PharmaLedger – Selected Use Cases for Acceleration of Blockchain Adoption in Healthcare

June, 2020 – Following PharmaLedger's January kick-off, strengthening the Innovative Medicines Initiative (IMI) goal to accelerate healthcare innovation, the PharmaLedger project is pleased to announce selected use cases. Representatives of the 29 entities achieved this first major milestone on their three-year collaboration journey to deliver a common and widely trusted blockchain-based platform and use case reference implementations for supply chain, clinical trials and health data. The selected use cases are intended to prove the value in the reference implementation areas, accelerating the delivery of innovation to benefit the entire healthcare ecosystem, with a constant focus on delivering value to the patient.

Selected Use Cases in each reference domain comprise:

Supply Chain. The use cases focus on delivering a supply chain blockchain core for reference implementations of **clinical supply** of investigational medicinal products and downstream **traceability of finished products.** This core includes key capabilities such as material traceability, inventory visibility, digital recalls and pack-level identity that ensures scalability to other supply chain scenarios. Drug sample distribution, and early access programs are other specific supply chain scenarios that are envisioned to leverage this core solution. Within the supply chain domain, a use case linked to trust in medicine has been selected. This use case delivers a blockchain-anchored **eLeaflet** to a mobile app, website or printer, obtained through a scan of the data matrix code on every pack. Blockchain guarantees the integrity of approved product information as a "single source of truth" while preserving patient privacy. eLeaflet, or Electronic Product Information (Epi), can serve as a foundation for future scalability of functionalities that create value for the patient such as recalls, product information updates, known drug interaction issues and instructions on disposal of medicines in an environmentally friendly manner. The scan also provides a multi-factor authentication - **anti-counterfeit** functionality - for the check of medicines, embedded counterfeit features, and the product status, which might indicate stolen or illegally diverted products.

Health Data. **Accelerating recruitment for clinical trials**, a major source of cost and concern for both patients and trial sponsors, is a key objective of the project. PharmaLedger will create a trial to patient health profile matching capability to streamline the process. Patient privacy during the matching as well as transparency of the usage of the patient data is required. The industry approach will define common pre-screening criteria across the trial sponsors and will ensure GDPR compliant patient permission. The use case **Personalized Medicine** will support enhanced trust and allow data privacy and security through blockchain, de-identification and encryption, when approaching better and personalized treatments. For both Health data and Clinical trials domains, the PharmaLedger project will work on **dynamic permissioning** in order to strengthen patient data ownership and full control over who, and when, a stakeholder is allowed access health data.

Clinical Trials. The **eConsent use case** will also create a digitally enabled, trusted consent process for patients in order to reduce the massive burden associated with current paper-based processes. The use case on **medical device (IoT)** will integrate IoT data with advanced analytics. This use case aims at supporting trusted data, as well as high data traceability and auditability for remote data capture; this will allow to reduce patient burden due to reduced site visits and increase flexibility to participate in clinical trials.

"For Blockchain to achieve its potential in helping our society become digitally trustworthy, mass adoption and true horizontal innovation needs to take place. PharmaLedger contributes to that by proposing and developing both, use case specific solutions and an overarching open source platform."
Clarisse Dias da Mota – Blockchain Business Analyst - Novartis / PharmaLedger PMO Culture and Adoption

"Clinical research is a complex process involving various actors where trust, data sharing, security, and visibility need to be established. This project and its use cases provide the opportunity for the industry to engage, share, and work together to address those." Disa Lee Choun - Head of Innovation, GCSO – UCB / PharmaLedger DRA Lead Clinical Trials and Health Data

PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

#####

About Pharma Ledger.

Sponsored by the Innovative Medicines Initiative (IMI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) under the Horizon 2020 programme, PharmaLedger is a 36 month project that brings together 12 global pharmaceutical companies and 17 public and private entities; including technical, legal, regulatory, academia, research organizations and patient representative organizations.

Industry Leader
NOVARTIS

Coordinator
POLITÉCNICA

Consortium Members:

- Universidad Politécnica de Madrid (Project Coordinator) - ES
- Novartis (Industry Leader) – CH
- Projecto Desenvolvimento Manutenção Formação e Consultadoria, Lda - PT
- RomSoft SRL - RO
- Arteevo Technologies Ltd. - IL
- Technovative Solutions Ltd. - UK
- EKON Modelling Software Systems Ltd. IL
- Centre for Research and Technology Hellas - GR
- AbbVie INC. - NL
- AstraZeneca AB - SE
- Bayer Aktiengesellschaft - DE
- Boehringer-Ingelheim GmbH - DE
- GlaxoSmithKline Research and Development Limited - UK
- Janssen Pharmaceutica NV - BE
- Merck Sharp & Dohme Corp - US
- Novo Nordisk A/S - DK
- Pfizer Ltd - UK
- F.Hoffmann-La Roche AG - CH
- UCB Biopharma SPRL - BE
- Katholieke Universiteit Leuven - BE
- Onorach Ltd - UK
- National Research and Development Institute for Cryogenics and Isotopic Technologies - RO
- University Hospital Würzburg - DE
- Democritus University of Thrace - GR
- Hospital do Espírito Santo de Évora - PT
- Ospedale Pediatrico Bambino Gesù - IT
- Imprensa Nacional-Casa da Moeda - PT
- European Patient Forum - BE
- European Forum for Good Clinical Practice - BE

www.imi.europa.eu |www.pharmaledger.eu|Twitter| Linked In| YouTube

Disclaimer: this communication reflects the author's view and neither IMI nor the European Union, EFPIA are responsible for any use that may be made of the information contained therein.