USING BLOCKCHAIN TO ACCELERATE EFFICIENT CLINICAL TRIALS DURING A PANDEMIC

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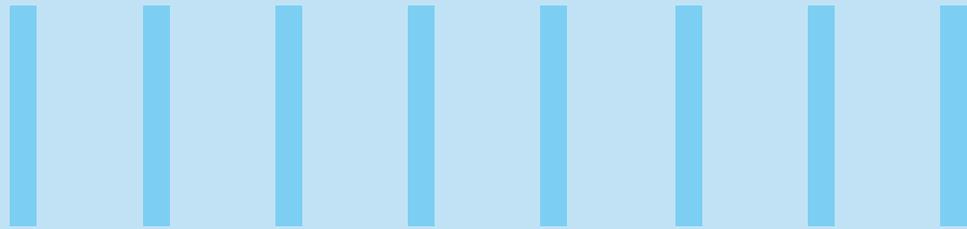
The world is bracing itself against the global pandemic which has claimed thousands of lives across the world. Several developed economies in the world have been unable to defend their populations from the onslaught of COVID 2019, despite state-of-the-art healthcare systems. Since its outbreak, the virus has spread like wildfire to more than 190 countries, claiming the lives of approximately 3 to 4 % of all those infected. Scientists around the world are racing against time to find a treatment or a vaccine for the COVID 19 virus. The rate of infection from this contagion is growing exponentially with every passing day. Healthcare systems are under tremendous stress because of the spiraling number of patients needing critical care.

Developing Vaccines and Drugs

The process of developing drugs and vaccines is lengthy and expensive, often associated with high costs and high failure rates. It takes roughly 5 -15 years for the time to market, complex and expensive process as it costs around $800M - $2.5B per drug, with high risk as the success rate is 1 in 5 drugs make it to market and only 1 in 3 drugs reaching the market is "profitable".

The high cost of vaccine or drug development is a major deterrent for the pharmaceutical companies to undertake

clinical trials. Over the past two decades, the researchers invested in similar epidemics of H1N1 Influenza, Ebola, Zika and SARS COV-2. In some of the cases like for SARS, Ebola, and Zika, the epidemics ended before a vaccine development was completed. In the case of H1N1, the vaccine was not available before the pandemic reached its peak. Ultimately the vaccine was incorporated into commercially available seasonal influenza vaccine[3].

Patient recruitment, retention, and monitoring could account for up to 30% of the clinical trials costs[4]. Key bottlenecks exist in tracking supplies, administration and adherence to the trial requirements. Citizens often shy away from registering for trials due to privacy concerns for their data after the event. The FDA has also issued a guidance stating conduct of clinical trials during the pandemic must ensure safety of patients as well as professionals while maintaining data privacy.

Envisioning a blockchain ecosystem to accelerate clinical trials

We visualize a digital technology backed ecosystem that economizes the cost, while expediting the lifecycle with complete transparency and privacy. A decentralized distributed ledger technology based platform to track and accelerate supply chain, leveraging smart technology and wearable devices to efficiently and economically gather real-world evidence could be the answer. An anonymized data collection and consent management process would tremendously increase the rate of participation by allowing the candidates to share case records and diagnostic parameters, without actually disclosing personal identifiable information.
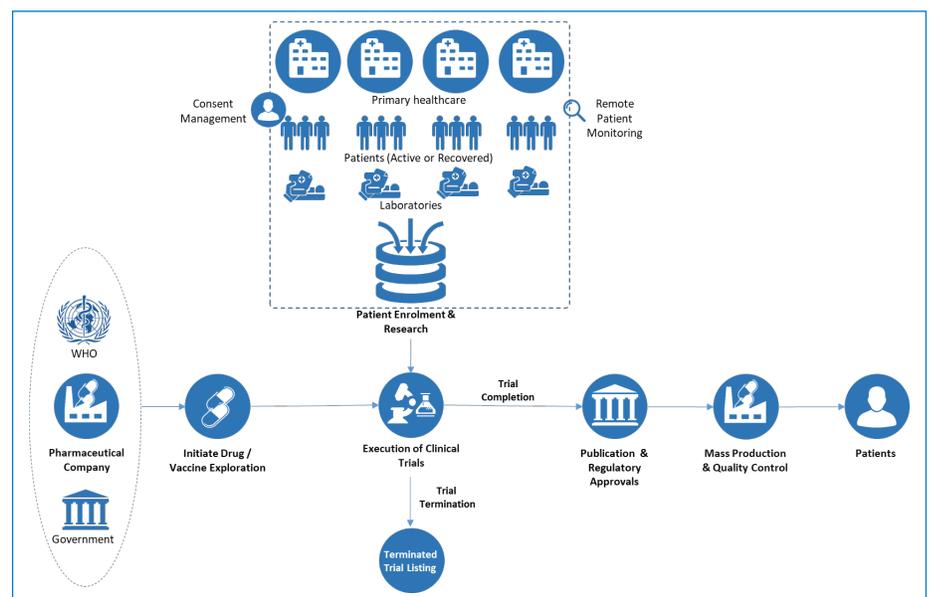
Drug or Vaccine Development Development

Initiate Drug/Vaccine Exploration via a proposed Blockchain network

The notification of an epidemic or possible pandemic will be communicated to regulators, government agencies, WHO, pharmaceutical manufacturers and research organizations on a Blockchain network. Pharma's will invite and onboard patients, clinical logistics companies will ensure collection and delivery of samples and medication. Contract research organizations and laboratories will conduct diagnostic evaluation of the progress of the patients. Thus, the various stakeholders in the value chain for drug/vaccine exploration, will have a stake in the proposed Blockchain network.

Patient Consent Management and Data Privacy

Pharmaceutical research entities will invite participation of the convalescing and recovered patients on the pandemic in the research as per regulatory guidelines. On the blockchain ecosystem, the locus of control of all personal as well as diagnostic data will reside with the individual patient. Therefore, during the trials, the patients participating will explicitly offer consent and allow usage of diagnostic data. On completion of trials control of such data will reside explicitly with individuals on the blockchain. Cryptographic hashing PII will ensure privacy and prevent any unauthorized misuse. Assurance of data privacy will encourage higher participation by potential candidates.

Execution of Clinical Trials

Pharmaceuticals can manage the supply chain of drugs to be administered to patients in the course of trails on the Blockchain to ensure end-to-end real time traceability. Remote patient monitoring technologies can be integrated with the Blockchain platform to ensure secure persistence of diagnostic metrics. Laboratories empaneled for trials can be on boarded to the ecosystem to ensure seamless collection of samples and reporting of tests to relevant researches in a secure manner.

As in the prevalent pandemic situation, such an ecosystem can reduce complexity in the chain of custody of medication and supplies in clinical trials. This is a crucial phase for the candidate vaccine, as the response of the human body and its effects need to be recorded with precision and studied before the drug is approved for wider adoption. This will also ensure the patient's adherence to the trial protocols and thorough record-keeping. Hence reducing the overall effort and duration of the trials.

The efficacy and the side effects of the vaccine tested would be recorded during the trial phases and would be shared in real-time with the regulatory authorities. The authorities perform the audit, validate provide necessary approvals for the progress of the clinical trials. Thereby ensuring accelerated turnaround for vaccine or drugs.

Trust on a Blockchain Ecosystem

The special circumstances of an outbreak of the scale of COVID have created an environment where many pharma and biotech companies have agreed to partner and pool their efforts towards defeating the spread of the virus, rather than compete.

A Blockchain ecosystem for clinical trials offers an unprecedented level of transparency and trust for collaboration amongst various stakeholders in the value chain of clinical trials diagnostic results recorded on blockchain assure of authenticity, immutability and real time information sharing across stake holders of the ecosystem, facilitating faster turnaround and approval form the regulators.

Thus Biotech, pharmaceutical research companies and regulators can collaborate on such a blockchain ecosystem, share findings on drug discovery with implicit trust. This public private partnership will enable faster and improved trial outcome. Agencies like Coalition for Epidemic Preparedness Innovation (CEPI) are already working in this direction. In response to the recent Covid-19 outbreak, CEPI partnered with private companies, government agencies and academia to develop coronavirus treatments[6].

Mass Production and Quality Control

With the regulatory review and approvals, the vaccine is sent for mass production. Pharmaceutical companies and contract manufacturers maintain thorough manufacturing and quality control mechanisms, linked to their enterprise ERP systems. The system carefully records the drug packages against a serialized drug identifier. Various manufacturing and storage facilities can collaborate on the manufacturing and distribution processes using a blockchain-based supply chain network.

Tracking the provenance of these drugs and recording the process on a blockchain will ensure a robust supply chain with an efficient flow of physical goods, the related information and the financial transactions. Efficient tracking of material and information will help to tackle the problem of counterfeit drugs. Real-time monitoring of the vaccine in transit also prevents any drug contamination.

Conclusion

This crisis warrants that governments around the world focus on preemptive measures to strengthen response mechanisms to pandemics, and for biotech and pharma research giants to demonstrate greater agility in turning around cures as well as preventive care for whatever vagary nature throws at us. A blockchain-enabled approach for tamper-resistant, clinical trials management system, enables collaboration of patients, researchers, and regulatory authorities engaged in clinical research. Blockchain offers immediate benefits to patients by empowering better control and access to their data, to researchers, by affording them useful tools to maintain the credibility of the trial findings and adherence to reporting requirements. Blockchain stands to enhance the integrity of clinical trial data and promote trust throughout the clinical research community by ensuring patient consent management and Tamper-resistant clinical data management.

Thus embracing Blockchain could accelerate clinical trials, enforce trust and reliability of data and expedite the quest for the panacea to Covid-19.

About the Authors

Rohini Trehan, Practice Manager, Blockchain Services, Infosys
A seasoned IT Leader with rich experience in Technical Consulting and Delivery across technology and industry domains. Rohini has extensive experience in managing large accounts, incubating and developing new practices and sustaining delivery excellence. Her passion for technology coupled with all-round delivery experience is the rigor she brings in driving innovation in her portfolio. As a Practice Manager with the Blockchain Service line, she is responsible for thought leadership, design of disruptive solutions & consulting towards Blockchain led business transformations for clients across industry verticals.

Divik Bansal, Principal Consultant, Blockchain Services, Infosys
Divik handles global engagements in Healthcare, Life Sciences, Energy and Utilities in Blockchain. He also offers executive level advise and thought leadership focusing on how blockchain can be applied to specific business units and how to it can leveraged by public or private sector organizations. He also has expertise to undertake assessment of corporate strategy to evaluate blockchain potential applicability and business impact.

Sanal J Nair, Senior Consultant, Blockchain Services, Infosys
Sanal is responsible for business solution development for Healthcare and Lifesciences engagements in blockchain practice. He has 13+ years of IT and Consulting experience. He works closely with clients and development teams enabling use case enrichment through design thinking workshops, development of blockchain implementations and enterprise application integration.

References

1) WHO Coronavirus disease (COVID -19) Pandemic

2) Jhons Hopkins - Coronavirus (COVID-19) Information and Updates

3) https://www.nejm.org/doi/full/10.1056/NEJMp2005630

4) Eastern Research Group

5) The complex development of vaccines

6) Covid-19: Pharmaceutical companies and agencies that partnered for coronavirus vaccine development

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