HORIZON 2020

PharmaLedger

Results in Brief

Demonstrating blockchain's transformative potential for healthcare

Integrating IT within clinical trial processes, PharmaLedger shows how blockchain's ability to keep information secure, traceable and reliable could revolutionise healthcare.

HEALTH

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While healthcare could benefit from further digitalisation, large-scale initiatives have proven troublesome. Institutions such as hospitals and pharmaceutical companies lack the necessary expertise and their size renders processes very complex.

As it is also often difficult for specialist SMEs to win procurement processes or be validated as IT suppliers within this sector, the end result is often small-scale, localised innovations.

"Systemic innovation gets stuck at the planning stage. It is hard to embrace change and experimentation, never mind overcoming the technical hurdles around cost-effective and sustainable digitalisation and cybersecurity," says Maria Eugenia (Xenia) Beltran, project coordinator of the EU and industry-funded PharmaLedger project.

Working through SME partners, PharmaLedger provided pharma, hospital pharmas, hospitals, patients and citizens the opportunity to explore blockchain technologies, resulting in a healthcare digital trust ecosystem (DTE).

The DTE, which allows healthcare stakeholders to collaborate under trusted conditions, was developed through trials with practical end-use applications, along the value chain of clinical trials.

“Our agile infrastructure is providing experimental opportunities to start exploiting blockchain, even though its potential is still only emerging,” explains Beltran, from the Polytechnic University of Madrid, the project host.

The project’s various software products reached the pre-qualification stage, based on GMP standards, reducing the investment time needed before adoption of the processes.

From architecture to ecosystem

With the participation of potential adopters (patients, clinical researchers amongst others), the project developed seven flagship use cases.

These were: clinical trial recruitment (anonymised patient matching to clinical trials); clinical trial eConsent (auditable, version-controlled, real-time and immutable informed consent forms management); clinical supply (medicine distribution tracking); finished goods traceability (visibility of commercial product inventory for replenishment and recall); electronic product information – ePI (latest approved product information for all manufacturers); detecting falsified medicines (multifactor packaging authentication and data analytics); and IoT medical devices and personalised medicine (real-time data processing for patients).

“Collectively, these use cases represent many of the challenging areas of healthcare today,” notes Beltran.

Each case was evaluated for both its overall technical performance and its ability to meet end users’ needs – tested through simulated operational environments.

While all use cases were advanced to the pre-production stage, the ePI was most advanced. Industry members, health authorities, healthcare professionals, patients and other stakeholders can use the system’s app to access the most recent product information directly from the manufacturer.

The overarching DTE was itself developed to a preoperational stage, with five nodes (authorised communication hubs for network tasks) able to exchange trusted information. Additionally, the platform can connect to other platforms, including legacy systems and archives, through the project’s data sharing units (DSU) and data adaptors – integrating industry standards, such as GS1 or HL7.

“In a highly regulated sector, our solution allows clinicians to reliably trace who is taking part in trials, when, where, what they are taking and the results – improving the efficiency of trials and precision of the medicines, ultimately benefiting patients,” says Beltran.

Development of scalable and sustainable solutions

PharmaLedger can help reduce the administrative burden on trial sponsors. Additionally, tamper-evident patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) offer verifiable assessments of the healthcare experiences and outcomes of patients.

“This provides the reliable data needed to help turn clinical evidence into personalised interventions,” explains Beltran.

PharmaLedger’s technology has been licensed with an MIT open source licence.

To ensure the sustainability of the project’s results, the not-for-profit PharmaLedger Association was created. So far, membership includes several pharmaceutical companies and healthcare organisations.

Keywords

PharmaLedger, blockchain, healthcare, clinical trials, hospitals, pharma

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