



# BLOCKCHAIN TECHNOLOGY to Manage Clinical Trials Data

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## BLOCKCHAIN TECHNOLOGY TO MANAGE CLINICAL TRIALS DATA<sup>1</sup>

Blockchain is transforming the healthcare system through its decentralized principles and improves accessibility and security of patient information. Blockchain is a system for storing and sharing information that is secure because of its transparency and patients are able to manage their own care. Such innovative technology has a high affinity with digital medicine like mobile health (mHealth) and provides reliability to the medical data. Each block in the chain is both its own independent unit containing its own information, and a dependent link in the collective chain, and this duality creates a network regulated by participants who store and share the information, rather than a third party.

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<sup>1</sup> Tomomitsu Motohashi, Tomonobu Hirano et al. (2019). Secure and Scalable mHealth Data Management Using Blockchain Combined with Client Hashchain: System Design and Validation. Journal of Medical Internet Research. Retrieved from: <https://www.jmir.org/2019/5/e13385/pdf>



### BLOCKCHAIN IN HEALTHCARE TECHNOLOGY FOR SECURING CLINICAL TRIALS<sup>3</sup>

The goal is to test the decentralized framework for information integrity, transparency, provenance, and patient empowerment (Figure 3). Blockchain provides an effective means of creating audit trails (records of changes) to any file in a way that is easy to verify but secure. This can really help users keep track of their data. The cryptographic keys/signatures that access the chain are a good way to protect permissions, but they should not be considered silver bullets. BloqCube is a ready-made blockchain software that aims to speed up the clinical research and provide complete data integrity. The system allows integrating common clinical trial management systems (CTMS) with payment and accounting platforms on the basis of blockchain to receive a full-scale solution for medical institutions and clinical trial investors. (Table 1)

BLOQCUBE (BLOCK CHAIN SOFTWARE FOR DATA INTEGRITY) <sup>4</sup>
A point of care solution
Meets Regulatory needs
Automates major processes
Minimizes intermediaries using smart contracts
A real time view of activity and financial expenses
Saving and speeding up of clinical trials

**Table 1.** BloqCube value proposition

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<sup>3</sup> Prototype of running clinical trials in an untrustworthy environment using blockchain. (2019). Daniel R. Wong, Sanchita Bhattacharya & Atul J. Butte. *Nature communications*. Retrieved from <https://www.nature.com/articles/s41467-019-08874-y.pdf>

<sup>4</sup> Innovecs. Retrieved from: [https://innovecs.com/blog/blockchain-in-healthcare/#block-id-single-blog-content-text\\_block-2](https://innovecs.com/blog/blockchain-in-healthcare/#block-id-single-blog-content-text_block-2)

## BLOCKCHAIN SOLUTION<sup>5</sup>

In 2017, the Digital Treasury Corporation, in cooperation with the Taipei Medical University, introduced **phrOS**, a **blockchain-based operating system** for personal healthcare records. phrOS places patient information on blockchain to achieve transparency between various medical organizations. It also increases information security via the Decentralized Ledger Technology (DLT). Both doctors and patients have access to this data through a mobile application. Patients can input data about their current health condition, and doctors can monitor it in real time (Figure 1). Another blockchain healthcare solution is **MyClinic.com**. This service was developed by Medicalchain, a UK start-up, together with the Groves Medical Group, a private clinic chain.

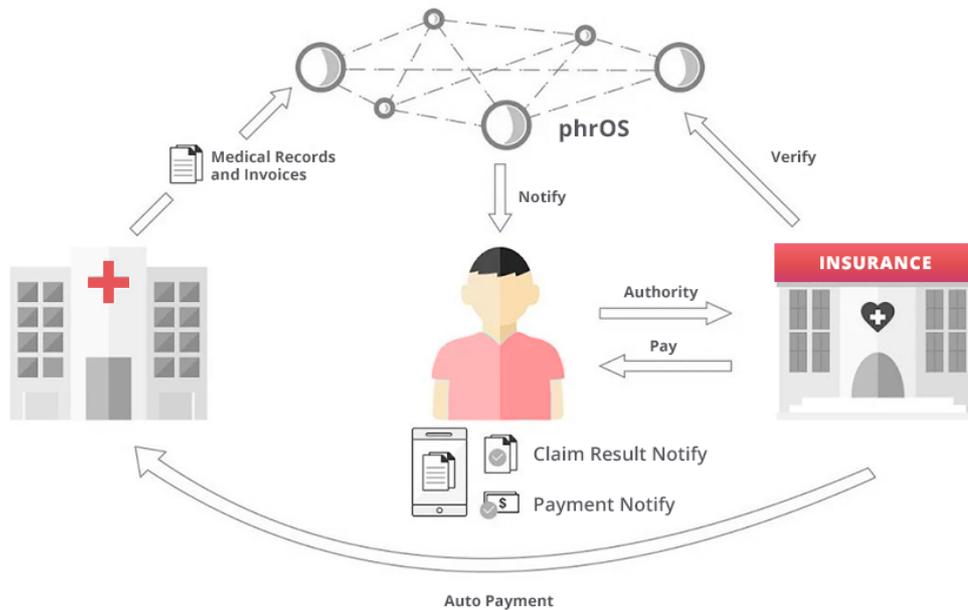


Figure 1. phrOS, a blockchain-based operating system

<sup>5</sup> Sad Ali Siyal , Aisha Zahid Junejo, Muhammad Zawish, Kainat Ahmed, Aiman Khalil and Georgia Soursou. (2019). Applications of Blockchain Technology in Medicine and Healthcare: Challenges and Future Perspectives. *Cryptography*. Retrieved from: [https://www.researchgate.net/publication/330113931\\_Applications\\_of\\_Blockchain\\_Technology\\_in\\_Medicine\\_and\\_Healthcare\\_Challenges\\_and\\_Future\\_Perspectives/link/5c2e223d92851c22a3581a5d/download](https://www.researchgate.net/publication/330113931_Applications_of_Blockchain_Technology_in_Medicine_and_Healthcare_Challenges_and_Future_Perspectives/link/5c2e223d92851c22a3581a5d/download)

### BLOCKCHAIN HEALTHCARE TECHNOLOGY FOR ELIMINATING THE RISK OF MEDICATION FORGERY<sup>6</sup>

One million people die because of counterfeit medications. The World Health Organization has reported that approximately 10 percent of all medicine in the world is forged. It relates mostly to locations such as North America, Asia, and Europe. (Figure 2). The Organization for Economic Cooperation and Development (OECD) has estimated that the counterfeit medical sector costs more than USD 200 billion yearly. Medical blockchain technology can help reduce risks caused by fake remedies, and, consequently, help save lives.

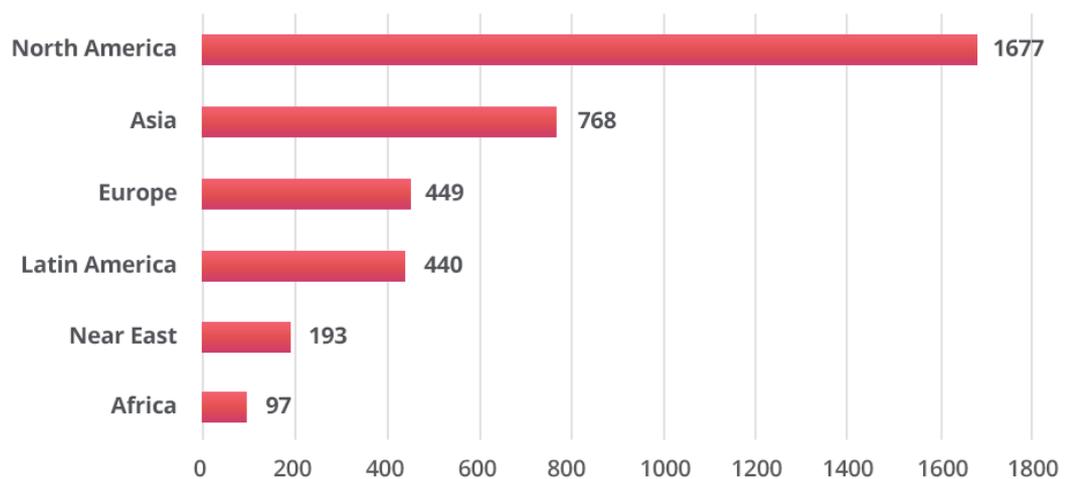


Figure 2. North America, Asia, and Europe incidences of counterfeit medications

<sup>6</sup> Seyednima Khezr et al. (2019). Blockchain Technology in Healthcare: A Comprehensive Review and Directions for Future Researc. Appl. Sci. Retrieved from: <https://www.mdpi.com/2076-3417/9/9/1736>



#### SMART CONTRACT FOR TRIAL MONITORING<sup>7</sup>

A clinical study report contains clinical information, sample case report forms, information related to the investigatory products, technical statistical documentation, and technical statistical details such as derivations, computations and analyses. The smart contract designed for this channel accesses the transaction log to automatically generate audits for evaluating the performance, protocol adherence, and efficacy of the trial among sites participating in the study. This can significantly reduce the burden of manual audit and incidents of selective-reporting, under-reporting or mis-reporting. This is also applicable to periodic generation of reports for continuous reviews. This improves the credibility and integrity of the study report submitted to the regulatory authority. Protocol amendments occur frequently in clinical trials, with an average of 2.3 amendments per trial. When they need to be applied, it is important to execute and track the amendments across all participating sites and ensure that stakeholders are aware of and comply with any updates. This could be achieved through a blockchain-based trial management system SO regulatory agencies can monitor and retrieve necessary information without the burden of maintaining a node for each clinical trial under surveillance. Blockchain can improve mobile health applications, monitoring devices, sharing and storing of electronic medical records, clinical trial data, and insurance information storage.

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<sup>7</sup> Olivia Choudhury et al (2019) A Blockchain Framework for Managing and Monitoring Data in Multi-Site Clinical Trials. Retrieved from: <https://arxiv.org/pdf/1902.03975.pdf>

