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Demonstrating the vision of Blockchain Enabled Healthcare

DIA Europe 2021 | 16th March

Daniel Fritz | Novartis
Ken Thursby | MSD
Patrick Maher | Novartis
**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.

**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
29 Members | 10 EU Member States, Switzerland, Israel and USA

- 12 EFPIA members (ABBV, AZN, BAYER, BI, GSK, JANSEN, 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 business use cases from different healthcare domains.

**PHARMALEDGER OBJECTIVES**

- 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.
- Allow security of information and greater access across use cases.
- Provide a legal and ethical framework to ensure regulatory compliance.
- Define and formalize an effective governance for a sustainable PharmaLedger framework.
- Patient empowerment
- Supply chain transparency
- Clinical trial efficiency
- Define and formalize an effective governance for a sustainable PharmaLedger framework.
### PhD Program Overview

#### Year 1: Design & Foundations

- **Q1**: PharmaLedger Kick-Off
- **Q2**: Use-case short-list
- **Q3**: Use-case specification
- **Q4**: Marketing & Engagement
- **Q5**: Est. Ethical & Legal requirements' framework

#### Year 2: Development & Deployment

- **Q1**: Use-case definition
- **Q2**: Platform Architecture Planning and Development
- **Q3**: Specification for application & tools
- **Q4**: Blockchain protocol selection
- **Q5**: Design Platform Governance & Operating Model

#### Year 3: Validation & Sustainability

- **Q1**: Reference Domain applications development
- **Q2**: Architecture – blockchain platform & API implementation
- **Q3**: Governance Application, Legal & Ethical framework implementation
- **Q4**: Use-case pilot implementation

### Roadmap

<table>
<thead>
<tr>
<th>Year</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
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<tbody>
<tr>
<td>2020</td>
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<tr>
<td>2022</td>
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</tbody>
</table>

- **2020**: Design & Foundations
- **2021**: Development & Deployment
- **2022**: Validation & Sustainability

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**PharmaLedger**

**DIA Europe 2021**

**Advancing Health Priorities**
Anonymized matching of qualified patient to trial requirements
Enable voluntarily enrollment
Less dependency of intermediaries
Lower time and cost

Clinical Trial eRecruitment
Clinical Trial eConsent
Clinical Trial IOT devices
Clinical Supply
Finished Goods Traceability

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

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

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

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

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
Blockchain Enabled Healthcare Value Chain

- Clinical Decision Support Systems
- Finished Goods Traceability
- Electronic Health Records (eHR)
- Adverse Event Reporting
- Batch Recall
- Anti Counterfeit Check

Successful use cases build a ‘value bundle’
CONNECTING THE SUPPLY CHAIN THROUGH THE 2D DATA MATRIX

Data embedded in the 2D barcode

GTIN
“Product Number”

LOT #
“Lot/Batch Number”

EXP DT
“Expiry Date”

SER #
“Unique Serial Number”

Product Master Data, Leaflet, Artwork, Transport Docs, Customs Docs

Batch Genealogy, Batch Record, Inspection Results, COA

Order Information, Returns, Chargebacks and Rebates, Inventory, Track & Trace, Authentication

Product Master Data, Leaflet, Commercial Data

Batch Genealogy, Recalls

Batch Genealogy, Recalls

Shelf Life / Inventory Management

Product Quality Inquiry

“Pharma to Table”, Authenticity, Adverse Events

PharmaLedger
• Every package contains typically a paper leaflet, billions are used every year
• Paper Leaflets provide valuable **Product Information** to HCP’s and Patients about their medicines
• They are closely regulated and updated over the product life

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**e-Product Information is not a new idea.**

**Can blockchain help realize the promise of ePI?**

- Readability of print
- Updates not instant… linked to production and may limit availability
- Cost to produce
- Environmental impact

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* Enable **trusted transactions** between multiple entities
* Enable trusted and **secure content**
* Allow **interoperability with other digitally enabled services and systems**
15 – 19 MARCH | VIRTUAL

**Future Vision**

Health Authorities 20+

Manufacturers, 100+

HCP & Patients, millions

**Review and Approval**

- e-leaflet versions

**Dissemination**

Resolver (Blockchain)

**Transaction Infrastructure (Blockchain)**

- GTIN
  - Serial Number
  - Batch Number
  - Expiry Date

Recall Warning

This Batch is being recalled. Please return
Patient safety and trust in medicines...

**Patient Safety**
- Fake drugs lead to therapeutic failure, disease complications, and death.

**Public health**
- Counterfeits decrease trust and efficiency of health care systems, leading to less access

**Economic impact**
- Loss of income on companies impacting innovation and jobs
- Loss of tax income for National Revenue authorities (i.e. Counterfeit goods are almost always smuggled)
- General impact on the global and local economy

In 2016, the total value of counterfeit pharmaceuticals traded internationally is estimated to be worth **USD 4.4 billion**

**WHO**
November 2017

**EUIPO-OECD**
April 2020

1 in 10 medical products in developing countries is substandard or falsified

Rapid increase of rogue online pharmacies—96% of websites offering pharmaceuticals operate illegally.

EUIPO-OECD
April 2020
<table>
<thead>
<tr>
<th>ACTORS</th>
<th>INPUTS</th>
<th>PROCESS</th>
<th>OUTPUTS</th>
<th>ACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>DataMatrix scan with app</td>
<td>Access eLeaflet (ePI)</td>
<td>eLeaflet</td>
<td>Patient</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Global Trade ID Number Batch Expiry Serial</td>
<td>Perform MFPA checks:</td>
<td>Results</td>
<td>Patient</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>1. Valid product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Valid serial No.?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Valid prod. status?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Feature available?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Suspect product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>Authentication Feature Input</td>
<td>Manufacturer verifies feature(s)</td>
<td>Results or Patient</td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>Results of checks &amp; Business rules</td>
<td>Anti-Counterfeit Data Collaboration (ACDC)</td>
<td>Analytical reports and real-time alerts</td>
<td>Manufacturer Law Enforcement</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Multi-Factor Product Authentication (MFPA) and Anti-Counterfeit Data Collaboration (ACDC)**
ANTI-COUNTERFEIT
USE CASE VISION

• Building on current legislation:
  - Falsified Medicines Directive in EU
  - Drug Supply Chain Security Act in the USA

• Empowering Patients to be part of the solution

• Interoperable and trust driven

• Leveraging Big Data to generate real time insights

ANTICOUNTERFEITING USE CASE

Users
- Private User
- HCP/HCO
- Dispensary
- Distributor
- Law Enforcement
- Manufacturer

Users Interface
- Law Enforcement
- Pharmaceutical Industry

Data Input
- 2D Data Matrix
- Authentication Feature
- GTIN (01): 0345312000011
  EXPIRY: 2019-11-25
  BATCH/LOT (10): ABCD1234

MFPA Functionality
- Product Status ePI

ACDC Functionality
- Multi-Factor Authentication
- Permissioned
- Multi-flow
- Authentication Feature
- ACDC

ACDC Users
- Regulatory Authorities
- Law Enforcement
- Smart Contracts

Data Analytics
- Permissioned
- Multi-flow

Pharmaceutical Industry
Which markets?

- Leading Health Authorities and Manufacturers want to move from a paper to ePI
- Some National pilots have emerged for ‘ePI on a phone’ in pioneer countries
- No standards are developed for ePI or method of access

Innovation in Singapore

- HSA open to ePI and paperless, launching pilot Nov-19
- Singapore EDB open to blockchain, investment by IMDA $12M innovation fund
- Opportunity to test value of ePI-by-blockchain with small scale demonstration

Innovation in Germany

- National ePI pilot “GI4.0” launched in April-20, using the GS1 2D data matrix for access of the ePI
- Opportunity to expand the “value bundle” for patients, potential to give “batch specific” leaflets and deliver content direct from manufacturers
BUILDING ON INDUSTRY SYNERGIES TO ACCELERATE VALUE TO PATIENTS, HEALTH AUTHORITIES AND MANUFACTURERS

Singapore Demonstrator
- Confirmed
- To be confirmed

Note: only 12 PharmaLedger Companies shown to demonstrate synergies. 29 organizations are in PharmaLedger, refer to last slide for full details
Feature #1: Digital key multi-use
Get ePI
Authentication of product, so fake products aren’t legitimized by a genuine eLeaflet

Feature #3: Patient-Centric App
Any product from any manufacturer
Patient always gets correct info digitally

Feature #4: Patient-friendly approach to issues with ePI and Authentication
Putting Patient Safety first
Demonstrating challenges and how we could manage them

Feature #2: Trusted Content
Getting secure eContent direct from the Manufacturer… statutory content only
<table>
<thead>
<tr>
<th>DEMO DATAMATRIX</th>
<th>DATA</th>
<th>OUTCOME</th>
</tr>
</thead>
</table>
| **1** | TRAVATAN EYE DROPS | GTIN: 06005534003750  
Batch Number: SADC1  
Serial Number: 43023992515022  
Expiration Date: 23. June. 2024 | ePI for the Novartis Product is shown  
Authenticity check verified |
| **2** | FLUARIX TETRA | GTIN: 01183111111274  
Batch Number: GSK1  
Serial Number: 430239925150  
Expiration Date: 08. March. 2022 | ePI for the GSK Biologicals Product is shown  
Authenticity check verified |
| **3** | KEYTRUDA | GTIN: 07111534003740  
Batch Number: KEN1  
Serial Number: 43023992515022  
Expiration Date: 23. June. 2024 | ePI for the Merck Product is shown  
Authenticity check verified |
| **4** | KEYTRUDA | GTIN: 07111534003740  
Batch Number: KEN1a  
Serial Number: 53023992515022  
Expiration Date: 23. June. 2024 | ePI for the Specific batch is shown  
Authenticity check verified  
Excipient change with allergy information  
Enhancement to Feature 1 |
<table>
<thead>
<tr>
<th>DEMO DATAMATRIX</th>
<th>DATA</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5</strong></td>
<td>KEYTRUDA</td>
<td></td>
</tr>
<tr>
<td>GTIN: 07111534003740</td>
<td>Batch Number: KEN2</td>
<td>Unknown Serial Number.</td>
</tr>
<tr>
<td>Serial Number: 53023992515093</td>
<td>Expiration Date: 23. June. 2024</td>
<td>Question: Should the ePI be shown in this circumstance?</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td>KEYTRUDA</td>
<td></td>
</tr>
<tr>
<td>GTIN: 07111534003740</td>
<td>Batch Number: KEN3</td>
<td>Product has passed Expiry Date</td>
</tr>
<tr>
<td>Serial Number: 63023992515022</td>
<td>Expiration Date: 24. Jan. 2021</td>
<td>Question: What would be an appropriate message to the patient?</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td>KEYTRUDA</td>
<td></td>
</tr>
<tr>
<td>GTIN: 07111534003733</td>
<td>Batch Number: KEN1</td>
<td>Unknown GTIN.</td>
</tr>
<tr>
<td>Serial Number: 43023992515022</td>
<td>Expiration Date: 23. June. 2024</td>
<td>Question: What would an appropriate message be in this circumstance?</td>
</tr>
</tbody>
</table>
**Stakeholders & Value Proposition**

- **Health Authorities**
  - Supports EMA and EU strategy for digitizing Healthcare
  - Efficiencies in review and approval processes
  - Low cost to serve, because of decentralization

- **Patient Groups**
  - Faster availability of breakthrough medicines as new indications are approved
  - Latest trusted and transparent information
  - Improved access to product information
    - Digital Heath

- **Manufacturers**
  - Production line efficiencies
  - Purchase costs for the leaflets
  - Eliminate handling of leaflets, sampling and inspection

- **Citizens**
  - Clarity of information, by searchable content, language specific
  - Less waste material

- **Environmental**
  - Paper industry is very energy intensive
  - Less waste material

- **HCP’s**
  - Latest approved version of the leaflet always available
  - Improved access to product information
  - Clarity of information, by searchable content, language specific
TAKE AWAYS

WHAT WE WANT TO AVOID

• Patient confusion
• Proliferation of different ePI solutions
• Added complexity
• Legitimizing fake medicines

WHAT WE DESIRE

• A trusted platform for secure data and information exchange
• Digital PI is not just equivalent to paper, but better
• Global standards for ePI
• Expansion of digital value beyond ePI
• Flexibility for different stakeholders on their journey to ePI to participate
Data Privacy and the vision of a Blockchain Enabled Healthcare

DIA Europe 2021 | 19th March

Hernando Giraldo | Boehringer Ingelheim
Nenad Georgiev | KU Leuven
Baldwin Mak | Boehringer Ingelheim
Who
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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, BI

Scientific Manager
CERTH

Technical Manager
NVS & RMS

Sustainability & Innovation Manager
PFZ

Ethical / Legal Manager
NOVO & KUL

Dissemination & Communication Manager
TVS & NVS

General Assembly
One representative from each consortium member entity
<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q1</th>
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<tbody>
<tr>
<td><strong>Year 1</strong></td>
<td><strong>Year 2</strong></td>
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<tr>
<td>Design &amp; Foundations</td>
<td>Development &amp; Deployment</td>
<td>Validation &amp; Sustainability</td>
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<td>2020</td>
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<td>2022</td>
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</tr>
<tr>
<td>• PharmaLedger Kick-Off</td>
<td>• Use-case definition</td>
<td>• Reference Domain applications development</td>
<td>• Reference Domain Application Evaluation and validation</td>
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<td>• Marketing &amp; Engagement</td>
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<td>• Continuous Platform Promotion and 3rd Party engagement</td>
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<tr>
<td>• Est. Ethical &amp; Legal requirements' framework</td>
<td>• Design Platform Governance &amp; Operating Model</td>
<td>• Use-case pilot implementation</td>
<td>• Implement Governance and Operating Model</td>
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<td><strong>ROAD MAP</strong></td>
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**2020**
- Q1: PharmaLedger Kick-Off
- Q2: Use-case definition
- Q3: Platform Architecture Planning and Development
- Q4: Use-case short-list

**2021**
- Q1: Use-case specification
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- Q3: Blockchain protocol selection
- Q4: Marketing & Engagement

**2022**
- Q1: Est. Ethical & Legal requirements' framework
- Q2: Design Platform Governance & Operating Model
- Q3: Reference Domain applications development
- Q4: Continuous Platform Promotion and 3rd Party engagement

**Year 1**
- Q1: Design & Foundations
- Q2: Development & Deployment
- Q3: Validation & Sustainability
- Q4: Platform Architecture Planning

**Year 2**
- Q1: Design & Foundations
- Q2: Development & Deployment
- Q3: Validation & Sustainability
- Q4: Use-case pilot implementation

**Year 3**
- Q1: Design & Foundations
- Q2: Development & Deployment
- Q3: Validation & Sustainability
- Q4: Continuous Platform Sustainability Planning
SELECTED USE CASES

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

CLINICAL TRIALS
- Clinical Supply Traceability
- Finished Goods Traceability
- eLeaflet ePI
- Anti-Counterfeiting

SUPPLY CHAIN
- Health Authorities
- Citizens
- Health Authorities
- Environmental
- Manufacturers
- Patient Groups
- HCP’s

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15 – 19 MARCH | VIRTUAL
Do not want to share their personal data with private companies to use their services: 41%

Are worried that the data they share online may be accessed by third parties without their knowledge / consent: 55%

Have little/no understanding of what private companies and public bodies do with the data collected from them: 59%

Strongly believe they have lost control over their personal data: 81%
FLOW OF HEALTH DATA IN HEALTHCARE

Fragmented health data across multiple sites

- Low transparency over data accesses
- Incomplete/inaccurate records of data
- Low security of data
- Low control over personal health data
- Single point of failure

Complex ecosystem
hospitals, physicians, clinical sites, pharmacists, laboratories, sponsors, insurers
Data protection evolved over time towards a mechanism for power redistribution in the context of personal data collection:

- Introducing measures to avoid the risks associated with the processing of personal data
- Empowering individuals to take control over the use of their data by granting them data protection rights
- Integrating accountability requirements for ensuring compliance with the data protection principles
Blockchain is a shared and synchronised database maintained by a consensus algorithm.

Decentralized network to process information in such a way that the underlying “meaning” of the information is completely obfuscated.

- Enables accountability by allowing visibility and traceability over who accesses data
- Allows more control for data subjects over their data
- Guarantees data integrity and security

<table>
<thead>
<tr>
<th>Autonomy</th>
<th>Centralized</th>
<th>Decentralized</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Authority</th>
<th>Centralized</th>
<th>Decentralized</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>Availability</th>
<th>Centralized</th>
<th>Decentralized</th>
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<th>Confidentiality</th>
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<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
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<table>
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<th>Tenacity</th>
<th>Centralized</th>
<th>Decentralized</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
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</tbody>
</table>
VISION FOR ENHANCED PRIVACY WITH SELF-SOVEREIGN IDENTITIES

- Healthcare consumers
- Healthcare providers
- Industry representatives
- Regulatory authorities

✓ Zero-knowledge proof for verifying attributes while maintaining user **anonymity**
✓ Opportunity to issue **abstract** verifiable claims
✓ Possibility to limit attributes in verifiable claims to the minimum necessary (**data minimisation**) 
✓ Exchanging verifiable claims off-chain via encrypted channels (**data security**)

Decentralized identity

did:example:123456789abcdefghijk

DID Document

created: 19/11/20 12:44
public key: 22x65445sa
type: RSSigningKey2018
owner:
did:example:123456789a...

PharmaLedger

IDENTITY MANAGEMENT TASK FORCE

PharmaLedger

DIA EUROPE 2021 ADVANCING HEALTH PRIORITIES

15 – 19 MARCH | VIRTUAL
PharmaLedger’s Regulatory, Legal & Data Privacy Framework has the objective to provide an ethical and legal backbone framework for the project, paying special attention to EU data protection and privacy legislation in order to promote and ensure compliance.

The outcome of this framework will be a comprehensive overview of guidelines for compliance on the relevant principles, which will also reflect in the technical requirements of PharmaLedger’s platform and use cases.

**Description of Work**

- **Legal and Ethical Inventory**: Preliminary analysis to establish the first draft of the relevant ethical and legal requirements and identify the key principles that should be considered in the general setting of PharmaLedger.

- **In-depth Legal and Ethical Study**: Detailed analysis of the relevant applicable EU legislation, case-law and doctrine regarding the use cases and the platform development.

- **Legal and Ethical Evaluation**: Assessment to verify that the identified ethical and legal requirements are adequately implemented in the design and development of the project’s outcome.
eConsent use case
Inadequate processes to ensure the quality of clinical trials

Inaccurate or incomplete clinical trial records.

Compliance with the clinical trial protocol make up

>50%

>50%

5-10%
KEY COMPONENT

Informed Consent
What is impacted by the Informed Consent? **Everything! No participant consent = No trial**

Screening

Data Collection, Procedures and Analyses

Secondary data Sharing

**FLOW OF CLINICAL TRIALS | PROBLEM**

**BLOCKCHAIN PLATFORM**

One trusted, immutable and shared source of consent and trial data

Process automation in a trusted environment

Permission access to data specified by role in near real-time
INFOMED CONSENT | KEY INFORMATION PROVIDED TO PATIENTS IN CLINICAL TRIALS

Purpose of Trial and Description of Procedures

Description of Risks and Benefits for Participation in Trial

Alternatives Treatments

Rights and privacy of Trial Participants

It’s a cumbersome but KEY process

• Important to have easy-to-understand language
• Allow patient to ask as many questions as necessary
• Give as much time as needed to potential subjects to make decision

2-7% Informed consent related issues observed by Good Clinical Practice inspections

Blockchain technology can ensure adherence to a patient’s consent and their rights and safety during the trial.
CURRENT SITUATION

CHALLENGES

- Complex, and inefficient
- Non-compliance risk
- Siloed information – less transparency and more confusion
- Spot-check inspections are limited to post non-compliance
Conducting a clinical trial in a blockchain ecosystem

- **Transparency**
- **Security**
- **Trust**
- **Efficiency**

- Sponsor
- Ethics Committee
- Regulatory Authority
- Laboratory
- Clinical Sites
- Authorized Clinical Research Organisation
- Clinical Research Associate
- Trial Participant
**Why Blockchain**

**Uses + Value of Blockchain**

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

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

---

- **Consistency of information** viewed by relevant participants
- **Patient ownership** and ability to decide which information is shared

---

- **Changes in study protocol** provided to patient in near real-time
- **Awareness and visibility** of consent status changes applied in near real-time
### Value Proposition to Stakeholder

<table>
<thead>
<tr>
<th>Trial Participant</th>
<th>Clinical Site</th>
<th>Sponsor / Clinical Research Associate / Clinical Research Organization</th>
<th>Regulatory Authority / Ethics Committee</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct versions used</td>
<td>Reduced time required for document review</td>
<td>Reduced time required for document review and verification</td>
<td>Confidence in informed consent being obtained and recorded as per GCP, using correct versions</td>
<td>Compliance demonstration following consent provided</td>
</tr>
<tr>
<td>Re-consent needs notified in real-time</td>
<td>Ensures correct current version used and recorded correctly</td>
<td>Confidence in use of correct versions</td>
<td>Immediate notification of new versions submitted for approval</td>
<td>Real-time changes in sample testing following consent withdrawal</td>
</tr>
<tr>
<td>Withdrawal of consent in real-time</td>
<td>Any re-consent needed notified</td>
<td>Ensure patient safety</td>
<td>Real-time approval of new versions (time saving)</td>
<td></td>
</tr>
<tr>
<td>Clearer explanation of clinical trial’s information</td>
<td>Ensure auditability, traceability of data</td>
<td>Simplifies management of different versions of document as used at different locations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial efficiency</td>
<td></td>
<td>Site / country / language specific versions can be managed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient empowerment</td>
<td></td>
<td>Ensure auditability, traceability of data</td>
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### ADVANTAGES TO ALL

- Patient Empowerment & Engagement
- Transparency (Traceability and Access)
- Trust (Security and Integrity)
- Reduced Process Time and Operational Expenses
- Real-time updates and changes
Block chain technology has the potential to transform healthcare

- Patient Empowerment & Engagement
- Transparency (Traceability and Access)
- Trust (Security and Integrity)

Broad adoption of blockchain technology in healthcare will only occur when

- Both technological and non-technological challenges are addressed

Creation of a win/win situation for all stakeholders in a decentralized ecosystem while mitigating risk
THANK YOU

PharmaLedger

NOVARTIS

NovoSoft

Novo Nordisk

AstraZeneca

Boehringer Ingelheim

Bambina Gesù Ospedale Pediatrico

Uniklinikum Würzburg

Hospital Espírito Santo E.P.E.

Bioscience Solutions

MSD

Pfizer

Roche

Inspired by patients. Driven by science.

Technological solutions for the connected world.

INCM

KU Leuven

GTP

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See you next year