

Clinical Trial Vetting on Public Blockchains

White Paper

PharmaCoin

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Abstract

Clinical trials have been playing an integral role in the healthcare industry in distributing pharmaceutical drugs for consumer use. However, the process of receiving FDA approval and having drugs distributed to consumer markets is an extremely expensive and tedious process. From the discovery phase to the experimental phase to the release in worldwide markets the process can take up to years and cost hundreds of millions to billions of dollars. One key aspect of the entire process is the vetting of people who wish to participate in these experiments and help researchers assess and improve their drugs in the development cycle. This white paper outlines PharmaCoin's blockchain-based vetting system. We seek to improve the vetting system by enabling potential participants to create a profile while our platform anonymously matches them to the best fit a pharmaceutical organization's precise requirements. This paper primarily focuses on our technical design and architecture.

1. Problems in clinical trials today

Although clinical trials are certainly a valuable component in the healthcare industry, it is not without flaws, particularly the vetting process.

- **Inefficient**
 - Pharmaceutical organizations are finding it more and more difficult to get the outreach they desire in seeking out viable participants
 - The time it takes to seek out and correctly vet a number of participants consumes a lot of time and resources across the various stages of development
- **Expensive**
 - The entire development cycle of researching, experimenting, and releasing a drug costs hundreds of millions to billions of dollars
 - Specifically the vetting part itself consumes roughly a 25%-33% of the entire budget; that's millions of dollars which could be used to spearhead other projects or fasttrack current ones

2. Solution

Our proposed solution is a decentralized blockchain app that anonymously matches potential participants to the most viable clinical trials.

- **Enterprise**
 - Pharmaceutical organizations will subscribe to our services and be able to market their ongoing trials with the necessary specifications for participants.
 - Potential participants will be matched and presented to them according to a specific rank based on how viable the candidate is
- **Consumer**
 - Meanwhile, patients can create their profile and input their necessary information and let our platform match them to the best fit trial.
 - Once a match is found, our platform puts the two parties in contact and allow enterprises to proceed with their development
- **Encourage trial participation**
 - Each time a participant successfully completes a trial, we will reward them with an ethereum token as “token” of gratitude on top of any compensation from the pharmaceutical companies

3. Value Prop- “LinkedIn for clinical trials”

- **PharmaCoin-** “LinkedIn for Clinical Trials”
- One complete cycle of clinical trials can potentially cost up to billions of dollars, but with an improved vetting system for patients, pharmaceutical organizations can save hundreds of millions in the process. Pharmacoin seeks to provide a unique, intuitive platform for individuals to “create their profile”, “apply” to trials and be efficiently vetted and matched. Pharmacoin emphasizes confidentiality and efficiency above everything else.
- **“Get vetted, get cured”**

4. Revenue Model:

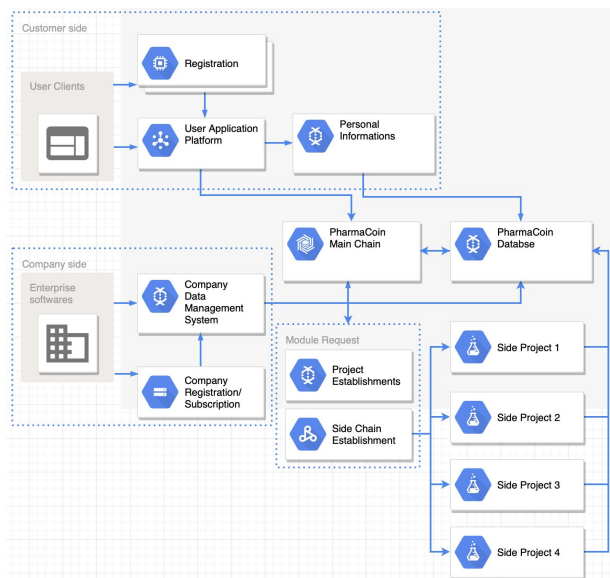
- We plan to tokenize the overall system, where we will pay users a token for simply uploading their information into our decentralized system. This financial incentive allows users to take control of their data, but our revenue stream comes directly from working with medical institutions and clinics who will pay for access and automation of the clinical trial data. These companies will have a streamlined vetting process, and will pay us a certain fee per patient, and we simply connect users to the medical institutions.

5. Use of Blockchain:

- **Use of the main chain**
 - The major blockchain that record all the transactions and user identities. It will decentralize the relationship between patients and the pharmaceutical companies. It is the network that connects them with minimal recruiting cost and high efficiency. It is the “LinkedIn for clinical trials”.
- **Use of blockchain tokens**
 - The transactions between patients and the pharmaceutical organizations are through tokens. That being said, after the patients get matched with and have done the clinical trials, they will be paid by tokens instead of dollars or other currencies. The amount of tokens is decided by how much the clinical trials cost, how long the clinical effects will last, how much risks the trials might bring to the patients’ bodies, how much the pharmaceutical organizations are willing to pay, etc.
 - How much the tokens are worth will be decided by the market, which means that our tokens will be just like the BitCoins. The patients could sell the tokens and exchange for real currencies at their own will
- **Transparency**

- The patients could see the entire transactions on the network. They could see the user identities and the amount that they got paid. Therefore, they could ensure that they are paid correctly. In other words, they could tell that the amount of tokens that they themselves get from the same trial of the same pharmaceutical company will be the same as what other patients will get if they are all at the same body conditions
- **Anonymity**
 - With the help from blockchain, the patients won't be able to know other patients' names, and so anonymity will be preserved and their clinical trials won't be revealed to other patients.

6. Technical Design and Architecture



- **PharmaCoin main chain:** The major blockchain that records all the transactions and user identities. It could be hosted on many existing framework or use our own independent decentralized protocol and implementations.
- **PharmaCoin Database:** The centralized database to store encrypted clinical data. To avoid possible fraud and leak of information, the actual information of each user and their data is managed in a different secured database. The Database communicates to the blockchain to establish secure connections and exchange for data if any information is requested.
- **PharmaCoin sidechains:** For large scale clinical trials or special requests. It is possible to establish a sidechain to develop separate

projects. The sidechains can be deeply customized to fit user/company requirements.

- **Architecture:** There are two separate process for users: customers and the firms.
 - **Business:** The process of a business model on the PharmaCoin would be the clinical company send a module request to the PharmaCoin, then, a contract is created to record responsibilities, requirements, terms and conditions and all other details is defined in the contract. Once everything is digitally signed using secure algorithms, a module/sidechain(depends on the requirements) is created and then it is published to the main PharmaCoin blockchain and the data is going to be synchronized to the main chain.
 - **Users:** user register their information by inputting their personal informations, all other details with a unique hashcode and password. Then it register to the main chain using the hashcode with its signature. Each request and information have to be signed by the user in order to be authentic. Personal informations is submitted to the PharmaCoin database for security.

7. Appendix

- a. This project is a hybrid project between blockchain and database, part of the system is actually centralized, but our team think it is necessary to host a separate database for seek of security of our client data. Note that majority of the functions and usage does not require access to the database. The database only exist when it is required to access detailed patient informations.
- b. Team: Shivam Dave is studying Computer Science, and he is passionate about technology (ML, AI) and entrepreneurship. Serena Wu is studying Computer Science and Data Science, and she enjoys analyzing data for business applications. Rishi Modi is studying business, and is leading the Business Strategy and Development on the team. Collin Cao is studying Computer Science, but he is focused on AI/ML, also interested in Blockchain technologies. Our Primary mentor is Virendra Parikh who Founded MobileChamps in 2009. His company provides blockchain advisory services from business model innovation, strategy development, ecosystem development. In addition, Viral Modi is a Pharmacist who is able to provide the consumer perspective on drugs and clinical trials.