Delphus

Revolutionizing Clinical Studies and Data Transparency through the Blockchain

By the Scintillating Team

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1 Abstract

We are developing Delphus, a decentralized scientific management platform that makes research data verifiable and streamlines audits. Scientific research lacks adequate verifiability and transparency. 33% of NIH researchers admit to some form of scientific misconduct, 86% of people lack trust in academia and research, and 91% of participants desire greater transparency on their studies' progress. Further, organizations are disincentivized to improve: tracking data provenance, recruiting participants when applicable, and controlling access are necessary, but organizations lose time and money with inefficiencies in these processes that could be better spent on research, greatly increasing the time it takes to publish results or go to market with a new product.

Delphus is a platform for trust and compliance. The current iteration of our product targets research inefficiency through a secure, decentralized study management platform powered by the blockchain. Delphus manages the lifetime of a scientific study, including finding patients, creating trials, recording user consent, submitting data points, and paying out participants.

Using the blockchain, Delphus immutably timestamps and records all consent and data points to provide transparency at every step. It stores data on a network of servers around the world, preserving data accessibility and allowing control on a per-site and per-investigator basis. This makes research auditable and verifiable, saving trust, time, and money.

2 Problem

Recently, several large-scale scandals have tainted the reputation of clinical studies and impeded research efforts crucial to human well-being. For example, Novartis hid data manipulation from the FDA for their new $2.1 million treatment so that the organization would approve their drug despite concerns for human safety [8]. The Harvard–affiliated Brigham and Women's Hospital paid $10 million to settle claims against researchers who manipulated and falsified information for grant money [6] [7]. Duke University paid $112 million to the FDA and redacted 12 scientific papers for falsifying research claims [4]. These issues undermined the credibility of these organizations and decreased public trust in research. Furthermore, due to these incidents, potential participants became wary of data mismanagement, as they lacked control over the use of their data. As a result, recruitment of patients became a significant and costly challenge.

These scandals reveal a primary issue for researchers today:

1. It is difficult for the sponsor of the research to audit the data for scientific misconduct and identify at-fault individuals

    - Delphus provides a timestamped audit log that provides the identity of the researcher who entered the data. It can also be manually verified.

On the other hand, Delphus also streamlines the process for participants, increasing retention and engagement:

1. 91% of participants want to view their data but few researchers have the time to do so for every individual case [1].
    - With Delphus, selected data and updates are encrypted to the participant so they can see how their data is being used throughout the trial process, increasing retention and visibility.

Other sub-problems solved by Delphus are enumerated below:

2.1 Patient recruitment requires significant study resources

Most medical and clinical studies encounter significant problems with acquiring suitable patients and their data. It is not uncommon for studies to either fail at this initial stage when their funding runs out or to have to drastically change the scope of their research; generally speaking, 30% of a *successful* clinical study's time is wasted on this fundamental task [3]. Further, once these patients are acquired, they tend to drop out due to poor communication with the clinicians. [5]. Thus, many trials fail due to a straightforward, fixable problem.

2.2 Mandated data transparency is costly for centralized systems

Currently, most data in studies is hidden behind a centralized server; for example, on ClinicalTrials.gov, less than 10% of data is made public [2]. However, if study data is shared through transparent means with correct citations, then this data could contribute to other studies and expedite the process of participant selection and data collection through reputable sources. With Delphus, data can be easily shared using techniques such as proxy re-encryption to secure personally-identifiable information. Further, such data sharing can also give participants insights into their own data if selected by the researcher, and participants can also see where their data is being used through a study's lifetime through Delphus updates.

2.3 Regulatory compliance is difficult in other blockchain systems

HIPAA and HITECH are both extensive regulations that represent an obstacle to health data on the blockchain due to its intrinsically open nature [2]. This poses significant entry risk to those who intend to create such a transparent medical database. Yet with proper regulatory compliance, the blockchain becomes a tool to assist study management. Delphus solves the transparency issue by using encryption of medical data through elliptic curve cryptography and only committing hashes on-chain.

3 Technical Solution

Novel smart contracts on the Ethereum blockchain provide Delphus's main functionality. Traditional systems run on a central server, recording data updates in an easily-modified database. However, blockchain contracts act to publicly log all changes, preventing tampering through technical transparency. Written in Solidity, Delphus's contracts manage study creation, patient consent, researcher access control, and data uploading. When users access the site for the first time, Delphus's built-in account manager automatically generates an Ethereum account for them, eliminating the need to install third-party extensions like MetaMask. Alternatively, users can log in with a Google or Facebook account, using Torus to handle their Ethereum information. Researchers then use their account to create a study, submitting a transaction to our smart contract and providing the native currency of Ether (ETH) for payment. The contract handles creation of the study metadata and stable conversion of funds from Ether to the intermediary stablecoin Dai.

When a participant joins a study, they use their Ethereum account to send a signed consent acknowledgement to the contract, acting as a cryptographic demonstration of identity. They can then view any data and updates the researcher has allowed them to view.

Researchers collect data in the standard XForms format, supporting text, numerical, image, and file uploads, along with custom form validation and skip logic. They can easily import forms from other XForm-compatible software, including Enketo, ODK Collect, and SurveyCTO, and store previously-used forms as shareable templates. The contracts also support multiple forms per study for different types of data submission.

Upon data submission, each record is uploaded to the InterPlanetary File System (IPFS), a decentralized storage network designed for permanency, using end-to-end encryption for confidentiality. Delphus then submits the hash fingerprint of the data to the blockchain, which acts to publicly timestamp the data so auditors can later inspect it.

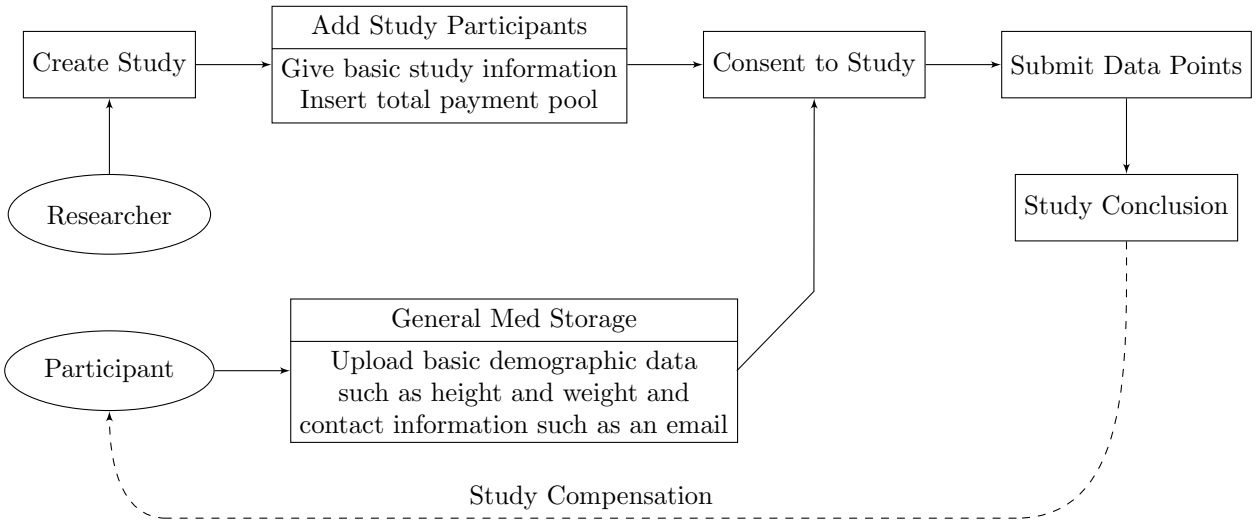
Researchers can manage both who has administrative control of the study (e.g. submitting data points, adding new participants, concluding the study) and who can read the study's data. All changes to control and data access are recorded on-chain, providing an audit log that discourages manipulation. For more complex access control levels, we are also currently designing software using the NuCypher re-encryption protocol to control more granular data access.

To prevent sensitive information from being discussed over insecure channels, Delphus also provides integrated end-to-end encrypted chat. At any time, a researcher may click the chat icon next to a participant account to open a conversation. Delphus uses Riot, a chat client with audited encryption algorithms powered by the Matrix protocol.

By creating an easy-to-use interface for these decentralized technologies, we hope to make their benefits more accessible for researchers and participants alike.

4 Product Flow

Below is a brief overview of the Delphus interface between researchers and patients.



Researchers have a very straightforward usage of Delphus:

1. Researchers create a study and give it a name, citation, description, expiration date, consent form, payment pool, and any additional data that they need as additional fields.

2. The platform then automatically exchanges the ETH deposited into DAI in order to keep a stable amount of money in the study. Then, researchers sign the transaction to finalize the creation of the study.

   That is all the researcher has to do to set up his or her study, but he or she can always manage said study from the "Your Studies" navigation option.

Patients have a similarly easy platform to navigate:

1. Patients can studies either by submitting a request through a list of public, ongoing studies, or by being added by the researcher.

2. During the study, patients can follow posted study updates, communicate with the researcher through end-to-end encrypted chat, and view the history of all (encrypted) data upload.

3. Eventually, the study ends after the researcher has finished gathering necessary data. The system will automatically pay out the payment into the wallets of the patients, from which they can exchange it into dollars at their leisure.

5 Economics

Delphus first targets the research market, including universities, hospitals, and pharmaceutical companies, representing a $4.8bn market. These institutions often use bespoke traditional systems, which they may have been using for years or just switched over to. To make transitioning to Delphus easier, we have made the platform extensible with standardized import/export functionality to migrate over existing studies. Further, to support customers' needs, we can leverage Delphus's adaptable foundation to do custom feature development.

For the research industry, there are three pricing licenses used by Delphus: a pay-as-you-go model, a dedicated model, and an on-site model. In the pay-as-you-go model, benefiting smaller studies, fees are directly proportional amount to the number of participants. For the dedicated model, Delphus will set up a dedicated sidechain to improve scaling, but for a higher overall price. The final model for large-scale studies, the on-site model, features a sidechain *running on the customer's server* with routine commitments to the main Ethereum network.

Contracts are given as software as a service (SaaS). They allow access to the Delphus platform and users while also allowing full customization to suit the need of the contractor.

6 Team and Advisors

Thanks to our past projects, we have extensive experience with blockchain technology; during Delphus's development, we designed novel methods of data storage and interfaces with stable cryptocurrencies like Dai. Learning from other projects' difficulties in adoption, we also prioritize user experience at all costs, aiming to make often-cryptic blockchain technology simple to use.

Further, we are well-connected in the healthcare space. Our advisory team consists of experienced founders in this field. We are working with leaders in clinical trial management systems, such as Satish Tadikonda, founder and CEO of Virtify and Enmed; Jim Yim, serial angel investor, entrepreneur, and CEO of Medtricbio; Chris Vento, executive at Innoventify; and Sunil Ravipati, a top engineer at Oracle with experience in the CTMS space. We are also working with Ashwani Verma, who has 20+ years of experience in healthcare auditing.

Pillar VC and their external connections have also mentored us, and their experience with multiple, highly profitable CEOs as founders has given us extensive media contacts and connections. Our legal expertise comes from Mintz Levin, providing a strong legal presence.

With our experienced team and the connections that we have, we believe we are at a very strong position in this sector of the market.

7 Timeline

Below is a brief summary of major company events since the creation of Delphus.

1. February 2018 – the Scintillating team creates Delphus at MAHacks III, winning first place at the competition.
2. March 2018 – Scintillating comes runner-up at the MIT Bitcoin Expo.
3. April 2018 – Scintillating presents Delphus at Babson College as part of Blockchain Week.
4. September 2018 – Scintillating places first at DoraHacks Boston with Delphus.
5. November 2018 – Scintillating goes international by competing in Japan.
6. February 2019 – Scintillating presents Delphus at the Harvard Healthcare Innovation Fair.
7. June 2019 – Scintillating presents at the MIT Startup Spotlight.
8. November 2019 – Scintillating is recognized with 3 international awards at ETHWaterloo.

Regarding future plans, we expect to begin our first trials in spring 2020 after obtaining audits and are actively collaborating with MIT and Novartis to find suitable test trials.

We also plan on thoroughly auditing our technology with both a HIPAA and smart contract audit, verifying the security of our product. Finally, we hope to finish raising our seed round so that we can expand our product scope and team while funding hardware and auditing expenses.

After establishing ourselves in the research market, we plan to expand to other fields through the knowledge and contacts gained in research, including transportation, aerospace, and ultimately business auditing, as they require similar audit log functionality.

References

[1] Patients' attitudes and preferences about participation and recruitment strategies in clinical trials, Mar 2009.

[2] Office for Civil Rights HHS Office of the Secretary and OCR. Summary of the hipaa security rule, Jul 2013.

[3] Sujay Jadhav. Blockchain technologies poised to disrupt stagnant trial timelines, Feb 2018.

[4] Alex Keown. Falsified data forces duke to pay $112 million settlement, other universities under scrutiny as well, Mar 2019.

[5] U.S. Department of Health Human Services. 4.3 difficulties in recruiting and retaining participants, Jun 2016.

[6] Ivan Oransky and Adam Marcus. Harvard and the brigham call for more than 30 retractions of cardiac stem cell research, Oct 2018.

[7] Kelly Servick. $10 million settlement over alleged misconduct in boston heart stem cell lab, Apr 2017.

[8] Katie Thomas. Novartis hid manipulated data while seeking approval for $2.1 million treatment, Aug 2019.