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Clinical Trial Management System using Blockchain for Secure and Efficient Record Keeping

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Abstract

In today's developing environment, there is always a need for upgradation to easier lifestyle among people. Technology has improved in almost all areas of concern to facilitate people's work. But even today, there is no efficient tool for managing Clinical Trial records. Clinical Trial records management is considered to be an important job when it comes to discovery of new medicines into the market. It is important to monitor the behaviour medicines for different group of people, at different locations, different age groups and gender. Only when the medicine's behaviour is known, it can be administered to patients of several concerns. There are various EHMS used in hospitals to manage their data. But it should also be noted that, it is important to secure the data from theft or modification. Using Blockchain technology is one of the best ways to secure data from theft or modification. Clinical Trial Management system using Blockchain can be an efficient way to store trial reports safe.

Keywords: Clinical Trial Records, EHMS, Blockchain.

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1. Introduction

The evolution of the modern clinical trials started when six treatments for scurvy were under trials during 18th century [1]. The advent of clinical trial management system began from late 20th century, due to the complexities in the pharma industries. During those time, managing clinical trials were a difficult task due to sophisticated environment, involving huge patient populations, vast case studies, complex protocols, lack of stationary requirements. With paper-based trial management, the process becomes more time-consuming and erroneous data. During 1980s and 1990s, the computerised systems and databases were introduced which laid the foundation for the development of CTMS.

A software programme referred to as a Clinical Trial Management System (CTMS) is made to automate and simplify the management of scientific trials, from recruiting and making plans to finishing touch and reporting. Organisations engaged in scientific research, consisting of authorities, organizations, college establishments, pharmaceutical companies, and agreement research companies (CROs), depend closely on those systems. By developing schedules and milestones, selecting take a look at locations, and defining protocols, CTMS permits researches to easily plan and design scientific studies. CTMS facilitates the identity and recruitment of scientific trial participants who meet the eligibility requirements through numerous platforms, along with affected person databases, digital health facts, and referral networks. By imparting tools for website start, schooling, monitoring, and overall performance evaluation, CTMS makes dealing with medical trials web sites easier. Clinical trial data, which include digital case file bureaucracy (eCRFs) [2], patient data, and observe documentation, may be correctly accrued, saved, and controlled with the use of CTMS.

1.1 Clinical Trials

The Clinical Trials are important in medical research and drug development industries. Trials of each process is noted and updated for upcoming researches, manufacturing, accommodating [3]. Stakeholders of key trails is involved in managing trials.

1.2 Role of CTMS

Streamlining protocol development and testing procedures are the development process of managing research sites, investigators, and subjects [4]. The reviews of each trial

in real-time analysis and monitoring of test progress are achieved through the process that provide reports that encourage compliance [5].

1.3 Functionality and Features

Inspection and site monitoring for security and confidentiality of the trial's that are being managed by the authorized owner. monitor course uptake and enrolment of updating financial updating and budgeting [6]. Trails are monitored for the documentation and compliance for analysis and reporting.

1.4 Reasons for including Blockchain in CTMS

- **Security**

Blockchain is best known for its high security through cryptographic decentralized techniques. When a data is stored in Blockchain, it is immutable which means it can't be modified or deleted. It makes use for hashing and encryption techniques for this purpose.

- **Integrity**

Whenever a transaction is made, it is verified and validated by participant network through a consensus mechanism, which means only valid and accurate data is added to Blockchain.

- **Decentralization**

The Blockchain technology is a network where the system is not centralised. Due to the decentralized architecture, each node is independent of other node.

- **Privacy**

It contributes security and data's sharing through the cryptographic rules to protect sensitive information where still accessed to authorized data to access and test data. Networks of Blockchain can restrict access to data authorized user, it can facilitate secured sharing of data while maintaining confidentiality.

- **Automation**

Blockchain enables self-executing contracts with predefined set of rules and treaties, automation of different process, such as consent authority management, transaction

processing, without any interventions. It can increase efficiency and decrease the costs, risk of bug or errors pr disputes.

- **Transparency**

Blockchain distributed technology improves transparency and tracking of data transactions from the beginning to conclusion. Each transaction is recorded on the timestamp of Blockchain, for every other Blockchain recorded is stored as a chain structure for its security, each information is connected to the next information stored in the Blockchain. The chain like structure is formed for the data's so that the data cannot be lost. It reduces fraud and improves regulatory requirements.

2. Related Works

Globally, clinical trials are governed by a mixture of organizational mechanisms, regulatory frameworks, and industry best practices developed by different clinical research participants global clinical trial activity is governed by common aspects and perspectives but strategies specificity may vary from country to country or region to region.

- **Paper Record Systems**

Even today, most of the clinical trials are conducted and managed with help of pen and paper method [7]. It includes marking down all the participant data, event data, and the trial information, interconnected with each other.

- **Electronic Health Management Records**

Electronic health record management is an upgradation of the traditional paper- based records management. The electronic health record management is done with the help of electronic data capture (EDC). There are various EDC platforms to process all these works with clinical trials [8].

- **Manual Methods for Conducting Trials**

Manual methods are the kind of clinical trial management which involves both electronic systems and paper and pen-based records. Here the paper records are integrated with electronic data capture [8].

- **Collaborative Initiatives**

There are certain platforms which take collaborative measures to take over the management of trials in their own risks policy. They act as sponsors for conducting trials, provide required resources for the event, agencies [9], advertises among people for taking up the trial etc.

- **Managing Trials based on Project Management Strategies**

There are various project management strategies like waterfall, agile, spiral, incremental, iterative models [10]. These models are applied to manage a project efficiently right from the beginning. The clinical trial management system can also be done efficiently with the application of these methods.

- **Data Analytics**

The data analytics and business intelligence tools [11] are used in CTMS to analyse the reports, data records, trial results, pattern of success rate of various trials in various regions, countries. To manage the vast data, data analytics tools play an important role for easy work flow.

- **Data Management using Websites**

CTMS are now done using website with specific concern for managing the trial data. Using website makes it easier for both the users and organization conducting trials. The trial management websites provide a unified platform [12] for managing and conducting trials both in a single unit.

3. Proposed Work

Even though there are various websites to manage and conduct clinical trials, it is often risky to store the data in a website server. The prime threats for website would be data theft,

data modification, publishing incorrect data, unexpected deletion of data. Hence it is mandatory to store the data in a secure environment. Blockchain technology [13] is used by most of the industries for this purpose.

The traditional clinical trial management system faces various challenges to work efficiently. Ensuring the patient data security is first concern. The CTMS must has the capability to protect patient's data from hackers. The CTMs should follow the rules and format proposed by health ministry of the government. Hence regulatory compliance becomes a challenge [14].

Selecting participants for trials is a complex job where the participant's health should be in compliance with the requirements. There are various other complexities like age, gender, locality. Maintaining the quality of the trial results is mandatory when it comes to authorize a medicine or medical practice [15].

The motive of using Blockchain in clinical trial management system is to overcome all these challenges in managing the trials in the hospital industry. Blockchain in trial management can make vast difference in managing the data, maintain the quality of the trail results, managing participants, hosting trials, data security [16] throughout the trial process. Here is how the Blockchain based CTMS works typically,

- **Study Setup and Design:** Firstly, the CTMS software allows the organizers to host trials in the website. They specify the eligibility criteria, tracking timelines and other parameters necessary for the trials.
- **Participant Recruitment and Screening:** The CTMS software program enables participant recruitment by maintaining a database of potential participants and tracking their eligibility based on pre-defined criteria. It streamlines the screening system by automating eligibility checks and managing verbal exchanges with potential participants.
- **Collection of Trial Reports:** The reports of each participant are collected and stored in the decentralized database. Each participant report is identified by a unique trial in which acts as the primary key for storing the data in the Blockchain.

- **Hashing and Linking Each Report:** A hash key is generated by the python Bcrypt for each report using the unique trial id as its primary key. And also, each report's hash value is linked with the previous one.

- **Chaining:** Each report has 2 hash values where the first one is its own hash value and the second one is the previous report's hash value. This forms a chain where to modify a single report it has to be modified with the previous and the cycle goes on. Hence the system becomes immutable.

3.1 Architecture

The figure 1 shows the architectural flow of the system. The components used are discussed below.

- **Templates Folder**

All the HTML files are stored in a separate folder called templates in a flask web application. The flask framework searches for the pages that are to be loaded in the templates folder.

- **Static Folder**

The styles and scripts required for making the webpage interactive are placed in a separate static folder. This static folder contains all the static files like CSS, JavaScript, Images included in the website.

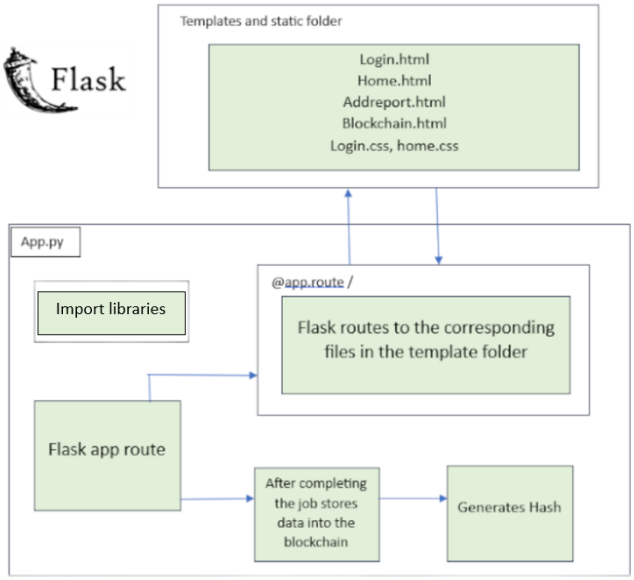

Figure 1. Architecture

- **App.py**

In general, in all the flask web applications, there is a program which acts as the heart of the entire web application. Here the app.py does all the work from importing libraries for specific purposes to displaying the content dynamically. App.py is the program which when run coordinates all the other components of the web app.

3.2 Flowchart

The CTMS using Blockchain workflow involves conducting trials and storing the reports in a secure environment.

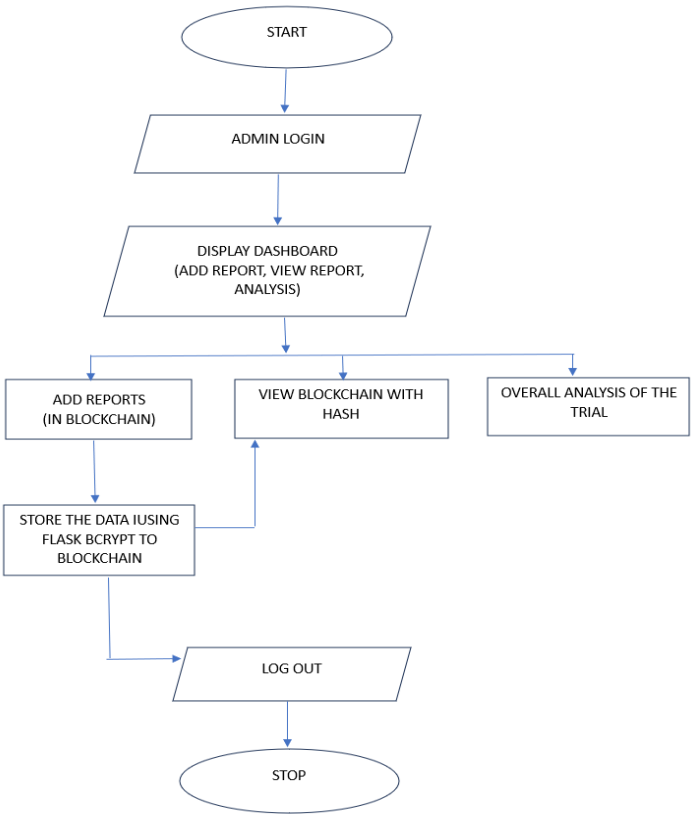

Figure 2. Flowchart

- Admin Login

A user id and password are created for admin and validated using JavaScript.

- Dashboard

Once the admin has logged in, a home page displays the dashboard of the system which contains, options to add trial reports, view the reports and view analysis.

- Add report

The trial data which are given as input are collected using http post and get methods and stores the data in the database. Each report has its own hash key and connected to the previous report's hash key.

- View Blockchain

The reports which are stored are connected to together in a Blockchain network, through hashed key values provide by Sha 512 hashlib in python.

- Analysis:

The final reports of all participants are monitored for identifying the result of the trial.

4. Results and Discussion

This clinical trial management system focusses on providing an integrated platform for hosting and managing all the trial events and also storing of trial data in a secure manner. Blockchain is used for the purpose of storing the data in a decentralized network which can be secured with the help of hash values provided by SHA 512 hashlib from python. Using Blockchain can be powerful in so many ways:

- **Data Integrity**

Since Blockchain is best known for its immutable character, it provides extreme level of data integrity.

- **Transparent System**

Tracking of each and every transaction or update becomes easier with the help of Blockchain which means auditing process becomes simple.

- **Prevents Insecure Sharing**

Using Blockchain paves way for allowing only authorized user to update or modify data. Here sharing of the data becomes highly secured without any risks.

- **Regulatory Compliance**

Due to the transparency and auditable nature of CTMS using Blockchain, it provides great streamlined regulatory compliance. The management of documents, system, organizations become easier.

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4.1 Software Requirements

- Html, CSS and JavaScript is used for frontend.
- Python for Blockchain.
- Python flask framework used for connecting templates and web-based APIs .
- To include Blockchain in the software, flask Bcrypt is used.

4.2 Modules

- **Home Page**

Once the admin has logged in, the dashboard window is navigated which has options to add reports, view reports and analysis as shown in Figure 3. Add report contains input fields, view report contains field for viewing Blockchain and analysis contains overall analysis of trials.

- **Add Reports**

Window for uploading trial reports for individual participants as shown in Figure 4. The page contains input fields for patient name, patient age, clinical trial report, trial id. Trial id is unique for each report and is used for connecting hash value for each report.

- **View Reports**

Uploaded trial reports are viewed in the Blockchain every detail added in the add page and viewed as shown in Figure 5. The first report has its hash value and has no previous hash value. The subsequent reports have 2 hash values i.e., the current hash and the previous hash.

- **Analysis**

The final overview of the trial conducted is given in the analysis part. All the reports are verified and the analysis works like a short survey which shows the percentage of total negative reports and positive reports on the basis of age, gender and locality of the trial population.

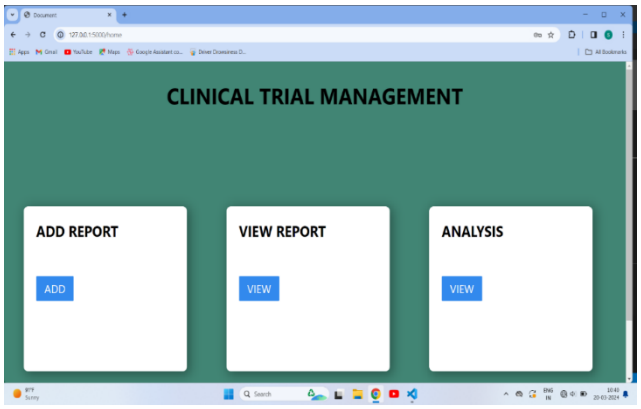

Figure 3. Dashboard

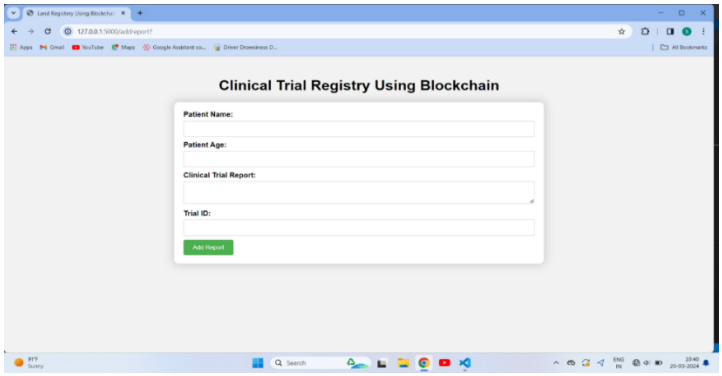

Figure 4. Add Report

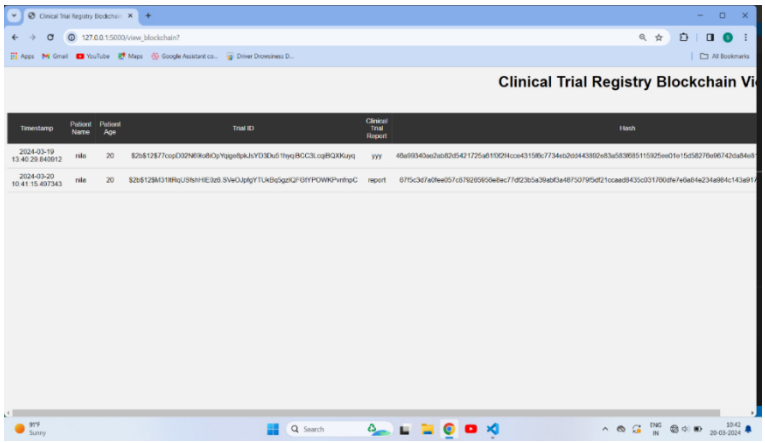

Figure 5. Blockchain View

The comparison of data security between traditional CTMS and Blockchain CTMS is given in the Figure 6. Traditional Clinical Trial Management Systems (CTMS) typically offer real-time analysis and monitoring capabilities, although reporting functionalities often necessitate manual input and verification. This reliance on manual processes can lead to limited transparency and auditability of data. Security measures in traditional CTMS rely on poor mechanisms which are vulnerable to threats

In contrast, Blockchain Clinical Trial Management Systems (CTMS) make use of Blockchain technology to revolutionize various aspects of clinical trial management. Real-time monitoring and reporting are facilitated by Blockchain's distributed ledger, with automated mechanisms ensuring accuracy and reliability of the system. Security in Blockchain CTMS is fortified by cryptographic algorithms and decentralized consensus mechanisms, ensuring data integrity and tamper-proofing through immutable data records.

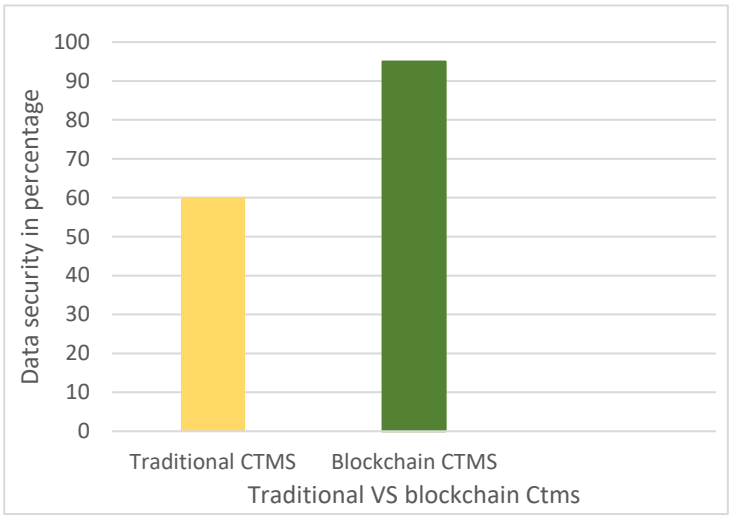

Figure 6. Traditional CTMS vs Blockchain based CTMS

5. Conclusion

The CTMS plays an important role in development of efficient medicine without fraud and corruption in the medical fields. The Blockchain based clinical trial management system has been identified to be an efficient method to conduct clinical trials in various locations, large population, wide age group of people, etc. The system provides an integrated platform for the organizations to host trials and store data such that it is immutable and safe. This

prevents fraudulent trial reports. To achieve this, python flask has been a very useful tool to develop web application with secure Blockchain module and hash library. Thus, a Blockchain based CTMS helps in making this process efficient with high data integrity, security and transparency.

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Author's biography

C. M. Nalayini is an Assistant Professor has nearly 18 years of experience in teaching. She has published many research papers in International Journals, International Conference and National Conference. She has also published book chapters in Springer Book Series. She has given Computer Training to Government School Higher Secondary Students in Chennai. She has taken classes for Women Welfare SHG Group. She has authored books such as C-Programming and Programming and Data Structures-II. Her area of specialization is Network Security. https://www.linkedin.com/in/c-m-nalayini-6a0875203/

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D. Sruthinila is an aspiring Engineering student who is pursuing under graduation from Velammal Engineering College. She is basically from Information Technology department. She has a great problem-solving capacity and solved numerous problems in platforms like SkillRack. She is a very much innovative student who is consistent in work.