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Blockchain validation framework for COVID-19 testing kit

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Abstract---Throughout the current pandemic situation, the functioning of the Covid-19 testing kits is very critical owing to its necessity in the diagnosis of the disease. The fabrication and supply of these kits is taking place at a large scale, therefore there may be some malpractices in the supply process. The authenticity of the kits is primarily significant and to keep the globe from using the defective kits is a big challenge. Therefore before using the kit, it must have permitted by some authentic and authoritative medical body such as EUA, ICMR, CCMB, etc. So, the validation of these testing kits is vital for the fair conveyance from production houses to the various agencies.. In this paper, we will discuss the framework which assures that the testing kit is approved by different metrics so that any malpractice in the supply chain is detected. The parties which are involved in these supply chain such as Validation, Notary and Manufacturers. Along with the above mentioned parties, buyer also acting an essential part and can inspect whether the kits is approved or not through its batch number. For inspection purpose, the framework is developed using Blockchain technology. For high security and data privacy, Blockchain ensures only trusted parties can enter and exit the network.

Keywords---Blockchain, Supply Chain Management (SCM), COVID-19, Testing Kit, Validation, Framework.

Introduction

COVID-19 disaster began from Wuhan, China in Nov'19. It was brought about by a coronavirus called SARS-CoV-2. It has been declared as a pandemic by WHO on

11'March'2020 and till 19'July'2020. This fatal disease causes 5,615,082 deaths across the world. The stats showing the number of deaths and the total number of cases that occur monthly is depicted in the fig1.1. During the Covid-19 catastrophe, testing kits are produced and distributed in enormous numbers to manage the pandemic quickly however it is highly unlikely to approve the validness of the result from these kits all around. In this pandemic, fast testing along with accurate results is needed. There are numerous validating parties who can authenticate the working of these kits. One of such approach is Supply Chain Management (SCM) which is described in the scope of Blockchain to cope with COVID-19[2].

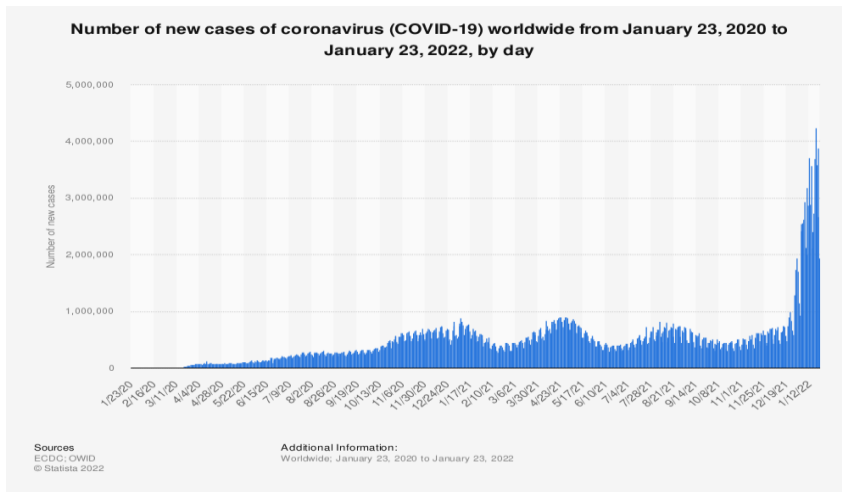


Figure 1.1: Total cases and Total Deaths occur worldwide (monthly)

The distribution of COVID-19 cases country-wise can be shown in the fig1.2.

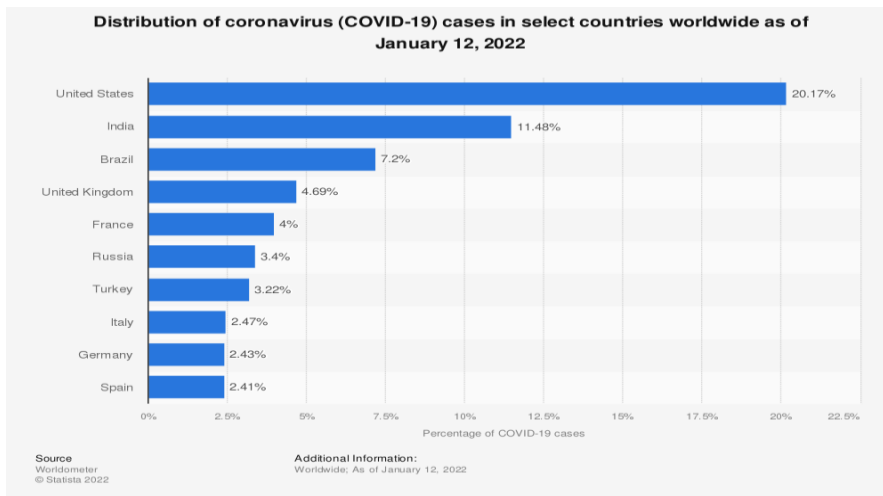


Figure 1.2: Distribution of cases in various Countries and Worldwide

SCM tracks the record of benefits from a raw product to a completed one or from provider to the purchaser. To keep up the unchanging nature, transparency between all the procedures in SCM can be achieved with the assistance of Blockchain.

Blockchain is the technology behind the concept of Bitcoin which is the effort of Satoshi Nakamoto in 2009[1]. Blockchain is a decentralized, immutable database or chain of records or blocks where every block holds the set of transactions, it is distributed shared ledger that brings transparency. This technology firstly implemented Bitcoin in 2014 as a cryptocurrency. It conquers different exchange matters like as double-spending problem, yet it isn't just constrained to the money related division as Blockchain catches the eye in different commercial enterprise sectors such as landed property, Education and Healthcare etc. get explored every day. In this paper, we implement the application of the pharmaceutical supply chain using Blockchain.

Motivation and Contribution

In order to ensure a safe or efficient supply chain for COVID-19 test kits, similar types of structures have been developed used in the pharmaceutical supply chain and other healthcare-related areas such as MedRec, ModelChain, MediLedger, etc. To develop these systems, many researchers have used various platforms such as Ethereum and Hyperledger Fabric to achieve transparency. All mentioned in comparison to R3 Corda, the platforms employed are not sufficiently protected and unable to provide privacy. Corda is a cryptocurrency that runs on a private Blockchain technology that runs on Java and Kotlin and is mostly used in the banking sector. The technique is not exposed to the user The current supply chain model for Covid-19 testing kits is as follows and there is a risk that manually maintained records of kit validation will be lost. The kit is sent to an authorized a celebration for validation; the validating party simply saves management of the supply chain. There's a danger that consumers won't be able to get accurate data about kit validity. This prompted the development of a Blockchain platform for pharmaceutical management of the supply chain .The following are the contributions to the SCM proposed COVID-19 testing kit framework. Our framework is very secure, ensuring that no unauthorized parties or nodes are incorporated into the chain, as well as great transparency. • Each transaction is checked by a Notary, ensuring that no duplicate or inaccurate transactions are added to the chain. • The mistakes may be proven to the consumer through punching the Serial Number if the package isn't always validated. So, our framework is greater green than the present technique utilized in trying out package deliver chain management. To the nice of author's expertise and belief, this framework may be applied in real-global software and might update the existing approach.

Organization of the paper

This article explains how Blockchain technology workings, how it canister be used to fight the COVID-19 outbreak, and how test kits function using the R3 Corda permission Blockchain platform, supply chain management can be used to identify whether a kits has been validate by a validating party or not. The

remainder of the document is divided into sections. The second section digs into the work of additional healthcare researchers as well as COVID-19. 3rd section consists of background, what Blockchain, R3 Corda, and COVID-19 testing kits are all about. Section 4 consists of the proposed model, the supporting tools, or systems required. Section 5 consists of a future scope, a conclusion, and a list of references.

Literature Review

In the survey, very little work has been done in the healthcare supply chain, or developing a Blockchain-based COVID-19 is a problem that requires a solution. Ijazul Haq[3] provides a Blockchain use case study in the pharmaceutical industry business to combat counterfeit pharmaceuticals and demonstrates how drug supply traceability may be achieved. In the article, he discusses permission Blockchain and provides an example of how diverse parties, such as a system can be used by a nurse, a doctor, or a patient.

Sandip Jangir [4] provides a novel architecture for medicine supply chain management based on the distributed ledger and smart contracts. This system was built on the Ethereum platform, which allows for privacy, real-time drug tracing, and demand-supply management. Extensive analysis and testing findings in form of Consumer Privacy, Information Transparency, Immutability, High Availability, Non-repudiation, No Single Point of Failure and real-time drug tracking have been taken for proof of concept of the proposed framework.

Tsung-Ting Kuo[5] offers ModelChain, a platform that integrates Machine Learning into private Blockchain networks to preserve healthcare data. In addition, he created a novel proof-of-information technique for evaluating the Blockchain-based networked subset of artificial intelligence is in order. Si Chen [6] proposed the Blockchain-based supply chain excellence management structure that can be used in the real world and provide a hypothetical foundation for intelligently applying management to the scheme. Mohamed Torky[7] offers a novel approach for dealing with COVID-19 that uses Blockchain to detect unknown COVID-19 infected instances. P2P movable application, Infectivity Verifier Structure, Blockchain Framework, and Mass-Surveillance Structure are the four primary components of the framework.

Backgrounds

Blockchain

Blockchain is a decentralized technology in this several nodes or system contributes to the common ledger which stored unchallengeable records or sets of the transactions that are protected through cryptographic capacity or exceptionally statistical numerical complications. This function utilize of the form [8] which can be shown by the equation (1):-

$$H: \quad K \quad \times M \quad \rightarrow \quad \{0, \quad 1\} \quad ^n \quad (1)$$

Where H represents hash and n represents the number of bits returned through the function.

A local copy of the ledger is stored on every node that creates transparency i.e. if any change is done to the record or new exchange is performed then all nodes will refresh their local ledger respectively. The architecture of blockchain can be represents in figure 3.1 -

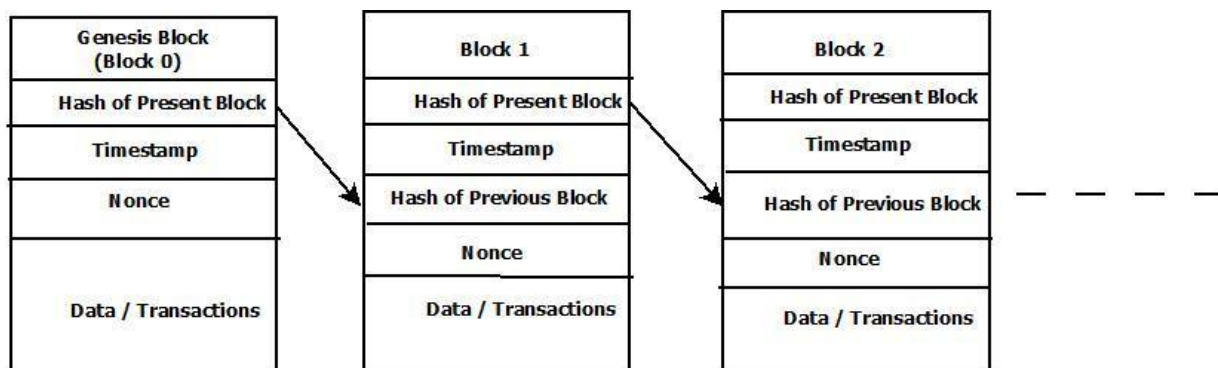


Figure 3.1.1: Architecture of Blockchain

Blockchain technology is fault-tolerance i.e. if any node fails then there will be no impact on other nodes. This technology is highly secured and no other technology can beat it in terms of transparency. Blockchain is the prime choice to grant 21st century cyber-security, and till now there is no rift raised in it that makes its good option to use in the field of Healthcare and SCM, and good to use in the pandemic like COVID-19. With the help of blockchain, anyone can exchange digital assets where they don't have to rely on any third party or to trust each other and exchange the asset under the contract called smart contract which was developed by Nick Szabo in early 1990s[9]. A smart contract is a piece of code or agreement on which trading parties concede to certain terms and conditions. Every time, ownership of an asset changes then the new transaction will save to the blockchain by default, and to check the correctness of the transaction, the process of mining is performed by the group of people or nodes called miners then they get incentives accordingly. Miners validate the transaction by applying a consensus algorithm to decide whether a block of the transaction to be added in the Blockchain or not. There are two types of consensus algorithms used called proof-based and voting-based. In proof-based consensus algorithms, nodes solve the cryptographic hash function to reach an agreement to decide the present state of a distributed ledger. The first proof-based consensus algorithm called Proof-of-Work (PoW) was proposed by Satoshi Nakamoto. Some of the other proof-based algorithms are Proof-of-Stake (PoS), Proof-of-Elapsed-Time (PoET), Proof-of-Luck (PoL), Proof-of-Space [10]. In a voting-based consensus algorithm, the voting approach is used in which a threshold value is set, let say 'y' then minimum 'y' participating nodes should agree on the decision that block should be added in the blockchain or not. Some of the voting-based consensus algorithms are Byzantine and Crash. In market, n number of blockchain platform is available but we can classify in some specific ways such as public, private, hybrid and consortium Blockchain. In a public Blockchain, anyone can leave or join the network and anyone can participate in the decision of the current state of the system or what block should be added, Ethereum[11] and Bitcoin are some famous public Blockchain. The private Blockchain is restricted by an association

and provides rights to all others; Hyperledger Fabric [12] and R3 Corda are few popular private Blockchain. In consortium Blockchain, the Blockchain is managed by some pre-selected nodes and rights given to all other nodes can be restricted, Quorum and Hyperledger is some consortium Blockchain. In the Hybrid Blockchain, the blockchain consists of features of both centralized and decentralized computing. Eg. Dragon chain [13].

In this paper, we use R3 Corda to develop the proposed system as it is a permission, private platform, and different consensus or self-developing algorithms can be used that are decided by the notary. We cannot use Ethereum, as it is a public platform that is not secure as much as R3 Corda.

R3 Corda

The Corda mostly pointed to financial area and it hold up smart contract and this is the decentralized system [15]. In this Corda, Have good facility of smart contract which are responsible for acceptance or refuse the transactions. This is individual Blockchain which controls users to remove or add, if any node transfers data to another node so data is only visible among those two nodes but in other platforms, we can see every node data. The building block of Corda is a “state object” that represents a specific instance of specific agreement representing a section of contract or real-world contract. The data is secured in Corda by adopting the SHA-256 hashing algorithm. To achieve globally distributed consensus Corda provides three main tools and they can be defined as below:

- *Smart contract logic* which appraises constraints to check valid or not using set of rules.
- *Notary pools* that implement uniqueness and timestamping services.
- *Flow framework* that reduces the process of writing complex multistep protocols.

With the help of transactions, updations’ are done in which Corda inputs existing states’ objects and outputs new state objects. There are two main aspects of consensus [14]:-

- Transaction Validity
- Transaction Uniqueness

In Corda, the transaction may be built at any time and by anyone as there is no need for crypto-economic. Unlike Bitcoin and Ethereum, Corda does not use miners or proof-of-work as it does not order transactions using a blockchain. Instead each state point to a notary that guarantees it will approve the transaction if all the input states are un-consumed. Transactions are defined in Corda with the help of JVM it means class file execution completely deterministic. The applications developed or run on the Corda platform are called CorDapps(Corda Distributed Applications). CorDapps is the set of JAR files containing class definitions that are programmed in Java and/or Kotlin. A class definition includes many elements called Flows, States, contracts, Services, and Serialization White lists.

COVID-19 Testing Kit

COVID-19 pandemic is a serious public health issue, the spread of the virus and a better understanding of the scope can only be gained by more widespread testing. There are two types of tests present for COVID-19[16] i.e. viral tests and antibody tests. The viral test detects a current infection whereas antibody tests might detect past infection, and may be unable to detect the current infection as the body takes 1-3 weeks to make antibodies to battle with contamination. The symptoms of COVID-19 infection are dry cough, fever, weakness, and so on the off chance that any of the indications are found in anybody, at that point they can go for viral tests. If the results are positive then protective steps are followed that are prescribed by a doctor but if the results are negative then it doesn't mean that you are not infected, the case might be possible that at the time of testing early samples are collected and can get the result negative i.e. in both the cases the protective measures has to follow. The viral test detects SARS-Cov-2 nucleic acid or antigen, which causes COVID-19 is present or not by taking the samples from the respiratory system.

There are various methods available for COVID-19 testing [17]:-

- Reverse transcription-polymerase chain reaction (RT-PCR): - It identified SARS-Cov-2 that contains RNA only, as it used reverse transcription to obtain DNA and then PCR to amplify DNA. RT-PCR gives the result in a few hours. It has advantages like reliability, high throughput, and automation.
- Isothermal amplification assays: - It amplifies the virus's genome. This method is faster than PCR because it does not include repeated heating and cooling. Unlike RT-PCR, this method does not have an additional step of RNA to DNA conversion as it directly amplifies RNA.
- Antigen: - It searches for the antigens proteins from the viral surface. The positive test results from antigens are highly accurate but there is a chance of a false-negative result. So, in case of a negative result, the samples are again tested with PCR testing.
- Serology: - Blood tests are capable to detect once-infected humans who have cured; however, the timing of when people are tested is necessary. SARS-CoV-2 antibodies' potency and defensive span are unaware. The potential act of antibody testing for decisive if an individual is immune to COVID-19 is not clear and the potential to recognize SARS-COV-2 antibodies in human beings improving from an infection, asymptomatic humans, and those who had delicate symptoms demands further research.

The testing kits are manufactured at a high pace and great thing to deal with COVID-19 pandemic. The components of a rapid IgM/IgG testing kit are [18]:-

- Test cassette
- Droppers
- Package Inserts
- Buffer Bottle

The kits are store at normal temperature or freeze (2-30° C) and the test cassette should unresolved in the preserved pouch until no. The kit can take the sample of Serum/ Plasma/ blood. The test can be performed by following the steps which are mention below:-

- Collect the samples and make necessary preparations such as keeping the

kit at room temperature before the test.

- By using micropipette/dropper add sample to the sample well.
- Add 1 drop of serum/plasma or 3 drops of blood to the sample well immediately.
- Lastly, stay for the indications to shown and examine the outcome at ten minutes because the outcome is valid only for 20 minutes.

Proposed Framework and Tools Used

Implementation

A node contains numerous classes and performs various functions which can be shown by an example of a validator node in the figure4.1.1. The Node send the request through the API program in the formation of HTTP protocol request, and then API will call the flow start. Flow start defines various logics or routines to update the ledger e.g. Update COVIDKitDetail. After the call made, initial steps will be taken i.e. build of a transaction and sign the transaction by their secret keys. Now the transaction will be sent to the counterparty or opposite party between whom the transaction is taken place in our case it is denoted by Manufacturer. He will check the transaction and check whether the transaction is notarized by a notary or not. If everything is fine then the transaction will be stored and go to the vault, then return to the API, and HTTP response will be generated. All procedures will be the same for the Manufacturer node and all is secured by a cryptographic hash function SHA-256. All information will be store in the encrypted form and each node has its own private and public key.

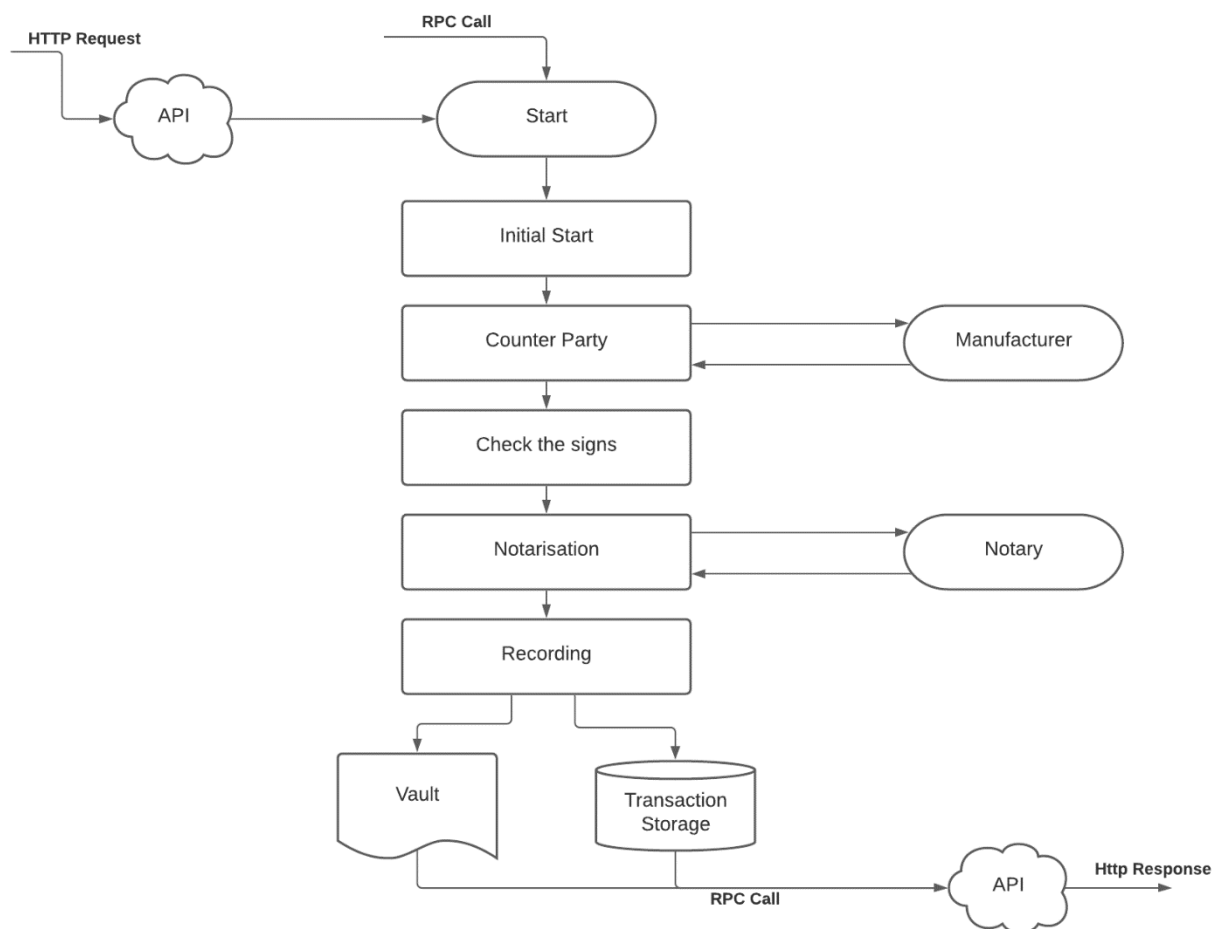


Figure 4.1.1: Architecture of Validating Node

Framework and Entities

In COVID-19 pandemic situation testing kits are showing great role to expedite test shortly and hope get make free with COVID-19. For betterment testing kits one of the most important point is official check and which for smooth testing functioning. The before use of testing kits accomplish must be authenticate, through authorized authority in this case precision and usefulness focus on very effective role. In order to guarantee this, the maintenance of the supply chain of testing kit is to be done by making use of blockchain technology because there will be a possibility that the manufacturer can provide kit straight to the consumer, or it is also possible that any fault can occur in between of the supply chain. The flow of control or data can be shown by the fig4.1.

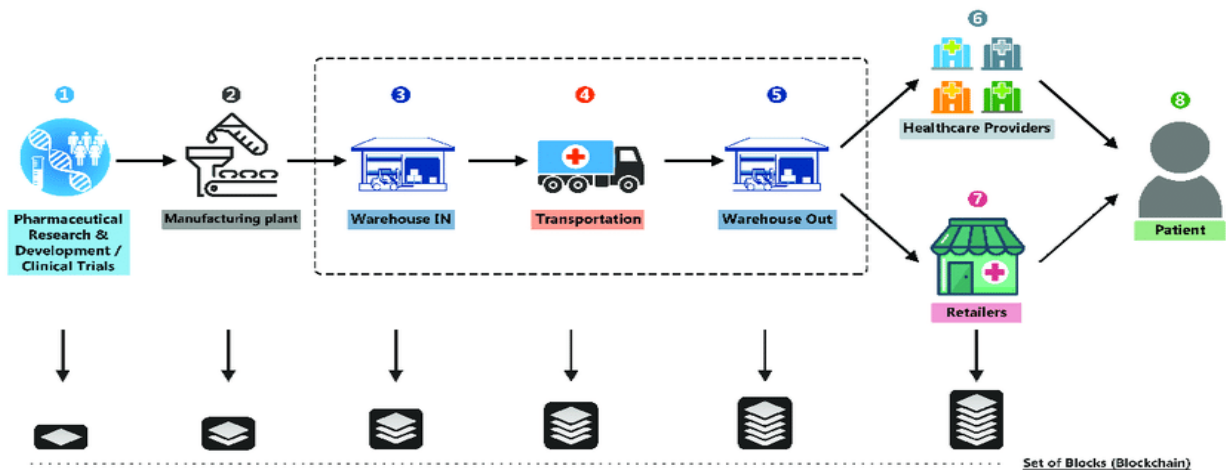


Figure 4.2.1: Data flow diagram of the proposed framework

The people involved in the complete procedure will be the following:-

Notary:-

In order to verify and validate any transaction or updating and checking the presence of any dependencies Corda platform have a network service known as notary.

Manufacturer:-

Keeping in mind the rules and regulations by various medical agencies the manufacturer built the testing kit, and send the kit for validation to any certified validating party, and then finally supply it to the customer. All the mandatory information required for the traceability will be furnished on the supply chain.

The details filled by the manufacturer can be shown below by an example:

```
{ "nameOfKit": "RT-PCR",
  "nameOfManufacture": "India-MART",
  "manufacturingDate": "2022-01-27",
  "expiryDate": "2023-01-27",
  "kitInfo": "OK" }
```

The next step after giving required details and a distinctive id, which can be a serial number will be created for future use.

COVID kit details are added with batch number **ff567009-af4c-1ed6-b5a9-e1131682e653**

Suppose the validating party rejects the testing kit then the manufacturer has to update details of the kit to the chain which can be shown below:

```
{"serialNumber": " ff567009-af4c-1ed6-b5a9-e1131682e653 ",
  "manufacturingDate": "2022-01-27",
  "expiryDate": "2023-01-27",
  "kitInfo": "Updates by ICMR"}
```

Validating Party:-

ICMR can be considered as an authorized validating party. It is their responsibility to approve the further usage of the testing kit[19]. All the required standards are taken care while allowing the use of the testing kit. But if the testing kit is US-FDA attested no further approval is required. The validation of the kit is a standardized procedure involving lot of test reactions, methodology and reagents. These procedures led to the development of the validation report which is given to the manufacturer. Based on the report manufacturer performs necessary corrections otherwise supply it to its customer.

In order to maintain transparency the validating party (ICMR) uploads some of the information like serial number, comments, approval status and the details of the approver.

Kit produced which added to the chain will be sent to the validating party and update the details to the chain that can be shown below by an example. In the approval field, the party has to fill the value “Approved” or “Not Approved”. If the value is not approved then the kit cannot be supplied to the consumer, i.e. it is mandated for the manufacturer to again send the kit to the validating party for its approval after making necessary changes accordingly. The comment section/column includes the necessary changes that the party asked for.

```
{ "serialNumber": " ff567009-af4c-1ed6-b5a9-e1131682e653 ",
  "approval": "Not Approved",
  "comments": "Not Accurate",
  "approvedBy": "ICMR" }
```

After the necessary changes made by the manufacturer, the validating party will again evaluate the kit and carry out the various test. If the kit found satisfactory then the party have to update the details to the chain as per below mention an example:

```
{ "serialNumber": " ff567009-af4c-1ed6-b5a9-e1131682e653 ",
  "approval": "Approved",
  "comments": "Work properly",
  "approvedBy": "ICMR" }
```

When the kit reached to the consumer side from manufacturer, the consumer can see the details like serial number, kit information, date of manufacturing as well as the date of expiration. This is viewed by punching the serial number. If no validation party is involved the consumer may get an error. The format of the error is given below.

```
{ "status": " No ",
  "message": "Kit is not available with this Serial
Number",
  "data": "Not Found" }
```

If a kit is approved by the validating party then the user can see the details shown below:

```

{ "status": "OK",
  "message": " Kit is available with this Serial Number ",
  "data": {
    "nameOfKit": "RT-PCR",
    "nameOfManufacture": "India-MART",
    "manufacturingDate": "Thu Jan 27 00:00:00 IST 2022",
    "expiryDate": "Fri Jan 27 00:00:00 IST 2023",
    "approvedBy": "ICMR"  }}

```

The power of Blockchain lies in transparency; we can see all the phases of the testing kit. An example can be shown in the fig4.2.2. From the figure, it is very much clear that how the rejection or approval of the testing kit takes place.

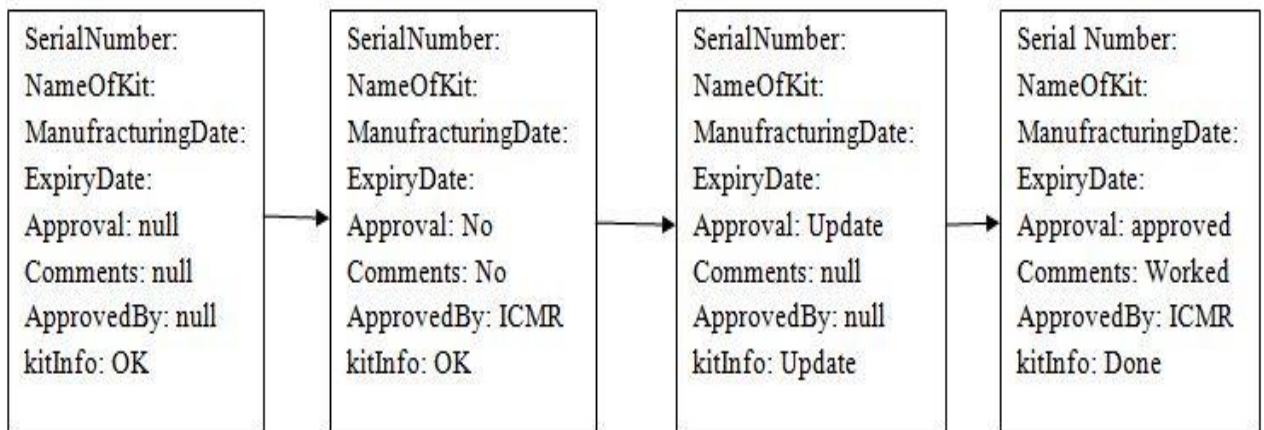


Figure 4.2.2: Supply Chain of Testing Kit

Tools Used

R3 Corda platform is used for the given framework, and the development is done through Cord applications [20].

- IntelliJ IDEA
It is an IDE which facilitates development in most used languages like Kotlin, Java and required pulgins.
- JDK1.8
Corda is a Java based application hence it requires JDK for development.
- Postman
Postman is an API with responses for JSON and HTML and a compact layout [22].

Comparison of Ongoing Approach and Proposed Approach

The comparison is made between the traditional approach and new proposed framework on the basis of various parameters can be shown in the Table 4.4.1.

Table 4.4.1 Comparison between Approaches

Parameters	Current Traditional Approach	Proposed Framework
1. Methodology	Kit has to be validated before use.	Same
2. Transparency	✘	✓
3. Security	✘	✓
4. Hardware and software Requirement	Less	More
5. Immutability	✘	✓
6. Cost Effective	More	Less

Conclusions and Future Scope

In this manuscript, we represent structure in healthcare fields for validation of testing kits through Blockchain technology. We focused different entities which are concerned in supply chain management and employing this supply chain management by R3 Corda. In this paper we also discuss different tools and functioning scenarios of the proposed framework. In the upcoming, this works canister extensive in various ways i.e. firstly, we can eliminate the use of the third-party application at the same time we can also replace various factors in building for making a more secure system and ease of usage increase simultaneously. On the other hand, nodes in the chain can extend according to the demand for making complex chain if needed and more content can be added to the chain in the form of files. Lastly, we can implement this framework in various related research areas because nowadays, validation of things required in every field for making their reliability more strong and we have to make all procedures transparent by which users trust increase correspondingly. So in short we can use this framework in other related areas. In last, As we as a whole desire that COVID-19 must be finish as soon as, which doesn't destined we can't utilize this system, as already discussed that above mention framework/structure can be actualized in different territories.

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