

PharmaLedger – Strong foundations in project’s first year sets stage for accelerated development and ecosystem engagement

December 18, 2020 – PharmaLedger’s 29 consortium members, joined by the new Advisory Board members, held the first-year virtual plenary meeting this week. The aim of the meeting was to review the achievements accomplished during 2020 as part of the three-year collaborative project journey. Despite the current COVID-19 challenges, the project made significant progress towards its goal to deliver a widely trusted blockchain-based platform with use case reference implementations that will validate the platform and bring value to patients and the health care ecosystem. A key achievement from the year is the delivery of business and functional descriptions for eight use cases selected in the areas of supply chain, clinical trials and health data. This sets the stage for technical realization of the demonstrators in 2021.

Among the eight use cases, the electronic Product Information (ePI) use case was selected as an accelerator for the blockchain platform development. This first working demonstrator serves as the testing bed for the PharmaLedger platform components and basic architecture, focusing on leveraging the innovative Open Data Sharing Unit (*OpenDSU*) solution for off-chain storage. Additionally, the project analysed and prepared the first recommendations for a future governance model, planned to be operational after the project ends in December 2022. The project established an ethical and legal requirements framework for the project activities and operational pilots. Moreover, PharmaLedger’s culture and adoption work package delivered the [PharmaLedger.eu](https://pharmaledger.eu) website, a strong social media presence, a public webinar, and supported the engagement of project representatives at many conferences throughout the year. Also within 2020, PharmaLedger has engaged with the European Blockchain Convention for a collaboration on dissemination of the project results, strengthening the continuous education and awareness about the impact of blockchain in transforming healthcare for the better.

The PharmaLedger Advisory Board

The project is pleased to announce the establishment of the Advisory Board, staffed by experts in relevant and complementary fields to PharmaLedger’s activities. The members will contribute to, and help steer realization of use cases in the supply chain, clinical trials and health data domains, as well as the overall blockchain environment strategy. They will also support the project’s deliverables in such areas as governance for a sustainable blockchain-enabled platform beyond the project, regulatory and stakeholder engagement and adoption. The board consists of the following members:

- **Walid Al Saqqaf**, Entrepreneur and Founder of Insureblocks
- **Jose Antonio Cano**, Research Director, International Data Corporation (IDC) Spain
- **James Canterbury**, Principal at Ernst & Young and Leader of the International Society of Pharmaceutical Engineers (ISPE) Blockchain Special Interest Group
- **Robert Celeste**, Founder of the Center for Supply Chain Studies
- **Catherine Chronaki**, Secretary General at HL7 Europe and President European Federation for Medical Informatics (EFMI)
- **Jesper Kjær**, Director of Division, Data Analytics Centre, Danish Medicines Agency
- **Jim Nasr**, CEO of Acoer and Architecture Lead for PhUSE Blockchain Working Group

Outlook

PharmaLedger is now established as an effective driver for adoption of blockchain solutions in healthcare and engagement with regulatory agencies. With the additional value brought by the Advisory Board and increased outreach to stakeholders, the project now transitions from design and foundation to development and deployment of the solutions. Early in 2021, stakeholders can look forward to the publication by PharmaLedger of its original white paper on the *OpenDSU* methodology, which will be followed by a blue paper focused on the intricacies of this methodology for off-chain storage and interoperability. During 2021, the project will heavily focus on education with the release of public trainings and tutorials for the software development community, which highlights the project’s effort in building its open source platform. Dissemination and Communication will follow with public and

internal webinars, the production of video explainers and further engagements for dissemination with conferences and associations. Finally, the project will develop the future governance model and strengthen the further sustainability plan of PharmaLedger.

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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.



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 Modeling 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

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