PROJECT DEMONSTRATION & DOCUMENTATION

Record Explanation Video For Project End To End Solution

Team Id	NM2023TMID04410
Project Name	Project- Drug Traceability

INTRODUCTION:

- Regulating and monitoring a traditionally fragmented pharma supply chain has been a global challenge for decades. Without a trusted system and strong collaboration between stakeholders, threats such as counterfeits can easily intercept the supply chain and cause monumental disruptions.
- There is a need for improved ways of working to help build up supply chain resilience, and one way is by implementing better end-to-end traceability using blockchain technology such as Hyperledger Fabric.
- Through six key features, pharmaceutical manufacturers, patients, and Healthcare Practitioners (HCPs) can now participate in data sharing, with extended use cases of integrating blockchain with warehouse platforms, a patient-facing mobile application, and an interactive dashboard for real-time verification and data transparency.
- The effectiveness of a traceability solution is heavily dependent on the amount of data collected and is affected by poor adoption and scalability. Existing limitations that need to be addressed include the lack of mandated serialization in Asia and blockchain interoperability.
- To maximize the value of blockchain, collaboration is the key. Pharmaceutical manufacturers need to invest in new technologies, such as blockchain, to help them break out of data silos and operationalize data to build supply chain resilience.
- With the introduction of blockchain technology, companies are now able to implement solutions with more effective track and trace results, providing quality assurance to pharmaceutical manufacturers, patients, and Healthcare Practitioners (HCPs), and even improving operational efficiencies.
- Business impact of end-to-end traceability using blockchain technology, and the effects it brings about, such as improving supply chain resilience and combating counterfeits, as seen in successful live use cases in Asia.

A BLOCKCHAIN-BASED DRUG TRACEABILITY SYSTEM FOR PHARMACEUTICAL SUPPLY CHAINS:

- The stakeholders are envisioned to access the smart contract, decentralized storage system and on-chain resources through software devices that have front-end layer denoted by a DApp (Decentralized Application) which is connected to the smart contract, on-chain resources, and decentralized storage system by an application program interface (API) such as Infura, Web3, and JSON RPC.
- The stakeholders will interact with the smart contract to initiate pre-authorized function calls and with the decentralized storage systems to access data files.
- Finally, their interaction with the on-chain resources will be for obtaining information such as logs, IPFS hashes, and transactions. More details on the system components are presented below.

Stakeholders include regulatory agencies such as FDA, manufacturers, distributors, pharmacies, and patients.

- These stakeholders act as participants in the smart contract and are assigned specific functions based on their role in the supply chain.
- They are also given access to the on-chain resources such as history and log information to track transactions in supply chain. Further, they are authorized to access information stored on the IPFS such as the drug Lot images, and information leaflets.

Decentralized Storage System (IPFS [42])provides a low-cost off-chain storage to store supply chain transactions data to ensure reliability, accessibility, and integrity of the stored data.

- The integrity of data is maintained by generating a unique hash for every uploaded file on its server, and the different hashes for the different uploaded files are then stored on the blockchain and accessed through the smart contract, and any change that occurs to any of the uploaded file is reflected in the associated hash.

Ethereum Smart Contract is used to handle the deployment of the supply chain.

- The smart contract is central and essential for tracking the history of transactions and manages the hashes from the decentralized storage server which allows the participants to access the supply chain information.
- Moreover, the functions of the different stakeholders in the supply chain are defined within the smart contract and access to these functions is given to the authorized participants by using modifiers.
- A modifier is basically a way to decorate a function by adding additional features to it or to apply some restrictions.
- The smart contract also handles the transactions, such as selling drug Lots or boxes.

On-chain Resources are used to store the logs and events that are created by the smart contract allowing track and trace.

- Moreover, a registration and identity system is used as an on-chain resource to associate the Ethereum address of the different participants to a human readable text which is stored in a decentralized way.

Pharmaceutical Industry:

The pharmaceutical industry faces a range of complex challenges and problems, two of which are counterfeit drugs and regulatory compliance. Let's dive deeper into each of these challenges:

1.Counterfeit Drugs:

- Production and Distribution Counterfeit drugs are fraudulent or fake medications that may contain incorrect ingredients, incorrect doses, or no active ingredients at all.
- They can infiltrate the supply chain at various points, from production facilities to distribution networks, making it difficult to trace the source.

Public Health Risk:

- Counterfeit drugs pose a significant threat to public health. Patients who unknowingly consume counterfeit medications may not receive the treatment they need, leading to worsened health conditions or even death

Economic Impact:

- The pharmaceutical industry and healthcare system suffer financially from counterfeit drugs, as they often result in product recalls, legal liabilities, and increased costs for quality control and security measures.

2. Regulatory Compliance:

Complex Regulations:

- The pharmaceutical industry is highly regulated, with a myriad of rules and standards to ensure product safety and efficacy.
- Regulations differ from country to country, and compliance is a complex and costly process.

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Data Integrity:

- Regulatory bodies require that data related to drug manufacturing, testing, and distribution be accurate and secure.
- Maintaining data integrity across the entire product life cycle is a considerable challenge.

Changing Landscape:

- Regulatory requirements and standards are subject to change and evolve over time. Staying current with these changes and ensuring compliance is an ongoing challenge.

Global Operations:

- Pharmaceutical companies often operate on a global scale, which means they must comply with multiple sets of regulations and standards, adding to the complexity of ensuring regulatory compliance.

Addressing these challenges requires innovative solutions, and blockchain technology has emerged as a potential tool to tackle both counterfeit drugs and regulatory compliance:

Blockchain for Drug Traceability:

- Blockchain's immutable ledger can provide end-to-end traceability of pharmaceutical products. Each step in the supply chain can be recorded, ensuring the authenticity and provenance of drugs.

Smart Contracts:

- Smart contracts can automate compliance with predefined rules and regulations. They can ensure that each party involved in the supply chain adheres to regulatory requirements.

Data Security:

- Blockchain can enhance data security, ensuring the integrity and confidentiality of sensitive information, a crucial element of regulatory compliance.

Global Consistency:

- Blockchain can offer a consistent and tamper-proof ledger, which can assist in achieving global compliance standards.

- Addressing these challenges is essential to maintaining the integrity and safety of pharmaceutical products and to ensure the trust of healthcare providers and patients. Blockchain technology, when implemented effectively, can play a pivotal role in mitigating these challenges.

These problems can have significant consequences:

The problems of counterfeit drugs and regulatory compliance in the pharmaceutical industry can have significant consequences, affecting various stakeholders and the industry as a whole:

Counterfeit Drugs:

1.Public Health Impact:

Consequence: Patients who unknowingly consume counterfeit drugs may not receive the intended treatment, leading to worsened health conditions, complications, or even fatalities.
Result: Public health risks and loss of trust in the pharmaceutical industry.

2.Increased Healthcare Costs:

Consequence: Counterfeit drugs can lead to treatment failures, necessitating additional medical interventions and hospitalizations.
Result: Escalating healthcare costs for both patients and healthcare systems.

3.Legal and Reputational Damage:

Consequence: Pharmaceutical companies associated with counterfeit products face legal liabilities and reputational damage.
Result: Damage to brand reputation and financial losses.

4.Supply Chain Disruptions:
Consequence: Identification and recalls of counterfeit drugs disrupt the pharmaceutical supply chain.
Result: Supply chain inefficiencies and additional costs due to recalls and investigations.

Regulatory Compliance:

1.Product Delays and Launch Challenges

Consequence: Failure to comply with regulatory requirements can delay the launch of new drugs or expansion into new markets.
Result: Lost revenue opportunities and increased development costs.

2.Legal and Financial Penalties:

Consequence: Non-compliance with regulations can lead to legal actions, fines, and penalties from regulatory authorities.
Result: Financial losses, damage to the company's reputation, and increased compliance costs.

3.Data Integrity and Quality Issues:

Consequence: Failure to maintain data integrity can lead to compromised product quality and safety.
Result: Product recalls, patient harm, and legal repercussions.

4.Global Market Access Challenges:

Consequence: Variations in regulatory standards between countries can hinder market access and the global distribution of pharmaceutical products.
Result: Limited market reach and missed business opportunities.

5.Operational Inefficiencies:

Consequence: Excessive regulatory burdens, documentation, and compliance processes can lead to operational inefficiencies.
Result: Increased costs, slower time-to-market, and resource allocation challenges.

Blockchain for End-To-End Traceability and Anti-Counterfeit Verification:

According to a report by the World Economic Forum, the top three advantages of blockchain adoption for pharmaceutical and healthcare ecosystems are full traceability, data immutability, and increased security. These benefits will prove useful to address the challenges of poor trust, data sharing, and visibility across the supply chain.

Blockchain is a distributed ledger technology that records transaction data in a “block” and is linked to the preceding “block,” forming a long chain in chronological order.

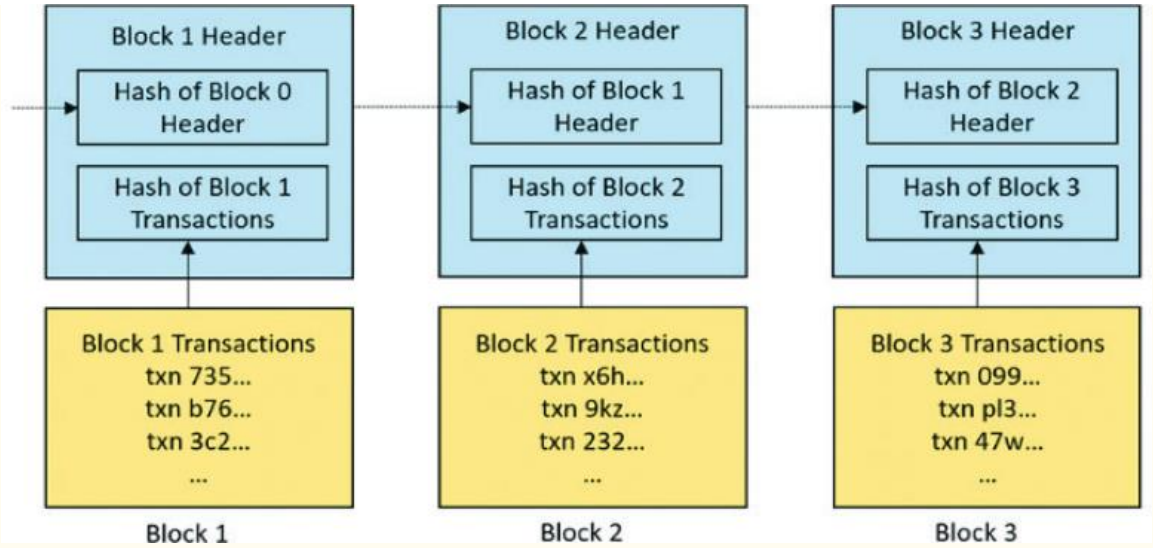


Fig. 1

How blocks are chained to form a blockchain.

Selecting a Blockchain Framework:

One of the existing blockchain frameworks, Hyperledger Fabric, is an open-source industry-grade framework hosted by The Linux Foundation. Designed for enterprise applications across industries, Hyperledger Fabric has automatic executable smart contracts (or chain codes) that are business logic algorithms and are mutually agreed upon by all parties on the network. With each transaction, every party will endorse the transaction based on a sophisticated pre-set endorsement policy.

Providing higher data security compared to traditional centralized solutions that may suffer from a single point of failure or attacks by malicious parties, Hyperledger Fabric passed a series of detailed security reviews and assessments in 2021 and was deemed "natively secure by both design and default" by the Cloud Security Alliance.

Deploying Blockchain for Anti-Counterfeit Verification:

More than one in 10 drugs in developing countries are estimated to be counterfeited, with types of therapeutic categories being falsified growing annually.

This has resulted in the pharma supply chain to suffer from eroding trust – a study revealed that seven in 10 patients were concerned about receiving harmful counterfeit or substandard products. In 2021, the Edelman Trust Barometer reported that more than 50% of countries they surveyed reported decreasing trust in pharmaceutical companies compared to 2020.With an estimate of over 1 million deaths caused by counterfeit and substandard drugs annually, patients around the world are increasingly demanding to know the origin of their drugs.

Hyperledger Fabric can be used in combination with tamper-proof serialization labels to allow more secure verification of product provenance in real-time. Counterfeiters who create a fraudulent identity or tamper with the data violate endorsement policy and the abnormal data transaction will alert all users in the ecosystem.

Using blockchain, pharmaceutical manufacturers are now able to connect stakeholders along the pharma supply chain for meaningful real-time interactions such as adverse-event reporting.

Real-Time Verification Solution:

For effective track and trace and to especially fight counterfeits, all stakeholders along the pharma supply chain need to be connected and break out of the traditional information silos. eZTracker is the first production-grade traceability solution that empowers pharmaceutical manufacturers, distributors, HCPs, and patients with real-time traceability (Figure 2)

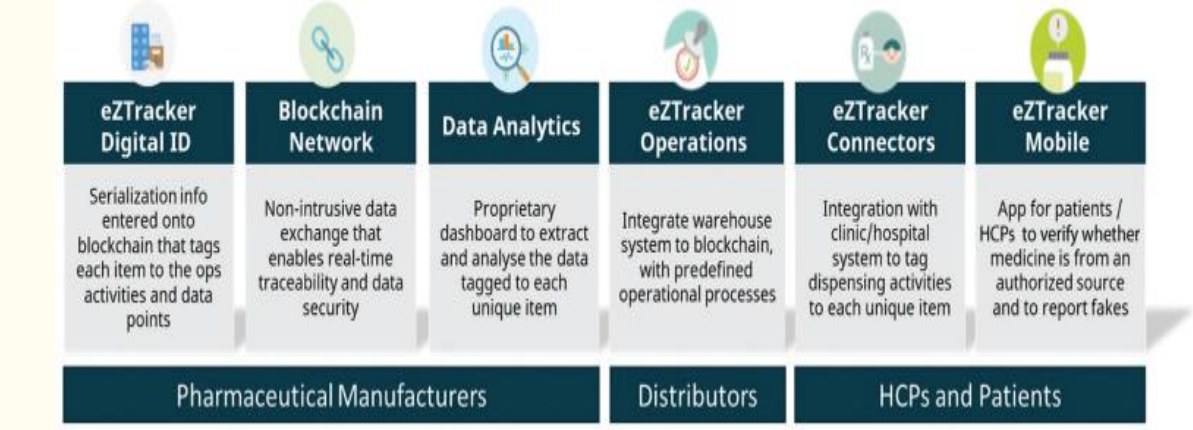


Fig. 2

Six eZTracker features to enable end-to-end traceability.

Pharmaceutical Manufacturers:

To enable track and trace, products are first serialized at a pack level. The encrypted Digital ID for each product is uploaded onto the blockchain as a new block and linked to new data transaction points, creating a string of traceable and immutable historical data.

By integrating warehouse operations systems with blockchain, pharmaceutical manufacturers can upload existing key master product data through a simple Extract, Transform, and Load (ETL) system and tag select information to each Digital ID. With this Application Programming Interface (API) integration, data can now be shared from various databases and made visible on the blockchain.

For eZTracker, Digital IDs are encoded into 2D data matrixes on physical packs to allow them to be read by scanners across the supply chain . In 2022, eZTracker was successfully used to record and track more than 2 million labeled products on the blockchain.

Fig. 3

Printed encrypted 2D data matrix on product packaging.

Distributors:

Included in eZTracker Operations is the ZOIP app, a warehouse application that allows warehouse staff to scan 2D data matrix codes, tag products in the blockchain, and access key product information (Figure 4).

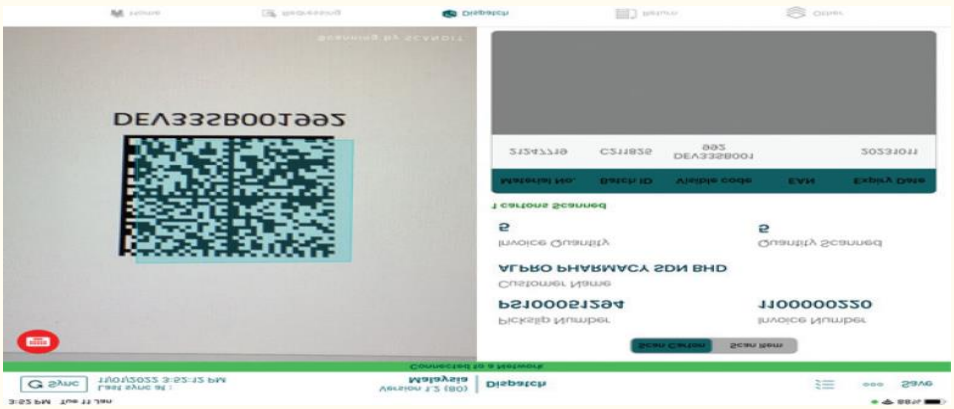


Fig. 4

ZOIParehouse application (scanning products).

The redressing team has the responsibility to use ZOIP to scan the newly affixed 2D data matrix to create unique box identities in the blockchain and tag the product to material and batch numbers. When the products are ready for dispatch, the picking team can seamlessly access previously logged information and important dispatch information, including the invoice number, quantity ordered, client name, expiry date, and more (Figure 5).

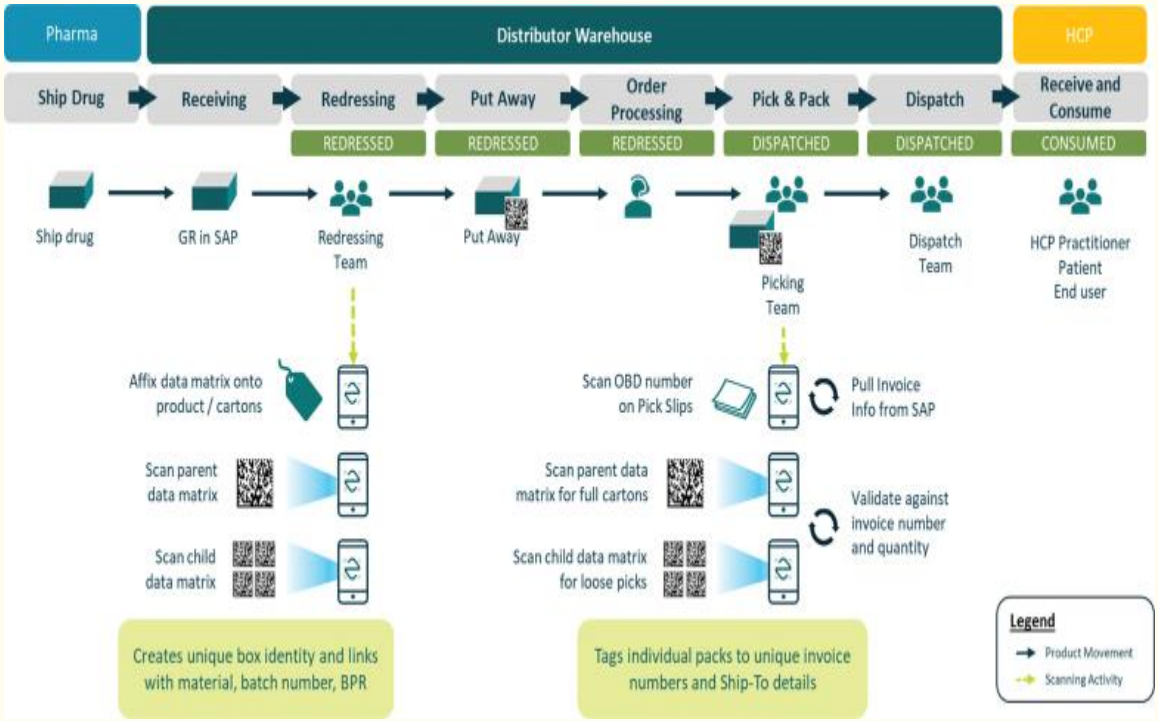


Fig. 5

eZTracker operations at a distributor's warehouse.

Healthcare Practitioners and Patients:

When dispatched products arrive at a clinic, hospital, or pharmacy, HCPs can validate the authenticity of the products received. Through eZTracker Connectors, built to connect and integrate healthcare management systems to the blockchain, HCPs can now tag products in their inventory to specific activities such as from storage to administration. Each unique pack can also be tagged to individual patients, and this is especially important for patient safety and quality assurance, such as in the case of product recalls where manufacturers and authorities can reach patients quickly and directly.

Because of the array of use cases applicable with blockchain, eZTracker also launched a mobile app to empower HCPs and patients with the ability to verify the authenticity of product distribution in

real-time. eZTracker is now used by more than 37,000 users in Hong Kong and Thailand with over 115,000 scans, of which more than 6,700 scans indicated potential counterfeits and cross-border movement of products.

Users can download the application from the Google Play Store or Apple App Store for free and scan the 2D data matrix on their products. If the mobile app verifies that the product comes from an authorized distribution source, users will be notified of key product information and its provenance (Figure 6)

Fig. 6

eZTracker mobile app (verification flow).

However, when an unauthorized product scan is detected, users will be alerted and prompted to report the incident with photographic evidence and a description. These reports will be sent to the pharmaceutical manufacturers who can then use them for further investigations.

Creating Insights from Blockchain Analytics for Counterfeit Detection:

With the launch of the integrated features and services, a robust and market-ready dashboard was built to operationalize data shared across the blockchain (Figure 7). Supply chain data are fed into the dashboards every 15 min and insights accessed are close to real-time. These data are later exported easily for auditing and reporting purposes. This helps pharmaceutical manufacturers investigate suspicious counterfeit activity and collect evidence to conduct investigations.

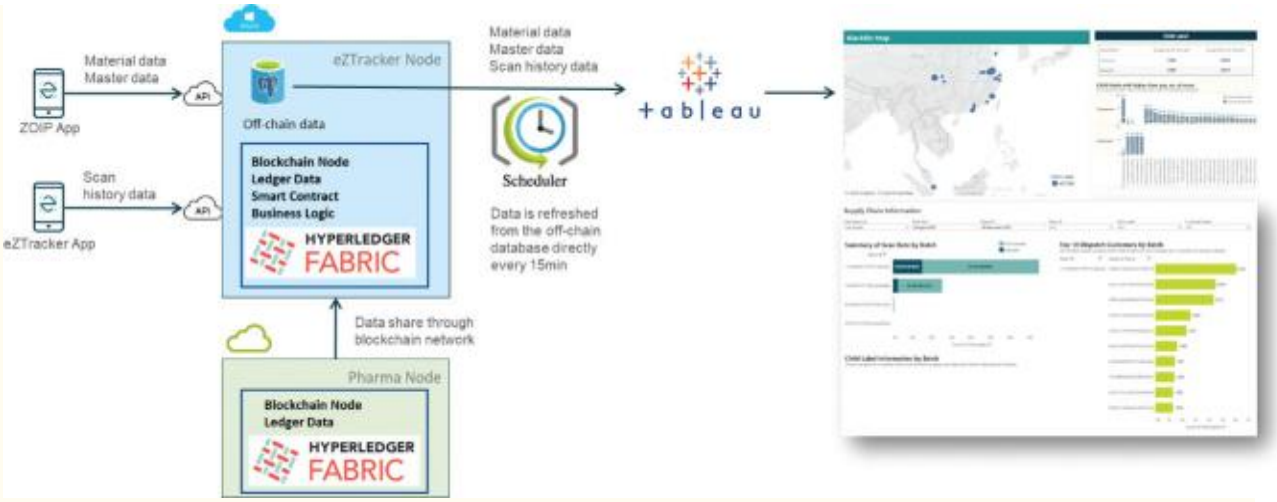


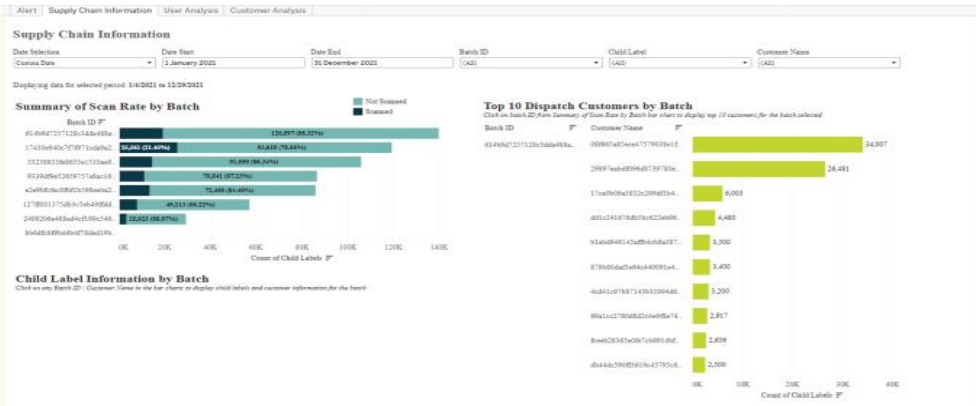
Fig. 7

Blockchain integration with tableau.

With these analytics, pharmaceutical manufacturers are empowered with data to make decisions that affect risk management, brand integrity, security, and compliance. With a concerted and proactive effort to combat counterfeits, pharmaceutical manufacturers can now work closely with consumers to build a more secure ecosystem.

There are currently three key components to the dashboard:

1.Product scan rates and dispatch information (Figure 8): product information is tracked to the individual pack level, and an unusually high frequency of scans could possibly indicate malicious parties looking to exploit vulnerabilities in the supply chain.



Three individual product scan rates and dispatch information.

2.Authorized Scans versus Cross-border Scans (Figure 9): product scans on the mobile app are timestamped and uploaded into the blockchain. “Authorized” scans show products from an authorized source, whereas “Cross-border” scans could indicate products from unauthorized distributors, which could affect quality assurance and authenticity for the final user of the product.

Fig. 9

Comparison graph of “authorized” versus “cross-border” scans.

1. Geolocation data (Figure 10): data of individual pack movements is collected when a product is scanned. Data can help to identify clusters of suspicious behavior and even the movement of these suspicious goods, with the ability to zoom in on certain districts, neighborhoods, and specific coordinates.

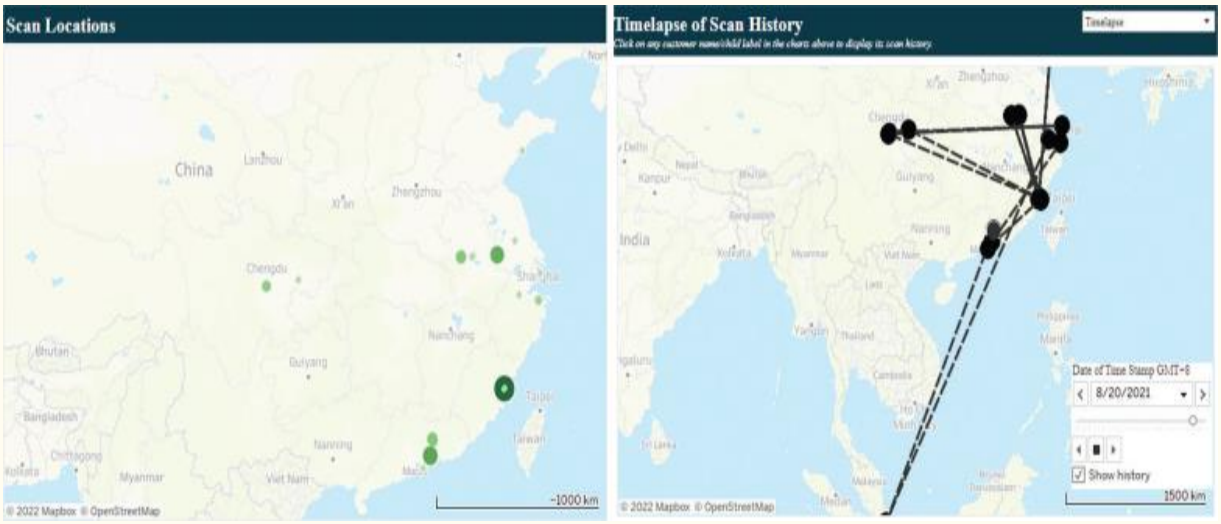


Fig. 10

Geolocation data and timelapse of scan history.

With blockchain-enabled end-to-end traceability, the data and reports submitted by consumers allow pharmaceutical manufacturers and local authorities to have a better understanding of potential counterfeit activities in the market and conduct more effective and data-driven counterfeit investigations.

Other Benefits Of End To End Solution:

Timely Product Recalls:

Even as products are dispatched to clinics, hospitals, and pharmacies, each product's digital ID can be tagged to key patient information, such as date of administration, contact details, product batch number, and more. This allows for more effective product recalls as manufacturers can engage patients directly instead of regular processes, which can take months or even years.

Cold Chain Monitoring:

Temperature-sensitive products such as vaccines that are not kept at recommended storage requirements may lose their potency when exposed to heat. These damages result in waste and can incur up to US$35 billion in losses annually for the pharmaceutical industry. When temperature data are collected in silos and not shared, it is difficult to detect products that are compromised. With blockchain, temperature data from loggers across the supply chain can be added to the network to provide real-time temperature reports and more effective cold chain monitoring. To improve efficiency even further, consumers can now verify for themselves whether the product was stored at approved temperatures through the mobile app and report any adverse events such as sub-standard storage of products.

Electronic Product Information:

A product label is updated five times in a year on average, and pharma companies spend millions of dollars updating artwork, printing, and working out the logistics for distributing updated labels. Paper package inserts and patient information leaflets do not give patients access to the latest approved information about the product. With ePI, manufacturers can manage their depository of product information online to produce consistent quality information. Instead of manual intervention, they can engage patients directly using the mobile app and trigger alerts and warnings in the event of product recalls and other updates in product information. Patients connected digitally can easily report adverse events. ePI is also cost-effective and reduces environmental impact.

Improved Supply Chain Resilience:

End-to-end traceability improves supply chain visibility and data-sharing access. Manufacturers can access actionable insights to develop effective strategies to optimize their resources and tackle existing supply chain inefficiencies that free up net working capital. Positive working capital

management reduces company risk and improves financial flexibility and performance, especially during a disruption such as the COVID-19 pandemic.

Challenges to the adoption of blockchain in pharma supply chain:

Lack of Mandated Product Serialization:

In Europe and the United States, drug serialization has been mandated since 2017 by the authorities, which helped facilitate the adoption of traceability solutions to improve transparency.

However, in the ASEAN region, serialization is not widely practised, and this makes end-to-end traceability difficult to achieve uniformly across the region.

Even with mandated serialization, reliable tracking technology is still necessary to enable effective product traceability.

In a study, more than four in 10 pharmaceutical data management vendors exceeded a Ransomware Susceptibility Index (RSI) of 0.6, which meant that manufacturers were easily exposed to risks of data manipulation and disruption.

Conventional data management architectures are not immune to vulnerabilities and may create distrust and impede data sharing across the supply chain.

Data collection processes also need to evolve as poor quality of information impacts the success of traceability solutions.

With different stages of the supply chain implementing non-standard processes to track products and enter varied data inputs, integration and data sharing require complex mapping, which is time-consuming and inefficient.

Multi-Cloud Infrastructure and Future of Interoperability:

To enable end-to-end traceability, the blockchain must be agile enough for organizations to join seamlessly.

In January 2022, eZTracker developed the first multi-cloud blockchain in the pharmaceutical industry. This means that client and partner nodes on any popular public cloud can integrate with eZTracker to connect and share data securely.

With this cloud-agnostic architecture, automated node setups for partners and clients allow them to enjoy faster go-to-market times (Figure 11).

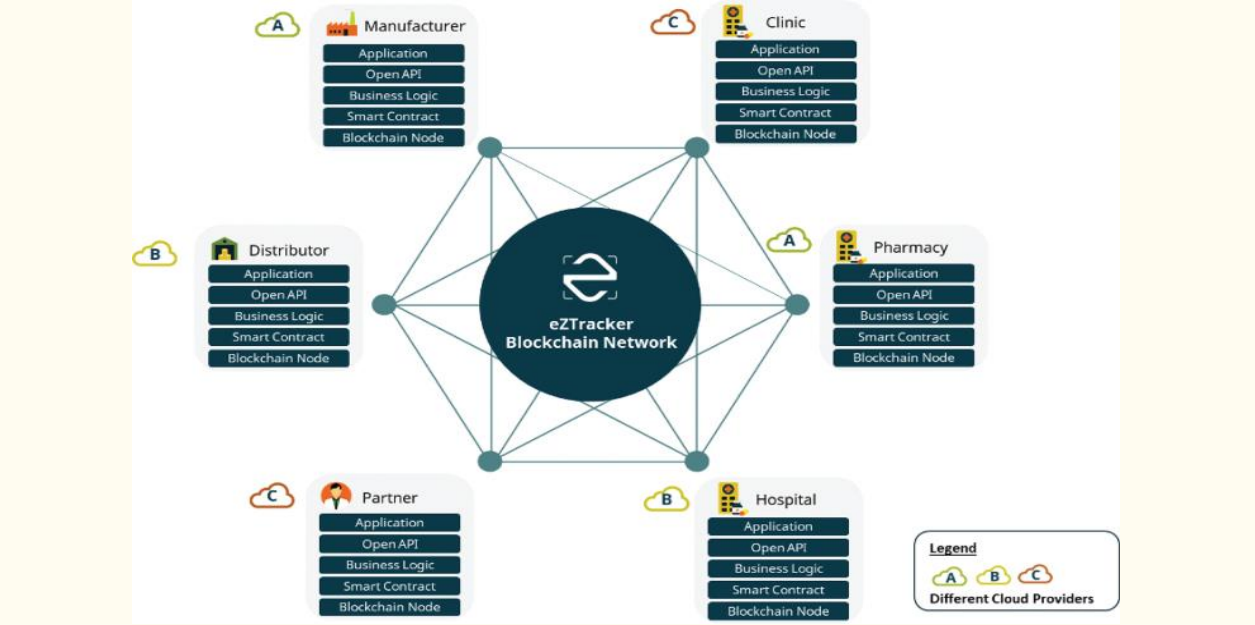


Fig. 11

Multi-cloud blockchain architecture.

However, as the solution scales, there is a risk of fragmentation in the pharmaceutical supply chain if multiple blockchains exist independently, creating data and value silos. Blockchain interoperability helps enable scalability, reduce risk, and eliminate silos. The supply chain needs to prioritize blockchain interoperability to better scale traceability solutions, increase adoption, and potentially achieve global transparency through collaboration.

CONCLUSION:

- To better safeguard the pharmaceutical supply chain, adoption of blockchain for track and trace is the key for end-to-end traceability to improve patient safety and long-term supply chain resilience.

- Through its immutable, secure, and scalable network architecture, blockchain has shown to effectively build a culture of trust and collaboration to reduce data silos across the supply chain.

- Furthermore, this increased data transparency benefits pharmaceutical manufacturers, distributors, HCPs, and patients, as it unlocks the possibility of enabling real-time verification solutions for quality assurance and dashboards that help unlock insightful data analytics.

- Blockchain adoption, scalability, and interoperability will remain critical criteria of success for end-to-end traceability solutions. The private and public sectors need to set a unified

data-sharing standard, collaborate across interoperable blockchain networks, and build trusted and connected data ecosystems.