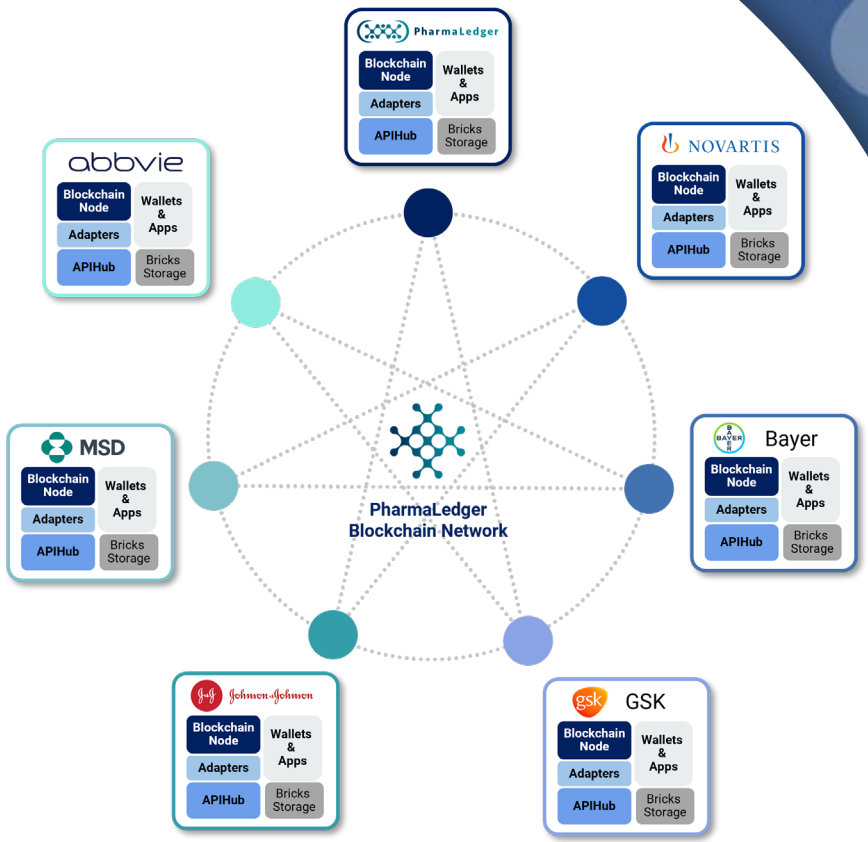
# PharmaLedger

BLOCKCHAIN ENABLED HEALTHCARE

# Trusted healthcare enabled dataspaces: *the PharmaLedger use cases*





***IoT Week***

***UPM – Giuseppe FICO /Ma. Eugenia BELTRAN***



*This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 853992. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.*



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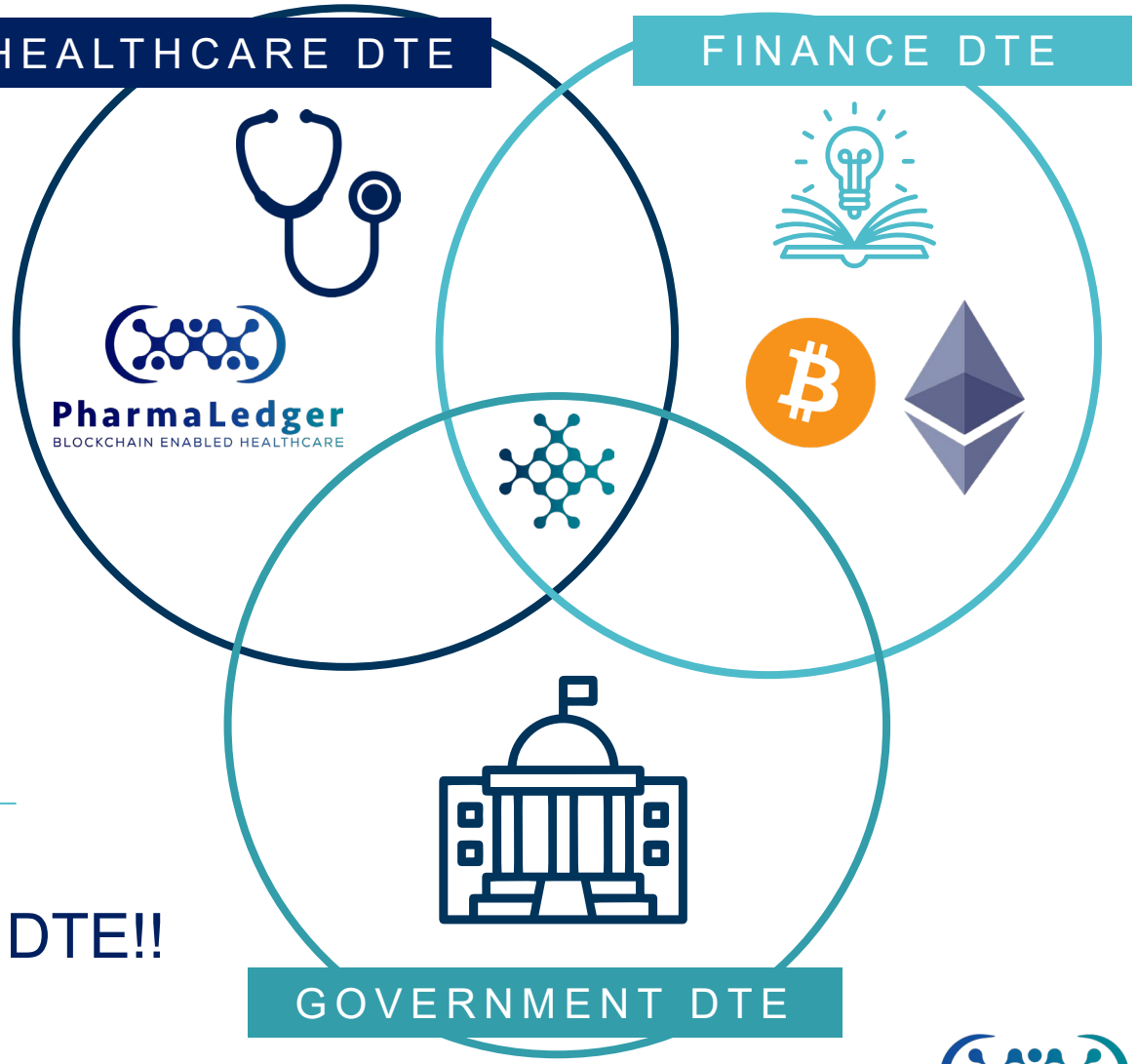
# PharmaLedger: A DIGITAL TRUSTED ECOSYSTEM(DTE)

## THE BIGGER PICTURE: PHARMALEDGER AS A CORE DTE PLATFORM

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!!

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Source: https://www.gartner.com/imagesrv/cio/pdf/Gartner_CIO_Agenda_2017.pdf

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# PHARMALEDGER IN A NUTSHELL

## 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 with 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.

**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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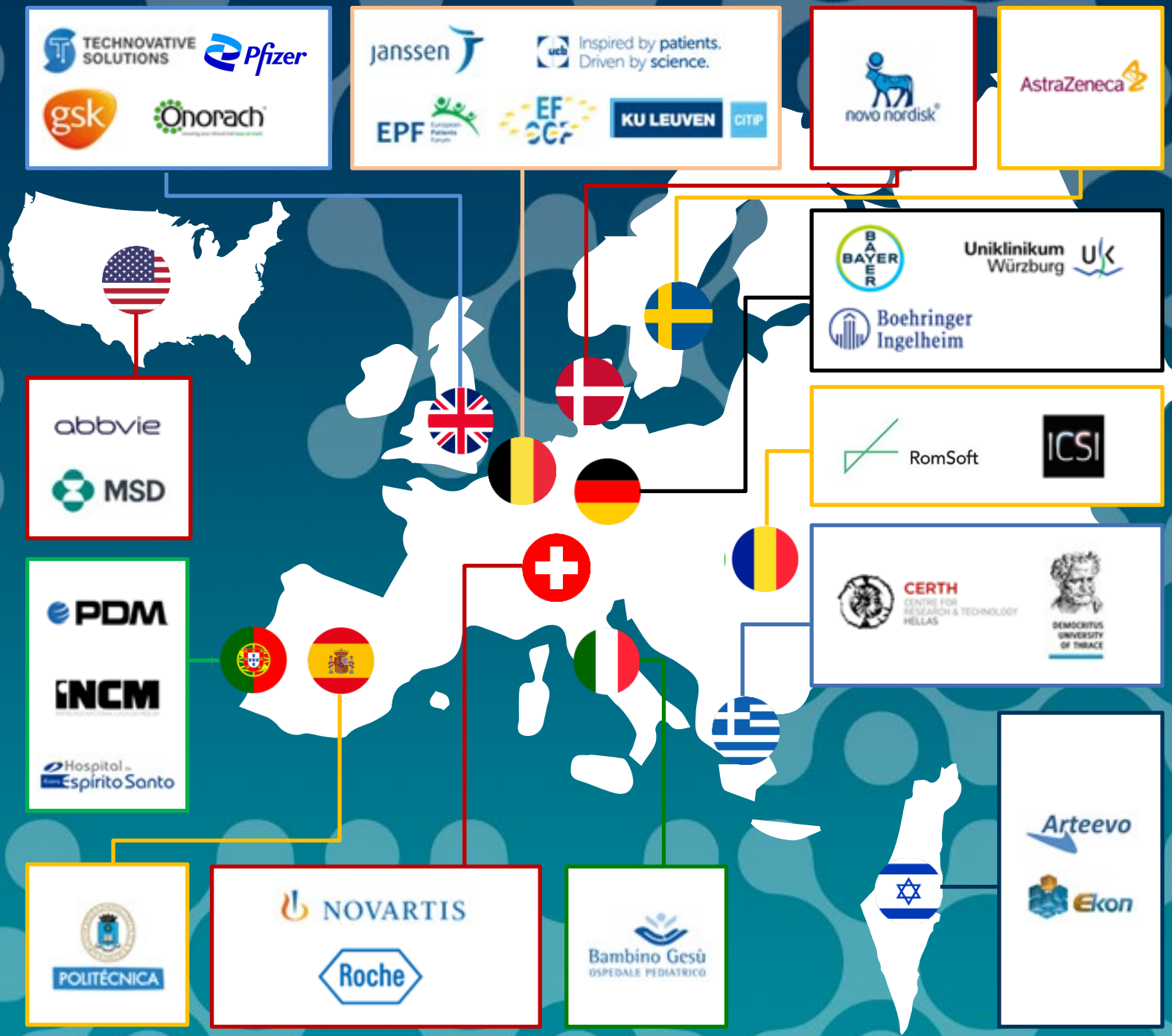
# THE PHARMALEDGER CONSORTIUM

29 Members – 10 EU Member States, Switzerland, Israel and USA

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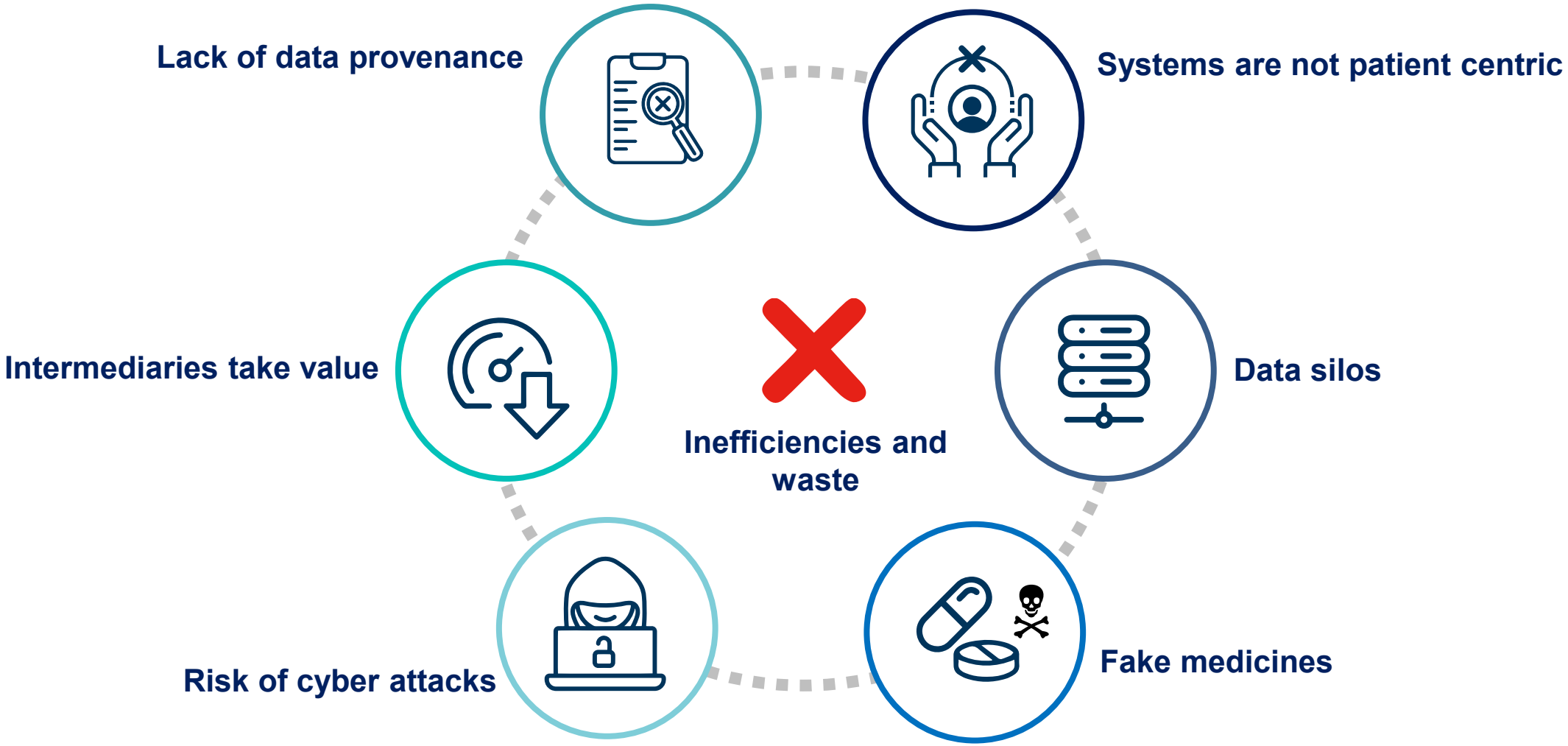
# THE BIG **PROBLEM** (WHY PHARMALEDGER)

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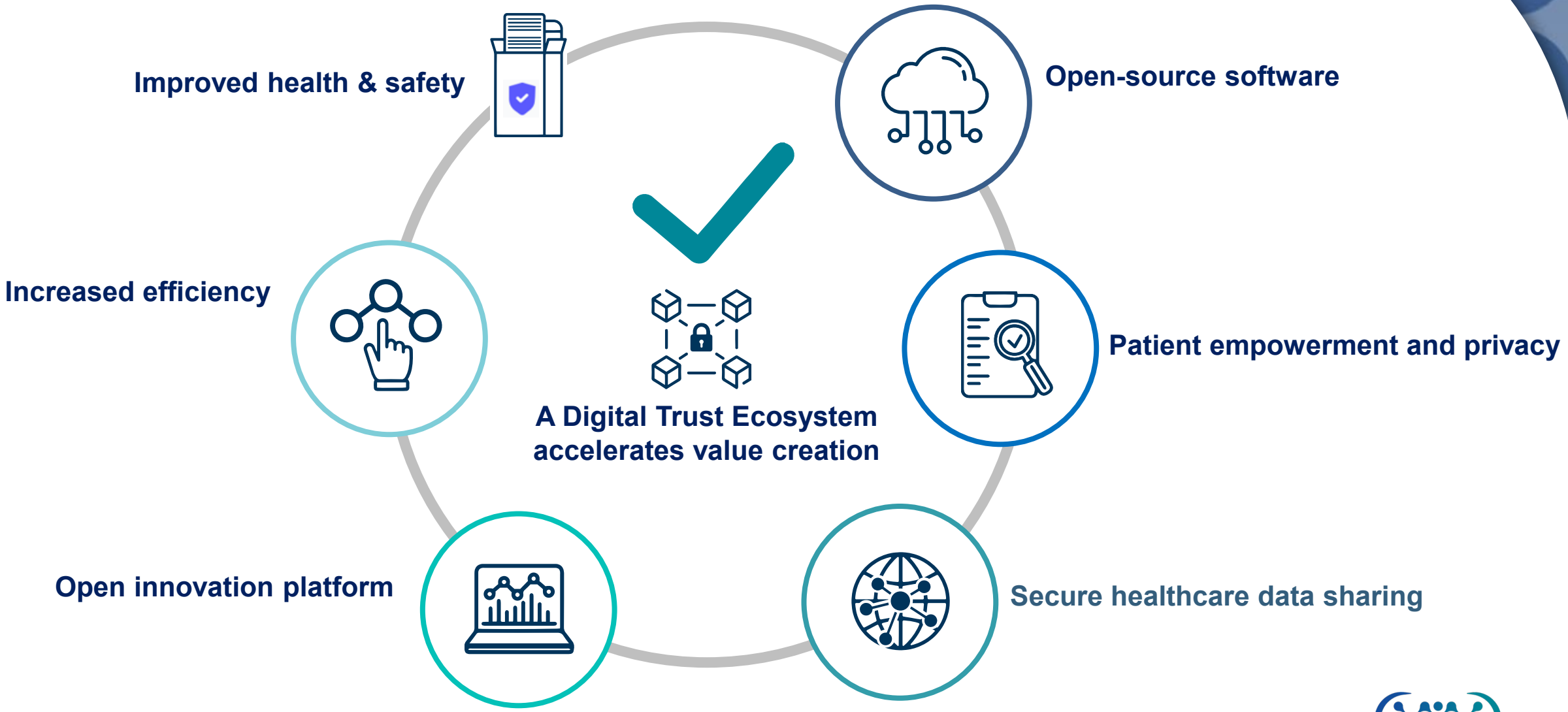
# THE **OPPORTUNITY** (VISION)

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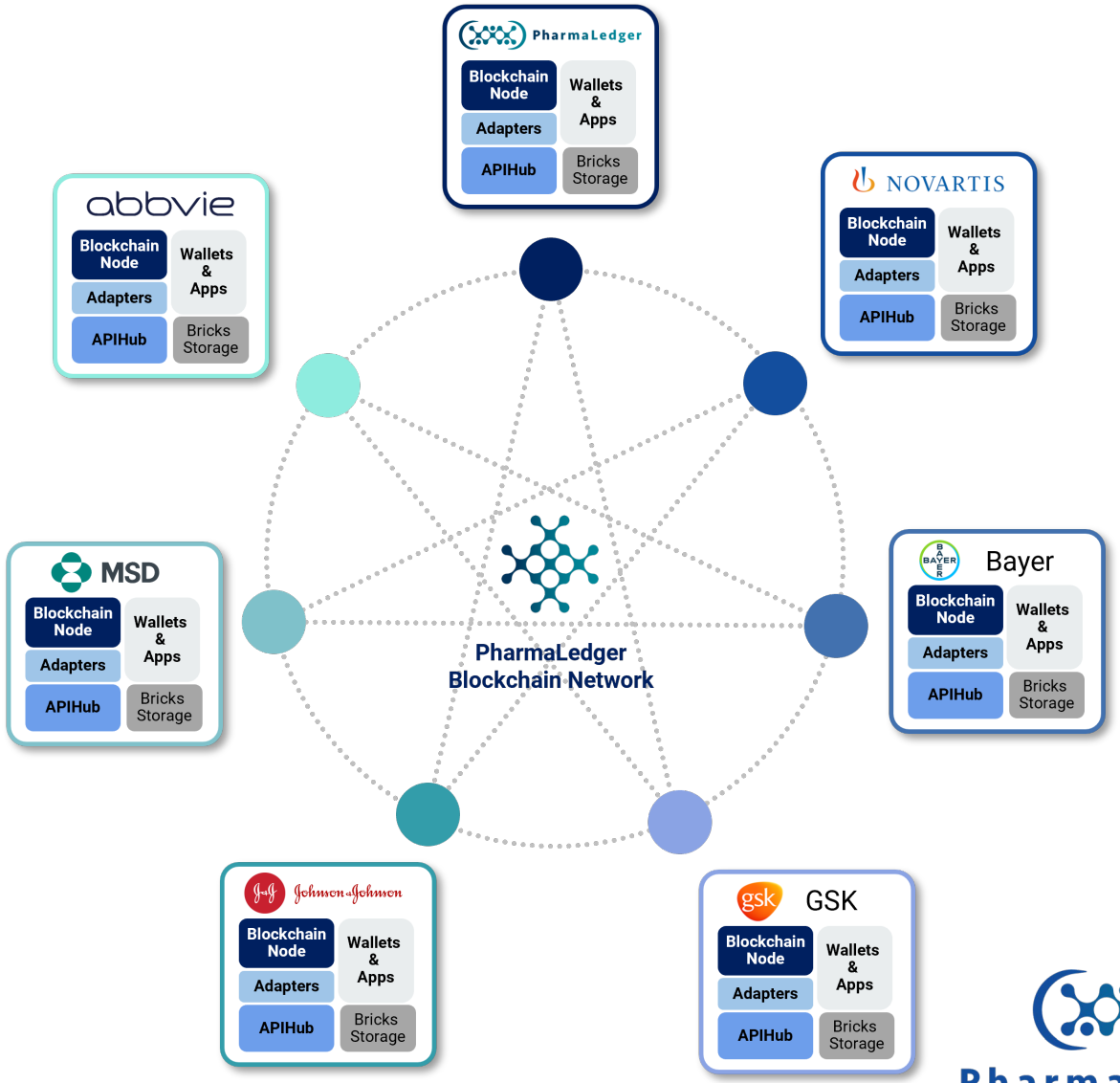
# PharmaLedger PLATFORM ARCHITECTURE: Underpins a trusted dataspaces

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

PharmaLedger is an enabling platform for trusted data management

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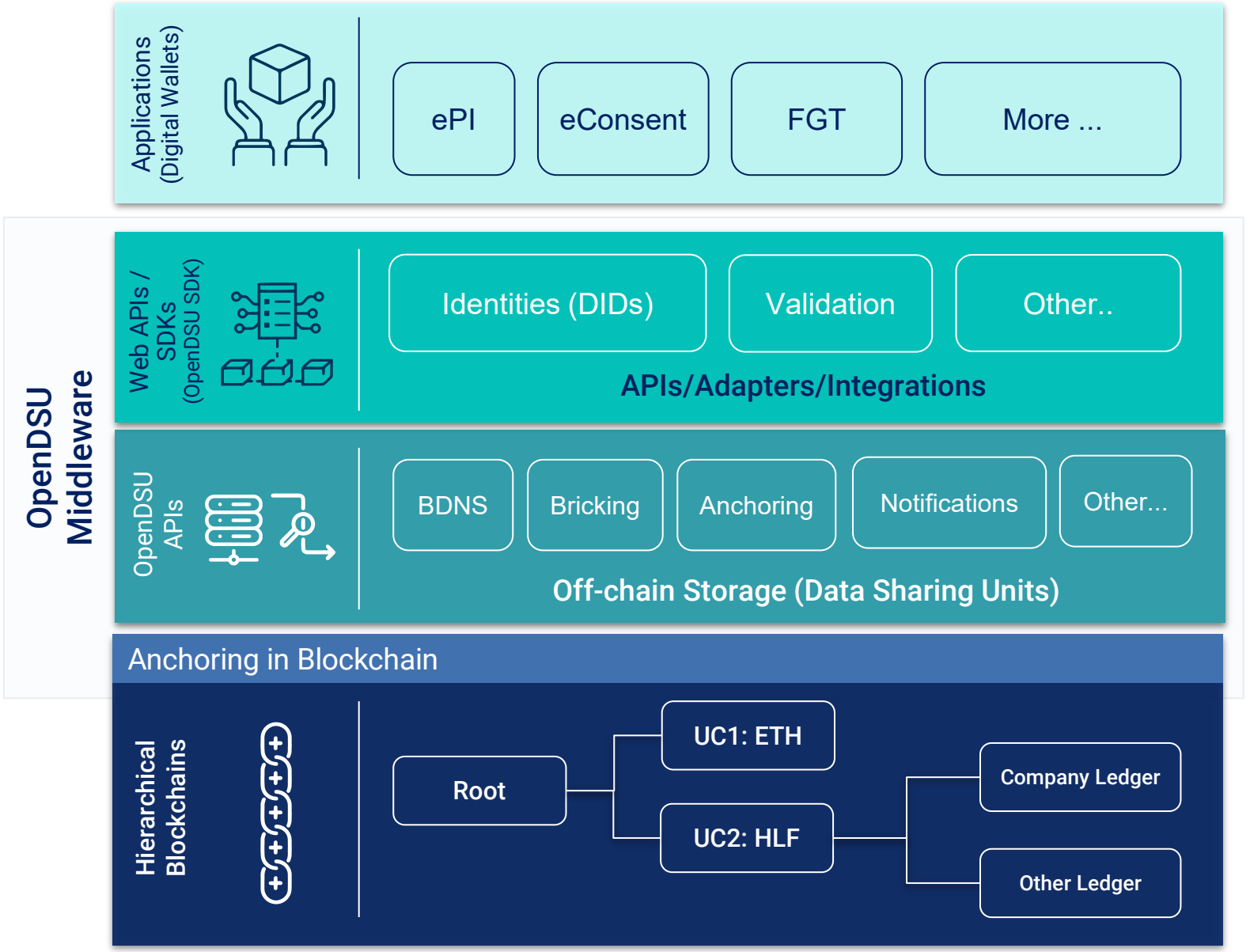
# PHARMALEDGER
# PLATFORM OVERVIEW




**Applications** — Use Cases

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

**Integration** — APIs, Adapters etc.

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

**DSU** — Data Sharing Units

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

**Anchor** — Hashlinks, Versions

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

**Blockchain** — Hierarchical Blockchains

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

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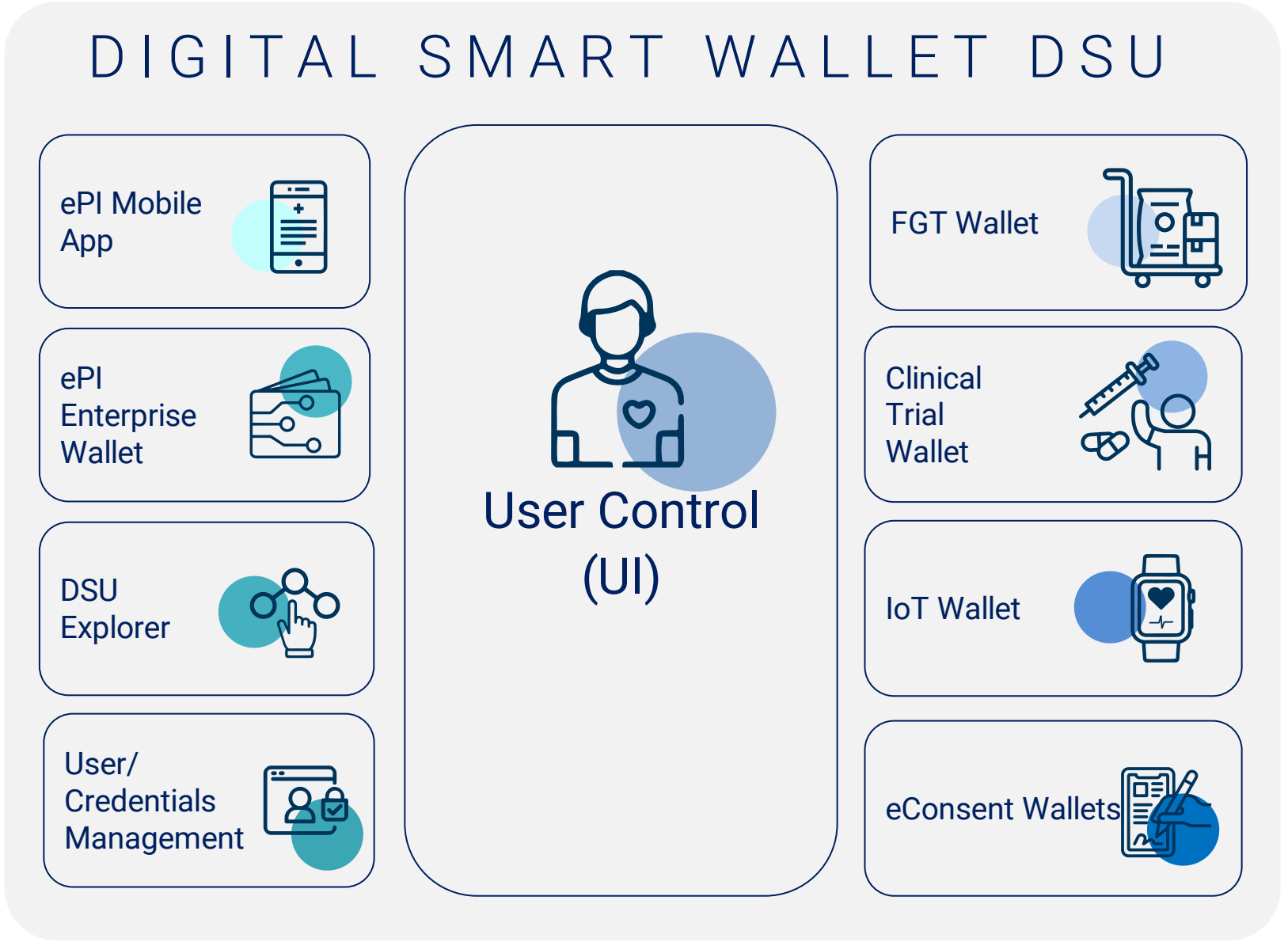
# THE VISION OF THE OPENDSU **SMART WALLETS**

**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

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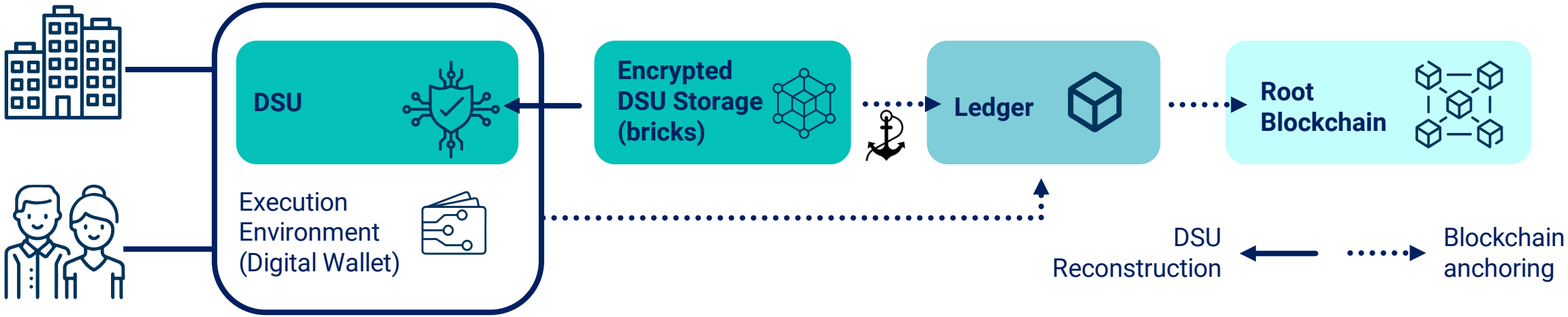
# Generic approach for **all use cases**

- 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

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# 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 = $\Sigma$ 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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# USE CASES VIEW

**Clinical Trial eRecruitment**

Anonymized matching of patients to clinical trial inclusion and exclusion criteria

**Clinical Trial eConsent**

Auditable, version-controlled, real-time and immutable Informed Consent Form

**Clinical Supply**

Trusted Tracking of investigational medicine distribution to the patient

**Finished Goods Traceability**

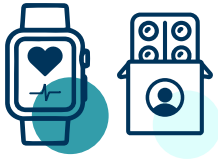
Visibility of commercial product inventory for replenishment and recall notifications

**ePI Electronic Product Information**

Latest approved product information for all manufacturers in one app

**Anti-Counterfeiting**

Multi-factor Packaging Authentication and data analytics



**Medical Device IoT & Personalized Medicines**

Dynamic acquisition & real-time data processing for patients

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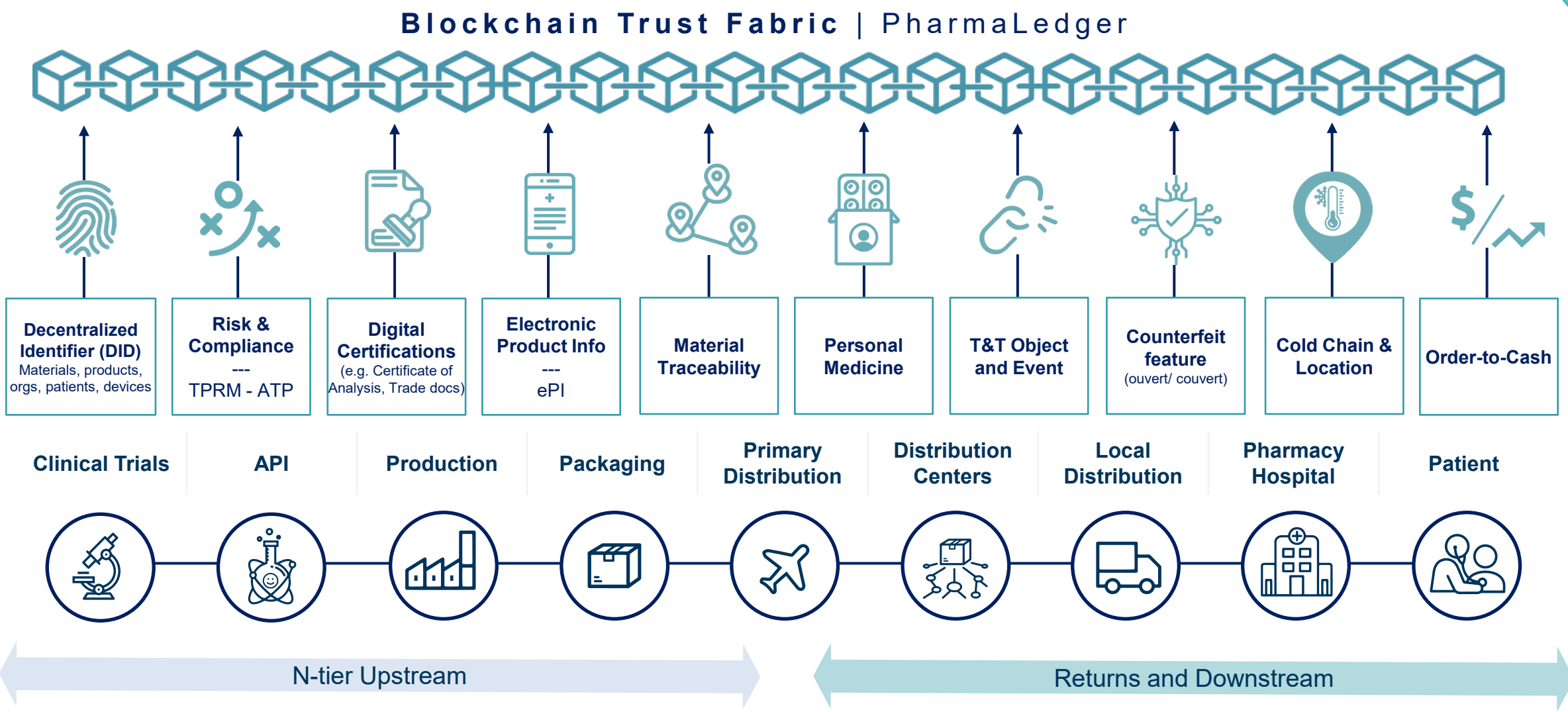
# END TO END **SUPPLY CHAIN TRACEABILITY** MODEL

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# END TO END **SUPPLY CHAIN TRACEABILITY** MODEL

PTM

**Pharmaceutical Traceability Model**

**Decentralized Applications (DApps)**

**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 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 **HEALTH DATA MARKETPLACE** MODEL

PTM

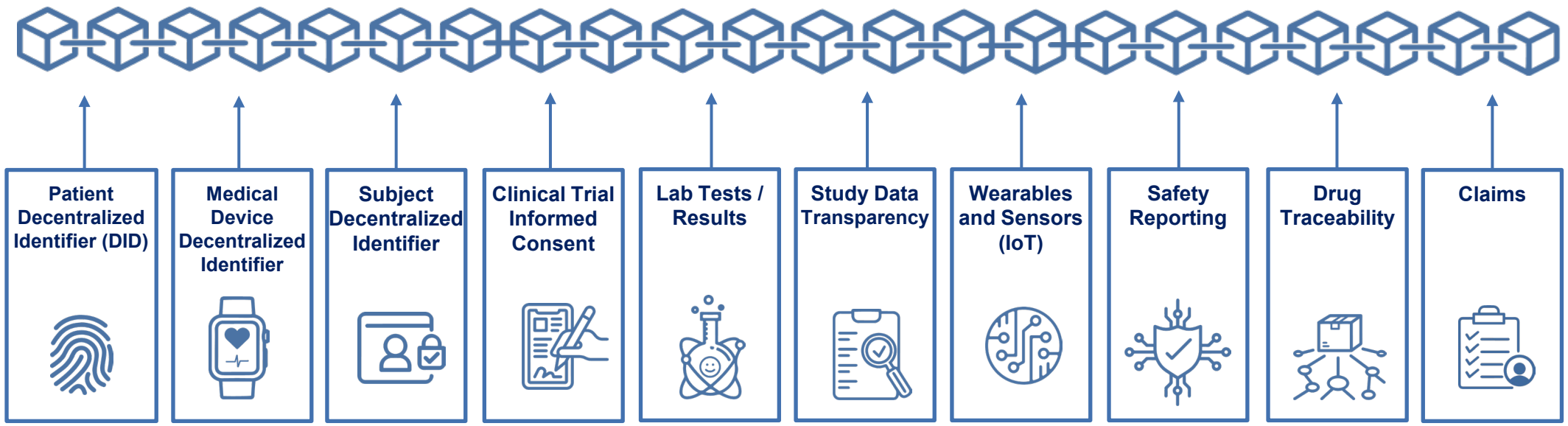
**Health Data Marketplace**

**Decentralized Applications (DApps)**

## 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

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# END TO END **CLINICAL TRIALS** MODEL

PTM

**Health Data Marketplace**

**Decentralized Applications (DApps)**

**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**

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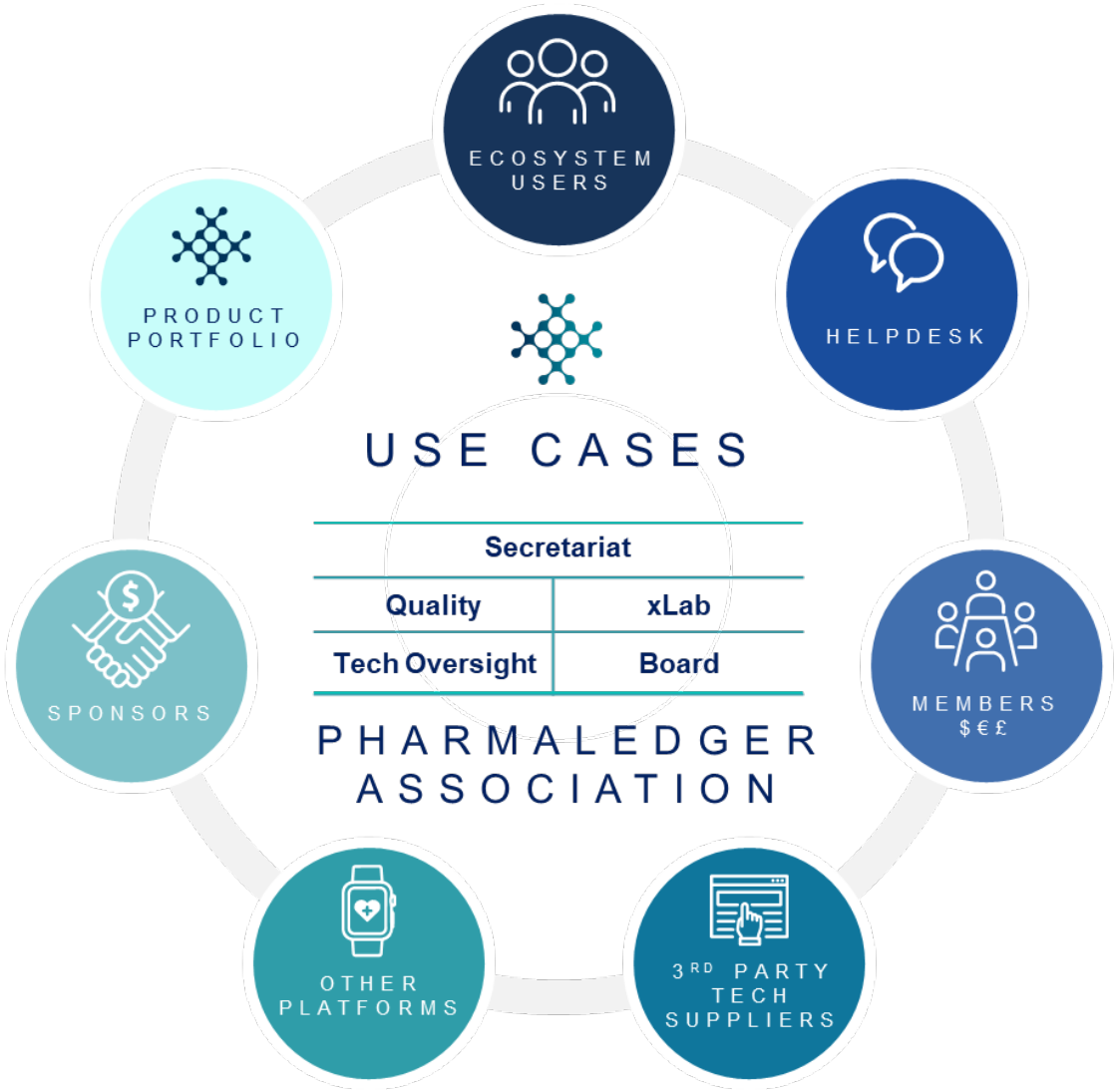
# PHARMALEDGER ASSOCIATION BEING CREATED




- 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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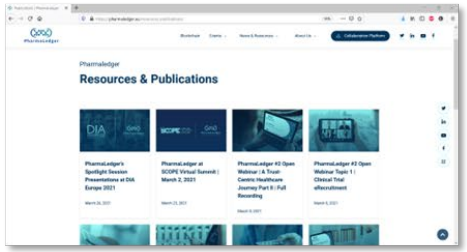
# STRATEGIC ROADMAP

| | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 |
|---|---|---|---|---|---|---|
| 3RD PARTY ENGAGEMENT | Outreach & Training | Solution qualification | Launch of 3rd Party Products | | | |
| PRODUCTS | Qualification | ePI Launch | ePI enhancement and operation | | | |
| | | Anti-Counterfeiting | | | | |
| | | Finished Goods Traceability and Clinical Supply Chain | | | | |
| | | Cinical Trial Recruitment, eConsent, IoT and Personalized Medicine | | | | |
| PLATFORM | Version 1.0 Deployment | Version 2.0 for multiple products | Version 3.0 for 3rd Party Products | Continuous platform enhancement | | |

# JOIN US ON THIS JOURNEY

[www.pharmaledger.eu](http://www.pharmaledger.eu)

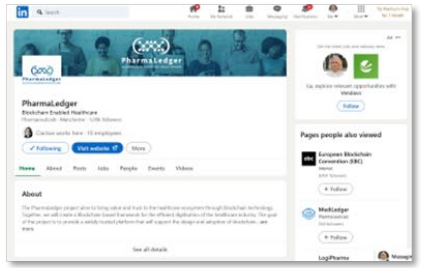
Contact: Maria Eugenia BELTRÁN (me.beltran@lst.tfo.upm.es)




Website

Newsletter

Webinars

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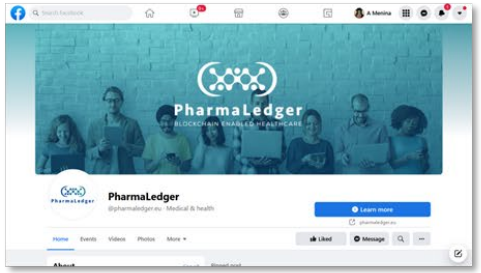


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