PharmaLedger
ASSOCIATION

PharmaLedger Association
Digital Trust in Healthcare

Digital Magazine | August 2024

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Editorial

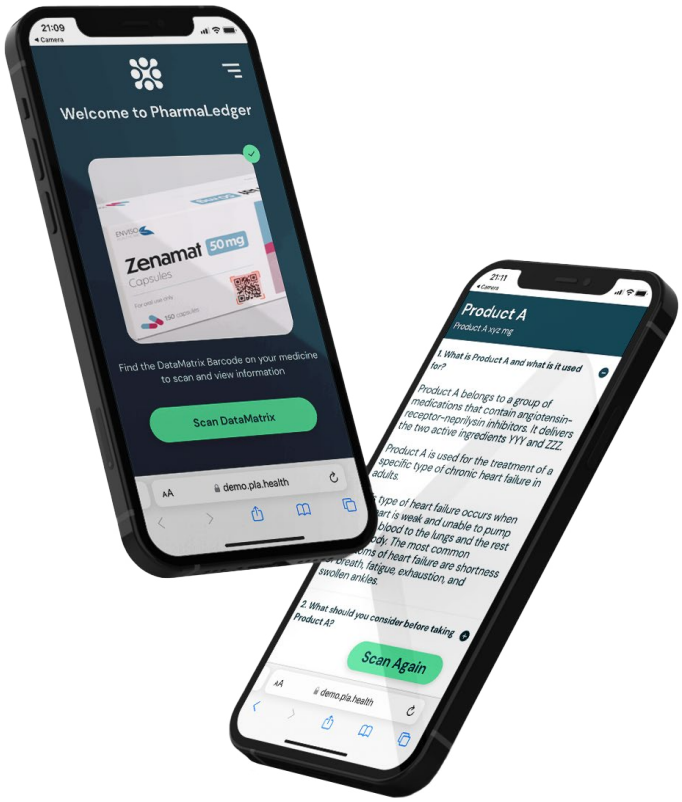
Welcome to Digital Trust in Healthcare.

It's already halfway through the year. Time certainly does fly when you are busy re-shaping the meaning of collaboration in digital healthcare. A lot has happened in the first half of 2024 at PharmaLedger.

As you explore the highlights we are pleased to share **updates on key initiatives, an interactive demo of ePI by PharmaLedger™ lightweight web App, an insightful Annual Report and announcements.**

Navigating the dynamic landscape of digital healthcare is no easy task for any individual organization, regardless of its size. At PharmaLedger we continue to lead the charge toward a patient centric Digital Trust Ecosystem and a new model of collaborative innovation among industry peers.

It's about collaborative actions that lead to collective benefits.



We invite you to share this Magazine with colleagues and partners.

PharmaLedger is the innovation venue for all Life Sciences and healthcare professionals and organizations. Do not watch from the sidelines, there are multiple ways to engage, contribute and benefit.

Product Trust Platform

ePI by PharmaLedger™ 2.2

ePI by PharmaLedger™ has taken a significant step forward with the release of version 2.2. The latest update expands our readiness for a global reach within 46 countries and comprehensive support for 29 languages. For a complete status update follow the link below, and to experience the application first hand, try our interactive demo.

29 Languages : Say hello to...

Languages			
Danish	French	Bulgarian	Korean
Dutch	Italian	Croatian	Arabic
English (American)	Portuguese (Brazil)	Czech	Greek
German	Portuguese (Portugal)	Polish	Turkish
Norwegian	Romanian	Slovak	Ukrainian
Swedish	Spanish (Spain)	Slovenian	
Finnish	Spanish (Latam)	Latvian	
Greek	Hungarian	Lithuanian	

46 Countries

North America	South America	Europe	Africa	Asia	Oceania	Middle East
Canada	Brazil	All EU Countries	Botswana	Singapore	Australia	Turkey
Mexico	Ecuador	Norway	Nigeria	South Korea		Kuwait
United States		Switzerland	Rwanda			United Arab Emirates
		Ukraine	South Africa			
			Uganda			

Interactive Demo

1. Scan QR Code

2. Scan the 2D code

Try these examples

Animated image

Language Selection

Expired Batch

* if mobile device is in one of the three languages, this leaflet is shown automatically in that language. If mobile device is in language e.g. English, the user needs to select a language

PharmaLedger ASSOCIATION

Innovation xLab Updates

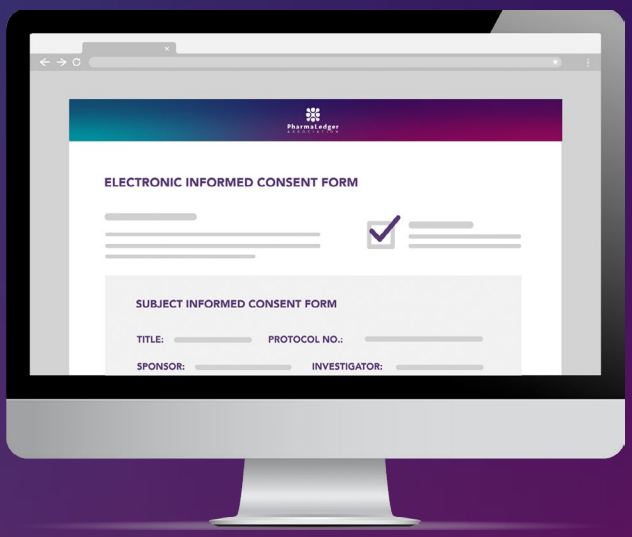
Informed Consent in Healthcare

Informed consent on data privacy and use is a cornerstone of the digital world, yet many of us are powerless when faced with complex legalese terms and conditions and a lack of clarity over the actual impact of checking those boxes and signing forms. Not checking these boxes often means no service can be obtained, leaving little options for most.

In the context of healthcare the burden on the user and the stakes are even higher. While your email, name and date of birth are sensitive information, the access to your medical history and current status is critical in a world where (almost) anything can be monetized by the servicing parties.

Depending on the current legislation of your country, healthcare related Informed Consents can contain a multitude of data usage permissions beyond the scope of the medical procedure.

Those are also usually presented as one single form that bundles multiple purposes for



data collection and usage, leaving patients powerless to decide what they actually consent to and enabling organizations to use your data for decades.

As long as informed consent is treated as a mere bureaucracy and a matter for legal experts, leaving its format, ownership, content, accessibility and portability unchallenged, we will be giving up the control of the most sensitive information about ourselves and allowing unknown players to monetize our data without our intent or participation on the profits.

Ongoing Working Group

eConsent in Clinical Trials

Some of the most common challenges in clinical trials include inefficient information flow, non-compliance, and lack of trust.

The Group proposes using blockchain technology to address these issues, offering an immutable, transparent digital ledger to automate processes and control data access. e-Consent offers key benefits for stakeholders such as patient empowerment, reduced process time, increased trust, transparency, and decreased operational costs.

The e-consent Group of PharmaLedger is composed of 12 different organizations representing Clinical Research organizations, Bio-pharma, technology experts, Quality and Compliance experts and patient representatives.

The Group kicked-off in Q4 2023 to redefine the Use Case and past deliverables, align on e-consent goals, high-level requirements, and benchmarking analysis, setting a foundation for future developments.

The Group is currently at the stage of completing a paper and project funding proposal to be put in front of the PharmaLedger broader membership for endorsement and project funding confirmation. If successful the team will move into development and prototyping phases.

Organizations and experts in the area of eConsent, Patient Engagement, Legal and other related areas are welcome to join the PharmaLedger xLab Group, with or without membership status at the PharmaLedger Association.

Initiation Phase | **Project Phase** | **Graduation Phase**

Decentralized Supply Chain

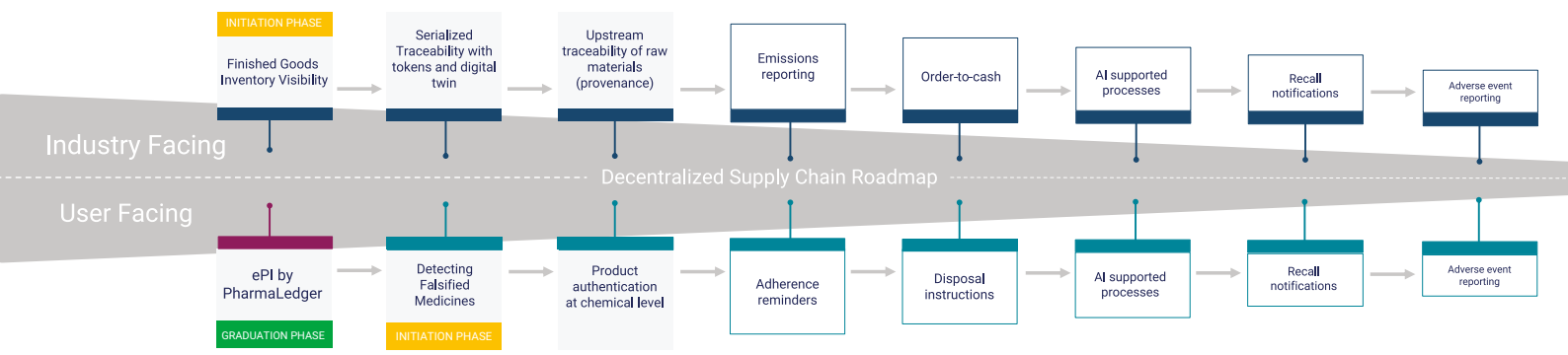
Supply Chain end-to-end traceability and visibility is certainly one of the most complex use cases to be delivered with an Ecosystem approach. While many organizations claim to have already enabled it, the reality is that true traceability involves more complexity than just the technology and more use cases than any single player alone could resolve.

There are competent organizations that indeed have developed modules and platform solutions that can increase visibility over product flow. However, the challenge remains with the integration of multiple modular solutions and the enforcing of a single platform vendor in a diverse and decentralized landscape of parties, technologies and interests.

PharmaLedger's advocacy for a shared infrastructure layer above companies, markets and based on defined standards aims at addressing these challenges. This ultimately means that multiple iterations of traceability proposals and collaborative research and piloting needs to take place with the participation of teams representing the viewpoints of an equally diverse group of stakeholders.

PLA's vision for a trusted and decentralized supply chain incorporates a multitude of use cases, modules and approaches that are known but also the ones that are yet to be discovered and formulated.

Supply Chain Visibility, Traceability and Security Working Roadmap



Ongoing Working Group

Pharmaceutical Supply Chain Visibility, Traceability and Security

The first Traceability working group of PharmaLedger is being notably driven by Patron members and is currently working on three “Proof of Value” initiatives.

They are designed to demonstrate the capability and benefits of inventory visibility at batch level using a blockchain based network which includes manufactures, distributors, wholesalers and public health administrators.

The aim of this group is to evaluate the architecture and scalability of existing traceability modules already in use by some of the participating organizations. This is a means of accelerating the viability of the foundational elements of a first traceability distributed network.

Besides the architecture and scalability evaluation, the end goal of the Group is to enable both serialized and non-serialized product visibility, prove the viability of a unified secure backend infrastructure for

industry peers, and create a shared roadmap and governance model.

The goal of PharmaLedger’s traceability strategy is to achieve a shared infrastructure capable of accelerating and enabling industry parties to immediately adopt it, and third parties to connect their own solutions at the Application layer. Given the complexity of achieving end-to-end traceability through a global infrastructure, the xLab will continue to welcome the creation of initiatives aimed at improving the resilience of the global healthcare supply chain.

The Counterfeit Crisis

The global pharmaceutical market is a complex ecosystem susceptible to exploitation. The rampant growth of counterfeit medicines, fueled in part by an increase in online pharmaceutical sales, poses a grave threat to public health and economy.

Counterfeiters are sophisticated, capitalizing on vulnerabilities in the supply chain. They mimic legitimate products with alarming accuracy, making it more and more difficult for consumers, healthcare providers, and regulatory bodies to distinguish between authentic and fraudulent medications.
This crisis is exacerbated by the complex, opaque nature of the pharmaceutical supply chain, which offers ample opportunities for counterfeits to enter the market.

The impact of consuming counterfeit drugs is widespread and severe. The economic burden on individuals, healthcare systems, and governments is substantial, having been estimated at billions annually. Even more devastating is the hundreds of thousands of patients every year that experience failures in their treatment, develop drug resistance, or suffer adverse reactions due to taking falsified or substandard medications.

As a patient-centric organization, Pharmaledger is especially committed to addressing this crisis and protecting patients from the dangers of counterfeit drugs while enabling the industry, regulatory bodies and law enforcement to jointly access data intelligence in prevention. It is imperative that we address this issue head-on through a combination of enhanced supply chain security, multi-stakeholder engagement and technological innovation.

Ongoing Working Group

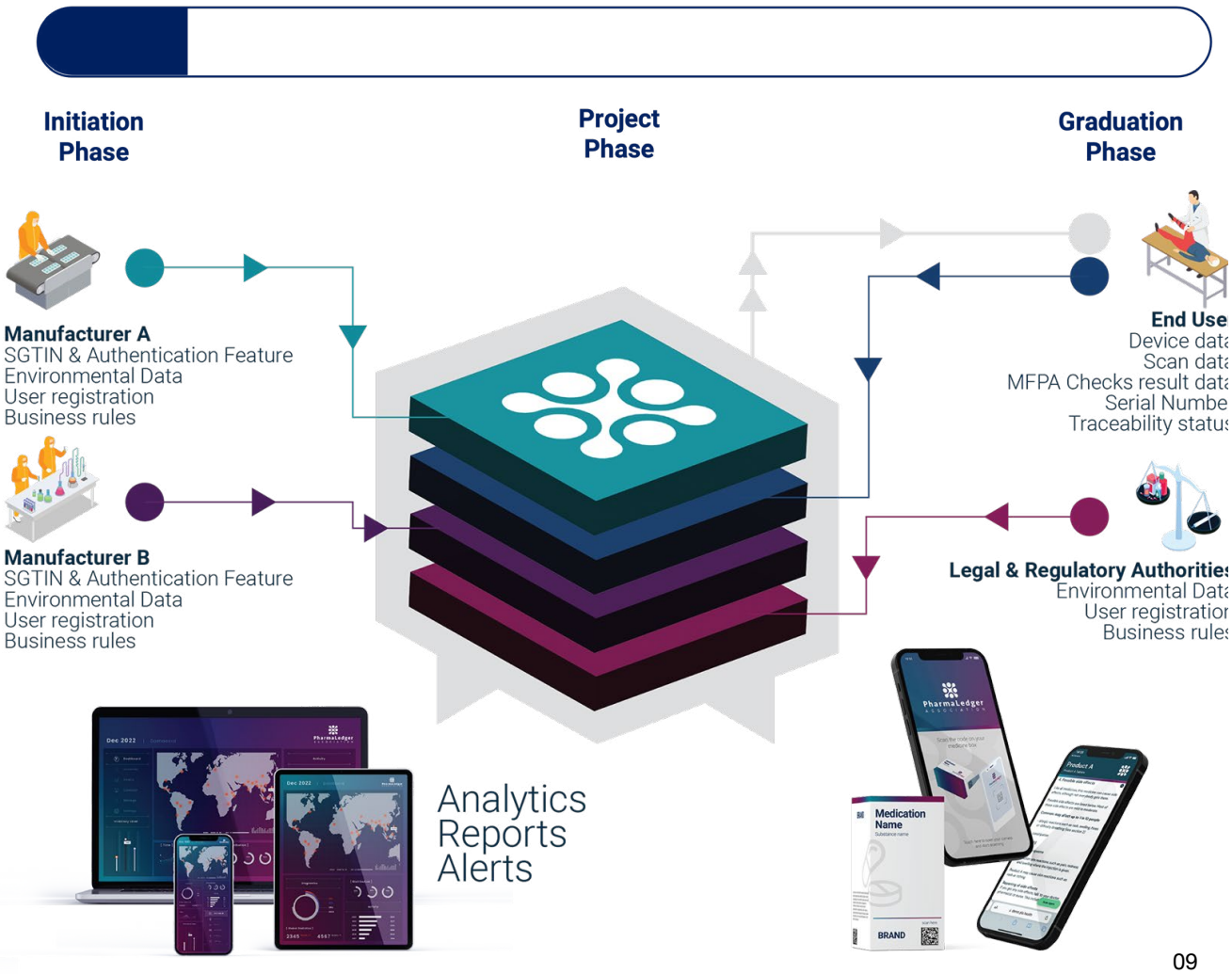
Detecting Falsified Medicines

The Detecting Falsified Medicinesv(DFM) working group convened in late May. It currently consists of eight diverse organizations from the tech and pharmaceutical industries.

They reviewed the use case demonstrator from the PharmaLedger Project and also shared the group's current activities to better understand what is available and can be reused for the project proposal. A common vision has been agreed upon:

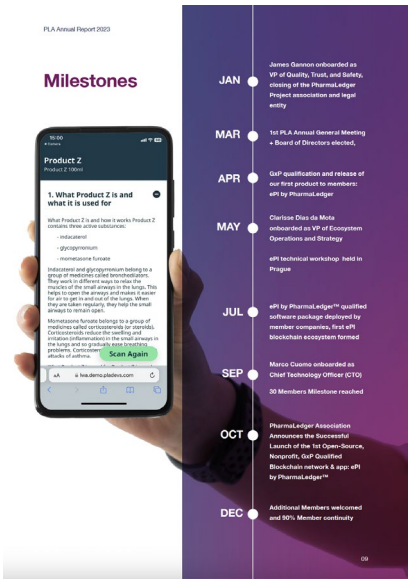
"Enhance patient safety and improve health by eradicating counterfeit medicines with innovative, technology-agnostic solutions and data-driven AI, provide global access to legitimate and authentic medicines, and foster transparency and trust for patients and healthcare providers."

The group is preparing an xLab project paper to be submitted for endorsement and confirmation of funding by the broader Association.



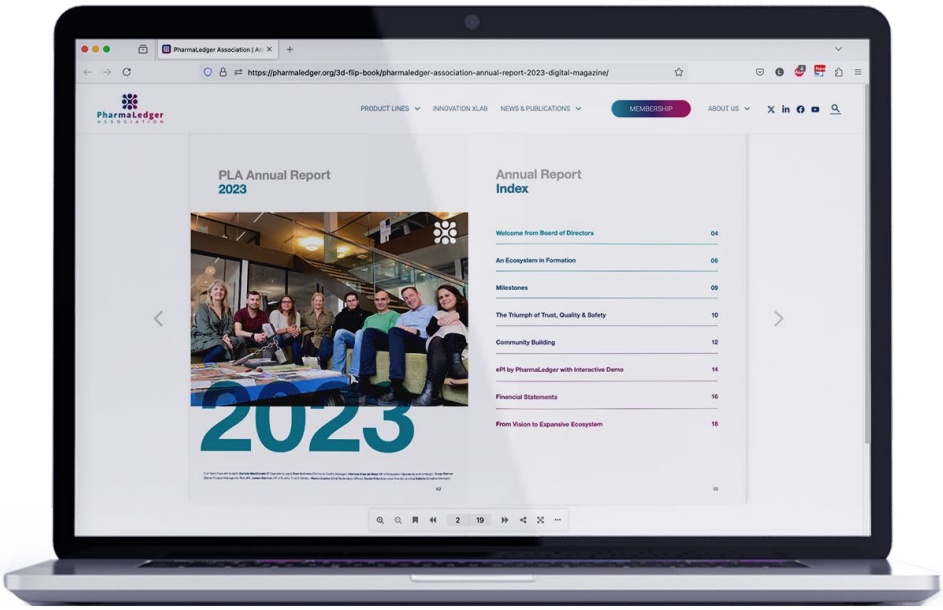
PharmaLedger Association Annual Report 2023

At the beginning of July we published our 2023 Annual Report, reflecting on our first year as a collaborative force in the digital healthcare space. **Read the report to dive deeper into our successes, and gain valuable perspectives from our leadership today.**



Read our Annual Report in Digital Magazine Format

or download the PDF version



Leveraging digital technology to support safety and environmental sustainability

500 million. That's the number of physical pieces of product information Takeda sends out each year, from product summaries for health care providers to labels and packaging leaflets for each of our medicines and vaccines. In 2024, QDENGA will be one of Takeda´s first products to participate in an industry partnership working to reduce this number to zero.

For the QDENGA world stock keeping unit (SKU), patient information leaflets in multiple languages will be hosted electronically by Takeda and accessible via the PharmaLedger Association's electronic product information (ePI) web application. As a result, fewer resources will be used in packaging; reduced shipping volume and weight will lower our distribution-related GHG emissions for QDENGA.

Health care providers can access the web application and scan the serialized code on the pack of product to find the most updated ePI leaflet in their preferred language. The application will also warn the user should the relevant product be past its expiry date.

The project is part of PharmaLedger®, a global initiative and nonprofit organization facilitating the creation of a Digital Trust Ecosystem in Healthcare together with health care stakeholders.

SUPPORTING DENGUE CONTROL AND PREVENTION

The Dengue Case Repository represents a significant milestone in our commitment to effectively manage dengue fever. This in-house repository consolidates data from several sources—public and private, international, national and regional—offering a powerful platform for analytics, collaboration and proactive management to map current dengue risk. It can also help us predict future outbreaks using AI models, positioning Takeda at the forefront of dengue fever control efforts in the future.

Looking ahead

The story of QDENGA is only beginning. We are committed to continuing our work to accelerate access to those threatened by the disease. We look forward to a day when, through partnership and innovation, dengue is no longer a growing burden for the millions impacted by it today.

Takeda Annual Report and PharmaLedger Collaboration

As part of Takeda's 2024 Annual Integrated Report, their decision to scale their use of ePI by PharmaLedger™ was shared with the world.

Read about PLA and Takeda here

Read Takeda's report here

"With PharmaLedger, we will transform the healthcare ecosystem by making it more transparent, secure, trusted, and efficient. We have begun leveraging it by introducing electronic product information leaflets to replace physical ones and will soon enhance supply chain security by launching finished goods traceability in Asian markets."

— **Michael Ritter,** Head, Serialization & Digital Enabling, Global Engineering at Takeda

PLA Newsroom

June 2024

Revolutionizing Logistics: Digital Twins in Pharma Supply Chain Traceability

Counterfeiters, mislabeling of drugs, and fraudulent packaging have severely damaging impacts. According to one EUIPO report, counterfeit medicines cost the global economy billions of dollars annually, while causing hundreds of thousands of fatalities and detrimentally affecting countless others... **Read More**

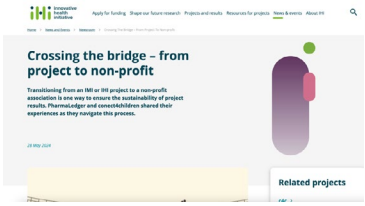
May 2024

PLA Press Release: New Board and Association Members

PharmaLedger, a leading Association driving innovation in digital healthcare, has publicly announced the appointment of new members to its Associates' network. These additions strengthen PharmaLedger's collaborative network, bringing valuable expertise in data security, supply chain management, and patient advocacy ... **Read More**

May 2024

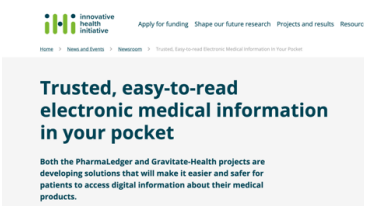
Crossing the bridge – from project to non-profit



Transitioning from an IMI or IHI project to a non-profit association is one way to ensure the sustainability of project results. PharmaLedger and conect4children shared their experiences as they navigate this process... **Read More**

June 2024

Trusted, easy-to-read electronic medical information in your pocket



Both the PharmaLedger and Gravitate-Health projects are developing solutions that will make it easier and safer for patients to access digital information about their medical products... **Read More**

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TAMER

The Innovation xLab
Get Involved

PLA is the venue for collaboration to incubate, develop, and launch Healthcare 4.0 products. Member, non-member organizations and expert individuals alike are all welcome to contribute to the xLab, PLA's R&D innovation arm.

Click here to submit a letter of interest, mentioning your motivations and area of support together with your CV for individuals.

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