

PharmaLedger: Blockchain Enable Healthcare

Introduction to the OpenDSU emerging standard

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Innovative Medicines Initiatives (IMI)

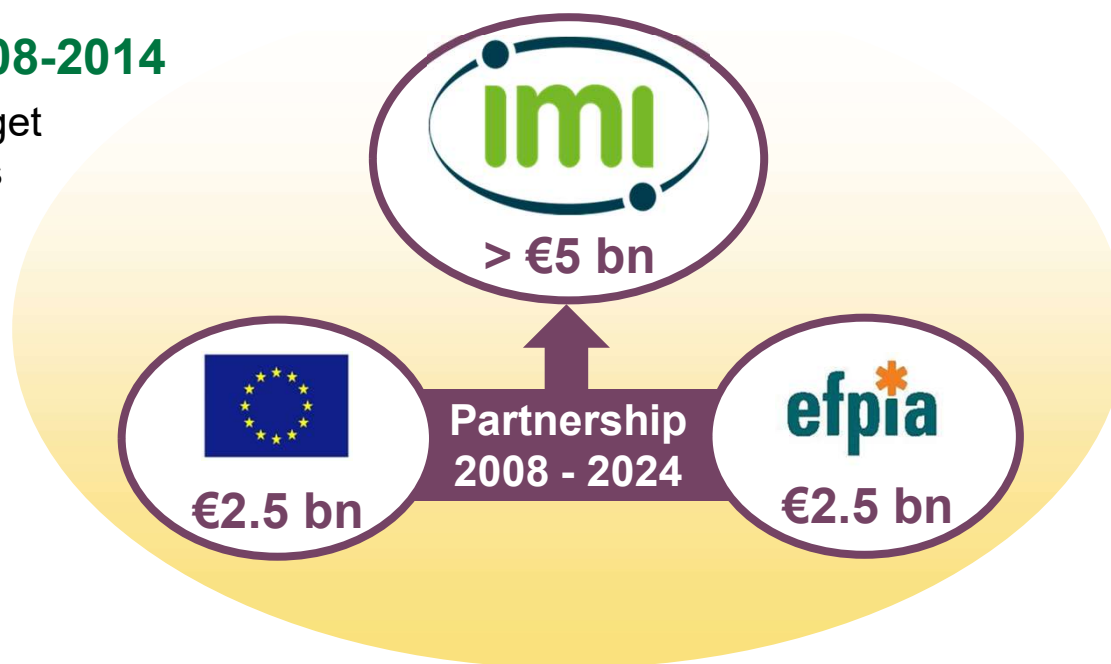
Europe's partnership for health

IMI1: 2008-2014

€2 bn budget
59 projects

IMI2: 2014-2024

€3.3 bn budget
More ambitious
More open
Greater scope
60 projects so far



PharmaLedger in a Nutshell

Who? PharmaLedger partners comprises of pharmaceutical companies, hospitals, universities, patient organizations, tech companies... building an ecosystem!

Why? To **empower patients**, increase **trust** among healthcare stakeholders, support medicine drug traceability and data privacy, and build a **new culture of collaboration in healthcare**.

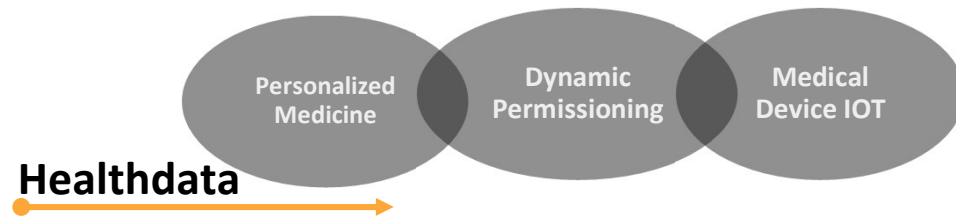
What? A scalable blockchain **platform validated through reference use cases** in supply chain, clinical trials and health data that will serve trendsetters for the industry, enabling early adopters.

How? PharmaLedger will **design, validate** and provide **agile delivery** of innovative blockchain-enabled healthcare **applications** across the industry, from manufacturers to patients; while creating an **innovative governance** approach for **sustainability**.

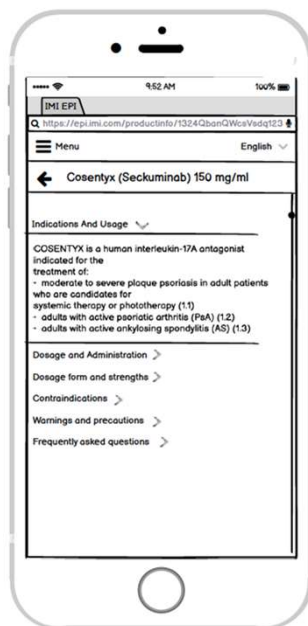
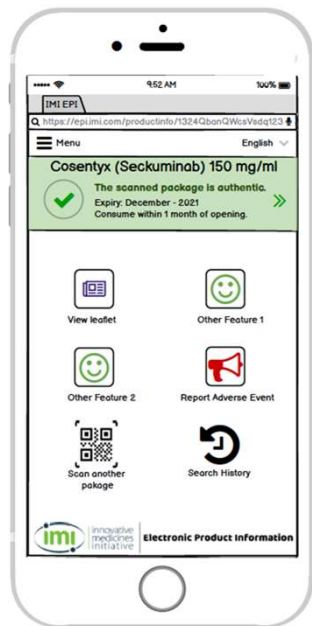


- ❖ **Duration:** 3 year, Jan '20 – Dec '22
- ❖ **Consortium:** 29 partners, largest of its kind
- ❖ **Budget:** EUR 22 million
- ❖ **Focus Areas:** Supply Chain, Clinical Trial, and Health Data

Selected Use Cases



Supply Chain eLeaflet – ePI



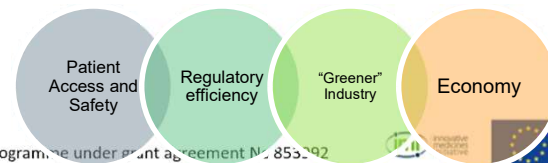
Description

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

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



Identities & Privacy

If you don't pay, then you are the product, but that is too simple:

“It's the gradual, slight, imperceptible change in your own behavior and perception that is the product.”

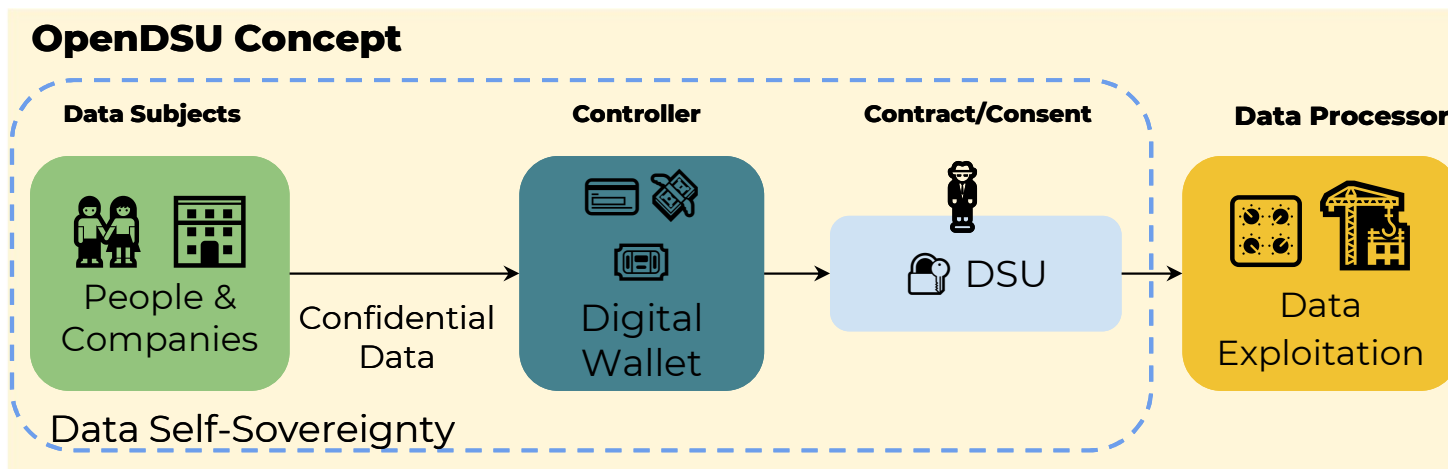
Jaron Lanier

Digital Self Sovereignty



Self Sovereignty: Identities, Data, Applications!

Data Sharing Unit (DSU) emerging standard



- Main purposes are
 - inherit Blockchain properties (traceability, integrity)
 - fulfill security, confidentiality and data privacy
- Putting the users (people / companies) in control of their data

The vision of the Digital Wallets

Digital Wallet DSU

Passwords DSU



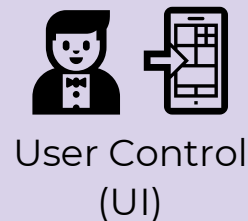
2FA DSU



Keys DSU



Personal Data DSU



User Control
(UI)

Medical Data DSUs



Credentials DSU
(Legal, Education, etc)



Currencies DSUs



Other DSUs
(Tickets, Cards, etc)



- Dynamic, interoperable and portable Digital Wallet
- Customizable to the needs of the users (individuals and companies)
- Supports and device such as servers, smartphones, wearables, browsers...
- Open for new features and applications
- **Probably the next big applications platform**
- Defining the way how we interact within an DTE (Digital Trust Ecosystem)

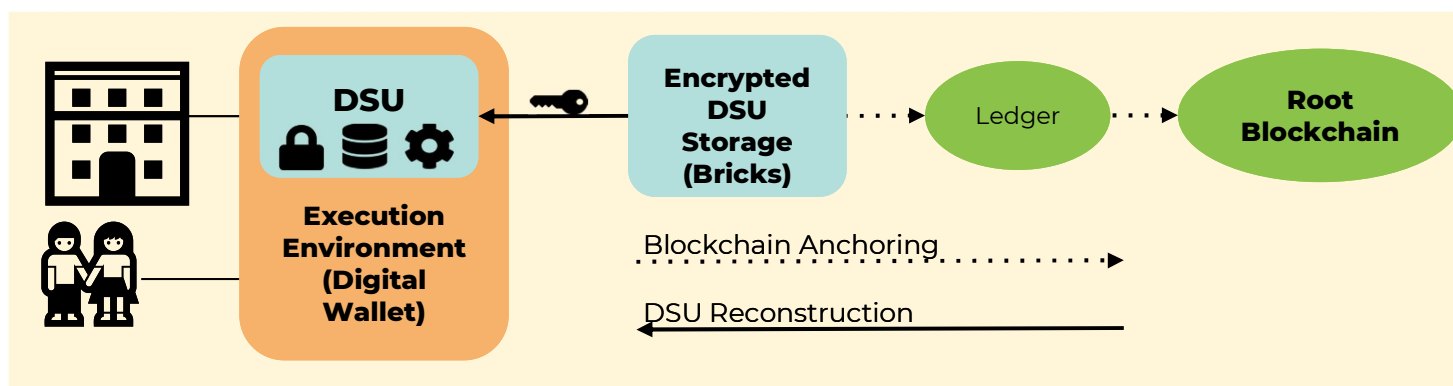


PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

Thank you!



OpenDSU Main Components

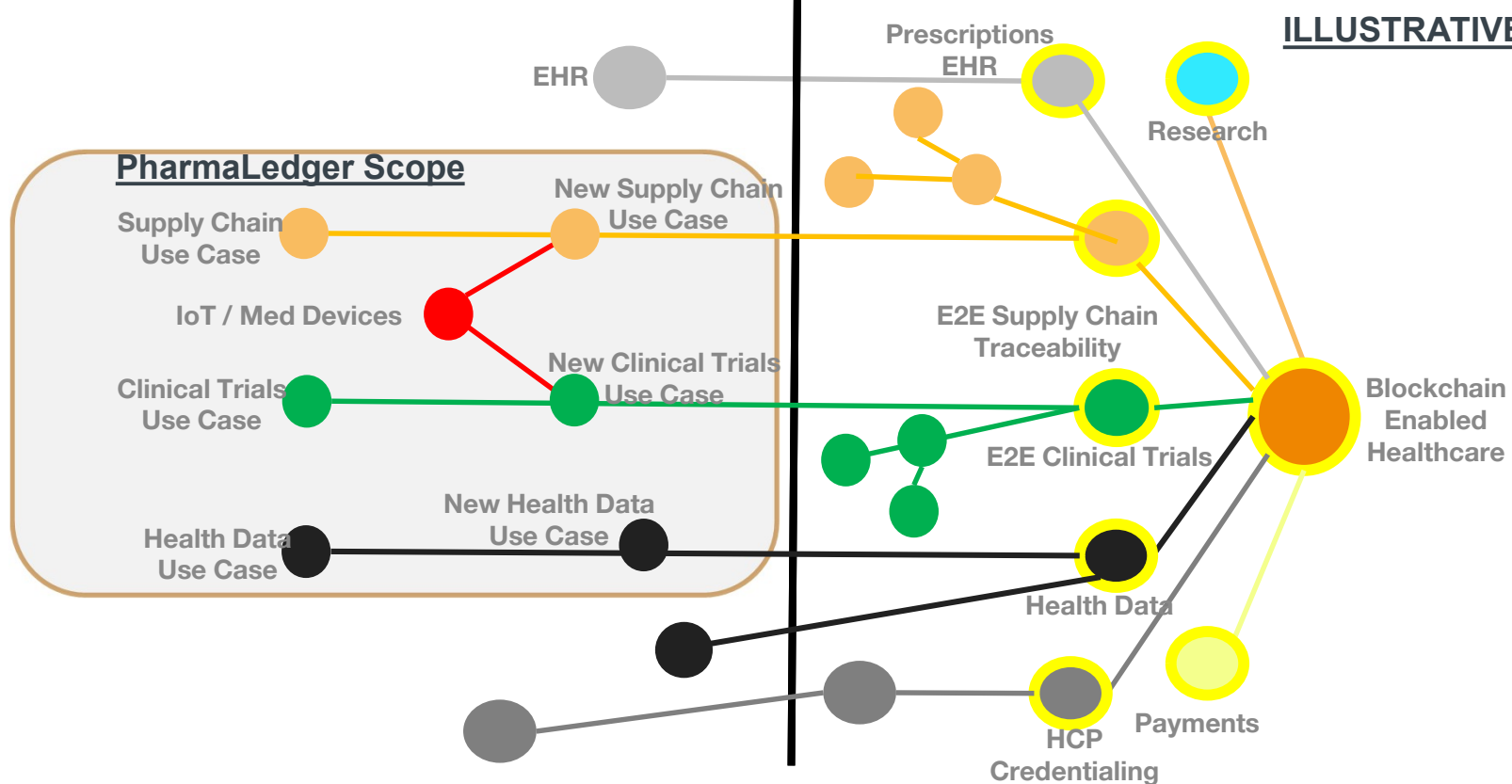


Defining an **open standard** for handling off-chain storage to achieve a **single standard** for interoperability: Digital Wallets, Encrypted Data Vaults, Decentralised Key Management Systems, Cloud and Edge Agents

PharmaLedger Use Cases

- Supply Chain
 - eLeaflet (electronic Product Information – ePI) **MVP planned go-live 12/2020**
 - Anti-Counterfeiting
 - Finished Goods Traceability
 - Clinical Supply Chain
- Clinical Trial
 - eConsent
 - IoT devices (medical) for assessment/endpoints
 - ~~Bio-specimen tracking~~
- Health Data
 - Personalized Medicine (health data marketplace)
 - ~~Digital Immunization Passport~~
 - ~~RWE – Support diagnosis and prevention~~
 - Accelerated Recruitment for Clinical Trials

IMI PharmaLedger Conceptual Roadmap



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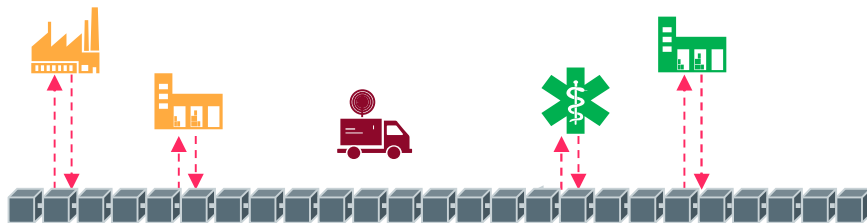


Supply Chain E2E Traceability Core Design



Serialization allows authenticity of end points, without transparency on distribution

Simplified Scenario



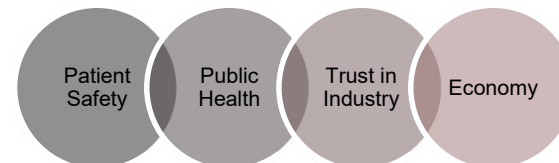
Description

The Pharma Supply Chain is complex – every node in the chain is consuming & providing data from/to other nodes.

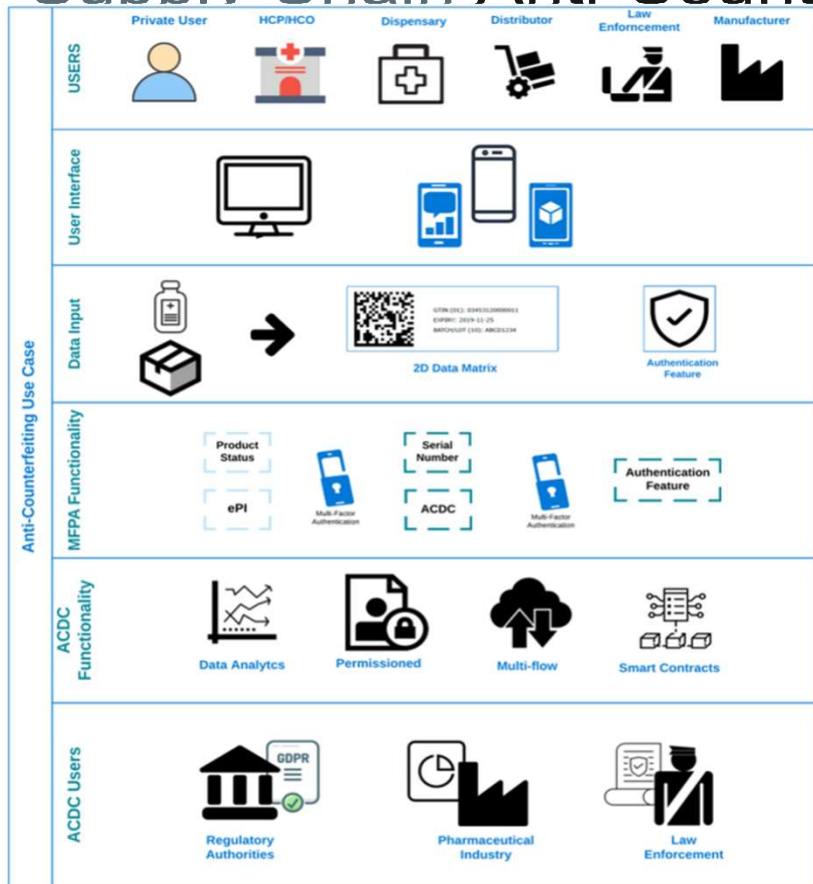
The use case looks at methods of data capture and transfer, on/off chain storage in a mobile and integrative flexible architecture which will allow for a trusted downstream Supply chain visibility with near real time data availability.

Blockchain and PharmaLedger Value Proposition

- Trusted Source of Truth**
 - Near real time transparency and accountability
- Privacy and Security**
 - Information shared without revealing partner / patient i
- Interoperability**
 - A flourishing pharma eco-system
- Scalability to additional use cases**
 - open access for partners not initially known



Supply Chain Anti-Counterfeiting



• Desc

Multi-Factor Product Authentication (MFFPA). publicly available smartphone application to medicine users (patients or guardians), extendable to institutional (registered) users.

Anti-Counterfeiting Data Collaboration” (ACDC) analytics. ACDC enables the additional real-time check. It is envisioned as a virtual database which connects on/off chain data and produces analytics, alerts, reporting and real time insights.

Access will be extended to law enforcement and regulatory authorities in the future.

Blockchain and PharmaLedger Value Proposition

- Trusted Source of Truth**
 - The authoritative and trusted answer on a medicines authenticity
- Privacy and Security**
 - Decentralized Identities (DIDs) could guarantee anonymity in read-only, public access scenario (also guarantees counterfeiters anonymity....)
- Interoperability**
 - The same solution can be adopted by all manufacturers and markets without lock-in to proprietary solutions
- Scalability to additional use cases**
 - Link to eLeaflet / ePI, digital recall, alerts, etc.

Patient Safety

Public Health

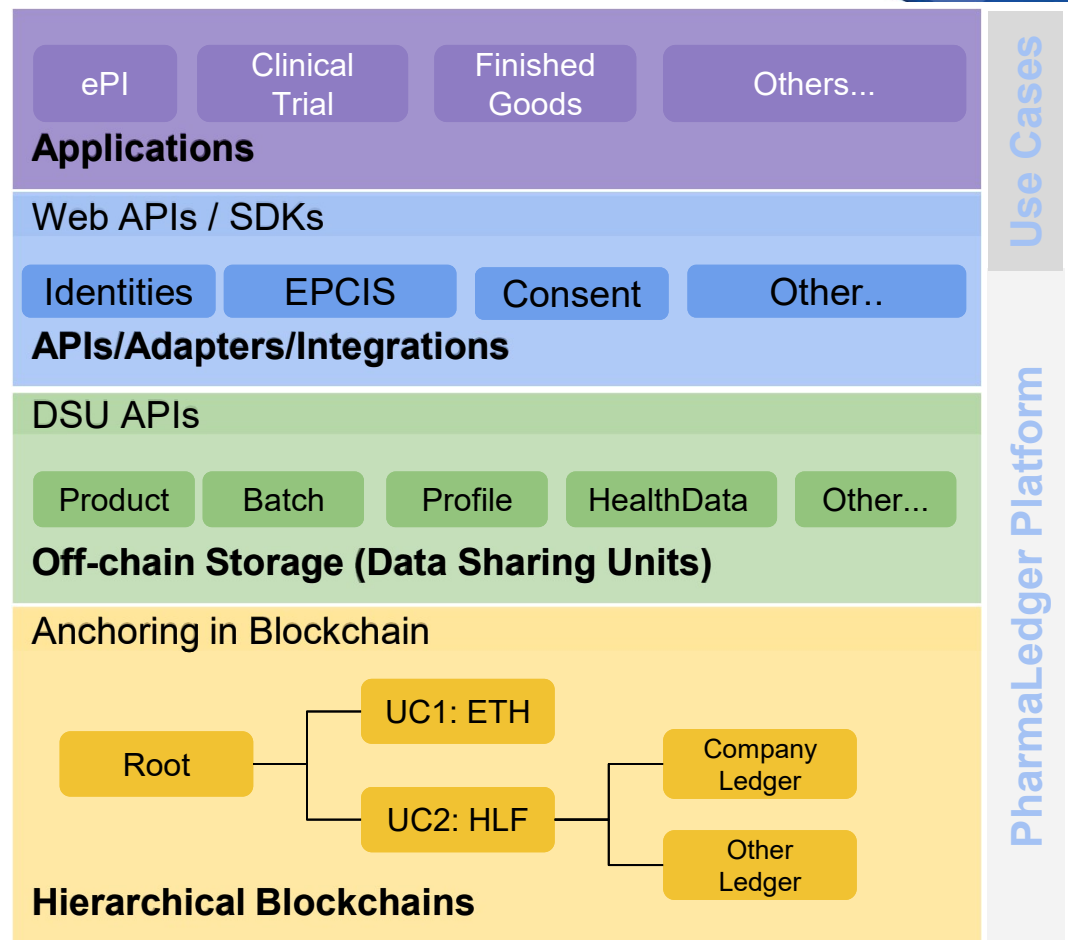
Trust in Industry

Economy

PharmaLedger Architecture

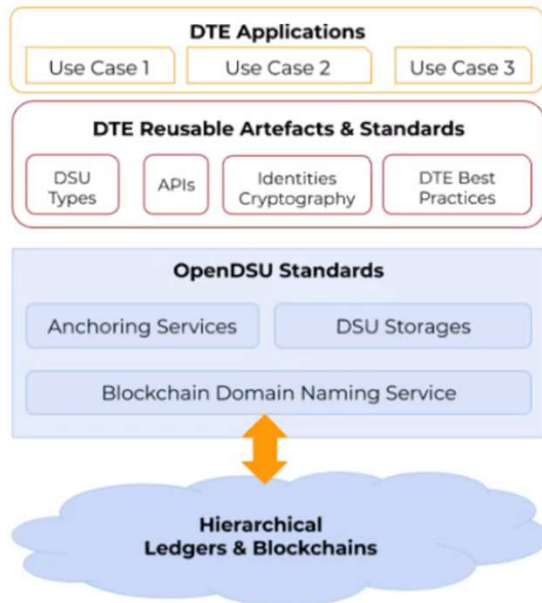
Blockchain enabled Healthcare

- Layered Architecture
- Blockchain Agnostic
 - Can use any blockchain
 - Integrity & Traceability
- Hierarchical Blockchains
 - Increase security for ledgers with small number of replicas
- Off-chain data and computation integrity
 - Secret Smart Contracts
 - Use Case Specific Optimisations



DTE – Digital Trust Ecosystem

The Bigger Picture



- There are multiple DTEs
- Independent authorities and consortias could establish DTEs
- Cryptographically Established Trust (Digitally Signed Data & Code)
- Common Best Practices (UX & Security)

We are building the Healthcare DTE