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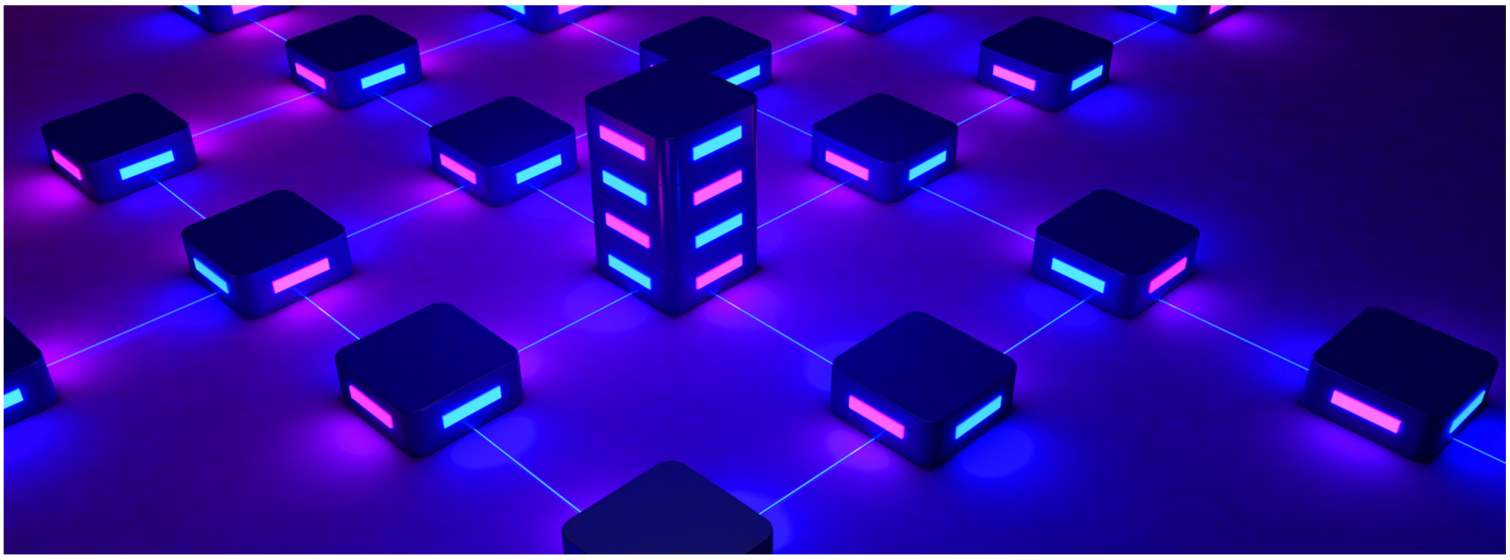
PV CHRONICLE

The official newsletter of DTRAS GLOBAL



IN THIS ISSUE

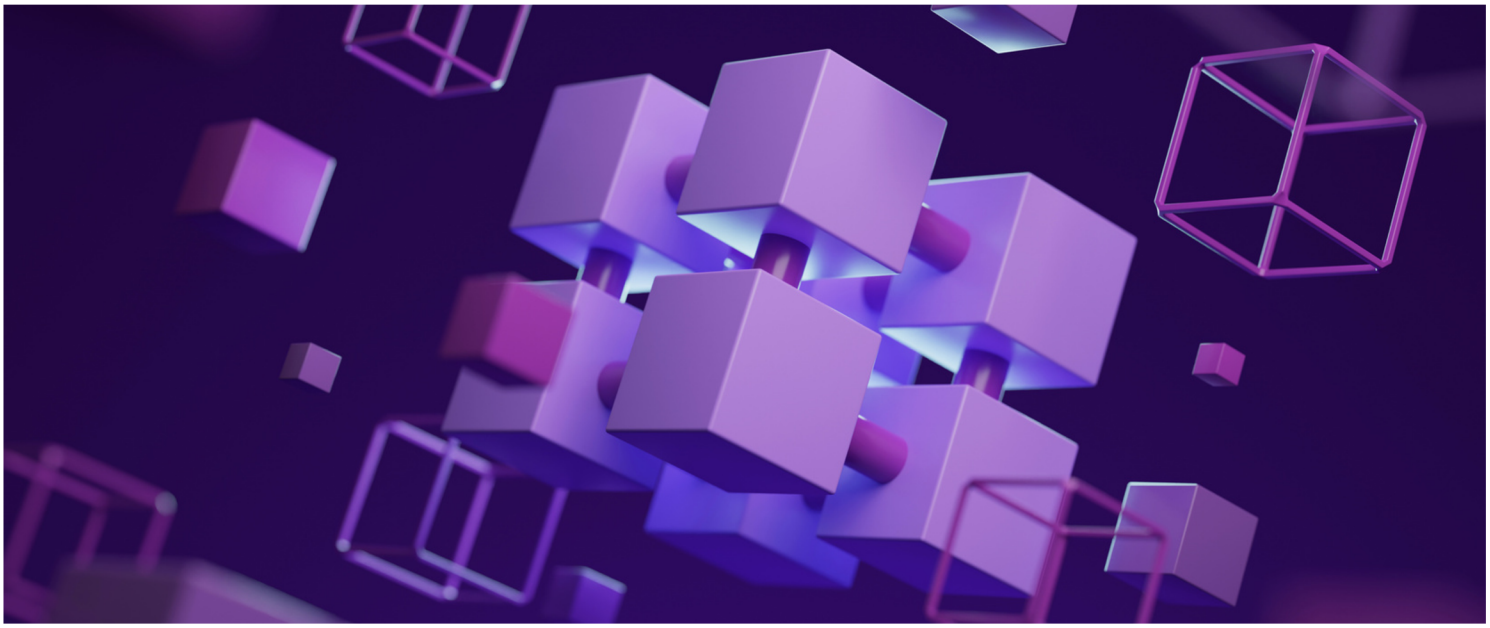
Blockchain in PV: A Game Changer for Drug Safety?

by Dr. Balaji Ommurugan

Pharmacovigilance (PV) has long relied on traditional centralized systems for adverse event (AE) reporting, signal detection, regulatory submissions, and drug safety monitoring. However, these systems face challenges related to data integrity, security, transparency, and real-time access.

Blockchain technology is making waves across industries, but how can it transform pharmacovigilance (PV)? The drug safety domain faces challenges like data integrity, real-time reporting, and regulatory transparency. Blockchain's decentralized, tamper-proof ledger offers a revolutionary way to improve AE reporting, data security, and compliance.

But how does blockchain compare to the current PV technology stack? Can it truly be a game changer? Let's break it down.



How Blockchain Changes The Game ?

Blockchain brings a revolutionary shift in pharmacovigilance by addressing key challenges that current systems face. One of the most critical improvements is data integrity—while centralized PV databases are prone to manipulation and selective reporting, blockchain ensures an immutable and tamper-proof ledger where data, once recorded, cannot be altered or deleted. Another major advantage is adverse event (AE) reporting. Today, AE reports are often manual, delayed, and fragmented across different regions and regulatory systems. Blockchain introduces real-time, direct AE submissions from patients, healthcare providers, and pharma companies, ensuring immediate accessibility and transparency.

Transparency is another key area where blockchain surpasses traditional PV systems. Currently, data is often controlled by pharmaceutical companies and regulatory bodies, with limited visibility for other stakeholders. A blockchain-powered PV system offers an open, decentralized ledger, making drug safety data more accessible and trustworthy. When it comes to signal detection, existing PV systems face delays due to data silos and the lack of interoperability across global databases. Blockchain, combined with AI-driven analytics, can instantly identify patterns in adverse event reports, leading to faster and more effective safety signal detection.

Regulatory compliance is also a cumbersome process under current systems, requiring manual audits and extensive paperwork. Blockchain simplifies this by enabling smart contracts, which can automatically validate AE reports against ICH, FDA, EMA, PMDA, and CDSCOrequirements, reducing compliance risks and streamlining reporting processes. Interoperability remains a significant challenge in pharmacovigilance, as data is stored in region-specific databases that often do not communicate with each other. Blockchain provides a unified, real-time global access system, ensuring seamless information exchange across regulatory agencies, pharmaceutical companies, and healthcare providers.

Finally, blockchain enhances security through cryptographic encryption and role-based access controls. Unlike centralized PV databases that require multiple permissions and are vulnerable to breaches, blockchain ensures high-end security and data protection, reducing risks associated with unauthorized access or data tampering.By addressing these core issues, blockchain has the potential to create a more transparent, efficient, and secure pharmacovigilance system, fundamentally transforming drug safety monitoring on a global scale.

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Immutable & Tamper Proof AE Reporting

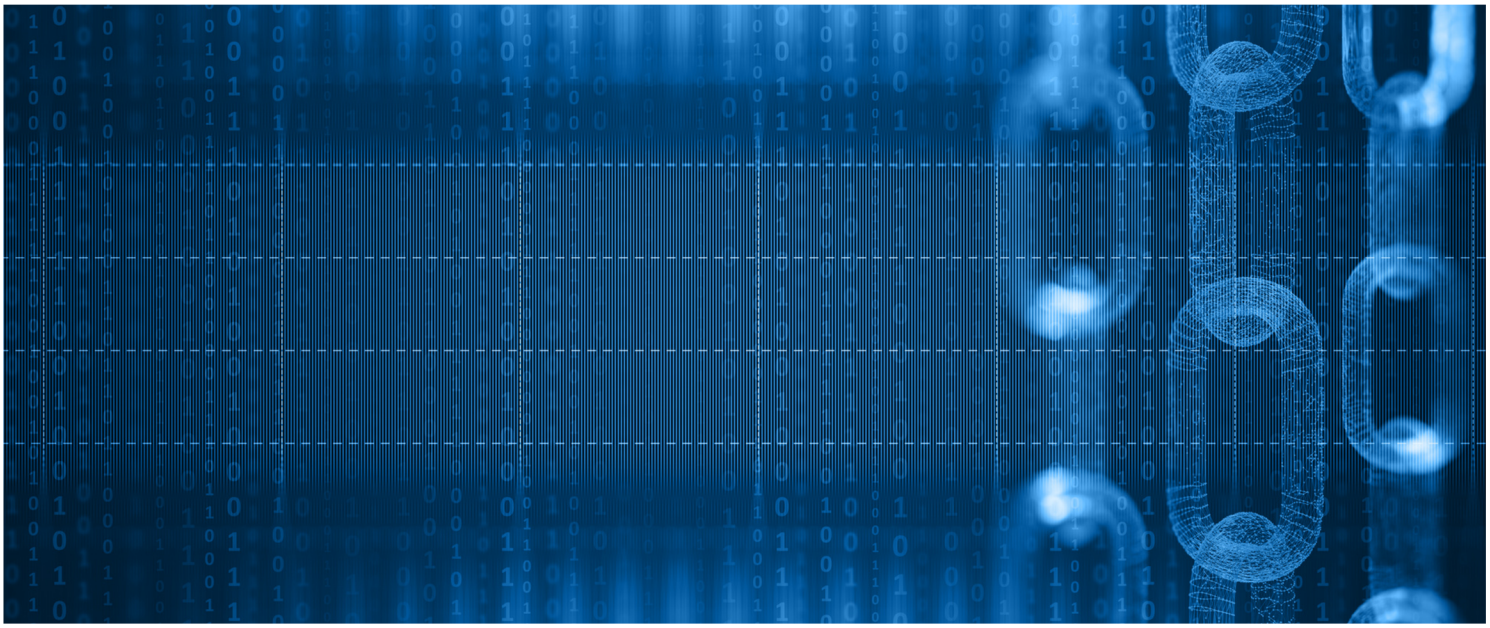
Pharmacovigilance (PV) is a cornerstone of drug safety, ensuring that adverse events (AEs) are monitored, reported, and analyzed to protect public health. However, the current AE reporting system faces multiple challenges, including delays, human errors, and concerns over data integrity. Reports are often submitted through emails, call centers, and web portals, making them susceptible to manipulation, misplacement, or suppression. Blockchain technology offers a revolutionary solution to these problems by introducing a tamper-proof, decentralized, and transparent system for AE reporting. By leveraging blockchain, stakeholders in pharmacovigilance—including regulators, pharmaceutical companies, and healthcare professionals—can access real-time, immutable records, significantly improving drug safety oversight.

The Challenge: AE Reporting is Slow, Error-Prone, and Vulnerable to Manipulation

Traditional AE reporting systems rely on centralized databases controlled by regulatory agencies or pharmaceutical companies. This approach creates several inefficiencies. Reports are often submitted manually and require multiple validation steps, leading to delays and data discrepancies. Moreover, pharma companies play a crucial role in reporting AEs to regulators, but this dependency raises concerns about underreporting or selective data disclosure. Another major issue is the risk of data manipulation. Since AE reports are stored in centralized systems, there is a possibility of altering or deleting reports, either intentionally or due to human error. This compromises the transparency and reliability of pharmacovigilance data, which can delay critical safety decisions and put patients at risk.

How Blockchain Provides a Tamper-Proof AE Reporting System

Blockchain technology solves these challenges by recording AE reports in an immutable, decentralized ledger. Once an AE report is submitted on the blockchain, it cannot be altered or deleted, ensuring that the data remains authentic and verifiable at all times. With blockchain, patients and healthcare professionals can report AEs directly onto a secure, distributed network, eliminating the need for intermediaries. Smart contracts—self-executing protocols on the blockchain—can automatically verify report completeness and flag duplicate or incorrect entries, making the process more efficient and reliable.



Furthermore, regulators can access AE data in real time, removing the dependency on pharmaceutical companies for safety reports. This ensures instant access to critical drug safety information and prevents delays in regulatory decision-making. The transparency and security offered by blockchain lead to a more trustworthy pharmacovigilance ecosystem, benefiting all stakeholders.

A Real-World Example: Blockchain in AE Reporting

In 2024, a blockchain-based pharmacovigilance trial was conducted to evaluate the impact of this technology on AE reporting. The results were transformative, demonstrating a 40% reduction in AE reporting time compared to traditional methods. This was achieved through real-time data submission, automated verification, and seamless regulatory access. Moreover, the blockchain system ensured that all AE reports remained permanently recorded, eliminating the risk of data manipulation. Regulators had direct access to the blockchain-based AE database, reducing reliance on pharmaceutical companies for safety data. This increased data integrity, transparency, and patient trust in the reporting process.

The Future of Blockchain in AE Reporting

As blockchain adoption grows, it is expected to become the backbone of global pharmacovigilance systems. The future of AE reporting will likely involve integration with artificial intelligence (AI) and natural language processing (NLP), allowing for automated classification of adverse events. Additionally, global PV networks could be built on blockchain, where regulators, pharmaceutical companies, and healthcare professionals share real-time drug safety data in a secure environment. Another exciting prospect is decentralized patient-driven safety reporting, where patients have direct control over their AE reports. This could lead to greater public trust in pharmacovigilance and more proactive drug safety monitoring. Blockchain is reshaping the future of AE reporting, making it faster, more secure, and completely transparent. As the industry moves toward fully adopting this technology, we are entering an era of tamper-proof pharmacovigilance, ensuring that drug safety decisions are based on accurate, real-time data. The question is no longer whether blockchain can transform AE reporting—it's whether the industry is ready to embrace this transformation.

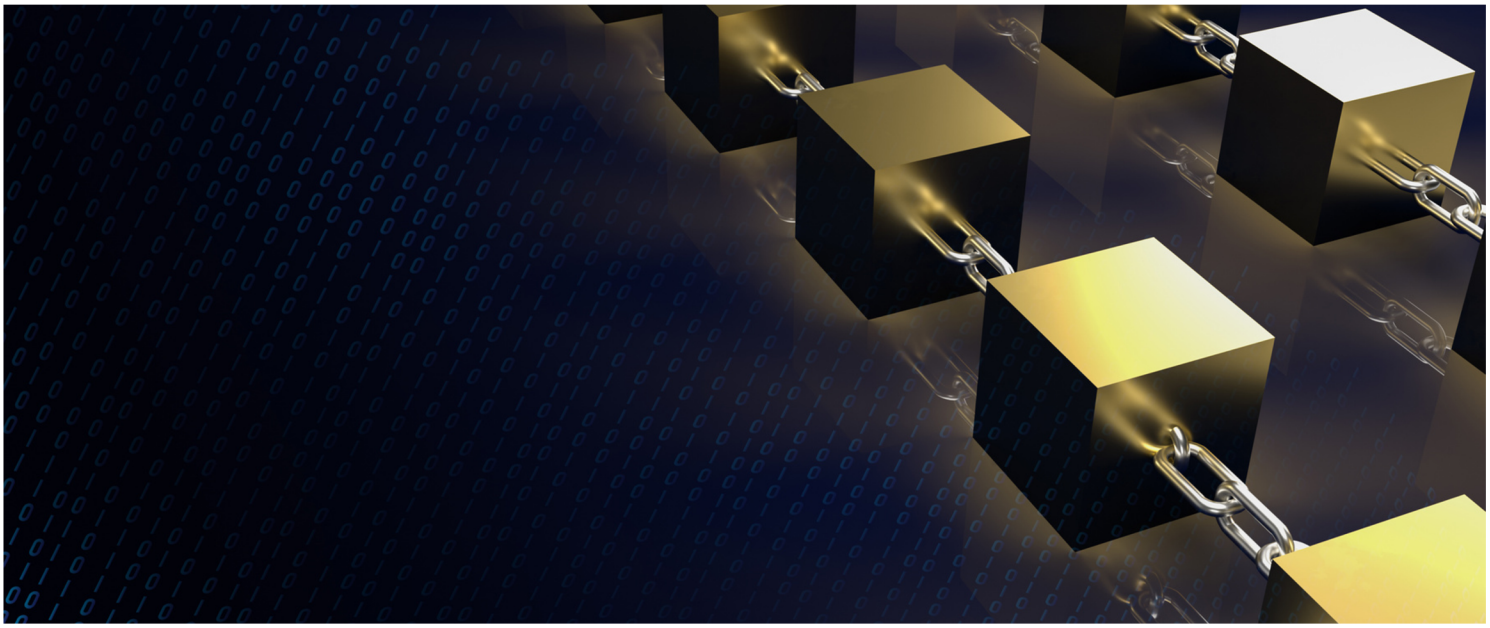
AI + Blockchain for Real-Time Signal Detection

The Challenge: Siloed Databases and Delayed Signal Detection

Signal detection in pharmacovigilance depends on disparate and unconnected data sources, including FAERS, VigiBase, and electronic health records (EHRs). These siloed systems do not communicate in real time, making it difficult to detect emerging drug safety signals promptly. Another major hurdle is the delayed integration of global AE data. Regulatory agencies and pharma companies rely on periodic data updates, which means that potential safety risks may not be identified until weeks or months after an adverse event occurs. This lag can delay crucial regulatory actions and increase patient exposure to harmful drugs. Moreover, duplicate or fraudulent AE reports remain a persistent challenge. Since AE data is collected from multiple sources, manual deduplication and validation are required to ensure accuracy. This process is time-consuming, resource-intensive, and prone to human error, further slowing down safety assessments.

How Blockchain + AI Revolutionizes Signal Detection

By integrating blockchain with AI-driven pharmacovigilance, safety signal detection can become instantaneous, transparent, and fraud-proof. Blockchain's decentralized ledger records every AE report in real time, ensuring that safety data is accessible across global networks without delay. Unlike traditional systems, where data integration can take months, blockchain enables immediate cross-referencing of AE reports worldwide. AI models, when combined with blockchain, can analyze global datasets in real time, detecting patterns that indicate potential safety concerns. Blockchain ensures that these datasets are tamper-proof and free from manipulation, while AI performs instant disproportionality analysis (DPA) to identify statistically significant safety signals. Additionally, blockchain prevents duplicate and fraudulent reports by verifying each AE entry through cryptographic validation. AI further strengthens this process by identifying inconsistencies, flagging suspicious reports, and automating deduplication, removing the need for manual intervention.



Future Vision: Fully Automated, Bias-Free Signal Detection

The future of AI + blockchain in pharmacovigilance is one where signal detection is real-time, automated, and completely unbiased. Advanced blockchain-based AI models could perform continuous disproportionality analysis, eliminating delays in signal identification and reducing the burden on human reviewers.

With smart contracts executing real-time safety assessments, regulatory authorities and pharmaceutical companies would receive instant alerts on emerging drug risks, allowing for proactive decision-making instead of reactive crisis management.

By integrating blockchain with AI-driven pharmacovigilance, the industry moves toward a future of unbiased, real-time, and fraud-resistant drug safety monitoring—ensuring that no safety signal goes undetected and no patient is left at risk.

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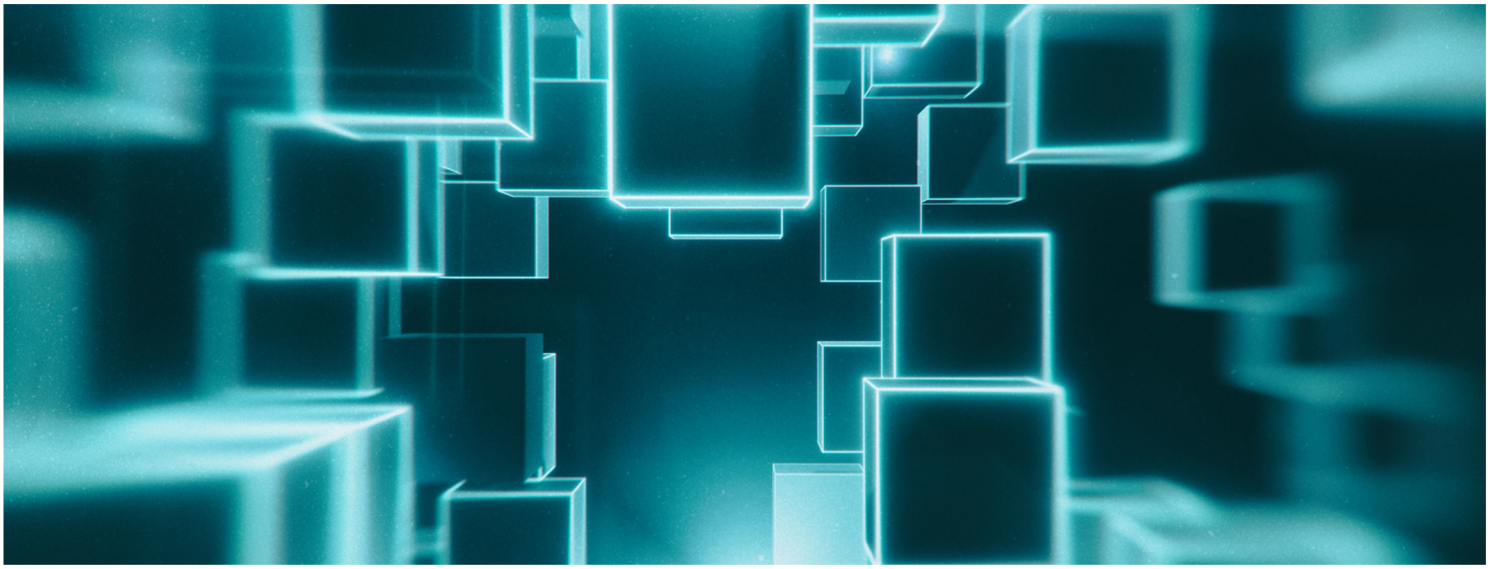

Smart Contracts for Regulations

The Challenge: Manual Processes and Delayed Compliance

Ensuring regulatory compliance in pharmacovigilance (PV) remains a labor-intensive and reactive process. Companies must manually validate AE reports, ensure adherence to global standards like E2B(R3), and submit periodic reports to regulatory authorities. This reliance on paperwork, manual checks, and periodic audits leads to delays, formatting errors, and compliance risks. One of the biggest challenges is that regulatory inspections typically happen after compliance issues arise, rather than preventing them in real time. Companies often discover errors too late, leading to warnings, fines, or reputational damage.

How Blockchain + Smart Contracts Solve Compliance Issues

Blockchain-powered smart contracts introduce a real-time, automated compliance layer that can revolutionize regulatory adherence. Smart contracts are self-executing agreements embedded within the blockchain, programmed to validate AE reports instantly against ICH, FDA, and EMA compliance rules. The moment an AE is reported, the smart contract automatically checks for formatting errors, missing fields, and regulatory inconsistencies, ensuring compliance before submission. By replacing manual audits with automated blockchain-based verification, companies can eliminate compliance errors before they happen. Smart contracts also enable real-time auditing, flagging non-compliance the moment it occurs rather than waiting for scheduled inspections. Additionally, regulatory authorities gain instant, live access to PV data stored on the blockchain. This removes the need for manual data requests, document submissions, and post-hoc inspections—regulators can monitor compliance continuously and proactively.

Case Study: Automated Compliance Checks

A 2024 blockchain-PV pilot in Europe demonstrated the power of smart contracts in pharmacovigilance compliance. The study found that automated compliance checks reduced regulatory errors by 60%, significantly lowering the risk of submission delays and compliance breaches. By integrating blockchain and smart contracts, the future of pharmacovigilance compliance will be real-time, transparent, and proactive, ensuring that regulatory requirements are met automatically and without human intervention.

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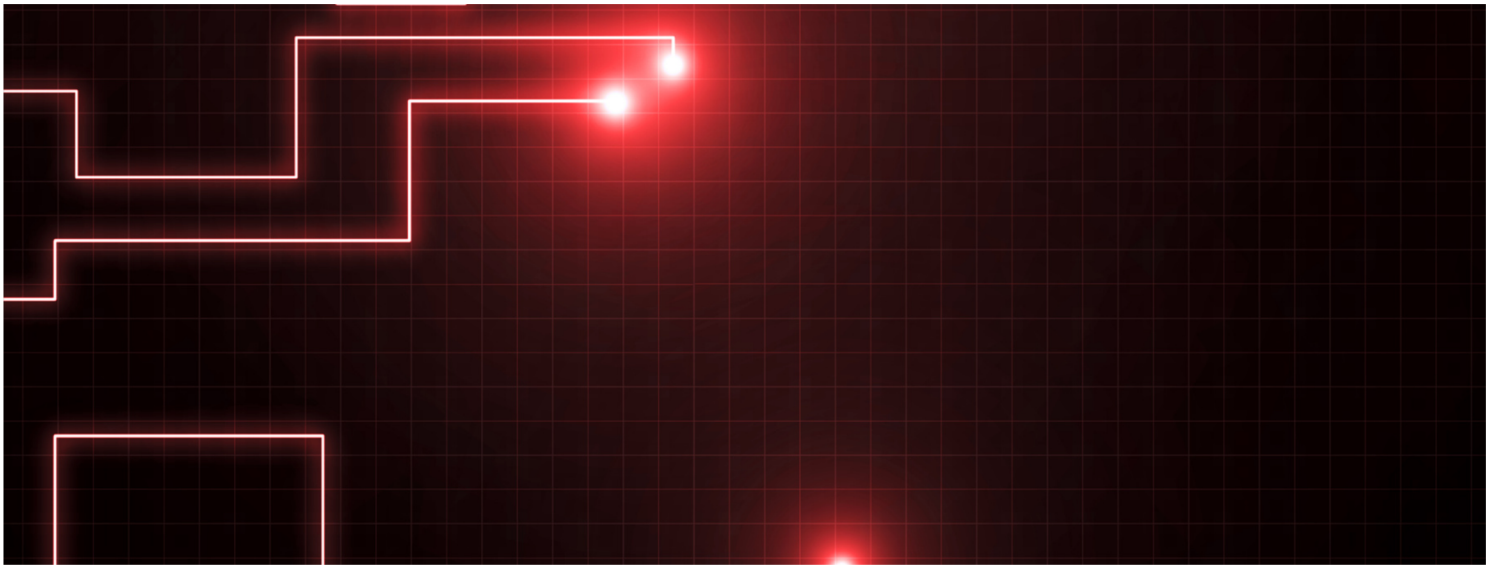

Global Interoperability & Decentralized PV Databases

The Challenge: Fragmented Pharmacovigilance Systems

Pharmacovigilance data remains highly fragmented across regions, with varying data standards and regulatory requirements. Different agencies—such as the FDA, EMA, PMDA, MHRA, and CDSCO—each operate their own safety databases with unique reporting formats, including E2B(R3), HL7, GDPR, HIPAA, and 21 CFR Part 11. These incompatible systems create delays in global safety monitoring, making it difficult to track emerging drug risks across borders. Moreover, pharma companies must submit safety data separately to each regulatory authority, leading to duplication of efforts, delays in adverse event (AE) signal detection, and compliance complexities. This lack of interoperability results in missed safety signalsthat could have been identified earlier with a unified system.

How Blockchain Enables Global PV Interoperability

A blockchain-based decentralized PV database can unify global drug safety efforts by creating a single, shared ledger accessible to all stakeholders. With role-based access controls, regulatory agencies can securely share real-time AE data while remaining compliant with regional privacy laws such as GDPR, HIPAA, and 21 CFR Part 11. Instead of isolated safety monitoring, a blockchain-powered PV network would enable instantaneous cross-border signal detection, allowing regulators and pharma companies to identify drug risks in real time rather than waiting for periodic data exchanges. This transformation would eliminate redundancy, improve efficiency, and enhance global drug safety.

Vision for 2030: A Fully Blockchain-Powered PV Ecosystem

By 2030, the future of pharmacovigilance could be a fully decentralized, blockchain-driven ecosystem where global regulators collaborate in real time. Safety signals would be detected instantaneously, regulatory compliance would be automated through smart contracts, and drug safety monitoring would no longer be limited by geographic boundaries. In this vision, blockchain will bridge the gaps between different regulatory frameworks, enabling seamless, secure, and transparent drug safety monitoring. This shift will ensure that emerging drug risks are identified and mitigated faster than ever before, ultimately protecting patients worldwide.

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