By **Team Pharmars**

PHARMA SYNC

(Optimizing Security and Transparency in Pharmaceutical Supply Chains using Decentralized Hybrid Blockchain)

PROBLEM

BioPlus® Specialty Pharmacy
A Carelon Company

October 25, 2021

Data Breach

Network Server Impacted

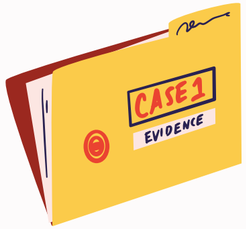
Exposing the PHI of
350,000 individuals

Privacy Concerns & Issues Surrounding Trade Secrets

PROBLEM

1.5 Lakh Pharmacies

(According to DGDA officials)



34 Cases

Over manufacturing of fake medicines

27 Crores

Fined since 2017

19 Firms

Have been revoked

47 Firms

Prohibited

Drug Counterfeiting

PROBLEM

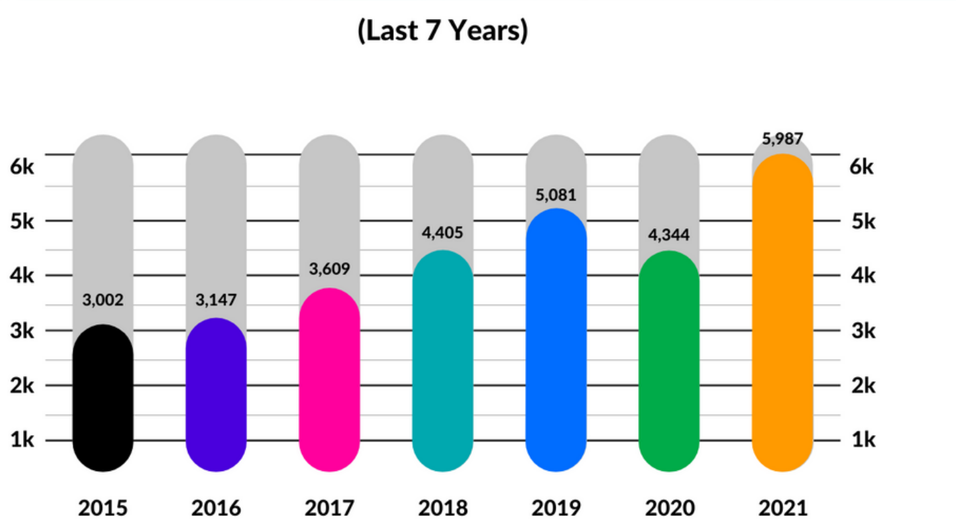
Drug Counterfeiting

Annual Sales

The annual sales of adulterated or substandard drugs in Bangladesh are estimated to exceed Tk1,500 crore, accounting for 20% of total sales.

Global Situation

In many developing countries, including those in Africa, Asia, and South America, counterfeit medicines constitute a significant portion, ranging from 10% to 30% of all medicines on the market



Source: Pharmaceutical Security Institute

PROBLEM

The traded value of pharmaceutical supply chains has expanded over the past 20 years as a result of the globalization of the pharmaceutical sector, from $113 billion in 2000 to $629 billion in recent times

Emergency on Drug Shortage

Emergency drug shortages pose serious problems because they prevent timely access to life-saving drugs which jeopardizes patient health and safety

Cold Chain Management

According to SDCExecutive, CDC statistics from the first quarter of 2021 indicated a 20% loss of the Covid vaccine owing to problems with the cold chain

Product Recalling

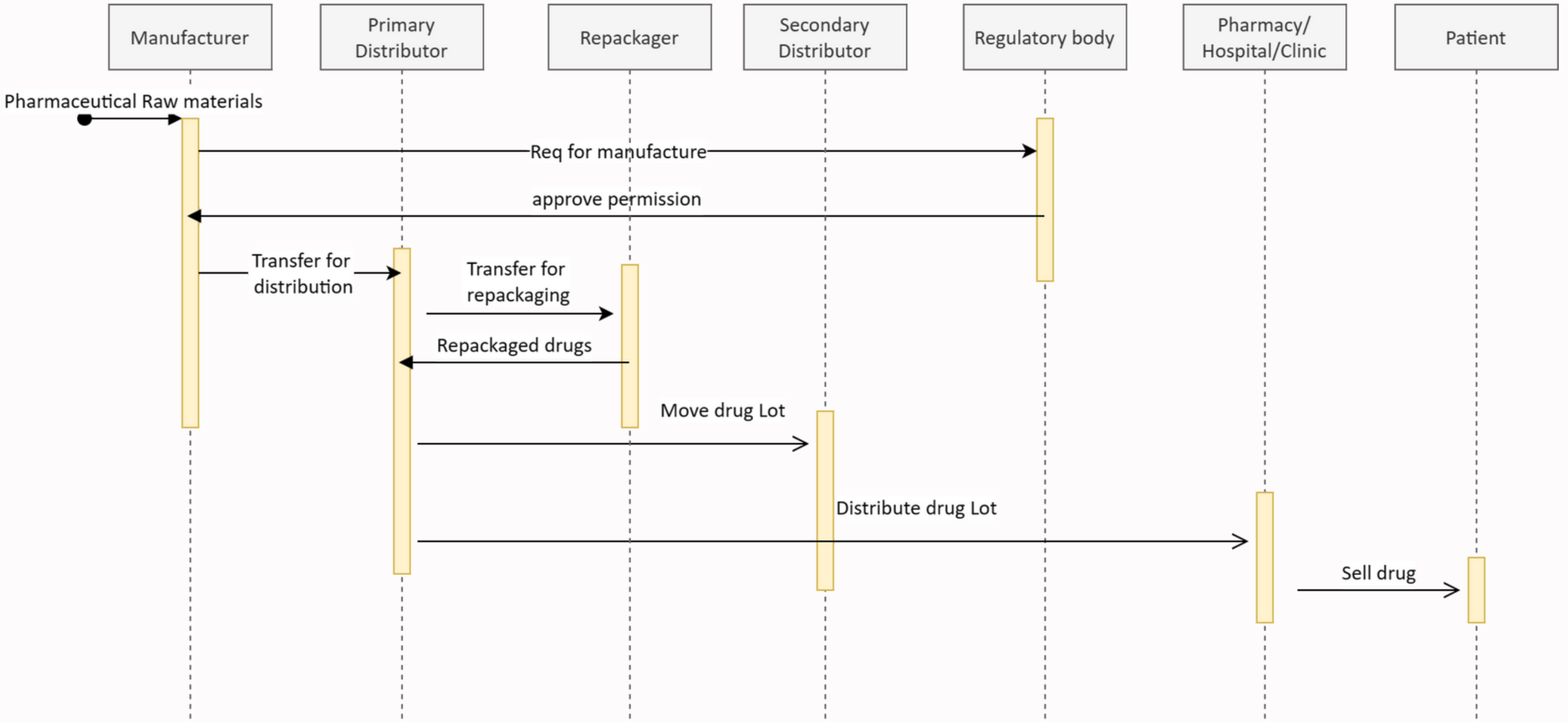
According to FDA statistics, 14,000 drug recalls happened in the last 4 years. That averages out to nearly four drug recalls a day

Cost and Compliance Issues

Regulation changes entail numerous compliance obligations that raise complexity and costs such as, failure to follow written procedures, SOP

PROBLEM

CONVENTIONAL PHARMACEUTICAL SUPPLY CHAIN CHALLENGES

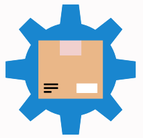


- Fake Manufacturers
- Defects in Manufacturing Causes Drug Recall
- Suppliers don't respond on time during emergency drug shortage crisis
- Mislabelling Causes Drug Recall
- Inadequate Packaging
- Regulatory Body - Cost and Compliance Issues
- Illegal Online Pharmacies
- Mismanaged Freezers for Cold Drugs

PROPOSED SOLUTION

PHARMA SYNC



Optimizing Security and Transparency in Pharmaceutical Supply Chains using Decentralized Hybrid Blockchain

SOLUTION OVERVIEW

Hybrid Blockchain

Fine-grained user access control

ZkKYC Sub-module

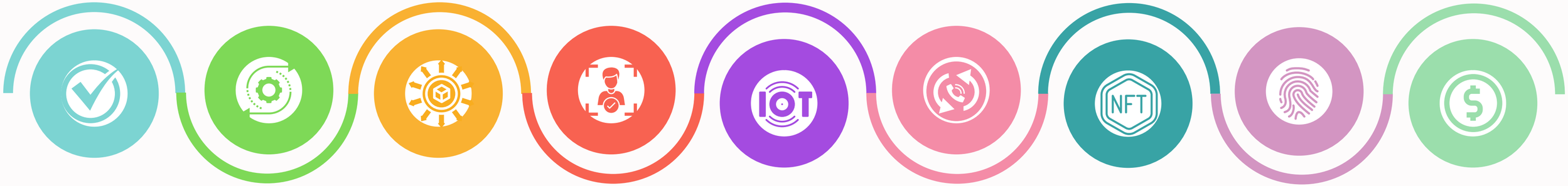
Inter-supply chain participant identification and verification

Recall Management

Efficient traceback and elimination of defective products

Schnorr Digital Signature

Authenticity of user-uploaded data



ZK-Proof

Seamless end-to-end and secured data sharing pipeline

Decentralized Identity

Privacy-enhanced DID solution using Hyperledger Aries, Indy, and Ursa

IoT Integration

Early fault detection and control counterfeiting

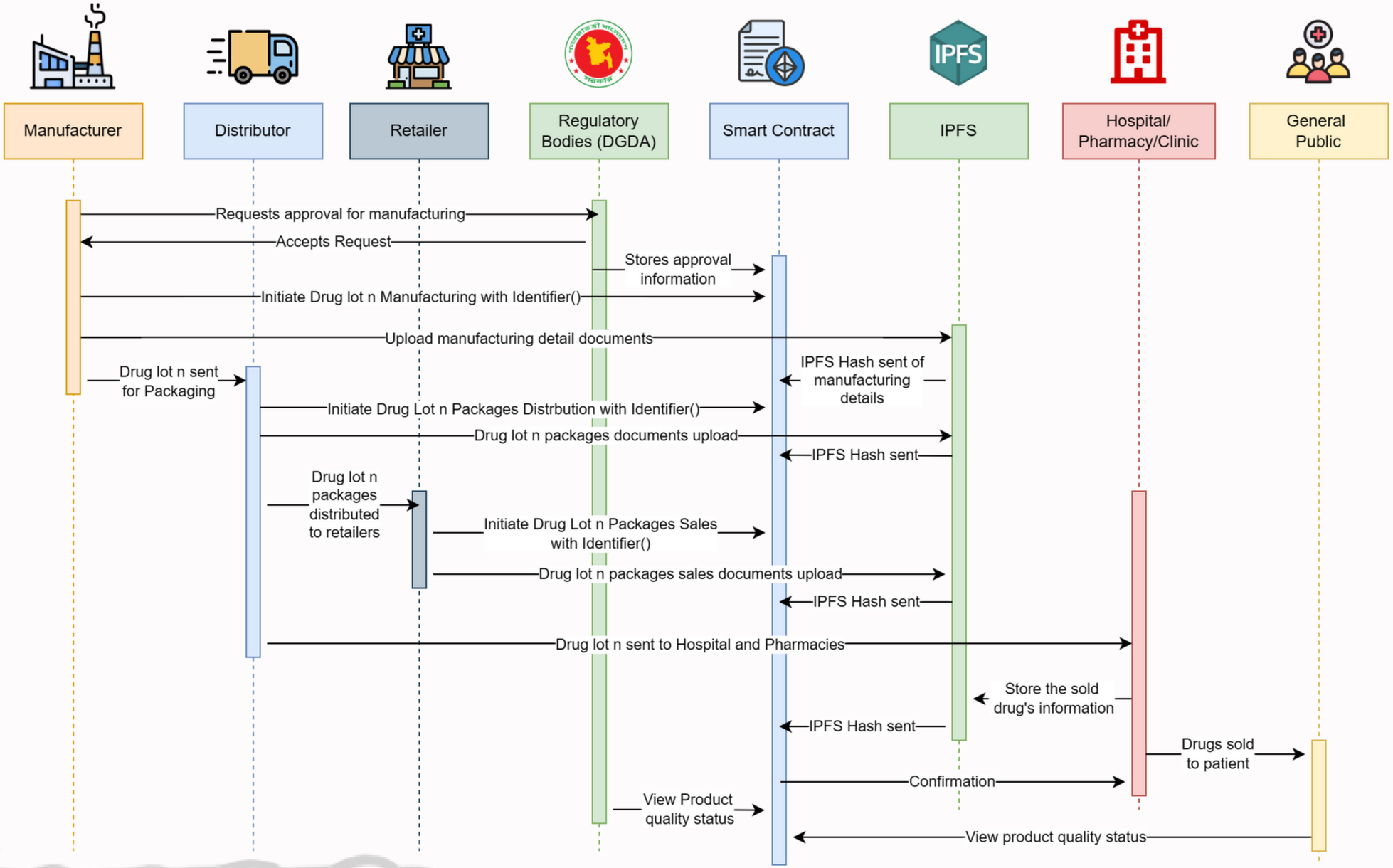
Soul Bound Token

Compliance data accessibility and verification

Staking Payment

Trustless payment structure using smart contract staking method

ENSURING CUSTOMER TRANSPARENCY WHILE HIDING THE BUSINESS SECRETS



PROPOSED SOLUTION

SDG ALIGNMENT

SDG 3: Good Health & Well-being

IoT integration to measure supply chain products, such as temperature and humidity

SDG 9: Industry, Innovation & Infrastructure

Fine-grained user access control

SDG 8: Decent Work & Economic Growth

Recall management system to ensure efficient traceback and elimination of defective products

SDG ALIGNMENT

SDG 12: Responsible Consumption & Production

ZkKYC submodule for inter-supply chain participant identification and verification

SDG 17: Partnerships

Seamless end-to-end and secured data sharing pipeline for supply chain management system

SDG 16: Peace, Justice & Strong Institutions

Ensuring compliance data accessibility and verification by issuing soul-bound token NFT

PharmaSync outmatches manual and centralized systems in many aspects

YES NO VULNERABLE

	System Aspects	Current Manual System	Digital Centralized System	Blockchain-based PharmaSync
	Secure trade secrecy & privacy	✗	?	✓
	Transparency	✗	✗	✓
	Real-time tracking & monitoring sensitive information	✗	?	✓
	Incorruptible records	✗	?	✓

PharmaSync outmatches manual and centralized systems in many aspects

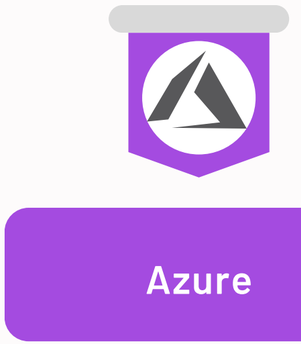
YES NO VULNERABLE

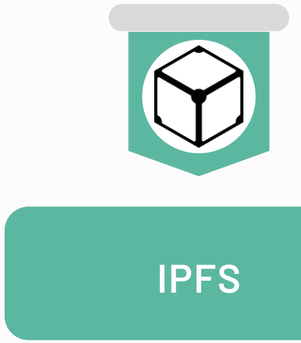
	System Aspects	Current Manual System	Digital Centralized System	Blockchain-based PharmaSync
	Digital, fast processing	✗	✓	✓
	Co-ordination among stakeholders	✗	✓	✓
	System availability at all times	?	✗	✓
	No SPOF	✗	✗	✓

TECHNICAL ARCHITECTURE

USER APPLICATION

NEXT.JS

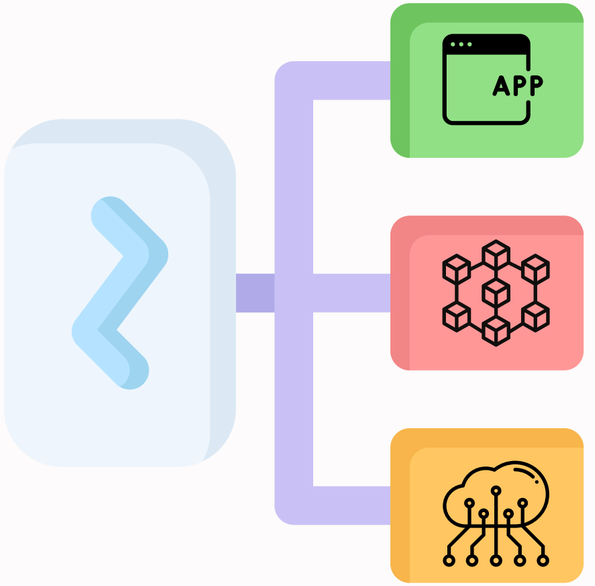




TECHNICAL ARCHITECTURE

1. **Zero Knowledge Proofs**
2. **ZK-KYC**
3. **Schnorr Digital Signature**

Application Component Architecture



Application Layer

Blockchain Service Layer

Data Layer

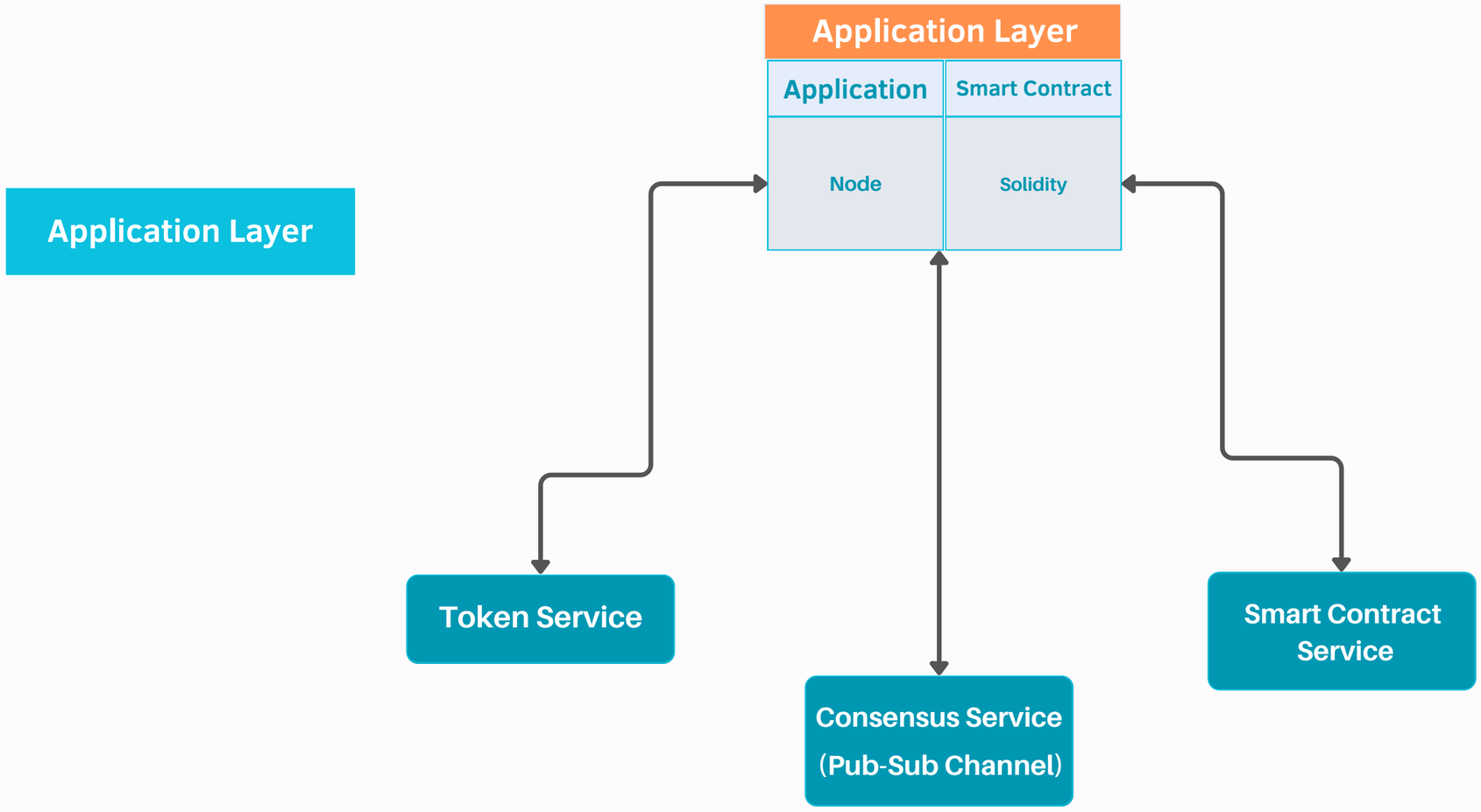
End User Application

Web Application

Mobile Application

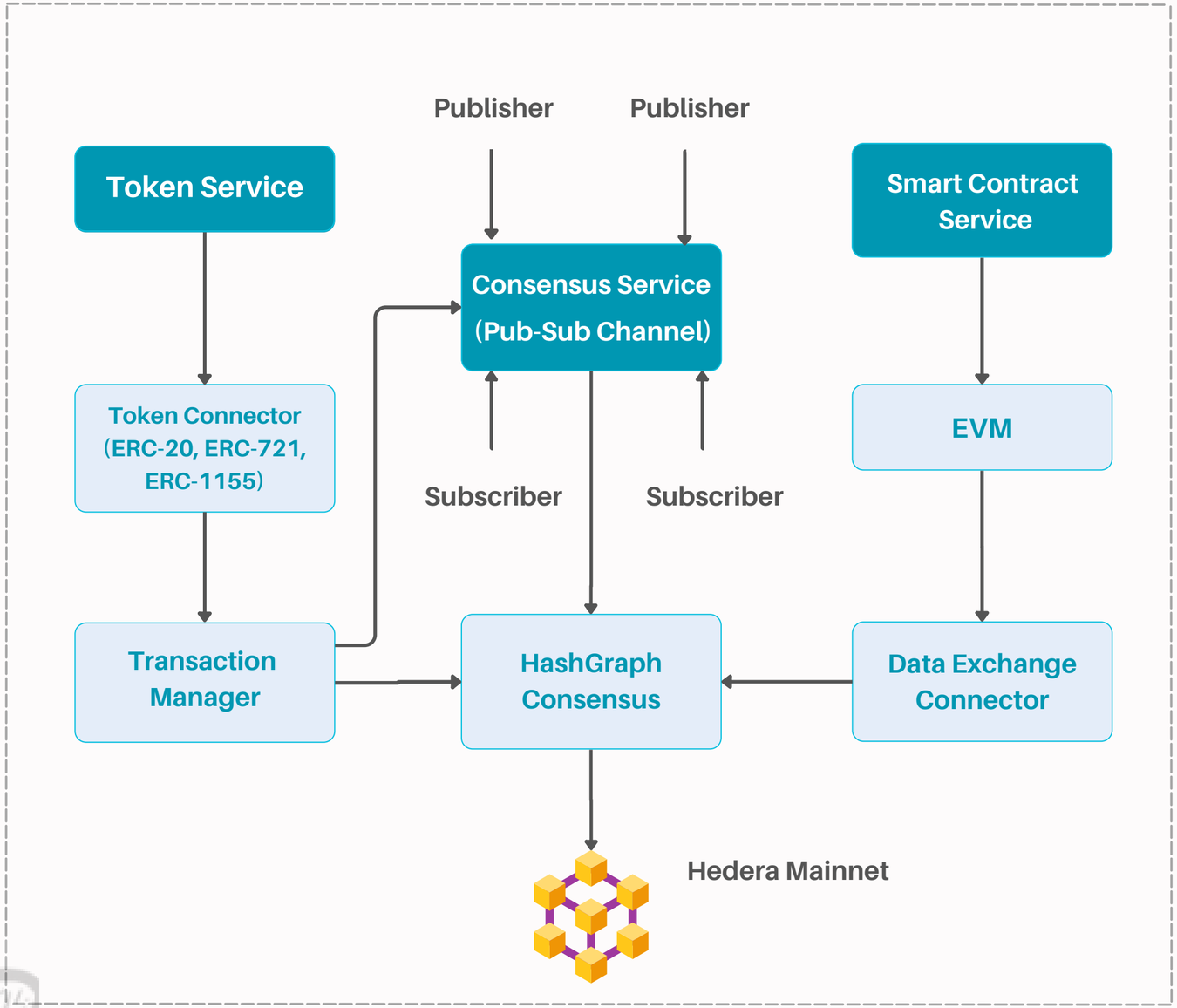
IPFS (InterPlanetary File System) is the decentralized data storage for storing and retrieving documents.

TECHNICAL ARCHITECTURE

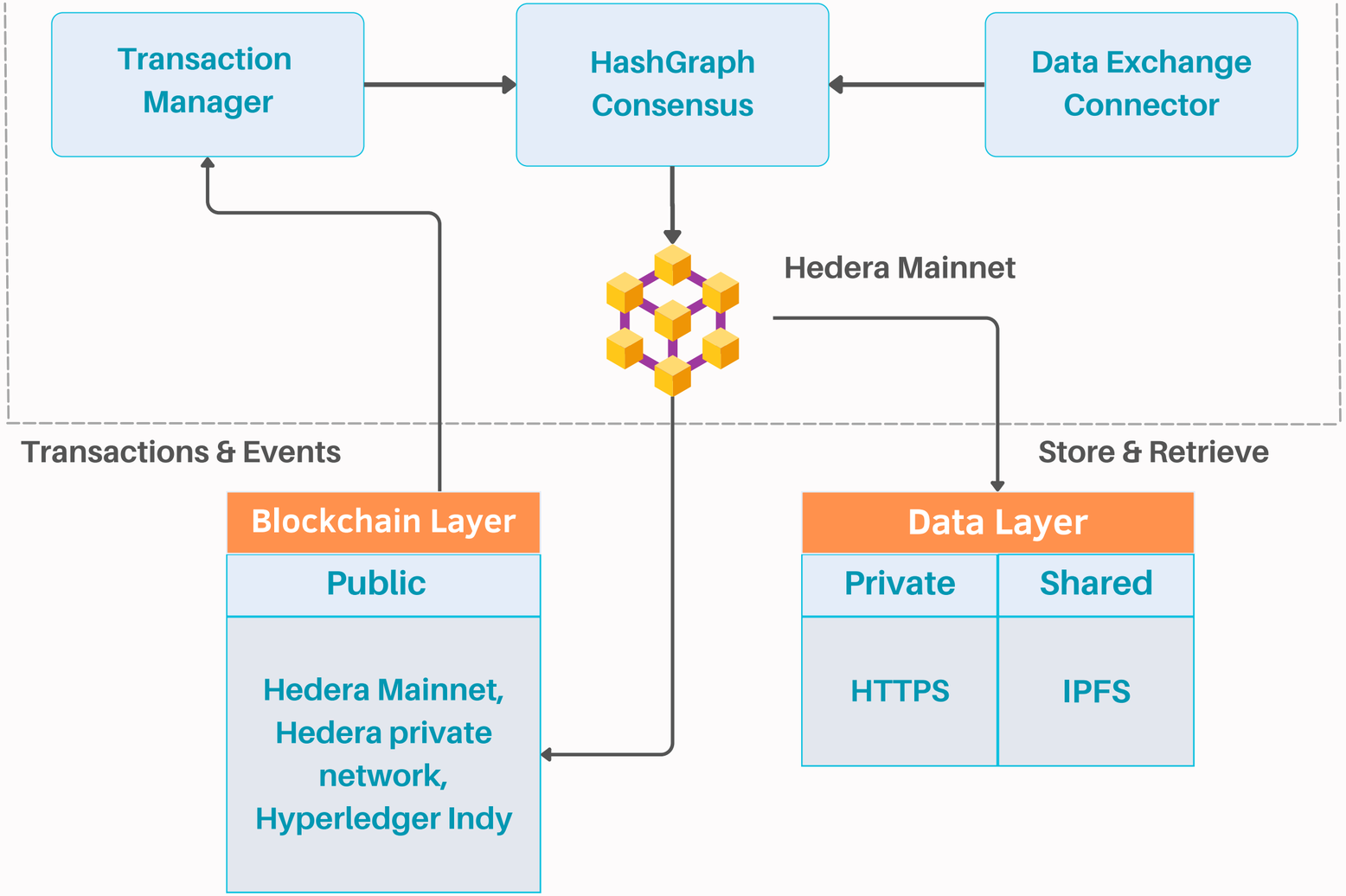


TECHNICAL ARCHITECTURE

Blockchain Service Layer



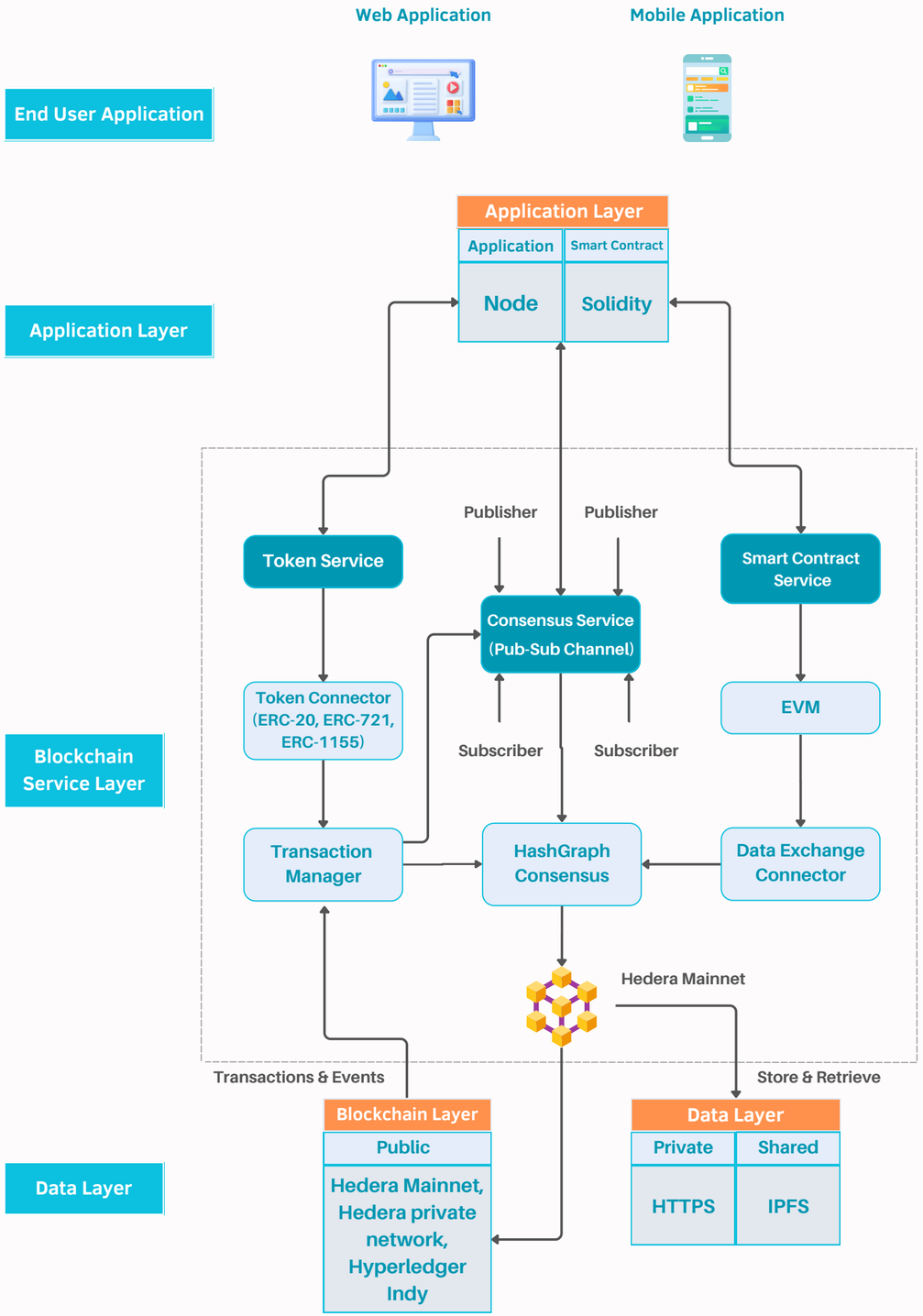
TECHNICAL ARCHITECTURE



Data Layer

PharmaSync

TECHNICAL ARCHITECTURE



ZK-PROOF CONSTRUCTION

Manufacturer, M
Distributor, D

Transaction:

Manufacturer's Public Key, $p_{(m)}$
Distributor's Public Key, $p_{(d)}$
Batch ID: B
Quantity of Drugs: Q
Price per Unit: P

Equation for Quantity

$$C_{(Q)} = (p_{(m)}.Q) + (p_{(d)}.(-Q))$$

Equation for Price

$$C_{(P)} = (p_{(m)}.P) + (p_{(d)}.(-P))$$

Condition:

$$C_{(Q)} + C_{(P)} = 0$$

[By verifying these equations using Bullet-proofs, it is possible to prove the validity of the drug transaction without revealing any specific values of the quantity or price]

SCHNORR DIGITAL SIGNATURE

(Authentication & Verification)

Key Generation

Distributor generates Private Key, d

So, Public Key, D = d.G [Elliptic Curve Point Manipulation]

[Pre-defined Base Point]

Signature Generation

Distributor selects nonce, k

So, Public Key, K = k.G [Elliptic Curve Point Manipulation]

Commitment Value: e = Hash (message || D || K)

Response, s = (k + e.d) mod n

[Order of the Base Point]

Signature Verification

e = Hash (message || D)

K = s.G - e.D

Manufacturer verifies the signature (s,e) and Public Key, D

Partners

The key partners associated with PharmaSync are -

Directorate General of Drug Administration (DGDA)

Bangladesh Association of Pharmaceutical Industries (BAPI)

Healthcare IT Providers

Partnership with DGDA

01 Regulatory Support and Validation

02 Market Access and Credibility

03 Collaboration on Industry Initiatives

04 Access to Regulatory Data and Insights

05 Enhanced Data Integrity and Traceability

06 Streamlined Regulatory Compliance

07 Efficient Recall Management

08 Collaboration and Industry Insights

Partnership with BAPI

01 Industry Validation and Credibility

02 Market Access and Networking

03 Regulatory Advocacy

04 Collaborative Development and Innovation

05 Technological Advancement

06 Strengthened Member Services

07 Industry Leadership

08 Industry Influence

Partnership with Heathcare IT Providers

01 Seamless Integration

02 Expanded Market Reach

03 Enhanced Functionality

04 Domain Expertise

05 Differentiation and Innovation

06 Enhanced Value Proposition

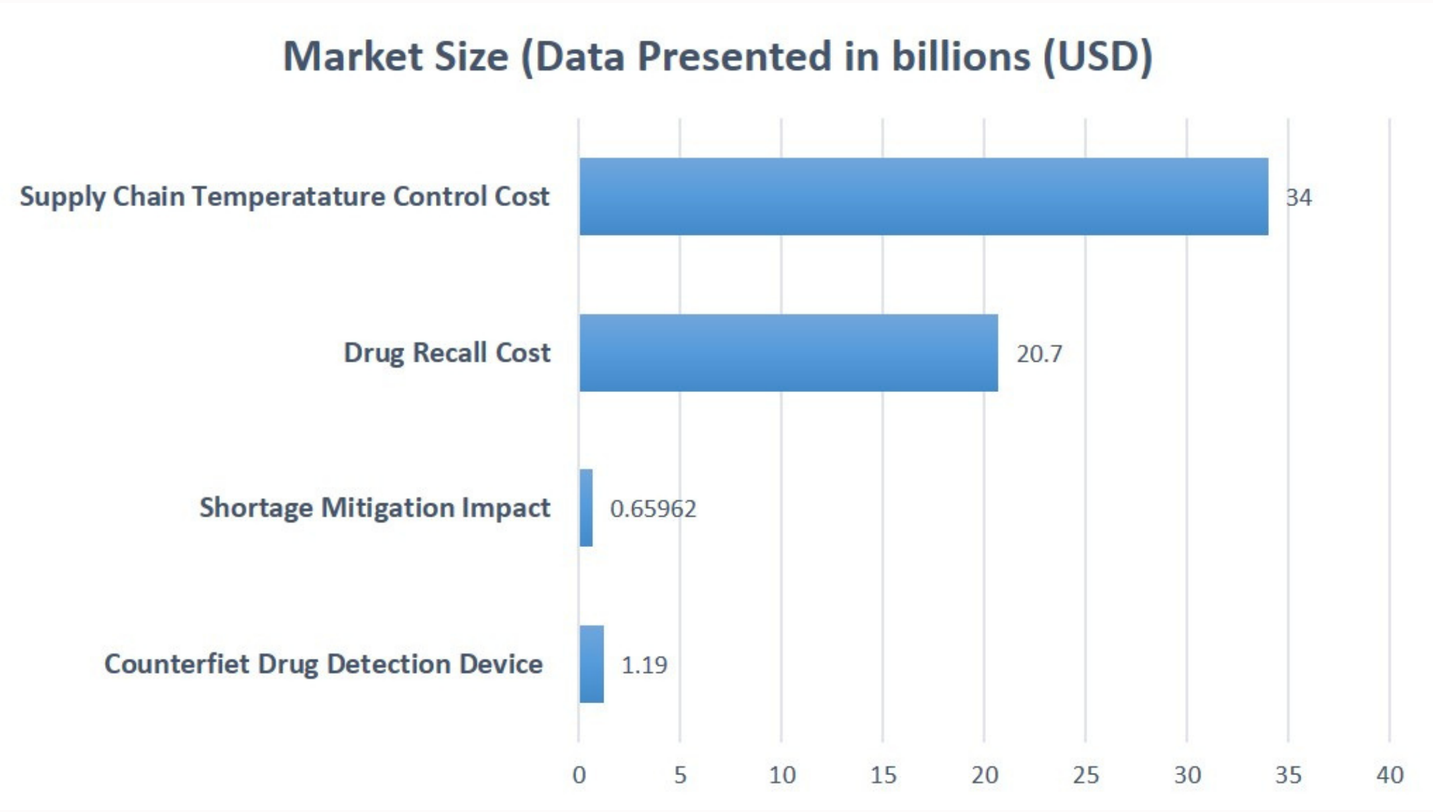
07 Industry Leadership

08 Collaborative Business Growth

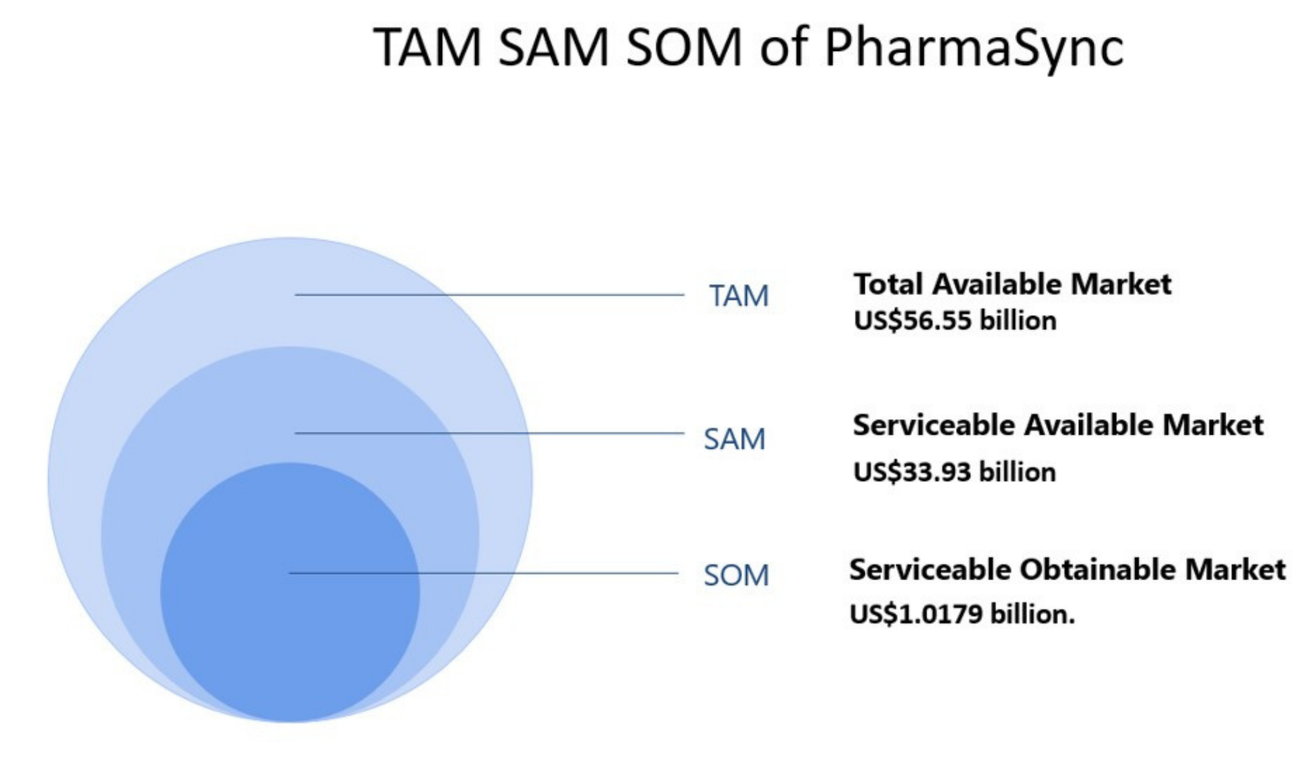
MARKET SIZE (GLOBAL)

MARKET AVENUES CONSIDERED

- GLOBAL COUNTERFEIT DRUG DETECTION DEVICE MARKET
- GLOBAL FINANCIAL COST INCURRED IN SHORTAGE MITIGATION
- GLOBAL DRUG RECALL FINANCIAL IMPACT
- GLOBAL SUPPLY CHAIN TEMPERATURE CONTROL COST



PharmaSync's Market Potential



TAM: To calculate TAM, all the aforementioned financial impacts and costs have been considered.

SAM: To calculate SAM, we only considered pharmaceutical companies that are blockchain-ready.

SOM: To calculate SOM, we considered only 3% of the SAM, which is an acceptable number of a new startup in the technology arena.

MARKET POTENTIAL IN BANGLADESH

257 licensed pharmaceutical firms in Bangladesh according to DGDA

Satisfying 98% of the domestic demand

Bangladesh is the only LDC that fulfills approximately 98 percent of its own internal demand for pharmaceuticals.

80% are generic medicines and the remaining 20% are proprietary medicines

The volume of fake drugs being sold on the open market at any given moment may be as high as 2,500 crore taka, or around 233.64 million US dollars

VALUE PROPOSITION

Point of Parity

- Streamlined Registration Process
- Compliance with Regulatory Standards
- User-friendly Experience
- Comparable to Existing Solution Market

Point of Difference

Unlike other blockchain solutions, PharmaSync incorporates-

- A ZkKYC submodule for secure participant identification and verification
- Reduces fraud risks and enhances trust
- Utilizes the Schnorr digital signature algorithm for an added layer of trust and verification during data exchange between parties

VALUE PROPOSITION

Enhanced Compliance with Regulatory Standards

Our solution enables pharmaceutical companies to maintain compliance with regulatory standards, reducing the risk of non-compliance and associated penalties. This aligns with the need to address the increasing number of FDA warning letters referencing data integrity deficiencies.

Improved Traceability and Recall Management System

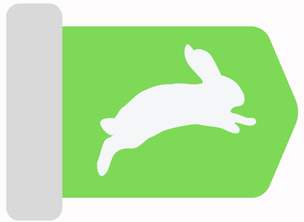
Our solution incorporates a recall management system that ensures efficient traceback and swift removal of defective products from the market, minimizing the impact on consumers and resources.

Increased Accountability

The real-time monitoring and tracking capabilities of PharmaSync ensure accountability across the supply chain, fostering responsible practices and adherence to quality standards.

Increased Public Trust

By promoting transparency, security, and accountability, PharmaSync builds public trust in the pharmaceutical industry, bolstering the reputation of companies and improving customer confidence.



Faster Operations

Through automation and digitization, PharmaSync expedites operations, reducing lead times and enabling faster delivery of pharmaceutical products to market.

Jan - June 2024

Blockchain Integration/
Application Development

July - Dec 2024

Product testing and quality assurance

Jan - Mar 2025

Partnership with regulatory authorities and convincing them to implement our software

Apr - Onwards 2025

Commencement of Operations, Focus on service excellence and building relationships in the industry

DISTRIBUTION TIMELINE

BLOCKCHAIN

MediLedger

FarmaTrust

BLOCKPHARMA

Existing Solutions

- Most of them use private blockchain as framework (Hyperledger Fabric etc.)
- Transactions per second for other public blockchains - 30 [Ethereum]

COMPETITIONS

HYPERLEDGER FABRIC

- Private Nodes
- Limited set of participants
- Modular architecture
- PBFT and Raft consensus.

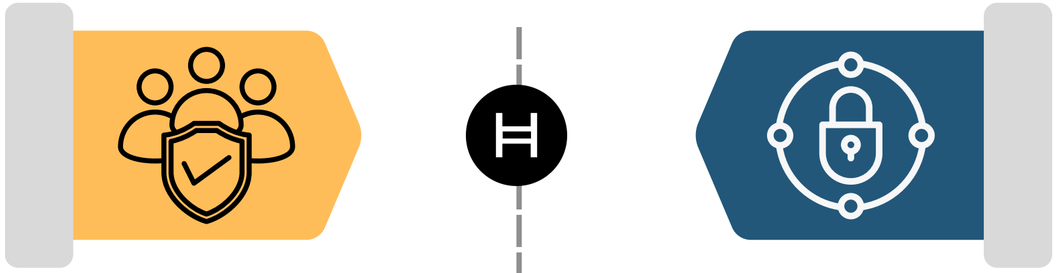
PharmaSync uses HEDERA Hashgraph Network as a platform for blockchain development

Hedera Hashgraph is known for its high transaction speed, with a potential of up to -

- **10,000 transactions per second,**
- **and a block time of 3-5 seconds.**

HEDERA

(Public-Permissioned Blockchain)



Public Blockchain

- Product quality related information
- Government compliance data

Permissioned Blockchain

- Other business-related information
- Order information

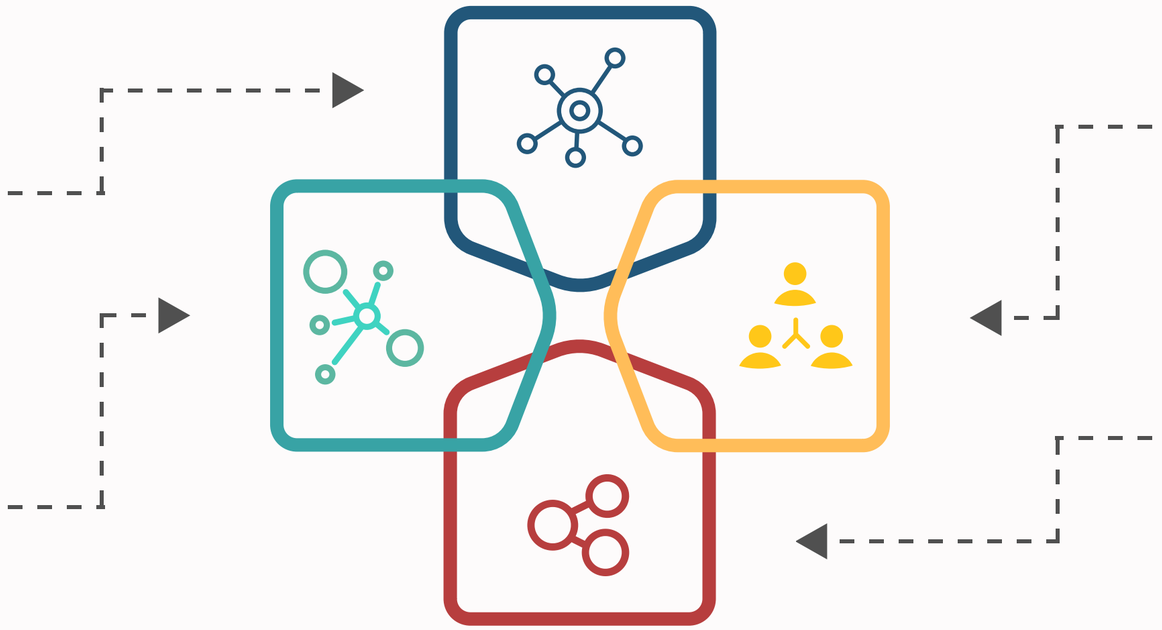
It uses a novel consensus mechanism called Hashgraph, which is based on a directed acyclic graph (DAG)

GOVERNANCE

Network Membership Governance

Formal onboarding with compliance agreement, allowing stakeholders to switch to blockchain-based SSI-enabled identity management systems

Issuers provide guidelines, eligibility is confirmed through consensus nodes, the monitoring body maintains on-chain applications, and stakeholders oversee the off-chain part



Smart contracts and encoded laws regulate permissions, granting stakeholders access controls

The Pharmars Team manages and communicates network operations and integrates third-party IoT devices

GOVERNANCE

Business Network Governance

A decentralized pharmaceutical supply chain network ensures transparency, traceability, and privacy for stakeholders

Pharmars develops and maintains intangible assets like smart contracts, compliance rules, streamline processes and IoT devices

Monitoring off-chain SLA adherence using Hyperledger consensus nodes, automating penalty system and auditing

GOVERNANCE

Technology Infrastructure Governance

01

Hedera Network Services and hybrid-chain architecture for distributed, resilient supply chain infrastructure

02

Evaluate technologies like Hedera, Hyperledger Indy, Aries, Ursa for DID management, privacy, and secure data storage

03

Implementing public and private chains for transparent data storage and transaction security

04

Strategic policies for managing hybrid-chain architecture, IT infrastructure risks, monitoring and ensuring robust contingency plans for supply chain operations

RISKS & MITIGATION

Business Risks

Supplier Power

Low

Since blockchain is decentralized, the supplier power is usually low in this industry. PharmaSync doesn't intend to rely on any provider too much initially.

Threat of New Entry

Moderate

Establishing a working blockchain solution requires technical expertise. However, the barrier can be lowered as the technology becomes more accessible.

Buyer Power

Moderate

In countries like Bangladesh, where blockchain technology is not yet accessible, the buyer power can be considered low. However, in developed countries PharmaSync might run into challenges.

Threat of Substitution

Moderate

There are solutions available in the market that may not be as holistic as PharmaSync. On the other hand, PharmaSync's differentiation would help to mitigate the risk.

Contingency Plan

- Diversify suppliers
- Expand market reach & education

RISKS & MITIGATION

Technical Risks

Performance limitations, network congestion, and consensus challenges

Implement optimization techniques, explore off-chain solutions, and conduct thorough performance testing

Integrating various tools, technologies, and frameworks

Conduct comprehensive compatibility testing, ensure proper documentation, and engage experienced developers

External IoT devices, decentralized file storage, and hybrid-chain approach

Implement robust security measures, conduct regular audits, and monitor for potential vulnerabilities

Contingency Plan

- Establish a dedicated technical support team for prompt issue resolution.
- Maintain regular backups of data and have a disaster recovery plan in place.

MEET THE TEAM

PHARMA SYNC

01

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THANK YOU