VISION

Enable the **Digital Trust Ecosystem in Healthcare 4.0 (DTE-H)** to solve problems that can't be solved by silos or single organizations.

MISSION

To provide a global governance, compliance and operating model that enables innovation and inspires collaboration among healthcare stakeholders.

KEY FACTS

- Result of a 3-year, 30-member project completed in 2022
- Not-for-profit Swiss Association
- Pre-competition umbrella organization
- Patient focused, ecosystem-led, inclusive

- Technology agnostic, open-source solutions
- Innovation lab for new use cases
- Funded through membership fees and grants
- More at https://pharmaledger.org/
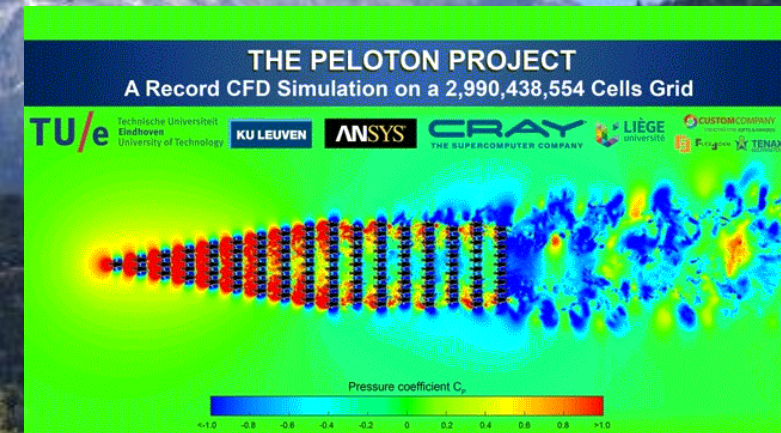
PharmaLedger
ASSOCIATION

PATIENTS & USERS

MEMBERS & SPONSORS

PRODUCT PORTFOLIO

PLₐ

AWARENESS & EDUCATION

GOVERNANCE & COMPLIANCE

INNOVATION LAB R&D

TECHNOLOGY OVERSIGHT

OUR MEMBERS

Members list | January – September 2023

Blockchain is a Team Sport

Peloton

THE PELOTON PROJECT
A Record CFD Simulation on a 2,990,438,554 Cells Grid

TU/e Technische Universiteit Eindhoven University of Technology · KU LEUVEN · ANSYS · CRAY THE SUPERCOMPUTER COMPANY · LIÈGE université · CUSTOM COMPANY · TENAX

Pressure coefficient C_p

<-1.0 -0.8 -0.6 -0.4 -0.2   0   0.2 0.4 0.6 0.8 >1.0

THE PROBLEM WHY PHARMALEDGER

Lack of data provenance, visibility and **transparency**

Systems are not patient centric: identities and data are monetized

Intermediaries add cost, time and complexity

Inefficiencies and waste amplified across the value chain

Data silos limit secure and trusted data exchange and require reconciliation

Increasing **risk of cyber attacks and concerns with data privacy**

Counterfeit (falsified) medicines impact health and economies

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BLOCKCHAIN – THE FIVE A'S

Asset

Audit

Automate

Anonymize

All for one, one for all
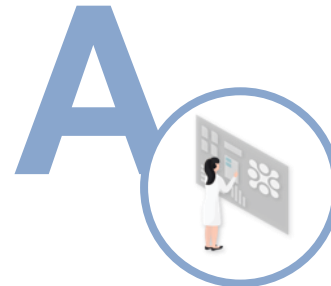
manage assets like cryptocurrency (solves the double spend problem), products, and data

immutability, no changes possible without consensus
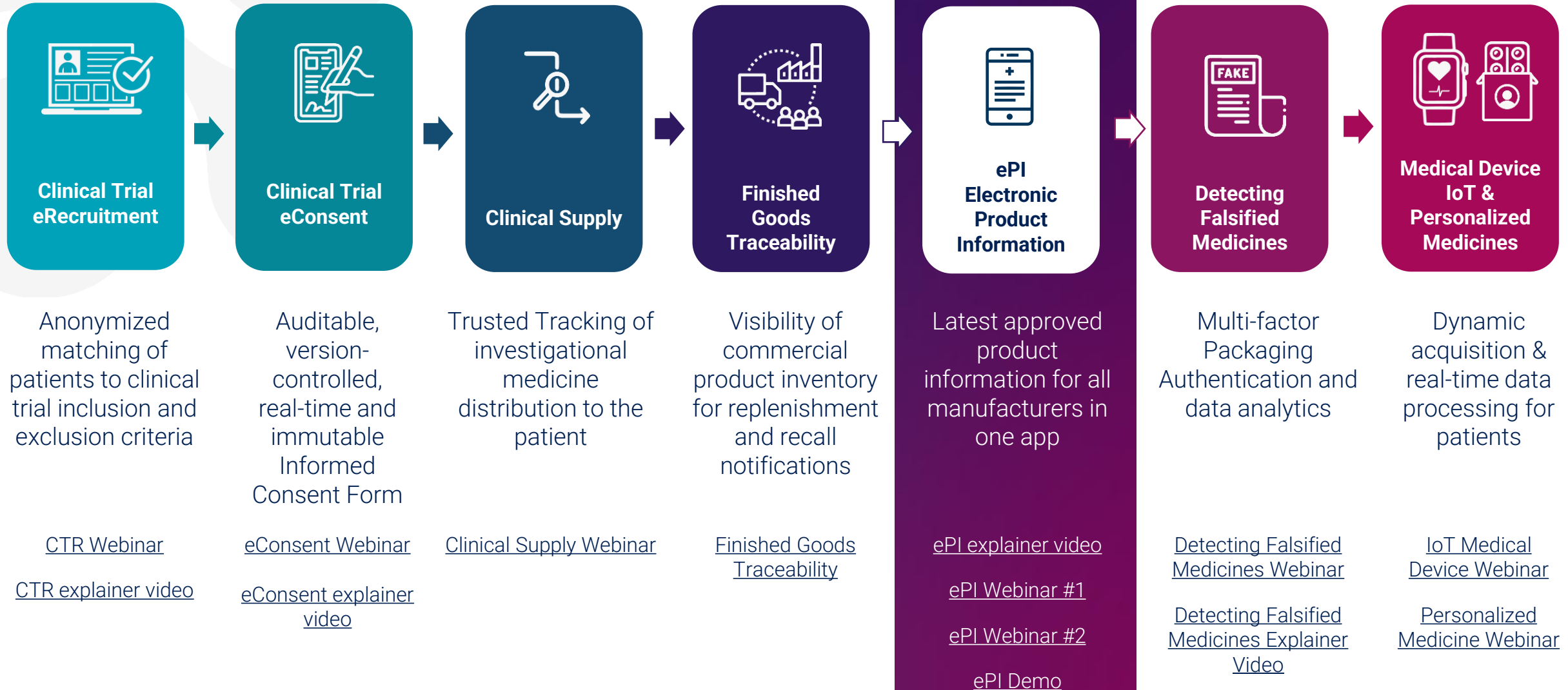
leverage smart contracts

protect privacy

consortium approach, no single/central authority

WHAT
PHARMALEDGER PROJECTS TRANSFERRED TO PLA

PharmaLedger
ASSOCIATION

Clinical Trial eRecruitment	Clinical Trial eConsent	Clinical Supply	Finished Goods Traceability	ePI Electronic Product Information	Detecting Falsified Medicines	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

CTR Webinar

CTR explainer video

eConsent Webinar

eConsent explainer video

Clinical Supply Webinar

Finished Goods Traceability

ePI explainer video

ePI Webinar #1

ePI Webinar #2

ePI Demo

Detecting Falsified Medicines Webinar

Detecting Falsified Medicines Explainer Video

IoT Medical Device Webinar

Personalized Medicine Webinar

RESTRICTED

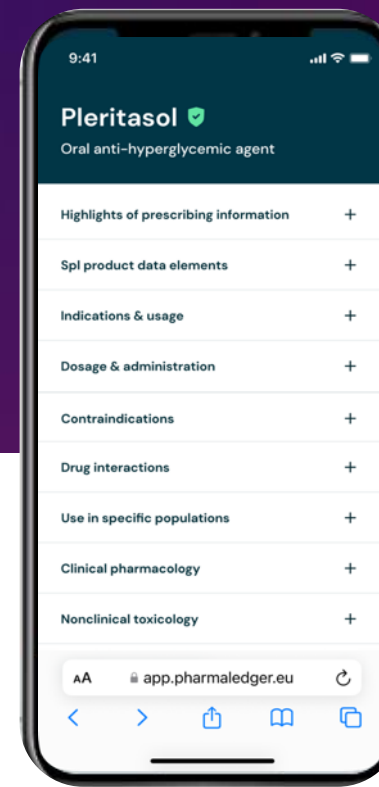# APP ePI & DETECTING FALSIFIED MEDICINES
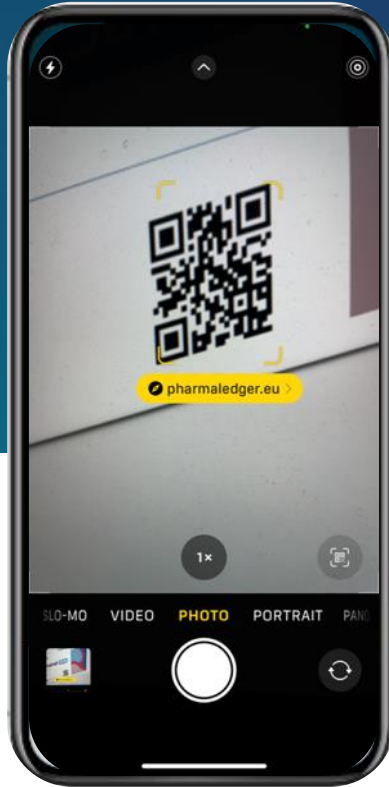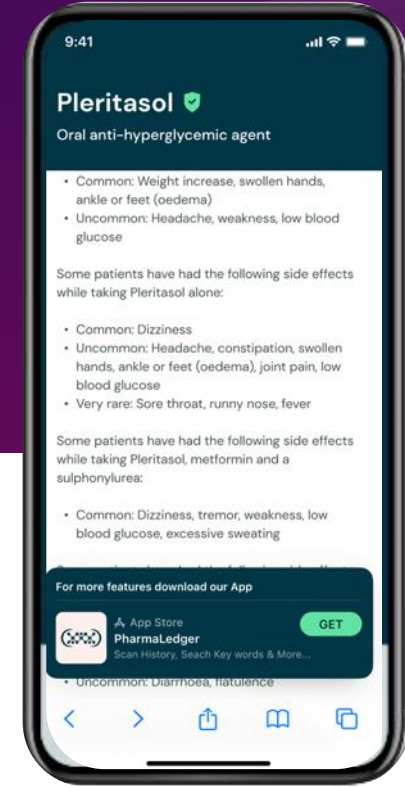

1.
Scan QR Code
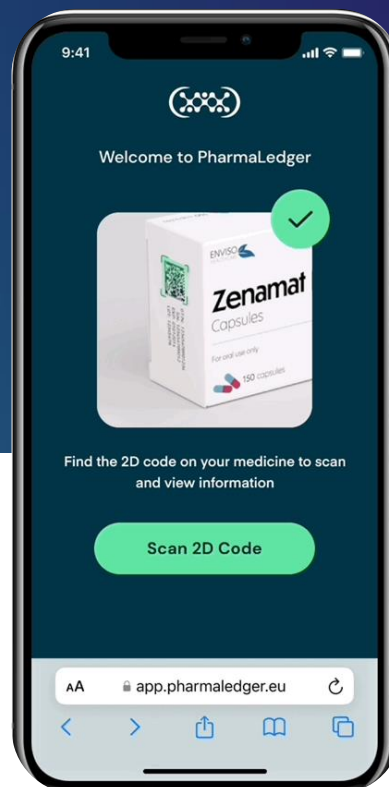
2.
Visual Instruction to scan the 2D code
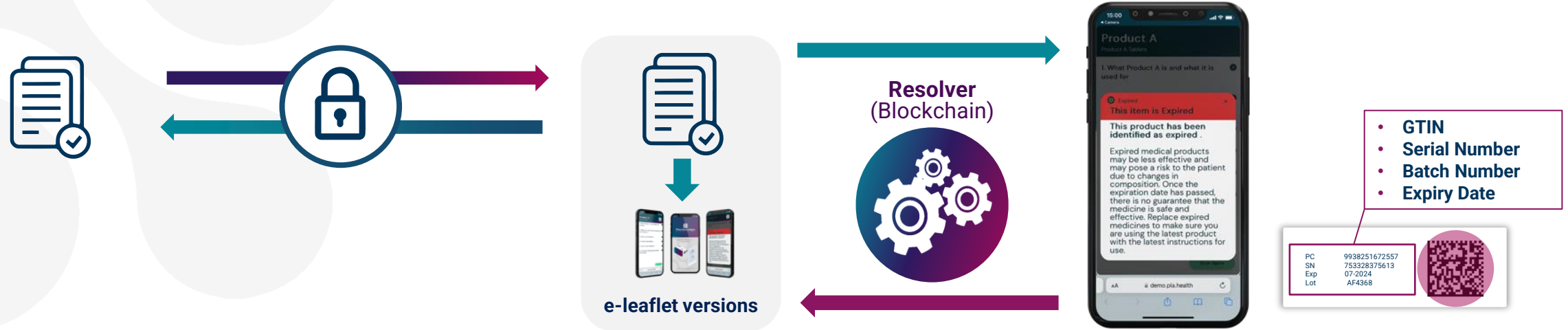
3.
Scan 2D Code

4.
Get eleaflets. secure, latest and direct
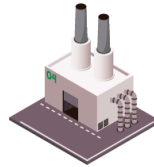
5.
Pop-up, optional download of App

BLOCKCHAIN? FOR ePI!

Resolver (Blockchain)

e-leaflet versions

- GTIN
- Serial Number
- Batch Number
- Expiry Date

PC	9938251672557
SN	753328375613
Exp	07-2024
Lot	AF4368

Review and Approval

Dissemination

**HEALTH AUTHORITIES
20+**

**MANUFACTURER
100+**

**HCP & PATIENTS
1.000.000+**

✓ Global lookup Resolver for ePI

✓ No central server, enhanced security

✓ No single point of failure (high availability)

✓ Ensures patient data privacy

✓ Product Information data integrity

✓ Scalable and enhanceable: approvals, recalls, updates, adherence reminders, drug interactions, disposal...and many more

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DEMO
Demonstration of User Experience

Example of where you would find the two codes on a medicine package

2.

1.

Your Brand XXX mg/ml
Galenical Form

Active substance

demo.pla.health. >

SLO-MO VIDEO **PHOTO** PORTRAIT PANO

TRY IT

Use these

1.
Open the camera of your device and scan the QR Code to open the WebApp.

2.
With the WebApp open, scan the 2D Matrix code to access the ePI

Demonstrates getting an ePI through the serialization code.

Demonstrates multilanguage capability

Solution will be expanded to do batch recall (by batch number), patient adherence reminders (by GTIN), anti-counterfeiting (serial number check) and many other capabilities.

PharmaLedger ASSOCIATION

DETECTING FALSIFIED MEDICINES

|	
Trust	Increased confidence in a medicine's authenticity and collaborative industry action against crime
Privacy & Security	No personal data captured without consent
All for one, one for all	Open-source software can be adopted by all manufacturers in one app without proprietary lock-in
Scalability	Builds on eLeaflet / ePI as a complementary solution and authentication feature technology agnostic

Blockchain and DFM

Patient Safety   Health Systems Efficiency   Fight Crime   Reputation
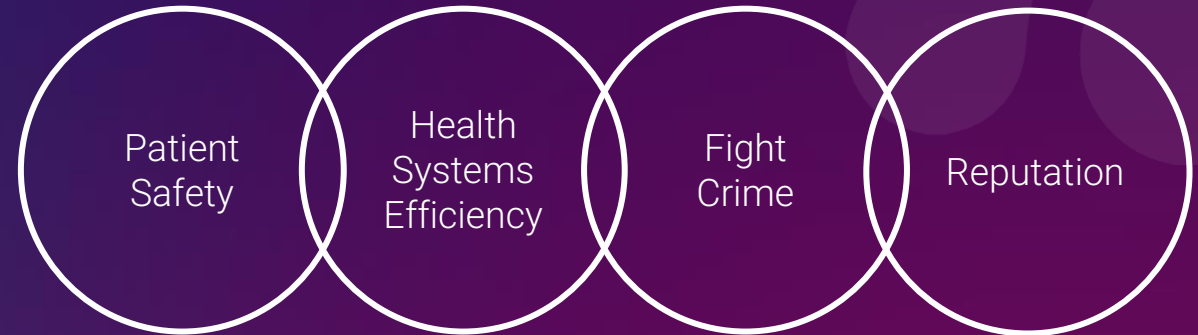
Multi-Factor Packaging Authentication (MFPA)

Empower patients and Health Care Providers to perform 7 different checks with a publicly available smartphone app.
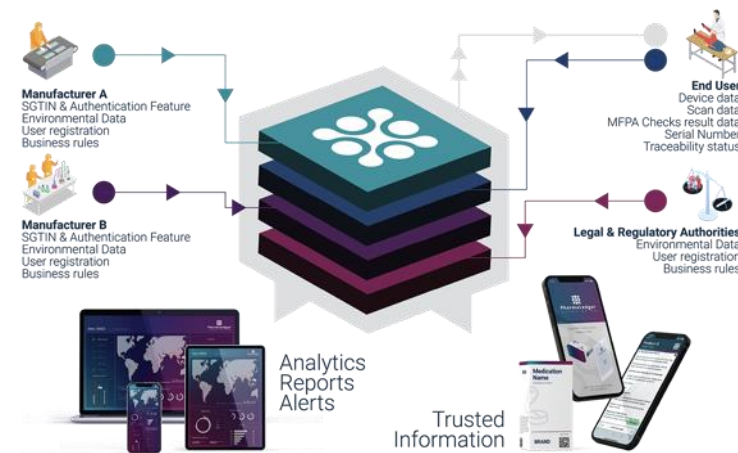
1. registered on blockchain?
2. product match?
3. valid batch expiry date?
4. valid serial number?
5. valid product status?
6. not flagged as suspect?
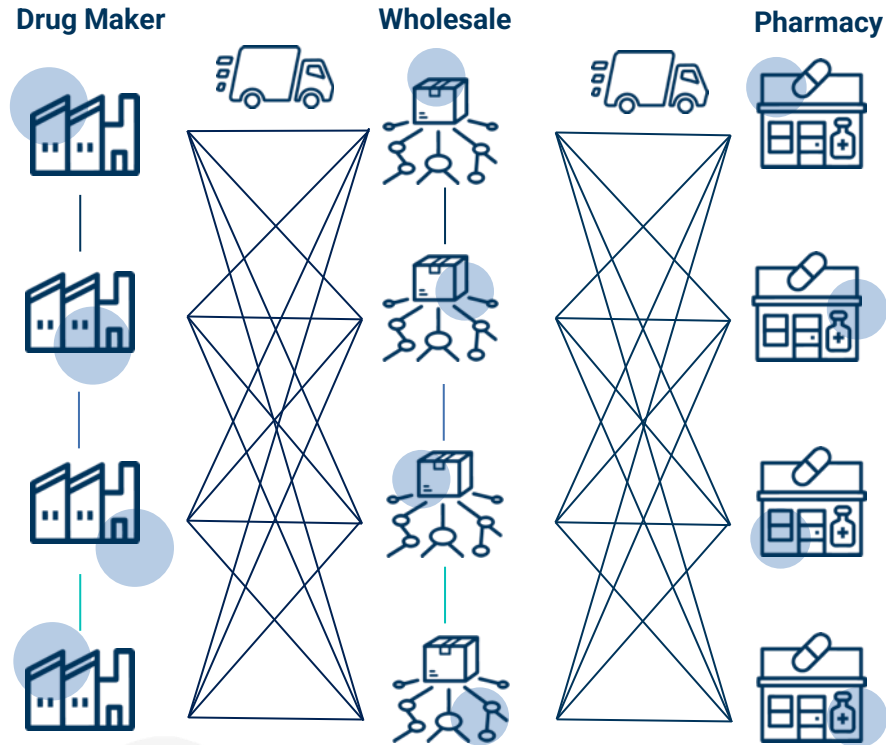7. valid feature (camera check)?

Anti-Counterfeiting Data Collaboration (ACDC)

Repository of scanned events enable real-time alerts and advanced analytics.

TODAY
The Pharma Supply Chain ...

Drug Maker   **Wholesale**   **Pharmacy**

Lack of interoperability

Inconsistent availability of downstream ecosystem data

Siloed information & high number of IT interfaces

Inconsistent demand management and inaccurate forecasting

THE FUTURE
Finished Goods Traceability

...enabled by Blockchain

PharmaLedger puts patient safety at the heart of everything we do through enabling improved collaboration among ecosystem partners to support secured, trusted data sharing and by delivering end-to-end visibility of downstream data to optimize supply chain operations

PharmaLedger
A S S O C I A T I O N

This presentation does not end here and today!
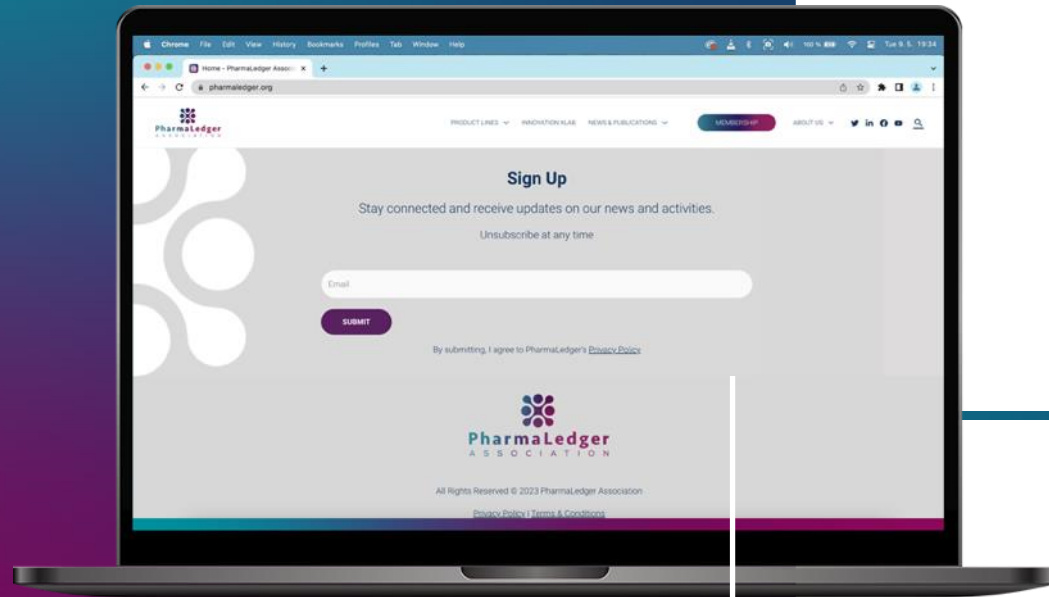
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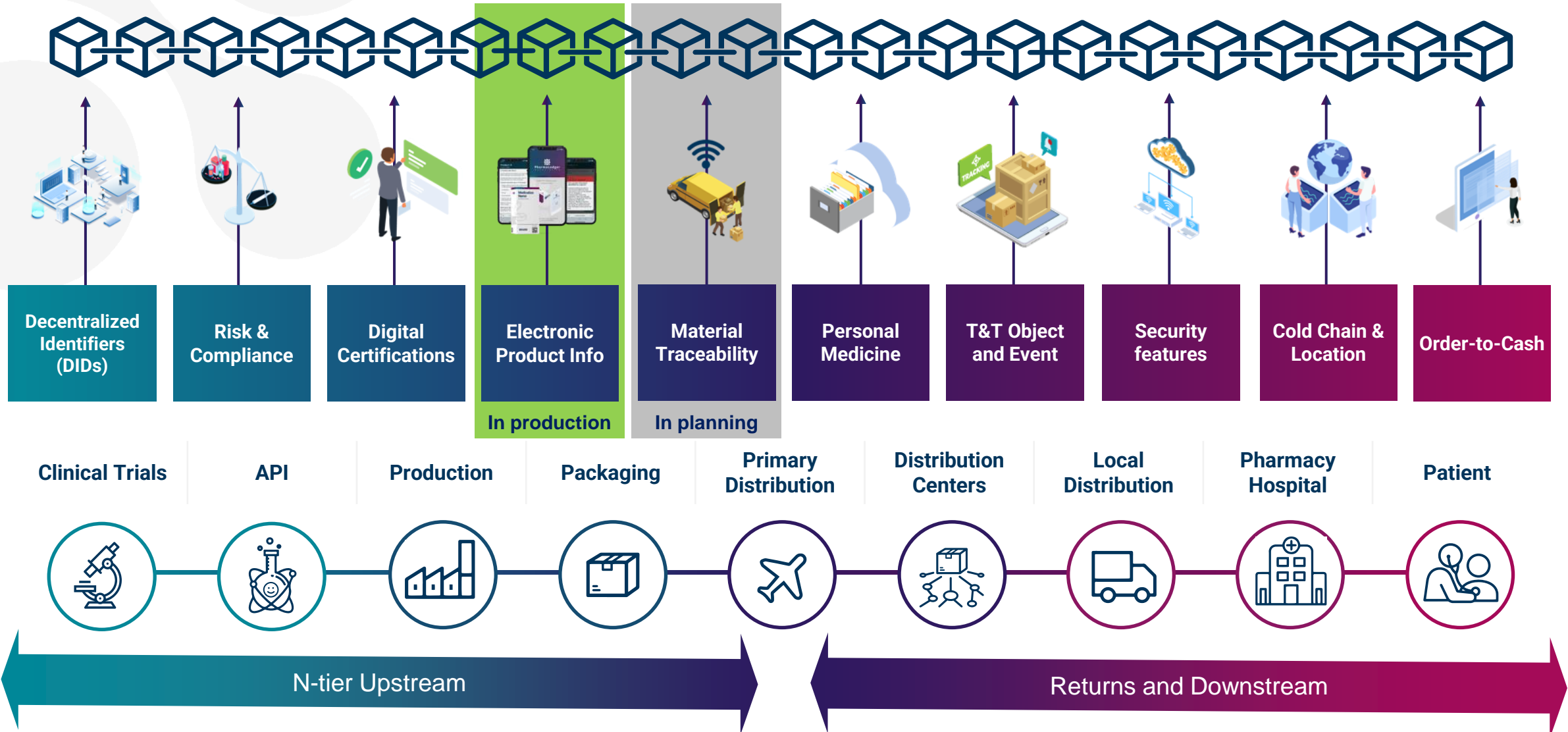
PLA Governance

End-to-end Supply Chain Traceability Vision

Blockchain Trust Fabric | PharmaLedger

PharmaLedger
ASSOCIATION

Decentralized Identifiers (DIDs)	Risk & Compliance	Digital Certifications	Electronic Product Info	Material Traceability	Personal Medicine	T&T Object and Event	Security features	Cold Chain & Location	Order-to-Cash

In production   **In planning**

Clinical Trials	API	Production	Packaging	Primary Distribution	Distribution Centers	Local Distribution	Pharmacy Hospital	Patient

N-tier Upstream   Returns and Downstream

Digital Transformation Model Evolution

Traditional model for incremental innovation

Company (Innovator) → push →

- Not patient focused
- Minimal collaboration
- Proprietary solution increases fragmentation, cost, complexity
- Results in vendor and/or technology lock-in
- Solution roadmap and governance defined by a 3rd party
- Only incremental change, limited to early adopters
- Competitors quickly appear and split the market

Collaborative model for digital transformation

An ecosystem of interdependent stakeholders, including customers and patients

Has a chronic problem that can't be solved individually

Some engaged stakeholders collaborate on an innovative solution by pooling resources and risk

They leverage existing standards if available or achieve consensus on a de-facto standard

They agree on an approach to realize, test, learn, pilot and prove the value

When the value is proven, more stakeholders adopt

ROADMAP

PRODUCTS

| | 2023 | 2024 | 2025 | 2026 | 2027 | 20287 |

ePI Qualification — **ePI Launch** — **ePI adoption, enhancement and operation**

Traceability Working Gp — **Traceability Project** — **Finished Goods Traceability (FGT)and Clinical Supply Chain**

eConsent Working Group / Project — **Clinical Trial Recruitment, eConsent, IoT and Personalized Medicine**

DFM Qualification — **Detecting Falsified Medicines (DFM) adoption, enhancement and ops**

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

PLATFORM

Version 1.0 Deployment — **Version 2.0 for multiple products** — **Version 3.0 for 3rd Party Products** — **Continuous platform enhancement**

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