NEWS RELEASE

Doctors use Bitcoin tech to improve transparency in clinical trial research

Two clinicians have devised a new system to prevent clinical trial documents being secretly altered to make new medications look more effective than they are. The new method aims to solve this problem using blockchains, the technology that underpins the virtual currency Bitcoin.

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 http://f1000research.com/articles/5-222/v1.

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.”

Ends

For more information:

Andrew Baud, Tala (on behalf of F1000), +44 (0) 20 3397 3383 or +44 (0) 7775 715775

About F1000Research

F1000Research is an open science publishing platform for life scientists that offers immediate publication and transparent peer review, avoiding editorial bias and ensuring the inclusion of all source data. This process helps scientists to avoid the traditional, anonymous, pre-publication peer-review process that can cause long delays before new results become visible.

All articles must pass an initial in-house quality check prior to publication on F1000Research. Following open, invited peer review where the referee’s name and affiliation and the referee reports are published alongside the article, authors can make revisions that are then published as new article versions.

Since its launch in January 2013, F1000Research has published more than 1000 articles across the life sciences, written by 4,000 authors. For more details on F1000Research go to www.f1000research.com