PharmaLedger Association Annual Report 2023

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PLA Annual Report
2023

PLA Team From left to right: **Darlene MacDonald** (IT Operations Lead), **Sam Andrews** (Technical Quality Manager), **Clarisse Dias da Mota** (VP of Ecosystem Operations and Strategy), **Sonja Steiner** (Senior Product Manager for PLA ePI), **James Gannon** (VP of Quality, Trust & Safety) , **Marco Cuomo** (Chief Technology Officer), **Daniel Fritz** (Executive Director) and **Lia Salmito** (Creative Manager)

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Welcome

Words from
our Board of Directors

It is with great enthusiasm that we welcome you to the PharmaLedger Association's Annual Report for 2023.

Together we have accomplished some remarkable achievements and impactful outcomes with the potential to significantly transform the lives of patients and organizations in healthcare.

From our first AGM meeting in March, to the launch of "ePI by PharmaLedger" and the first decentralized, GxP-relevant blockchain network in healthcare, each milestone represents a testament to the collective efforts and commitment of our growing association.

Our organization has remained steadfast in our purpose to create a digital trust ecosystem in healthcare and to promote cooperation and innovation for the mutual benefit of patients and other stakeholders. This goal is the glue that brings us together and gets us through challenging times with resilience, adaptability, and the strong desire to keep marching on.

As you peruse through this report, we encourage you to reflect on the profound impact of your efforts, resources, and support. Whether through your financial contributions, volunteer efforts, or advocacy, each action has played a vital role in advancing our mission and building momentum towards making a positive change in the world.

2024 is filled with optimism and determination as we expand our programs (xLab), embark on new initiatives (traceability, eConsent), and deepen our impact. With continued support and partnerships, we are confident that we will achieve even greater heights in the years to come.

On behalf of the PharmaLedger Association, we extend our heartfelt gratitude to each and every one of you for your ongoing support, dedication, and belief in our mission. Together, we are making a difference.

Thank you for being a part of our journey.

Warm regards,

Sarah Bevan
Chair of the PLA
Board of Directors

Daniel Fritz
PLA Executive Director

Insights
An Ecosystem "in formation"

A short history of PharmaLedger's origin

The genesis of PharmaLedger lies in a collaborative effort between the European Commission and the European Federation of Pharmaceutical Industries and Associations. Funded through the EU's Horizon 2020 and Innovative Health Initiative grant programs, the project came to life in 2019.

A consortium, meticulously coordinated by the Polytechnic University of Madrid's LifeStech with industry coordination from Novartis and MSD, was formed, bringing together 12 global pharmaceutical companies and 18 public and private entities. These organizations were awarded a place at the Forbes Blockchain 50 list of 2021 for their efforts. The work officially began in early 2020, marking the start of our research and innovation initiative.

From 2020 to 2022, the PharmaLedger community thrived. As the research project concluded, a strong network of supporters and partners emerged, all convinced of the project's core value: a secure, shared infrastructure for life sciences and healthcare powered by cutting-edge technology.

Recognizing this potential, consortium members unanimously decided to continue this vital work in the real world by establishing a non-profit association.

By the end of 2022, the PharmaLedger Association (PLA) initiated its fundraising operations with the PharmaLedger Project as its first investor.

**Building Consensus on what the PLA is (and what it is not)**

PLA is a unique organization positioned to uphold and govern the collective values of patient focus, ecosystem inclusive leadership, neutrality, not-for-profit, simplicity, transparency, open-source

model, change agility, and technology agnosticism. Evolving the purpose, vision, and mission from the initial consortium focus of a "blockchain-enabled healthcare" to a broader yet more defined focus on enabling a Digital Trust Ecosystem for Healthcare.

PLA accommodates different types of meanings for the word Ecosystem. While our technologists design and build state-of-the-art digital solutions and interconnected networks calling them a "technical ecosystem", without adoption and community engagement those are of no practical value to the real world.

The most important ecosystem enabled by PharmaLedger is the engagement of members, partners, and collaborators. In turn, it is this community that provides PLA's most unique differentiator – equitable stakeholder participation and input through our governance structure, xLab, and Collaboration platform.
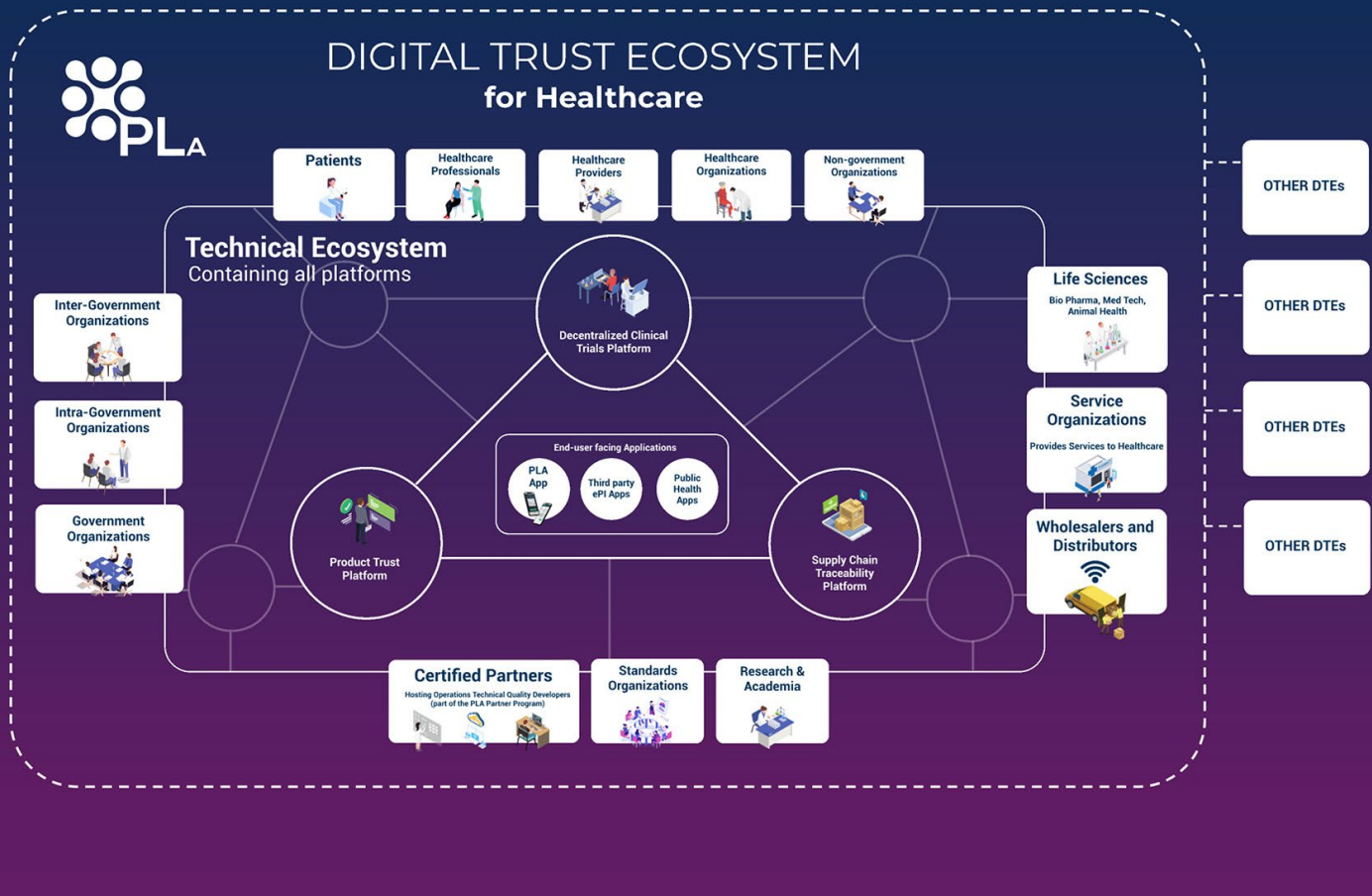
PharmaLedger is not a vendor, a customer, or a competitor. PLA is an umbrella organization - a neutral venue where all healthcare-related organizations can claim space to collaborate, compromise, learn from each other, share risks and investments, fail fast, and continue to pursue the vision of digital healthcare. This vision follows ground rules to safeguard patient's interests while enabling existing and new business models to better position themselves to serve the life sciences and healthcare sectors.

Ecosystem, Operations & Strategy (EOS) : Year in Review
Coordinating the Association as an ecosystem requires a multidisciplinary approach to stakeholder management including in areas of communications, lead generation, value identification, marketing and promotion, financial management & fundraising, culture, and compliance among others.

In 2023 we have made enormous progress in maturing PLA Operations, successfully passing internal and external audits, formalizing procedures and optimizing resource allocation. Matching the standards of our corporate members as well as supporting our smallest nonprofit members has equal importance. Through this culture, we have concluded 2023 with above 90% member retention.

Brand Development & Product Marketing Strategy
To build upon the established reputation of PharmaLedger, PLA adopted key project assets for its branding. In March 2023, we launched a refreshed brand identity, including a new website, social media presence, templates, and promotional materials. This evolution honors our PharmaLedger roots while incorporating a more modern design and a diverse color palette that reflects PLA's structure as an Association and its expanding reach.

"By PharmaLedger™" is the brand of all PLA related initiatives. Our product branding strategy for 2023/2024 has been of a non specific nature signifying PLA's neutrality and non-commercial identity. Positioning PharmaLedger as a background brand demonstrates the intention to connect healthcare solutions with an "above market" view and enable stakeholders to adopt the shared infrastructure as an additional feature to their existing solutions. This is especially relevant for national and regional public health Apps and end user facing platforms.

Member collaboration platform
In Q4 2023 the EOS team delivered a unique space for collaboration and seamless communication to PLA members. An online member platform where profiles, networking, opportunities, events, projects, working groups and messaging are enabled, has become the new convergence zone of PLA members. This platform is a part of our value creation strategy. While the PLA continues to mature and expand its capacity to directly benefit all healthcare stakeholders, the platform serves a crucial purpose in fostering a connected community. By facilitating transparency and member-to-member interaction, it creates indirect value opportunities for all our members.

Expanding PharmaLedger's footprint & Ecosystem leadership
In its first year, the Association made significant strides towards its goal of reach and impact. Through active engagement, PLA has expanded its member footprint to 16 countries across 3 continents. This tangible progress demonstrates PLA's dedication to serving a global healthcare community.

Building bridges across healthcare continues to be a core focus for PharmaLedger. In 2023, we saw our membership base expand, welcoming a diverse range of organizations from advocacy groups, pharmaceutical companies, and technology providers.

These partnerships have been instrumental in enabling our strategic initiatives and ensuring that our solutions are aligned with real-world needs. PharmaLedger-associated organizations represent

NGOs, Patient Advocacy, Academia, R&D, Human Health and Animal Health pharma and biopharma, government initiatives, and Subject Matter Experts in the areas of technology, supply chain, health data, and clinical trials.

Our Board of Directors welcomed new members in 2023, bringing together a wealth of experience and diverse perspectives, helping to balance the scales and equalize opportunities for strategic input across all associate types. This strengthened board will be instrumental in guiding the PLA as we navigate the dynamic healthcare and technology landscape. Their leadership ensures continued good governance, financial viability, and a commitment to inclusivity, driving value creation for our members.
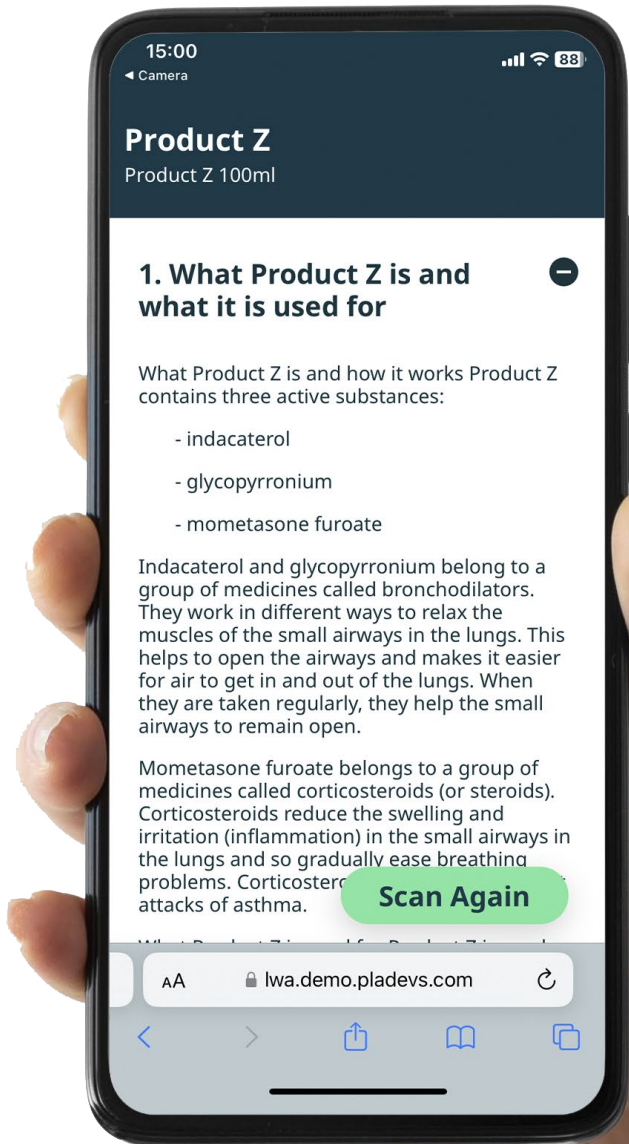
Looking towards the future
2023 presented its challenges, but also significant accomplishments and valuable learning experiences. We're leveraging these insights to propel us forward in 2024. Our focus remains on strengthening the member ecosystem. Key initiatives include a brand-new website, engaging social media channels, and a mobile app version of our collaboration platform. These enhancements aim to increase convenience and drive active participation. Additionally, we'll be refining our strategy and launching new fundraising initiatives. Ultimately, our goal is to establish open collaboration as the de facto standard for digital healthcare.

Clarisse Dias da Mota
VP of Ecosystem Operations and Strategy

Milestones

15:00
◀ Camera

Product Z
Product Z 100ml

1. What Product Z is and what it is used for

What Product Z is and how it works Product Z contains three active substances:

- indacaterol

- glycopyrronium

- mometasone furoate

Indacaterol and glycopyrronium belong to a group of medicines called bronchodilators. They work in different ways to relax the muscles of the small airways in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When they are taken regularly, they help the small airways to remain open.

Mometasone furoate belongs to a group of medicines called corticosteroids (or steroids). Corticosteroids reduce the swelling and irritation (inflammation) in the small airways in the lungs and so gradually ease breathing problems. Corticoster... attacks of asthma.

Scan Again

🔒 lwa.demo.pladevs.com

JAN — James Gannon onboarded as VP of Quality, Trust, and Safety, closing of the PharmaLedger Project association and legal entity

MAR — 1st PLA Annual General Meeting + Board of Directors elected,

APR — GxP qualification and release of our first product to members: ePI by PharmaLedger

MAY — Clarisse Dias da Mota onboarded as VP of Ecosystem Operations and Strategy

ePI technical workshop held in Prague

JUL — ePI by PharmaLedger™ qualified software package deployed by member companies, first ePI blockchain ecosystem formed

SEP — Marco Cuomo onboarded as Chief Technology Officer (CTO)

30 Members Milestone reached

OCT — PharmaLedger Association Announces the Successful Launch of the 1st Open-Source, Nonprofit, GxP Qualified Blockchain network & app: ePI by PharmaLedger™

DEC — Additional Members welcomed and 90% Member continuity

James Gannon
VP of Quality, Trust & Safety

Insights
The Triumph of Quality, Trust, and Safety at PLA

In an era where technological innovation is not just an asset but a necessity, the PharmaLedger Association (PLA) has positioned itself at the forefront of revolutionizing healthcare and pharmaceutical industries through blockchain technology.

In our first year, our Quality, Trust, and Safety (QTS) function at PLA has made significant strides in enhancing the integrity, transparency, and efficiency of pharmaceutical processes. The successful creation of our Quality Management System (QMS), the qualification of Electronic Product Information (ePI) as our inaugural Good Manufacturing Practice (GxP) product, the launch of the world's first GxP blockchain network, and the pioneering adoption of open source in healthcare mark milestones not just for PLA but for the broader industry. These achievements underscore our commitment to fostering a safer, more reliable pharmaceutical supply chain, ultimately improving patient care and trust in healthcare systems worldwide.

Innovating Quality Management: The Creation of QMS

The cornerstone of our QTS success has been the development and implementation of a robust Quality Management System (QMS). This system was designed to meet the stringent requirements of the pharmaceutical industry, ensuring compliance with global regulatory standards. By integrating the latest technology into our QMS, along with our partners, we have established a transparent and secure framework for managing quality processes. This technology first greenfield approach has significantly reduced errors, improved audit trails, and enhanced overall product quality. The QMS has been instrumental in streamlining operations, facilitating better decision-making, and fostering a culture of continuous improvement within the Association.
Pioneering Standards with ePI Qualification

The qualification of electronic Product Information (ePI) as our first GxP product represents a landmark achievement in our mission to modernize healthcare information dissemination. The ePI platform utilizes blockchain to provide up-to-date, verifiable, and secure product information directly to healthcare professionals and patients. This initiative not only improves access to accurate drug information but also enhances patient confidence by minimizing the risks associated with outdated or incorrect product data. The successful qualification of ePI underscores our capability to meet GxP standards, setting a precedent for future blockchain-based healthcare solutions.

Launching the World's First GxP Blockchain Network

2023 saw the launch of the world's first GxP-compliant blockchain network operated by pharmaceutical manufacturers, a testament to PLA's innovative spirit and dedication to advancing healthcare technology. This groundbreaking network provides a secure, scalable, and compliant infrastructure for the life sciences and healthcare sectors. This initiative has garnered significant interest from industry stakeholders, demonstrating the potential of blockchain technology to transform healthcare logistics and supply chain management.

Impact and future directions

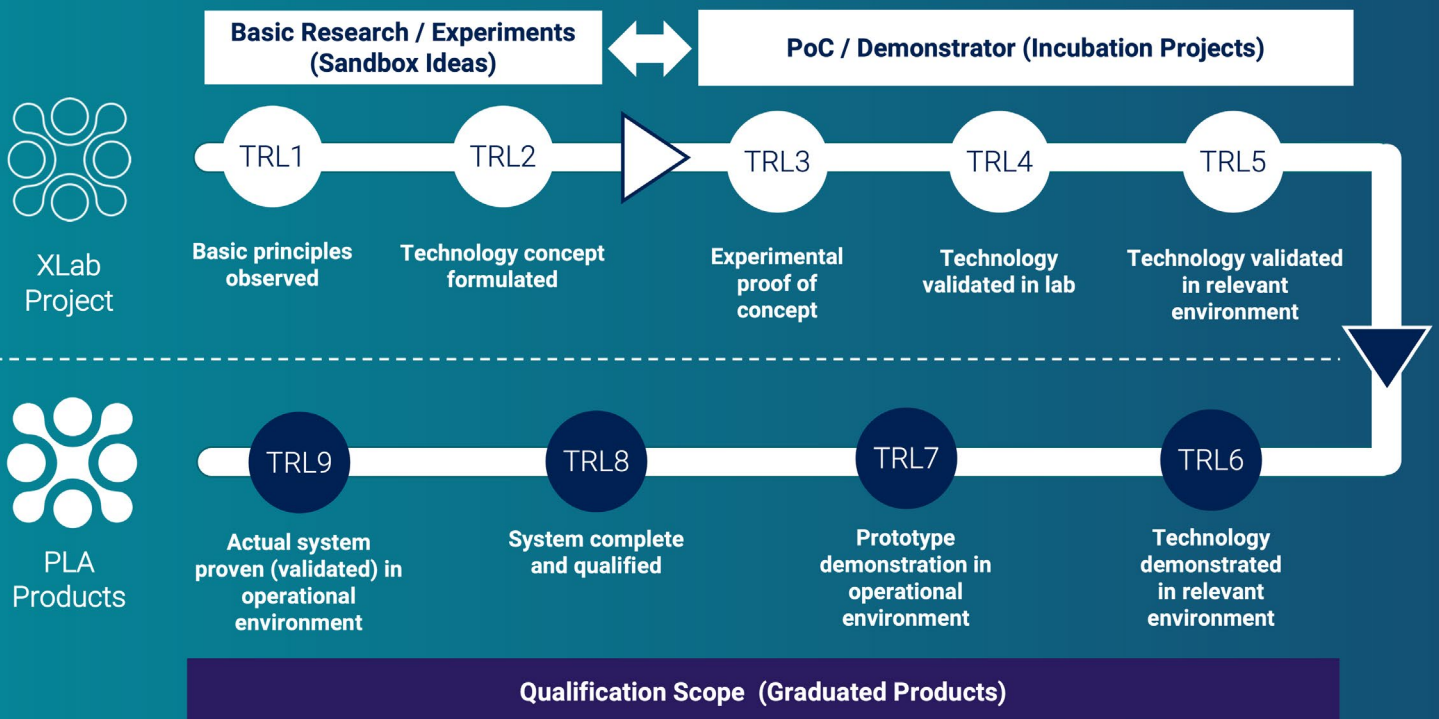**Embracing Open Source for Healthcare Innovation**
PLA's commitment to open-source principles has played a crucial role in our achievements this year. By adopting an open-source approach, we have fostered collaboration and transparency within the healthcare technology community. This strategy has accelerated the development and adoption of blockchain solutions, facilitating shared innovation and ensuring that our technologies are accessible to a broad range of stakeholders. Our open-source initiatives have not only enhanced the quality and safety of healthcare solutions but have also encouraged the industry-wide adoption of blockchain technology.
Impact and Future Directions

The accomplishments of the QTS department at PLA have had a profound impact on the life sciences and healthcare industries. By pioneering the use of blockchain, cryptography, digital wallet and other technologies, we have set new standards for quality, trust, and safety. Our initiatives have demonstrated the tangible benefits of open source technologies in enhancing the reliability of the pharmaceutical supply chain and improving patient access to information.

As we look to the future, PLA is committed to continuing our innovation journey. We aim to expand our blockchain solutions to address more complex challenges within the ecosystem, exploring new applications for our GxP-compliant network and furthering the development of open-source healthcare technologies.

In conclusion, 2023 was a period of remarkable success and growth for the Quality, Trust, and Safety department at PharmaLedger Association. The creation of our Quality Management System, the qualification of ePI, the launch of the world's first GxP blockchain network, and our pioneering adoption of open source in healthcare represent significant milestones in our mission to transform the life sciences and healthcare industries. These achievements not only reflect our dedication to innovation but also our commitment to improving patient care and safety. As we move forward, PLA remains devoted to leading the way in technological advancements, ensuring that we continue to set benchmarks for excellence in digital healthcare.

Basic Research / Experiments (Sandbox Ideas) ⟷ **PoC / Demonstrator (Incubation Projects)**

XLab Project

TRL1 — **Basic principles observed**
TRL2 — **Technology concept formulated**
TRL3 — **Experimental proof of concept**
TRL4 — **Technology validated in lab**
TRL5 — **Technology validated in relevant environment**

PLA Products

TRL9 — **Actual system proven (validated) in operational environment**
TRL8 — **System complete and qualified**
TRL7 — **Prototype demonstration in operational environment**
TRL6 — **Technology demonstrated in relevant environment**

Qualification Scope (Graduated Products)

Marketing &
Communication

Community Building

2023 was a big year for the Marketing & Communication Department. From the creation of the new visual identity and brand guidelines, to the design and launch of our first Association website, the rebranding and creation of our new social media channels. The sheer amount of materials, presentations, videos and ideas was enough to keep us inspired the whole year.

+6k
Social Media
Followers

1555
Newsletter
Subscribers

10+
Publications

27
News
Mentions

MARCH

Website Launch
PLA Linkedin Launch
PLA Social Media Rebrand
PR - Launch of DTE-H

APRIL

PR - 1st product announcement

MAY

PharmaLedger Project Asset takever

JUNE

1st Newsletter
PR - 30+ members
ePI Patient Voice Progress Report
PLA Insights Video Series

AUGUST

ePI Showcase page launched
PharmaLedger Project
Showcase page launched

OCTOBER

2nd Newsletter
PR - 1st GxP Qualified Blockchain
Ad Campaigns Live

NOVEMBER

Collaboration Platform Launch

Marketing & Communication
Social Media Presence

LinkedIn

Lauched in March, the new PLA page grew quickly and by the end of the year grew exponantially. With more than 5K page views, it became the primary source of interaction with members of the healthcare industry and life science industries.

X

X was a great platform for us to connect with blockchain and technology communities. With a particular growth in October 23, due to the launch of our GxP Qualified Blockchain Network, we surpassed the 1K follower mark with more than 20K impressions.

Facebook

In our strategy, Facebook is a social media tool better fit for content directly related to patient advocacy groups and NGOs. In 2024 we will benefit from the expertise of our patient organization members to continue bringing valueable content to these communities.

YouTube

Though considered a social media tool, we use YouTube as a repository in which we share our Explainer Videos, Interviews and Podcasts and our Insights Video Series.
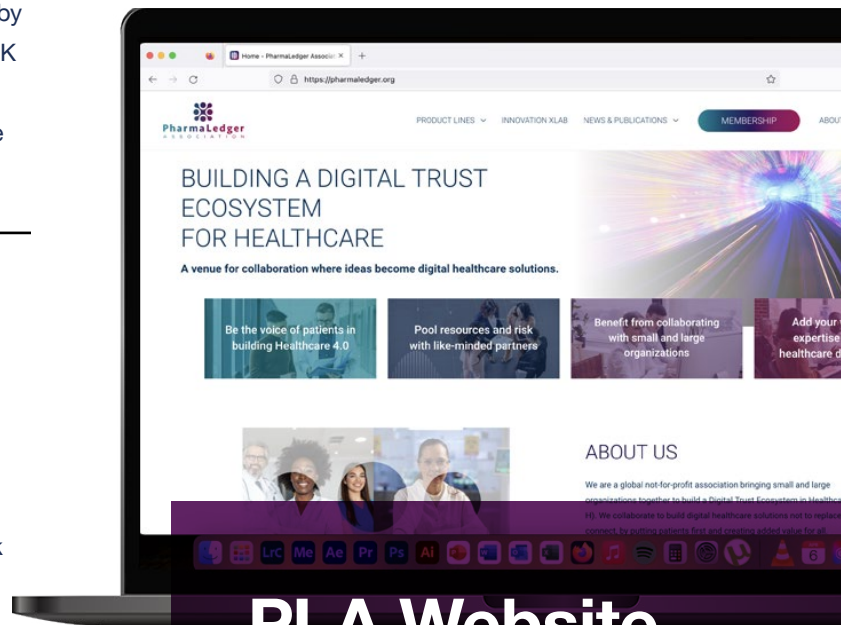
PLA Website

The PharmaLedger Association Website was fully launched in 2023 focused on being the primary source of information about the Association and its Projects Portfolio.

The First Product
ePI by PharmaLedger™

Advancements in Product Trust and Patient empowerment

One of the standout achievements in 2023 has been the qualification and deployment of our Electronic Product Information (ePI by PharmaLedger™), the world's first GXP-qualified nonprofit blockchain-based network and App. At the core of the ePI initiative, several real-world challenges are being addressed in the areas of Patient Access, Environmental responsibility, Supply Chain resilience, and regulation.

The PharmaLedger approach has the potential to revolutionize and simplify the Product/Patient information leaflet's (PIL) life-cycle management for industry and regulators alike while offering patients higher accessibility and usability. Both accessibility and usability are crucial for effective patient communication. Accessible ePILs will ensure that no patient is excluded from receiving important medication information, while usable ePILs will ensure that the information provided is comprehensible and actionable, enhancing patient safety and treatment outcomes.

Launch of ePI by PharmaLedger™: A Transformative Initiative for sustainable value creation

At a time when more than 50 countries across the globe are simultaneously exploring a myriad of possible approaches to electronic product information (ePIL), the increase in digital silos does little to benefit the healthcare ecosystem. This disperses resources, dilutes investments, and limits the distribution of benefits, creating inequity rather than value. Why should some patients only see a static document on a website while others benefit from improved accessibility, up-to-date information, and enhanced experience? PharmaLedger's ecosystem approach to ePIL offers a complementary solution to address the limitations of traditional paper or digitized documents. It is capable of supporting the different paces of digital adoption and inclusion around the world with a projection of value creation through the decades to come.

ePI by PharmaLedger™ is a transformative initiative for digital activation and has laid the foundation for PLA's Product Trust and Traceability platforms. These platforms establish core principles for what they are meant to become, a shared infrastructure for the industry and an equitable and privacy-preserving access point for patients and healthcare providers.

## Current Features of ePI by PharmaLedger:

Accessibility & User-centricity

- User-friendly design and navigation
- Text-to-speech functionality and Font Size manipulation
- Multi Device compatibility
- Multilingual capabilities
- Structured and Searchable text and content
- Simple smartphone scan of the package barcode to get the correct leaflet without searching
- Animated image capability for usage, disposal, and other visual instructions
- Same user experience, regardless of the manufacturer sourcing the product information

Trust, Safety & Compliance

- Always displays the health authority's most up-to-date approved information
- Information from trusted and secure source
- ePI complies with regulatory requirements across different regions, providing a standardized approach to information dissemination.
- Expiration check and notification
- No promotion, advertisement, or private data collection
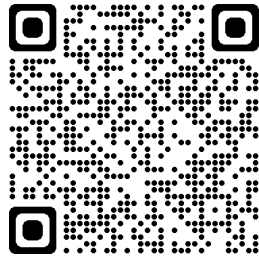- Validated to GxP Standards, ensuring 'right eLeaflet' for the 'right product' and 'right barcode'

Interactive Demo
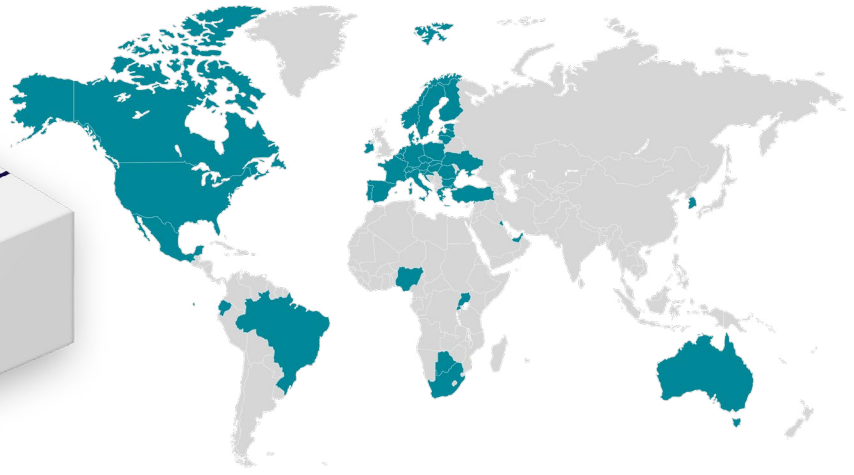
2.

Visual Instruction to scan
the 2D code

1.

Scan QR Code

Try these examples

Animated image

Leaflet in multiple languages available *
Dutch
German
French

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

Markets Expansion Readiness		Available Languages	
Singapore	South Korea	English (American)	Croatian
Belgium	United States	French	Greek
Luxembourg	Norway	German	Romanian
EU (All Countries)	Ukraine	Dutch	Bulgarian
Canada	Kuwait	Swedish	Latvian
Botswana	Mexico	Finnish	Slovenian
Nigeria	Turkey	Norwegian	Estonian
Rwanda		Danish	Lithuanian
Uganda		Italian	Hungarian
South Africa		Spanish (Spain)	Korean
Australia		Spanish (Latam)	Polish
Switzerland		Portuguese (Brazil)	Ukrainian
Ecuador		Portuguese (Portugal)	Turkish
Brazil		Czech	Arabic
United Arab Emirates		Slovak	

PLA Finances
Financial Statements

Balance Sheet | Assets	31.12.2023 CHF	31.12.2022 CHF
Cash and cash equivalents	773'233.56	116'794.38
Cash at bank	*773'233.56*	*116'794.38*
Accounts receivable	749'252.42	260'000.00
Other current receivables	575.70	4'337.20
Accrued income and prepaid expenses	14'520.00	71'112.28
Current assets	**1'537'581.68**	**452'243.86**
Property plant and equipment	10'600.00	5'670.00
Office machines & EDP equipment	*10'600.00*	*5'670.00*
Intangible assets	283'000.00	0.00
Development costs	*283'000.00*	*0.00*
Non-current assets	**293'600.00**	**5'670.00**
	1'831'181.68	**457'913.86**

Balance Sheet | Liabilities and Equity	31.12.2023 CHF	31.12.2022 CHF
Accounts payable	25'498.06	123.55
Other current liabilities	99'212.70	8'158.60
Deferred income an accrued expenses	1'502'240.08	305'834.42
Prepayments	*1'395'000.00*	*270'000.92*
Other accrued expenses	*107'240.08*	*35'833.50*
Current Liabilities	**1'626'950.84**	**314'116.57**
Liabilities	**1'626'950.84**	**314'116.57**
Equity as of 1. January	143'797.29	0.00
Profit	60'433.55	143'797.29
Equity as of 31. December	**204'230.84**	**143'797.29**
	1'831'181.68	**457'913.86**

Profit and Loss Statement	2023 CHF	3.05 until 31.12.2022 CHF
Net proceeds from services	**2'103'366.37**	384'093.00
Membership fees	*2'103'366.37*	*0.00*
Grants and other revenues	*0.00*	*384'093.00*
Third party services	-965'991.52	-138'041.73
Gross profit	**1'137'374.85**	246'051.27
Staff costs	**-742'803.15**	-40'990.10
Wages and salaries	*-375'000.00*	*-33'333.30*
Social securities and pension funds expenses	*-85'754.70*	*-7'333.40*
Other staff costs	*-16'721.87*	*-323.40*
Purchased servised expenses	*-265'326.58*	*0.00*
Other operating expenses	-258'879.34	-44'739.97
Maintenance and repair expenses	*-111'060.13*	*-4'959.22*
Insurance expense	*-1'806.70*	*-51.50*
Administrative expense	*-48'268.76*	*-14'162.42*
Advertising expense	*-97'743.75*	*-25'566.83*
EBITDA	**135'692.36**	160'321.20
Depreciation	-73'886.55	-376.93
EBIT	**61'805.81**	159'944.27
Financial expense	-1'072.26	-146.98
Profit before tax	**60'733.55**	159'797.29
Tax	-300.00	-16'000.00
Profit	**60'433.55**	143'797.29

IMPORTANT

These financial statements were prepared under the provisions of the Swiss accounting law in particular the articles of the Swiss Code of Obligations about commercial bookkeeping and accounting (Art. 957 to 962).

The main accounting and valuation principles used, which are not already specified by the Code of Obligations, is described as follows:

Intangible assets
- This item comprises product-related development costs.
- They are measured at acquisition/production cost less straight-line amortization of 20%.

PLA:
From Vision to
Expansive Ecosystem

PharmaLedger began with a vision to create and foster a collaborative ecosystem for digital transformation in healthcare.

In 2023, we made notable advances towards that goal, buiding our Association as an incubation and developmet hub where stakeholders from across the industry and across the globe - researchers, manufacturers, technology experts, and patients alike - could connect, share knowledge, and lead innovation for better healthcare.

Our first year as an association was a powerful example of the potential of collaboration, facilitating project initiatives that brought together diverse teams under a collective vision.

Yet, that vision extends beyond the industry itself. By also empowering patient advocacy groups with a platform to share their voices and ensuring that patients' needs remain at the heart of all that we do, we aim to benefit the whole of Healthcare 4.0.

As we look forward, PharmaLedger's commitment to expanding our Digital Trust Ecosystem in Healthcare remains steadfast. We firmly believe that industry-wide problems require industry-wide solutions, therefore, we'll continue to build connections and facilitate collaboration.

Together, we are leading the industry into a future where innovation benefits the entire global healthcare ecosystem.

PharmaLedger.org