

Doctors use Bitcoin tech to improve transparency in clinical trial research

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Their successful application of this method to a recently reported, randomised clinical trial on cardiovascular diabetes & ethanol, is outlined in a paper that has just passed peer review on open science publishing platform [F1000Research](#).

Undeclared changes to protocols is a major issue in clinical research. If initial analyses show a medication to be ineffective, researchers can continue to analyse new health outcomes until a positive result is found. If only the positive findings are reported, the medication might be mistakenly approved.

Despite an international mandate requiring all trials to be registered before the experiments begin, the problem still persists as universal enforcement is difficult.

A blockchain is a decentralized database of bitcoin transactions; every transaction is publically recorded, timestamped and stored across a large, international network of computers, making it impossible for the records to be tampered with.

The innovative approach by Greg Irving, of the University of Cambridge, and John Holden, a General Practitioner, involves converting a clinical trial document into a bitcoin to take advantage its blockchain infrastructure.

Under their system the original clinical protocol is given a unique digital

signature, determined by the document's text using an online tool called the SHA256 Calculator. This signature is converted into a public bitcoin key using Strongcoin, another online tool, which is then "spent". This transaction is timestamped and recorded as a blockchain, multiple copies of which are stored in a computer network.

Anyone who wants to check whether a clinical protocol has been altered can generate a new bitcoin key using the text of the document that they have access to; if this key is different to the one in the blockchain then this confirms that alterations to the text have been made. This approach has the potential to prevent ineffective or even unsafe medications being distributed to the public.

Blockchain registration of trials could have prevented the infamous Study 329, which erroneously reported that an antidepressant was effective in adolescents. Analysis of the eight original health measures showed the drug was ineffective. However the researchers then analysed a further 19 outcomes and found four to show a positive effect, but only reported these four in the final publication giving a false impression of the drug's value.

This blockchain approach is increasingly used in fields such as software development, engineering and genetics. Drs Irving and Holden have broken new ground by successfully applying it to a clinical trial.

Dr Irving said: "Trust in scientific research has been diminished by evidence that some data is being manipulated. The declaration of Helsinki states that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject. Yet despite the creation of numerous trial registries, problems, such as differences between pre-specified and reported outcomes, persist.

Amy Price of Oxford University, who reviewed the article, said:

"Blockchain improves and expands the role for trial registries or publishing protocols. The approach could be used for Randomized Controlled Trials and a whole range of observational and experimental studies where registries are needed but do not currently exist."

Rebecca Lawrence, Managing Director of the F1000 Group, said:
"Public trust in the medical research community has been severely damaged by evidence of malpractice, including outcome switching, data dredging and selective publication.

"The blockchain [method](#) proposed in this new paper offers a timely and promising solution to these problems. We are pleased to be able to bring it to public attention, quickly and transparently, via *F1000Research*, where it will no doubt stimulate much-needed debate on this issue."

Provided by Faculty of 1000

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