

# PharmaLedger

## BLOCKCHAIN ENABLED HEALTHCARE

Trusted healthcare  
enabled dataspaces:  
*the PharmaLedger use  
cases*



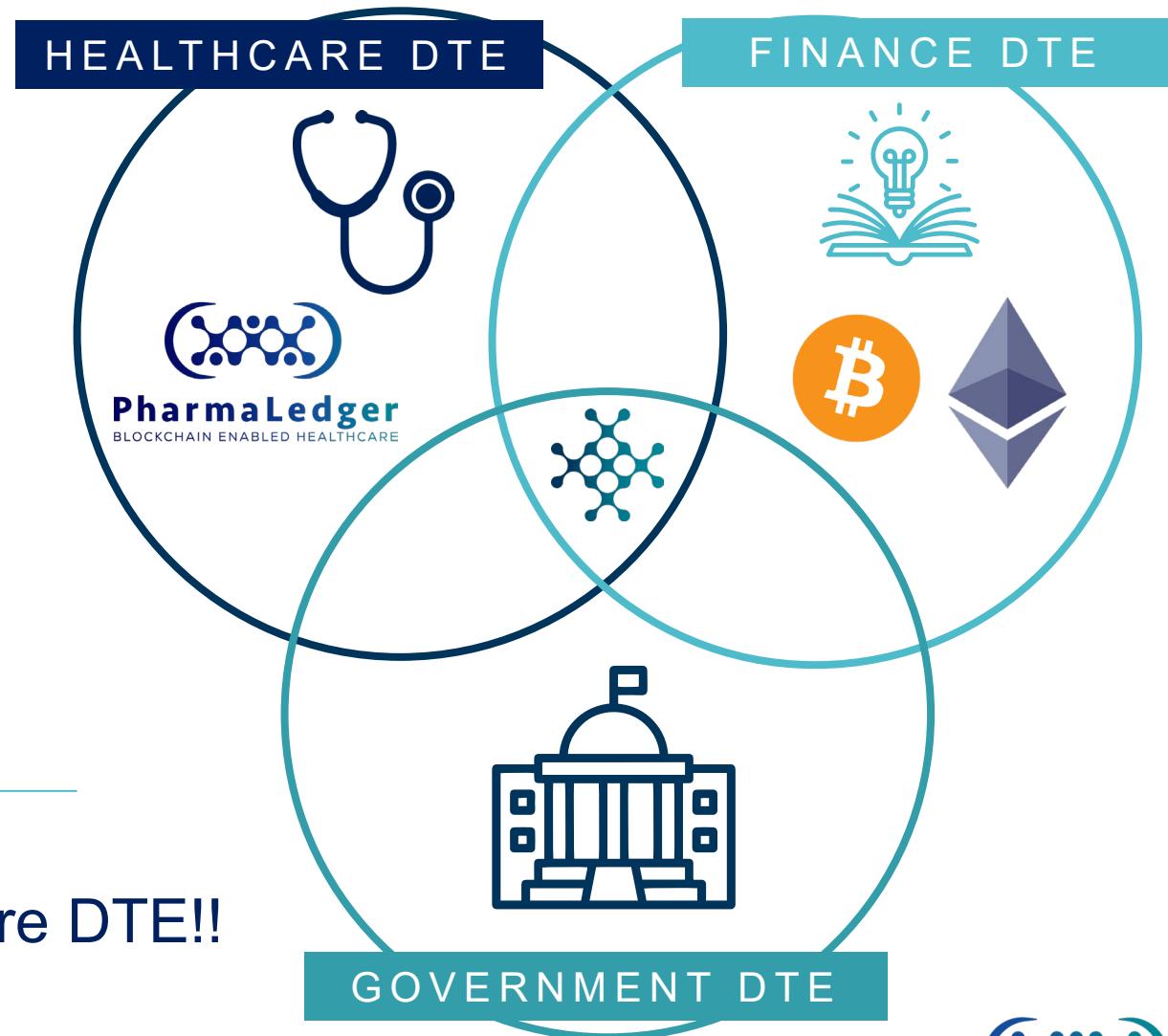
**IoT Week**  
**UPM – Giuseppe FICO / Ma. Eugenia BELTRAN**

# 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!!**



**PharmaLedger**

# PHARMALEDGER IN A NUTSHELL

## WHO ?

Pharmaceutical companies, hospitals, universities, patient organizations, tech companies... **building an ecosystem!**

## WHY ?

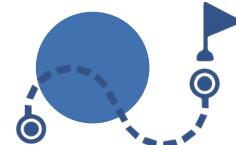
To **empower patients**, increase **digital trust**, enable medicine drug traceability and **data privacy**, and foster a **new culture of collaboration in healthcare**.

## 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

NOVARTIS

POLITÈCNICA

PDM

Arteeko

RomSoft

Ekon

TECHNOACTIVE SOLUTIONS

CERTH  
CENTRE FOR RESEARCH & TECHNOLOGY HELLAS

AstraZeneca

gsk

MSD

Pfizer

ucb  
Inspired by patients.  
Driven by science.

Boehringer Ingelheim

Onopach

Uniklinikum Würzburg UK

Hospital do Espírito Santo E.P.E.

INCM  
IMPRESA NACIONAL CASA DA MOCADA

EF CCP

KU LEUVEN CITIP



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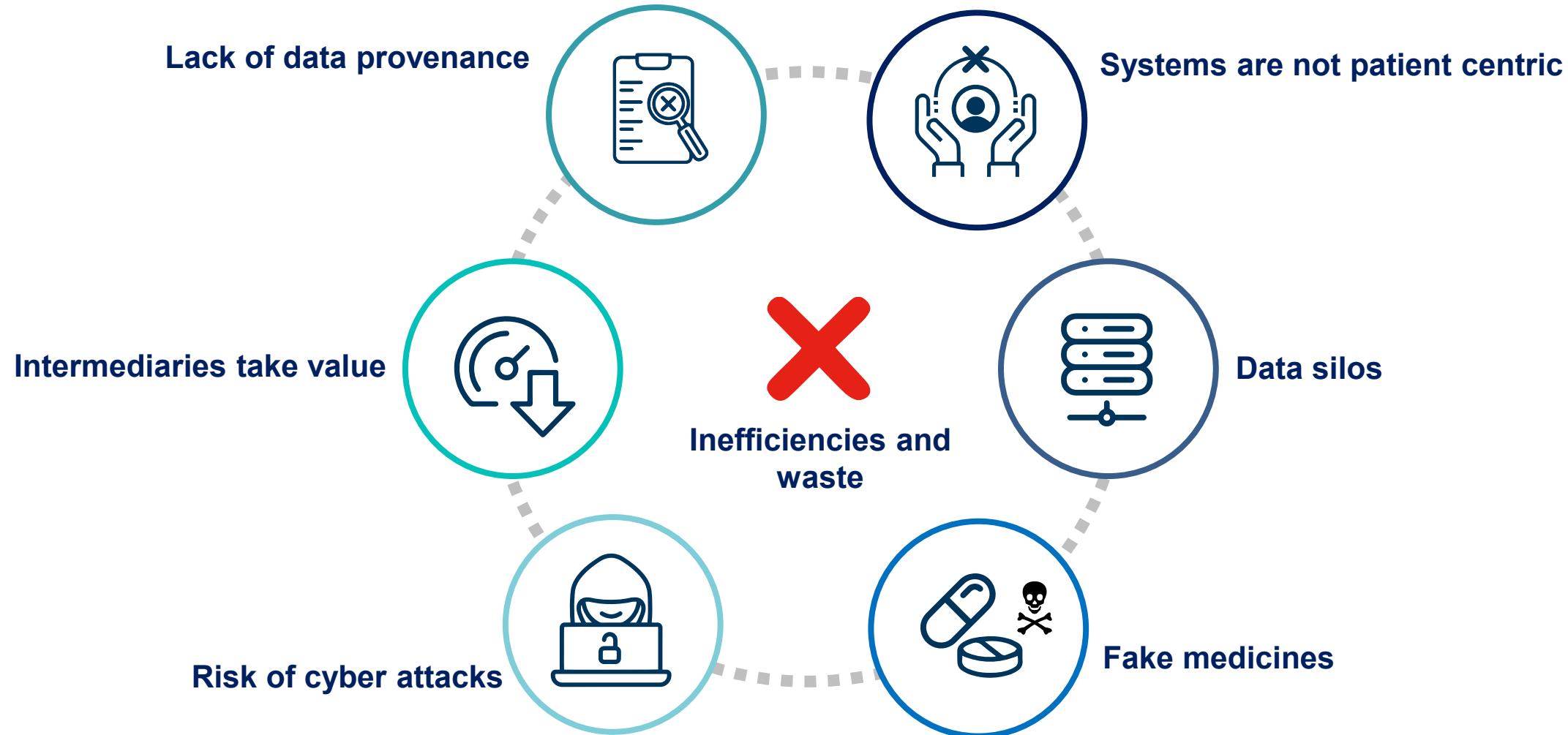
# PharmaLedger

## THE PHARMALEDGER CONSORTIUM

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

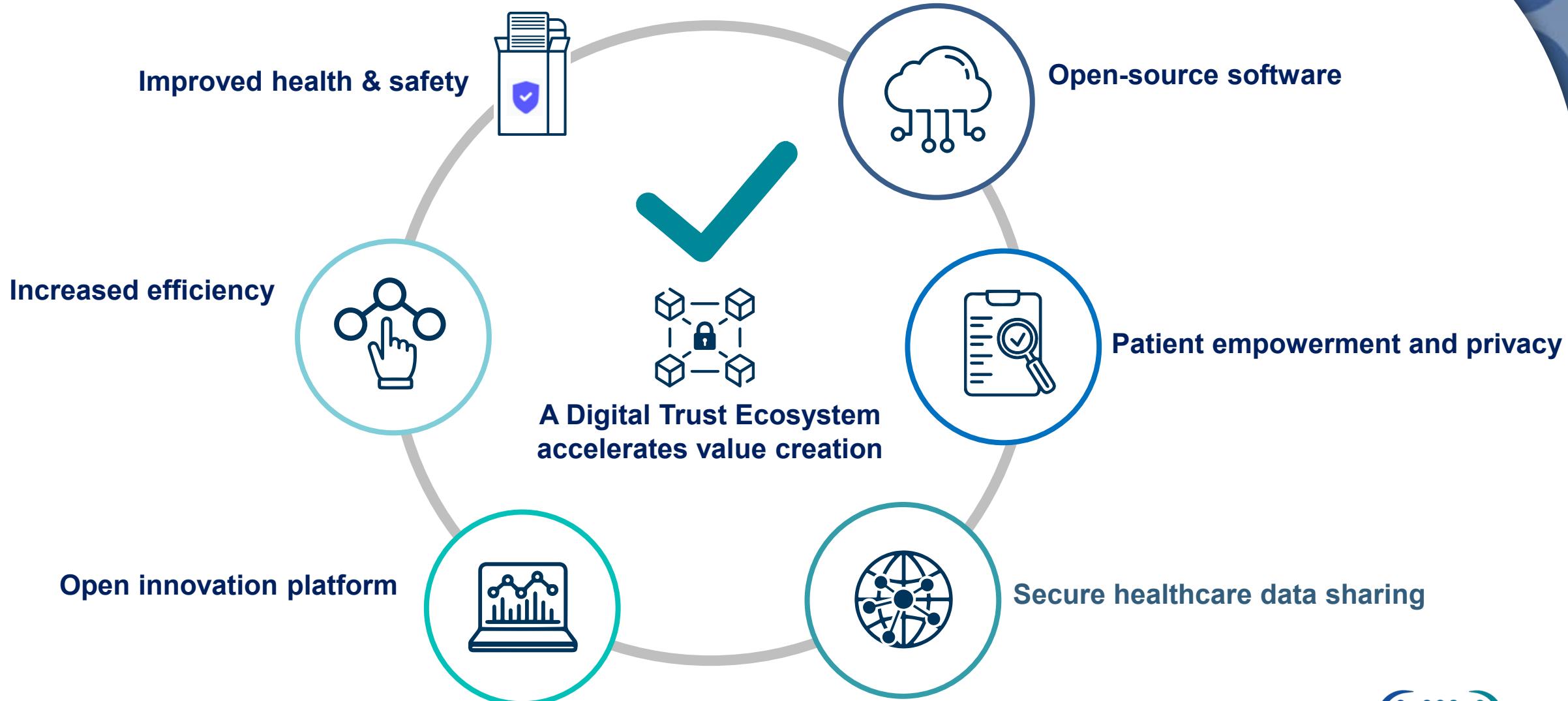


# THE BIG PROBLEM (WHY PHARMALEDGER)



**PharmaLedger**

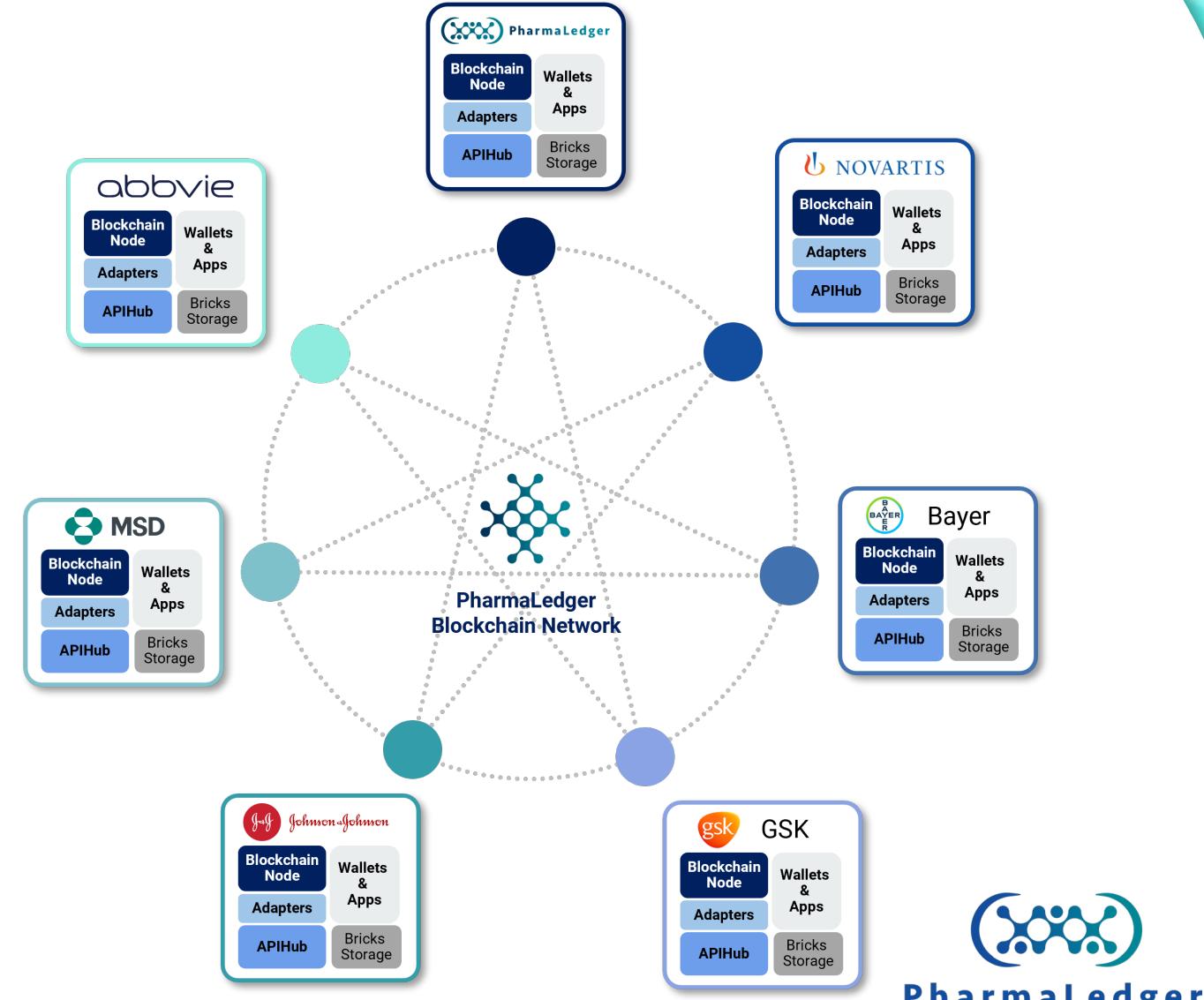
# THE OPPORTUNITY (VISION)



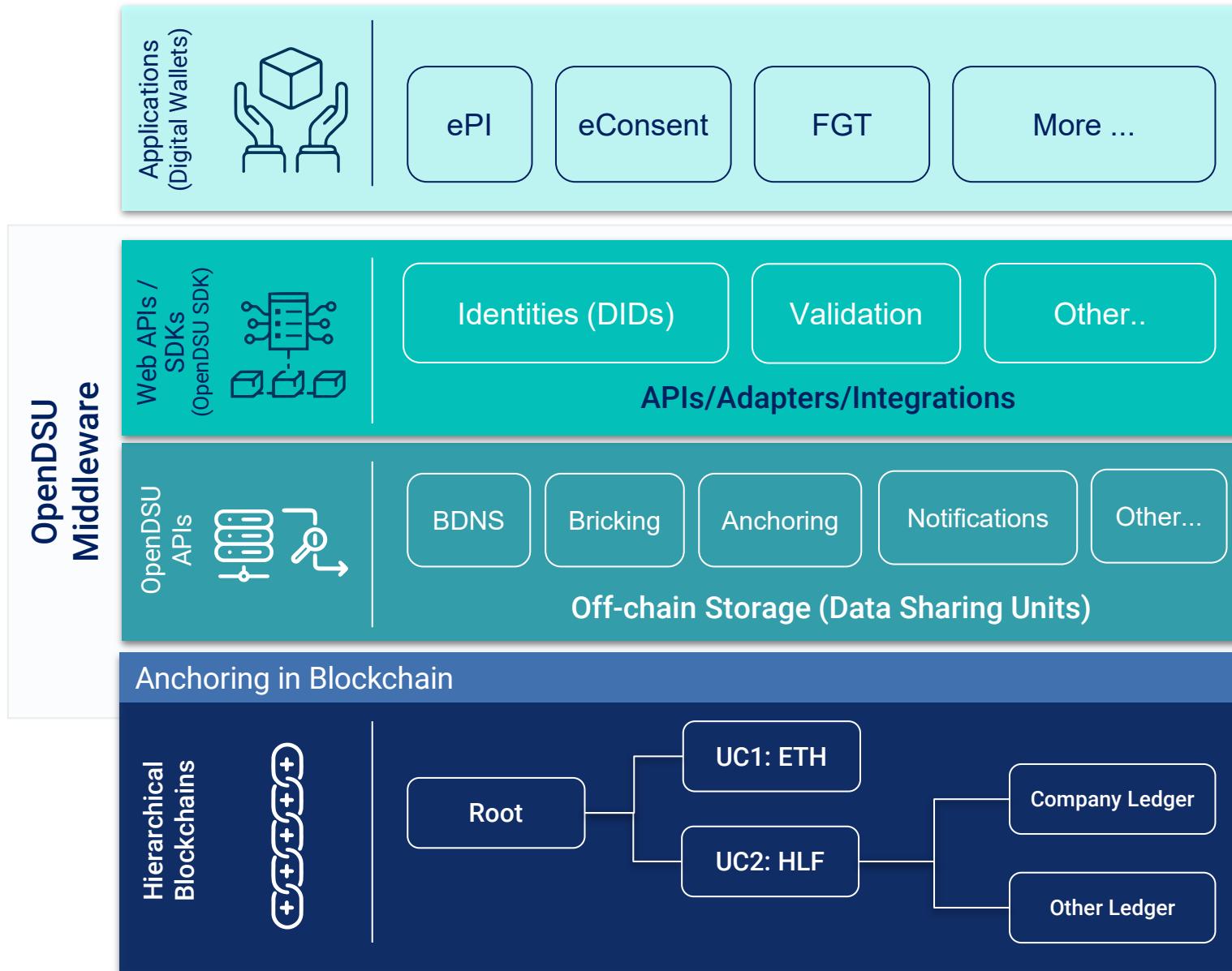
# PharmaLedger PLATFORM ARCHITECTURE: Underpins a trusted dataspaces

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

PharmaLedger is  
an enabling  
platform for trusted  
data management



# PHARMA LEDGER 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

## D S U 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

# THE VISION OF THE OPENDSU SMART WALLETS

## DIGITAL SMART WALLET DSU

**Dynamic, interoperable  
and portable Digital Wallet**

Stored in DSUs

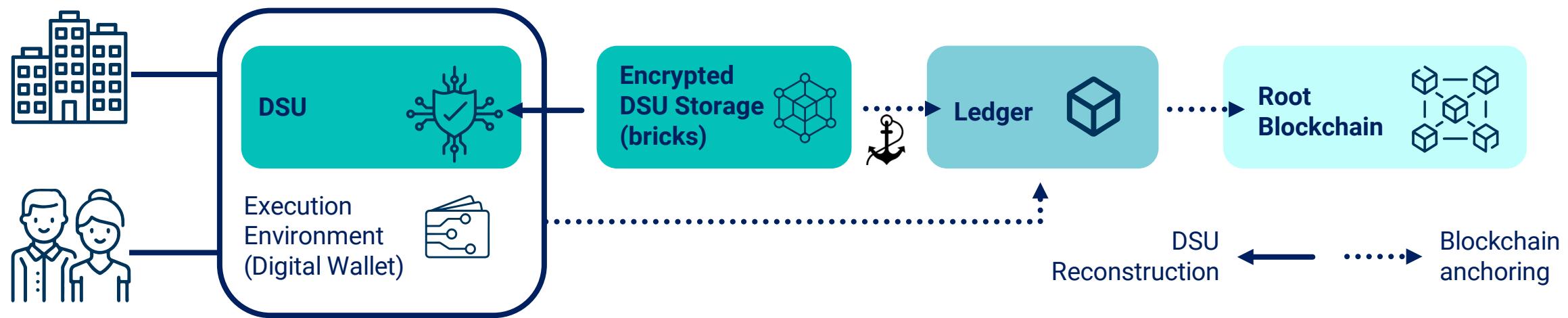
Customizable to the needs  
of the users (individuals  
and companies) : Contain  
DSU embedding SSApps

Supports any device such  
as smartphones,  
wearables, browsers



## 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

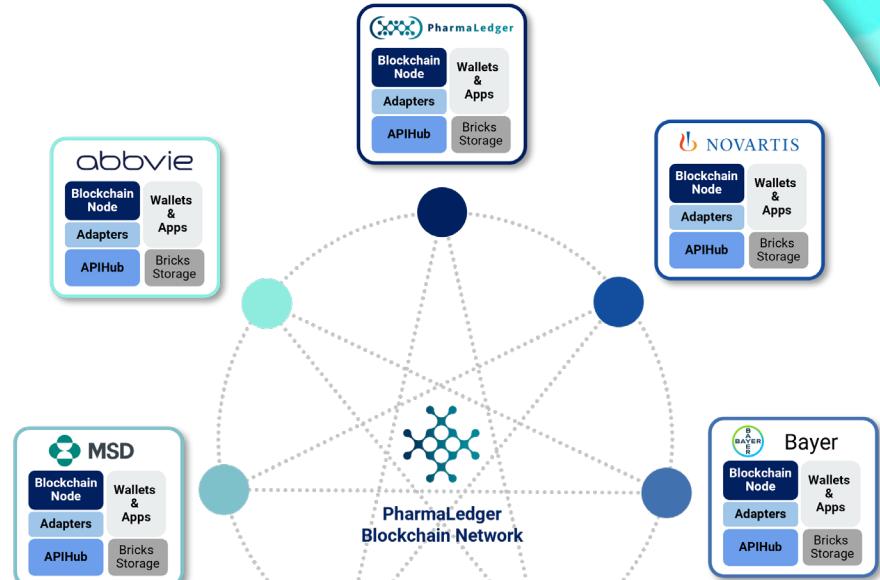


Defining an **open standard** for handling off-chain storage to achieve a **single standard** for interoperability:  
Digital Wallets, Encrypted Data Vaults, Decentralised Key Management Systems, Cloud and Edge Agents



# 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 =  $\Sigma$  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



PharmaLedger

# USE CASES VIEW



Clinical Trial  
eRecruitment



Clinical Trial  
eConsent



Clinical Supply



Finished Goods  
Traceability



ePI  
Electronic  
Product  
Information



Anti-  
Counterfeiting



Medical Device  
IoT &  
Personalized  
Medicines

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

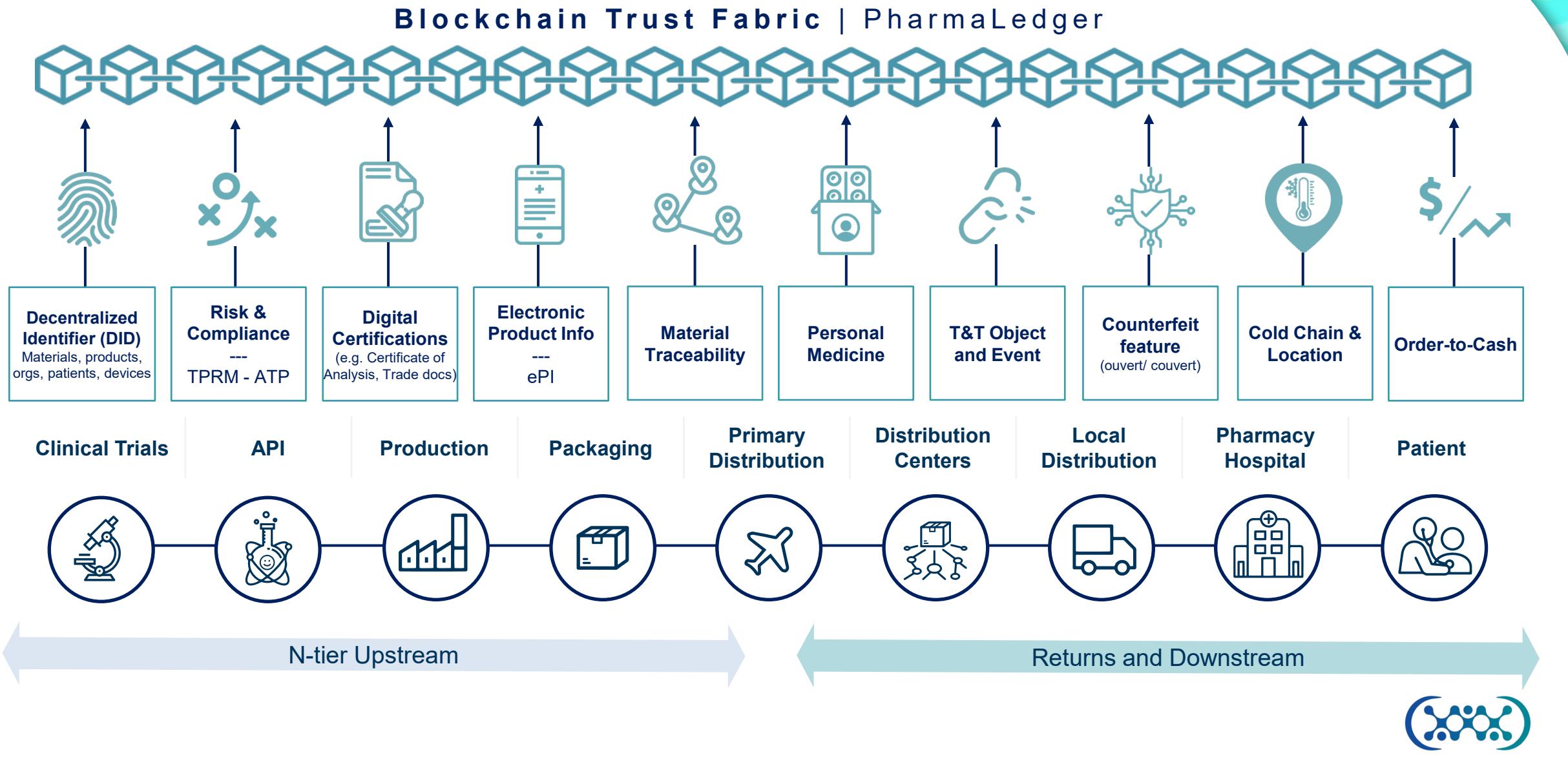
Multi-factor Packaging Authentication and data analytics

Dynamic acquisition & real-time data processing for patients

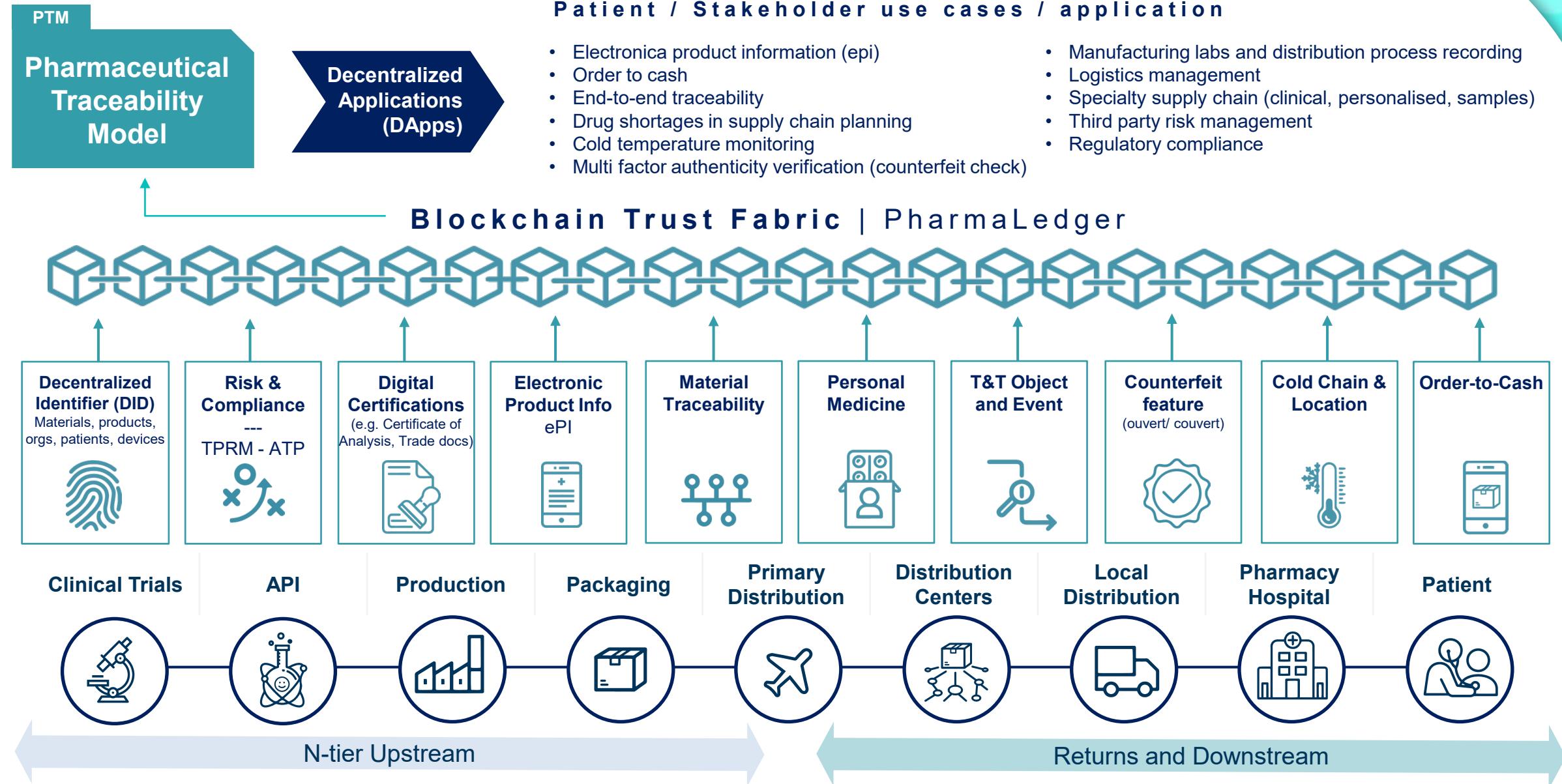


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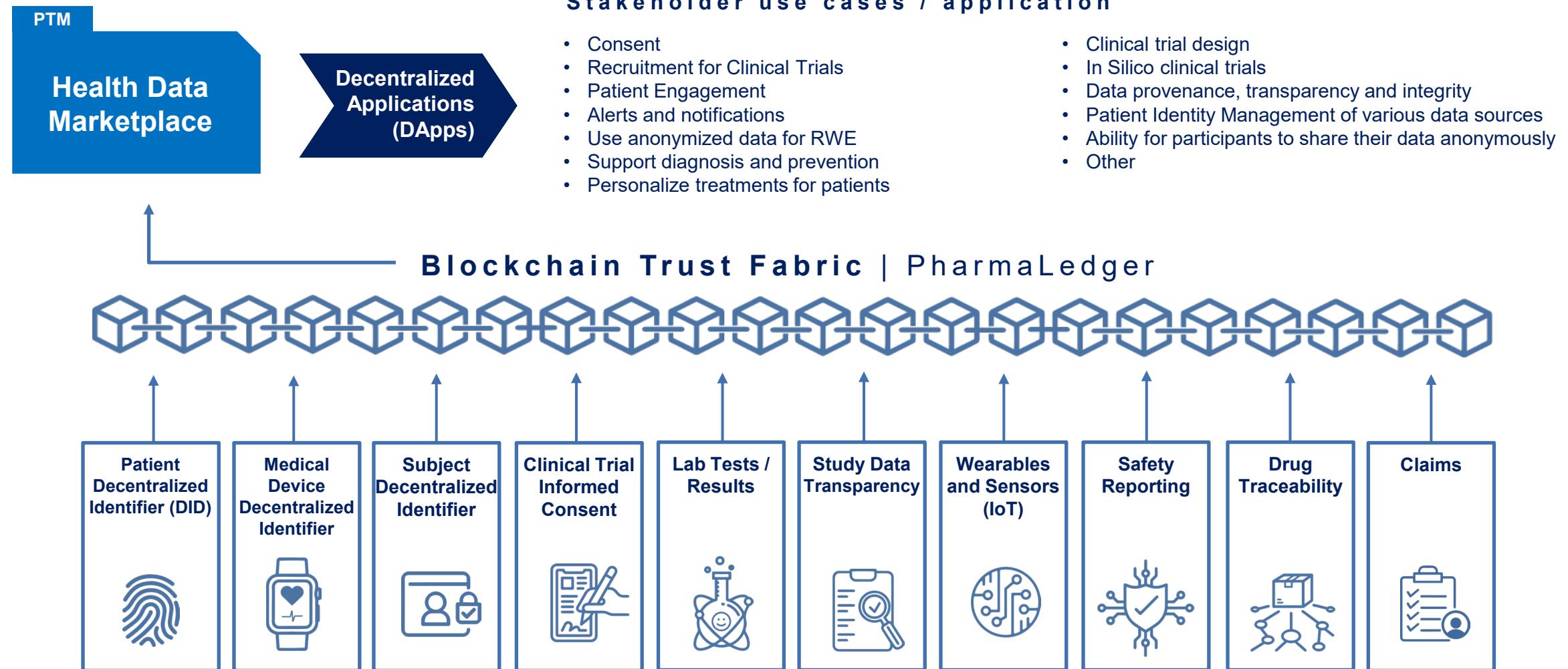
# END TO END SUPPLY CHAIN TRACEABILITY MODEL



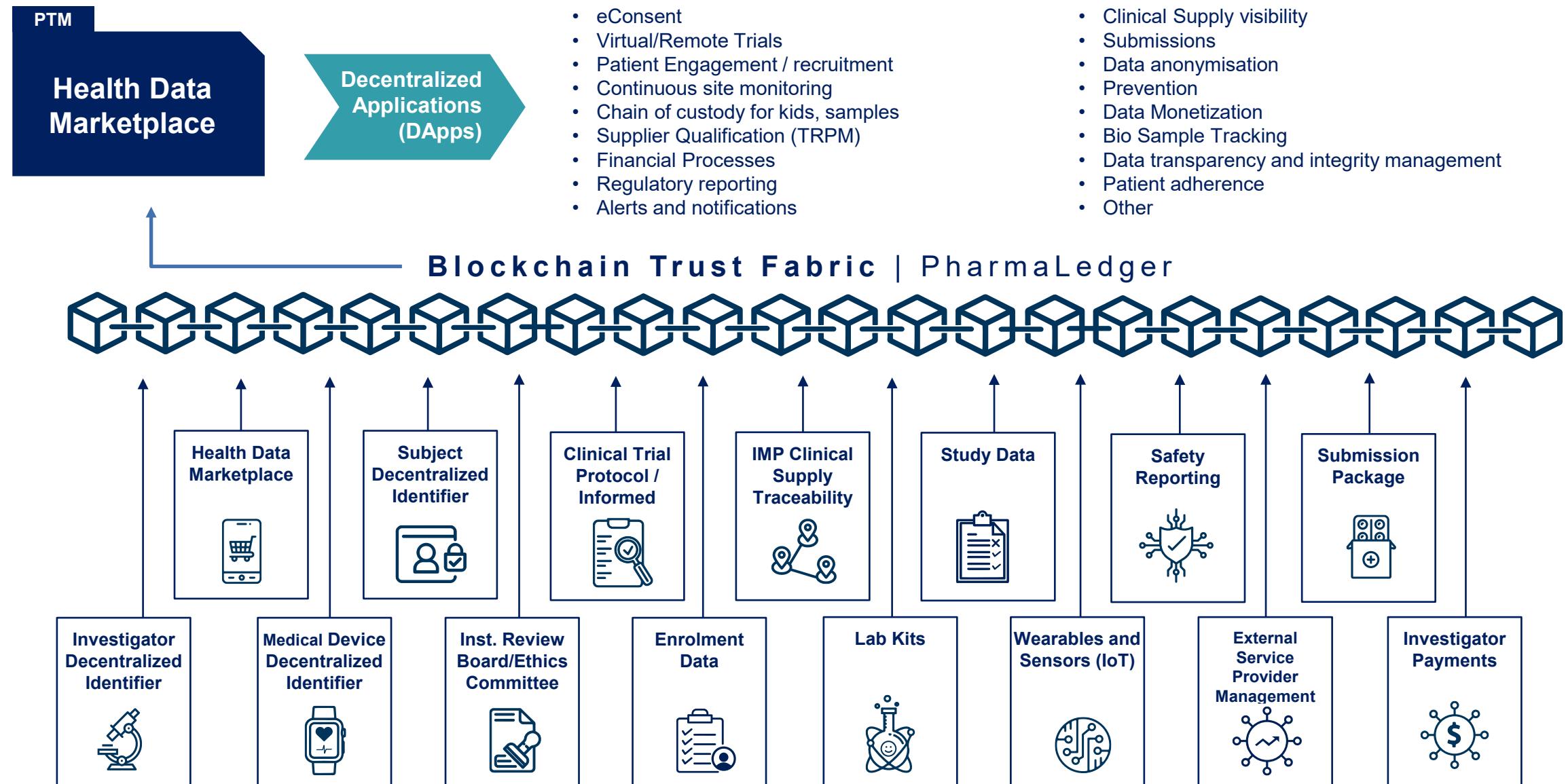
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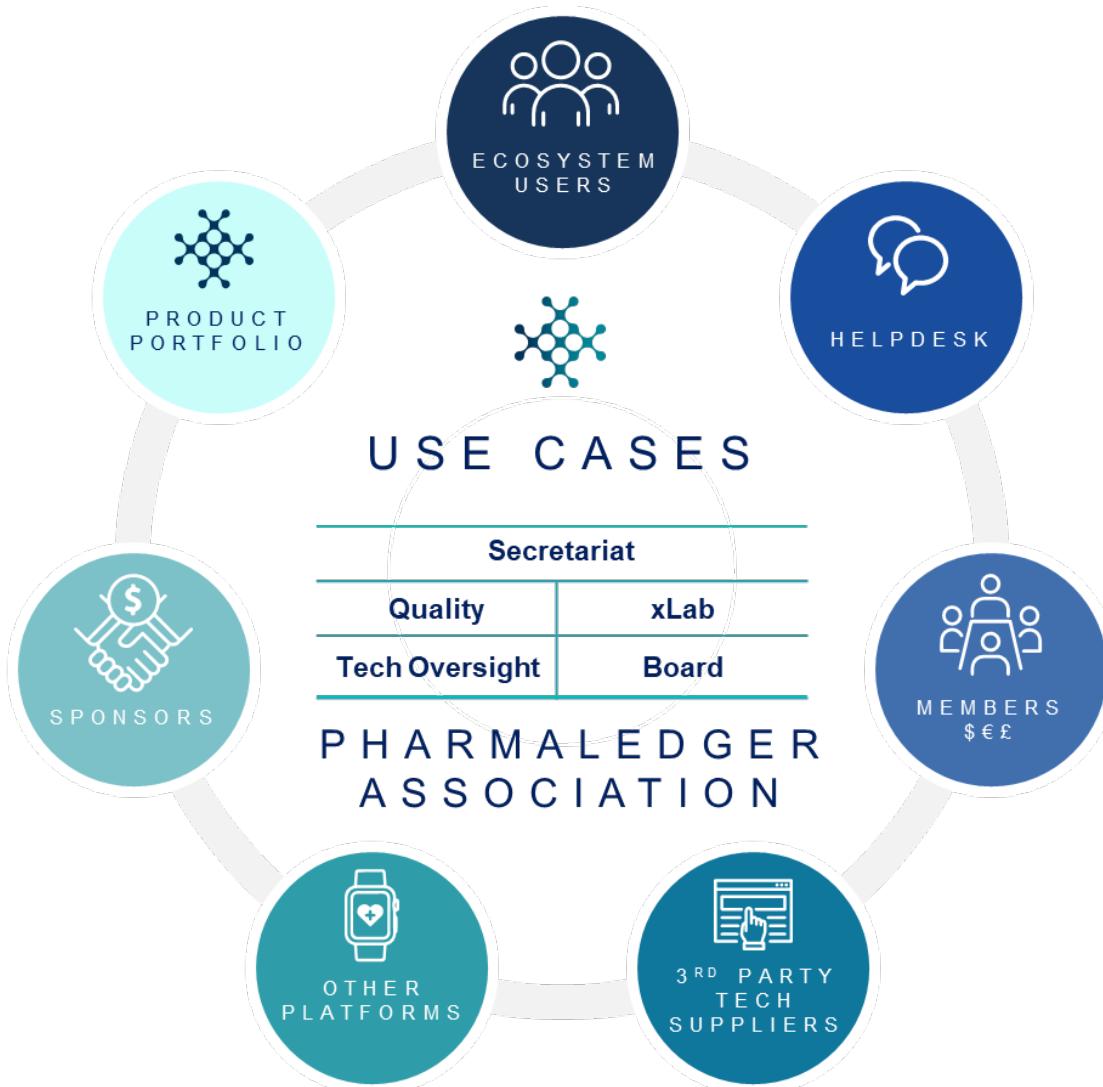
# END TO END HEALTH DATA MARKETPLACE MODEL



# END TO END CLINICAL TRIALS MODEL



# PHARMALEDGER ASSOCIATION BEING CREATED

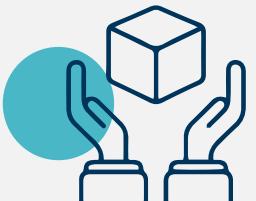
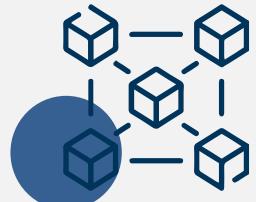


- DTE with sovereign dataspaces to support new and innovative services and business processes for a healthcare DTE including private companies and industries as well as academic, governmental and NGO amongst other organizations
- Ensuring privacy, ownership and control of data through data sovereignty
- Secure datasharing
- Validated and tested software, qualified for HealthCare organizations



**PharmaLedger**

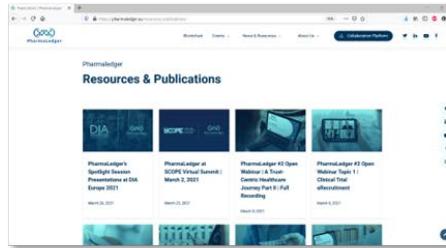
# STRATEGIC ROADMAP

3RD PARTY ENGAGEMENT	2022	2023	2024	2025	2026	2027
	Outreach & Training	Solution qualification	Launch of 3rd Party Products			
	ePI Launch	ePI enhancement and operation	Anti-Counterfeiting	Finished Goods Traceability and Clinical Supply Chain	Clinical Trial Recruitment, eConsent, IoT and Personalized Medicine	
	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)

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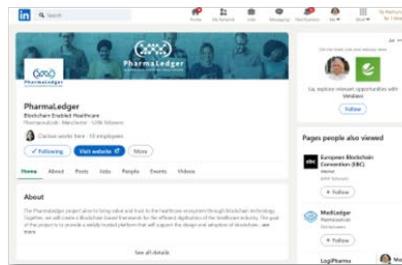
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PharmaLedger

# THANK YOU



Inspired by patients.  
Driven by science.



CENTRE FOR IT & IP LAW



Uniklinikum  
Würzburg



Hospital do  
Espírito Santo E.P.E.



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