DEFINE PROBLEM/PROBLEM UNDERSTANDING:

The pharmaceutical supply chain (PSC) consists of multiple stakeholders, including raw material suppliers, manufacturers, distributors, regulatory authorities, pharmacies, hospitals, and patients. The complexity of product and transaction flows in PSC requires an effective traceability system to determine the current and all previous product owner ships. In addition, digitizing track and trace process provides significant benefit for regulatory oversight and ensures product safety. Block chain-based drug traceability offers a potential solution to create a distributed shared data platform for an immutable, trustworthy, accountable and transparent system in the PSC .

However, there are still several challenges related to the application of block chain technology for drug traceability. Some of these challenges include privacy, trust, transparency, security, authorization and authentication, and scalability .

Two potential block chain-based decentralized architectures were proposed to meet critical requirements for drug traceability . These architectures are Hyper ledger Fabric and Bess. The authors also identified several open research challenges related to the application of block chain technology for drug traceability .

SPECIFY THE BUSSINESS PROBLEM:

The global counterfeit drug trade impacts all pharmaceutical stakeholders including hospitals, pharmacies, wholesale distributors, global health programs, and regulatory authorities.The Illegal drug market contributes immensely toward producing fake and fraudulent medicines as its actors add contaminated, improperly stored, and falsified ingredients. This is enabled because there is a lack of technical and business solutions that offer adequate traceability and provenance solution.

For example, a substandard version of the anti-cancer drug Avast in® was purchased and delivered to thousands of cancer patients in the U.S causing potential treatment complications for patients.The Asia Pacific, African, and Latin American regions are most vulnerable to counterfeit drugs with almost 30% of the drugs produced and consumed are counterfeit leading to almost 1.5 million deaths per year.8 In the European region the number of reported cases of counterfeit drugs have doubled compared to previous years.9 A recent report by a prominent European research project highlights that the counterfeit medication industry is considered more lucrative and profitable business than selling legal medicines and it estimates a revenue loss equals almost 4.5% in drug sales amounting to €10 billion every year.

The increased access to medications via online pharmacies and unauthorized distribution channels makes it difficult to ensure product safety in the supply chain.13 In addition, limited data visibility about inventory and stock levels across the supply chain presents greater opportunities for counterfeits to enter the market.3,4 Drug traceability is the process of identifying the originality and legitimacy of the product that enables all stakeholders to track and trace the transactions at every stage in the supply chain.14,15 Regulations such as the US drug supply chain security act (DSCSA) requires all supply chain stakeholders to implement reliable measures that improve product traceability, the actual implementation of DSCSA will be in a phased manner by the year 2023.

The business problem in Drug Traceability Smart Contracts on Ethereum Block chain revolves around the need to enhance the transparency and security of pharmaceutical supply chains. Counterfeit drugs and substandard medications pose significant risks to public health, and traditional tracking methods are often insufficient. Implementing a smart contract solution on the Ethereum block chain aims to address this problem by enabling real-time, immutable, and transparent tracking of pharmaceutical products throughout the supply chain, ensuring that consumers receive genuine and safe medications while facilitating regulatory compliance for pharmaceutical companies

Block chain technology is a decentralized, distributed ledger system that provides an efficient and trusted solution for product traceability. Block chain technology powers the crypt currencies and has been applied to variety of industries such as banking, supply chain, energy, commodities trading, health care and many businesses involving transaction processing. To deal with the issue of counterfeit drugs, block chain technology has the potential to provide pragmatic solution for drug traceability and provenance in a secure and immutable manner. Block chain technology enables the creation of a distributed shared data platform for storing and sharing the transaction data among various supply chain stakeholders ensuring the information remains accessible, immutable, transparent and secure via cartographic techniques and accessible only to authorized parties. Thus, provides a proactive approach to track, detect, and manage counterfeits in pharmaceutical supply chains.

In this paper, we reflect on the potential and the limitations of block chain technology for drug traceability. We describe the current block chain enabled trends and describe two state of the art architectures, provide explanations on how these architectures are robust, secure, and scalable to provide better transaction privacy compared to existing solutions, and discuss potential opportunities for securing the pharmaceutical supply chain. The major contributions of our work are as follows:

- We discuss the reasons how the pharmaceutical supply chain benefits from a block chain-enabled drug traceability solution.
- We highlight the key benefits of using block chain solution for drug supply chain compared to existing solutions.
- We present two suitable block chain architectures for drug traceability, Hyper ledger Fabric and Beau private block chains.
- We identify, enumerate, and discuss several future research challenges that may hinder the successful deployment of blockchain solutions in the drug supply chain.

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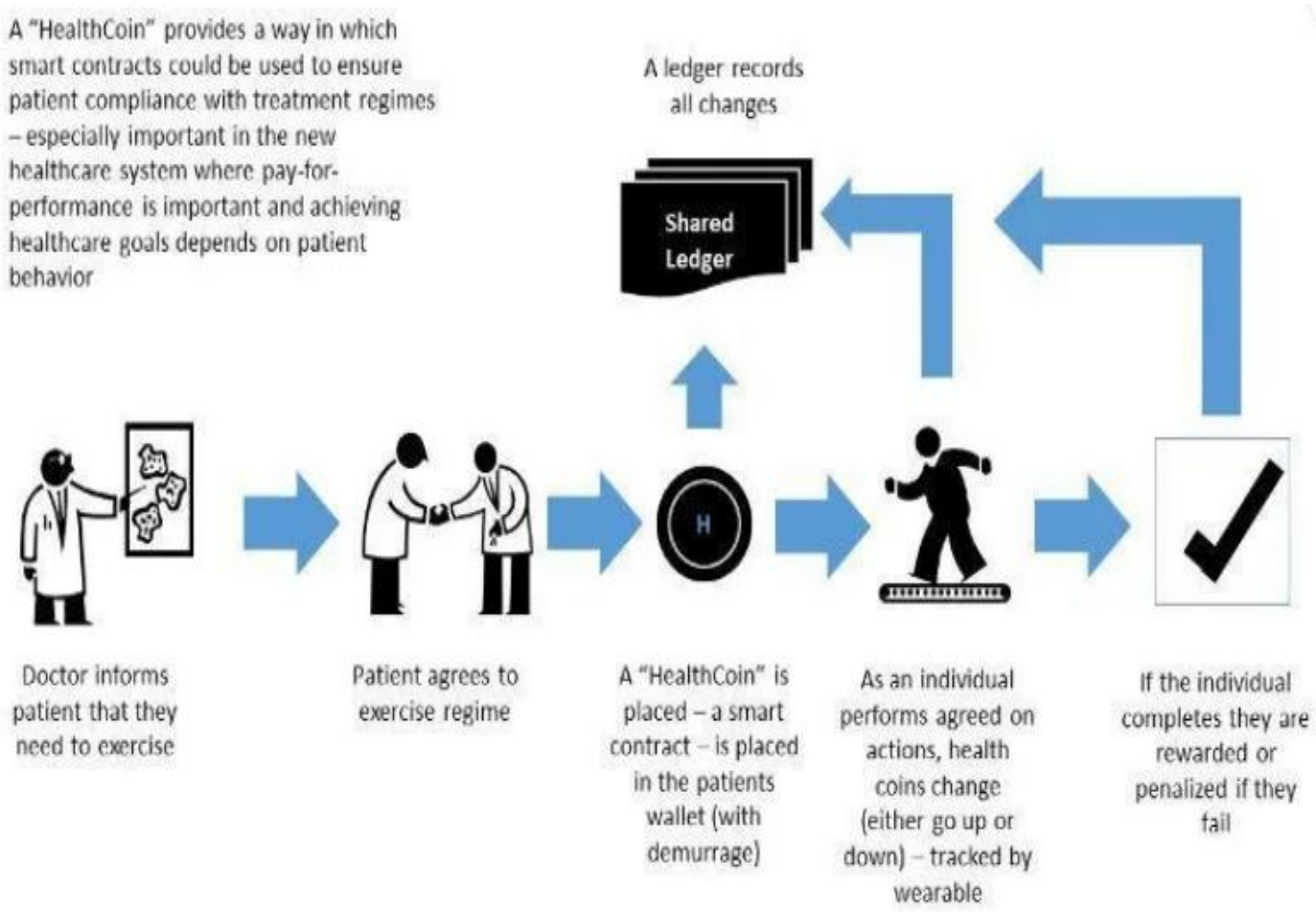

For example,

- substandard version of the anti-cancer drug Avast® was purchased and delivered to thousands of cancer patients in the U.S causing potential treatment complications for patients.
- The Asia Pacific, African, and Latin American regions are most vulnerable to counterfeit drugs with almost 30% of the drugs produced and consumed are counterfeit leading to almost 1.5 million deaths per year.
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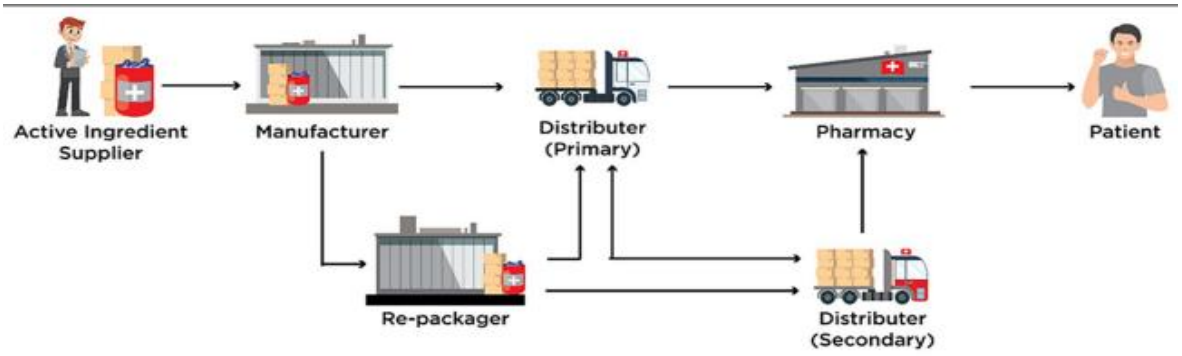
- A recent report by a prominent European research project highlights that the counterfeit medication industry is considered more lucrative and profitable business than selling legal medicines and it estimates a revenue loss equals almost 4.5% in drug sales amounting to €10 billion every year.

BUSINESS REQUIREMENT:

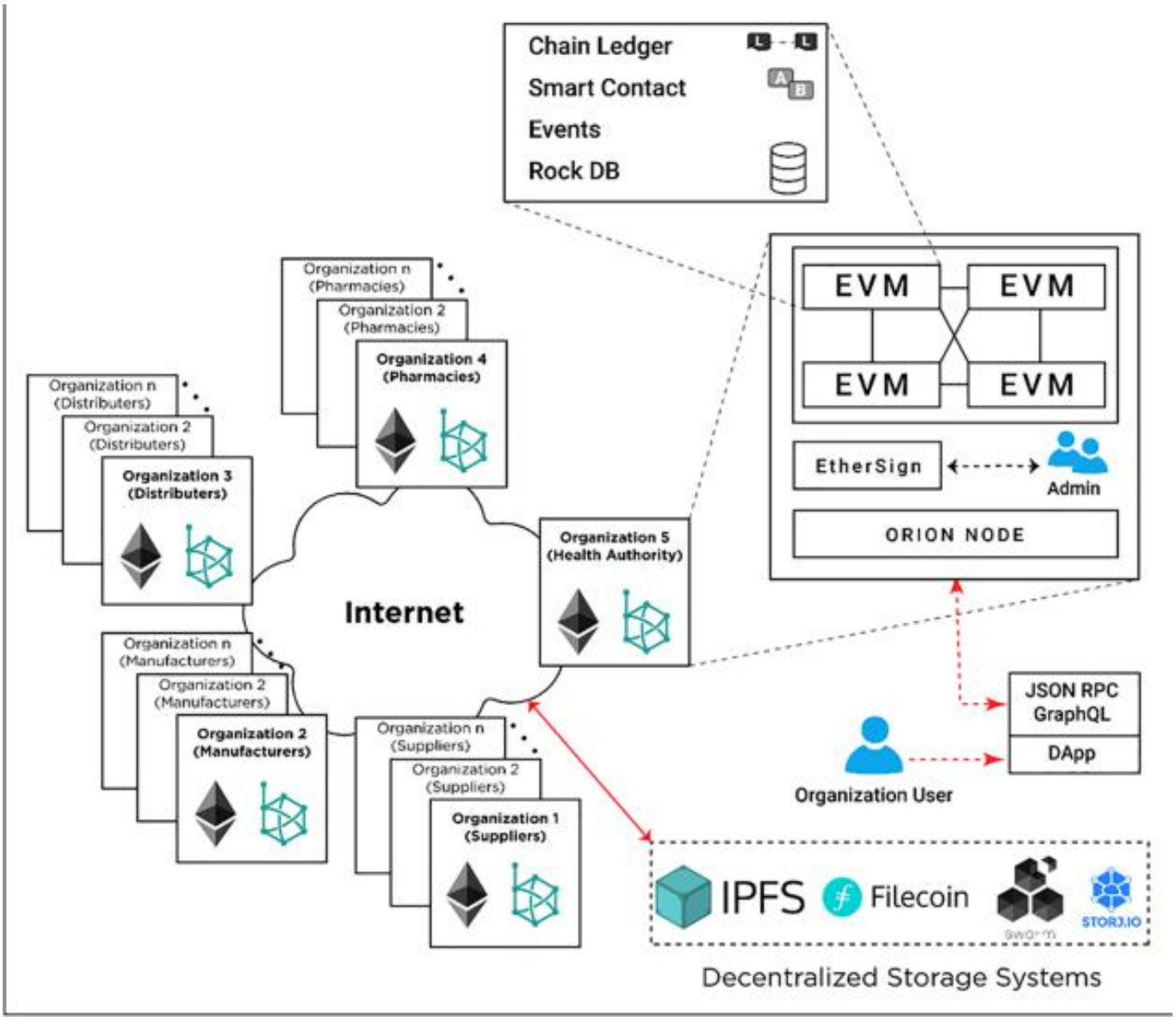
The Drug Supply Chain Security Act (DSCSA) is a law enacted by the United States Congress on Nov. 27, 2013, that sets forth requirements for trading partners regarding the tracing of prescription pharmaceutical products during distribution throughout the United States . The act requires the consistent traceability of pharmaceutical products from the manufacturer to the dispenser, and is one in a series of regulations intended to improve the safety of products in the U.S. pharmaceutical supply chain. Requirements include checking prescription drugs, checking the licenses of trading partners, identifying suspicious drugs, and reporting illegitimate drugs.

In India, there are several track and trace requirements for pharmaceutical products. The Ministry of Health has extended a deadline, announced a new deadline, and released new draft rules concerning key areas of the country's pharmaceutical regulations .

The business requirements for the Drug Traceability Smart Contract on Ethereum Block chain include the establishment of a decentralized ledger for pharmaceutical supply chains. This ledger should enable real-time recording and tracking of drug shipments, with each transaction being securely and immutably stored. Additionally, the system should provide visibility to all authorized stakeholders, ensuring transparency and traceability while protecting sensitive data through encryption and access controls. Compliance with regulatory standards and seamless integration with existing supply chain systems are also crucial while maintaining cost-efficiency to encourage widespread adoption in the pharmaceutical industry.



One of the main use cases of block chain is drug traceability. Drug fraud is a major problem faced by many pharmaceutical companies and, according to the Health Research Funding Organization, around 10% to 30% of drugs sold in the developing world are fake and, it's the underground economy is valued at around $200 billion annually. According to another report by the World Health Organization, around 16% of the counterfeit drugs contain the wrong ingredients. The main issue with such drugs is not that they're just fake, but it's mainly about the wrong ingredients that can put the patient's life in danger.


Chain Ledger
Smart Contact
Events
Rock DB
EVM
EVM
EVM
EVM
EtherSign
Admin
ORION NODE
Organization n (Pharmacies)
Organization 2 (Pharmacies)
Organization 4 (Pharmacies)
Organization n (Distributers)
Organization 2 (Distributers)
Organization 3 (Distributers)
Organization 5 (Health Authority)
Internet
Organization n (Manufacturers)
Organization 2 (Manufacturers)
Organization 2 (Manufacturers)
Organization n (Suppliers)
Organization 2 (Suppliers)
Organization 1 (Suppliers)
JSON RPC
GraphQL
DApp
Organization User
IPFS
Filecoin
STORJ.IO
Decentralized Storage Systems

LITERATURE SURVEY:

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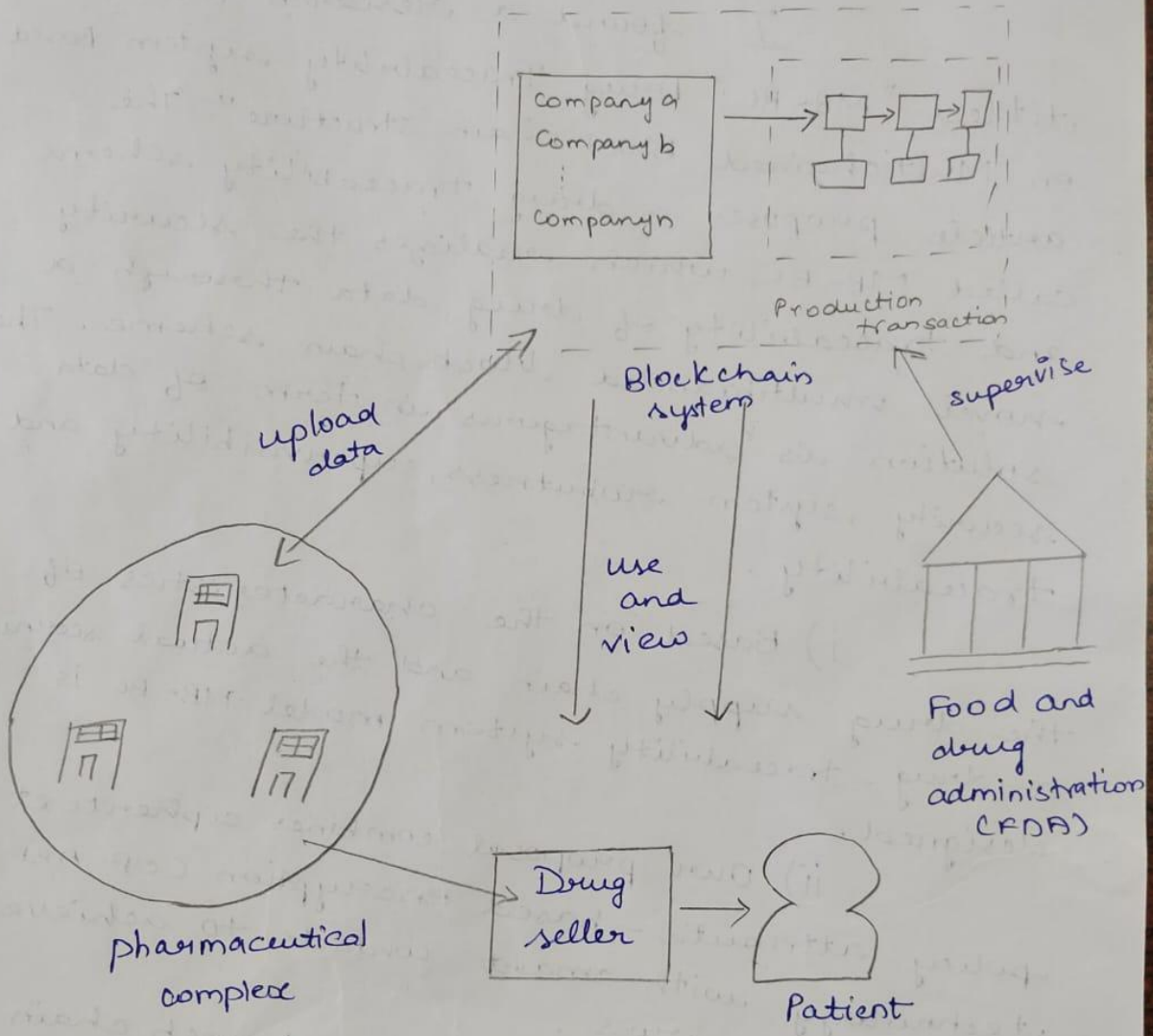
I found a research article titled "MB-BC: Drug Traceability system Based on Multichained Blockchain structure". The article proposes a drug traceability scheme called MB-BC, which realizes the security and traceability of drug data through a novel multibranded block chain scheme. The solution is advantageous in term of data security, system robustness, supervisibility and traceability.

i) Based on the characteristics of the drug supply chain and the actual scenio, a drug-traceability system model MB-BC is designed.

ii) Our proposal combines ciphertext policy attribute-based encryption (CP-ABE) technology with smart contacts to achieve fine-grained cross.

iii). In MB-BC, each branch chain can publish its own smart control, which can efficetively is an improved DPoS.

A systematic of the various technical implementation aspects of blockchain enabled supply chain traceability system.



a) Forensic Analysis of Drugs:

* Techniques for identifying and quantifying drug traces in various matrics such as blood, urine.
* challenges in the detection of novel psychoactive substance (NPS) and designer drugs.

b). Drug Metabolism :

* Metabolism of drugs in the body and the formation of drug metabolities.

* The role of pharmacokinetics in drug trace analysis.

c) Legal and Ethical considerations:

* The legal framework surrounding drug trace evidence and its admissibility.

* Ethical issue in drug trace analysis and potential baises in forensic investigations.

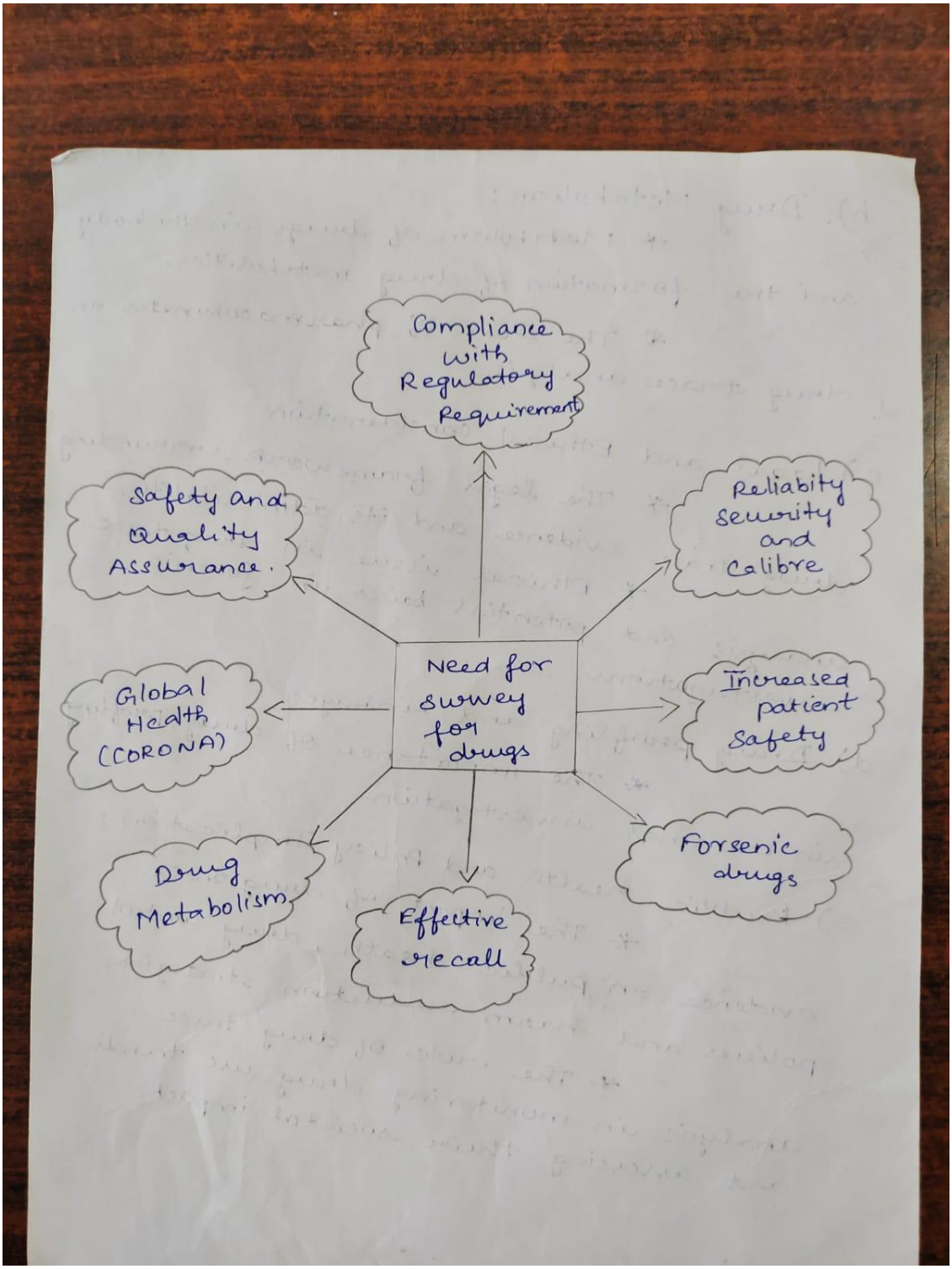
d) Drug profling and Linkage:

* The importance of drug profling in criminal investigation.

e) Public health and Policy Implication :

* The impact of drug trace evidence on public heath, drug control policies and harm reduction strategies.

* The role of drug trace analysis in monitoring drug use trends and assessing their societal impact.


Compliance with Regulatory Requirement
Safety and Quality Assurance.
Reliabity Security and Calibre
Need for survey for drugs
Global Health (CORONA)
Increased patient Safety
Drug Metabolism
Effective recall
Forsenic drugs

SOCIAL OR BUSINESS IMPACT:

The pharmaceutical industry has been implementing drug traceability to improve compliance and financial performance. The US Congress passed the Drug Supply Chain Security Act (DSCSA) in 2013, which mandates that drugs be traceable at the unit level as they move through the pharmaceutical supply chain. Regulators believe that improving drug traceability will reduce the incidence of counterfeiting, black/gray market drug distribution, and adulterated or incorrect orders, which will lead to a safer health care system .

The benefits of supply chain digitization include improved patient safety and protection against reputation risk of harming patients, ability to rapidly identify and isolate issues, leading to a more efficient recall process, optimized inventory levels, resulting in fewer supply disruptions and improved cash flow, and market share gains from competitors who are behind on DSCSA readiness .

Lack of visibility in the pharmaceutical supply chain has multiple repercussions. Drug shortages have adverse economic and clinical effects on patients — they are more likely to have increased out-of-pocket costs, rates of drug errors, and mortality.

The implementation of Drug Traceability Smart Contracts on the Ethereum Block chain holds the potential for significant social and business impact. From a social perspective, it can greatly enhance public health by ensuring that consumers receive genuine and safe medications, thereby reducing the risks associated with counterfeit drugs. This technology can also lead to increased patient trust in the pharmaceutical industry. On the business front, it can streamline supply chain operations, minimize the financial losses incurred through counterfeit drug distribution, and improve regulatory compliance, all of which contribute to cost savings and operational efficiency. Moreover, the transparency and data integrity offered by block chain smart contracts can facilitate collaborations and partnerships within the pharmaceutical ecosystem, ultimately benefiting the industry as a whole.

The US had about 150 -300 drug shortages every quarter from 2014 to 2019.

For drug managers, maintaining excess inventory to try to avoid shortages brings significant costs in storing pharmaceuticals — and waste when they are not used. They also struggle with being able to predict where a particular drug is likely to be needed at a particular time.

The average pharmacy holds 180 days of finished goods inventory, and could free up $25 billion if it reduced that to a target of 80 to 100 days. With increased competition from generics and rival brands, cutting costs in the supply chain lets them redirect money to competitive ends such as funding product development.

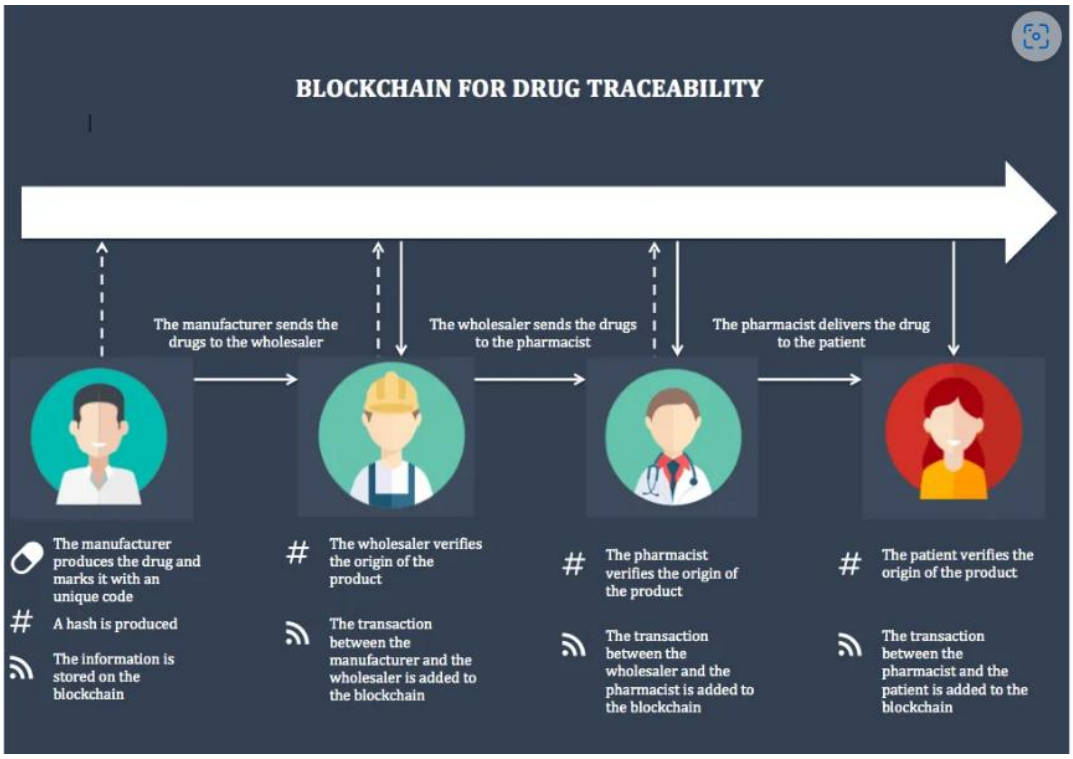
Compliance is another issue. Serialization compliance required by the FDA Drug Supply Chain Security Act requires manufacturers, re-packagers, wholesale distributors, and pharmacies to be capable of lot-level product tracing and to provide applicable transaction information, history, and statement.

Each patient is unique which means that similar patient strategies might not work due to inter-individual variability. Hence, access to complete medical records is essential in order to adapt the treatment and provide personalized care. Sadly, sharing information among the medical community is a major challenge. Even today, when shifting to a new medical facility, similar old tests are re-run and patients get to bear a large amount of cost. Moreover, the lack of a secure structure to share data leads to misuse of patient confidential information.

Also, today the patient cannot claim full-ownership of his medical records because the patient can change information or delete information on it. This could have severe repercussions on both his health and future

course of diagnosis. The downside of not sharing is not letting the patients get access to their own data which is again a problem when shifting to a new medical facility.

The role of drug regulatory authorities includes quality checks and monitor the quality, safety, and efficacy and post market surveillance of pharmaceutical products. They often oversee the manufactureTuring, distribution, and storage of pharmaceutical products so that illegitimate manufacturing and trade of counterfeit medicine can be detected quickly and adequately sanctioned. In block chainbased solutions, the role of regulatory agencies becomes more pertinent and complex as it becomes hard for these agencies to define the legal boundaries and environment for block chain technology. For instance, when a new transaction is executed in the network, it is difficult for these authorities to clearly define the jurisdiction and correct legal obligations of the stakeholders involved. Another challenge is to cope with the requirements of upcoming legislation such as FDA DSCSA, sterilization, and GDPR in block chain networks. Therefore, block chain technology is still incompatible with recent laws and regulations regarding the pharmaceutical supply chain.



To protect patients and prevent falsified medicines from entering the supply chain, the Eu's Falsified Medicines Directive was passed to increase the security of the manufacturing and delivery of medicines across Europe. The main focus is on counterfeit and falsified drugs that can be ineffective or even dangerous.

By 2023 in the US, lot-level tracing will move to unit-level serialization. Russia’s serialization gives pharmacy companies until this year for complete unit- and batch-level traceability. Brazil’s track and trace regulations go into effect in May 2022. In South Korea and India, companies must uniquely serialize drug products. Saudi Arabia’s vision 2030 plan includes adopting technology for tracking all human registered drugs manufactured in Saudi Arabia and those imported from abroad. China has published regulations providing for the development of a new national drug traceability system by 2022.Regulations that require that manufacturers add serial numbers to medications give them more data than previously, a benefit for having information about the status of drugs wherever they are in the supply chain. But getting this right requires that partners in the supply chain participate in the tracking.