Client/Sponsor/Support

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Vendia Information

Vendia is a tech startup founded by my wife, Shruthi Rao, and Tim Wagner. Shruthi is formerly from AWS and worked on business development for Lambda and also launched Amazon Managed Blockchain. Tim Wanger invented AWS Lambda and is called the "father of serverless." They each have seen the potential of blockchain technology but also have seen that it isn't feasible for companies to set up and maintain servers. In addition the technology isn't scalable and it is too slow. They decided to start a company that solves those challenges and with Vendia they created the next version of blockchain that is serverless, scalable, and fast.

Vendia just closed their series B funding and continues to build on their early success.

Vendia is committed to supporting students learning their platform and highly encourages questions and feedback through their community forum: https://community.vendia.net/ Don't hesitate to ask questions there, they won't bite :)

Background

In the United States the Federal Drug Administration (FDA) approves medications for specific use cases, if the medication has been shown to be both effective and safe. To prove safety and effectiveness of a new drug, pharma companies conduct multi-phase clinical trials in collaboration with health care providers and under oversight of the FDA. For a successful study, all three parties need to exchange data in a controlled and auditable manner. For example, a

health care provider needs to be able to identify their patient and track treatment, but they should not know whether the patient is part of the treatment group (receiving the actual medication) or the control group (receiving a placebo or established medication). On the other hand, the FDA and pharma companies need this information, but generally have no need to know a patient's personally identifiable information (PII), such as their name, date of birth, or address. In the interest of patient privacy, PII should be redacted before it is transmitted by a healthcare provider. At the same time it is important that the FDA can verify the integrity of study data. The technical means used to transfer data should make it impossible to - for example - remove a study participant or manipulate laboratory data to improve the chances of approval for a new medication. While we generally believe in the moral integrity of humans, this is a real risk given the cost of developing a new drug (~$1B). Especially when the drug maker has to show that the medication is more effective than existing alternatives.

The Goal

The goal of this class is to build a proof of concept distributed information system with suitable user interfaces that could be used by the FDA, pharmaceutical companies, and participating health care providers to exchange study data as it is produced (i.e., in near real time) in a secure, trusted (i.e., auditable), and controlled (i.e., minimally permissive) manner. We will build our information system on top of the Vendia Share platform, which supports data exchange through an immutable, cryptographically verifiable, distributed ledger and provides the primitives to control data flow (e.g., redaction). In the following, we go into more detail on the use case, which you will translate into technical requirements and a suitable implementation during this class.

The Use Case

Pharma company “Bavaria" is working with “Jane Hopkins Hospital”, on a phase 3 medical trial for a new antiviral medication involving ~100 patients. The trial is monitored by the FDA and focused on effectiveness. (We assume that safety has been established.) All three parties agree on the criteria for including patients in the trial. For the sake of simplicity, we can think of the criteria as the following:
* A ICD-10 diagnostic code that must be associated with the patient, to ensure they actually need treatment.
* A short list of ICD-10 codes that represent illnesses that may result in complications. Patients with these diagnoses should not participate in a phase 3 trial.
* A patient age range.
* A short list of known, incompatible medications (named as their active ingredient) that can be matched exactly.

Researchers at Jane Hopkins have reviewed a set of patients that they intend to include in the study. They want to use a smart contract that the other parties can read to verify the eligibility criteria. Once a patient is “accepted” per smart contract, Jane Hopkins will share their record with Bavaria and the FDA. However, they will not share any personal information on file, not

even the information evaluated in the smart contract (i.e., the date of birth). All parties trust the smart contract. Personal details would only be shared with the FDA, if an investigation was necessary, for example due to unexpected side effects.

With the anonymized list of eligible patients, but absent any further information, the FDA selects participants for the treatment and control group without sharing this information. They receive doses of the medication as well as an identically packaged, frequently used generic medication from Bavaria. Every dose is marked with a tracking code and a boolean “generic” flag by Bavaria. The FDA re-labels these doses with their own code and assigns them to individual patients before sending them to Jane Hopkins. Only the FDA has visibility into the tracking code mapping. This way, neither the treating physicians at Jane Hopkins, nor the researchers at Bavaria can determine which patient is in the control and treatment group until the study is complete.

Throughout the study, Jane Hopkins tracks every treatment, including the tracking number and records the viral load of study participants weekly.

At the end of the study, the FDA shares the treatment/control group assignment with both Bavaria and Jane Hopkins to allow for study evaluation. At this point, Jane Hopkins also shares complete, anonymized patient records, so that Bavaria and the FDA can investigate whether certain medications or pre-existing medical conditions affected effectiveness in unexpected ways.

Disclaimer

The above is a gross simplification (and modification) of how medical studies work, but the process and your resulting code are still meaningful and adaptable to real-world scenarios.

Tech Stack/Requirements

Front End - React is highly recommended. It is easy to use and is a valuable skill to have on your resume. Popular alternatives are: Vue or Angular. You have complete agency over what styling frameworks you want to use, but two suggestions are Tailwind or Bootstrap. The app should be responsive (an essential component in a quality UX).

Back End - Vendia Client SDK (recommended) or Vendia GraphQL API. Vendia utilizes an entirely serverless architecture, so there is no need for any additional infrastructure beyond these two methods.

Authentication & Authorization - Cognito, Firebase, and Auth0 are the three major authentication services that are exceptionally easy to integrate. 30-minute video that walks you through how to add Firebase authentication to a React app.

Source Control - Github. Used for monitoring individual contribution.
Security

1. Demonstrate that the patient info remains private and that the FDA and Bavaria can NOT get the PII of the patients.
2. Demonstrate that Jane Hopkins can NOT find out which drugs are new vs placebo
3. Demonstrate proper access of Doctor vs Admin for Jane Hopkins

Non-Functional Requirements (NFR)

1. Responsiveness
2. Usability
3. Accessibility

Supplemental Notes

Jane Hopkins

1. Jane Hopkins will have all the patient info. PII
    a. Name (first & last)
    b. Patient Picture
    c. DOB
    d. Insurance number
    e. Height
    f. Weight
    g. Blood Pressure
    h. Blood type
    i. Temperature
    j. Oxygen Saturation
    k. UUID = patient ID
    l. Address
    m. Allergies
    n. Current medications
    o. Family history
    p. Currently employed
    q. Currently insured
    r. ICD health codes
        i. This wiki link describes ICD-10 codes:
            1. https://en.wikipedia.org/wiki/ICD-10
        ii. For the class, we will want to filter out any codes related to pregnancy.
    s. List of visits (weekly basis)
        i. Date/time
        ii. General notes
        iii. HIV Viral Load

    1. High HIV viral load is considered to be above 100,000 copies per milliliter of blood. Can be higher than 1 million.
    2. Lower HIV viral load is below 10,000 copies per milliliter of blood.
    3. Goal of drug is to get to 0
2. Jane Hopkins doesn't know if the patient is receiving the new medication or the placebo
3. Determine patient eligibility based on ICD health codes

Bavaria

1. Bavaria ships drugs to FDA
2. Bavaria knows which drugs are new vs placebo
3. Bavaria doesn't know results until the end of the study
4. At the end of the study the FDA will notify Bavaria of: patient number, did they receive new or placebo, HIV number

FDA

1. Mapping data for new vs placebo to patient UUIDs
2. Have the FDA provide the parameters to Jane Hopkins for determining patient eligibility.
    a. Exclude ICD-10 Pregnancy codes
    b. Exclude DOB greater than 1/1/2005
3. Once Jane Hopkins says that the study is over, FDA informs Jane Hopkins which UUIDs were assigned new vs placebo
4. In the end they are able to see the report results, excluding PII

Dummy data will need to be generated for this project

1. Create at least 20 patients
2. Only about ½ of the patients should be eligible for new drug
3. Bavaria will need a batch of drugs… Let's say that half are new from Bavaria and the other half are placebo.
4. FDA will need a way to map the the drugs to the patients so that they know which ones are receiving new vs placebo

WebApp

This isn't a strict guideline, YOU decide how the personas are supposed to look

Jane Hopkins - Two users

Doctor profile

A. View patients
    a. Edit patient information
    b. Enter appointment info
    c. Enter dose - track the count

Admin profile

A. Patient profile should include a marker for eligibility
B. Mechanism to check if patients have received all doses (let's go with 5 doses)
    a. If so notify FDA that study is complete
    b. Provide FDA with results BUT not PII

FDA - Single user

Admin profile

A. Functionality to assign placebo vs Bavaria drugs to eligible patients that will be enabled after "receiving" the batch of drugs from the FDA

B. Functionality that will be enabled only after 5 doses to all eligible patients has been administered which will notify Jane Hopkins that Bavaria can access results

Bavaria - Single user

Admin profile

A. Functionality that sends a batch of placebo and Bavaria drugs to FDA, all with unique IDs (5 doses times 10 patients (if using 20 patients) = 50 doses)
B. Functionality that monitors ongoing trials in real time (eg. patient status, current dose)
C. Functionality that generates a post-trial report

Schema


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