ETH Zurich

Bloodchain

BETH Hackathon

11-15. February 2019

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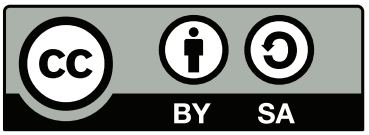
This report was created as a part of the Open Challenge Hackathon for BETH: Blockchain School for Sustainability course that took place at ETHZ 11-15. February 2019.



Executive Summary

As part of the open challenge category of the BETH hackathon we wanted to explore whether blockchain technology could help address some of the major challenges facing pharmaceutical companies in tracking of samples and sample's metadata in as part of clinical studies. As in other industries, blockchain has been gaining interest in the healthcare industry and a number of companies are testing out blockchain-based solutions to their challenges.

As a proof of concept to test if a blockchain-based solution would be feasible for this type of challenge, we built a blockchain-based application as a web service. The idea would be that this solution would entirely be run by the pharmaceutical company who is conducting the clinical studies. The main goal of our proof of concept is to show that a single point of truth can be established regarding the sample lifecycle and the collected data and also to show that patients can be empowered to gain better control over the samples and data that is collected during a clinical trial.

During the BETH hackathon project, we were able to set up a functional blockchain solution for this particular challenge of sample tracking in clinical studies. Naturally we had to make a number of assumptions to simplify what is a very complex process with many different players, but we believe that the outcome of this hackathon project is very promising and that it would be worthwhile to test this further with a pilot in the healthcare industry.

Although it is difficult to predict what the future will be for the use of blockchain-based technology in the healthcare industry there is no doubt that the number of Proof of Concepts and Pilots will continue to play a big role in the coming year. However, a productive use case will be necessary to convince partners in the industry to join blockchain networks.

Contents

1 Introduction

As a part of the 2019 BETH: Blockchain School for Sustainability course we were invited to participate in a hackathon for two days. The ideas was that the students build a team of 5-7 people and work together on one of seven challenges that were offered by the course organizers. Our team selected the open challenge category to explore a persistent problem in the healthcare industry. We wanted to look at how the sample management process during clinical trials can be simplified, automated, harmonized and how patients that participate in a clinical trial can be empowered to have a better control over the samples and the derived data. For this hackathon project we aimed to propose a solution for a clinical trial sponsor (e.g. a pharma company) that will allow them to have a real-time overview of the lifecycle of samples that are taken from patients during a clinical trial. The current challenge with this process is that it is manual and very time-consuming and that it relies heavily on Excel/Word, emails and phone calls to get the information needed and to resolve issues. Additionally, the patients enrolled in clinical trials currently have no direct access and overview of the samples and derived data that is generated as a part of a clinical trial.

The objective of the challenge is to show how a solution can be created that makes use of blockchain technology to manage the chain of custody of the end-to-end lifecycle of samples as they move from one laboratory to another while tracking basic sample information for each step and enabling patients to have access to their data and to directly withdraw their consent if necessary.

1.1 Background and Motivation

Clinical studies are sponsored and conducted by pharmaceutical companies all over the world. These studies are a necessary so that the safety and efficacy of a treatment can be evaluated and the data that is produced in the clinical studies is needed for the regulatory approval so that novel treatments can be made available to patients that need them.

In recent years there has been a significant increase in the number of registered clinical trial (Figure 1) [Cli19]. One of the reasons for this increase in clinical studies is due to an increased complexity of clinical protocols and the volume of amount of data that is collected with increasing coordination challenges [Fas18]. This results in addition to the rise in the number of clinical studies boost the trend for pharmaceutical companies to outsource or partner with CROs (contract research organizations) and academia for many of the research activities. And ultimately this cause an increased complexity of clinical trial and clinical sample management, where many of the challenges are focused on the tasks of study planning, sample tracking and sample management for a given study across multiple organizations.

A simplified view of the clinical sample management process and which are the main challenges of this process is shown in Figure 2. The basic process is that central laboratories ship sample kits containing pre-labelled test tubes to clinical trial sites where patients are recruited and samples are drawn from them. The sample kits with the patient samples then get shipped again to the central laboratories who collect and repackage the samples and send them onwards to Analysis laboratories. There can be more than one of these Analysis laboratories that need to receive the sample, run various analysis, often combined with some output of the analysis and then sent to the next Analysis laboratory. As the last step, a Result laboratory receives the sample and runs a biological assay on the sample which produces a result file that is needed for further analysis of the treatment's safety and efficacy.

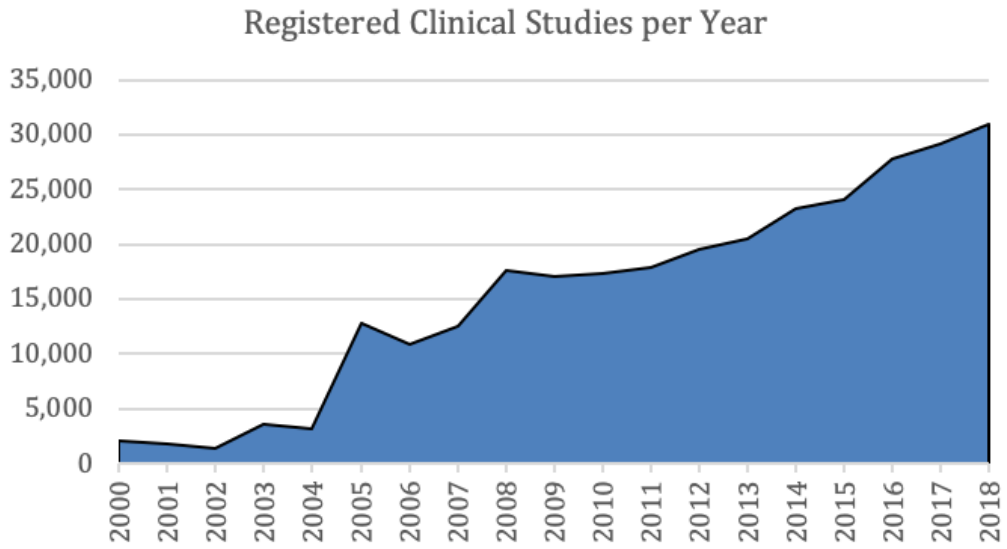


Figure 1: The number of registered clinical studies per year

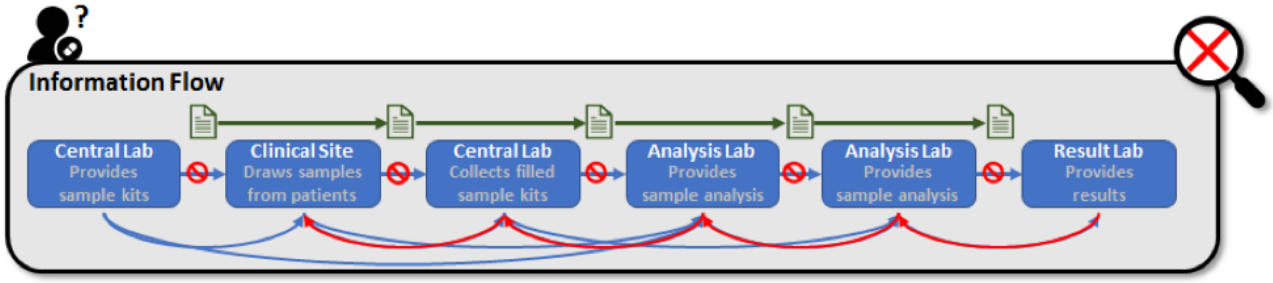


Figure 2: Challenges in Clinical Sample Management. The figure shows the information flow from central laboratories to the final results laboratory. The arrows indicate the direction of the information flow, the lack of transparency and the complex back and forth communication that is needed.

Some of the main challenges with this process are due to the increased outsourcing of the clinical studies which results in an unclear overview of the sample lifecycle and the chain of sample custody. As a consequence, there is a lot of unnecessary back-and-forth in regard to finding out the exact sample location and the completeness of result data. An additional complication is that throughout all the steps in the sample lifecycle management there is very little automation and data is normally send as Excel files and Word documents between location with little or none traceability between them. Often each one of the participants creates their own identifier for the sample resulting in difficulties linking the sample history and results together. Finally, the current process doesn't allow for an easy patient participation and doesn't provide a way for a patient to directly see which data has been collected from their samples.

In this hackathon project as part of the Open Challenge category, we explore if blockchain technology can be leveraged to improve the current clinical sample management process by ensuring data integrity, transparency, patient consent and in addition reducing overall costs through automation of the end-to-end process. The ultimate goal is to create the process which is displayed in Figure 3. This proposed process improvement would eliminate the need of sending documents back-and-forth by email or by using file sharing solutions. By utilizing blockchain technology, large parts of the process could be automated and by design tamper and thus providing much improved end-to-end visibility and clearer roles and responsibilities.

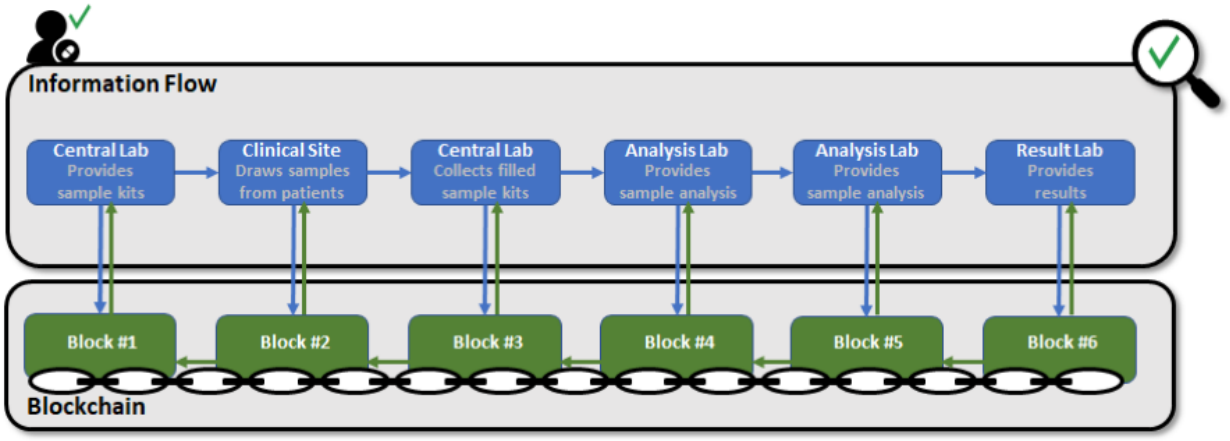


Figure 3: Future vision of the Clinical Sample Management by utilizing blockchain capabilities. The figure shows the information flow from central laboratories to the final results laboratory, this time with much clearer communication lines with full visibility of all aspects of the process and empowerment of the patients.

1.2 Blockchain

Blockchain is a relatively new technology that is believed to have originated from Satoshi Nakamoto's wish to create an electronic cash system that was completely peer-to-peer without the need to have a central third party such as banks or financial institutions [Nak08].

Blockchain can potentially streamline asset exchange by allowing transactions to occur without the need for intermediary within the process. The record of this digital ledger is not exclusive to financial transactions, but virtually to everything that has a value including information. Blockchain addresses the trust, transparency and process efficiency that daily businesses experience [Ban18].

One can broadly distinguish between three types of blockchains, private, public and federate. Public blockchains are based on Proof of Work (PoW) consensus algorithms and are open source and in general they are not permissioned, meaning that anyone is allowed to participate. Private blockchains, on the other hand, make use of blockchain technology in the way that one can set up groups and participants who can verify each transaction. Finally, the federated blockchains operate under the leadership of a consortium with a permission needed to participate in the transactions with the consensus process controlled by a pre-selected set of nods. In general, the public blockchains are considered to be the safest but the private ones have their biggest use cases where scalability and data privacy is needed [Blo18].

1.2.1 Blockchain in healthcare Industry

For applications in the healthcare industry and our use case of sample tracking in clinical trials, there are many characteristics of blockchain technology that are attractive. For instance, as described above in our challenge, there is a spectrum of independent stakeholders that interact and transact with each other when it comes to managing samples throughout their lifecycle in clinical trials. These stakeholders include healthcare institution, pharmaceutical companies, insurance companies, regulatory bodies to name a few and last but not the least the patients themselves. Potentially, blockchain based solutions can allow the different parties to interact and transact with each other with regard to specific information sharing, depending on the

nature of the interaction as these interactions require a high level of security and confidentiality. This is a core feature of blockchain where interaction takes place over a decentralized network, where there is no single owner, central administrator nor intermediary. This should not only enforce further immutability of the chain and trustfulness, but also makes processes efficient and cost-effective. Furthermore, blockchain provides an audit trail and a promise of immutable and tamper proof data which is a must for any process that is entering the health care space. This should be appealing for the regulator and businesses to implement, as it reduces the complexity of auditing [Are19; Ban18; Goo18].

It is sometimes difficult to distinguish between hype and reality when it comes to judging the actual potential of blockchain-based applications in the healthcare industry. Hype cycle analysis from Gartner can often provide some interesting insights into the maturity and adoption of new technologies and applications, and if they can potentially help to solving real business problems. A solution is considered to be suitable for mainstream adoption when it has reached the last stage of Plateau of Productivity [Gar19]. According to a recent Gartner analysis of the hype cycle specifically focused on specific blockchain businesses applications in the healthcare are at least 10 years away from reaching the plateau of productivity [Lev18]. Furthermore, even more established use cases such as use in Supply Chain are still also estimated to be over 10 years away from realization (Figure 4).

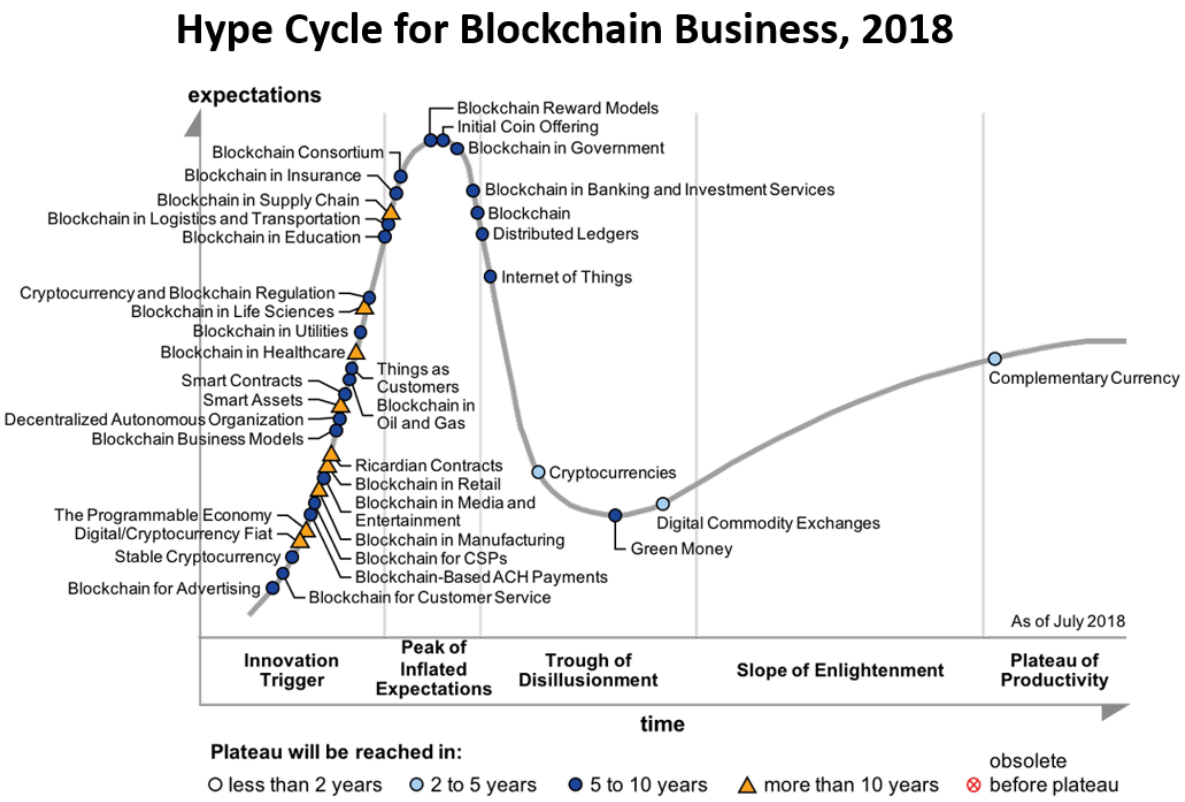


Figure 4: Gartner Hype Cycle for Blockchain Businesses. Each hype cycle shows technologies and applications as they move through 5 stages: Innovation Trigger, Peak of Inflated Expectations, Trough of Disillusionment, Slope of Enlightenment and Plateau of Productivity. As the figure shows, only blockchain technologies are anywhere close to maturity.

There are some ongoing initiatives that may indicate that the timelines to productive use of blockchain-based solutions in the healthcare industry are shorter than indicated by the Gartner analysis above. One of these initiatives is the Mediledger project which aims to provide an open

and decentralized network for the pharmaceutical supply chain[1]. This project was initiated in 2017 and although their website claims that they will launch commercially in Q4 2018 there is no update regarding a commercial launch and a recent Newsweek article states that they will launch in 2019 [Lan19]. It will be very interesting to follow if this initiative will be a success and the network will grow or if potential partners are reluctant to join a blockchain network. In addition to the MediLedger project there are some promising activities starting to establish pharma-wide consortia such as Innovative Medicine Initiative (IMI) [IMI18] and Pistoia Alliance [Nit18].

1.2.2 Challenges of blockchain in healthcare industry

Blockchain applications for the healthcare industry are at a very early stage of growth. Even if there is a lot of promise, there are many current challenges that need to be addressed, and many more that haven't been identified yet. Some of these challenges include; the need for platform flexibility to accommodate diversity of designs, management of legacy data and balance between open and confidential information. Furthermore, security is always considered to be one of the most important and the basic core feature of any blockchain technology and solution. However, this is not entirely true, as there is an interface between the blockchain platform and its users, where user personal key can be stolen and misused. Furthermore, there are other barriers including; integration between legacy system and the blockchain, need for highly skilled personal which are currently limited in supply, lack of regulation (consequently increases uncertainty) and lack of legal enforcement with regard to smart contracts. Finally, blockchain technology requires a high initial investment cost, yet the emerging multiple eco-system has produced negative perception, that could impede a wide spread adoption to blockchain-based solutions in the healthcare industry [Bha18; Goo18].

1.3 Ethical dimension: data privacy and security

Good clinical practice requires as much transparency as possible in regards to where, when and by whom the data was entered, as well as which are the parties that have permission to access or modify which data. The timelines that are agreed for the results generated in clinical trials depend upon having a fast, easy, and transparent way to locate and share large quantities of data with specific individuals, often across long distances. Even if the pharmaceutical industry is highly regulated and suffers from the delays of heavy protocols when it comes to public health and safety, there is a public distrust when it comes to data privacy and how the results can be linked to the patients taking part in clinical trials and used by third parties.

Patient participation is the sine qua non condition for clinical trials to happen and for medical research to innovate, however in practice, the informed consent process is hard to handle in a rigorous and satisfactory way. The US Food and Drug Administration (FDA) reports some metrics that are related to the frequency of clinical investigator-related deficiencies, which show that almost 10% of trials they monitored suffer from consent collection issues, such as: failure to re-consent when new information becomes available, use of expired forms or non-validated, unapproved forms, consent document not signed or not dated, missing pages in consent document provided to subjects, failure to obtain written informed and many more [FDA14].

[1] https://www.mediledger.com/

Clinical trial consent for protocols and their revisions should be transparent for patients and traceable for stakeholders: CROs, labs or pharmaceutical companies. The central purpose of blockchain is to store digital information on a distributed network to make a shared and continually reconciled database. In essence by implementing blockchain as a distributed electronic ledger that keeps track of data, whether that data is related to product inventory, in our case blood samples, healthcare data coming from the test results, it guarantees the validity of a transaction by recording every change across the entire distributed network.

Our goal was to implement a process allowing the collection of patients' informed consent, which is bound to protocol revisions, storing and tracking the consent in a secure, unfalsifiable and publicly verifiable way, and enabling the sharing of this information in real time. For that, we built a consent workflow using blockchain that brings a built-in layer of transparency and traceability this way improving privacy, security, and transparency within each transaction.

2 Sustainability

In 2015 the United Nations set 17 sustainable development goals (SDG) to be achieved by the year 2030 as a blueprint to ensure a more sustainable and better future for everyone. They address the global challenges we will face in the upcoming years such as poverty, inequality, climate change and environmental degradation to just name a few [UN19]. The theme of BETH is sustainability and the idea of creating incentives to follow sustainable practices in our everyday life. This chapter discusses today's issues in the healthcare domain and how the developed application tackles these problems. With its focus on the medical sector, Bloodchain has an immediate influence on goals 3 and 8. A short discussion at the end of the chapter explains the secondary downstream effect of Bloodchain on numerous other goals such as goal 7 and goal 15.

Figure 5: Sustainability Development Goals

2.1 Problems in the healthcare industry

Costs are increasing rapidly in the healthcare sector. This is particularly true in Switzerland as shown in Figure 6.

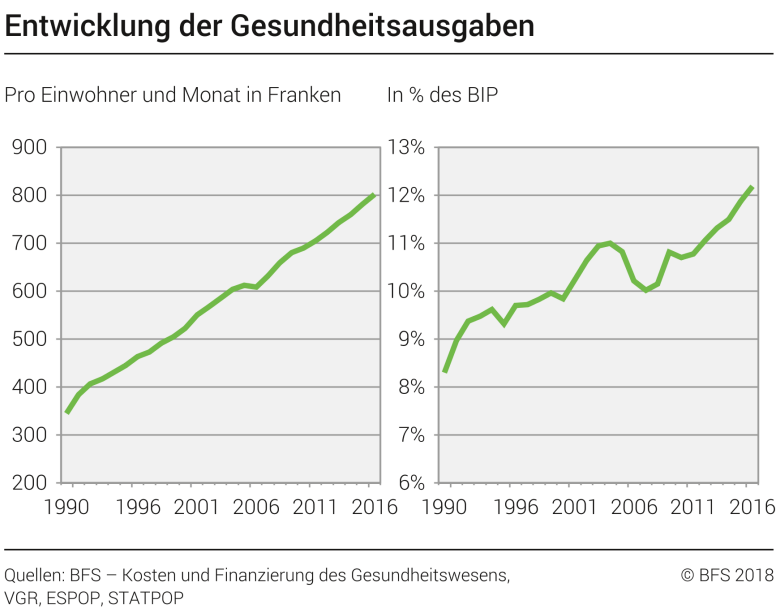


Figure 6: Development of costs in the health system in Switzerland.

But other developed countries such as the United States struggle with high healthcare costs too [Eps19]. Some reasons are very high expectations on medical services and the ever-increasing quality and price of medical devices [Are18]. Administration being a common source of costs, it is important to use modern technologies to increase efficiency in that domain. While information systems are ubiquitous in the healthcare sector, the current situation is far from optimal. As explained in the previous chapter, a multitude of software systems are used to communicate between the different clinical sites. The situation is similar in hospitals, where numerous software solutions compete against each other. Furthermore, today's clinical information systems lack completeness in their functionality and generally accepted standards are missing [Sch18]. Clearly, there is a lot of room for improvement in the administrative domain.
Even though this is not so much an issue in Switzerland, it should be noted that increasing costs in the healthcare sector combined with heavy privatization lead to worrying inequality as shown in Figure 7 [Bel18].

2.2 Bloodchain: a step in the right direction

Bloodchain aims to combine the notion of trust of blockchain technology with the power of conventional centralized databases to increase efficiency, improve transparency and enable data traceability in clinical studies. Increasing efficiency in the health system and assisting technological advances benefits all people across society. This has an immediate effect on SDG 3. Bloodchain also spurs innovation which is the scope of SDG 8.

Of paramount importance to achieve any of the SDGs is a change of the mindset of our society. The profit-oriented objectives of many multinational companies significantly influence our behaviour and perception of our surroundings, putting both democracy and our environment at risk. By using blockchain technology as a source of trust, Bloodchain not only raises the consciousness for transparency and data traceability in clinical studies, but also more generally.

The secondary effect of Bloodchain to increase awareness in the society for the behaviour in everyday life is thus not only important in the medical domain, but can represent a first stepping stone to revolutionize the awareness in the consumption of goods and services in general, such as

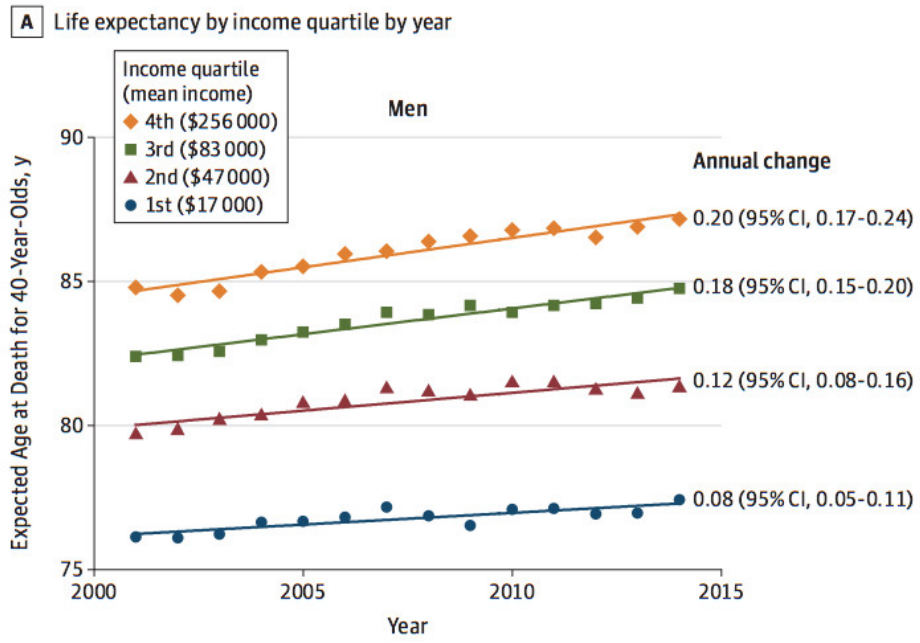


Figure 7: Changes in race- and ethnicity-adjusted life expectancy by income group in the US, 2001 to 2014.

food and crude materials used in electronic devices. This is the downstream effect of Bloodchain on a wide range of SDGs as mentioned previously.

3 Method

As described in section 1.1, when pharmaceutical companies conduct a clinical study it is a common practice to outsource most of the steps in the process, such as the sample taking, central lab activities and many of the analysis steps. Since the samples can be sent around to multiple labs during their lifecycle, sample tracking is a very cumbersome, fragile and error-prone process.

The application that we propose to address some of these challenges was designed as a web service that is entirely run by the pharmaceutical company who is conducting and is responsible for the clinical trial. The main goal of the solution is to establish a single point of truth regarding the sample life cycle and any associated data that is collected. With the new application the complete lifecycle of a sample and the chain of custody throughout each step can be registered and easily visualized. Figure 8 shows a simplified view of the application design.

- Patients are recruited by clinical sites or "sitelabs", which will take samples from patients (http://localhost/sitelab).
- The samples will then be sent to other laboratories, or analysis laboratories, which will conduct tests and submit the data (http://localhost/analyserlab).
- The pharmaceutical firm that initiated the clinical study has its own web interface that shows all samples and each action that took place (http://localhost/admin).
- The patient will have their access as well to be able to revoke their consent and prevent their samples and data to be used further (http://localhost/patient).

- All transactions that occur are written to the blockchain and associated data gets entered to an underlying database.

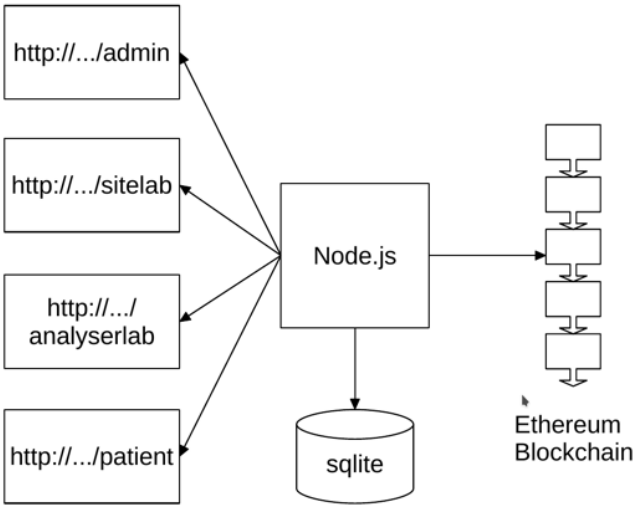


Figure 8: A simplified view of the design of the Bloodchain application. There are different roles, such as sitelab, analyserlab, patient and admin that access via a single webserver, which communicates with a centralized database and the blockchain.

3.1 Design Decisions

The majority of the data generated from any of the transactions is stored in a centralized database. This is the case because storing data directly on the blockchain is extremely expensive and there is no need of storing the entire database on the blockchain to ensure the main features of the system. Each action-entry is hashed and stored on the blockchain. As a result, any modification of a database entry would be discovered when it is compared against the hash stored on the blockchain. Figure 9 shows an example of how data submitted by an analyserlab is processed and stored within the software stack.

3.2 Consent Revoke Mechanism

It is an integral part of any clinical trial that volunteers or patients are recruited to participate in the trial. Those that agree to take part are required to give their consent by using informed consent forms. By doing so, they agree to giving a sample (or several samples) and also agree that their samples can be analysed and the resulting data used in further analysis. To create trust, Bloodchain gives the user the ability to revoke their consent at any time during the clinical trial (http://localhost/patient) and request that their samples and data is no longer used. Once revoked, samples for which the patient revoked the consent can no longer be processed. The consent can only be revoked and once it has been revoked it cannot be activated again. The database itself is not aware of the "consent". The logic is purely implemented in the blockchain-contract which has a sole revoke method. Revoking the consent makes it impossible to report any further data to all affected samples.

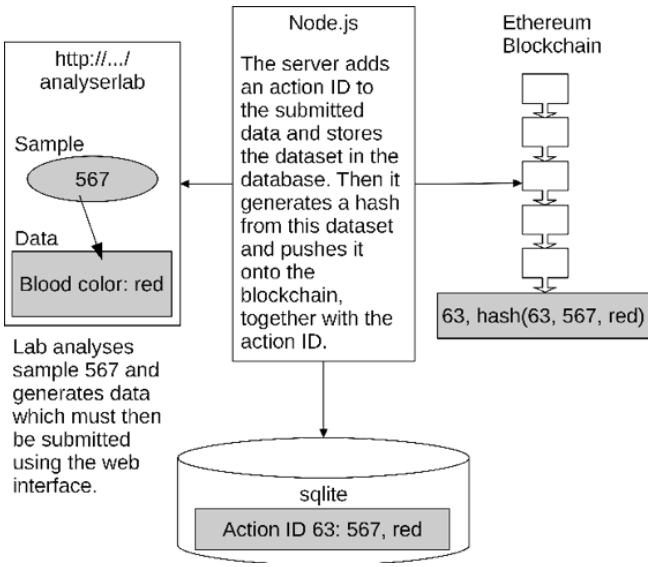


Figure 9: Example of how an analyserlab submits a transaction through the web interface. The server adds an actionID to the transaction and the data is stored in a centralized database. The server then generates a hash of the transaction data and pushes it to the blockchain along with the actionID to ensure traceability and immutability.

3.3 Assumptions

The clinical sample management process is very complicated with many different players involved and multiple studies that are running simultaneously. For the purpose of the hackathon project a number of assumptions were made to simplify the overall process.

First of all, it was assumed that each patient has a unique ID and that this ID stays the same regardless of which clinical studies they are enrolled in. Furthermore, it was assumed that the starting point of each of the lifecycle events is the Central Laboratory who sends out sample kits, even though in reality this may be different. For simplification it was also assumed that each patient is only enrolled in a single study and only one type of sample (blood) is collected. Finally, the assumption is that the patient informed consent can only be revoked, that is once it has been revoked it cannot be activated again. Lastly, the overall process was simplified by leaving out some additional participants and actions, such as couriers and sample preparation or destruction tasks.

3.4 Software stack

Since there were only two days to build a functioning prototype, it was decided to use *Adonisjs*. *Adonisjs* is a fast prototyping web framework for *Nodejs*. For the database layer *sqlite* was used which gives the advantage of not having to set up a whole database system since *sqlite* is a file based database. For the blockchain part the *Truffle* framework was used. *Truffle* is a development and testing environment for Ethereum. It is useful to write, test and publish smart contracts.

3.5 Smart contract implementation

To implement the functionalities described above, smart contracts are used. The code was written in *Solidity 0.5.0* and deployed on a virtual Ethereum blockchain using *Ganache*. *Ganache*

is a part of the *Truffle* framework and gives the user the ability to simulate the actions that can be performed on the main Ethereum chain without any cost. The smart contracts that were written during the hackathon are listed below.

- `Transaction.sol`
- `ConsensusContract.sol`

3.5.1 Transaction.sol

The `Transaction.sol` smart contract stores the hash of the metadata of a transaction on the blockchain and provides the necessary tools to check that this metadata was not altered. In the code a `struct` Transaction is defined, which has two parameters: `uint transaction_id` and `uint dataHash`. The variable `transaction_id` is used to uniquely identify each transaction, whereas the variable `dataHash` stores the hash of the metadata of a specific transaction. It was decided to store the hash of the metadata instead of the metadata itself to avoid storing large data on the blockchain. This is to ensure that the recurring costs of the application are kept low. Four functions are implemented to perform the necessary actions on a specific transaction:

- `addTransaction`
- `getHash`
- `getTransactionCount`
- `getTransaction`

The function `addTransaction` generates a new Transaction instance and stores it on the blockchain. On the other hand, the other three functions are used to check that the transactions stored on the blockchain are not altered. For example the function `getHash` returns the metadata hash corresponding to a `transaction_id` and is used to check the consistency of the blockchain with the database. If the two metadata hashes do not coincide then a third party has modified the metadata in the database and the fraud is discovered. In addition to that, the function `getTransactionCount` enables to quickly verify, whether every transaction stored in the database is also uploaded on the blockchain. Finally, `getTransaction` reads transactions from the blockchain.

3.5.2 ConsensusContract.sol

The `ConsensusContract.sol` smart contract stores the status of the consent of a patient to be part in a clinical study on the blockchain. A `struct` Consensus with three parameters is defined: `bool consensus_status`, `uint timestamp` and `uint keyhash`. The boolean variable `consensus_status` is `true` if the patient consents to be part of the clinical study and `false` otherwise. The unsigned integer variable `timestamp` stores the time at which the consent of the patient is given. Lastly `keyhash` stores the hash of a secret key that is given to each patient at the moment of registration to a clinical study. This secret key can be used by a patient to revoke his consent at any point in time. Three functions are implemented:

- `createconsenus`
- `getconsensus`
- `revokeconsensus`

The function `createconsensus` stores a new Consensus instance on the blockchain when a patient registers itself for a clinical study. In this case the boolean variable `consensus_status` is set to `true`. In addition `getconsensus` allows to check the status of the consent of a specific patient. If further transactions on the patient's sample were performed while the status of the consent was false, a fraud its discovered. In conclusion `revokeconsensus` enables every patient to revoke its consensus for a clinical study using its secret key. It is important to notice that if a patient revokes his consensus for a clinical study but his action is ignored by the pharmaceutical company, the patient can initiate legal action against the company using the blockchain as a proof of his will.

3.6 Source code

The source code and instructions for installation can be found under the BETH 2019 GitHub project: https://github.com/betherworld/Bloodchain. The GitHub entry also provides examples of the interface and explanation of the usage of the application, including a demo.

4 Evaluation

Despite only having two days for the design and implementation of a workable solution during the hackathon, a number of objectives were achieved. First of all, a working prototype of the sample management process was successfully implemented according to the assumptions discussed in chapter 3.2. This prototype already shows the potential of a blockchain-based solution for the challenge of clinical sample management. The authors firmly believe that if extended and adopted by pharmaceutical companies, this implementation would allow for a single point of truth for the sample management during clinical trials. The solution also has a potential to provide a clarity of the chain of custody of samples through transactions while ensuring the safety and immutability of any sensitive and critical data that is produced during clinical trials. Additionally the implementation empowers the patients to revoke their consent to a participation at a clinical trial at any moment in time. The solution that was implemented is also based on the concept of having a single webserver that is owned and operated by the pharmaceutical company that owns and is responsible for the clinical trial. Strictly speaking that is not necessarily the objective of a blockchain solution, and in a larger, productive implementation it should be considered to have each of the external partners own and operate their own node that connects to the blockchain. This of course would necessitate that each of the external partners possesses the necessary capabilities to implement, operate and maintain blockchain-based technologies.

Although there is a lot of promise and hype currently surrounding blockchain, we have to keep in mind that blockchain is still in the early stages of growth. There are still many unanswered questions and challenges that need to be addressed, such as platform flexibility to accommodate diversity of designs, how to manage legacy data and how to balance between open and confidential information to name a few. There is also a lack of regulation and lack of harmonizing of regulations between countries, especially in novel application such as for the healthcare sector. In addition, blockchain development requires highly skilled personnel that still is limited in supply. Currently there is quite a high initial investment cost to start with blockchain-based technology and there is a potentially negative perception based on recent scandals surrounding Bitcoin. Finally, emergence of multiple eco-system might prevent from wide spread adoption

and add to the confusion of which flavor of blockchain technology is best suitable for which application.

5 Conclusion

In this project novel ways to solve the challenge of sample tracking, data management and chain of custody in clinical studies were examined by implementing a solution based on blockchain technology. Applying a number of assumptions, a workable solution was implemented during the duration of the hackathon. Even though developed in two days, the final result shows the potential of a blockchain-based application. An important factor to keep in mind is that the spread of blockchain technology is a process that depends on the level of acceptance of the different stakeholders in accepting the technology as it matures.

Blockchain may not necessarily always be the most suitable technology to be used to deal with any business challenges that arise. Its applicability will ultimately have to be assessed on a case-by-case basis depending on the challenge at hand. Within sample tracking in clinical trials, the challenge presented here, there are vast numbers of tasks that are transactional in nature and the authors believe that this is a case that is well suitable for a blockchain-based solution. This will also allow to organize and maintain data more efficiently and at a later stage expend to other parts of the process and potentially integrate with other emerging technologies such as machine learning, and artificial intelligence (AI). The hope is that all of these technologies will offer as a tool that allow companies to focus on tasks related to trial design, facilitation, human interaction, data interpretation and other knowledge driven tasks and not necessary put the main focus on the empty "busy-work" of managing the files transfers between parties and spending large amounts of time on finding missing data.

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