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Research Article

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Pharma Supply Chain Reimagined Using Blockchain Technology in Cloud

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Abstract In this technology generation, 'Blockchain' has been one of the most innovative methods used to keep information in a trustworthy and secure framework. Blockchain is becoming more widely acceptable and used across different industry spaces. However, what is so special about Blockchain? What are the main benefits of using Blockchain versus other information frameworks?

This analysis focuses on explaining Blockchain and particularly creating a Blockchain use case for the Supply Chain in the Pharmaceutical industry. The Pharma Supply Chain is one of the most vulnerable points to introduce and distribute fake goods to consumers. The impact regarding the worldwide fake pharma market is major, and this study presented attempts to minimize fake goods by creating a pharmaceutical validation process at the various touch points of the supply chain by using a combination of blockchain and the best cloud solutions currently available.

Keywords Blockchain, Pharma Supply Chain, cloud solutions

1. Introduction

In very simple terms, Blockchain is a digital ledger stored in blocks of data. Each block contains an identification key, the 'ledger' data and the identification key of a previous block, which forms a chain of information in blocks.

Blockchain departs from the idea of having a secure, trustworthy and decentralized information framework. This very concept now questions if the information frameworks that exists today (with the exception of Blockchain) are secure and trustworthy; moreover, if centralized information is a problem.

Security in a centralized environment, in this day in age, is definitely a concern. Companies, organizations or institutions hosting information create centralized information environments with proper or improper security mechanisms in place. The centralized information hosted could be vulnerable to data corruption or hacking. If these data attacks are successful, it could potentially affect the integrity of information and have very costly consequences.

As an example, one of the most famous use cases for Blockchain is Bitcoin. Whether Bitcoin is a sustainable economic platform or not, due to economy factors and adoption, that is beyond this study. However, the use case for Bitcoin using Blockchain goes back to the very core of centralized financial information questionably being mishandled by financial institutions. Historical economy crashes made the public question if there is a mathematical explanation, accountability and data integrity in the realm of our current financial system. On the other hand, Blockchain does not exist in one single machine or centralized system, exists in all the machines of its users and all of the users have a copy of the information. Making the information transparent to all of its users, trackable and accountable.

2. Issues In Pharmaceutical Industry

Pharmaceutical counterfeiting ranges globally from US$163 billion to $217 billion per year, making the pharmaceutical counterfeiting industry the world's largest fraud market. Placing this problem into perspective, the illegal counterfeiting pharmaceutical goods market accounts for more than 2% of the global economic output. The following statistics and problems in the pharmaceutical industry are alarming:

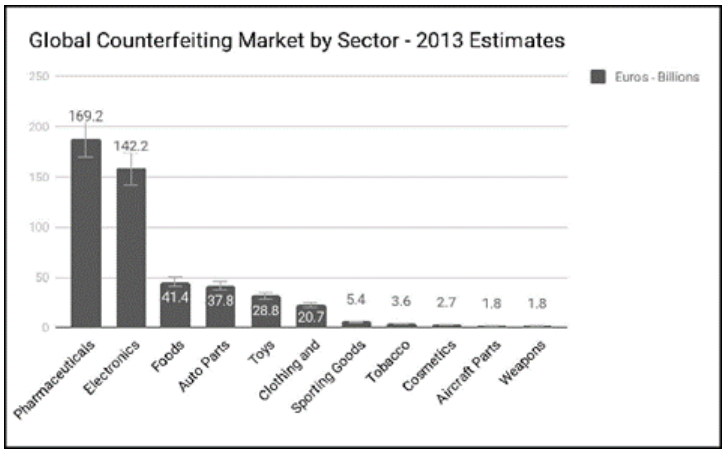

Fig. 1: *Global Counterfeiting Market by Sector*

Table I: Global Issues Regarding Fake Pharmaceuticals

Known Facts and Issues on Pharmaceuticals
70% of the drugs in developing regions, such as Africa, are fake drugs
The World Health Organization estimates that 50% of
the drugs sold online are fake
90% of the drugs purchased online come from a different country than the website claims
450,000 preventable malaria deaths each year are caused by counterfeit pills

Common pharmaceutical fraudulent scenarios happen during the supply chain process, where fake drugs are introduced during the supply chain's change of custody. Some vulnerable supply chain's security spots are: counterfeiting, cargo thefts, digital distribution, shipment and consumer goods validation. The pharmaceutical supply chain logistics is a very vulnerable component for the pharmaceutical sector. Pharmaceutical companies have to deal with security distribution issues in their end to end supply chain and making sure cargos are not tampered. Unfortunately, there are no proper systems or designs in place to effectively communicate and track the movement of drugs from one point to another during the logistic process. This does not mean that the movements of drugs are not tracked currently, but the lack of real time validation from one step to the next step within the supply chain makes it vulnerable to fraud and unethical practices. While we are considering Blockchain, we have two options public blockchain or private blockchain. Each has its own advantages and disadvantages. Here are some of the salient points to consider which choosing them for our specific use case:

Table II: Feature Comparison by Public and Private Blockchains

Feature	Public Blockchain	Private Blockchain
HIPPA, HITECH regulations.	✗	✓
Enhanced Privacy and Security	✓	✓
Controlled Access w/content filtering	✓	✓
Secure exchange of pharmaceutical / drugs data	✓	✓
Mobile / IoT Interface	✓	✓
Open Source / APIs (meaningful use)	✓	✗

Distributed arch for transparency and trust	✓	✗
Scalability and Performance	✗	✗

3. Generic Pharmaceutical Supply Chain

The pharmaceutical supply chain and its distribution process is very complex. Figure 1 below shows a generic supply chain process in the pharmaceutical industry. The process includes multiple parties, for example: manufacturers, resellers, wholesalers, insurance and distribution centers. Since this process involves multiple parties, there is a need for product data consolidation and validation at each touch point of the supply chain to ensure pharmaceuticals have not been tampered.

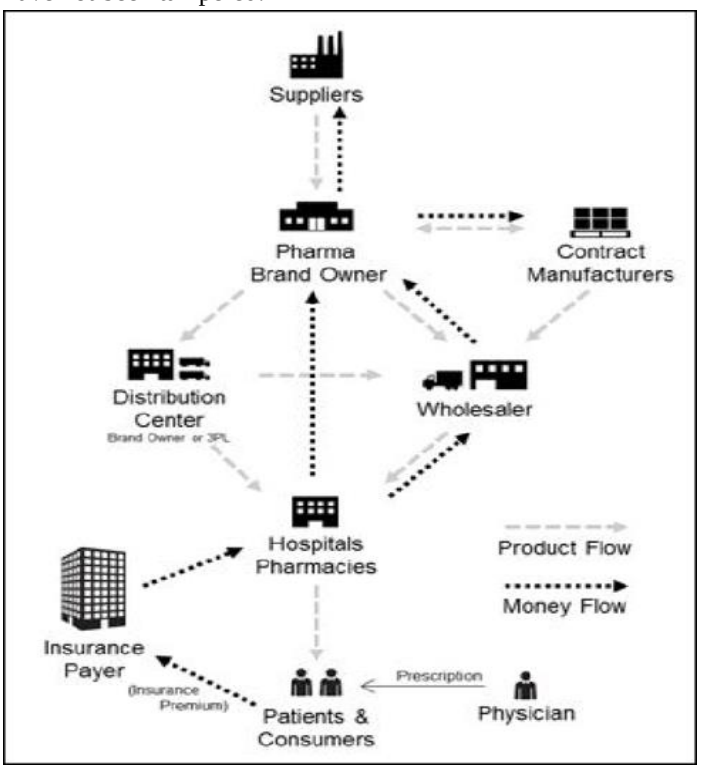

Fig. 2: *This figure shows the generic pharmaceutical supply chain*

Other considerations for monitoring and supervision need to be taken into account for tracking purposes as well, such as temperature conditions in order to maintain pharmaceutical integrity. Even though this topic is outside of the security aspect, it is a consideration for monitoring the integrity of the final product.

4. Ideal Pharmaceutical Supply Chain

Some of the technology requirements to support the practices an ideal pharmaceutical supply chain is to monitor the authentic pharmaceutical inventory at every stage of the supply chain and at each change of custody. From the moment a pharmaceutical product is being produced, to each step of the distribution process at every point of sale until it reaches the consumer. An inventory validation from the sender and receiving parties at the product level would ensure the authentic pharmaceutical is being transferred properly and fake drugs are not being replaced instead. The end consumer can also have a way to validate the purchased pharmaceutic is authentic.

The U.S Food and Drug Administration (FDA) has identified a number of practices to be the basic foundation of the pharmaceutical supply chain (see Figure 2 displays U.S Food and Drug Administration Supply Chain Best Practices). These practices, in an ideal scenario, should be maintained with checks and balances both from an integrity standpoint and technological standpoint. The breach of the practices has led the pharmaceutical fake market be where it is at today.

Unfortunately technology is not the only solution to stop the fake pharmaceuticals distributed around the world. However, the proper technology in place can definitely contribute greatly across the practices mentioned above.

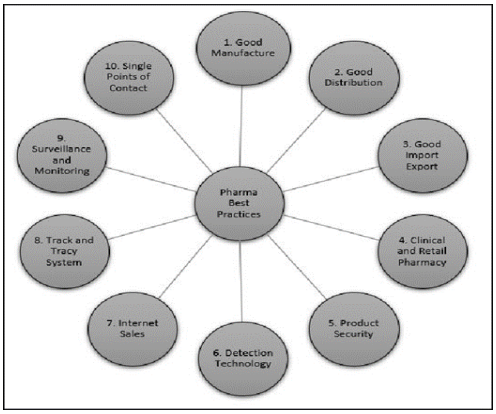

Fig. 3: *This figure represents the US Food and Drug administration Supply Chain best practices.*

Good Manufacturing Practices: The manufacturer ensures the quality of the products to be distribute. As part of the quality control, standards are expected to be in place for those products that are authentic. Also, the manufacturer is expected to have standards in place to also identify fake products.

Good Distribution Practices: When the pharma products are ready to be shipped and distributed to the various points of sale and/or warehouses, the distribution process is expected to have standards in place to account for the inventory at each of these distribution touchpoints.

Good Import and Export Practices: Due to the Global necessity of Pharmaceuticals, Import and Exports are necessary for the logistics process. Adequate regulations need to be in place to transport pharma goods from country to country. Allowing manufacturers to effectively import and export pharmaceuticals in a seamless process.

Clinical Retail Pharmacy Practices: This is the last stage before the pharmaceutical products are distributed to the end consumer. Proper storage and monitoring of the pharmaceuticals are required to be in place in order to provide the consumer the pharmaceuticals with the appropriate quality at which the pharma was designed for.

Product Security: Corporate policies, quality procedures, employee training and security personnel are examples of security measures. Many other security measures can be put in place in order to maintain pharma goods from: counterfeit, false labels, cargo thefts and product tampering.

Detection Technology: Detection tools are necessary to assure the quality and authenticity of medical products. These tools would detect false labeling, falsified and counterfeits from the authentic pharma goods.

Internet Sales: This practice is one of the most worrisome of all, as it serves for sales of fake and illegal pharmaceuticals. This distribution channel is expected to have controls in place for the end consumer to validate the authenticity of purchased goods as some of the pharmaceuticals sold online are either fake or do not even have the active ingredient.. There are sites that assist the medical regulatory authorities to distinguish legal online distribution from illegal entities.

Track and Trace Systems: The ability to know where the pharmaceuticals are at a certain point in time. Section V explains in more detail the current technologies used in this generation regarding supply chain for pharma.

Surveillance and Monitoring: The World Health Organization (WHO suggested to establish a Global Surveillance and Monitoring System (GSMS) due to the alarming pharma global counterfeiting. This institution is in charge to prevent, detect and respond to falsified medical products. Single Point of Contacts: Establishing a Single Point of Contact to distribute communications to various contacts or network. Examples of such communications could be: alerting consumers of counterfeit pharma, alerting authorities and judicial officials, request certain audits on suspicious activities etc. A established network and list of actions would also need to be in place for this practice.

5. Current Technologies for Pharmaceutical Supply Chain

There are pharmaceutical supply chain software in the industry e.g. 1) Vanguard Software - Supports Supply Chain planning activities and 2) One Network - A cloud based 'many to many' network environment. In addition, there are multiple other generic supply chain software that can be leveraged to sustain the pharmaceutical supply chain. However, all these current technologies available in the pharmaceutical supply chain are mostly software driven. There is nothing necessarily wrong with this technology approach with the only caveat that they are all centralized systems. Meaning, the inventory is sustained by a platform where the controller of the platform has the ultimate inventory list and lacks system or fraud accountability due to its centralized information approach.

6. Blockchain's Natural Capabilities

Three basic properties of Blockchain are: 1) Blockchain is Encrypted and hence provides high levels of protection against hacking. To date, a blockchain has never been breached 2) Since Blockchain is Auditable, encapsulating an unchangeable record for every transaction, movement, and status along a product's journey to satisfy the demands of regulatory compliance

3) Blockchain can be monitored in Real-time, delivering instant tracking capabilities compared to the days required by current systems.

Compliance is a major factor to be considered while trying to solve the problem using Blockchain. Drug Quality and Security Act (DQSA) was enacted by the United States Congress in 2013. One of the main components of compliance with DSCSA is that pharmaceutical manufacturing companies need to put serialization into effect by applying a unique identification number to each and every item being shipped, down to the smallest unit sold. The serial number will permit each item to be identified, tracked, and traced.

7. Proposed Pharmaceutical Supply Chain Using Blockchain Technologies

Blockchain has a great potential to provide a complete solution to the various types of issues encountered by the Pharmaceutical Industry. Some advantages of Blockchain over the traditional supply chain process are as follow: 1) Enhances supply chain logistics process visibility and its transparency 2) Reduces theft, counterfeiting, and the damages caused to drugs while in transit 3) Combines logistics management and compliance management into a single, unified platform

4) Ensures compliance with both present and known upcoming global pharmaceutical regulations 5) Secures all data tracked and transmitted across the supply chain and prevents its unauthorized access 6) Ensures medications move from manufacturer to patient safely and securely 7) Blockchain can improve the efficiency of delivering a safe and effective medicine to patients and also track its movement very efficiently in real time 8) With blockchain making real-time data available, pharmacies and other retailers can improve their internal and external inventories by tracking product movement from in-store and in-transit information 9) Ability to record every step in the supply chain process in an immutable ledger will resolve many of the problems that exists in the industry today.

Figure 3 below, shows a diagram of how the pharmaceutical supply chain advantages previously mentioned would be represented in a blockchain model. All logistical components send information to the blockchain.

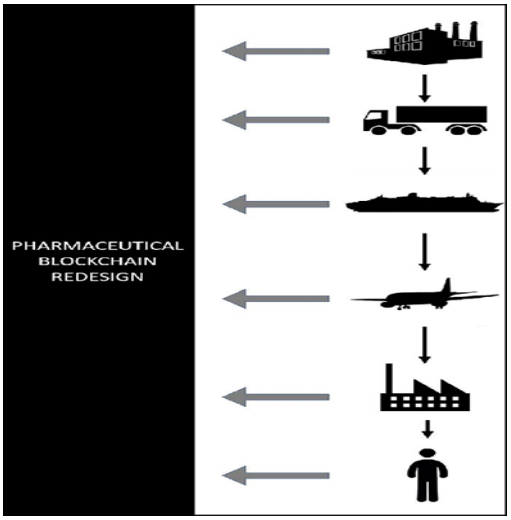

Fig. 4: *This figure shows the proposed pharmaceutical supply chain using Blockchain.*

8. Challenges Using Blockchain

TABLE III: Main Challenges When Implementing Blockchain

Blockchain Challenges
1. Complexity and Cost
2. Energy Consumption
3. Integration Issues
4. Public Perception
5. Privacy and Security

Table III above shows the top 5 challenges in implementing the Blockchain technology.

Complexity and Costs: The technology behind the Blockchain architecture is highly complex. As the size of the blockchain grows, the requirements for storage, bandwidth, and compute power required by fully participating nodes in the network also increase. This leads to high costs.

Energy Consumption: Blockchain mechanism requires the computation of complex mathematical problems to verify and process transactions and to secure the network. These calculations require large amounts of energy to power the computers solving the problems. In addition to the energy used to run the computers, a sizable amount of energy is also required to cool down the computers.

Integration Issues: Integrating Blockchain with legacy systems like CRM, ERP etc will be challenging. Hence we need to identify the right use case to implement Blockchain while carefully considering the challenges and its results.

Public Perception: As Blockchain is an emerging technology, for majority of the public does not fully understand how it works, hence it would be harder to get a buy-in from the public to use this technology for solving the issues.

Privacy and Security: Blockchains as in the original design are publicly visible. As it is not regulated it brings an element of high risk in the overall environment. Hence uploading sensitive data like medical records, financial information, crucial business data into blockchain will be not an option for majority of the business.

9. Proposed Technical Architecture

The architecture is structured into back-end, front-end, and IoT sensor devices as outlined in Figure 1. The architecture is composed by the following components based on AWS cloud solution:

Ethereum Blockchain Network: Ethereum network in AWS ECS cluster or AWS EC2 instances is used to verify shipment / temperature data registered in the front-end during each stage of the shipment process by smart contracts.

Smart Contract: Smart Contracts are used for every shipment, it ensures temperature data associated with each shipment is normal so that the medical products or drugs are not contaminated during the shipment.

Database: AWS Dynamo or AWS RDS is used to store shipment / temperature related data and user credentials.
Server: Interfaces the communication between the blockchain network and front-end users and storing data in the database. AWS EC2 / AWS ECS / AWS EBS is used as the foundation for the blockchain infrastructure.
IoT Devices: IoT devices are used by the end-users to register new shipments and track/send records of temperature data to the Server. AWS IoT service is used to connect to these IoT devices. AWS IoT Button can be used to track shipment points and loading / unloading of Pharmaceutical goods at various stages of the shipment.
Sensors: Thermal sensitive devices configured to send data in a regular interval to a Mobile / IoT Device. These sensors can transmit data to the Mobile / IoT Devices via Bluetooth or Infrared technology.
Fig 3 shows at a high level design of the architecture that we are proposing. We propose building an entire blockchain network and infrastructure running on AWS could that can be auto scaled and reduce the complexity and cost. AWS Blockchain Templates that are managed and certified AWS CloudFormation templates can deploy the Ethereum blockchain framework as containers on an Amazon Elastic Container Service (ECS) cluster, or directly on an EC2 instance running Docker. Ethereum blockchain network is created in in the Amazon VPC, allowing to use our VPC subnets and network Access Control Lists. Ethereum can also have built-in artificial intelligence components, including deep learning algorithms for example, to implement smart contracts and support Dapps development. We can assign granular permissions using AWS IAM to restrict which resources an Amazon ECS cluster or Amazon EC2 instance can access. Lambda function will deploy smart contracts to blockchain, it also executes simulated blockchain transactions.
The basic infrastructure that we are proposing is as follows. The first layer would be: thermal sensitive devices will be installed in all the shipment containers in all mode of transportation, it will keep monitoring the temperature and sending the temperature data in regular intervals to IoT or Mobile devices installed or carried within its range. These IoT or Mobile devices will take these inputs and transmit to the AWS server where the blockchain network is deployed. For every new shipment or group of medical product containing specific temperature requirements, a smart contract is configured and deployed in the server-side. AWS cloud server hosts the Ethereum node that participates in the Ethereum network and can watch changes on its smart contracts, create new smart contracts, or call smart contract functions. Data that is sensitive or too large to store in the blockchain is stored in a database in AWS RDS or Amazon Dynamo. This includes the raw temperature data, as these are too large to be stored in a smart contract. The smart contract verifies the temperature range, and stores the verification result in the smart contract. We can also use AWS IoT button to interface with AWS cloud to register the updates to track the shipments and temperature data in the Blockchain. We also propose using AWS IoT in our architecture, it is a serverless way to connect to IoT devices and start data processing. It supports MQTT and HTTP. It secures the communication using X.509 Certificates. AWS IoT can connect to large number of sensors, store and process data in real time.
This architecture depends heavily on internet connection for real time data processing. In a typical scenario the warehouse and at some points of shipments may have bad Internet connectivity, during these points we need to have an offline mechanism to store data internally until it can be uploaded in the next availability of internet connection. It is very critical to have this facility in place so we do not lose any temperature and tracking data during the shipments.

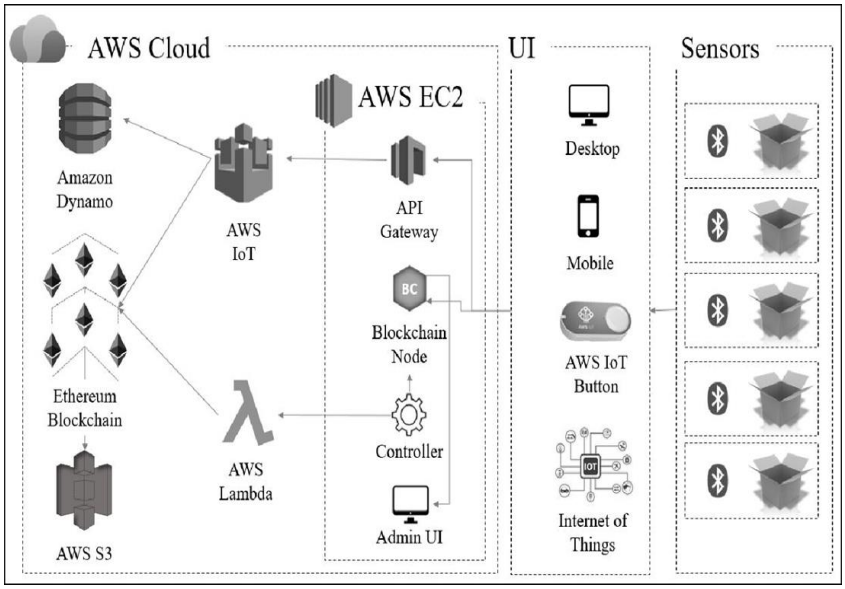

Fig. 5: *Proposed technical architecture to implement Blockchain for Pharma Supply Chain using Cloud Solution.*

10. Pros And Cons in The Design

Blockchain can transform supply chains, ecosystems and industries to streamline their own business. Full transformation of supply chains will not happen immediately. Having said that supply chains can already start using blockchain for small portions of their operations. Smart contracts can help eliminate costly delays and waste currently due to manual handling of paperwork.

One of the greatest advantages of the design discussed in this paper is the use of cloud technology. This makes it very easy for the distributed blockchain network to record transactions for the international shipments in different countries as a local region cloud node can be used to register the transactions at various stages of the shipment. This shows that the design has potential to be efficient in a Global Supply Chain scenario. Blockchain is not a solution by itself to supply chains, several technologies should be integrated to enable the digital supply chain process. Primary advantages of using Blockchain is to automate transactions, ensure traceability in a secured manner to protect from cyber threats.

Even though blockchain technology brings a lot of advantages to the table for collaborating parties, it's important to understand that blockchains are also not necessarily the magic solution for all our supply collaboration challenges. It has its own downsides and here are few. Data once registered in blockchain is immutable, Once a transaction is agreed and shared across the distributed network it becomes close to impossible to undo. In fact, over time, it becomes harder and harder to undo. Hence the need to be very careful in what data is going into the blockchain, quality of these transactions needs to maintain very high standards. Similarly, Smart Contracts are immutable. Once the smart contact is added to the blockchain, it becomes immutable, and it cannot be changed. If there are flaws in the code that may be exploited by hackers, they are there forever. The risk of a 51% attack applies to blockchain solutions in general. If someone controls more than half of the computing power currently being, then that person can surreptitiously write an alternative transaction history, which then would lose the integrity of the Blockchain network. Blockchain is open, and everyone sees everything. Thus, blockchain has no real anonymity.

11. Conclusion, Summary & Future Research

The Pharma Supply Chain is one of the most vulnerable points to introduce and distribute fake goods to consumers. The impact regarding the worldwide fake pharma market is major. Pharmaceutical counterfeiting ranges globally in the hundreds of billions of dollars per year, making the pharmaceutical counterfeiting industry the world's largest fraud market. To solve this unsecure supply chain issue, a blockchain solution coupled with cloud services is suggested. The solution attempts to monitor in real time the movement of

pharmaceutical goods across the supply chain. In this real time monitoring, many measurements are captured such as: temperature, locations, senders, receivers and transference. Also, the blockchain permit validation in a decentralized manner, something that the current technologies being used in the supply chain lacks.

The technical architecture presented is structured into back-end, front-end, and IoT sensor devices. The architecture is composed by the following components based on AWS cloud solution: 1) Ethereum Blockchain Network 2) Smart Contracts 3) Database (AWS Dynamo) 4) Server (AWS EC2) and 5) Front End Devices such as Desktop, Mobile and IoT Devices. This technical architecture leverages the many services that Amazon is currently providing. This will enable all the backend application to talk to each other in a seamless manner.

While blockchain's best-known, most used and highest impact application is Bitcoin, the potential impact of the technology is much greater and wider than virtual currencies. Transactions of any kind are usually faster and cheaper for the user when completed via a blockchain, and they also benefit from the protocol's security. In this paper we have tried to blend the two latest innovations: 1) Cloud Services and 2) Blockchain technologies to solve the problems faced by the pharmaceutical industry in the Supply Chain segment.

Blockchain is still an evolving field, hence more changes are expected in the way we can use this technology to maximize the benefits. In future when we use the hybrid of centralized and decentralized models Blockchain technology could be quite complementary in that scenario. Blockchains allow data to be shared securely with full integrity. Blockchain is the future of supply chain transparency.

Going forward more research needs to be done on utilizing Artificial intelligence, machine learning, and IoT to run across the network, to optimizing, automate and streamline the end-to-end supply chain between all trading partners. As the combination of these powerful technologies can enhance the current capabilities of Blockchain to a next level.

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