

ImmunoCharge: Phase 4 Clinical Trial App for Pandemic Vaccination

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Abstract- *Immuno-Charge is an application that focuses on collecting clinical data for clinical trial purposes and helps to fix appointments for vaccination. The application acts as a bridge between the user and pharmaceutical company as it provides required data to the company and provides an easy interface to use, both for user and company. It also keeps records and track of vaccines taken by users. Users must fill in the data that is provided to them in a question-and-answer format. The limitation is that the authentication of the user's medical data & symptoms is not done. The progress of immunization can be a long, complex process that regularly lasts 10-15 years and includes a combination of public and private enterprise involvement. Vaccines are designed, tested, and directed in a really similar way to other drugs. Clinical trials are research studies or observations done in clinical research. Such planned biomedical or behavioral studies on human members are designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs etc) and known intercessions that warrant encouraging thought about and comparison. Clinical studies provide information about measurement, safety, and feasibility.*

Keywords- Phase 4, Clinical trial, Vaccination, App

1. INTRODUCTION

Vaccine improvement could be a long, complex process, often lasting 10-15 years and involving a combination of public and private association. Vaccines are developed, tested, and regulated in a very similar manner to other drugs. Vaccines are generally more thoroughly tested than non-vaccine medications because the number of human volunteers in vaccine clinical trials is generally higher.

Clinical trials are asked for considerations conducted in individuals aimed at evaluating therapeutic, surgical, or behavioural advocacy. They are the essential way in which analysts can, in the unlikely event, determine that a modern treatment, such as a modern drug or calorie counting or therapeutic device (e.g., a pacemaker) is safe and convincing for the individual. A clinical study is regularly conducted to note the chance that unused treatment is more compelling and / or has fewer destructive side effects than standard treatment. A clinical trial can also look at ways to create a better life for people with a life-threatening illness or ongoing health problem. Clinical studies, in some cases, consider the role of caregivers or back bundles.[1]

The various phases of clinical trials help the researchers to find a safe and effective drug, vaccine or device. These includes, Stage 1 trial tests an exploratory treatment on a little gather of frequently sound individuals (20 to 80) to judge its security and side impacts and to discover the right sedate measurement. Stage 2 trial employs more individuals (100 to 300). Whereas the accentuation in Stage I is on security, the accentuation in Stage II is on adequacy. This stage points to get preparatory information on whether the medication works in individuals who have a certain illness or condition. These trials moreover proceed to consider security, counting short-term side impacts. This stage can last a long time. Stage III trial assembles more data around security and adequacy, considering distinctive populaces and distinctive measurements, utilizing the sedate in combination with other drugs. The number of subjects ordinarily ranges from a few hundred to almost 3,000 individuals. In case the specialist concurs that the trial comes about positive, it'll endorse the exploratory sedate or device. The stage 4 trial is additionally alluded to as post showcasing observation and as the title proposes, it is conducted after the sedate is as of now promoted and accessible to the common open. The most objective of the stage 4 trial is to check the drug's execution in genuine life scenarios, to ponder the long-term dangers and benefits of utilizing the medicate and to find any uncommon side effects.[2]

Immuno-Charge is an android application that serves two major functionalities, one, collects clinical information which is utilized for clinical trial reasons; and another, helps to track and record the vaccination of users. In addition, there's a post-survey strategy where information will be collected and will be sent to respected companies, where they will be able to get a knowledge on the adequacy of the drug/vaccine on people. In addition, the application aims to reduce the overall time for the clinical trial process to bring drugs / vaccines to market. This is achieved by providing groups of people based on their immune response and other characteristics to us through the data provided and we take one member from each group and infer it to other members. This gives a straightforward interface and strategy for the client and the support company that conducts clinical trials (pharmaceutical company), so that they are able to be prepared for any crisis circumstance in future. As per the prerequisite, the client

can also search about the immunization accessibility within the closest area and can keep a record of the vaccine that they have taken. This would moreover offer assistance to share the data with the specialist around the whole number of immunizations taken by the clients.

2. LITERATURE SURVEY

Cureitt is the foremost prevalent clinical trials app established by Dr. Giri Ramsingh M.D. This app basically utilized faster treatment to patients who needed to do clinical trials effortlessly. The biggest issue of trials isn't to urge the right data around clinical trials. The foremost imperative portion is this app as a stage to interaction between patients and healthcare professionals. It is mainly for oncology clinical trials and numerous therapeutic information areas are included. Patients can upgrade their information for trails additionally incorporating login and signup highlights for individual account creation. Here numerous sorts of clinical trials related to cancer are accessible like Breast cancer, Colon and rectal cancer, prostate cancer, lung cancer, Brain tumour, Thyroid cancer, pituitary tumour etc. Primary include of this application is to discover closest clinical trials. The most lack is, it is all almost cancer related no other maladies are accessible. Its highlights are difficult to get for a common individual. But the Immuno-Charge app is easy to understand and not complicated as it fills up medical data for trials. And all steps are so simple.[3]

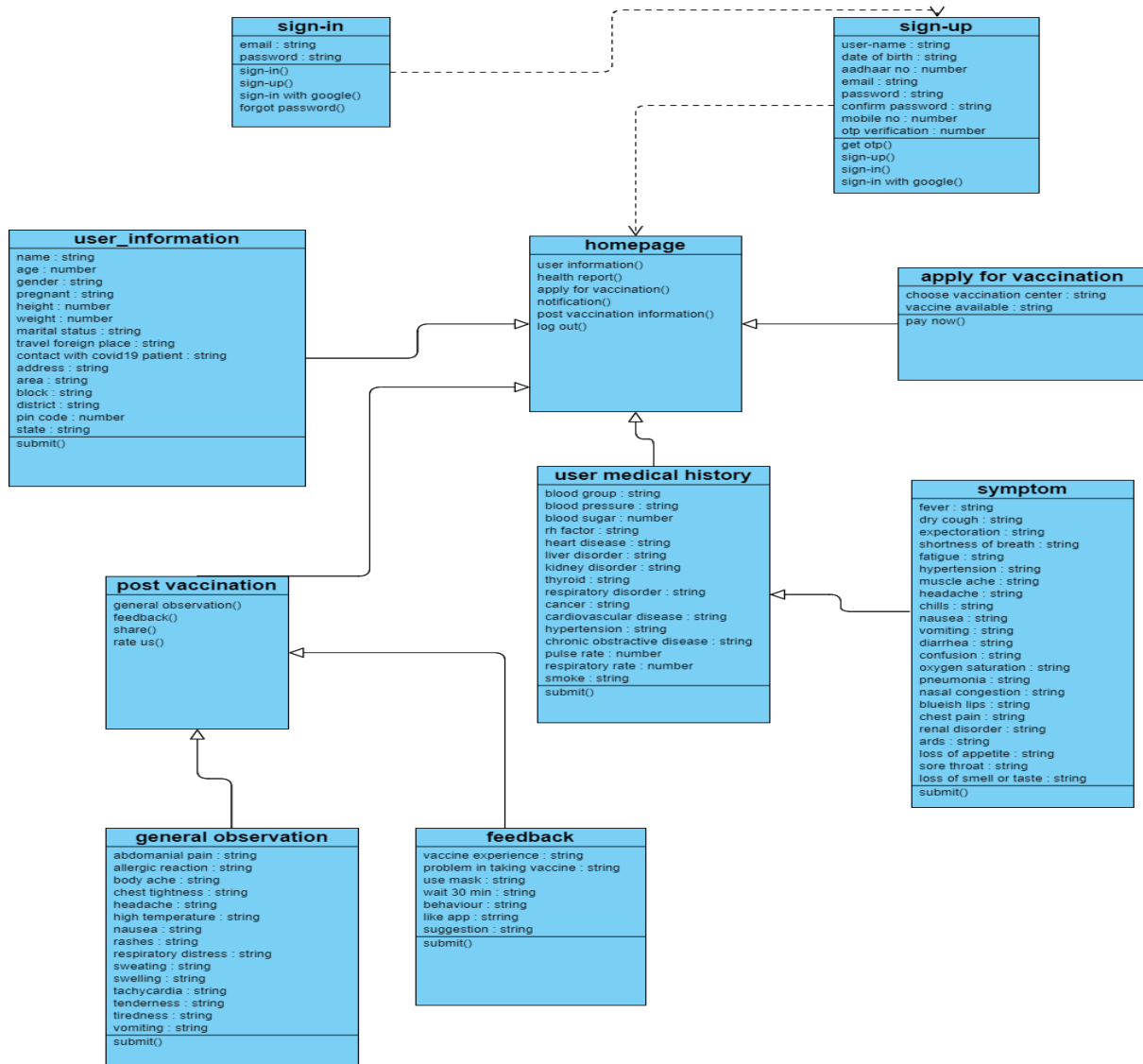
mPower may be a free clinical trials stage created by Sage Bionetworks. It is primarily utilized for trials of Parkinson's malady. It essentially gives health surveys counting side effects, triggers and solutions. Conjointly inquire to do a few exercises like tapping on screen utilizing fingers to degree the tapping speed and coordination, play a brief memory amusement to memorize around memory and consider, hold your phone for 10-15 seconds to degree tremor in your hand. Information is exchanged to the cloud-based synapse information examination stage. They dissect the combined coded ponder information where they explore for designs that will offer assistance in superior understanding of the side effects of Parkinson's disease. Typically, not a restorative treatment. They don't anticipate restorative side impacts from partaking in this consideration. There's a plausibility of an information breach and the client may be recognized. This hazard is moo but it isn't zero. When patients take part in this path a few hazards may be happened that are not known.[4]

Clinical Ink Engage (EU) is a free app published in the Health & Nutrition list of apps. The company that develops Clinical Ink Engage (EU) is Clinical Ink, Inc. The latest version released by its developer is 2.15. SureSource is a user-friendly app created specifically for clinical trial participants. The app includes the following features: appointment reminders via text message, email, or directly within the app, as well as assistance with locations and directions for our forthcoming appointment visits. It also serves as a reminder to take medications on schedule or to complete duties for a clinical trial. Its content feed displays relevant films that assist users better comprehend the trial and prepare for forthcoming activities or appointments. There are also questionnaires for the trial tasks. It may also be able to link to medical equipment or sensor devices, making it easier to record data for a study. The disadvantage of the application is: The application is only available for Apple iOS smartphones only.[5]

Surokkha is a Bangladeshi vaccination app. It gathers personal information such as phone numbers, national identification numbers, dates of birth, and Co Morbidity. Users must express their consent for emergency health services to collect, keep, use, supply, share, and analyse their personal information. Users must agree to the privacy policy while registering, and only then can they use the app. During registration, the user is assigned a system-generated unique user id. The data will be saved on the server with a unique identifier. To get vaccinated, the user must first find the local vaccination centre and then make a vaccine appointment. By delivering an OTP to the specified mobile phone number, the application confirms the user and allows them to register. At a later point, registrants can check the status of their application, download their Vaccine Card, and download their Certificate. There is no option to cancel a vaccine reservation. This programme is riddled with flaws. It takes a long time for the app to load. Responsiveness is lacking and has to be improved.[6]

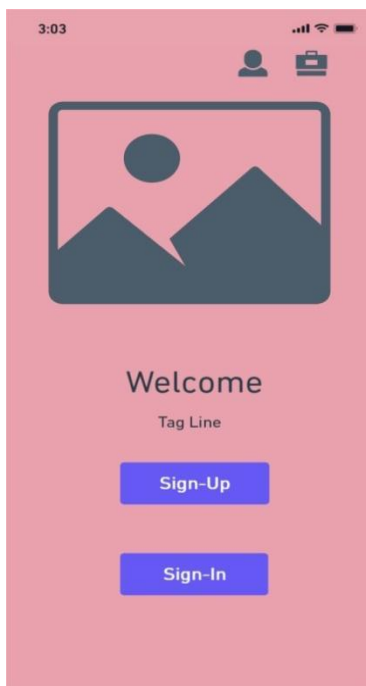
3. PROPOSED MODEL

Class Diagram

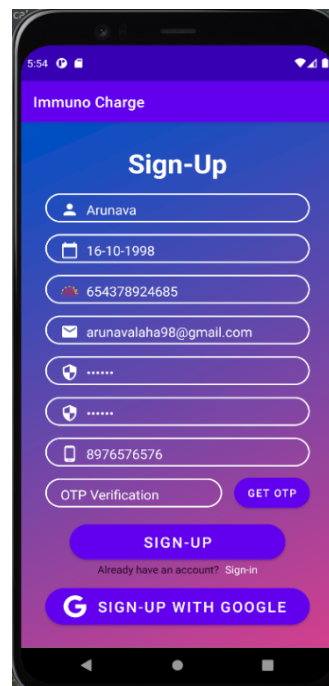


The modeling of the various modules of the application is represented by the class diagram. The UML class diagrams would aid in software design and maintenance of the application. It would help us visually examine the relationships between the objects.

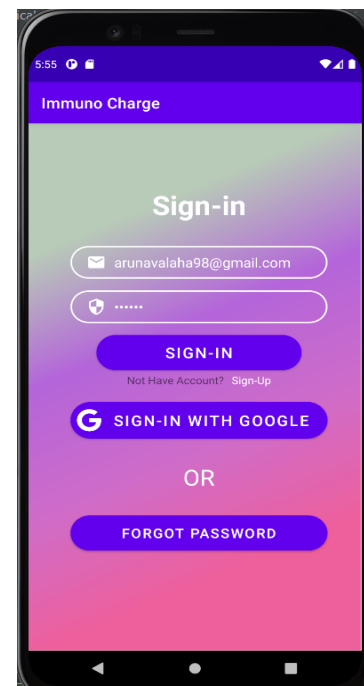
User, first, creates an account through the “Sign-Up” page and login through the “Sign-In” page thereafter. User’s Sign-Up credentials are saved in the Firebase Database by Google with a unique id. Only the registered user can sign-in and log out by the logout option in the navigation menu in the homepage.



Welcome Screen

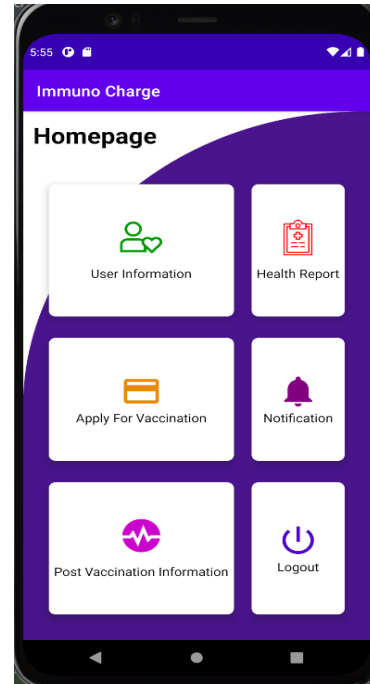


Sign-Up Screen



Login Screen

The Homepage contains options like “Clinical Trials”, “Vaccination”, “Notification” & “History”. This page helps us to navigate to different modules of the application . Also there will be a side menu bar, which consists of a profile picture of the user as well as the user's name. It will also consist of options like “Profile”, where the basic information of the user will be shown; “About”, where the information of the application will be given; “Feedback”, where user can give their perspective about the application; “Share”, user can give the application link to their friends & families to download and use; “Rate”, here user can rate the application on the scale of one-to-five on the basis of their liking towards the app; “Logout”, user can logout from the application by a single click. And along with these “Home”, “Clinical Trial”, “Vaccination”, “Notification” & “History” options are provided in the side menu bar in the homepage.



Homepage of Application

The user must first provide their basic information via the Clinical Trial tab, after which all this information is stored in the database with an OTP confirmation. Then a unique ID is generated for the user, which identifies him. The user fills in the medical information page where we record the health status information to record the user's health status prior to the clinical trial phase. This medical information is also helpful in verifying the user's eligibility criteria for a clinical study. Then the user fills in the information about the symptoms of the disease that he has. The Symptoms page helps determine the severity of the condition. In addition, this collected information is helpful for the company to conduct its clinical study for a drug / drug and to easily find its target population. Not only can the company understand the trend in the drug's effectiveness and categorize the population based on the time it takes to get the result. When the categorization is complete, we can infer the time it will take to get a result, in which group of people the drug is more effective and what side effects the drug / drug has. The identity of the user is hidden from the companies conducting the clinical study until the user gives permission. The data is passed on to the company with the unique ID.

Generic Medical Issues After Vaccination

Do you feel the following difficulties?

Abdominal pain:- Y/N

Allergic Reaction:- Y/N

Body Ache:- Y/N

Chest Tightness:- Y/N

Headache:- Y/N

High Temperature:- Y/N

Nausea:- Y/N

Rashes:- Y/N

Respiratory Distress:- Y/N

Sweating:- Y/N

Swelling:- Y/N

Tachycardia:- Y/N

Tenderness:- Y/N

Tiredness:- Y/N

Vomiting:- Y/N

Submit

User Information Page

User Information

Name:- Abc Jkl Xyz

Age:- XX Yrs

Gender:- M/F/O Pregnant:- Y/N

Height:- in cms Weight:- in kg

Marital Status:- Drop-down

Occupation:- Drop-down

Have you travelled anywhere internationally in the last 30 days? Y/N Place Name

In touch with Covid-19 Patient:- Y/N

Address:-

Block:- Drop down List

Area:- Rural Urban

District:- Drop down List

Pincode:-

State:- Drop down List

Next

Post-Assessment Page

The “Vaccination” tab will help to locate the nearest vaccination centre about the vaccine that the user required. Also, it will give timely information about the vaccine that is required by people of age in between 1 -15yrs.

The “Notification” page is for notifying the user time to time about the clinical trial available for them, vaccination details and centre, and the information required to be informed to the user. The “History” page will keep all records of the applied trial, and vaccines.

User Medical History

Blood Group: B+

Low

Blood Pressure: Normal

High

Blood Sugar: 168

Rh Factor: Positive

Negative

Any Heart Disease? Yes No

Any Liver Disorder? Yes No

Medical History Page

Immuno Charge

Any Type of Cardiovascular Disease? Yes No

Hypertension? Yes No

Any Chronic Obstructive Disease? Yes No

Pulse Rate: in_bpm

Respiratory Rate: in bpm

Daily

Do you Smoke? Occasionally None

SUBMIT

Symptoms

$\leq 37.5_C$

Fever: 37.5 - 38.0 C

38.1 - 39.0 C

$> 39.0_C$

Dry cough: Yes No

Expectoration: Yes No

Shortness of breath: Yes No

fatigue: Yes No

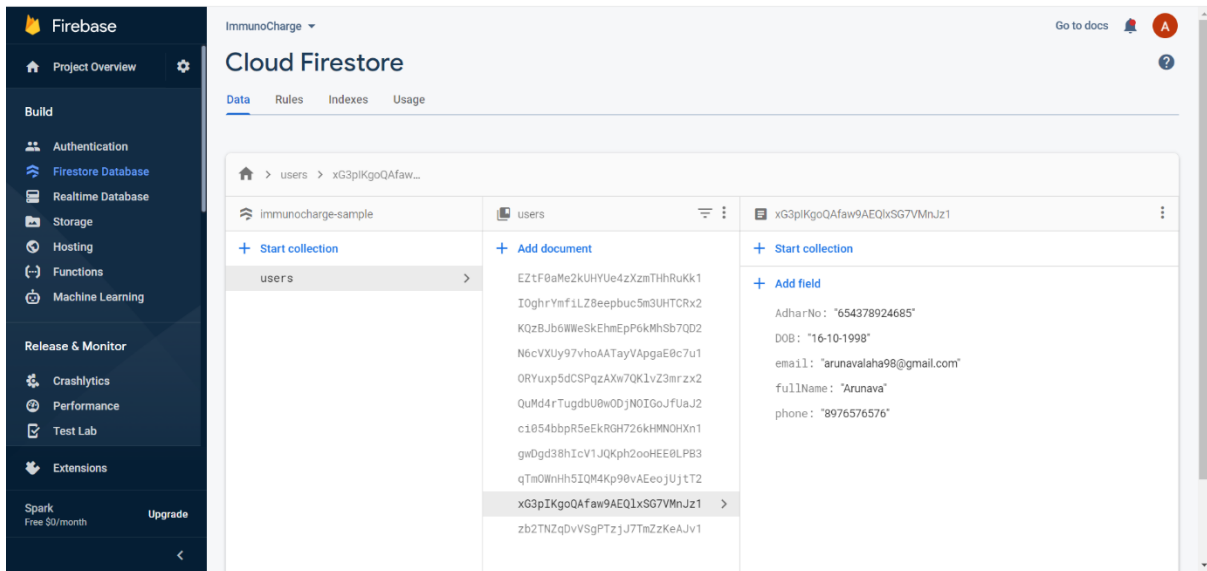
Hypertension: Yes No

Muscle ache: Yes No

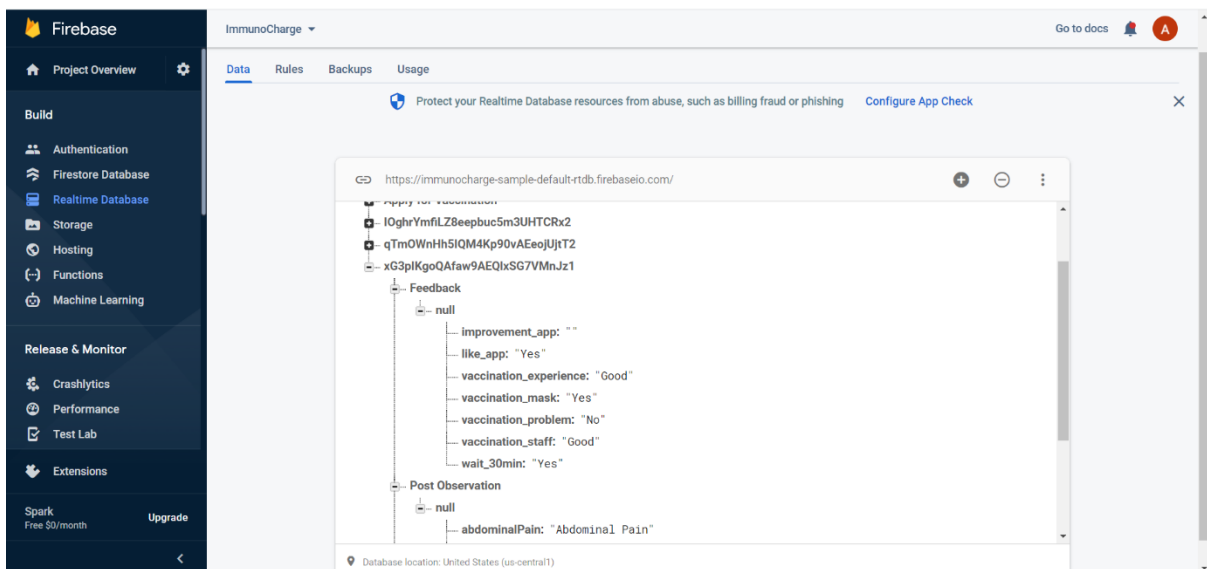
Symptoms Page

User need to maintain certain guidelines while using the application according to the government policy as well as the rules set by us.[7]

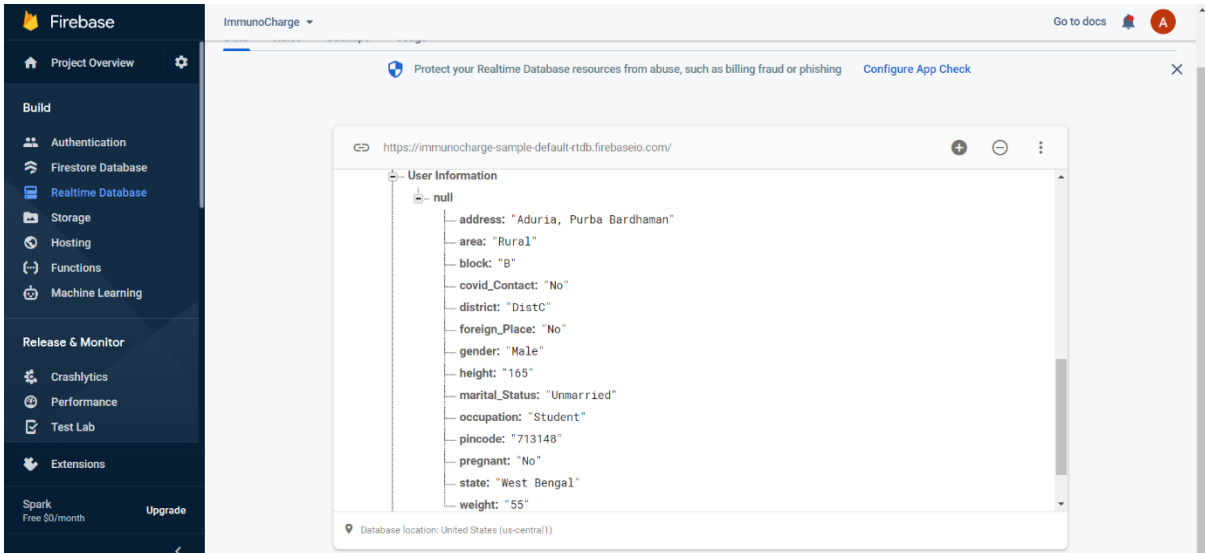
The whole data will be stored in Google Firebase Database.[8]



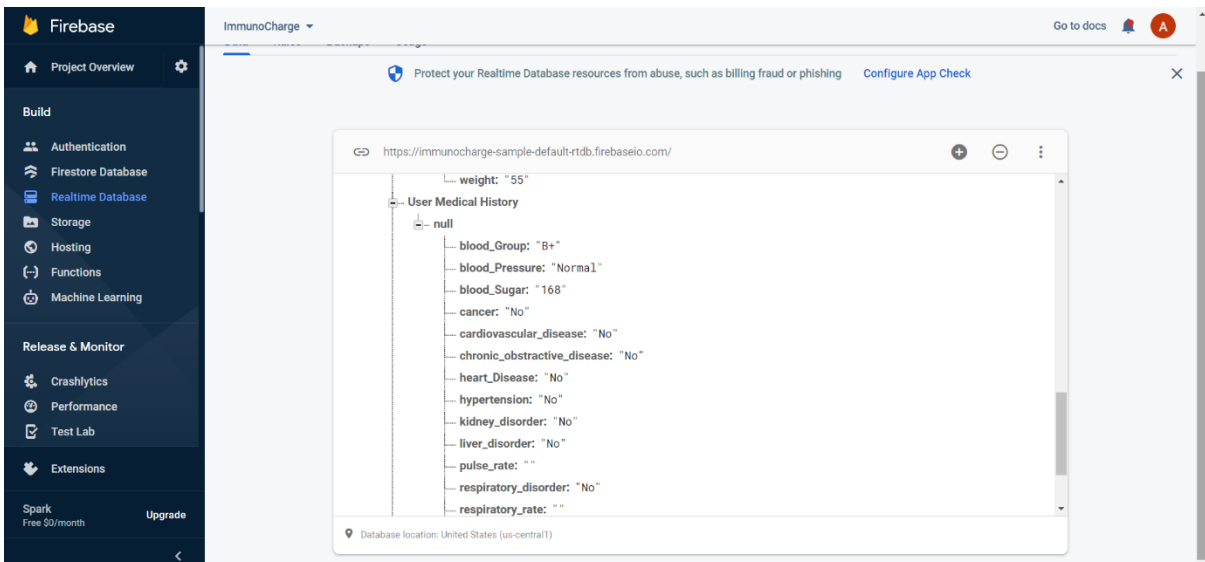
Here all User id will be stored along with user's details



User feedback will be stored in this section of database



Database of user information



Database of User Medical History

5. RESULTS AND DISCUSSION

On the completion of the application, the interested user will be able to get know about required clinical trials available and can take part in it, and the data provided by the user will be stored in firebase database wherefrom, the required data will be sent to the pharmaceutical company. This would help the interested users to decrease the chances of the spread of the disease or for cure purposes with the newly discovered drugs. The pharmaceutical companies could easily identify the target population with the application. The data collected from the user will give an insight about the effectiveness of the drugs/medicine. Regular monitoring of the user will be provided at the time of Clinical Trial to know their health conditions and to know the side effects that they are facing after taking the drugs/medicine. These data will be shared with the Pharma Company in order to increase its potential or the applied changes required. Also, they can identify the type of population that responds readily to the drugs. Also, the application is helpful at the time of an uncertain medical situation or pandemic in order to deploy drugs quickly in the market with the inference of the data that could reduce the time.

Vaccination is another functionality that will be provided with the application so that users can search for the nearest vaccination centre easily. Also, the age group between 1-15 years need to be provided with the vaccine course, so to ensure this entire group can get vaccines at time we notify the user with the information about the course and date of vaccination. Not only that we save all the vaccines taken by the user just in case needed anytime for any medical use.

Advantages of the proposed application:

1. Data is collected in a simple questionnaire form.
2. Privacy of the users will be maintained.
3. It will help the pharma company to find their target population easily.
4. It will include both a clinical trial and vaccination part.
5. Users can be able to search for vaccines and clinical trials with ease.
6. User will check his/her medical information and can update it with time.
7. Users will get time-to-time updates about vaccination.
8. Data will be stored in the firebase database.

Limitations of the proposed application:

1. User data is only collected and stored but further data processing is not being done.
2. Here out of all the data being taken, some of the data may not be used to infer the result.
3. Authentication of user's medical data & symptoms is not done but user information is authenticated.
4. We don't have any information about what type of clinical trial assessment data will be required for the Pharma Company.

6. CONCLUSION

The application gives the user a smooth user interface and navigation. It collects the information of the user easily in a questionnaires' form. The application builds an easy system of collecting information and tracking the CT process of the user. It helps the pharma company in better understanding their target population and also gets information about the effectiveness of their discovered drugs/medicine. It also helps in getting a fruitful population for the pharma company that conducts the clinical trial process. It also tries to maintain user privacy until given permission. And with the added functionality of vaccination, users get to know about the vaccination that is required for them. And also, they could track their vaccine related information. They could also attend post vaccination assessment in order to check the ill effects of vaccines on users.

7. REFERENCE

1. “Vaccine development and testing.” *The History of Vaccine* , 7 July 2021, URL:<https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation>
2. “Clinical Trials and its stages.” *National Institute of Aging* , 5 November 2021, URL:<https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies>
3. “Cureitt connecting clinical trials.” *CUREiTT* , 15 November 2021, URL: <https://cureitt.com>
4. “Reference of mPower 2.0.” *mPower* , 29 October 2021 , URL:<https://parkinsonmpower.org>
5. “Clinical Ink Engage - Health and nutrition application .” *Clinical ink* , 3 November 2021, URL: <https://engage-eu.clinicalink.com>
6. “Surokkha Vaccination App”. *Surokkha* , 25 October ,2021 , URL: <https://surokkha.gov.bd>
7. “Documentation for app developers.” *Android Studio* , June 2014 , URL:<https://developer.android.com/docs>
8. “Firebase Database Documentation”. *Firebase* ,April 2012 URL:<https://firebase.google.com/docs>