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Indegene CTO On Pharma And Blockchain's Promise Of Better Accountability, Trust

by Anju Ghangurde

Indegene's chief technology officer, Tarun Mathur, talks to *Scrip* about blockchain's potential in a number of areas across pharma's operations including the clinical supply chain and trials as well as its role in enabling improved trust in the healthcare data ecosystem.

The potential and opportunities of blockchain for healthcare are immense and pharma is working towards using this type of distributed ledger technology in areas such as supply chain, safe storing of health data, clinical trials and R&D.

In an interview with *Scrip*, Tarun Mathur, chief technology officer, Indegene, touched upon certain early and ongoing industry efforts around implementing blockchain solutions and where things may be headed in some key areas.

A long-timer at the technology-led healthcare solutions provider, Mathur outlined how blockchain, initially popularized by cryptocurrency bitcoin, could potentially have an important role going ahead in areas like patient engagement, given significant shifts underway in personal data ownership and management. Blockchains, experts assert, bring with them the promise of the decentralized handling of data as well as data sovereignty, which essentially entails giving individuals control over their personal data that can be shared with trusted parties.

On wider industry concerns that blockchains and the EU data protection regime are in conflict by their very construct, Mathur noted that the fundamental problem is that the EU requires that users should be able to request and have their personal data deleted from authorities that are holding their information.

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"Blockchain by its nature does not permit the deletion of data, so there is a disconnect," he said, echoing similar concerns that some other experts have referred to in the past around the "conceptual tensions" between EU General Data Protection Regulation (GDPR) and these novel decentralized databases.

Indegene, though, isn't examining this problem too intensely at the moment, with its focus more around blockchain usage in enterprise supply chain environments where such type of "data purge" requirement is not needed. (Also see "*DSCSA Pilot Used Blockchain To Trace Drug Through 'Last Mile' of Supply Chain*" - Pink Sheet, 28 Jul, 2020.)

"For those cases where it can be an issue (such as with patient recruitment for clinical trials), we are operating under the premise that personal data stored in the blockchain is owned by the user, not by a central authority. It's cryptographically locked to the patient in this case, and the patient can control who has access to it," Mathur said.

He believes that this potentially satisfies the data concern, but adds that Indegene is watching what other players in this space are doing and learning from that.

Halid Kayhan, a representative of Katholieke Universiteit Leuven, Belgium in the consortium of the PharmaLedger project, in a recent article noted that if a blockchain network is developed by adopting strong data protection by design and by default approach under the GDPR, specific features of blockchain may help achieve some objectives of the rules such as data sovereignty, trust in the accuracy of data, better accountability, and data integrity and security, among others.

"When combined with other technological solutions as in the case of self-sovereign identities, blockchains can provide greater autonomy and control to individuals on their personal data and opportunities to enforce their data subject rights with ease," Kayhan explained.

PharmaLedger, which is sponsored by the Innovative Medicines Initiative (IMI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), brings together several big pharma firms and public and private entities and aims to provide a trusted platform that supports the design and adoption of blockchain-enabled healthcare solutions.

Mathur, a former director of technology at Medsn, also referred to Indegene's "internal

experiments" deploying alternative technology stacks that target similar outcomes as blockchain app KitChain, which is sponsored by a large pharmaceutical consortium that includes *Pfizer Inc.*, *Biogen.*, *AstraZeneca PLC*, *GSK plc*, Thermo Fisher, *IQVIA.*, UCLA and Deloitte, among others.

KitChain is essentially an iOS and web app that brings "a single version of the truth", as the grouping supporting it puts it, to the clinical supply chain ecosystem, backed by decentralized identity and secure blockchain tools, to accelerate treatments to trial participants.

Mathur also believes that the decentralized nature of blockchain- put simply an online ledger - and the immutable actions of smart contracts within it could improve the trust quotient in the healthcare data ecosystem both for regulators and the public in general.

Q **What's the kind of potential that blockchain brings in terms of supporting remote data capture during clinical trials, reducing the number of times patients would need to visit the clinic for tests and what does this imply in terms of opportunities for expanding decentralized trials?**

> **A** Blockchain has the trait of being an immutable ledger and together with smart contracts has the ability to provide traceability to all events that are recorded in the ledger. For decentralized trials, we need to see that the data captured is authentic, complete, unaltered, and generated from a trusted source. Blockchain platforms can support these needs, however these platforms are not sufficient on their own. We see the ecosystem of remote devices, labs and online engagement and assessment tools as necessarily adopting this new framework in order to greatly expand the scope of decentralized trials. With the shift towards Web 3.0 and more advanced blockchain based platforms, we think the industry is heading there, though it will take time.

Q **Has blockchain technology been able to increase the quality and number of patients recruited for clinical trials and is big pharma deploying this widely as of now? What about blockchain-backed supply chain solutions for clinical trial drugs like we've heard of KitChain – has Indegene been involved in similar projects?**

> **A** At this time, we do not believe that big pharma has wide adoption of blockchain

solutions for clinical trial patient identification, recruitment, or engagement. With the current shifts in personal data ownership and management, we do see some opportunities where blockchain technology will be impactful, and in some cases may become a necessity with how we engage with patients.

With remote engagement, blockchain as a mechanism for personal identification may be a strong use case. An example would be a patient who is being asked to join a metaverse type application that is restricted to certain patient cohorts. It could be that only patients that own a specific NFT [Non-fungible token] in their blockchain are able to get access to that application. As online presence moves from the Web 2.0 to Web 3.0 model, we believe that the decentralization of personal data that is embodied in the Web 3.0 goals will impact the digital experience for all users of this next generation globally connected network. This includes patients, investigators, sponsors, and researchers involved in clinical trials. Users will be expecting their digital experiences to be in alignment with these new standards, so big pharma will necessarily have to adopt them as clinical trials are leveraging more remote digital touchpoints. Some advanced forms of remote patient diagnostics may only be possible through next generation modalities such as Metaverse where patient identities, attributes, and health data could be stored in a blockchain. Today, we seem to be at early stages that warrant proof-of-concepts and experiments but do not seem ready to scale at big pharma enterprise levels.

Indegene is not currently involved in blockchain-backed supply chain solutions. We are aware of KitChain and its origins, however, currently see it as proof-of-concept with a vision towards a more feature complete solution.

We have also seen and done internal experiments using alternative technology stacks that target similar outcomes. For example, a solution based entirely on AWS [Amazon Web Service], taking advantage of AWS Quantum Ledger Database could provide some of the benefits of the permissioned blockchain model that KitChain uses, but leverage the advantages of the established enterprise grade infrastructure of AWS. They key point here is the trust established with the cryptographically secure and immutable database and the API [application program interface] interfaces to interact with applications and devices. We don't see the decentralization of the ledger infrastructure as a major necessity in sponsored clinical trial supply chain.

Q The distributed ledger, experts say, could allow individual patients to store their medical data via anonymous methods, making it visible to trial recruiters, who could then reach out to the patients if their data qualify for the clinical trial. Doesn't that on the flip side raise the risk manifold with varying levels of understanding at the individual patient level of systems and their options as well the need to build a trust ecosystem?

A Yes, this is a very important point. Just because the technical viability is in place, does not mean that all users will be able to use this capability, use it responsibly, or use it correctly to get the outcomes they are expecting. When we are talking about a very broad audience of patients which straddle all levels of access, understanding, and capabilities it is essential to consider the risks. Ideally, we would like to see some core industry standards for the protocols and methods and then a robust opensource presence for the patient facing applications. This would drive significant acceleration in the evolution of the patient experiences and hopefully address the widest possible cross section of patients.

Q The UK-based DeHealth is working towards a reality where patients are in control and compensated for the use of their data with its DHLT cryptocurrency token as a means to an end – so it means patients getting paid for it with the token. (Also see "*DeHealth Applies Blockchain To Medical Data Transactions In Bid For Transparency*" - Medtech Insight, 6 Jul, 2022.) Is this where things will be heading, where patients can perhaps monetize their data?

A A patient's primary goal is to improve their health outcome and we should not lose sight of that as the primary objective of what we do in life sciences. While the opportunity for patients to monetize their data may be a real artifact of the new technologies, I prefer to think that the technology allows better management of personal health data in that it is now centered with the patient and not with an institution such as payors or big tech. Patients being able to readily contribute data could yield reduced time to market and lower drug development costs as well as improved adverse event detection. To me, these are the more exciting aspects of the

technology. Yes, monetization opportunities will certainly be there, however I would like to think that the other advantages would be the greater good. The important thing here is that the data is centered with the patient and the patient has transparency into who has access to their data, what data they have access to, and ideally how it's used.

Q We've heard of the multi-stakeholder collaborative PharmaLedger project sponsored by IMI and the EFPIA, which is to deliver a blockchain-based platform for the healthcare sector, using the supply chain, clinical trials, and health data as case studies. Any key learnings that Indegene has been able to draw?

A We are not involved with the project. Based on the public information, it certainly reinforces the potential of the distributed ledger but also highlights that the devil is in the details. Our understanding is that the development work is ongoing and we hope to learn more about this project as it evolves.

Q A senior Novartis exec was quoted as saying that "Blockchain is a team sport". But generally in team sports, there are some stars and some who may need a bit of hand-holding/support to deliver. What's your assessment of the current strengths, weaknesses of the entire biopharma blockchain team/ecosystem, so to speak?

A Within the biopharma space, a few major strengths are clear. First is that backing from enterprise biopharma can certainly shift the emerging technologies into robust enterprise solutions that operate at scale. The other strength is that the detailed understanding of process, expected outcomes, stakeholders, and exceptions are well known in the drug life cycle. That domain understanding is needed to address the comment about those that need 'hand-holding'. If there is a player that has potential but needs investment in resources and expertise, the industry is able to do that. The weaknesses largely come from time. Biopharma has historically been slow to adopt disruptive technologies. For blockchain based solutions, the industry is combating pressures to quickly make disruptive changes while at the same time

grappling with processes that slow moving.

Q In blockchain technology, data is decentralized and is stored across multiple servers and is also immutable. Does this mean its widespread use in the trials arena will potentially help check the data tampering/integrity scourge that's eroded industry trust at the end of both regulators and the wider public?

A If data tampering is detected, the blockchain has the benefit of being able to trace the lineage of that tampering and identify the root. This will certainly be a significant advantage to those seeking trust. The decentralization of data is also a major factor primarily for the wider public. Concerns around large tech organization owning and monetizing personal information without transparency is at an all-time high and risks of data breaches at these centralized locations will continue to grow. The decentralized nature of blockchain and the immutable actions of smart contracts within the blockchain will definitely help regulators and mostly the wider public have better trust in the healthcare data ecosystem.

Q Do you see blockchain also playing a pivotal role in checking counterfeiting - Merck is said to have implemented a blockchain-based pilot in Hong Kong for Gardasil-9?

A I am not familiar with the Merck pilot, so can't comment on that. Use cases where blockchain combined with better drug tagging can address counterfeit drug detection are generally understood, however. A well encoded dense tag on medication that can be scanned by a camera or other device scanner like RFID can be checked on the blockchain to verify if the drug is genuine, not expired, and being dispensed by the authorized dispenser. In fact, we can see that with the right type of application this could even fit into a patient-focused drug adherence program.

Q With blockchain-anchored e-package inserts being explored, going forward would the paper insert be a rarity and also ensure huge savings for industry? These inserts are estimated to account for over 10% of recall issues, as per some experts.

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A We have seen many attempts to digitize package inserts over the years. We have to keep in mind the audience of these inserts and their utilization. The core question is how many patients actually read the inserts and would making it digital improve that metric? The efforts to read a paper insert is quite low compared to having to use an app, be online, and have the hardware necessary to see the e-package insert. Our feeling is that shifting to a blockchain-anchored -package insert would not necessarily move the recall needle by a significant amount. It does have the plus point of being able to see the lineage of changes to the inserts, however we think that modern approaches to the analytics and linking pharmacovigilance processes to labels combined with improved readability for patients would be more impactful than migrating to blockchain-anchored inserts.

Q Finally, in which part of pharma's operations do you see blockchain being most compelling in the short term and when do you see blockchain emerging as really mainstay across industry?

A We do see short-term opportunities where decentralized apps using blockchain platform technologies could help accelerate supply chain within clinical trials. A lot of work is going on in this space and we believe there will be continuing adoption of this even in the short term. Additionally, within biopharma enterprise commercial content development, we see use cases where a well-designed blockchain application that maintains the ledger of content creation, updates, and repurposing globally would reduce the time to market or time to market for content by providing full traceability. Today, these efforts are done using inconsistent means and many manual interventions. This could potentially be automated and standardized robustly using blockchain technology. While migrating patient data into the blockchain and enabling smart contracts to govern the data and the data transactions is a very compelling use case, we think that will take time to reach the critical mass needed to be very impactful on the industry.