Digital Trust Ecosystem in Healthcare

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Blockchain in Healthcare Conference
University of Zürich
20 October 2021
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Agenda

• Why Blockchain - The 5 A’s
• Consortium approach - PharmaLedger
• Use cases
• Governance and Legal Implications
• Q&A
Blockchain – the 5 A’s

**Asset**
- **A**: manage assets like cryptocurrency (solves the double spend problem), products, and data

**Audit**
- **A**: immutability, no changes possible without consensus

**Automate**
- **A**: leverage smart contracts

**Anonymize**
- **A**: protect privacy

**All for one, one for all**
- **A**: consortium approach, no single/central authority
The Innovative Medicines Initiative is the largest public-private partnership aiming to boost pharmaceutical innovation in Europe and to speed up the development of better and safer medicines for patients. IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.

www.imi.europa.eu
**Who?** Pharmaceutical companies, hospitals, universities, patient organizations, tech companies... building an ecosystem!

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

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

**How?** A public-private partnership of like-minded, collaborative partners working together and engaging patients, HCPS, regulators, other IMI projects and 3rd parties through several communication channels.
The Consortium
29 complementary partners from 10 EU Member States, Switzerland, Israel & US

- **12 EPFIA members** → ABBV, AZN, BAYER, GSK, JANSEN, MSD, NOVO, NVS, PFE, ROCHE, UCB, BI
- **5 SMEs** (Blockchain/ICT) → RMS, PDM, AVO, TVS, EKN
- **4 Research & Tech. Universities** → UPM, CERTH ICSI & DUT
- **1 Social & legal sciences Uni** → KUL
- **2 Patients organizations** → EPF, EFGCP
- **1 Government authority** → INCM
- **1 CRO** → ONO
- **3 Hospitals** → OPB, HES, UKW
Gartner defines **digital ecosystem** as an interdependent group of actors (enterprises, people, things) sharing standardized digital platforms to achieve a mutually beneficial purpose.

- Independent but collaborating parties
- Establish trust in interdependent ecosystems
- Cryptographically & blockchain established trust
- Organised per industry or geographical location
- Common best practices
**Value Chain - Use Cases View**

- **Clinical Trial eRecruitment**: Anonymized matching of qualified patients to trial requirements. Enables voluntary enrollment.
- **Clinical Trial eConsent**: Auditable and immutable ICF. Dynamic and real-time ICF management. Less protocol deviations. Specific versions can be managed administratively agile. Pilot real study with Pediatric heart failure patients.
- **Clinical Trial IoT devices**: Dynamic acquisition and processing of data. Remote patient monitoring. Real-time notifications. Pilot real study with Pediatric heart failure patients and 2 devices.
- **Clinical Supply**: Immutable record keeping. Creates trust among partners. Interoperable data points for decision making. Improved ability to track drug accountability and reconciliation. Value added for clinical sites/investigators (reduce admin burden).
- **Epi - Electronic Product Information**: Achieves EMA key principles for EPI. Environmental footprint - CSR. Multi-use of barcodes as digital key for delivering bundled digital services and value. Multi-factor product authentication. Authentication feature agnostic. ACDC (anti-counterfeiting data collaboration) regulatory and law enforcement value. Leveraging ePI one app for additional anti-counterfeiting check.
- **Anti-Counterfeiting**: Establishes a trusted environment for patient-centric decentralized applications.
- **Personalized Medicines**: Uses blockchain’s trusted network to leverage RWE for research. Uses Machine Learning and AI. Value-Based health delivery in clinical practice.
Governance
The BLT
(Business Legal Technology Sandwich)

Legal Implications
• Identity
• Antitrust
• Consortium Agreement
• Legal form
• Data Privacy / Confidentiality
• Regulated Industry (Patient Safety)
• Existing legislation
• Ethics
• Jurisdiction
• Liability
• Informed Consent
• Intellectual Property

Ecosystem Big Picture

Governing Pillars
- Accountability
  Ensure accountability of management to board and board to shareholders
- Transparency
  Ensure full disclosure of dealing with regulators, shareholders and stakeholders
- Fairness
  Ensure equitable dealings and protect shareholder value
- Independence
  Ensure and recognize stakeholder rights; avoiding conflict of interest

Ecosystem
- Wholesalers
- Manufacturers
- Physicians
- Distributors
- Retailers
- Hospitals
- Patients
- Physicians and HCS
- Banks and Wholesalers
- Regulatory and Academia Body

Consortium
- Purpose?
  - Network Effects
  - Lower Risks
  - Sharing Knowledge
- Type?
  - Working Group
  - Private Sector Entity
  - Hybrid
- Key Success Factors
  - Governance
  - Leadership
  - Clear Objectives
- Existing Consortium?
  - Airbus
  - PSCI
  - Insurance B3i
- Strategic Questions
  - Legal Foundation
  - Intellectual Property
  - Financial contribution

Minimum Viable Ecosystem (MVE)

Ensuring accountability of management to board and board to shareholders
Ensuring full disclosure of dealing with regulators, shareholders and stakeholders
Ensuring equitable dealings and protecting shareholder value
Ensuring and recognizing stakeholder rights; avoiding conflict of interest

Governance
Leadership
Clear Objectives

Purpose?
Type?
Key Success Factors
Existing Consortium?
Strategic Questions
Blockchain: Decentralization

**Architecture Decentralization**

... how many physical computers is a system made up of? How many of those computers can it tolerate breaking down at any single time?

**Political Decentralization**

... how many individuals or organizations ultimately control the computers that the system is made up of?

**Logical Decentralization**

... does the interface and data structures that the system presents and maintains look more like a monolithic object, or an amorphous swarm?

**Structure and Decision Examples**

- Traditional corporations are politically centralized (one CEO), architecturally centralized (one head office) and logically centralized (can’t really split them in half)

- Blockchains are politically decentralized (no one controls them) and architecturally decentralized (no infrastructural central point of failure) but they are logically centralized (there is one commonly agreed state and the system behaves like a single computer)

Source: Vitalik Buterin: [https://medium.com/@VitalikButerin/the-meaning-of-decentralization-a0c92b76a274](https://medium.com/@VitalikButerin/the-meaning-of-decentralization-a0c92b76a274)
# Definition of Governance, Ecosystem and Consortium

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<th>Terms</th>
<th>Definition</th>
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| Governance     | • system of rules, practices, and processes by which an entity is directed and controlled.  
                • Governing models involves balancing the interests of the company's stakeholders, such as shareholders, executives, customers, suppliers, financiers, the government, and the community.  
                • Consortium Agreement (CA) defines onboarding, decision making, IP, etc.                                                                                 |
| Ecosystem      | • network of organizations—including suppliers, distributors, customers, competitors, government agencies, and so on—involved in the delivery of a specific product or service through both competition and cooperation.  
                • as in a biological ecosystem, entities co-evolve through cooperation and competition, thus, creating a constant evolving relationship in which each entity must be flexible and adaptable in order to survive  
                • an Ecosystem may consist of participating entities of a Consortium  
                • Eg: eBay, Amazon Marketplace, Uber, Healthcare Ecosystem                                                                                               |
| Consortium     | • group made up of two or more individuals, companies, or governments that work together to achieving a common objective.  
                • Entities jointly pool resources, and is only responsible for obligations set out in a consortium agreement  
                • Entities in a consortium remains independent in their daily business operations, as is outside the agreed objectives  
                • Eg: Airbus, Hyperledger, Insurance B3i                                                                                                                  |
Governance Model Options

Ecosystem led

Service provider led

Foundation Led (Independently Governed)

Foundation Led (Ecosystem Governed)
### ROADMAP

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**Year 1**
- PharmaLedger Kick-Off
- Use-case short-list
- Use-case specification
- Marketing & Engagement
- Est. Ethical & Legal requirements’ framework

**Year 2**
- Reference Domain applications development
- Architecture – blockchain platform & API implementation
- Governance Application, Legal & Ethical framework implementation
- Use-case pilot implementation

**Year 3**
- Continuous Platform Sustainability
- Guidelines and lessons learnt
- Implement Governance and Operating Model
- Continuous Platform Promotion and 3rd Party engagement
- Strategic Positioning

**Strategic Positioning**
- Blockchain-Enabled-Healthcare!
PharmaLedger Platform Overview

### Use Cases

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

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

#### Data Sharing Units (DSU)
- Encapsulates Data and Business Logic (code)
- Build-in Data Privacy and Confidentiality
- Supports integration with Decentralized Identities & Verifiable Credentials
- Enables secure sharing

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

#### Hierarchical Blockchains
- Use case specific Blockchain technologies
- All Blockchains are anchored in the Root Blockchain
The Pharma Supply Chain is complex – every node in the chain is consuming & providing data from/to other nodes.

The use case looks at methods of data capture and transfer, on/off chain storage in a mobile and integrative flexible architecture which will allow for a trusted downstream supply chain visibility with near real time data availability.

PharmaLedger connects the supply chain eco-system for trusted and accelerated information sharing and facilitates incorporating new partners into the eco system, including patients.

**Description**

- Increased patient safety
- Fast and efficient recalls
- Optimized cost for the benefit of the health systems
- Simplified IT interfaces & unlocking previously siloed information

**Blockchain and PharmaLedger Value Proposition**

- **Trust**: Secure & timely supply of product, with digital identities
- **Interoperability**: Leveraging industry standards, such as Advanced Shipping Notices and Electronic Product Coding Information Services for end to end traceability
- **Immutability**: Secure and immutable sharing of information for reliable demand signals and counterfeit detection
- **Traceability**: Increasing regulatory compliance, providing product provenance and chain of custody
Supply Chain eLeaflet – ePI

Description

This use case starts with the creation of the ePI in digital form by the manufacturer, the review and approval of the ePI with the Health Authorities, updates to the ePI and dissemination of the ePI to the Patient/ Health Care Practitioner/ Provider (HCP).

Blockchain and PharmaLedger Value Proposition

- **Transparent and immutable** review and approval transaction records.
- **Smart contracts** set the transaction rules so only approved eLeaflets are published.
- **Facilitates transactions** between manufacturer systems and multiple health authorities with easy access for Patient with ‘One App’.
- **Decentralised system** for storing ePI provides secure platform, instead of central database, providing resilience against cyber attacks.
- **Data Self-Sovereignty and Anonymity** are paramount and not negotiable.

**Content Updates Languages**

**Review and Approval between Manufacturer and Health Authority**

**Patient Safety and Convenience**
Anti-Counterfeiting Process Overview

Multi-Factor Packaging Authentication (MFPA) and Anti-Counterfeit Data Collaboration (ACDC)

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**Patient**
- DataMatrix scan with app

**Manufacturer**
- Global Trade ID Number
- Batch
- Expiry
- Serial Number

Perform MFPA checks:
1. Valid ePI product?
2. Valid serial No.?
3. Valid prod. status?
4. Feature available?
5. Suspect product?

**Results**
- Patient
- Manufacturer verifies feature(s)

**Patient**
- Authentication Feature Input

**Patient**
- Results of checks & Business rules

**Manufacturer**
- Anti-Counterfeit Data Collaboration (ACDC)

Analytical reports and real-time alerts
- Manufacturer
- Law Enforcement
The use case intends to create a patient-centric, industry-wide clinical trial recruitment solution. The solution would aggregate clinical trials and screening criteria across the whole industry, and would use a matching algorithm to match the patient to relevant clinical trials.

**Blockchain and PharmaLedger Value Proposition**

- **Decentralized**: Creates a shared ledger of permissions, accessible by network participants, without putting any one party in charge.
- **Immutable**: Creates a permanent record of trials submitted by sponsors. Would discourage any illegitimate use of the trial matching infrastructure.
- **Trust**: Cross-industry record of match attempts could be shared with patients, increasing understanding of which trial criteria may be causing their match or failure.

**Current State**

Patient: “Any trials for diabetics?”

Joe

Trial A / B

Investigator

Pre-screen

Study Website

Pre-screen

“Sorry, no”

**Future State**

Patient: “Any trials for diabetics?”

Joe

“You match to these 3 trials”

Trial B

Permission to be matched

Blockchain

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen
If a potential trial participant does not feel confident, empowered, or safe when reviewing the informed consent document, the likelihood of their participation is lowered, impacting recruitment in the clinical trial.

The purpose of this use case is to provide all clinical trial actors (trial participant, healthcare organization, sponsor and representatives/CROs, ethics committees, vendors and regulatory authorities) with a blockchain based platform for trial oversight leveraging the status of digital consents provided by trial participants.

Smart Contracts

Shared Ledger (Record of data transfer)

Authorized CRO

Cloud Provider

Device Provider

Lab

App Provider

Patient

Sites

Auditor Regulator

Blockchain and PharmaLedger Value Proposition

Immutability

Creates an immutable entry on the blockchain, recording when consent was obtained, which is immediately visible to appropriately permissioned users in compliance with GDPR.

Trust

Reduces or eliminates audit findings and decreases opportunities for fraudulent data, by increasing the consistency of information being viewed across investigative sites.

Smart Contracts

Smart contracts can be implemented to lock access to trial systems until consent has been obtained, ensuring compliance with GCP.

Traceability

Have the traceability to allow sharing of clinical trial data with different parties involved, any changes in consent status are applied in near real-time.

Privacy

Ability for sponsors to anonymously contact subjects directly to request consent for samples or data to be used in other research activities, optimizing the materials already collected.