PharmaLedger

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Summary

We all want 100% certainty that the medical products that we are using are safe, that the instructions that come with our medicines are clear and up-to-date and that during the journey from the factory to our pharmacies our medical products have not been tampered with. Participants in clinical trials also have concerns about the safety of their data, which is often of a sensitive nature, and which needs to be shared with many individuals throughout the course of clinical trials. By harnessing the power of blockchain, the PharmaLedger project proposed new technological solutions that will improve the security of our medicines and boost trust in the pharmaceutical pipeline.

Secure, up-to-date product information in your pocket

With each package of medicine comes a hefty stack of instructions. But if you are a French person and you get sick on holidays in Crete, those instructions will be provided to you in Greek. That makes it much less likely that you will take the medicine correctly, which could have adverse consequences for you. Also, the information provided in the package is only up-to-date from the date that it was packed, so any more recent information cannot be included. That is especially relevant in the case of drugs that are being developed quickly in response to a threat, as happened during the COVID-19 pandemic. What's more, eliminating the thick stacks of paper that are provided with medicines could significantly reduce waste. If all of the information leaflets that are produced in one year globally were laid out flat and placed on top of each other, the pile of paper would be well over 500km high.

The PharmaLedger consortium built an electronic product information app which addresses these concerns, currently being piloted in Singapore and Ecuador and due to be launched soon in several other markets. Co-designed using patient feedback, the app allows you to scan a type of barcode on the package of any medication, which brings you to a digital version of the corresponding information leaflet that can be constantly updated in real time, in any language. The use of blockchain ensures that you always have the correct and up-to-date information that can be trusted, and this solution will dramatically reduce the amount of product information leaflets that have to be printed. And in a future version of the app, the scanned barcode will also be able to alert you if the medical product has been tampered with along the supply chain.

Privacy, security and more accurate information for clinical trials

Clinical trials require the storage, sharing and analysis of large amounts of data, some of which is sensitive and of a personal nature. At present, ensuring that data storage and use is in compliance with privacy regulations is time-consuming and difficult for all actors involved. It is difficult for patients to successfully extract all their data if they wish to leave a trial, and there is a heavy administrative burden on those carrying out the trials, who must review large amounts of documentation.

PharmaLedger's goal was to decentralise the entire clinical trial process so that data will be owned by the trial participant alone, real-time changes in data can be instantly realised, withdrawn consent can be translated directly to removal of relevant samples, and researchers can be sure that data is completely traceable and that they have up-to-date permission to use it.

Decentralising the clinical trial process paves the way for better remote patient monitoring which in turn opens the door to more at-home clinical trials of higher quality. PharmaLedger also worked on secure and safe blockchain-based systems for integrating real-world data and real-world evidence collected via Internet of Things (IoT) technologies – such as wearable devices – into clinical trials.

The first step to a completely decentralised system is the development of blockchain-based eConsent forms. Signed securely by the patients, these consent forms were developed by PharmaLedger and can be updated in real time enabling rapid re-consent for additional procedures as part of the trial, or near-immediate removal of samples or data from datasets if the patient decides to pull out of the trial. It also cuts down on the risk of fraudulent data being used in the project, as well as ensuring that data is being dealt with in accordance with regulatory requirements. The idea was that eConsent could be used in countries which have different regulations so this was also taken into account. Beyond the project's end, eConsent will continue to be optimised by the non-profit which has been set up to further the work of PharmaLedger, the PharmaLedger Association.

Managing supply chains and preventing counterfeiting

From manufacture to patient, there are many points along the supply chain where blockchain could be leveraged to improve security, reduce errors and increase trust in the final product. For instance, the majority of delivery dockets are currently paper-based and can easily be forged. Utilising blockchain would allow that entire process to be digitised, making it more accurate and more secure while enabling the tracking of a package of medicine and reducing counterfeiting. Blockchain-based solutions would also increase transparency within the supply chain – meaning that suppliers would have to undergo less audits and manufacturers would have more visibility on the process from raw materials to finished product. PharmaLedger envisioned a trustworthy depository of information that all the actors along the supply chain could access simultaneously, tracking medicine development in real time. The project investigated solutions to improve the supply chain using blockchain and that work will continue to be carried out by the PharmaLedger Association.

Currently, a 2D matrix code including a barcode and a serial number is the standard for identifying medical products. But a barcode and serial number can easily be faked, with a patient none the wiser. The black market trade in counterfeit medicines creates serious health risks. Estimates show that **between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs**, and that fake anti-malarial medication might be responsible for an additional 116000 deaths. The costs to EU governments of counterfeit medicines is **around EUR 1.7 billion**. In the future, patients will be able to scan the matrix code on the back of a medicine package using the PharmaLedger app and will receive an alert if the medicine packaging is fake.

Ensuring that the legacy of PharmaLedger lives on

The potential that blockchain presents for the healthcare system was proven by the PharmaLedger project, and the consortium developed a non-profit, membership-based association to ensure that the work led by the project will continue. The association currently involves 32 members who work together within various working groups to advance the research on the different use cases explored by PharmaLedger. Some of the projects that the Association will investigate is the further improvement of the electronic product information app, the integration of anti-counterfeit features into the app, furthering the eConsent form for digitising clinical trials and boosting digital traceability for finished products in the supply chain. If you have an idea for a blockchain-related project that could help improve the digital health ecosystem, you can submit a proposal to the PharmaLedger Association's Innovation X Lab, and if it is in line with PharmaLedger's values, a project may be initiated.

Achievements & News

[PharmaLedger - building trust in data sharing through blockchain, to accelerate digital transformation in healthcare](#)

October 2022

PharmaLedger's use cases are designed to build the case for the wider adoption of blockchain within the pharma industry.

[Building digital trust in healthcare using blockchain](#)

November 2024

We chatted to the VP of Ecosystem, Operations and Strategy of the PharmaLedger Association, Clarisse Dias da Mota, about the...

[Trusted, easy-to-read electronic medical information in your pocket](#)

June 2024

Both the PharmaLedger and Gravitate-Health projects are developing solutions that will make it easier and safer for patients to access...

[Crossing the bridge – from project to non-profit](#)

May 2024

Transitioning from an IMI or IHI project to a non-profit association is one way to ensure the sustainability of project...

Blockchain could help put people at ease about sharing their data

Throughout the pandemic, COVID19 contact tracing apps have popped up all over the world. In a recent article, ROMSOFT, a partner in the Pharmaledger project that creates custom R&D software, used the project's personal health data use case as a good example of how privacy concerns related to systems like tracing apps might be overcome, alongside artificial intelligence and machine learning.###

PharmaLedger proposes a protocol called Open DSU, or open data sharing unit. This is a unit of data that is located off the chain, encrypted and only then directly anchored in the blockchains. This means that patients are in control of their confidential data via a digital wallet on their smartphones. Instead of managing your money, you manage the keys to your private data.

'With a platform like PharmaLedger, any consumer app that will be built on top of it will follow the governance rules of the PharmaLedger platform, including the way data privacy is enforced,' the article reads. 'Enabling this type of ownership and providing information that is relevant, correct and easy to understand is essential in managing fear and increasing trust in data sharing.'

Find out more

- Read the **[article in full](#)**

PharmaLedger selects use cases to advance adoption of blockchain in healthcare

The goal of IMI's PharmaLedger project is to deliver an open source, blockchain-based platform for the healthcare sector, using the supply chain, clinical trials, and health data as case studies. Now, it has selected use cases in these

areas to validate the blockchain platform architecture.###

In the supply chain area, one of PharmaLedger's selected use cases will help to boost trust in medicines. A patient could simply scan a data matrix (QR) code on a packet of medicine to obtain (via a mobile app or website) a blockchain-anchored 'eLeaflet' on the medicine inside. The blockchain technology would guarantee the reliability of the information, and the solution could also be used to implement an anti-counterfeit feature where the user would be able to check product authenticity. Looking to the future, the eLeaflet could also be used to provide updates on the medicine, manage recalls, and offer advice on the safe (environmentally friendly) disposal of the drug.

In the health data field, PharmaLedger has selected a use case that will make it easier to match up patients with clinical trials (all while preserving patient privacy). In the clinical trials field, a use case on medical devices will integrate device data ('Internet of Things') with advanced analytics. This will support remote data capture during clinical trials, cutting down on the number of times patients would need to visit the clinic for tests.

In the health data and clinical trials fields, the project will also work on a use case that will strengthen patients' ownership of their data, giving them greater control over who can access their health data and when, with a view to enabling a health data marketplace.

PharmaLedger plans to open up the platform for external parties to connect their own use case solutions. The platform will work in a similar way to an app store which requires a minimum standard of compliance but which is open and flexible to the needs of different use cases.

Find out more

- Read the **full news story**
- Learn about the blockchain thanks to PharmaLedger's **short video explainer**

Participants

Show participants on map

EFPIA companies

- Abbvie Inc, North Chicago Il, United States
- Astrazeneca AB, Sodertaelje, Sweden
- Bayer Aktiengesellschaft, Leverkusen, Germany
- Boehringer Ingelheim Internationalgmbh, Ingelheim, Germany
- F. Hoffmann-La Roche AG, Basel, Switzerland
- Glaxosmithkline Research & Development Limited, London, United Kingdom
- Janssen Pharmaceutica Nv, Beerse, Belgium
- Merck Sharp & Dohme Corp, Whitehouse Station Nj, United States
- Novartis Pharma AG, Basel, Switzerland
- Novo Nordisk A/S, Bagsvaerd, Denmark
- Pfizer Limited, Sandwich, United Kingdom
- UCB Biopharma, Bruxelles / Brussel, Belgium

Universities, research organisations, public bodies, non-profit groups

- Dimokritio Panepistimio Thrakis, Komotini, Greece
- Ethniko Kentro Erevnas Kai Technologikis Anaptyxis, Thermi Thessaloniki, Greece
- Forum Des Patients Europeens, Brussels / Bruxelles, Belgium
- Katholieke Universiteit Leuven, Leuven, Belgium
- National Research And Development Institute For Cryogenics And Isotopic Technologies Icsi Rm Valcea, Ramnicu Valcea, Romania

- Ospedale Pediatrico Bambino Gesu, Roma, Italy
- Pharmaledger Association, Basel, Switzerland
- Unidade Local De Saude Do Alentejo Central Epe, Uniao das Freguesias de Evora, Portugal
- Universidad Politecnica De Madrid, Madrid, Spain
- Universitaetsklinikum Wuerzburg - Klinikum Der Bayerischen Julius-Maximilians-Universitat, Wurzburg, Germany

Small and medium-sized enterprises (SMEs) and mid-sized companies (<€500 m turnover)

- Arteevo Technologies LTD, Tel Aviv, Israel
- Ekon Modeling Sofware Systems LTD*Ekon, Modi'in-Maccabim-Re'ut, Israel
- Imprensa Nacional - Casa Da Moeda, S. A., Lisboa, Portugal
- Onorach LTD, Dundee, United Kingdom
- Pdm E Fc-Projecto Desenvolvimento Manutencao Formacao E Consultadoria S.A., Lisboa, Portugal
- Romsoft SRL, Iasi, Romania
- Technovative Solutions LTD, Manchester, United Kingdom

Patient organisations

- European Forum For Good Clinical Practice, Bruxelles / Brussel, Belgium

EU funding per project participant

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BLOCKCHAIN ENABLED HEALTHCARE

Facts & figures

Start Date
01/01/2020

End Date
31/12/2022

Call
IMI2 - Call 15

Grant agreement number
853992

Type of Action:
RIA (Research and Innovation Action)

Contributions
€

EU funding
8 290 694

EFPIA contribution
13 827 631

Total Cost
22 118 325

IMI2 Big data and knowledge management

Project links

Project website
pharmaledger.eu

Twitter
@PharmaLedger

LinkedIn profile

Project videos

CORDIS project page
Link

Project coordinator

Maria Eugenia Beltran Jaunsaras
Universidad Politecnica De Madrid
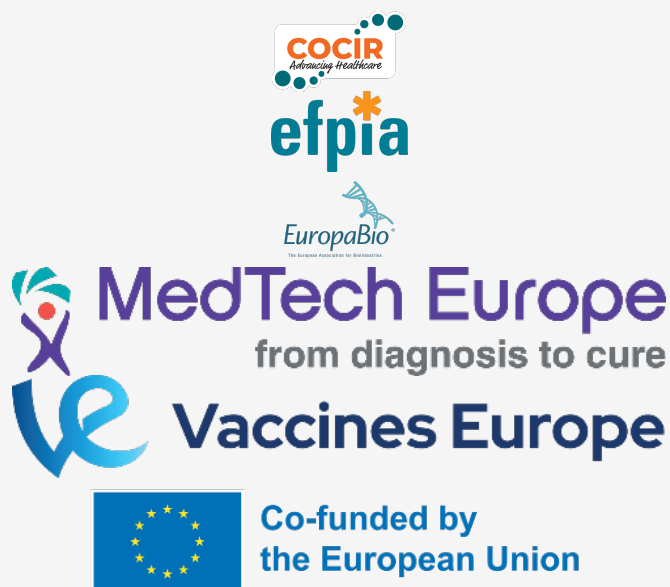
Newsletter

Our monthly newsletter provides announcements on IHI events, calls for proposals and news from our projects. Sign up now to stay informed.

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