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USE CASE

Improving End-to-End Traceability and Pharma Supply Chain Resilience using Blockchain

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Keywords: blockchain, COVID-19, eZTracker, hyperledger fabric, pharma supply chain, traceability

Abstract

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. Today, the COVID-19 pandemic has accelerated the need for greater data transparency, better deployment of technology, and improved ways of connecting stakeholder information along the supply chain.

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. This paper will explore the business value that blockchain brings to the pharma supply chain with better end-to-end traceability, using the example of an industry-grade blockchain solution called eZTracker.

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. Beyond anti-counterfeit verification, other potential use cases include effective product recall management, cold chain monitoring, e-product information, and more.

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.

Pharmaceutical supply chain is the backbone of a US$1.27 trillion industry,[1] but because of its highly complex and fragmented nature, it is hard to regulate and protect, and this makes it a valuable target for opportunistic parties such as counterfeiters looking to profit.[2]

As a result of the COVID-19 pandemic, there has been greater emphasis on transparency of data and connecting stakeholders along the pharma supply chain in real-time in the last few years.

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.

This paper seeks to explore the positive 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.

Received: April 28, 2022; Revised: July 20, 2022; Accepted: July 22, 2022; Published: August 12, 2022

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.[3] 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[4] (Figure 1).

There are four types of blockchain networks: public, private, consortium, and hybrid.[6] For enterprise applications, private or consortium blockchains are preferred, as they are permissioned blockchains that promote high security by limiting access to only approved parties and implementing data access controls and privacy policies across the network.[7] These are crucial in the healthcare and pharmaceutical ecosystem, which handles sensitive information such as patient health data and intellectual properties of manufacturers. Another benefit of permissioned blockchains is scalability because of the modular architecture.

Methods

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.[8]

Providing higher data security compared to traditional centralized solutions that may suffer from a single point of failure or attacks by malicious parties,[9] 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.[10]

Deploying Blockchain for Anti-Counterfeit Verification

More than one in 10 drugs in developing countries are estimated to be counterfeited,[11] with types of therapeutic categories being falsified growing annually.[12]

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.[13] In 2021, the Edelman Trust Barometer reported that more than 50% of countries they surveyed reported decreasing trust in pharmaceutical companies compared to 2020.[14] 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.[15]

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.

A shared visible ledger can also help improve supply chain transparency[16] by allowing HCPs and patients to access accurate product provenance data, verify product distribution channels, and report counterfeit incidents in real time.

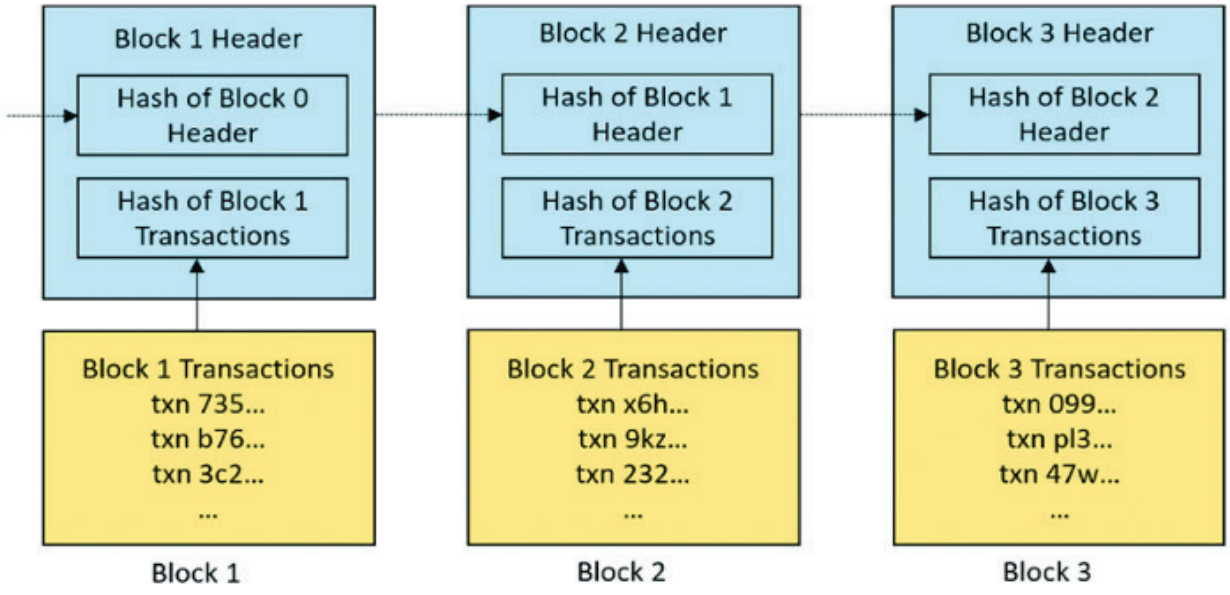

Fig. 1. How blocks are chained to form a blockchain.[5]

Citation: Blockchain in Healthcare Today 2022, **5**: 231 - http://dx.doi.org/10.30953/bhty.v5.231

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.

In 2019, Hong Kong authorities discovered clinics were administering counterfeit Human Papilloma Virus (HPV) vaccines.[17] This incident caused public panic and complaints among patients worried about the authenticity and safety of the vaccines. In the same year, 400,000 counterfeit beauty products were seized by Thailand's Department of Special Investigations, including dermal fillers.[18] Consequences of injecting falsified fillers include risks of unevenness of the skin, cell death, and even blocked arteries that may lead to blindness.[19]

In response to the incidents, several pharmaceutical manufacturers deployed eZTracker, an end-to-end traceability solution using blockchain that allowed patients and HCPs to verify the authenticity of distribution while providing pharmaceutical manufacturers with dashboards for real-time track and trace.

Results and Discussion

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).

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 (Figure 3). In 2022, eZTracker was successfully used to record and track more than 2 million labeled products on the blockchain.

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).

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).

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

Fig. 3. Printed encrypted 2D data matrix on product packaging.

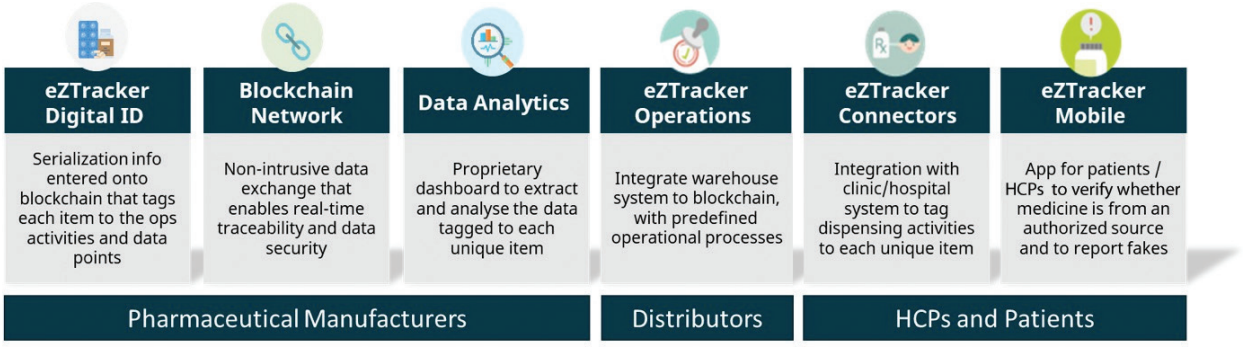

Fig. 2. Six eZTracker features to enable end-to-end traceability.

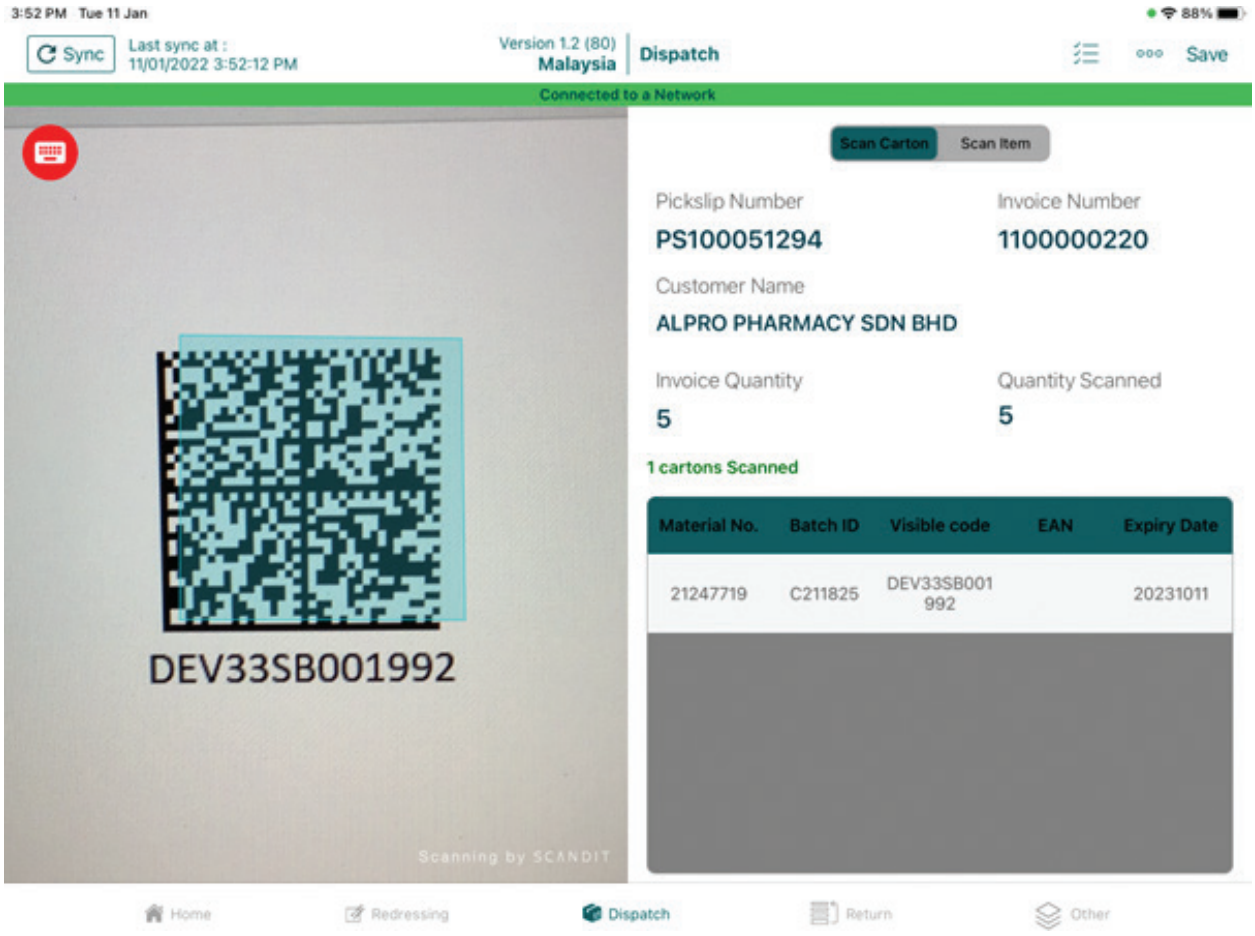

Fig. 4. ZOIP warehouse application (scanning products).

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).

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.

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:

Citation: Blockchain in Healthcare Today 2022, **5**: 231 - http://dx.doi.org/10.30953/bhty.v5.231

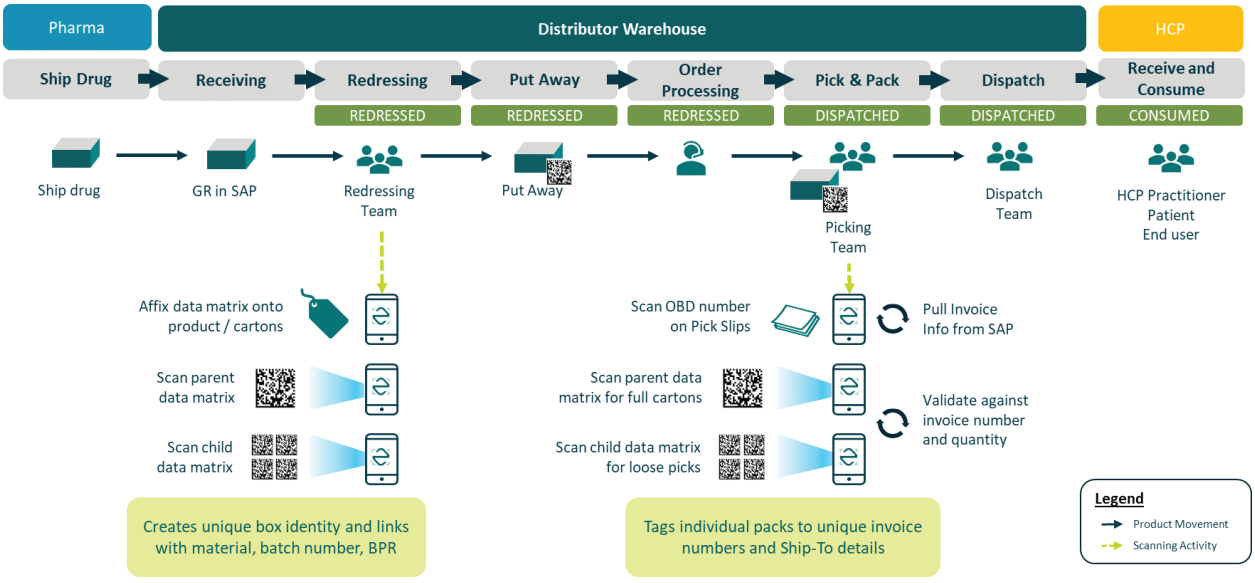

Fig. 5. eZTracker operations at a distributor's warehouse.

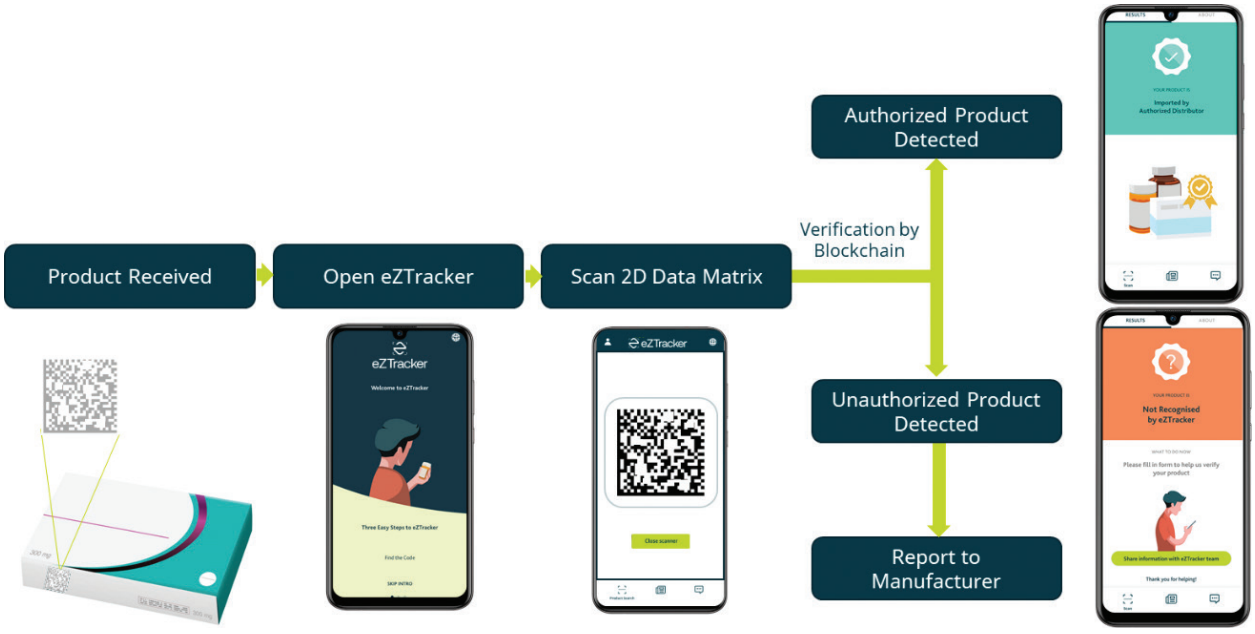

Fig. 6. eZTracker mobile app (verification flow).

(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.
(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.
(3) 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.

With blockchain-enabled end-to-end traceability, the data and reports submitted by consumers allow pharmaceutical manufacturers and local authorities to

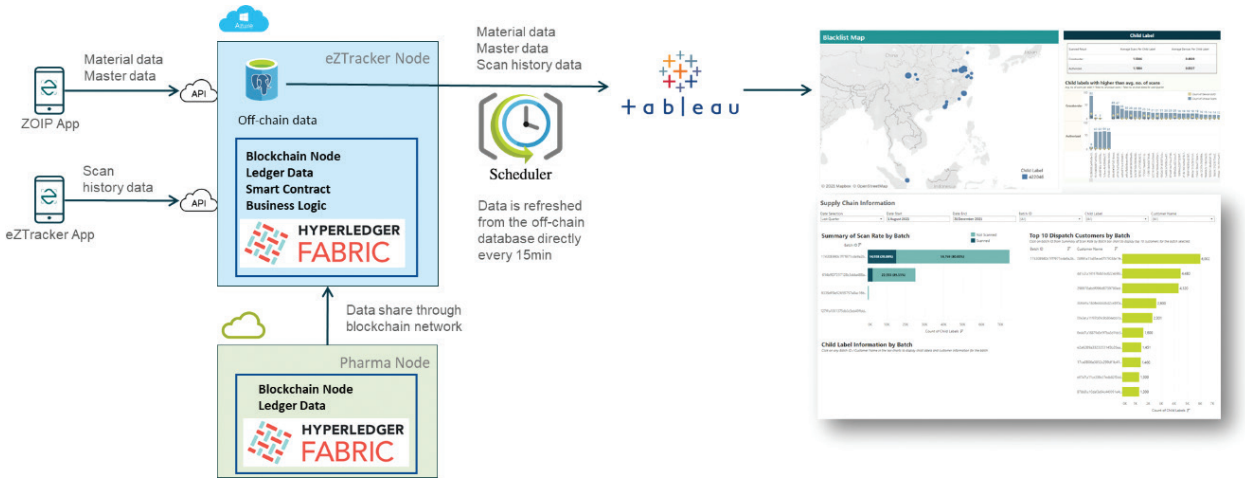

Fig. 7. Blockchain integration with tableau.

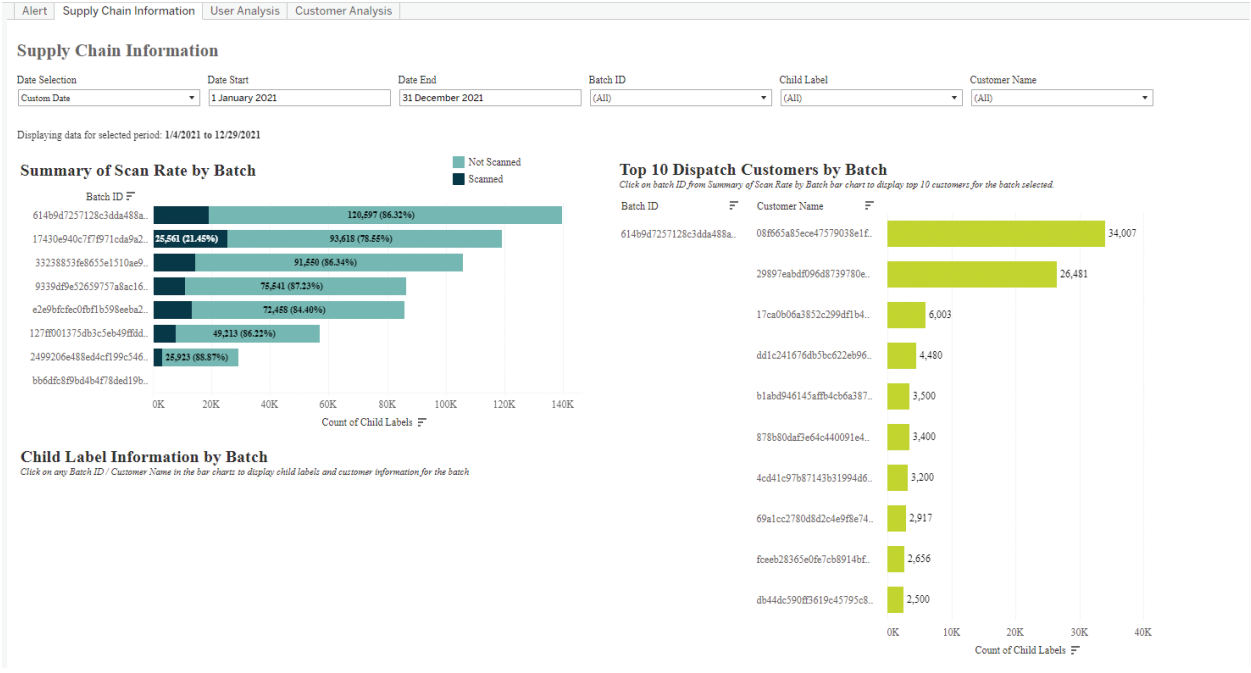

Fig. 8. Three individual product scan rates and dispatch information.

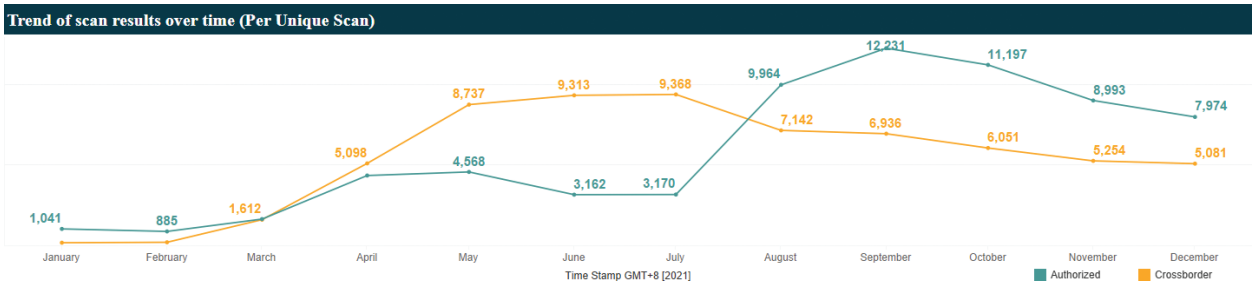

Fig. 9. Comparison graph of "authorized" versus "cross-border" scans.

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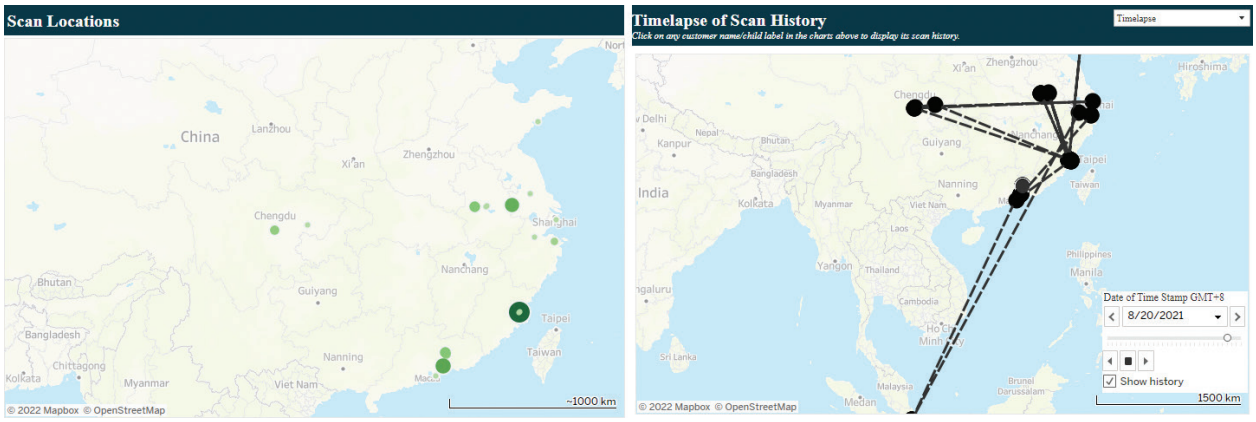

Fig. 10. Geolocation data and timelapse of scan history.

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 Traceability

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.[20] These damages result in waste and can incur up to US$35 billion in losses annually for the pharmaceutical industry.[21] 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.[22] 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.[23]

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.[24] However, in the ASEAN region, serialization is not widely practised, and this makes end-to-end traceability difficult to achieve uniformly across the region.[25]

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.[26] 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.[27] 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).

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.[28] Blockchain interoperability helps enable scalability, reduce risk, and eliminate silos.[29] 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

Fig. 11. Multi-cloud blockchain architecture.

Citation: Blockchain in Healthcare Today 2022, **5**: 231 - http://dx.doi.org/10.30953/bhty.v5.231

interoperable blockchain networks, and build trusted and connected data ecosystems.

Financial and Non-Financial Relationships and Activities

None

Funding

None

Contributors

Corrine Sim and Marianne Chang wrote the paper. Haisheng Zhang contributed to the technical blockchain portions of the paper.

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