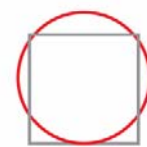




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Research Snapshot: Blockchain in Clinical Trials

Lowering the costs and complexities of clinical trials.



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Pharmaceutical research and development processes have evolved since Jonas Salk went to Pittsburgh and discovered the polio vaccine. Today, drug discovery processes are often hugely complex undertakings involving multiple research organizations, global testing sites, several regulatory organizations, and thousands of patients.

These complexities have increased clinical trial costs, which have risen to all-time highs.¹ Applying Blockchain to clinical trials can improve multiple issues, such as patient retention, regulatory oversight, partner coordination, and fraud. Improving these issues will reduce trial complexity and subsequently reduce trial costs.

Increase patient retention

Overall, 30% of patients admitted into a clinical trial will drop out and surprisingly 85% of trials don't maintain enough patients to complete testing.² Among the primary reasons for the high drop-out rates are normal, everyday life events that take priority over adhering to the trial routine. As many of us know, it is often difficult to consistently attend extra activities, e.g., a fitness regimen.

However, we also know that the more convenient an activity, the greater the likelihood that we maintain the schedule. Due to the trust and immutability that

¹ Kinect 365, Lane's survey of intramural NIH investigators

² Kristina Lopienski "Retention in clinical trials – Keeping patients on protocols" June 1, 2015

are inherent in Blockchain, researchers can utilize more sites to conduct routine testing and be assured that the results are true. Patients benefit by having more possible testing locations, which increases the likelihood that participants continue throughout the trial duration.

Create trust among sponsors and strategic partners

Often, trial sponsors outsource portions of a trial to contract research organizations (CRO's), and multiple CRO's often work on the same trial phase. The CRO's then hire other researchers to help. As the number of people working on the trial increases, the complexity of managing the trial increases and new challenges arise.³

The involvement of multiple researchers often creates challenges such as the lack of trust, unwillingness to share information, and resentment of being closely monitored.⁴ Better tools are clearly needed to manage this complexity.

At its core, Blockchain provides a potential solution by allowing parties that don't trust each other to transact in a trusted manner – directly facilitating trusted interaction between trial sponsors and CROs. Using Blockchain among the multiple strategic partners creates trust, enables non-intrusive monitoring, and allows data to be shared without risk.

Streamline regulatory monitoring

Currently, regulators review decisions and actions after they have occurred. This model often does not allow regulators to catch small issues before they develop into larger problems and puts regulators in the situation of maintaining compliance through the rear-view mirror. This situation can also result in trial sponsors not

³ Partnerships in clinical trials – US <http://www.clinicaltrialpartnershipsblog.com/2016/09/strategic-partnerships-in-clinical.html>

⁴ Ibid

having an accurate view of their compliance status if discrepancies are uncovered late in the trial process.

Blockchain brings regulators deeper into testing processes and enables them to have a real-time view into research, procedures, compliance, and decisions. In doing so, regulators become integrated into development processes and increase their effectiveness to ensure regulatory compliance.

Reduce fraud

Fraud takes many forms and includes situations such as fabricating data and misconduct.⁵ Fraud carries direct costs to the sponsor, as its discovery often requires the trial sponsor to spend the time and money to investigate and even repeat the aspects of trial that were found to be fraudulent.⁶ Additionally, fraud brings the non-monetary costs of negatively impacting consumer perception and tarnishing the reputation of the sponsor.

Blockchain improves trial accuracy and accountability through permanent and auditable records that greatly limits the most common types of fraudulent activities, including fabricating data, changing existing data, and other misconduct.

Summary

The development of new pharmaceutical solutions is critical to our global society. Therefore, making the process of finding these solutions more efficient and effective is also critical and Blockchain is a tool that can enable both.

⁵ Ashwaria Gupta "Fraud and misconduct in clinical research: A concern" April-June 2013
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3700330/>

⁶ Ibid

Moving forward with Blockchain implementations

Financial services continue to lead Blockchain development and regardless of your stage of Blockchain discovery, from Blockchain 101 to implementation, Red Chalk Group provides the advisory and technology development work you need to meet your goals.

To arrange a discussion with our team and learn more about our client lab where you can access our Blockchain prototypes, please visit us at www.redchalk.com.

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About Red Chalk Group's Management Consulting Practice

Red Chalk Group is a premier, boutique strategic advisor to senior executives at leading, global organizations. We are routinely engaged to advise on strategic growth platforms, technology disruption, investment decisions, and business-related intellectual property matters.

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