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

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

**What?** A scalable blockchain based 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.

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**Duration**
3 years
Jan 20 – Dec 22

**Consortium**
29 partners

**EEAB**
External expert advisory board
10 members

**Budget**
22 million Euros

**Focus Areas**
Supply Chain, Clinical Trial, and Health Data

**Ethics Board**
6 members

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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.

Disclaimer: Any information on this presentation solely reflects the author’s view and neither IMI nor the European Union or EFPIA are responsible for any use that may be made of the information contained herein.
29 Members – 10 EU Member States, Switzerland, Israel and USA

- **12 EFPIA members**
  (ABBV, AZN, BAYER, BI, GSK, JANSSEN, MSD, NOVO, PFE, ROCHE, UCB, NVS)

- **5 SMEs – Blockchain/ICT**
  (RMS, PDM, AVO, TVS, EKN)

- **4 Research Centers & Tech. Universities**
  (UPM, CERTH, ICSI & DUT)

- **1 Social & Legal sciences research centre**
  (KUL)

- **2 patients organizations**
  (EPF, EFGCP)

- **1 government authority**
  (INCM)

- **1 CRO**
  (ONO)

- **3 hospitals**
  (OPB, HES, UKW)
Develop a scalable, sustainable, beyond-state-of-the-art blockchain reference architecture validating three prioritized business use cases from different healthcare domains involving key healthcare ecosystem stakeholders.

- Clinical trial efficiency through data provenance and digitization
- Patient empowerment through self-sovereignty in a data marketplace
- Supply chain transparency through traceability and interoperability
- Clinical trial efficiency through data provenance and digitization

Define and formalize an effective governance for a sustainable PharmaLedger framework.

Provide a legal and ethical framework to ensure regulatory compliance.

Allow security of information and greater access across use cases.

Propose an integrated health data marketplace and a collaborative platform.

Enable agile and secure delivery of innovative applications.

Ensure privacy and confidentiality of PharmaLedger data and transactions.
“PharmaLedger brings together experts from both the pharmaceutical and technology sectors as well as patients and hospitals, making it a true cross-sector, multi-disciplinary, public-private partnership.

As such it is well placed to generate practical solutions that will allow blockchain technologies to be integrated into drug development and healthcare in a way that is supported by all stakeholders.”

Dr. Pierre Meulien
Executive Director
Innovative Medicines Initiative
**P R O J E C T  O R G A N I Z A T I O N & G O V E R N A N C E**

- **EU & EFPIA (Innovative Medicine Initiative)**

- **Project Management Board**
  - Project Leader: NVS | Coordinator: UPM

- **Ethics Board**

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**Steering Committee**

Project Management Board + Work Package Leaders + Scientific & Technical Managers

- **WP1**
  - Business Use Cases (MSD & UPM)

- **WP2**
  - Implementations & Solutions (ABBV & PDM)

- **WP3**
  - Architecture & Reference Implementation (NVS & RMS)

- **WP4**
  - Governance (PFZ & AVO)

- **WP5**
  - Regulatory, Legal & Data Privacy (NOVO & KUL)

- **WP6**
  - Culture & Adoption (NVS & TVS)

---

- **DRA1**
  - Supply Chain
  - J&J, Bayer & PDM

- **DRA2**
  - Health Data
  - UCB & UPM

- **DRA3**
  - Clinical Trial
  - UCB & ONO, OPGB

**Scientific Manager**
- CERTH

**Technical Manager**
- NVS & RMS

**Sustainability & Innovation Manager**
- PFZ

**Ethical / Legal Manager**
- NOVO & KUL

**Dissemination & Communication Manager**
- TVS & NVS

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**General Assembly**

One representative from each consortium member entity
**Applications**

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

Integration
- 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

**APIs / Adapters / Integrations**

Web APIs / SDKs
- Identities
- EPCIS
- Consent

OpenDSU APIs & Adapters
- Product
- Batch
- Profile
- Health Data

Off-chain Storage (Data Sharing Units)
- Finished Goods
- UC1: ETH
- UC2: HLF
- Company Ledger
- Other Ledger

**Use Cases**

Applications
- ePI
- Clinical Trial
- Finished Goods
- Others…
**SELECTED USE CASES**

**SUPPLY CHAIN**
- Clinical Supply Traceability
- Finished Goods Traceability
- eLeaflet ePI
- Anti-Counterfeiting

**HEALTH DATA**
- Personalized Medicine
- Clinical Trial Recruitment
- Medical Device IOT
- eConsent

**CLINICAL TRIALS**
### Roadmap

#### Year 1: Design & Foundations

**2020**

- Q1: PharmaLedger Kick-Off
- Q2: Use-case short-list
- Q3: Use-case specification
- Q4: Marketing & Engagement
- Q3: Est. Ethical & Legal requirements' framework

**2021**

- Q1: Use-case definition
- Q2: Platform Architecture Planning and Development
- Q3: Specification for application & tools
- Q4: Blockchain protocol selection
- Q3: Design Platform Governance & Operating Model

**2022**

- Q1: Reference Domain applications development
- Q2: Architecture – blockchain platform & API implementation
- Q3: Governance Application, Legal & Ethical framework implementation
- Q4: Design Platform Governance & Operating Model

#### Year 2: Development & Deployment

**2020**

- Q1: Reference Domain applications development
- Q2: Architecture – blockchain platform & API implementation
- Q3: Governance Application, Legal & Ethical framework implementation
- Q4: Design Platform Governance & Operating Model

**2021**

- Q1: Platform Sustainability Planning
- Q2: Continuous Platform Enhancement
- Q3: Continuous Platform Promotion and 3rd Party engagement
- Q4: Use-case pilot implementation

**2022**

- Q1: Reference Domain Application Evaluation and validation
- Q2: Guidelines and lessons learnt
- Q3: Implement Governance and Operating Model
- Q4: Continuous Platform Promotion and 3rd Party engagement

#### Year 3: Validation & Sustainability

**2020**

- Q1: Continuous Platform Sustainability
- Q2: Wide communication of project results
- Q3: Blockchain-Enabled-Healthcare!
- Q4: Strategic Positioning

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**Value Chain - Use Cases View**

- **Clinical Trial eRecruitment**
  - Anonymized matching of qualified patient to trial requirements
  - Enable voluntarily enrollment
  - Less dependency of intermediaries
  - Lower time and cost

- **Clinical Trial eConsent**
  - Auditable and immutable ICF
  - Dynamic and real-time ICF management
  - Less protocol deviations
  - Specific versions can be managed
  - Administratively agile
  - Pilot real study with Pediatric heart failure patients

- **Clinical Trial IoT devices**
  - Dynamic acquisition and processing of data
  - Remote patient monitoring
  - Real-time notifications
  - Pilot real study with Pediatric heart failure patients and 2 devices

- **Clinical Supply**
  - Immutable record keeping
  - Creates trust among partners
  - Interoperable data points for decision making
  - Improved ability to track drug accountability and reconciliation
  - Value added for clinical sites/investigators (reduce admin burden)

- **Finished Goods Traceability**
  - Leverages industry standards
  - Introduces digital identity
  - Reliable demand signals
  - Near real-time access to seamless and accurate supply information

- **Epi - Electronic Product Information**
  - Achieves EMA key principles for EPI
  - Environmental footprint – CSR
  - Multi-use of barcodes as digital key for delivering bundled digital services and value

- **Anti-Counterfeiting**
  - Multifactor product Authentication
  - Authentication feature agnostic
  - ACDC (anti-counterfeiting data collaboration) regulatory and law enforcement value
  - Leveraging ePI one app for additional anti-counterfeiting check

- **Personalized Medicines**
  - Establishes a trusted environment for patient-centric decentralized applications
  - Uses blockchain’s trusted network to leverage RWE for research
  - Uses Machine Learning and AI
  - Value-Based health delivery in clinical practice

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Organizations only have "one up, one down" data visibility, meaning they can see information from adjacent partners but not the entire supply chain. Regulatory compliance across multiple legacy systems results in paper-based manual processes that are slow and costly. Sponsors have little insight into if and how their product is being consumed, reducing the ability to improve processes.

The solution creates value for all actors by developing trust, enhancing efficiencies, and eliminating key pain points that improve our ability to get critical medicines to patients around the world.

**Blockchain and PharmaLedger Value Proposition**

- **Trust enabling**: Creates trust between partners through the use of a common platform.
- **Interoperability**: Interoperable data points (e.g., disposition of products) drives faster decisions. Single access to information across sponsors and couriers for clinical site personnel.
- **Immutable**: Immutable record-keeping reduces burden of audits and inspections.
- **Traceability**: Improved ability to track drug accountability and reconciliation. Reduced product waste through true end to end visibility.
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.

PharmaLedger connects the supply chain eco-system for trusted and accelerated information sharing and facilitates incorporating new partners into the eco system, including patients.

**Description**

- Increased patient safety
- Fast and efficient recalls
- Optimized cost for the benefit of the health systems
- Simplified IT interfaces & unlocking previously siloed information

**Blockchain and PharmaLedger Value Proposition**

- **Trust**: Secure & timely supply of product, with digital identities
- **Interoperability**: Leveraging industry standards, such as Advanced Shipping Notices and Electronic Product Coding Information Services for end to end traceability
- **Immutability**: Secure and immutable sharing of information for reliable demand signals and counterfeit detection
- **Traceability**: Increasing regulatory compliance, providing product provenance and chain of custody
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.
Supply Chain Anti-Counterfeiting

Description

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

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

Blockchain and PharmaLedger Value Proposition

<table>
<thead>
<tr>
<th>Trust</th>
<th>The authoritative and trusted answer on a medicine's authenticity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Privacy &amp; Security</td>
<td>Guaranteed anonymity in read-only, public access scenario</td>
</tr>
<tr>
<td>Interoperability</td>
<td>The same solution can be adopted by all manufacturer and markets without lock-in to proprietary solutions</td>
</tr>
<tr>
<td>Scalability</td>
<td>Builds on eLeaflet / ePI and existing serialization regulations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anti-counterfeiting use case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Users</strong></td>
</tr>
<tr>
<td>Private User</td>
</tr>
<tr>
<td>HCP/HCO</td>
</tr>
<tr>
<td>Dispensary</td>
</tr>
<tr>
<td>Distributor</td>
</tr>
<tr>
<td>Law Enforcement</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td><strong>Users Interface</strong></td>
</tr>
<tr>
<td><strong>Data Input</strong></td>
</tr>
<tr>
<td><strong>MFPA Functionality</strong></td>
</tr>
<tr>
<td>Product Status</td>
</tr>
<tr>
<td>ePI</td>
</tr>
<tr>
<td><strong>ACDC Functionality</strong></td>
</tr>
<tr>
<td>Data Analytics</td>
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<tr>
<td>Permissioned</td>
</tr>
<tr>
<td><strong>ACDC Users</strong></td>
</tr>
<tr>
<td>Regulatory Authorities</td>
</tr>
<tr>
<td>Pharmaceutical Industry</td>
</tr>
<tr>
<td>Law Enforcement</td>
</tr>
</tbody>
</table>

Patient Safety
Public Health
Trust in Industry
Economy

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If a potential trial participant does not feel confident, empowered, or safe when reviewing the informed consent document, the likelihood of their participation is lowered, impacting recruitment in the clinical trial.

The purpose of this use case is to provide all clinical trial actors (trial participant, healthcare organization, 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**

- **Immutability**: Creates an immutable entry on the blockchain, recording when consent was obtained, which is immediately visible to appropriately permissioned users in compliance with GDPR.

- **Trust**: Reduces or eliminates audit findings and decreases opportunities for fraudulent data, by increasing the consistency of information being viewed across investigative sites.

- **Smart Contracts**: Smart contracts can be implemented to lock access to trial systems until consent has been obtained, ensuring compliance with GCP.

- **Traceability**: Have the traceability to allow sharing of clinical trial data with different parties involved, any changes in consent status are applied in near real-time.

- **Privacy**: Ability for sponsors to anonymously contact subjects directly to request consent for samples or data to be used in other research activities, optimizing the materials already collected.
Blockchain and PharmaLedger Value Proposition

- **Trust**: Trusted & Verifiable Data Sharing by blockchain anchoring
- **IoT Cybersecurity Framework**: DID-based Identification, Dynamic acquisition and processing of data from consumer to medical devices to accelerate clinical development
- **Smart Contract**: Continuous and/or discrete remote measuring & patient trajectory in Clinical Trial
- **Privacy**: eConsent

Description

Connected health devices or networked IoT medical devices and remote patient monitoring (RPM) technologies, can provide quality data to support patient health records.

This use case aims at validating and testing the blockchain technology for a dynamic acquisition and processing of data from medical devices assigned to patients that will be monitored for heart failure; in the setting of an observational pediatric clinical study.
The use case intends to create a patient-centric, industry-wide clinical trial recruitment solution. The solution would aggregate clinical trials and screening criteria across the whole industry, and would use a matching algorithm to match the patient to relevant clinical trials.

**Blockchain and PharmaLedger Value Proposition**

- **Decentralized**: Creates a shared ledger of permissions, accessible by network participants, without putting any one party in charge.
- **Immutable**: Creates a permanent record of trials submitted by sponsors. Would discourage any illegitimate use of the trial matching infrastructure.
- **Trust**: Cross-industry record of match attempts could be shared with patients, increasing understanding of which trial criteria may be causing their match or failure.

**Current State**

Patient: "Any trials for diabetics?"

Joe

Investigator

Study Website

Pre-screen

"Sorry, no"

"Yes"

**Future State**

Patient: "Any trials for diabetics?"

Joe

"You match to these 3 trials"

Blockchain

Trial A / B

Pre-screen

Investigator

Pre-screen

"Sorry, no"

"Yes"

Trial C

Pre-screen

Study Website

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen

Pre-screen
The main focus is to validate the use of blockchain in combination with Machine Learning and Artificial Intelligence for the creation and application of algorithms and models that improve the healthcare provision.

The Personalized Medicine use case aims at establishing a trusted environment that supports patient-centric solutions for:

- a value-based health delivery in clinical practice
- the generation of RWE for research purposes.

This can be applied to improve the diagnosis, prevention and personalized treatment of patients.

**Blockchain and PharmaLedger Value Proposition**

- **Transparency**: Grants complete overview over own data
- **Security**: Allows data privacy and security through blockchain, de-identification
- **Trust**: Healthcare provision is improved by better clinical decisions, making value-based healthcare more achievable
- **Interoperability**: Improves the ability to connect data and reduces the delay time from provision of RWD

**Description**

<table>
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**Future State**

- **Application prediction model**
  - Based on data automatically gathered from information collected from patient
  - Prediction: AI or multivariate regression

- **Healthcare professionals**
  - Better prevention of risk factor
  - More accurate diagnosis
  - Personalized and effective treatment

- **Researchers**
  - Request access to patient’s health data

**Current State**

- **Approved application**: Use population health data to support diagnosis
- **Data**
  - Prediction: AI or multivariate regression

**Negative impacts**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>x Why, Who and How is my data being use?</td>
<td>x No access to all medical records with a complex, costly and time-consuming process.</td>
</tr>
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