



Project spotlight



PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

Project funded by



innovative
medicines
initiative



efpia

Project spotlight



PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

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AGENDA

1. Introduction to the PharmaLedger project
2. Use case 1: electronic Product Information (ePI)
3. Use case 2: electronic Consent (eConsent) for clinical trials
4. Next steps: PharmaLedger Association
5. Closing remarks

Project spotlight



PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

Project funded by



Meet the speakers



Maria Eugenia (Xenia) Beltran

*Head of Big Data LifeSTech &
PharmaLedger Project Coordinator*

Universidad Politécnica De Madrid



Marco Cuomo

Director Tech Products & Innovation

Novartis



Daniel Fritz

Executive Director

PharmaLedger Association



Colm Carroll

Scientific Project Manager

Innovative Health Initiative
Event Moderator



PharmaLedger

BLOCKCHAIN ENABLED HEALTHCARE

A DIGITAL TRUST ECOSYSTEM FOR HEALTHCARE

IHI PROJECT SPOTLIGHT: PharmaLedger



Blockchain is a team sport ...



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PharmaLedger

BLOCKCHAIN ENABLED HEALTHCARE

The PharmaLedger Project & Blockchain

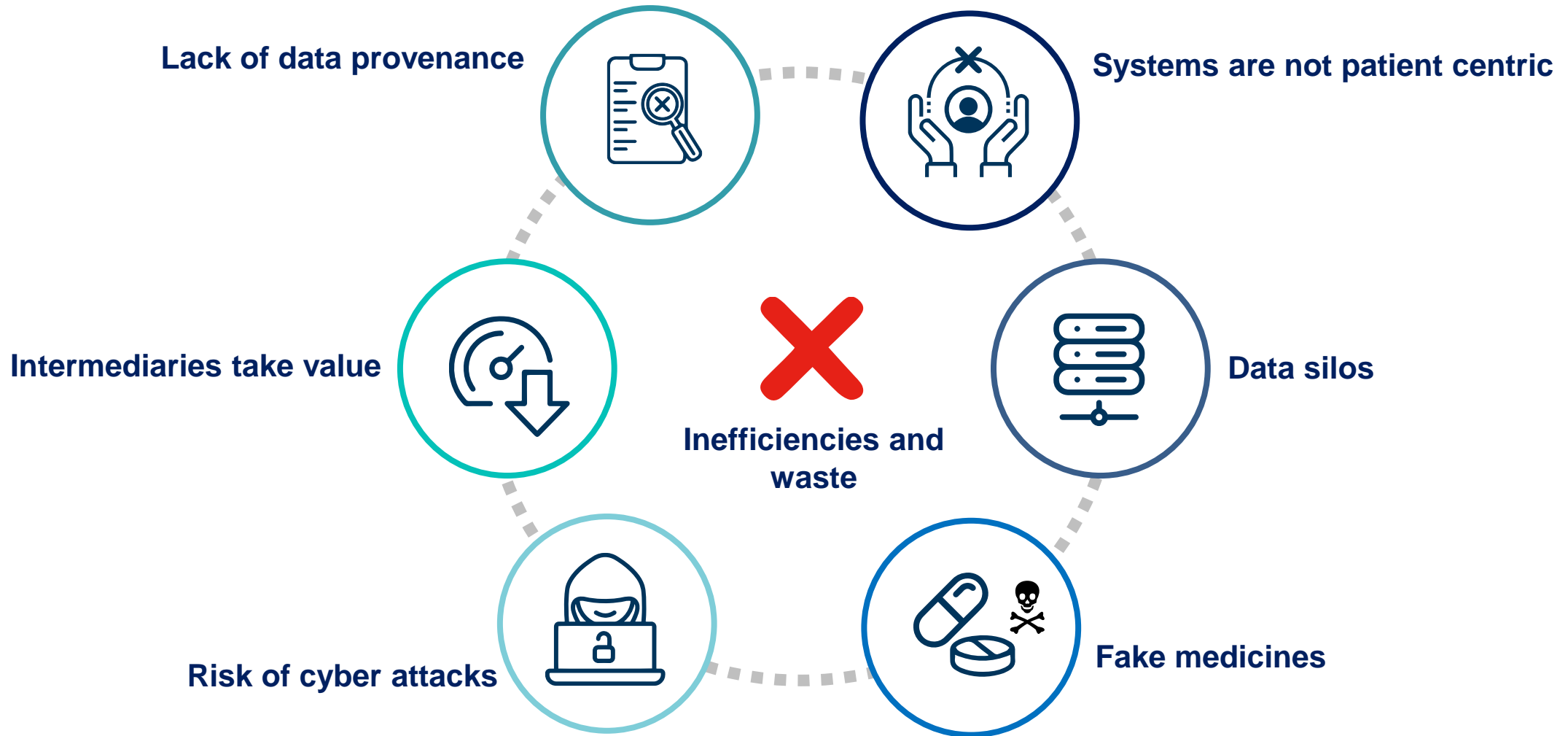
IHI PROJECT SPOTLIGHT: PharmaLedger



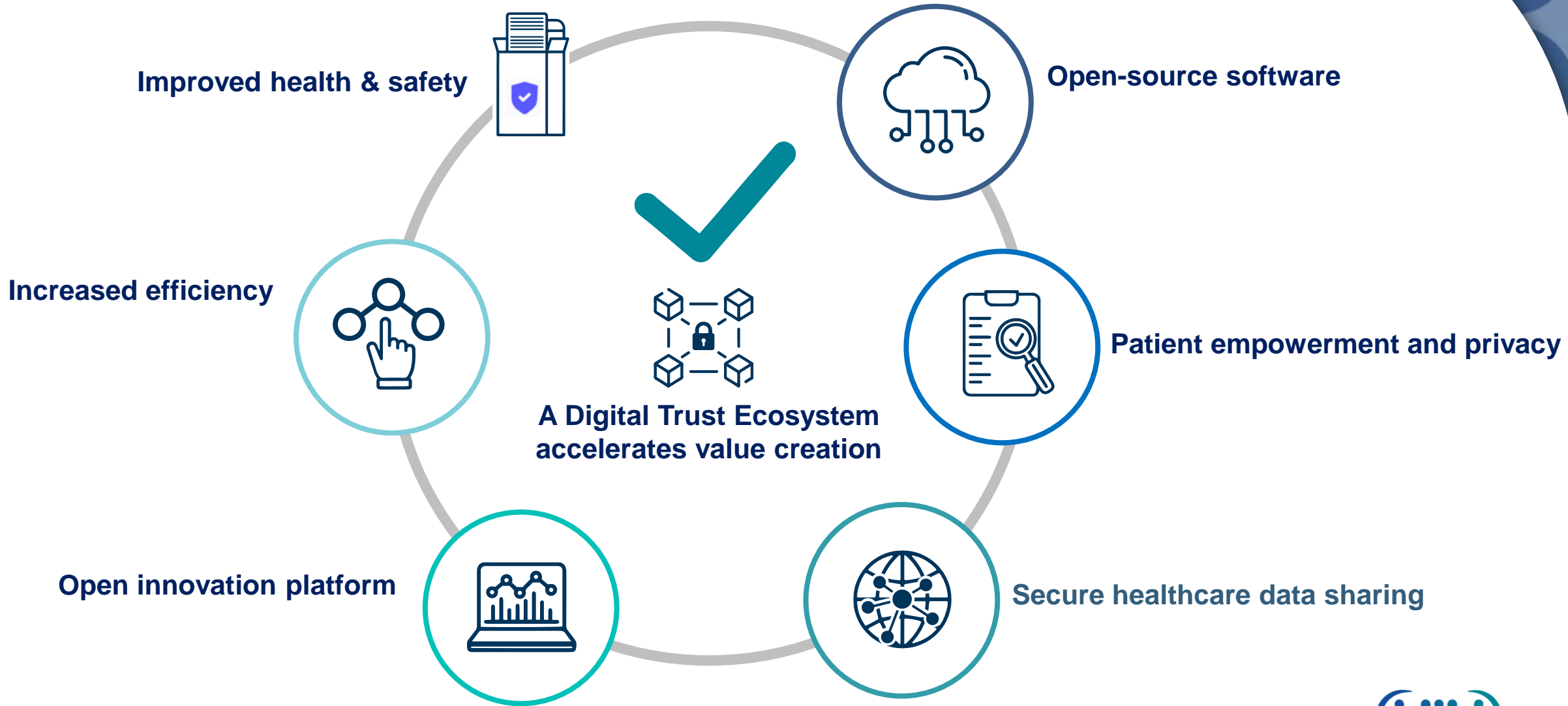
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THE BIG PROBLEM (WHY PHARMALEDGER)



THE OPPORTUNITY (VISION)



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



PharmaLedger



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PharmaLedger: Shared Story



In preparation before
the project

2018

Novartis on behalf of Industry submitted the topic in April 2018

Applicants submitted proposal- October 2018

1ST Stage Evaluation – November 2018

CHRISMAS Present by PO → Dec. 24th 2018



Set up 2nd Stage-
From Call to Grant Award

2019

KOM 2nd Stage–January 29-30th 2019
Industry & Applicants Meet

WP Leaders meet in Madrid April 2019

Work together as FULL consortium to
submit 2nd Stage in May 2019

Review, Hearing (BRU) & Approval
Jun-July 2019

Lot of effort for the Consortium Agreement
(CA) to sign the Grant Agreement by
December 2019



Project
LAUNCHING

2020

Official Project start: 01-01-2020

Project Kick off Meeting (KOM)

14th – 15th January 2020
Cubex Centrum, Prague

PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE



PharmaLedger

FOLLOWED BY A FULL CONSORTIUM & ROADMAP



Year 1 Design & Foundations	Year 2 Development & Deployment	Year 3 Validation & Sustainability
2020	2021	2022

- 1 • PharmaLedger Kick-Off
- Use-case evaluation and selection
- Use-case specification
- Marketing & Engagement: pharmaledger.eu
- Legal requirements' framework
- Platform Design and Development
- Governance & Operating Model evaluation

- 2 • Application development
- Blockchain platform & API implementation
- Platform Promotion and 3rd Party engagement
- Use-case pilot implementation and demonstration
- Exploitation and sustainability strategy
- Continuous communication and external engagement

- 3 • Application value proposition
- Security assessments
- Implement Governance and Operating Model
- Exploitation planning and ecosystem endorsement
- Documentation and communication of project results
- Transition to PharmaLedger Foundation for post-project governance
- Project close-down





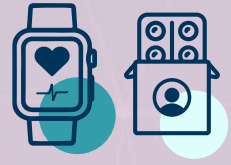
Jan.2020 – July 2021 - Reaching 1st Milestone (Halfway)

- **PROJECT STARTED WITH WP1 + WP3 + WP5 + WP6 and reached 1st Year Milestone in Jan 2021**
- **Getting the PharmaLedger Pillars**
 - Use cases prioritized and specified in first year
 - **8 use cases selected from 88 proposed Use Cases** → ePI accelerated (Industry Alignment for ePI Pilot)
 - Functional requirements + Deep dive visions
 - Creating tech requirements and mock-ups
 - Development of use-case demonstrators started (Tech. Specifications) → **Transition WP1 to WP2**
 - Ethical and Legal Study providing comprehensive evaluation and recommendations
 - Growing recognition and engagement of PharmaLedger in the industry (D&C)
 - Ethics & Advisory Board convened
- **Continuous Technical Developments**
 - Preparing architecture for the PharmaLedger Project (Platform Architecture foundation in place)
 - Introducing DSUs as heart of the architecture
 - Formation of the UC Teams: business + technical Teams (Open DSU training & Development)
 - Training of developers for blockchain and DSUs
 - By half time of the project All UCs presented a demonstrator (different stages)
- **Halfway Plenary Virtual Meeting July 2021 - PharmaLedger celebrates 1.5 years!**
 - Preparation for the Project Review (Nov 16) by IMI

VALUE CHAIN - USE CASES Deployment



July 2021 - December 2022



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

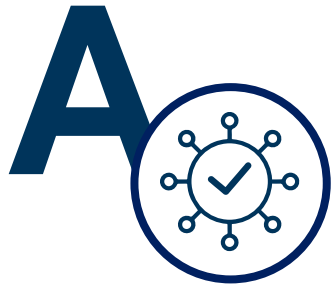
Latest approved
product
information for all
manufacturers in
one app

Multi-factor
Packaging
Authentication and
data analytics

Dynamic
acquisition &
real-time data
processing
for patients

BLOCKCHAIN – THE 5 A’S

Asset



manage assets like
cryptocurrency
(solves the double
spend problem),
products, and data

Audit



immutability, no
changes possible
without consensus

Automate



leverage smart
contracts

Anonymize



protect privacy

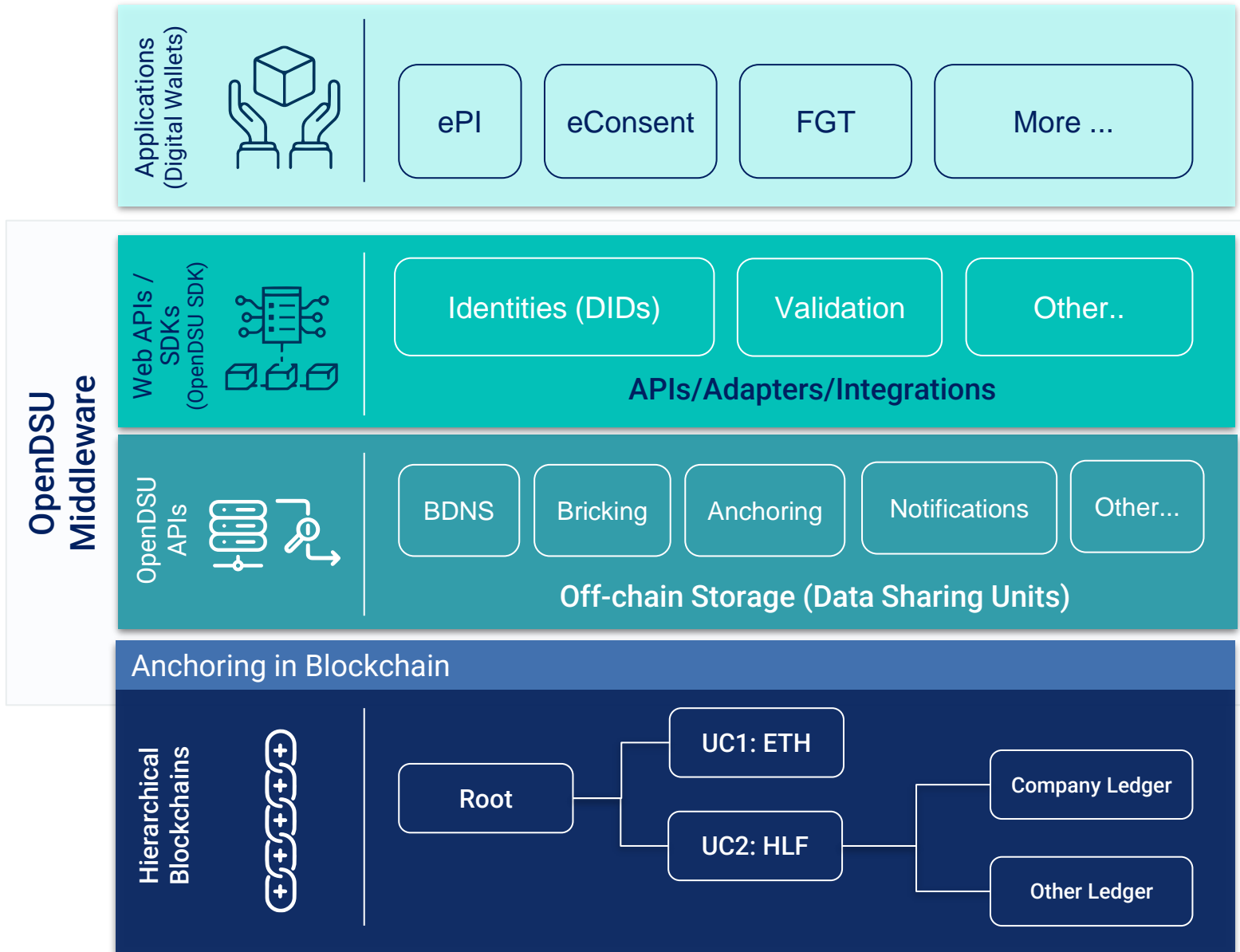
All for one,
one for all



consortium
approach, no
single/central
authority



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

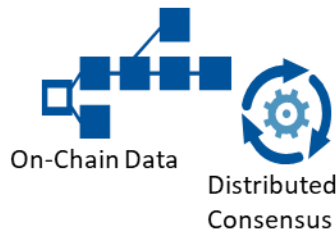
- Link the DSU in Blockchain
- Guarantees integrity, traceability, provenance, immutability

Blockchain Hierarchical Blockchains

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

BLOCKCHAIN TECHNOLOGY COMPONENTS

- Blockchain solutions drive the **next-generation** internet
- Blockchain promises to enable true Peer to Peer (P2P) interaction and transactions without the use of any intermediary



On Chain Data and distributed consensus
An algorithm enabling nodes to agree on what should be written to a blockchain ledger



Smart Contract
An immutable software program running on a blockchain platform



Zero Knowledge Proof
Proving to a verifier an attribute value without revealing the attribute value



Off chain Data
Internal and external data that is used in Distributed Apps or smart contracts



Crypto Token
Enabling for digital asset transfers, payments and marketable financial instruments, but also for structuring the flow within an application and for controlled access to resources



Decentralized Identity management
User-generated and managed identity without relying on a central repository because it is registered with distributed ledger technology

Scan the QR Code to learn about the Use Cases

CLINICAL TRIALS

HEALTH DATA



eConsent



Medical Device IOT



Personalized Medicine



Clinical Trial Recruitment



Decentralized Clinical Trials



SUPPLY CHAIN



Clinical Supply Traceability



Finished Goods Traceability



eLeaflet ePI



Anti-Counterfeiting



QUESTIONS & ANSWERS



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PharmaLedger

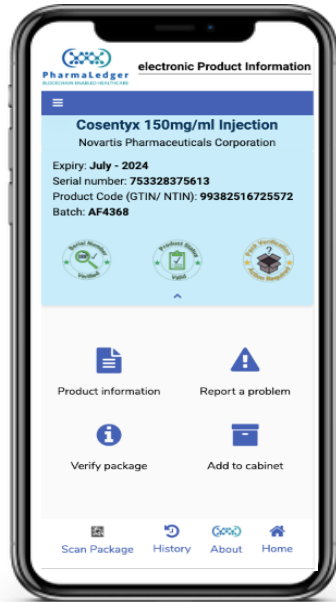
The PharmaLedger Demos Today

IHI PROJECT SPOTLIGHT: PharmaLedger



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'. Building multiple uses into the barcode to increase digital value

Security

Decentralized system and off chain storage for ePI providing a secure platform, instead of a central database, increasing resilience against cyber attacks

Privacy

Data Self-Sovereignty and Anonymity are paramount and not negotiable



PharmaLedger

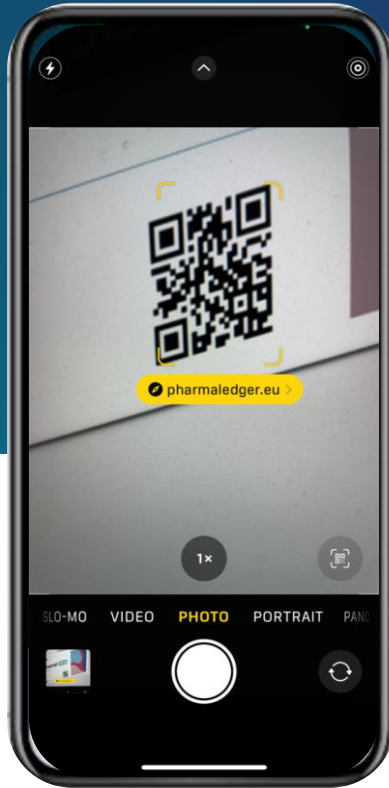
Patient Access and Safety

Regulatory efficiency

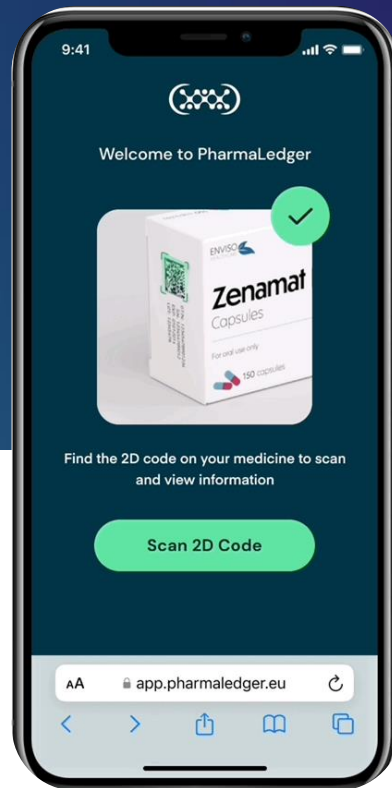
"Greener" Industry

Economy

APP ePI & DETECTING FALSIFIED MEDICINES



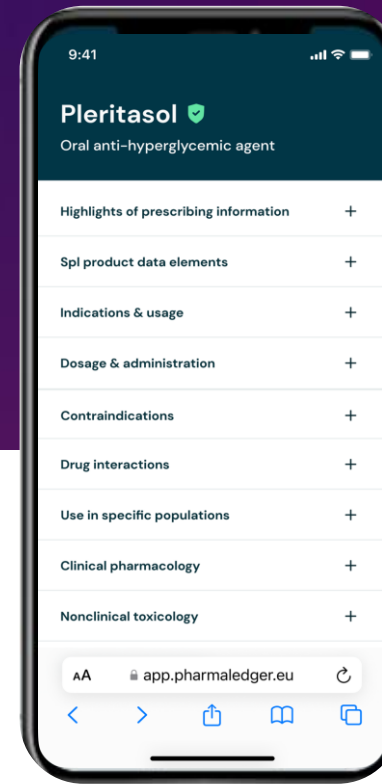
1.
Scan QR Code



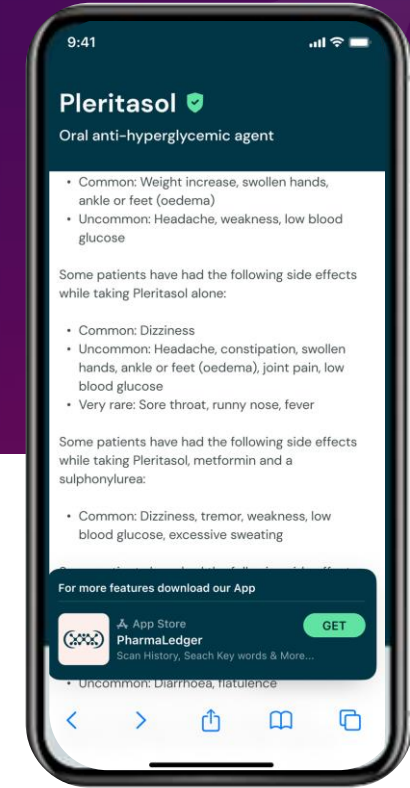
2.
Visual Instruction to scan the 2D code



3.
Scan 2D Code



4.
Get eleaflets.
secure, latest and direct



5.
Pop-up, optional
download of
App

PHARMALEDGER APP

SOLUTIONS ROADMAP



Electronic Product Information

Detecting Falsified Medicines

Adherence Reminders

Adverse Event Reporting

Link with other Health Apps

Multi-Language

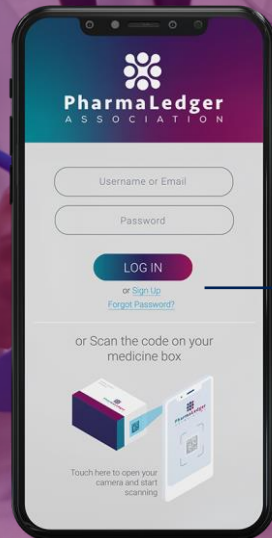
Video ePI

+

One app for all medical products
Convenient, Safe, Precise, Trusted

PATIENT FOCUS

ePI plus other digital benefits



User Friendly Information

Easier to read and search compared to paper

Structured, Searchable text

Direct... simple smartphone scan of the barcode on your pack to get the leaflet without searching

User Convenience

Same experience, regardless of manufacturer

History, previous scans and leaflets

Safety

Always most-up-to-date information

Information from trusted and secure source

Expiration check

Recall notification

Future versions will add more value

Video

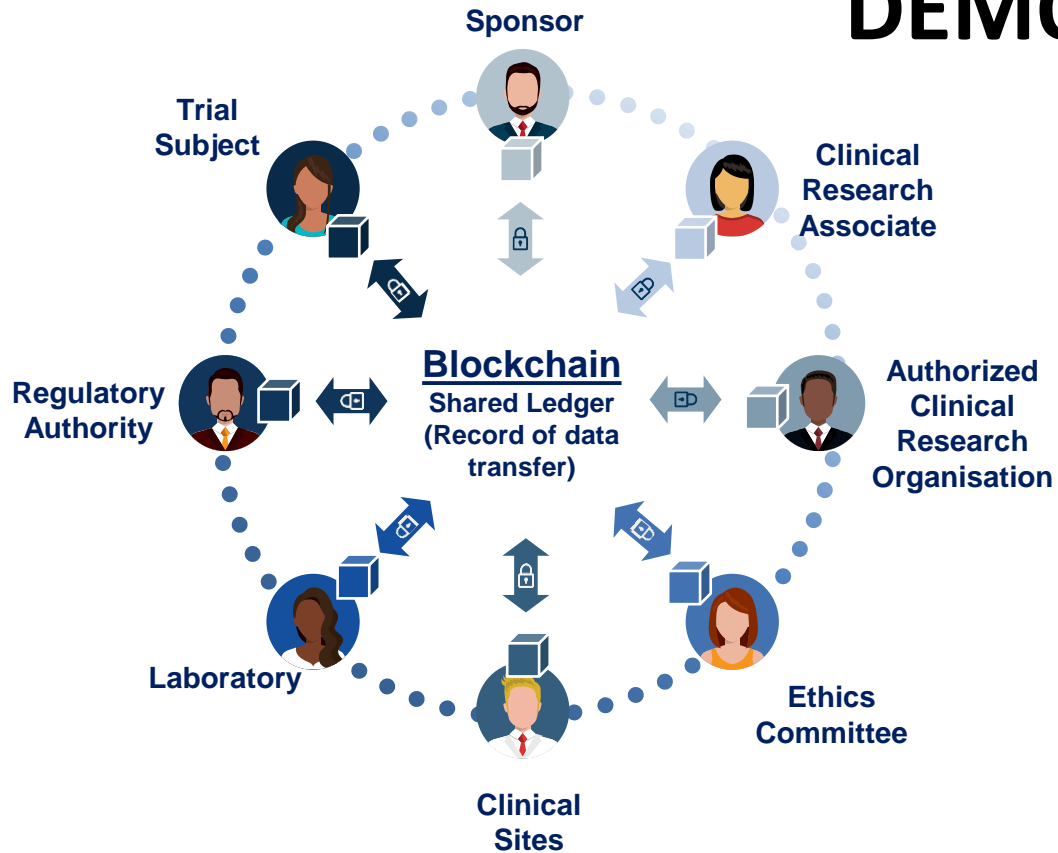
Adherence reminders to help patients manage their health condition

Adverse Event Reporting

Link with other Healthcare Apps

CLINICAL TRIAL E-CONSENT- PROMs & PREMs

DEMO



Consenting is an enabler for many processes in a clinical trial.

Trial subjects who do not feel confident, empowered, or safe when reviewing the informed consent impacts the likelihood of their participation and recruitment in the clinical trial.

Goal: To provide all clinical trial actors (trial subject, clinical sites, 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.**

Blockchain and PharmaLedger Value Proposition

Transparency



- **Immutable record** of participant consent
- **Immediately visible to appropriately permissioned users** (Patients, Sponsor, Clinical Research Organizations, Ethics Committee, etc.) including Patients Outcomes and Experiences

Security



- **Decreased fraudulent data**
- **Ensured adherence** and compliance to procedures
- **Automated processes** in line with **Good Clinical Practices (GCP)**

Trust



- **Consistency of information** viewed by relevant participants
- **Patient ownership** and ability to decide **which information is shared (EMPOWERMENT)**
- **Changes in study protocol** provided to patient in **near real-time**
- **Awareness and visibility** of consent status changes applied in **near real-time**
- **Registering Patients Outputs and Experiences**

Efficiency



Transparency

Data Integrity

Auditability

Trust

QUESTIONS

ANSWERS



PharmaLedger
ASSOCIATION



A Digital Trust Ecosystem for Healthcare

Created and governed by the healthcare ecosystem, for the healthcare ecosystem.

Digital Trust Ecosystem for Healthcare

The preferred way to connect, protect, empower, build and sustain the modern digital healthcare experience.

CONNECT

People, communities, supply chain nodes, researchers, authorities, Healthcare providers, insurers

PROTECT

Patients, Privacy, Intellectual Property, Data Security, Compliance, Brands, Reputation, Health systems

EMPOWER

People, Communities, Users, Data Owners, Health providers, Manufacturers, Regulators & Policy Makers, Innovators

BUILD

Trust, Efficiency, Emerging ecosystem solutions, Collaborative networks

SUSTAIN

Compliance, Trust, Safety, Standards, Quality



VALUES

- 1 Healthcare exists for patients
- 2 Leadership by members of the healthcare ecosystem
- 3 Diverse stakeholders are required to build a DTE
- 4 Decentralized governance without a powerful authority
- 5 Open source with multiple technologies and providers
- 6 Reduce complexity wherever possible
- 7 Accelerated innovation through agile mindset
- 8 Open collaboration software development model
- 9 Not-for-profit focused on continuous innovation
- 10 Transparency in all activities and decisions



PATIENT FOCUS

ECOSYSTEM LEADERSHIP

NOT FOR PROFIT

SIMPLER IS BETTER

INCLUSIVITY

NEUTRALITY

CHANGE AGILITY

OPEN SOURCE
MODEL

TRANSPARENCY

VENDOR AND TECHNOLOGY
AGNOSTIC

WHAT PHARMALEDGER USE CASES



Clinical Trial eRecruitment

Anonymized matching of patients to clinical trial inclusion and exclusion criteria

[CTR Webinar](#)
[CTR explainer video](#)



Clinical Trial eConsent

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


[eConsent Webinar](#)
[eConsent explainer video](#)



Clinical Supply

Trusted Tracking of investigational medicine distribution to the patient

[Clinical Supply Webinar](#)



Finished Goods Traceability

Visibility of commercial product inventory for replenishment and recall notifications

[Finished Goods Traceability](#)



ePI Electronic Product Information

Latest approved product information for all manufacturers in one app

[ePI explainer video](#)
[ePI Webinar #1](#)
[ePI Webinar #2](#)
[ePI Demo](#)



Detecting Falsified Medicines

Multi-factor Packaging Authentication and data analytics

[Detecting Falsified Medicines Webinar](#)
[Detecting Falsified Medicines Explainer Video](#)



Medical Device IoT & Personalized Medicines

Dynamic acquisition & real-time data processing for patients

[IoT Medical Device Webinar](#)
[Personalized Medicine Webinar](#)

YEAR 1 CORE OBJECTIVES (2023)

PRODUCTS

Go into production with ePI in Q1

- Current pipeline: Belgium, Luxembourg, Canada and Singapore
- Defining specific countries is important to secure quality of service and calculate the business case

Enhance ePI and Qualify Detecting Falsified Medicines

- Reliable operation and maintenance with continuous ePI enhancements to create more value
- Qualify “Detecting Falsified Medicines” functionality, available with or without ePI

PROGRAM

Create a realistic roadmap/ strategy on up-coming products and innovation activities

- The formation of the board & interests of the members and their input drive the roadmap & strategy
- Initial step is to setup a pipeline on existing use cases based on their Technology Readiness Level (maturity), resource availability and prioritization
- Allocation of funds to kick off setup of Xlab operations

ECOSYSTEM

Growth

- Attract 10 to 20 members (enough to sustain operations into 2024)
- Member acquisition depends on value proposition (use case/ product pipeline).
- Initiate strategic partnerships – e.g.: Gravitare Health, Patient Representative Organizations, Linux Foundation, GS1, EFPIA, etc.
- PLA Roadshows and promotion as an enabler of the future of digital healthcare...where the future starts NOW!

5 YEAR ROADMAP

3RD PARTY ENGAGEMENT



2022

2023

2024

2025

2026

2027

Outreach & Training

Solution qualification

Product planning is representative, actual products and launch dates to be confirmed.

PRODUCTS



ePI Qualification (QMS)

ePI Launch

ePI adoption, enhancement and operation

DFM Qualification

Detecting Falsified Medicines (DFM) adoption, enhancement and operation

FGT Qualification

Finished Goods Traceability (FGT) and Clinical Supply Chain

Clinical 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

BENEFITS

WHAT IS IN IT FOR ME?

1. Accelerated digital innovation and learning in your organization
2. Add your voice and expertise to digital healthcare development
3. Benefit from collaborating with small and large organizations
4. Share ideas of good solutions and let PLA fund the development
5. Pool resources and risk with like-minded partners to realize increased benefits
6. Promote your existing solution within the PLA network
7. Contribute with open-source development and find healthcare partners to work on innovative projects
8. Make decisions to the prioritization of our solution pipeline
9. Receive qualified and fully tested solutions
10. Operate a node on the PLA network to strengthen trust



PharmaLedger
ASSOCIATION

PROJECTS

CONTINUOUS INNOVATION

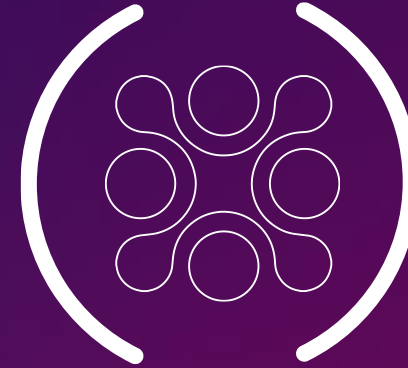


CORE PROJECTS

Core projects are funded directly by the PharmaLedger xLab from the annual xLab funding process

The xLab program team provides seed funding for high-risk, high-reward collaborative proposals in the area of innovative technology, relating to PharmaLedger's strategic goals

Core projects are subject to an annual review by the xLab program team. This is intended to be a lightweight process to ensure that projects are on track and getting the support they need.



SPONSORED PROJECTS

Members and non-members can sponsor research and development projects allowing for more in-depth collaborations between xLab participants and PharmaLedger Association member companies on specific mutual research interests and use cases.

xLab works closely with both the pharmaceutical organization and the xLab participants to understand what the interests are and cultivate the collaborations by consistently facilitating the development process.

MEMBERSHIPS & BENEFITS AT A GLANCE

	Patron (full member)	Standard Member (full member)	NFP/NGO Members (associate member)	Patient Organization (associate member)
Fees	Fixed Amount, renew annually	By # of employees, renew annually	No fees, renew annually	No fees, renew annually
Board of Directors	1 Guaranteed Seat, appointed within 90 days from membership confirmation	Ability to run, minimum of 2 and up to 5 seats on BOD	Up to 2 seats per class on BOD	Up to 2 seats per class on BOD
Direct input to strategic decision making	Yes	Yes, if part of the board	Yes, if part of the board	Yes, if part of the board
Member of the General Assembly	Agenda Input and One Vote	Agenda Input and One Vote	Agenda Input and One Vote	Agenda Input and One Vote
Qualified software and documentation access	Full	Full	By relevance	By relevance
Demo environment Access	Unlimited and possible customization	Limited / customization for a fee	Invitation based / for a fee	Invitation based / for a fee
Marketing and brand exposure	High	Limited	Limited	Limited
Product Role	Design & lead	Provide input & support adoption	Provide SME input / strategic insights / be appointed to lead initiatives	Provide SME input / strategic insights and leads patient voice in product development
Become a subcontractor to PLA	Yes, where no conflict of interest exists	Yes, where no conflict of interest exists	Yes	Yes
Sponsor Lab Projects	Yes	Yes	Yes	Yes
Operating a network Node	Read/Write	Read/Write	Read* *(exceptions may apply)	Read* *(exceptions may apply)

WHO PHARMALEDGER ASSOCIATION | MEMBERSHIP

A place to connect, protect, empower, build and sustain the modern healthcare experience

Pharmaceutical manufacturers

Distributors /Wholesalers

Service Providers

Healthcare Providers

Healthcare Organizations

Academia

Standards Orgs

Non-profits/Patient orgs

Healthcare Technology experts

... any organization with nexus to healthcare



HOW

HOW TO JOIN PHARMALEDGER

- Learn more, sign up for our newsletter and contact us at <https://pharmaledger.org/>

