A noteworthy research study by Podgorelec *et al*. [2] proposed an automated blockchain transaction signing using machine learning. They also proposed personalized anomaly detection in their work. Data storage in the blockchain ledger can be done only with the help of a digital signature, but this technique is time-consuming. To address this issue, they proposed a machine learning-based method for the automated signing of blockchain transactions. An analysis has been done using Ethereum. Customers are susceptible to fraud ratings in online shopping. Cai *et al*. [39] carried a substantial research work, addressed the fraud ratings problem, and discussed blockchain effectiveness in objective ratings and its leggings in subjective ratings. Their study checked blockchain performance under two types of attacks: ballot-stuffing and bad-mouthing. They found that blockchain is more robust for bad-mouthing as compared to ballot-stuffing. Outchakoucht *et al*. [40] amalgamated machine learning and blockchain to address the problems associated with access control in IoT (Internet of Things). IoT associates with the problem of decentralisation and dynamicity, which have been addressed in their work with the help of blockchain and machine learning, respectively. Their proposed framework was based on smart contracts and reinforcement learning. They used reinforcement learning to make agents learn from the environment and update the smart contract as per the results. Yin *et al*. [41] proposed supervised machine learning to remove anonymity from the Bitcoin blockchain. Bitcoin has enabled widespread illicit activities due to its high degree of anonymity. They used 385 million transactions to train the model and built a classifier able to categorise into 12 categories. Their proposed model had the capability of detecting yet-unidentified entities. They used a Gradient Boosting algorithm with parameters set with default values. They achieved a mean accuracy of 80.42% F1-score of 79.64%. In their article, they predicted a set of 22 clusters related to cybercrime and classified 153,293 clusters to estimate the Bitcoin ecosystem.

Another study attempted to address the needs of the ever-growing insurance market Dhieb *et al*. [42] and proposed a blockchain-based framework to detect fraud and increase monetary profits. Since the framework was based on blockchain, it allows secure transmissions among various agents. They employed extreme gradient boosting for insurance services and compared the performance with other algorithms. They used the auto-insurance dataset and found an increment of 7% invalidation as compared to the robust decision trees. They combined the proposed machine learning model with the hyper ledger fabric composer to implement a blockchain-based framework. Another substantial research by Pinquet *et al*. [43] detected suspicious users and transactions with the help of graphs generated with the help of the Blockchain network. In graphs, nodes were represented as users or transactions. They used many algorithms like Support Vector Machines, k-means clustering, and Mahalanobis distance. They also applied ensemble classification approaches like Random Forests and Extreme Gradient Boosting classifier (also popularly known as XGBoost classifier) to detect fraudulent activities in the famous Ethereum blockchain network.

Monamo *et al*. [44] used a K-means clustering technique to detect an anomaly in the records. It validated the model's performance on the Ethereum network, gained better results, and detected more fraudulent transactions. Arjoune *et al*. (2020) [45] employed multiple classification models to detect jamming attacks. The classification models used the achieve the desired objectives are Random Forest, support vector machine, and neural network. The classification approach projected in this study can process large-sized data in less time with greater efficiency. The transmission link state is monitored to verify whether it is attacked.

3.2. Fraud Prevention Using Blockchain

Estevez *et al*. [46] designed a system to prevent fraud in fixed telecommunication. They addressed the problem associated with the long-distance impact factor. They designed both classification and prediction modules. They classified subscribers into four different categories: fraudulent, normal, insolvent, and subscription fraudulent based on their history, whereas the prediction module was proposed to find a fraudulent customer. They employed fuzzy logic on a database with more than 10,000 subscribers residing in Chile. The database considered for the study had a fraud prevalence of 2.2%. Multilayer perceptron was used to predict potential fraudulent customers. The model was robust enough, identifying 56.2% using only 3.5% of the test data. For the total dataset, it gave a tremendous result of 97.6%.

Wiese *et al*. [41] addressed the problem of high false-positive rates using dynamic machine learning algorithms. They suggested that rather than analysing single transactions, a series of transactions must be analyzed for detection purposes. The use of biased machine learning methods was done to achieve better results. They used Support Vector Machines and Long Short-Term Memory Recurrent Neural Networks. The authors considered the European cardholder dataset for their study, which has 30876 transactions collected over 12 months. PERF Release 5.10 was used to determine performance metrics in each case. They used 41 features out of the total feature set to classify. The AUC valued 95% confidence using 30 trials. The maximum value of AUC of 99.216% was recorded, and the minimum of 91.903%. With the help of SVM, they achieved an AUC of 89.322%; it was also found that SVM took a shorter duration for classification.

Generative Adversarial Networks can be used to mimic minority classes as they are flexible, general, and powerful generative deep learning models. Fiore *et al*. [47] exploited Generative Adversarial Networks to increase the dataset for training. As a result, the performance of the classifier considerably improves. The generator and discriminator both were of 3 layers each. They successfully addressed the class imbalance problem using Generative Adversarial Network by producing great results – a specificity of 99.998% and a sensitivity of 70.229%. Rushin *et al*. [48] used a dataset with 80 million transactions gathered over eight months to detect credit card fraud. The considered dataset has 69 attributes containing information related to accounts, transactions, and account holders. The dataset also suffered from imbalance class problems, consisting of 99.864% legitimate credit card holders and only 0.136% as frauds. They used autoencoder and domain expertise to obtain a feature set for building the model. They created six different feature sets using original features, autoencoder features, and those generated by the domain expertise. They tested the performance of all six datasets with the help of the following classifiers, deep learning models, logistic regression, and Gradient Boosted Trees. Deep learning models outperformed in most cases, and the other two classifiers gave presentable results. Recently Dhir *et al*. [16] analyzed the application of machine learning and deep learning-based approaches in the field of cyber security. The study explained the threat models that embrace different attacks faced in the network. Another significant research work in healthcare was carried out in 2020, Chen *et al*. [45] proposed a new approach based on fuzzy entropy–based and projected a fuzzy entropy-weighted natural nearest neighbour method (FEW-NNN) for detecting the attack in the network traffic. The Fisher score and deep graph feature selection methods achieved the objective of dimension reduction. The proposed model was validated in publicly available datasets like KDD99 and CICIDS-2017 datasets and achieved prediction accurateness of 80% on KDD99 dataset. Gorla *et al*. [49] explored the issues encountered in blockchain for fraud prevention and detection in forensics. Blockchains can generate a decentralized situation in which any third party does not control transactions and data. It also has the capability to analyze fraud in the digital setting. This study proposed the inclusion of artificial intelligence to address the issues in fraud prevention. Another prominent research work carried out in 2020 by Nguyen [50] applied the blockchain model to prevent roaming fraud and maximize the benefits. This study investigated a profitable model on the basis of the Stackelberg game with the aim of enhancing the profits and encouraging users to participate in the blockchain system.

4. COMPARATIVE ANALYSIS

This chapter section compares previous works based on the techniques used and prediction accurateness achieved. The studies used for the comparative analysis are those that employed machine learning and deep learning algorithms in blockchain technology for fraud detection. Multiple frauds like Credit Card Fraud, Financial Fraud, Energy Fraud, Medicare Fraud, Fixed telecommunication Fraud, Network Traffic Attacks, Jamming attacks, Technical loss fraud, and Auto-claim fraud have been detected. Most of the studies that have been analyzed worked on Credit Card Fraud detection using automated learning techniques. A comparative analysis of all the studies is presented in Table **1**.

Table 1. Comparative analysis for fraud detection using blockchain technology.

Author	Fraud type	Dataset	Technique	Result
Awoyemi *et al*. [4]	Financial fraud	ULB Machine Learning Group	Naïve Bayes, K-nearest neighbor and Logistic Regression	Accuracy= 97.92%, 97.69% and 54.86%, respectively.
Maes *et al*. [51]	Credit Card Fraud	Serge Waterschool	ANN, Bayesian Networks	Accuracy= 70%, 74%, respectively.
Yee *et al*. [52]	Credit Card Fraud	WEKA	K2, Tree Augmented Naïve Bayes, and Naïve Bayes, logistics and J48.	Accuracy= 95.8%, 96.7%, 99.7%, 100.0%, 100.0% respectively.

(Table 1) cont.....

Author	Fraud type	Dataset	Technique	Result
Ford *et al*. [15]	Energy Fraud	WEKA	ECB neural network	TN: 75.00% TP: 93.75% FN: 6.25% FP: 25.00%
Bahnsen *et al*. [53]	Credit Card	From a European card processing company.	Logistic Regression (LR), and Random Forest (RF)	Bayes gave g savings of 23% more as compared to Random Forest.
Bauder *et al*. [18]	Medicare Fraud	2015 medicare PUF data	DNN, GBM, RF	Confidence= 95%
Randhawa *et al*. [54]	Credit card Fraud	European Card Holders	AdaBoost	Accuracy=99%
Khare *et al*. [55]	Finance Fraud	European Card Holders	Logistic Regression, Decision Tree, Random Forest and SVM	Accuracy= 97.7%, 95.5%, 98.6%, 97.5%, respectively
Estévez *et al*. [46]	Fixed telecommunication Fraud	DICOM	a multilayer perceptron neural network, fuzzy logic	Accuracy= 97.6%
Wiese *et al*. [14]	Credit card	European card holder	Support Vector Machines, Long short-term memory	AUC as 89.322%, 99.126%, respectively
Thennakoon *et al*. [56]	Credit card	fraud transactions log file and all transactions log file	Support Vector Machine, Naive Bayes, K-Nearest Neighbor and Logistic Regression	74%, 83%, 72% and 91% accuracy, respectively.
Yap *et al*. [49]	Technical loss fraud	Pre-Populated Database (PPD)	Support Vector Machines, Genetic Algorithm	Accuracy = 94%
*Via*ene *et al*. [19]	Auto-claim fraud	PIP claim data	Bayesian Neural Network	NA
Dornadula *et al*. [21]	Credit Card Fraud	European credit card dataset	Isolation Forest, local outlier factor, SVM, LR, DT, RF	Accuracy= 90.11%, 89.90%, 99.87%, 99.90%, 99.94%, 99.94%, respectively.
*Via*ene et *al*. [57]	Credit Card Fraud	Claims during 2000	Logistic regression	Accuracy= 99.42%
Pinquet *et al*. [43]	Credit card fraud	Claims during 2000	Backpropagation	NA
Panigrahi *et al*. [58]	Credit card Fraud	NA	Decision Tree, Naïve Bayes	Avg. Accuracy= 98%

(Table 1) cont.....

Author	Fraud type	Dataset	Technique	Result
Chen *et al*. [45]	Network Traffic Attack	KDD99	Fuzzy Entropy Weighted Natural Nearest Neighbor Method	Training Accuracy=80% Testing Accuracy= 80%
Arjoune *et al*. [59]	Jamming Attacks	Customized Dataset	Random forest, support vector machine, and neural network	Accuracy =96.6%

As stated in the above table, we can see that multiple learning techniques such as supervised (Decision Trees, Support Vector Machine, Naive Bayes, K-Nearest Neighbor), ensemble techniques (AdaBoost, Random Forest), multiple hybrid approaches (Bayesian Neural Network, Isolation Forest, local outlier factor) and neural learning approaches (Artificial Neural Networks, ECB neural network, Deep Neural Networks, multilayer perceptron neural network, Long short term memory) have been explored in the field of different types of fraud detections fraud detection. Different machine and deep learning-based algorithms have successfully achieved significant prediction accuracy. Different studies have used different evaluation parameters to test the performance of the classification models. The parameters used to assess the model's performance are accuracy, the area under the curve, confidence rate, and true-positive and false-negative.

CONCLUSION AND FUTURE WORK

In this chapter, we have combined machine learning or deep learning algorithms with blockchain to prevent and detect fraud. We have studied the framework of the blockchain, the various types of fraud committed by fraud, the benefits associated with the blockchain, and the research challenges. We also checked the contributions of different researchers in order to detect fraud using various algorithms. This study shows that bringing AI (machine learning/ deep learning) and blockchain together results in tremendous systems with the following capabilities: secure, transparent, decentralized, robust, encrypted, analytical, accurate, precise, and many more. The presented related work shows that machine learning and deep learning algorithms can precisely catch fraudulently. We have also seen that these technologies counter each other. The disadvantages associated with one can be remedied by the other. For example, a model requires a large amount of data to create better results, and the limitation of data can be rectified using blockchain. Since the model uses personal and private information, there is a grave fear of tampering with data. But since blockchain ledgers are tampering-free and decentralized, the task is easy and suitable. There are many such described limitations of these technologies, which can be rectified using the other.

The researchers should work to bring down the associated cost so that the majority can access this technology. Untouched domains like genetics and evolution should also be explored using these technologies as these domains suffer from limited and private data disadvantages. Blockchain and AI show signs of being a new emergent field that can help establish systems people did not even think of.

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CHAPTER 13

A Blockchain Approach for Health Care Sector to Prevent Fraudulent Activities in Medical Records

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Abstract: The Electronic Health Record (EHR) systems provide health information about patients. Data security, integrity, and management of EHR are crucial problems. Records can be modified and altered by different stockholders as the different users may be using them in more than one form. Medical records management is a suitable application for blockchain-enabled records that can be stored, tracked, and managed by all the transactions to prevent fraudulent activities. A novel framework has been presented here in the healthcare sector by using the blockchain concept. The major goal of this article is to implement BlockChain for electronic health records (EHR), and its decentralized approach eliminates the chance of a single point of failure, making the system robust. The proposed work also covers the extensible problem faced by BlockChain in common with the help of an off-chain repository of the data. The results indicate that computing is much more secure and free from a scam than the traditional health record system. Finally, the proposed approach suggests scenarios such as EHR where the introduced approach should prove adequate.

Keywords: Blockchain, Consensus, Decentralization, Firebase, Scalability, Smart contract, Solidity and ethereum.

I. INTRODUCTION

Blockchain technology was basically tailor-made for keeping a distributive financial ledger, but the Blockchain paradigm can be generalized to make a decentralized ledger to store information of any specific domain. The transactions between what is referred to as the singleton state-machine are secured by cryptography. Whenever a new data entry is made, the node encodes the logic, thus, validating it before uploading it to the Blockchain. The Blockchain technology-based ledgers used for storing data are primarily based on the use of

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"smart contracts" which allows automation and tracking of data-related characteristics such as Viewership Records new data entries [1].

The viewership and ownership permissions are shared through the peer-to-peer network, accessible to private members. In the smart contracts available on the Ethereum framework for Blockchain, we define the relationships between two entities and formulate the viewing instructions and data retrieval permissions for them to be available for external databases. Through this system, patients can choose and allow the sharing of their medical data among trusted providers, whereas providers are capable of adding new entries related to the patient. All these data transactions are secured by adding a cryptographic hash of the record on the blockchain, ensuring data integrity. Thus, validating and keeping the users indulged in the evolution of the data makes it more secure [2].

Traditional patient records require a large number of human work-hours. For instance, suppose a patient visits a clinic or a hospital, now his/her documents must be found and then transported to the required department, and then the actual examination of the patient can start. Besides, the high chances of mishandling the patient record files exist [2]. Fig. (**1**) shows the traditional medical record system.

Fig. (1). Traditional Medical Record System.

The medical care industry, specifically, frequently has been a significant objective for data robbery as prosperity records consistently contain private information like the names, government-upheld retirement numbers, and addresses of patients. Through blockchain, every record is protected with a unique blockchain ID that protects the records and makes them easily accessible to authorized personnel only. In the healthcare industry, doctors and their helpers receive a decentralized blockchain system; they have control over their patients' credentials and can simply check their histories [3].

The fundamental requirements of the medical care framework are the issues of legitimacy, information transportation, interoperability, contemplations of portable well-being, and the exchange of well-being records. For more information on this, check out the explanations for each of these crucial parameters below.

1.1. Healthcare System Security

Medical findings can be anything like patient records or the data that has been received from the patient's using sensors. Patient records are generally translated from paper-records to digitized medium, so they require more security and authority to be put in the right place to secure the medical findings and records [36]. Medical services records are being put away in information bases; just approved people have the option to get to those data, and access should be verified and approved. Current strategies to ensure records have demonstrated not to be as manipulated and replicate a patient's health records can have genuine outcomes [4].

1.2. Health Record Sharing

Healthcare systems are joint efforts of health and information technologies. The digitized way of data sharing can raise the chances of security problems along with the problem of civilian medical records. Healthcare record sharing can be tedious because the same individual's records can be stored in multiple places, which will raise the situation of duplicity in the system. A primary issue with well-being record sharing is interoperability [5].

1.3. Data Interoperability

Interoperability is the phenomenon of sharing and transporting medical records among various sources. The major drawback to interoperability is the usage of centralized data storage in medical organizations. Centralized information storage is an issue for medical care providers as they store all records in a single focal data set. The particular issues that emerge from concentrated information storage are the fragmentation of information, quality for health record exploration, slow access to health information, information quality, and the absence of framework interoperability. Numerous records are produced every day and are put away in a centralized area at various hospitals. Records that are distributed in various hospitals can be lost, and the information contained would not be accessible to the patient [6].

1.4. Mobility

Mobility is a quickly developing prerequisite in the Healthcare industry as patients become more portable and request their medical records meet a similar degree of portability. As smart gadgets, sensors, and other web-empowered devices become more prevalent, the ability to move those medical records is very important. Also, the need to have constant sharing and admittance to information from any place on any device intensifies, guaranteeing that the information is secure. EHRs have eliminated the physical transferring and documenting of outlines, making data available. Frameworks allow remote admittance of charts; professionals can even be off-site and still secure access to patient documents [7].

The expanded availability, mobility, and transparency gained by electronic medical records (EMR) increase the simplicity with which they can be accessed by medical services experts, yet besides can build the measure of fraudulent activities by unauthorized people. Healthcare information requires security and protection. Protection is the beginning stage that allows getting the patient's health record. EHRs make it simple for thieves to manufacture data. For instance, providers can, without much of a stretch, produce false yet believable cases by making counterfeit reports [8].

Various security norms have been grown, for example, HIPAA, DISHA, and COBIT, which have been applied to ensure patients' medical data. This incorporates overseeing access control of patient data, the security of patient information from an unapproved user, and the alteration of stored information. The size of medical care information increases; at that point, there is a need for security standards to ensure the information. The United States and numerous different nations have created security standards to secure their medical data. Any changes after the data are recorded would make it more difficult to hide.

From all these areas and current needs, it can be concluded that Blockchain improves the integrity and verification of such medical records. It helps the dispersion of information inside the organization. These highlights make an impact on information quality, cost, and value of medical services delivery inside the framework. In simple words, we can image blockchain as a chain of blocks, such that each block has 3 components. First is Data. It may be any information or group of information. For example, it may be the information of 1 bank transaction or a group of 5 bank transactions for the transfer of money. Second is

Hash. It can be considered as an encoded version of the block. So, if we change anything on the block (not just data), then the hash value of that block will automatically get changed. And the last one is previous Hash value. It is the hash value of the previous block in the blockchain. Medical record provider has a direct association with the blockchain. All health records are stored in the current medical software frameworks. Medical records identified with patients having Patient IDs are communicated to the blockchain network. All transaction is submitted in the blockchain network utilizing Patient IDs that do not contain individual data. The patient wishes to share his/her identity with the medical care provider, with whom they can share their private keys. This is the way the provider would then be able to get to the patient's medical record. The medical record remains confidential to the individuals who do not have the private key of the patient.

Blockchain can be an influence to mark some of the medical care greatest difficulties. In the case of traditional EHR (electronic health record), if a user needs to get to his health records, he would need to follow the process to get access to them. Data is centralized to a medical services association, and its control is given to the medical care area or associations. This problem makes it reasonable for a system that would be useful in changing the medical care area to be more transparent and reliable among all users.

The article is structured as follows. Section II presents the related study of blockchain technology in the healthcare sector, and Section III explains healthcare use cases. Section IV and V discuss the proposed framework and technology used to implement the proposed framework. The details of implementation and results have been discussed in section VI. Finally, section VII concludes the whole approach as suggested.

2. RELATED STUDY

To make the foundation frameworks straightforward, a systematic literature review has been done in many areas. A summary of a detailed review of major research works in the direction of various approaches toward healthcare management is presented below:

2.1. Health Care Approach

Various approaches toward health care management have been suggested by researchers. Uddin *et al*. [9] discuss the increased usage of the Internet of Things(IoT) in the day-to-day life of human beings has also led to the concept of

Remote Patient Monitoring, a Patient-Centric Agent using blockchain technology is commendable.

Agbo *et al*. [10] worked extensively on the research paper Blockchain Technology in Healthcare: security because the data of healthcare of a patient not only contains the records of his or her health and treatments but also personal information like contact address, contact number, and other sensitive information such as social security number.

Matthias Mettler and MA [11] studied the different areas and various fields where Blockchain can be used and how it can be used in other non-financial sectors. The major areas in which Blockchain can be implemented successfully are the areas of Smart Healthcare Systems, to fight counterfeit drugs in pharmaceutical companies, for digital signing of emails as well as contracts for legal purposes. The use of Blockchain helped the companies which were already existed in storing and transferring data more quickly and securely without any third-party intervention.

Ramani *et al*. [12] discussed in the field of healthcare record Securing and efficient data accessibility by using blockchain technology. Blockchain as a decentralized and circulated innovation can assume a key function in giving such medical care administrations. Smart contract and ethereum platform maintain authenticity, security, and prevent data alteration.

Vora *et al*. [13] proposed BHEEM: A Blockchain approach-based system for Securing medical records in 2018. Blockchain innovation settles the plans dealing with the security of EHRs, which have brought about information being commonly unavailable to patients. They have proposed a Blockchain framework that gives secure and data access to health records by patients, doctors, and outsiders while securing the patient's private data. The goal is to see how the proposed system satisfies the requirements of patients, doctors, and outsiders, and to see how the system maintains the protection and security concerns in the Electronic health record system. Table **1** summarizes the detailed review of contributions to EHR using blockchain techniques.

Table 1. Detailed review of contributions to EHR using blockchain techniques.

Authors	Proposed Methodology	Application Approaches
Uddin *et al*. (2018)	Remote Patient Monitoring	Rapid data storage and access authentication to the user.
Agbo *et al*. (2019)	Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)	The property of blockchains is decentralization, transparency, and immutability has been achieved.

(Table 1) cont.....

Authors	Proposed Methodology	Application Approaches
Chakraborty *et al*. [2019]	IoT, Transaction and access management, machine learning	Fetches data from the health record and the complete supervision of a patient follow-up.
Gordon *et al*. [2018]	Institution-driven and patient- driven interoperability	Clinical data authorization rule, unique patient keys
Griggs *et al*. (2018)	Hyperledger sensors Blockchain-based Protocol	Confidentiality, Immutability, Traceability, Speed, Privacy, Transparency
McGhin *et al*. (2018)	Ethereum Blockchain Technology	Security, Interoperability, Data Sharing, Data Access
Matthias and M A(2016)	Blockchain Described	Smart Healthcare Management, Digitally signing the contracts and emails in the Pharmaceutical industry.
Ramani *et al*. (2018)	Ethereum & Smart Contracts	Confidentiality, Integrity, and Authentication have been achieved by using blockchain technology.
Shahnaz *et al*. (2019)	Ethereum Virtual Machine (EVM), InterPlanetary File System (IPFS)	Increased Scalability, Integrity & Access Control of data using blockchain technology in the health record.
Vora *et al*. (2018)	Database Manager, Cipher Manager.	Secure and efficient access to medical data in EHR systems.

2.2. Healthcare Care Information System

Electronic medical records (EMRs) meet the opposition to converse patient's privacy and share healthcare medical records among researchers when they need it. El-Yafouri and Klieb [2] discussed the software technologies in the medical sector using EMRAM, a HIMSS model for considering the effect on organizations approving HIS and explaining different types of levels of adoption. Saranummi [14] explains the Electronic Health Record (EHR) and the Personal Health Record (PHR). The information within a health Care Delivery Organization (CDO), the second recording of the medical record of an individual, is owned by the patients themselves. Swan discusses safety and security features. The power to ensure identity develops opportunities for holding abstract assets such as medical records. This opens the way for the user to declare data stored within the system. Data transformation from Computerized Patient Records (CPR) to CPR across many CDOs to the Personal Health Record (PHR), where an identity would be used to get health records for patients from the system. HIPAA use as a standard for security measures in place for the storage and use of the medical record. Blockchain, together with current control systems, databases, and security, enables us to build next-generation information systems that can securely manage health records across the network while ensuring transparency and scalability of the medical records [15]. Table **2** summarizes the different types of health information systems.

Table 2. Health information systems.

Keywords	Brief Description
EMR	Electronic Medical Records: Organizational information utilized by a HIS to data.
HER	Electronic Health Records: keyword frequently utilized conversely with EMR, anyway the EHR orders various information of the data.
CPR	Computerized Patient Record: Patient information rendered in advanced configuration.
EMRAM	EMR Adoption Model: HIMSS created this Technology framework.
HIPAA	The Health Insurance Portability and Accountability Act (HIPAA): detail the necessities for safe health records, and safety efforts used for the storage of patient information.
HL7	Health Level Seven: An early norm to encourage the trading of information between associations processing medical care information.
PHR	Personal Health Record: Personalized universal assessment record.
CDO	Care Delivery Organizations: Organizations liable for the transfer of medical care services. These may incorporate medical clinics, hospitals, and specialist centers.
HIS	Health Information Systems: Systems normally possess CDA for overseeing care-related information, which may inform users just as associations.
ARRA	American Recovery and Reinvestment Act: Give incentives to medical care associations to modernize their HIT frameworks.
Snowed CT	Systemized Nomenclature of Medicine: Specialized pseudo-code for storing information about medical status, techniques, and findings. Used to record information in health records.

2.3. Blockchain Survey-Based Approach

A detailed review of major research works in the direction of various approaches toward healthcare management is presented in this section, and now the next section will describe different use cases for EHR and related work. Researchers have recommended the desired record [16].

With a gatekeeper database, an offline database can be used as a cache for health records. If authorization has been given and a researcher's suggestion has been made, the gatekeeper may roll back the results of the inquiry [17].

Researchers have proposed a framework that combines a smart contract and an Interplanetary file system to enhance decentralized remote side storage and data sharing for better utilization [18].

Researchers provide an interplanetary file system as a user for off-chain transactions in a database for storing massive volumes of personal data from the sensor [19].

3. PROPOSED METHODOLOGY

The most prominent things to be kept in mind while designing and developing new technologies to carry out the same task are, evidently, transparency and accessibility of medical history data to the patients while keeping the economic feasibility in mind. Moreover, patients will have to be convinced about the confidentiality of their information which is mandatory for them to indulge in the process with full disclosure [20].

The new technology should definitely consider adding exceptions cases while providing information to the patients as not every data can be transferred to patients, for example, psychotherapy notes or therapist's personal information. Not only maintenance of these records will be time-consuming, the patients involved hardly care enough to take out their time to indulge in the process [21].

There are three modules in the Blockchain-based medical service framework. These sections, when combined, would keep our structure running. Fig. (**2**) shows the Blockchain-based Medical Service System Framework.

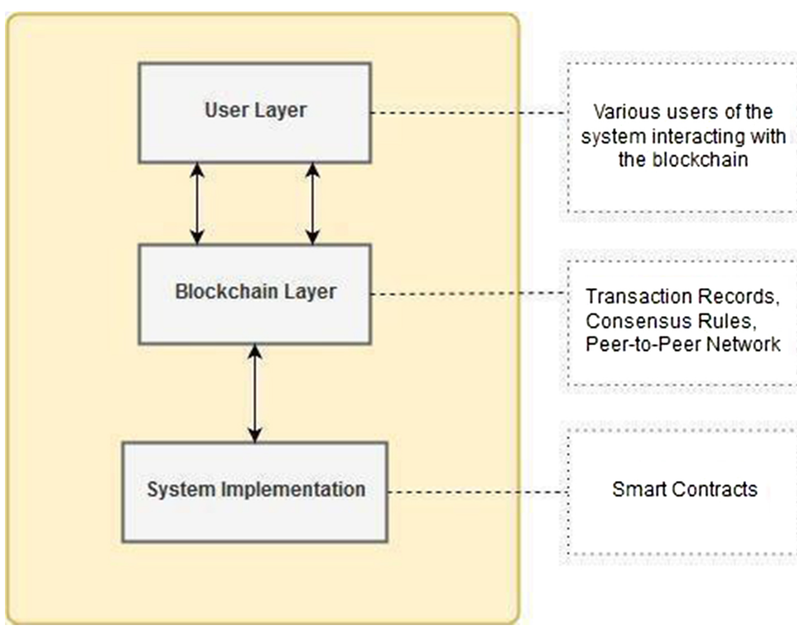

Fig. (2). System Design of Blockchain-based Medical Service Framework.

3.1. User Layer

Doctors, users, and staff are examples of users. A user has many features and tasks on the system, such as interacting with the system and performing simple task operations such as create, read, delete, update, and so on, which allows him to be identified on the system. Users can access system functions *via* the GUI (Graphical User Interface), and they can communicate with the blockchain layer *via* the GUI [22].

3.2. Blockchain Layer

The blockchain layer is the next layer of the framework; this is the middle layer of the framework that contains code for user communication with DApps that are running on the blockchain. This layer contains three modules.

3.2.1. Blockchain Assets

In 2005, Ethereum, an open-source, blockchain-based, decentralized software platform, was launched. A transaction is a piece of data that is transferred from one user to another, and only one transaction can change the state of record. The blockchain treats the transaction as data and treats it as an asset, essentially storing it for later use or so that the user can send it to another user.

3.2.2. Governance Rules

There are some rules that must be followed when computing a transaction using the Blockchain approach. To ensure the safety of the blockchain, there needs to be some kind of agreement. The use of Proof of Work (PoW) agreements is necessary to ensure that technology governance is maintained in a secure manner by connecting all nodes to the blockchain system.

3.2.3. Network

The fundamental concept is to construct a decentralized distributed platform through a peer- to-peer network in which all nodes are connected as peers with equal status. No node acts as the primary node in a blockchain system; the organization's foundation is maintained by all nodes. A decentralized system is produced by this Blockchain-based organization. As a result, the best choice this blockchain strategy has made was to use a company where each associated block has the same status and authority [23].

3.3. Implementation Layer

The framework is implemented using Ethereum. In the Dapp, smart contracts play a major role. The purpose of the health records agreement is to put the system's usefulness into practice. It performs the CRUD operations and defines the access permissions for these records. The OpenZeppelin agreement libraries provide a predefined agreement in other contracts, such as Roles. The majority of agreements that have been completed in various functions can be used to create your agreement from these libraries [24].

3.4. Preliminaries used in Framework

Preliminaries utilized in the system depict the system utilized for improvement of this blockchain-based medical service framework.

● **Consensus protocol**: In the blockchain system all the positive clients with access privileges have unique access rights to provide data transfer that are up to date in the system [25].

● **Hash cryptography**: Use of SHA256 hash in blockchain for data transfers. Hash algorithms consist of a feature, which includes unidirectional cryptography, with a faster computation, and have to resist collision [26].

Immutable record: All data transfer in a blockchain network is the record, at the equivalent level.

Mining: Miners use nodes of nonce esteems to get hash value in the system. To achieve this kind of output calls for excessive computational power. This technology offers all the foundations for application domains, which include digital currency [27].

● **Ethereum:** Ethereum was officially presented in 2015 and Ethereum is to make a smart contracts platform that could hold the component of software systems. This framework utilizes its own digital money, known as Ethers. Digital money could be utilized for accessing it between accounts associated with Ethereum. Ethereum gives the software engineers a language in which they make the blockchain system, this language is Solidity [28].

● **Ethereum Virtual Machine (EVM)**: Ethereum systems offer to incorporate the programming in the blockchain. It gives the user to make their applications work on Ethereum. The applications manufactured utilizing this system are known as Distributed Applications (DApps). They contain various rules that make a system for Distributed Applications (DApps). The applications based on smart contracts are executed on EVM [29].

Fig. (**3**) depicts users using web applications interacting with the Ethereum virtual machine. The user creates an instance of web3j an Ethereum virtual machine. Web3j is a lightweight, Java, and Android library for working with Smart Contracts and incorporating customers (nodes) on the Ethereum organization; this web3j instance connecting with ganache acts as the user. This user can manage Blockchain and connect to Ethereum also [29].

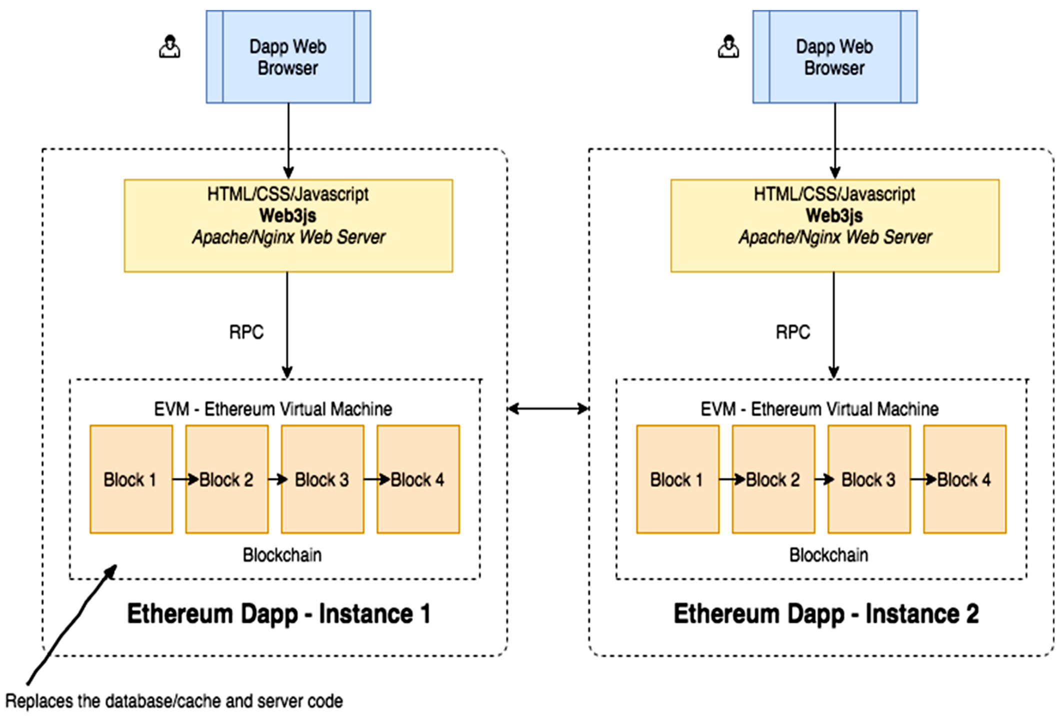

Fig. (3). User using web application interacting with Ethereum virtual machine.

● **Smart Contracts:** It executes on the blockchain system in this manner, making them secure from any sort of altering and modifications. Trust, transparency, the decentralized, and public nature of most blockchains, fast, Cost-effective, Security, and efficiency are some applications of the smart contract. Smart contracts are created on a blockchain platform with the aid of using or extra contracting parties. The agreement receives confirmed with the aid of using a P2P community whenever a transaction is processed. Distributed Ledger Authentication makes them secure. Some Advantages of Smart Contracts are Trust and transparency, the Decentralized and public nature of most blockchains, fast, security and efficiency, and Cost-effective. But there is some limitation of Smart Contracts, like Not written human language, requiring the third party, requiring trust in the design process, Issue in coding errors, and Not interoperable both with smart contracts on other blockchains [30].

Fig. (**4**) depicts the client interacting with a smart contract in the ethereum network resulting in the deployment of several instances of contract. Smart Contracts is a protocol that keeps the negotiation between two users of the system. It verifies the agreement between two users and executes the agreed-upon conditions. Ethereum is the biggest decentralized platform that allows making unlimited Smart Contracts using.

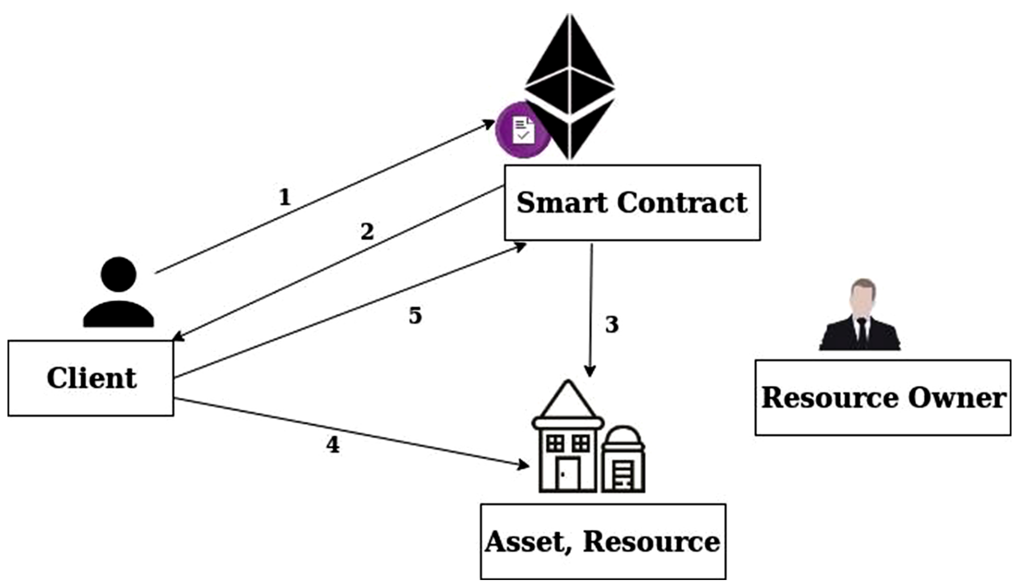

Fig. (4). Client interacting with smart contract in ethereum network resulting in the deployment of several instances of contract.

● **Transparency Protocol**: With Transparency Protocol, Increased transparency for the user in the blockchain network, and the possibility for a user to have access nodes on blockchain networks, store their data, and audit the path of all data transactions. Some challenges of transparency protocol are Seeks to trust in the government procurement process through working with four different peers, User operates in a system they do not have trust in other peers, and Poor monitoring mechanisms. So the solution of transparency protocol is to restore confidence in the entrusted government process, global environment of integrity, transparent coordinating process and better understanding of how data are being used [31].

● **Interplanetary File System (IPFS):** IPFS gives secure information stored on IPFS and is secure from any modification. All the medical records on IPFS contain a hashing value that is produced cryptographically. It is utilized as an ID to store information on the IPFS. The working of the IPFS protocol is done in a simpler manner. The first file record on IPFS is allocated hash, replication of documents does not permit to exist on the IPFS, and a block of the system record index and file data of the block [32].

4. TECHNOLOGY USED

Implementation of the proposed system requires various tools and technologies. The below-mentioned technologies have been used to perform the projected structure:

4.1. Programming Requirement

(I). Solidity - Solidity is a high-level language for executing a smart contract.

(ii). Etherium - Ethereum is a public, open-source, blockchain-based platform, and working framework having the features of a smart contract system. Ether is a digital currency produced by the Ethereum.

(iii) Javascript - JavaScript, contracted as JS.

(iv) web3j - web3j is a lightweight, exceptionally modular type-safe Java working with Smart Contracts.

(v) Ganache CLI - Ganache CLI, the Truffle set-up of Ethereum tool, individual blockchain for Ethereum development.

4.2. Hardware Requirements

To create this platform, a lot of programming is required and cannot be done without a powerful device. We require a fast-processing device that has a high-speed CPU. Working with blockchain requires a lot of computing power in each device in the network, and each block maintains a copy of the data. In the Ethereum network, there are mining nodes as well that have to perform a lot of computation. The minimum hardware requirements are 4 GB RAM, NVidia GTX Titan GPU, Hard Disk, and Intel i3 Processor.

4.3. Platform Used for Designing Blockchain

The Blockchain gives a protected method for executing Distributed records, an arrangement of records accessed over different nodes that utilize a network communication potentially remote. This is done in a distributed setup; all peers take an equivalent part in the administration. Issues in medical care coming about because of the ineffectual following of benefits between members are possibly addressable through such arrangements. The advantages and the members must be remarkably recognized and confirmed [33].

In the P2P model of Blockchain, record sections are stored at every node, and when joined, they give global access to the record. Transactions are stored permanently in blocks over the nodes. A network need not be heterogeneous, that all peers having a similar job, the organization is planned so members whose identity confirmation has been eliminated. The most significant feature of Blockchain arrangements empowers is to connect smart contracts to every transaction. A hospital and insurance agency would be associated with the analysis and medical care of a patient with a transaction [34].

Auditors can utilize carefully marked and time-stepped data stored in the records for dealing with the activities of organization members depicted in Fig. (**5**). The smart contract cannot change the process of reviewing however, it could improve the process; consequently, permitting it to be more careful utilizing the same [35].

5. IMPLEMENTATION

After the system has been planned in detail, the next stage is to move the system into a functioning one. For this, various interfaces can be created which will then be linked with the backend. On the backend, there can be numerous tools used so as to ensure maximum correctness as well as enhanced security.

The new technology should definitely consider adding exceptions cases while providing information to the patients, as not every data can be transferred to patients, for example, psychotherapy notes or therapist's personal information. The updating and removal of erroneously added data hence become impossible. This causes both patients and medical institutions to deal with compromised data in a fractured manner. The health records need to be cohesive, whereas this method of data storing results in a fragmented manner. One major cause can be the strategic barriers between the various medical institutions and Healthcare centers. Thus, a patient trying to retrieve his/her past medical treatment data is often hurdled by the economic incentive involved. Recent investigation shows that IT developers are providing information exchanging interface charge exorbitant prices making it even more impractical [36].

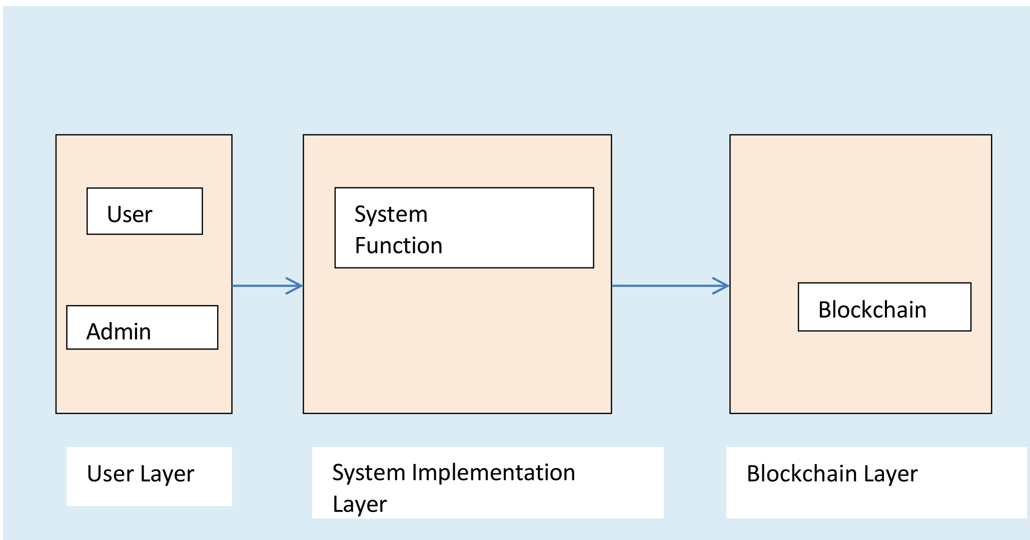

Fig. (5). Admin and User Interaction with DApp.

The doctor generates a request to acquire a medical-health-record of a patient, through which the doctor requests to fetch information about the patient's medical record from the database. After generating the request, we verify the doctor's identity. User being authenticated is referred to as the requester and the user whose authentication is being conducted is referred to as the verifier. Acquiring the patient record according to the doctor's request is the phase during which the patient's record is retrieved from the database. The next step is to generate new diagnosis data to be shown to the doctor. Encryption of the medical-health-record is the final phase where the medical-health-record which will be sent is encrypted.

The patient then verifies the credibility of the Doctor and also gets access to the previous feedbacks from other patients for the same doctor to make an informed decision. The newly created user can also create a password to prevent unauthorized access to his/her data as well as the Blockchain in general through his/her user interface. The encryption for the newly created record is carried out.

6. SMART CONTRACTS

This includes user records and Task's contract. Through this contract, access is given in CRUD operations are performed on the user record.

1. User Record contract— made for the only implementation of the functionality of the proposed framework. It defines task access as well as performs CRUD operations.

2. Task's contract—Tasks smart contracts belong to Asset's libraries, sub-libraries of OpenZeppelin libraries. Various other smart contracts are defined in the asset library for defining access tasks.

Algorithm for defining the User Record Smart Contract:

1: **Tasks assignment:**

2: **Function1**- Tasks defining (newR, newA) #newR =new tasks

3: add new tasks and accounts in tasks map

4: end function1

5: Add data:

6: **Function2**- add record(a=id,b=age,..)

7: If (mes.sender ==doc) then

8: Data is added to user's record

9: else close session

10: endif

11: end function2

12: show data:

13: **Function3**- show data(parent id)

If(mes.sender ==doc or user)then

If(user.id)==true then

Show data from (id)

Return (user record)

else close session

end if

end if

end function3

Data modify or update:

Function 4- modify user record (variables to modification or updation

if (mes. sender==doc) then

if (name==user name and id==user id) then

rerurn completed

else:

rerurn failed

end if

else: close session

end if

end function4

erase data:

Function5-Delete user record

if (mes. sender==doc) then

if (id==user id) then

delete record

```
return success
else: return fail
endif
else: close session
end if
end function5
mes=message, doc=doctor,
```

The Algorithm defines the working of the agreement for understanding records. The primary module of the Algorithm is defined identity, which is to be finished by the admin, and it incorporates two factors: newR and newA. The second module adds a patient record and it is finished by the doctors. The admin-appointed main role work. This module likewise keeps track that is performed by the verified user location of the specialist's record. An authenticity examination is finished by a specialist and could include the medical records of patients. The third module shows data to see the patient's information, and it requires the identity of patient to be passed as the element. It could utilize the framework to see the data stored of patient’s health records; it would restore those records that are mentioned to recover those records. It incorporates the approval for the access of data is only for patients or specialists. Just the patients and specialists could be permitted to see the records. Fourth module is to update medical data stored, and the approval is done verified user to assess these records. The last module is erased records where its names are utilized to delete the records of particular patients [36].

6.1. Performance Evaluation

Here Ethereum is used to implement the purposed framework, and the time between block is 10- 19 seconds. Block time means the time to generate a new Block. In Ethereum, we have a gas limit instead of the block size. The add user record function takes around one or two minutes, and it depends on the size of the data and user record function takes 50 sec approximately, and the time taken for a transaction to be confirmed is 38 sec.

Working of the algorithm in terms of the size of transactions is described below:

- No. of node/ hour (average) = 31473 and No. of transactions/hour (average) = 269

➢ Mean transaction per node = (No. of node/ hour (average)) / No. of transactions/hour(average) =31473/269 =117

➢ Mean transaction size = node size/mean transaction per node =21.6 KB/117

=0.19KB

So, calculations show that the Average transaction size is approximately 0.2KB.

Configuration used for testing the performance is mainly in a system consisting of 8 GB memory with 64-bit Windows OS version 10 along with Intel Core i7-6498DU CPU @ 2.50 GHz processor. The programming language used by Ethereum is Solidity which encapsulates JavaScript and python.

The framework was put under test for performance mitigation by using the following configurations:

● Intel Core i7-6498DU CPU @ 2.50GHz 2.60 GHz processor

● And 8.00 GB of memory with Windows 64-bit OS (version 10)

For the evaluation process, the transaction data was collected in two forms mainly, *i.e.*, transaction deployment time and transaction completion time. Thereafter, the metrics were used, which involved entities such as execution time, throughput and latency.

Latency is the delay in the time taken by the system for execution. Mainly latency period is the difference between the time of deployment and completion. Fig. (**6**) shows the average latency of the system. For the evaluation and analysis of the result, Apache JMeter version

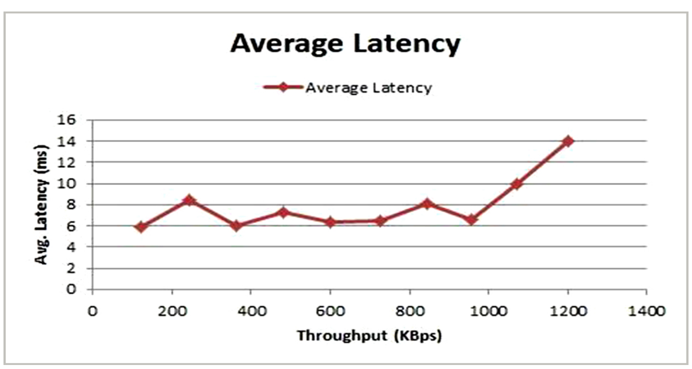

Fig. (6). Latency of the system.

5.1.1 and Apache version 2.0 was used.

Execution time refers to the time taken by the system from the time of transaction confirmation to the complete execution phase.

Through the evaluation, it was observed that the execution time increased with the increase in the number of transactions. It was also observed that with the increase in the number of users, the execution time increased as well. Next was the evaluation of the throughput. For the throughput, simulations were done on the JMeter in KB/sec unit. In the simulation process, it was observed that as the requests made by the users and the total number of users increased, the throughput also increased in a linear fashion. This linear increase in the throughput proved that the framework was effective in eliminating the scalability factor as well. Fig. (**7**) depicts the throughput of the system. Throughput refers to the maximum amount of data that can be transferred in unit time.

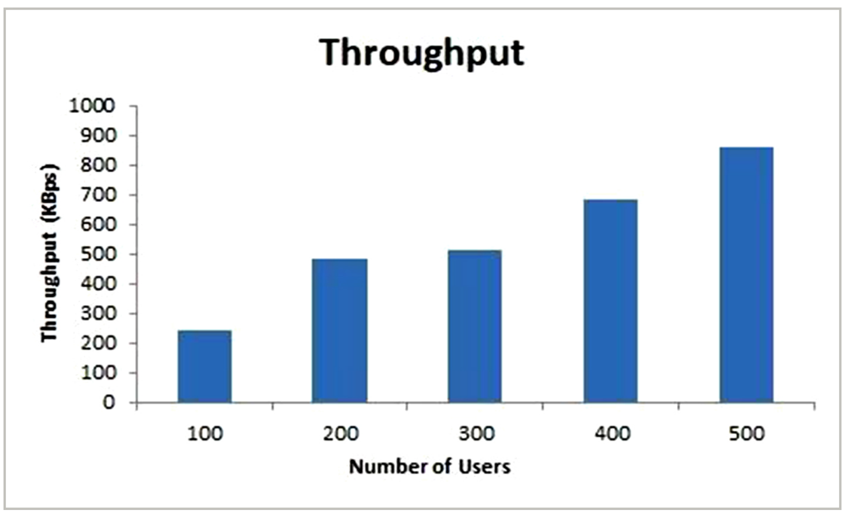

Fig. (7). Avg Throughput of System.

Latency was also evaluated by the JMeter, and it was measured in milliseconds. It was observed that the average latency fluctuated with respect to an increase in throughput, which after a certain limit, kept on increasing with an increase in throughput.

CONCLUSION

During the transfer of information between various parties, the design of the security of medical records for any EHR system remains a significant issue. A new extension that uses the blockchain approach to protect medical records is described in this chapter. EHR plan and assurance of the integrity of all records are provided by this new strategy. Using Blockchain, a framework has been developed to create a secure, distributed, and decentralized platform for medical records. This method helps to monitor medical professionals' lack of transparency and restricts access to the EHR system to the appropriate number of users. We focused on making the data in health records more secure, which opens up new research avenues for meeting other security requirements. For critical application deployment for any medical purpose, other security models that are more general, cater to the need for health data security, and identify untrusted hosts will be useful in future work. This would help us avoid fraudulent activities as well as save time when computing. The proposed work will be beneficial to a number of new application areas for implementing transparency toward patients, medical professionals, and related fields.

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