Trusted healthcare enabled dataspaces: the PharmaLedger use cases

IoT Week
UPM – Giuseppe FICO / Ma. Eugenia BELTRAN
A digital ecosystem is an interdependent group of actors (enterprises, people, things) that share standardized digital platforms to achieve a mutually beneficial purpose.

- Independent but collaborating parties
- Trust established cryptographically with blockchain
- Organized per industry, geography or incentive
- Common Best Practices

PharmaLedger: Accelerating a Healthcare DTE!!
PHARMALEDGER IN A NUTSHELL

**W H O ?**
Pharmaceutical companies, hospitals, universities, patient organizations, tech companies... building an ecosystem!

**W H Y ?**
To empower patients, increase digital trust, enable medicine drug traceability and data privacy, and foster a new culture of collaboration in healthcare.

**W H A T ?**
A blockchain-based platform with reference use cases in supply chain, clinical trials and health data. A governance function for sustainability and legal, regulatory and data privacy compliance.

**H O W ?**
A public-private partnership of like-minded, collaborative partners working together and engaging patients, HCPS, regulators, other IMI projects and 3rd parties.

**Duration**
3 years
Jan 20 – Dec 22

**Consortium**
29 partners

**EEAB**
External expert advisory board
9 members

**Budget**
22 million Euros

**Focus Areas**
Supply Chain, Clinical Trial, and Health Data

**Ethics Board**
6 members

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THE PHARMALEDGER CONSORTIUM

29 Members – 10 EU Member States, Switzerland, Israel and USA
THE BIG PROBLEM (WHY PHARMALEDGER)

- Lack of data provenance
- Systems are not patient centric
- Intermediaries take value
- Data silos
- Inefficiencies and waste
- Risk of cyber attacks
- Fake medicines

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THE OPPORTUNITY (VISION)

A Digital Trust Ecosystem accelerates value creation

- Improved health & safety
- Open-source software
- Patient empowerment and privacy
- Open innovation platform
- Secure healthcare data sharing

Increased efficiency
PharmaLedger PLATFORM ARCHITECTURE: Underpins a trusted dataspace

Cross company decentralized blockchain network with 7 nodes working now, more to come!

PharmaLedger is an enabling platform for trusted data management
**PHARMALEDGER PLATFORM OVERVIEW**

### Use Cases
- Legacy Systems, Systems of Records etc.
- Edge Devices (Mobile Apps, IoT, WebApps)

### Integration
- Bridges between Application and Blockchain platform
- Abstraction layer for Applications

### DSU
- Encapsulates Data and Business Logic (code)
- Build-in Data Privacy and Confidentiality
- Enables secure sharing

### Anchor
- Link the DSU in Blockchain
- Guarantees integrity, traceability, provenance, immutability

### Blockchain
- Use case specific Blockchain technologies
- All Blockchains are anchored in the Root Blockchain

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**OpenDSU Middleware**

**Applications**
- ePI
- eConsent
- FGT
- More...

**Web APIs / SDKs (OpenDSU SDK)**
- Identities (DIDs)
- Validation
- Other...

**Off-chain Storage (Data Sharing Units)**
- BDNS
- Bricking
- Anchoring
- Notifications
- Other...

**Anchoring in Blockchain**
- Root
  - UC1: ETH
  - Company Ledger
- UC2: HLF
  - Other Ledger

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Dynamic, interoperable and portable Digital Wallet

Stored in DSUs

Customizable to the needs of the users (individuals and companies): Contain DSU embedding SSApps

Supports any device such as smartphones, wearables, browsers
WHY OPENDSU

Generic approach for **all use cases**

- Data not stored on the blockchain but outside blockchain (in use case specific apps/wallets)
- Access to the blockchain through applications (digital wallets), which are handling the keys
- Offering reusability, interoperability between use cases and data portability
- Preserving data confidentiality & privacy

Defining an **open standard** for handling off-chain storage to achieve a **single standard** for interoperability: Digital Wallets, Encrypted Data Vaults, Decentralised Key Management Systems, Cloud and Edge Agents
PharmaLedger DTE: DTE participative dataspace

- DTE partners share and adhere to the same standards and guidelines
- Data stored off chain at the source allowing to share through DSUs.
- DataSpaces shared by members of PharmaLedger now (during project) but will be shared by the Association members (when project finished).
- PharmaLedger dataspace = Σ DTE (could be data providers, users and intermediaries)
- Data sovereignty, privacy and trust support relationships between participants.
- Currently dataspaces can be seen through Use Cases
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| **Anonymized matching of patients to clinical trial inclusion and exclusion criteria** |
| **Auditable, version-controlled, real-time and immutable Informed Consent Form** |
| **Trusted Tracking of investigational medicine distribution to the patient** |
| **Visibility of commercial product inventory for replenishment and recall notifications** |
| **Latest approved product information for all manufacturers in one app** |
| **Multi-factor Packaging Authentication and data analytics** |
| **Dynamic acquisition & real-time data processing for patients** |
END TO END SUPPLY CHAIN TRACEABILITY MODEL

Blockchain Trust Fabric | PharmaLedger

- Decentralized Identifier (DID): Materials, products, orgs, patients, devices
- Risk & Compliance: TPRM - ATP
- Digital Certifications: (e.g., Certificate of Analysis, Trade docs)
- Electronic Product Info: ePI
- Material Traceability
- Personal Medicine
- T&T Object and Event
- Counterfeit feature: (ouvert/ couvert)
- Cold Chain & Location
- Order-to-Cash

Clinical Trials | API | Production | Packaging | Primary Distribution | Distribution Centers | Local Distribution | Pharmacy Hospital | Patient

N-tier Upstream

Returns and Downstream

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**End to End Supply Chain Traceability Model**

**Patient / Stakeholder use cases / application**
- Electronica product information (epi)
- Order to cash
- End-to-end traceability
- Drug shortages in supply chain planning
- Cold temperature monitoring
- Multi factor authenticity verification (counterfeit check)
- Manufacturing labs and distribution process recording
- Logistics management
- Specialty supply chain (clinical, personalised, samples)
- Third party risk management
- Regulatory compliance

**Blockchain Trust Fabric | PharmaLedger**

**Decentralized Applications (DAApps)**
- Pharmaceutical Traceability Model
- Electronic Product Information (ePI)
- Material Traceability
- Personal Medicine
- T&T Object and Event
- Counterfeit feature
- Cold Chain & Location
- Order-to-Cash

**Risk & Compliance**
- TPRM - ATP

**Digital Certifications**
- (e.g. Certificate of Analysis, Trade docs)

**Electronic Product Info**
ePI

**Material Traceability**

**Personal Medicine**

**T&T Object and Event**

**Counterfeit feature**
- (ouvert/ couvert)

**Cold Chain & Location**

**Order-to-Cash**

**Blockchain Trust Fabric**

**Decentralized Identifier (DID)**
- Materials, products, orgs, patients, devices

**Clinical Trials**

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**Distribution Centers**

**Local Distribution**

**Pharmacy**

**Hospital**

**Patient**

**N-tier Upstream**

**Returns and Downstream**

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END TO END HEALTH DATA MARKETPLACE MODEL

Stakeholder use cases / application

- Consent
- Recruitment for Clinical Trials
- Patient Engagement
- Alerts and notifications
- Use anonymized data for RWE
- Support diagnosis and prevention
- Personalize treatments for patients

- Clinical trial design
- In Silico clinical trials
- Data provenance, transparency and integrity
- Patient Identity Management of various data sources
- Ability for participants to share their data anonymously
- Other

Blockchain Trust Fabric | PharmaLedger

Health Data Marketplace

Decentralized Applications (DApps)

Patient Decentralized Identifier (DID)
Medical Device Decentralized Identifier
Subject Decentralized Identifier
Clinical Trial Informed Consent
Lab Tests / Results
Study Data Transparency
Wearables and Sensors (IoT)
Safety Reporting
Drug Traceability
Claims
END TO END CLINICAL TRIALS MODEL

Stakeholder use cases
- eConsent
- Virtual/Remote Trials
- Patient Engagement / recruitment
- Continuous site monitoring
- Chain of custody for kids, samples
- Supplier Qualification (TRPM)
- Financial Processes
- Regulatory reporting
- Alerts and notifications
- Clinical Supply visibility
- Submissions
- Data anonymisation
- Prevention
- Data Monetization
- Bio Sample Tracking
- Data transparency and integrity management
- Patient adherence
- Other

Blockchain Trust Fabric | PharmaLedger

- Health Data Marketplace
- Subject Decentralized Identifier
- Clinical Trial Protocol / Informed
- IMP Clinical Supply Traceability
- Study Data
- Safety Reporting
- Submission Package
- Investigator Decentralized Identifier
- Medical Device Decentralized Identifier
- Inst. Review Board/Ethics Committee
- Enrolment Data
- Lab Kits
- Wearables and Sensors (IoT)
- External Service Provider Management
- Investigator Payments

Decentralized Applications (DApps)
PHARMALEDGER ASSOCIATION BEING CREATED

- DTE with sovereign dataspaces to support new and innovative services and business processes for a healthcare DTE including private companies and industries as well as academic, governmental and NGO amongst other organizations
- Ensuring privacy, ownership and control of data through data sovereignty
- Secure datasharing
- Validated and tested software, qualified for HealthCare organizations
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<td>Anti-Counterfeiting</td>
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<td>Qualification</td>
<td>Clinical Trial Recruitment, eConsent, IoT and Personalized Medicine</td>
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<td>Version 2.0 for multiple products</td>
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<td>Continuous platform enhancement</td>
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