Is Blockchain a solution for Pharmacovigilance?

Blockchain Pharmacovigilance (PV) deals with detection, medical assessments, evaluations, monitoring and, prevention of (ADRs)[1]. However, the apparent increase in the data volumes of ADRs are putting a lot of pressure on pharmaceutical companies to ensure patient safety, and assure compliance. According to FDA (US Food and Drug Administration), as many as 334,395 new ADR reports were received in quarter 1, 2019 alone[2].

This POV will explore how Blockchain can help addressing all the challenges that the pharmaceutical companies face during PV process.

PV plays a critical role in the following areas:

- **Patient/sonsumer safety:** Creates appropriate reporting structure to assess and monitor drug both in clinical trials and post that
- **Regulatory obligations & compliance:** Creates appropriate protocols for drug recalls, issuing patient/consumer warnings and, assure compliance
- **Enhanced process**: Creates and provides a better assessment and evaluation for the drug

companies to ensure long-term viability for the business and improved trust from the patients/consumers

What are the current challenges in Pharmacovigilance?

With the rapid increase of information across the globe, Pharmacovigilance (PV) practices/ departments need to face enormous and endless challenges in keeping up with the public expectation of drug safety, managing various channels/systems to report ADRs and clinical trials, dealing with a complex and large landscape of legacy systems, data security & privacy, and evolving regulations.

It is of utmost importance to have a comprehensive and thorough understanding of current challenges in PV practice to be able to address these challenges and craft an approach using enhanced technological solutions.

PV lifecycle diagram (Figure 1) depicts the overall PV process and the current challenges faced by PV departments.
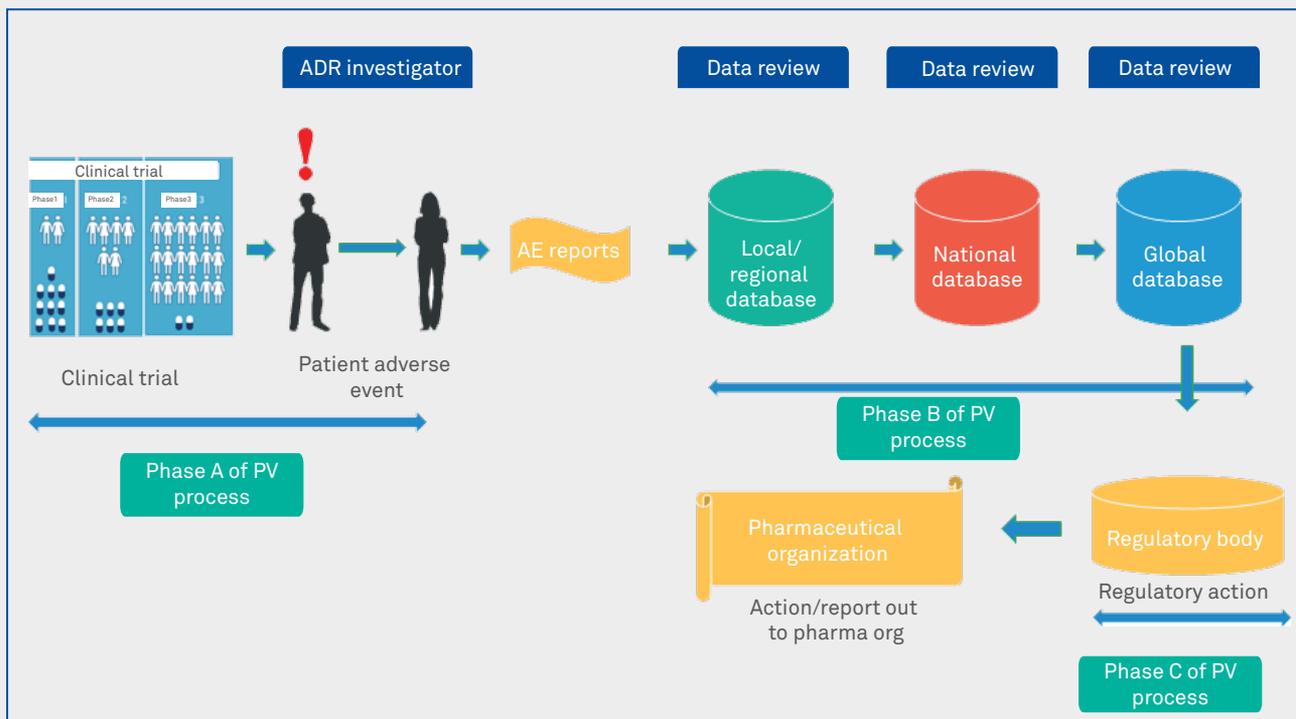

Figure 1: PV lifecycle

Phase A of PV process

1. **Controls around tracking and timestamping clinical trials:** Clinical trials are the foundation of any medical innovation and are conducted by all drug companies to understand and determine the safety of any drug. There are number of trial cycles that take place before any drug comes out in the market for consumption. These clinical trials generate huge amount of data for analysis. Drug companies can potentially manipulate clinical trials' data and fit the analysis to suit their own needs, can misquote its adverse effects/benefits and wrap it up in such a way that the regulatory authority will approve it for consumption. As these records and analysis are mutable, it is not difficult for drug companies to influence the outcomes.

2. **Patient monitoring post clinical trials:** One crucial aspect of PV process is performing patient monitoring post the clinical trials. Here the drug companies need to identify, monitor, and track all the participants who have had an adverse reaction to the drug. This is done before releasing the drug in the market for consumption. As the drug companies have to track huge volume of data, a number of patients across globe, patient monitoring post clinical trials is becoming a huge challenge for drug companies.

Phase B of PV process

1. **Multiple Complex Systems to report ADRs:** Drug companies are required to maintain multiple systems at regional, national, and global level for patients to report ADRs. This not only adds huge cost, but also adds a huge task for drug companies to perform analytics/assessment on multiple ADRs that gets reported globally daily. The whole industry is spending significant amount of money to maintain these advanced/legacy systems.

2. **Data Privacy/Security:** "Between 2009 and 2017, more than 176 million patient records were exposed in data breaches[3]" . As these are patients' records/medical history, it is crucial to ensure privacy & safety of these records. There are multiple systems across various channels to report ADRs, and patients' data is staged in various system, there are no control mechanisms to manage this flow of information. This eventually triggers huge risk of patients' data being lost or misused.

Phase C of PV process

1. **Aligning to regulatory bodies and their requirements:** Enhanced regulatory standards and increasing scrutiny around clinical trials, ADRs and drug monitoring are difficult to maintain for all the drug companies. The authorities and regulatory bodies have put in lot of rules and regulations to ensure drug companies are compliant with: reporting ADRs, privacy & security of patients' information & medical history and, audit trails and controls around any data change. Thus, all the drug companies are facing enormous challenges in aligning to regulatory bodies.

How Blockchain can address current challenges in Pharmacovigilance

Due to above said challenges faced in PV process, all pharma and drug companies are exploring Blockchain-based PV solutions to ensure drug monitoring and safety. As per a report, "The healthcare industry is aiming for the most aggressive deployments of Blockchain, with 35% of health and life sciences companies planning to be implement by 2019"[4].

Blockchain provides de-centralized and evenly distributed database in terms of nodes, safeguarding security and transparency of the data. Blockchain allows various entities to process data via various nodes with no central authority. This helps the entities to see real time transactions/revisions without the intervention of any third party. All the relevant parties are connected through nodes via distributed databases, and there is no centralized authority (Figure 2).
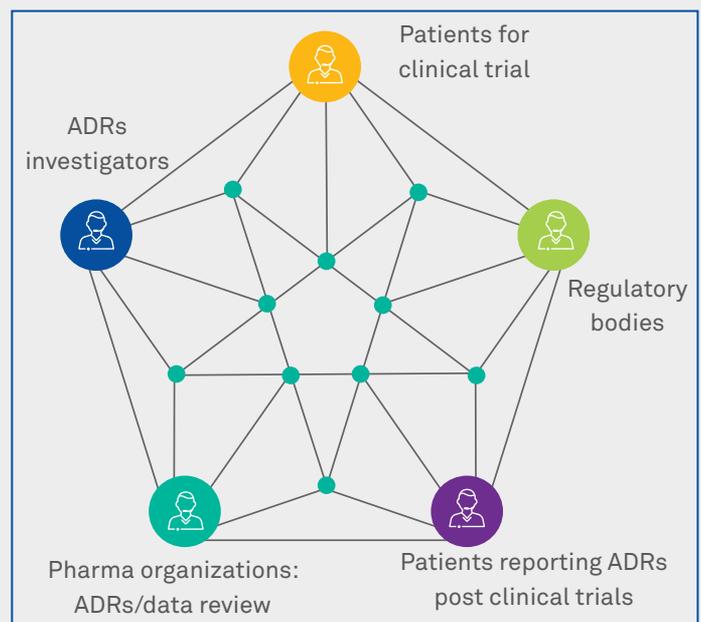

Figure 2: Blockchain addressing challenges faced in PV process

Challenges in PV process	Various entities in PV Process	Blockchain addressing these challenges
Controls around tracking and timestamping clinical trials	Pharma companies & patients	In Blockchain as data records are immutable, it provides very transparent and reliable approach to control, track and timestamp clinical trial data records. Pharma companies will be compelled to provide accurate results from these patient studies. This will ensure drug safety along with accurate results.
Patient monitoring post clinical trials	Patients & ADR investigators	Blockchain can enable smart contracts where if any patient is reporting ADRs, this will generate a code and the case gets directly reported to ADR investigators enabling them to act upon it quickly. This will also make sure that the drug companies are not influencing the patients/outcomes.
Multiple complex systems to report ADRs	Pharma companies, patients & ADR investigators	With Blockchain, real time data can be available with just a single click of a button. It can fill all the gaps pertaining to patient trustworthiness and safe medical practices. Patients will be aware and informed of every step on where their sensitive data/medical history is getting shared or used. It will also give them authority to allow/refrain anyone to temper with the data.
Data privacy/security	Pharma companies & patients, ADR investigators and regulatory bodies	Blockchain' s secure and trustless data sharing will enable the pharma companies, Regulatory bodies, ADR investigators, and the patients to create a reliable and trustworthy ecosystem where all the confidential data related to medical history, patients' personal data etc. will flow seamlessly and securely. This will allow patients to make more informed decisions as this data will be a single version of truth & immutable.
Aligning to regulatory bodies and their requirements	Pharma companies & regulatory bodies	Blockchain improves the transparency, reliability and efficacy which is the most critical requirement for any drug company in the heavily regulated industry. Be it reporting ADRs to audit trails, Blockchain can take care of all these requirements by its distributed ledger.

Figure 3: Blockchain addressing challenges in PV process

Are drug companies using Blockchain?

- **Pfizer, Amgen, and Sanofi:** Controls around tracking, Improving and timestamping clinical trials[5] . Pfizer, Amgen and Sanofi are working jointly to have use cases in patient health data & safety, improving and speeding clinical trials using Blockchain.

- **Pfizer, AbbVie, Roche, McKesson:** Drug compliance along with regulatory requirements[6]. Pfizer, AbbVie, Roche, and McKesson have partnered for project that uses Blockchain to align compliance and regulatory requirements with the regulatory bodies. It also prevents counterfeit medicines from entering the supply chain.

- **SimplyVital Health:** Patient monitoring and data sharing [7]. SimplyVital Health, a startup in healthcare that is using Blockchain technology to monitor patients after they have been treated. Their "ConnectingCare" Blockchain platform allows patients to share their medical data and records, creating an immutable trail.

Conclusion

Blockchain offers significant opportunities to reinvent the way drug companies' access, collect, distribute, share, leverage, monitor and audit clinical trial data or medical/patient records. However, in order to reap the benefits of Blockchain, drug and pharma companies must overcome barriers to adoption. To facilitate adoption, Pharmacovigilance seems to be a clear use case for the technology.

Blockchain can help address the challenges in Pharmacovigilance (PV). Blockchain provides de-centralized and evenly distributed database in terms of nodes, safeguarding security and transparency of the data.

Blockchain allows various entities to process data via various nodes with no central authority. This helps the entities to see real time transactions/revisions without the intervention of any third party.

Blockchain offers significant opportunities to reinvent the way drug companies' access, collect, distribute, share, leverage, monitor and audit clinical trial data or medical/patient records. However, in order to reap the benefits of Blockchain, drug and pharma companies must overcome barriers to adoption. To facilitate adoption, Pharmacovigilance seems to be a clear use case for the technology.

References

[1] ADR is defined by the World Health Organization (WHO) as a response to a drug that is noxious, unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function

[2] https://www.ismp.org/resources/quarterwatchtm-includes-new-data-quarter-4-2018-and-quarter-1-2019-focus-four-new-drugs

[3] https://builtin.com/blockchain/blockchain-healthcare-applications-companies

[4] https://www.beroeinc.com/category-intelligence/blockchain-technology-market/

[5] https://hackernoon.com/top-5-use-cases-of-blockchain-in-pharma-and-healthcare-that-you-should-know-about-77ccdd76369b

[6] https://medicalfuturist.com/top-12-companies-bringing-blockchain-to-healthcare/

[7] https://www.computerworld.com/article/3294996/by-2020-1-in-5-healthcare-orgs-will-adopt-blockchain-heres-why.html?page=2

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