

Success Story

Sharing our experience & lessons learned in IMI-IHI projects

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LifeSTech



LifeSTech



POLITÉCNICA

Life Supporting Technologies

Research & Innovation group
from Universidad Politécnica de Madrid
dedicated to the design, development &
evaluation of solutions based on ICT
(Information & Communication
Technologies) with focus
in health, well-being
and....





Creating and promoting
**NEW IDEAS, METHODS &
TECHNOLOGICAL SOLUTIONS**

covering every aspect of the value chain of e-health
organization

We are one of the largest
e-health research groups in Spain.
We maintain partnerships within
the public and private sectors in
different areas of research and
development

OUR VISION

To consolidate a milestone in the process of digitalisation of health, exploiting the power of data and technologies, in favour of patient care, disease prevention and personalisation of treatments, contributing to the quality of life improvement.

LifeSTech
Life Supporting Technologies

OUR MISSION

Reformulating traditional models of health and social care through technological innovation and research



INNOVATION COMING TO LIFE

With an area of over 150 m², it features monitoring and regulation of the environment, where ideas are born, developed and the most cutting-edge services are tested in the e-inclusion (AAL) and e-health (P-Health).



USER AREA

An open fully-domotized space with our greatest technological deployment, monitoring and tracking users in their interaction with different solutions and interfaces such as touch screens, hand gestures, natural speech, etc.



CONTROL ROOM

Communication systems, data storage & management, ensuring security and high availability of resources inside and outside the Living Lab.



VR ROOM

With two projection planes, Point-of-View tracking, wheelchair adapter, motion capture suit and other wireless VR equipment for immersive experiences.



There is a million ways of doing things. We choose to do them like this:

INVOLVED WITH SOCIETY

EMPATHY

COMMITMENT

DISRUPTION

JOY

VALUES

INFLUENCE

We contribute with research to the generation of tools for making the best decisions

CREATE

We create dedicated solutions to improve quality of life for all people

AWARENESS

We work hard to convey positive emotions through novel experience scenarios

EMPOWER

We help healthcare professionals and empower patients to take responsibility



IMI & IHI Two & One Stage Proposals

Building Health Data Spaces for the next generation of AI services and Medical Devices

COORDINATOR



TRUSTED DATA
MANAGEMENT

A blockchain-based platform covering privacy compliance in supply chain, clinical trials, and governance in health data.

20 PARTNERS

7 USE CASES

€ 23.5M

TECH MANAGER



PATIENT
EMPOWERMENT
– EPI –

A key piece -the Gravitate Lens (G-Lens)- which focuses (but does not conceal or filter) approved ePI content, and offers a route for patients to access trustworthy, up-to-date information that better meet their individual needs.

40 PARTNERS

6 PILOTS/USERS

€18.5M

COORDINATOR



ADHERENCE TO
TREATMENT

A disease-agnostic behavioral and adherence model for improving outcomes, cost-effectiveness, accessibility, sustainability and quality of healthcare overall.

27 PARTNERS

18K in 6 PILOTS

€ 11.9M

COORDINATOR



PATIENT-GENERATED
HEALTH DATA

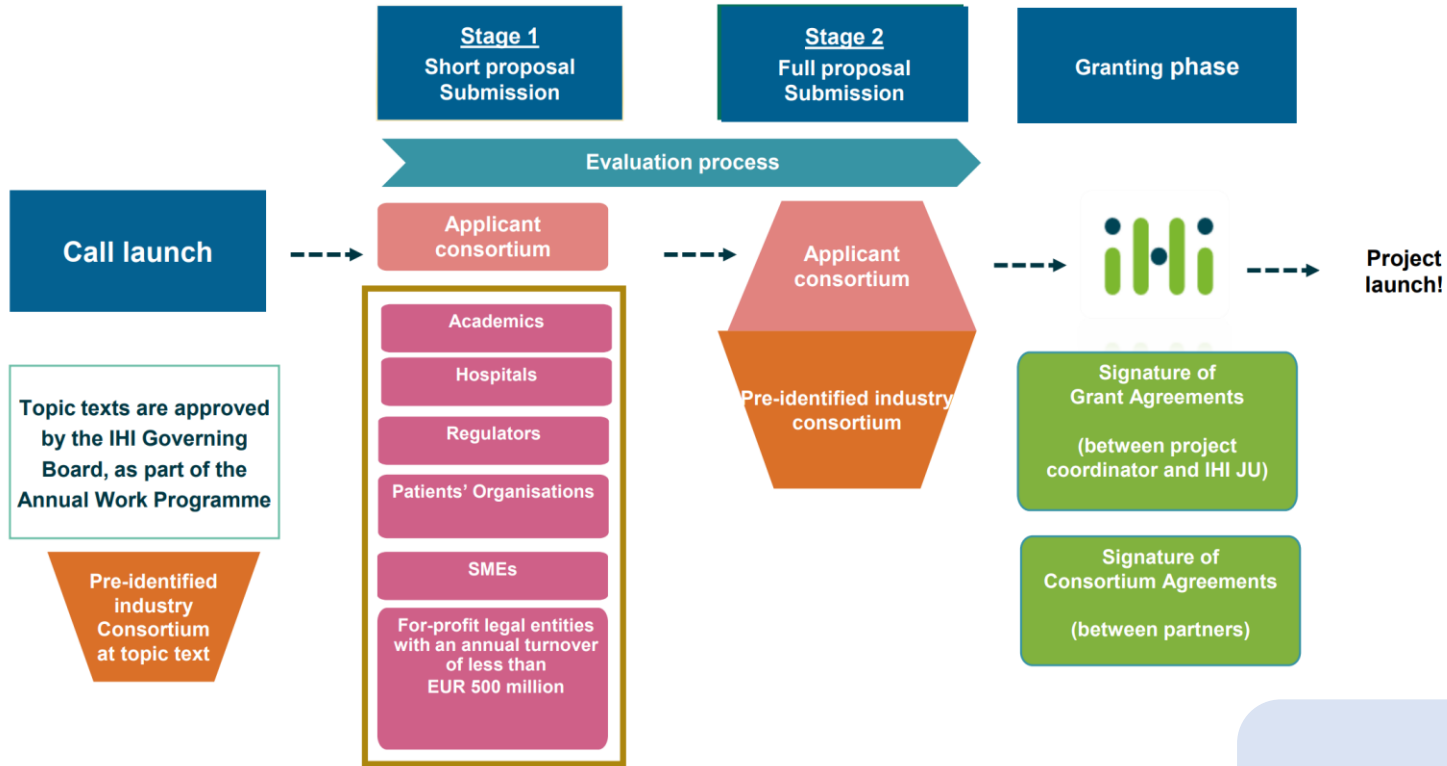
Improved outcomes through digital health solutions, patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs)

15 PARTNERS

10 USE CASES

€ 17M

IMI & IHI Two-Stage Proposals




Two-Stage Calls: Private members & Contributing Partners

Pre-identified (45% in-kind contribution)

- ✓ main drivers of the topic definition
- ✓ identify in-kind contributions via expertise and assets
- ✓ listed in the topic text (overall, not per partner)
- ✓ not eligible for funding


Not pre-identified

- ✓ any other participant part of the applicant consortium during the stage 1 not involved in the topic definition
- ✓ join the consortium afterwards (i.e. GAP or during the project implementation via amendment)
- ✓ can be eligible for funding



Propuestas

- Leer bien la call
- En los zapatos de la industria
- Puerta fría

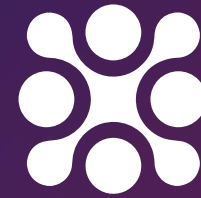


Ira vez
Preguntar y hablar con otros proyectos y coordinadores

Proyecto: Buena relación, proactivos, **Industry Leader, business oriented, DoA en la mano**



PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE



PharmaLedger
ASSOCIATION

FROM PROJECT **TO PRODUCT**

A FULL CONSORTIUM & ROADMAP



- 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

- 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

- 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

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

CHRISTMAS 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

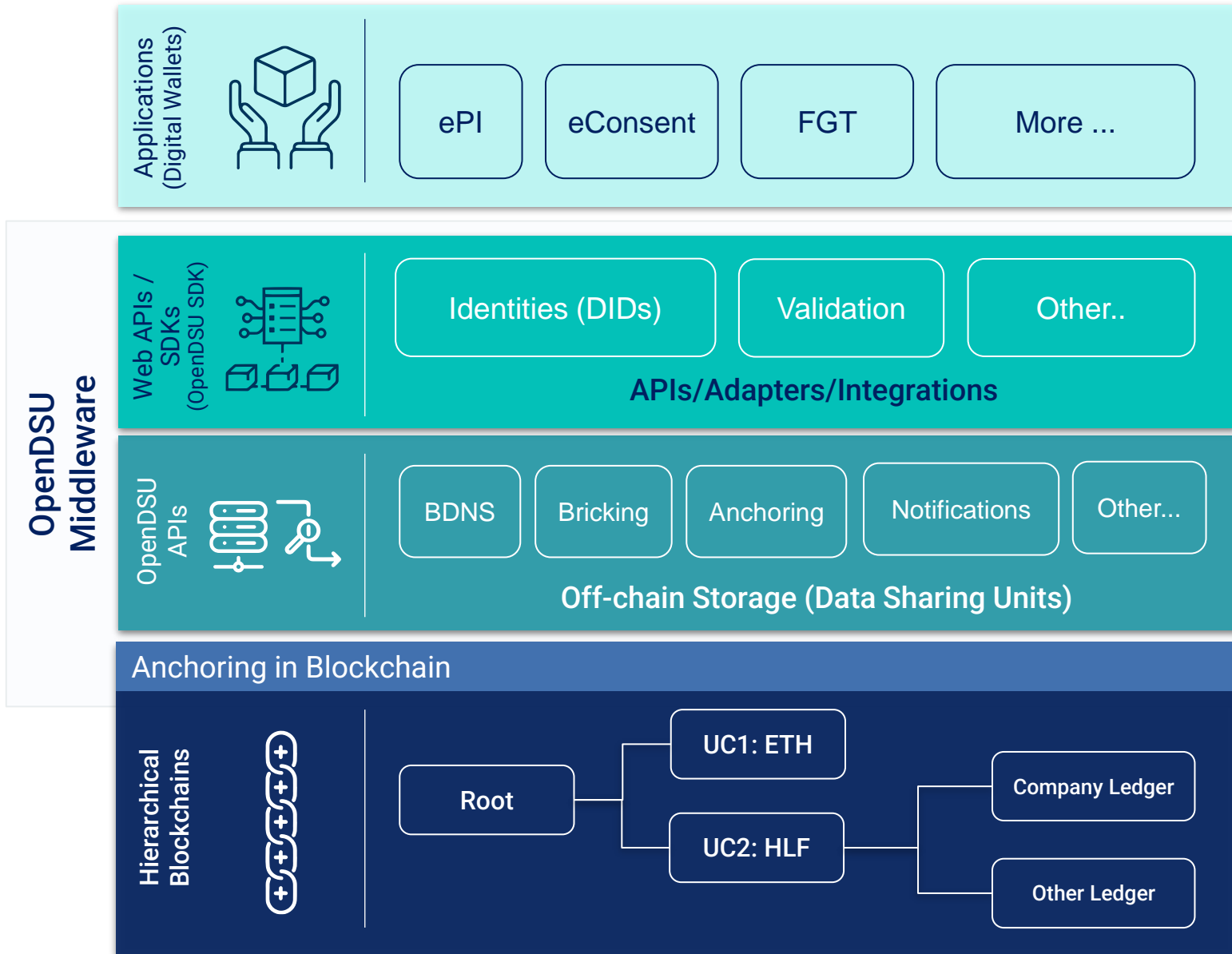
PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE



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

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

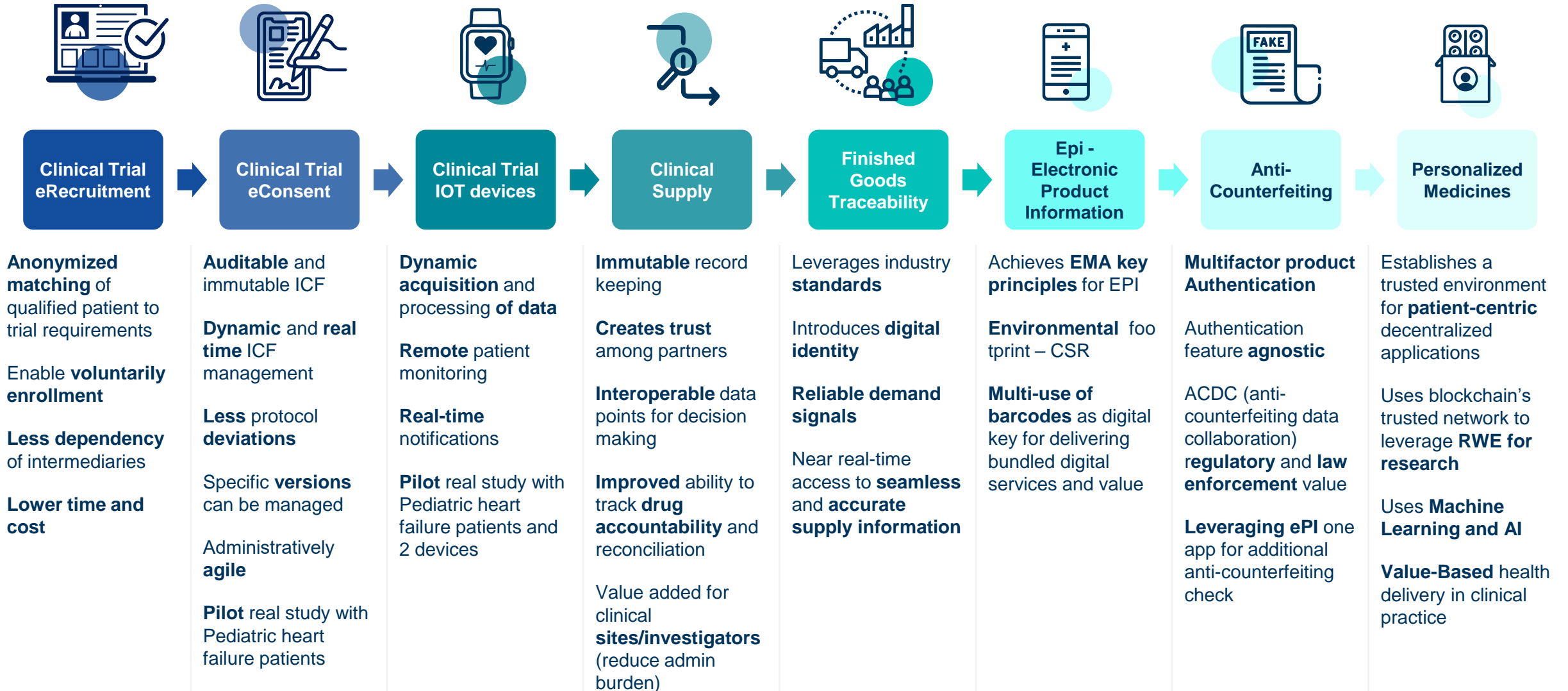
Anchor Hashlinks, Versions

- 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

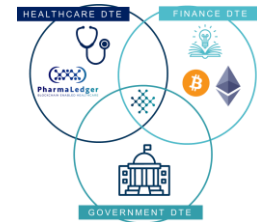
VALUE CHAIN – USE CASES VIEW



PharmaLedger PROJECT



July 2021 – Dec. 2022 – From Project to Product

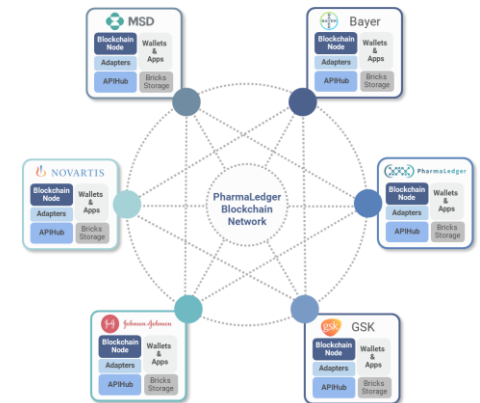


PROJECT Consolidated and Towards sustainability

- Successful IMI review! – **PharmaLedger Considered a Flagship IMI Project**
- We started with focus on "NextGen" PL Governance → Tiger Team for sustainability (Toledo & Lisbon Meetings)
- **PharmaLedger brand recognized** : Strong Communication & Engagement in social media, conferences, partnerships: EBC, DIA, LogiPharma, GS1, Rx360, SCOPE, etc; in Blockchain Community, EPFIA/IMI
 - Various Collaborations signed (e.g., IMI Gravitare Health)
 - PharmaLedger showcased in the IMI Digital Health Impact project)
- Close business + technical collaboration across WPs and UCs:
 - **All UCs in Prototype stage & ePI advanced in Pre-Production stage**
 - **WPs have reached all objectives**
- DSUs and Architecture consolidated **& 6 Nodes Deployed**

Foundations for the Digital Trust Ecosystem Created are in place

- Experience in blockchain and DSUs is consolidated, and awareness has been raised
- Ethics & Advisory Board followed up and successful final evaluation
- **Next Gen turned into PLA: PLA set → March 2022 (bylaws, Governance, landing page & branding, initial roadmap..)**
- Summer 2022: Endorsements to approve sustainability and Prepare for closing the project
- **PLA is in PharmaLedger → Getting ready to launch PLA in January 2023 as successor of PharmaLedger**



30 Members
10 EU Member States,
Switzerland, Israel and USA



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

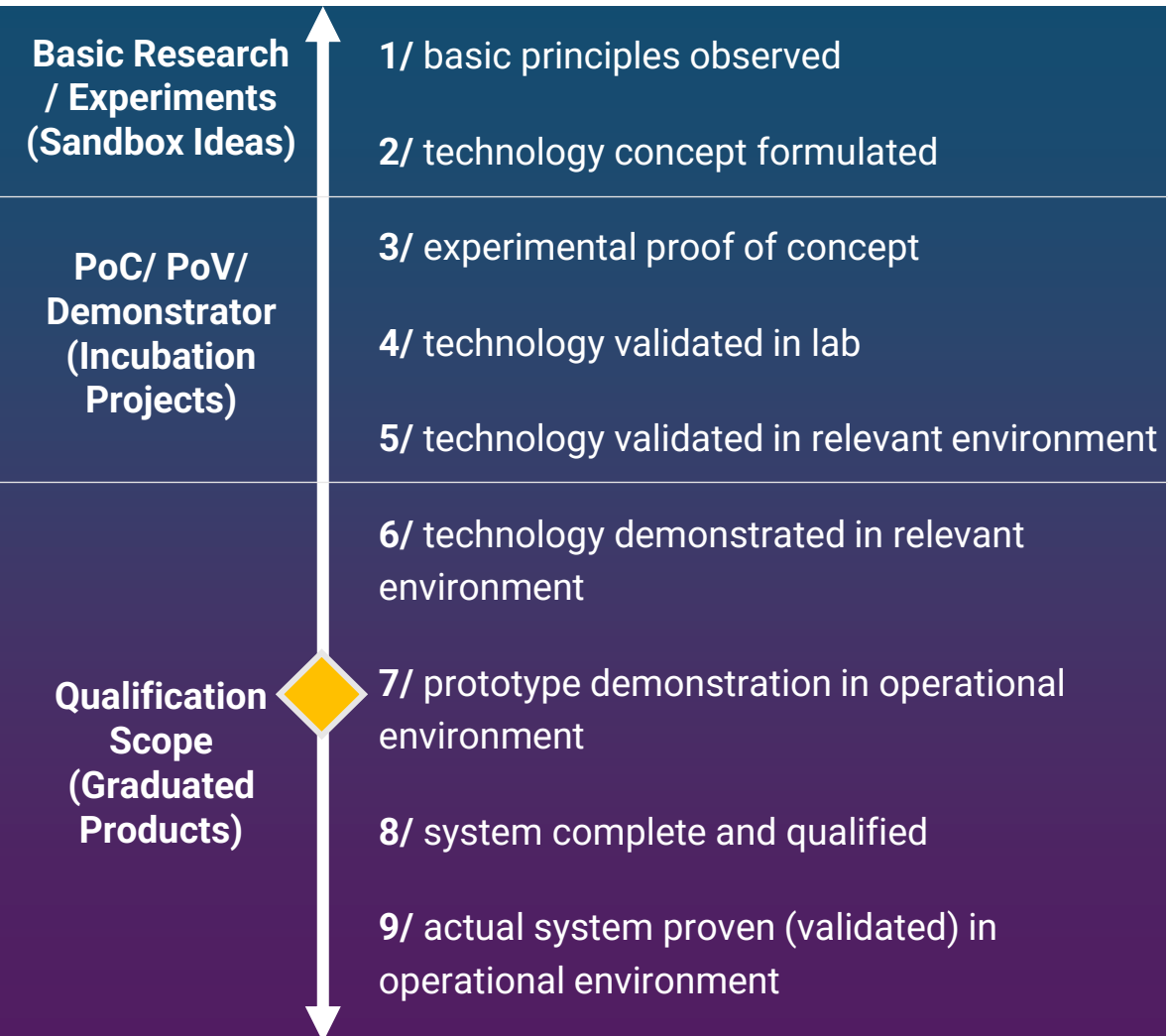
Business Model Canvas

DECENTRALIZED CLINICAL MANAGEMENT

<p>Key Partners </p> <ul style="list-style-type: none"> • Pharmaceutical industry • Trial Sponsors • Verifiable credential entities (GLEIF) • Standardization partners (FIHR) • CRO's • Trial participants • HCPs: Hospitals, Clinics, Universities, Investigators, Researchers • Laboratories • Ethics committees • Healthcare Regulatory authorities • Patient organizations • Trade alliances: EFPIA, PhRMA • Standards Orgs: GS1, HL7 • Legal counsel 	<p>Key Activities </p> <ul style="list-style-type: none"> • Clinical trial (Remote) • Scientific dissemination • Ecosystem members` Collaboration • Incubate new 'product' ideas, or enhancements • OS/Blockchain ecosystem maintenance • Ownership Data Privacy Reqs. • Contribute to local/global health & communities / Trials/ Patients 	<p>Value Proposition </p> <p>Business [user]</p> <ul style="list-style-type: none"> • Patient-centric trial • Patient empowerment & Security • Anonymity / Open & Inclusivity • Real-time updates and notifications • Remote decentralized CT in DTE • Remote trial monitoring • Remote patient monitoring • Access diverse populations (cultural / diversity) • Harmonized RWD and evidence creation for HC personalization 	<p>Customer Relationships </p> <p>How we interact.</p> <p>Attracting, maintaining, informing</p> <ul style="list-style-type: none"> • 3rd party Vendors • MedTech / Digital wearable device supplier • Member recruitment (BCB) • HCPs: Hospitals, Clinics, Universities, Investigators, Researchers 	<p>Customer Segments </p> <p>Who are PLA's customers?</p> <ul style="list-style-type: none"> • Patients / Guardians (traditional patients and underserved communities (ethnic and social economic populations)) • Communities impacted • Doctors, PIs, Researchers • Pharmacies • Hospitals • Clinics-site staff • Manufacturers, including MedTech and device providers • Distributors, wholesalers • Patient advocacy groups • CRO's • Clinical trial participants • Healthcare professionals • Clinical sites • IRB/EC's [ICF approval]
	<p>Key Resources </p> <ul style="list-style-type: none"> • IT & Technical support (customization, support desk, interoperability) • Data adaptors & Standards • Sponsors (trial managers, research associates) • Sites (investigators, coordinators) • Patients • Ethic committee members • MedTech devices & Platforms • Governance body • Quality Mgmt System 	<p>Transparency [Tx / Records]</p> <ul style="list-style-type: none"> • Trust & Transparency • Easy Information sharing • Removal of centralized processes and systems • Improved data capture <p>Technical / System</p> <ul style="list-style-type: none"> • Unified platform • Future interoperability with multiple wearable devices • Decentralized network • Data marketplace 	<p>Potential Channels </p> <ul style="list-style-type: none"> • App/Google store • Google/FB ads • Ad on health publishers (website) • Patient Associations • Physician Associations (per TA perhaps?) • Conferences (HIMMS, EFPIA etc) • Social Media (twitter, other platforms) • Traditional platforms (TV and other media ads) • Investigator networks 	
<p>Cost Structure </p> <ul style="list-style-type: none"> • Fixed cost structure funded by sponsor [Pharmaceutical Industry] which decreases when the number of trials on platform increases • Development • Quality Management System • Monitoring • Helpdesk [patient facing element] 	<p>Revenue Streams </p> <ul style="list-style-type: none"> • RWE data marketplace • Sponsorship advertising / Patient incentivization • Donations and grants • Through PLA structure/funding schemas 			



Development Status & Technology Readiness Level (TRL)



Technical Development & Documentation

- Technical development is almost concluded (integration of insights and evaluations)
- UC Description & Software Technical Specification
- Developed app, wallets and data adaptors
- Testing results (insights integrated)
- Users' documentation for Testing & Mockup
- All relevant documentation stored in teams but not together

Demonstrator Status

The demonstrator is available as a standalone solution with SSApps for all UCs` stakeholders (UC6, UC7 & UC9)

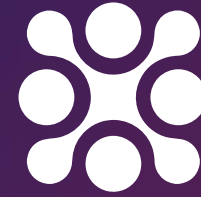
- Sponsor
 - Clinical Site
 - Clinicians
 - Researcher
 - Patients
- Testing & Validation performed

Patient/ User Feedback

- Mock trial and patient evaluation completed
- Results of feedback collection to be documented
- UC Team has done preliminary evaluation with partners – clear requirements integrated



PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE



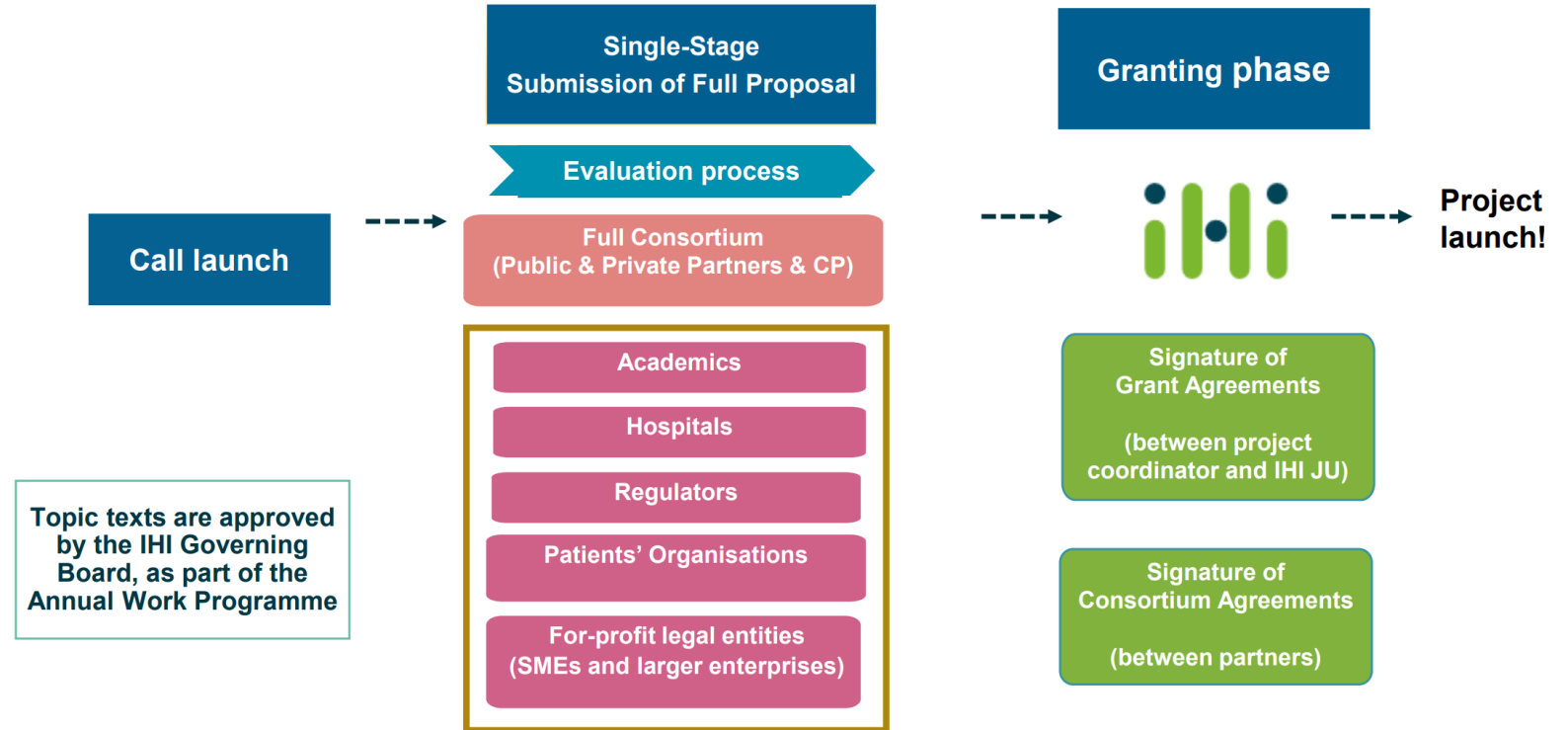
PharmaLedger
ASSOCIATION

FROM PROJECT **TO PRODUCT**

IMI & IHI – Single Stage Proposals

Propuestas:

- Leer bien la call
- **Gestionar el tiempo**
- **Comenzar con tiempo (6M)**
- En los zapatos de la industria
- Buscar consorcio industria (puerta fría)
- Industry driven
- **Cash** vs In-kind + Applicants 45% of the action's eligible costs + (IKOP, FC, **IKAA**) industry
- Posibilidad de no ganar (Industria) → Buena propuesta



Proyecto: Buena relación, proactivos, **Industry Leader, business oriented, DoA en la mano**

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