# Software Design Documentation

# for

# *Leveraging Digital Phenotyping to Support Patients with Glaucoma*

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# Table of Contents

## Code Revision History

| Name | Date | Reason for Changes | Version |
|---|---|---|---|
| Stellina Ao, Luis Ayala-Saldivar, Edson Castellanos, Mengying Chen, John Huang, Jooeun Jeon, Desiree Ramirez, Ashley Tran, Thang Tran | 03/30/2024 | Initial Application Framework | 1.0 |

# 1. Introduction

## 1.1 Purpose of Document

The purpose of this document is to describe the features, requirements, and specifications of the "Digital Phenotyping for Glaucoma" system. This document records all necessary information required for system design to provide system architectural guidance to the development team.

## 1.2 Scope of the Document

This document outlines the technical aspects of the system. This document describes the system features, design considerations, and architectural strategies.

## 1.3 Intended Audience of Document

This document will be useful for the software development team, the software testing team, project managers, and the potential users of the system. This document is best read in various ways depending on the role.

*Development Team*: must understand product requirements and implementation (s. 2-5)

*Testing Team*: must understand product purpose and requirements (s. 3-5)

*Project Manager*: must understand product purpose and requirements (s. 2-5)

*Users (patients)*: must understand product purpose and user interface paradigms (s. 1.3, 6.1-6.3)

*Users (physicians)*: must understand product purpose and user interface paradigms (s. 1.3, 6.4-6.6)

## 1.4 Identification of the System & Product

The official project name is *Leveraging Digital Phenotyping to Support Patients with Glaucoma*. There are no other relevant versions or names, but the smartphone application will be referred to as "the application" or "the system."

## 1.5 References

J. M. Wood, A. A. Black, K. Mallon, R. Thomas, and C. Owsley, "Glaucoma and Driving: On-Road Driving Characteristics," PLOS ONE, vol. 11, no. 7, p. e0158318, Jul. 2016, doi: https://doi.org/10.1371/journal.pone.0158318.

S. A. Haymes, R. P. LeBlanc, M. T. Nicolela, L. A. Chiasson, and B. C. Chauhan, "Glaucoma and On-Road Driving Performance," Investigative Ophthalmology & Visual Science, vol. 49, no. 7, p. 3035, Jul. 2008, doi: https://doi.org/10.1167/iovs.07-1609.

S. W. van Landingham, C. Hochberg, R. W. Massof, E. Chan, D. S. Friedman, and P. Y. Ramulu, "Driving Patterns in Older Adults with Glaucoma," BMC Ophthalmology, vol. 13, no. 1, Feb. 2013, doi: https://doi.org/10.1186/1471-2415-13-4.

A. Blane, "Through the Looking Glass: a Review of the Literature Investigating the Impact of Glaucoma on Crash Risk, Driving Performance, and Driver Self-Regulation in Older Drivers," Journal of Glaucoma, 2016.

## 1.6 Definitions, Acronyms, and Abbreviations

Refer to Section S: Glossary.

# 2. System Overview

The mobile application system will be developed using Dart, the Flutter framework, and Damoov's Telematics software development kit. The primary aim of the application is to unobtrusively gather raw sensor data from users' smartphones to process into driving events. These driving events will then be used to evaluate users' driving habits to monitor glaucoma with digital phenotyping. Physicians will be able to access patients' drives and determine the condition's progression. The mobile application system should be HIPAA-compliant requiring that any identifying patient information associated with a data record be anonymized. To accomplish this, our system will generate a JSON web token for user authentication and authorization. To ensure further security, the data will undergo encryption when migrated to Damoov's internal data storage platform, DataHub, through the backend, where scores and behaviors will be calculated. A unique identifier will also be generated for each user, accessible only to physicians to associate with each driving record.

The mobile application will have two separate interfaces tailored to patients and physicians. It will comprise a shared login page, physician and patient signup portals, various permissions screens, and respective home screens. The permissions screens will explain and request consent for patient data usage and the application's functionality. The patient home screen will also display a log of the patient's driving data refined to basic driving metrics such as drive duration, route, and length. The patient home screen should also be able to navigate to the personal section or profile page,s. The patient interface should generally be simple, have a larger font for better visibility, and be easily navigable while adhering to a palatable style guide. The physician home screen will have a queryable list of patients that will act as an in-app database. It will feature a search bar designed to locate a patient using their unique identifier, with the added functionality to filter by patient email or summary score. When a list item is selected, physicians will be directed to a new screen displaying detailed trip information, including scores for each trip. This screen will also provide in-depth statistics such as braking, acceleration, and cornering scores for the selected patient.The physician interface should be digestible with condensed patient-driving information, offering a suitable means for tracking and evaluating patients' glaucoma stages.

# 3. Design Considerations

## 3.1 Assumptions and Dependencies

3.1.1 Assumption of Network Connectivity: This project assumes that participants' cellular devices are consistently connected to a network. Reliable network connectivity is pivotal for the uninterrupted transmission of data and effective tracking of lifestyle patterns pertinent to glaucoma risk assessment.

## 3.2 General Constraints

3.2.1 Network Connectivity: The application may face challenges in accurately tracking patient movements in unstable network conditions.

3.2.1.1 The application's ability to accurately track and record patient movements and other relevant data may be compromised in unstable or poor network connectivity areas. This limitation could lead to gaps in data, potentially affecting the system's effectiveness in monitoring health risks.

3.2.2 User Permissions and Consent: The application's functionality depends on users granting necessary permissions on their mobile devices.

3.2.2.1 The system's functionality relies heavily on users granting necessary permissions on their mobile devices. These permissions may include access to location data, health monitoring data, and other personal information. User consent is critical, not just for operational feasibility but also for maintaining user trust and ethical integrity.

3.2.3 Legal and Ethical Compliance: The application must be HIPPA-compliant because the system collects sensitive data (e.g., GPS).

3.2.3.1 Given the sensitive nature of the collected data (e.g., GPS location, health information), the application must adhere strictly to HIPAA (Health Insurance Portability and Accountability Act) compliance and other relevant legal frameworks. This compliance ensures the protection of patient privacy and data security, which are paramount in healthcare applications.

## 3.3 Goals and Guidelines

This project aims to create a mobile application that tracks the patient’s driving patterns to determine their glaucoma severity. As our primary audience will have limited visual fields and may be of elderly age, the application should have a simple user interface to ensure that individuals with decreased visual fields and old age can operate the system. The first iteration of the mobile application should be completed by the end of February 2024. The patient side of the application was completed by the beginning of April. Soon after finishing the patient side, development started on the physician side and was completed by mid-April.

### 3.4 Development Methods

This project used Figma to prototype the application's design. Once the design was finalized, two teams worked on implementing the front-end and back-end of the application, respectively.The team met every week to discuss developments and workflow/targets to meet. We focused more on the concept of patients and then worked on phyisicians.

# 4. Architectural Strategies

### 4.1 Use of Particular Products

Dart, Flutter, Damoov's Telematics SDK integration, Firebase and Damoov's storage platform DataHub will be used for application development. Prototyping will be done with Figma to create concept user interfaces for the application.

4.1.1 Dart is an object-oriented programming language to develop mobile applications.

- 4.1.1.1 This product is easy to learn with prior knowledge of JavaScript and/or React Native.
- 4.1.1.2 This product is client-optimized with a stateful live reload and features for building specialized user interfaces important for this application's audience, including sound null safety and Flutter.
- 4.1.1.3 This product is the foundation for Flutter, an open-source framework with a UI toolkit for simple and fast app development important for the project's time constraints.

4.1.2 Damoov's Telematics SDK is a telematics toolkit that allows for driving data processing.

- 4.1.2.1 This product allows access to all data at any stage with on-demand data destruction adhering to the CCPA and HIPAA-compliant.
- 4.1.2.2 This product provides a license to distribute and integrate within the mobile application freely.
- 4.1.2.3 The integration of this product enables real-time smartphone sensor data collection and readily customizable processed driving events.

4.1.3 Damoov's Datahub provides a backend configuration to its Telematics SDK

- 4.1.3.1 Authorized personnel have on-demand access to all data and controlled data destruction through this product.
- 4.1.3.2 This product offers simple services to manage the SDK and API services and an analytics portal for viewing and exporting data.
- 4.1.3.3 This product is securely encrypted, protecting all captured patient driving data.

4.1.4 Figma is used to prototype the layout of the mobile application.

- 4.1.4.1 This product allows for the conceptualization and visualization of the system's user interfaces, considering the visual impairments of the intended main users.
- 4.1.4.2 The product is a communication tool for the mobile application's features and a style guide.

## 4.2 Reuse of Existing Software Components

The application will not reuse existing software components but will utilize Damoov's Telematics SDK and the user interface library Flutter.

## 4.3 Future Plans for Extending or Enhancing the Software

The system currently has the ability to monitor and label driving events. However, it should also employ a machine learning algorithm that assesses the user's glaucoma stage given various driving events as features. The physician responsible for the patient should be alerted if the machine learning algorithm detects that the patient's glaucoma may have progressed too rapidly or to a severe stage. Implementing the machine learning algorithm should be the primary focus of future iterations of the application. For this work the application requires users to build the algorithm to ensure proper use of it as well as notify physicians if a user's driving score drops.

## 4.4 User Interface Paradigms

4.4.1 Interface prompts new patients/physicians to register

- 4.4.1.1 To register an account, the User database will be updated, allowing credentials to be securely stored for users to conveniently log in and out as needed.
- 4.4.1.2 Interface visual design colors set to contrasting colors.
  - 4.4.1.2.1 No harsh colors ideal for individuals with glaucoma
- 4.4.1.3 Existing users will be prompted to log in
  - 4.4.1.3.1 The system authenticates credentials during both registration and login processes to ensure validity
  - 4.4.1.3.2 The system will also facilitate users in retrieving their credentials in case of loss

4.4.2 Interface opens up with a homepage that contains a navigation bar that should be present on both patient and physician screens providing distinct functionalities for both

- 4.4.2.1 The logged-in patients can access a homepage that lets the user know that tracking is enabled/on. They can also access a settings page where they can edit their profile, learn about the application and it;s purpose, the privacy statement and request their data.
- 4.4.2.2 The physician's homepage will be a central hub for physicians to oversee patient statistics. This includes the patient's score, and any other relevant details needed to assess the progression of glaucoma like acceleration, braking, cornering, sudden stops, phone usage.

4.4.3 Adaptive and Responsive Design

- 4.4.3.1 Cross-Device Compatibility: The interface adapts to different devices, ensuring usability and accessibility regardless of the device used.

4.4.3.2 Accessibility Features: Includes options for font size adjustments, contrast settings, and voice-over text for visually impaired users.

## 4.5 Hardware and/or Software Interface Paradigms

4.5.1 Smartphones must include a triaxial accelerometer, gyroscope, and magnetometer for recording sensor readings, as these sensors are required for driving data collection within the system.

## 4.6 Error Detection and Recovery

This project implements exception management and detailed issue logging to handle program errors effectively. These mechanisms prevent mishaps like inadvertent data exposure or incorrect data associations. Reducing such errors through thorough debugging ensures proper functionality. For the recovery process, these practices play a crucial role. They aid in troubleshooting or replicating issues, making it easier to identify errors and ensuring a swift resolution, thus maintaining an uninterrupted workflow.

## 4.7 Memory Management Policies

The mobile application will be developed using Dart, which uses a garbage collector to automatically manage memory, meaning that once the object is no longer in use, the garbage collector will automatically free up the memory used by any function or call. Memory leaks in Dart may arise when objects are inadequately deallocated, accumulating unused memory. To address this, attention should be given to closing streams, avoiding cyclic references, managing global variables, and using Dart DevTools to detect and rectify potential leaks.

## 4.8 External Databases

The application relies on Damoov's DataHub storage infrastructure. By integrating the Telematics SDK into the system, it generates a unique user ID and JSON web token for robust account authentication and authorization. This SDK seamlessly refreshes, processes, and validates data using the JSON web token mechanism. Through Firebase, the application ensures user verification, establishing a secure pathway to interact with Damoov's DataHub storage to retrieve requisite information. Authorized personnel are granted on-demand access to both raw and processed data, with controlled data destruction.

## 4.9 Distributed Data/Control over a Network

The data distribution process with  the smartphone's sensor readings, grabbing the users token from Firebase. The application processes the data along with the UID and sends it to Damoov's Datahub storage which uses server-side encryption, encrypting each data record with an Advanced Encryption Standard Key (AES-256 Key) for data security and privacy.

## 4.10 Generalized Approaches to Control

Code, research, and libraries are in private Github repositories and Dropbox folders. Before any changes are made, they are thoroughly reviewed and discussed.

## 4.11 Concurrency and Synchronization

The programming language Dart provides features and mechanisms to handle concurrency and synchronization in the context of asynchronous programming. Dart supports isolates which are lightweight concurrent threads of execution and have their own memory space allowing them to execute concurrently without sharing memory or data. Dart also supports the synchronized keyword "synchronized" that can be used to create a synchronized block of code, ensuring that only one isolate can execute the block at a time.

## 4.12 Communication Mechanisms

The HTTPS protocols update the application and data migration to DataHub storage. The application uses post and get requests to retrieve data from Datahub.

# 5. System Architecture

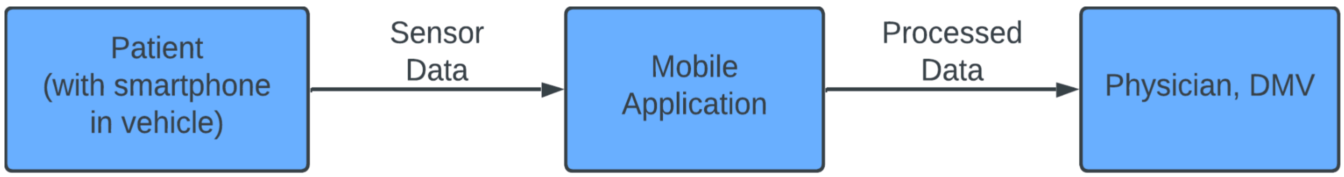



Figure 01: DFD Level 0

The system involves the patient, the application, and the physicians. The application must periodically collect sensor data from the smartphone while the patient is driving. Once the drive is completed, the application processes the raw data, which is sent to Damoov's DataHub . The processed data will be accessible through the physician's device or, in dire circumstances, relayed to the DMV as a CSV file.

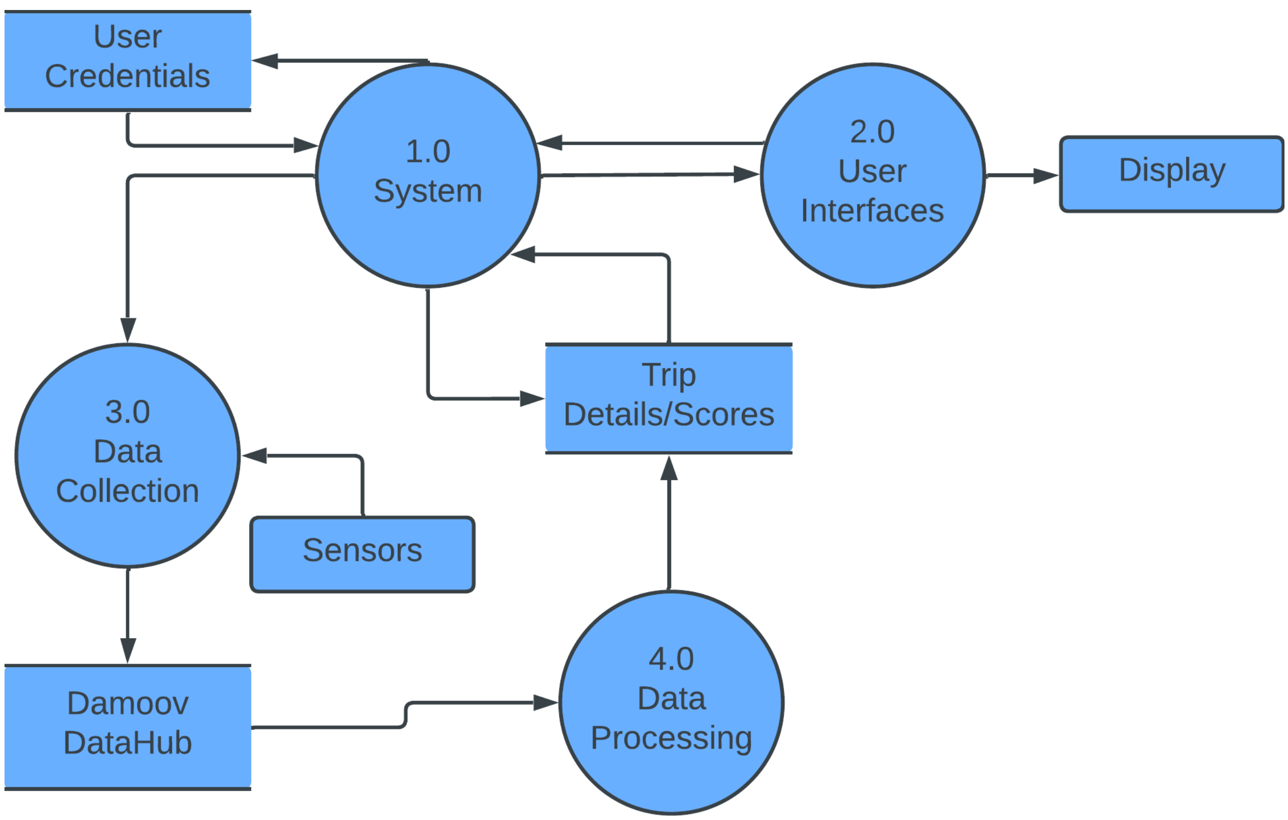



Figure 02: DFD Level 1

## Entity-Relationship

The system is responsible for collecting and processing driving data and displaying different user interfaces for the patient and physician. This is split into four modules in the system. The System module will communicate with the User Interface module to update the display. From the login screen, the User Interface module will send the user credentials to the System module to verify the account information stored in the User Credentials database. Once logged in, the System module will automatically collect data when driving is detected. The collected data will be encrypted and sent to the data storage platform DataHub. Once the driving has stopped, the Data Processing module will receive the data to analyze trip details and calculate driving scores. The processed data will be stored in a database where the System module can send it to the User Interface module to display.

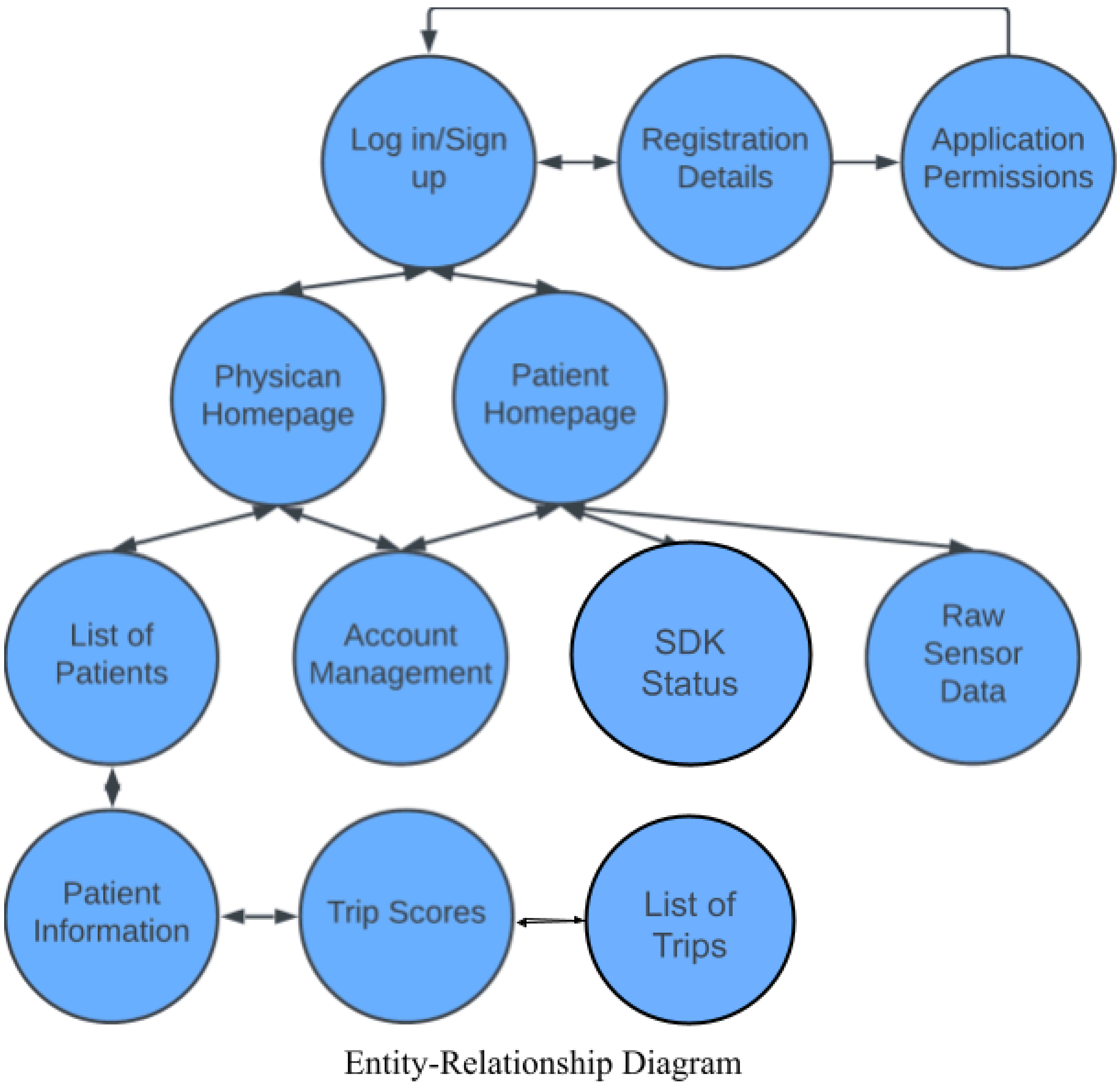



Figure 03: Entity Relationship

# 6. Detailed System Design

## 6.1 Module-1 Registration/Login/Logout

**Definition:** The module enables users to create an account, log in and log out when needed, and retrieve credentials if they are forgotten.
**Responsibilities:** The module is responsible for providing login and logout functions for existing users and a registration function for new users. This component also provides account retrieval for users who forget their credentials.
**Constraints:** This component requires users to provide physician or patient credentials when registering an account to help users enter different user interfaces. Patients cannot access the physician's page or observe their own driving data
**Composition:** This component requires physician credentials or patient credentials to proceed with the registration step. When registering as a physician, you also need to provide your full name, email, password, phone number and NPI. When patients register, they only need to provide their email address and password. Email and password will be used to log in. Patients may also select their physician from a dropdown menu of registered physicians.
**Uses/Interactions:** Users can register for an account, enter their email and password to log in to the application, and retrieve forgotten passwords.
**Resources:** Users need an internet connection to upload their credentials.
**Processing:** The system verifies credentials during registration and login to ensure authenticity. Processes user role information to provide appropriate access levels and interface customizations. Implements secure encryption methods for password storage and retrieval. Manages user sessions for secure login and logout operations.
**Interface/Exports:**

- User-Friendly Registration Form
- Secure Login Interface
- Password Recovery Option
- Role-Based Interface Customization
- Logout Button
- Confirmation Prompts
- Error Messages and Guidance

## 6.2 Module-2 Patient Homepage

**Definition:** The patient homepage component allows users to view the status of the tracking of the driving events. The patient can also access a tutorial that goes over the features of the application from their end, they can navigate to the settings to edit their profile, look at some information about the application, privacy statement and the ability to request their data.

**Responsibilities:** The patient homepage component's main responsibility is to provide an simple interface that shows the tracking status for driving events.When a drive begins, the speed of the vehicle will also be shown.

**Constraints:** The patient homepage component must not provide any information about the patient's driving score, driving habits, or driving events. This information must be made solely available to the patient's physician.

**Composition:** Within the settings page, the user may request to view the raw sensor information collected from each drive as a CSV file, in compliance with the California Consumer Policy Act (CCPA).

**Uses/Interactions:** The patient may use the patient homepage component to view the status of the SDK to ensure proper tracking of driving events and trips.

**Resources:** The patient's homepage must have internet access to perform computations and write the computed values to the patient's homepage.

**Processing:** The drive mileage may be calculated by monitoring the patient's driving route using their smartphone's GPS. Drive time can be calculated as the difference in start and end time, which are respectively measured as the time when an individual began accelerating quickly and the time when an individual ceased to accelerate significantly for more than two minutes.

**Interface/Exports:**

- Status of Tracking
- Quick Tutorial
- Settings
- User-Friendly Navigation and Layout

## 6.3 Module-3 Personal Information

**Definition:** The personal information component allows users to view and modify their personal information. It additionally enables users to add or change a physician.
**Responsibilities:** The personal information component allows users to view and add to their personal information (i.e., their age, their birthday, optional parameters) and their physician's name. Additionally, in compliance with the CCPA, individuals may modify their age and request that sensory information collected from certain drives be deleted. Patients will have access to view the application's mission statement and privacy statement from this module as well.
**Constraints:** The user may only search for physicians who have registered with the application.
**Composition:** The personal information module will be composed of a submodule listing the user's email, registered age or text field for entry, registered gender or text field for entry and the physician who has access to the patient's data.
**Uses/Interactions:** The patient may use the personal information page to view and modify their personal information and search for a physician within the list of registered physicians within the system.
**Resources:** The personal information page must have access to the internet to access the patient's information within the database and write the information to the page.
**Processing:** Upon registration, the patient's personal information will be stored in a secure and encrypted database associated with a unique user identification number (henceforth, user ID). The information will then be written to the personal information page every time the user accesses it. The dropdown menu within the signup module will display all registered physicians. Users may also be able to change passwords within this module by modifying the record in the database.
**Interface/Exports:**

- User Profile Editing Interface
- Physician Selection Tool
- Data Deletion Request Feature

## 6.4 Module-4 Physician Homepage

**Definition:** This component acts as a centralized dashboard for physicians to access and assess patient data.
**Responsibilities:** The physician homepage serves as the primary interface for physicians to interact with the system. It provides a comprehensive overview of all registered patients, their recent driving data, and alerts or notifications regarding any significant changes in a patient's condition.The patient list includes the patient email and their aggregated overall safety score. A list item may be clicked to view a list of summary scores including the total mileage, time, and number of trips a patient has driven. A patient's summary screen will be able to direct to a list of a detailed list of all recorded
**Composition:** This module may include subsections such as patient lists, recent alerts, and tools for data analysis. Each patient record could provide a quick overview of the patient's recent driving behavior and any notable trends or concerns.
**Uses/Interactions:** Physicians can use this module to navigate to individual patient profiles quickly, review detailed driving data, and make informed decisions about their care. This module might also offer functionalities for setting preferences, managing notifications, and accessing historical data for comparison.
**Interface/Exports:**

- Flutter
- Dashboard Layout
- Interactive Patient List
- Alerts and Notifications Panel
- Data Visualization Tools
- Quick Access to Patient Profiles
- Appointment Scheduler Interface
- Messaging Interface
- Customization and Settings
- Export Functionality
- Help and Support Access

## 6.5 Module-5 Patient View

**Definition:** The patient view component enables physicians to observe the driving statistics of their patients.
**Responsibilities:** The patient view component allows physicians to observe the patient's overall score, acceleration score, braking score, cornering score, etc. From this data, alerts or notifications can be generated to alert physicians about changes in a patient's condition. They may also view all recorded drives and an overall summary scores page for analysis and comparison.

**Composition:** This component includes all the patient's driving details, such as overall profile, driving time, acceleration, braking, cornering, etc., and provides specific scores to provide a snapshot of the patient's recent driving.
**Uses/Interactions:** This component allows the physician to access a patient's personal file to view their recent detailed driving data and conditions and quickly judge the patient's condition.
**Resources:** This component requires secure and accurate data processing tools to help physicians analyze patients' driving conditions.
**Interface/Exports:**

- Driving Data Dashboard
- Patient Profile Overview
- Alerts and Notifications Panel
- Patient Selection Interface
- Score Explanation and Guidance
- Data Visualization Tools

## 6.6 Module-6 Physician Personal Information

**Definition:** The Physician Profile Management module empowers physicians to seamlessly oversee their professional profiles within the system.
**Responsibilities:** This component allows physicians to diligently maintain their contact information, upload and revise professional credentials, and fine-tune system usage preferences to enhance workflow and interactions within the platform.
**Composition:** This module includes sections for updating personal and contact details, inputting professional qualifications, managing communication and notification preferences, as well as bolstering account security through robust password management tools.
**Uses/Interactions:** This module helps physicians keep their profile current for effective communication with patients and system administrators. It provides the flexibility to customize how notifications and reports are received, ensuring that physicians stay informed on patient activities and system updates in a manner that best suits their needs.
**Resources:** Physicians are equipped with a suite of features to refine their professional profile, including:

- A user-friendly interface for editing personal and professional details.
- A secure platform for managing and updating medical qualifications and credentials.
- A personalized system for setting notification preferences and alerts.
- Comprehensive support resources for assistance and troubleshooting within the system.

**Interface/Exports:**

- Intuitive Profile Editor for easy management of personal information.
- Credentials Management to keep professional qualifications up-to-date.
- Customizable Notifications and Alerts for tailored communication.
- Direct Access to Support and Help Resources for streamlined assistance.

# 7. Graphical User Interface Design

The Homepage UI is displayed when the application is first launched (Figure . The user can log in, sign up, or reset their credentials from this UI. The fonts and buttons are large, and the colors used are comfortable for patients with low vision and are high-contrast which makes it easy to read. These design considerations will be seen throughout every patient-related UI.

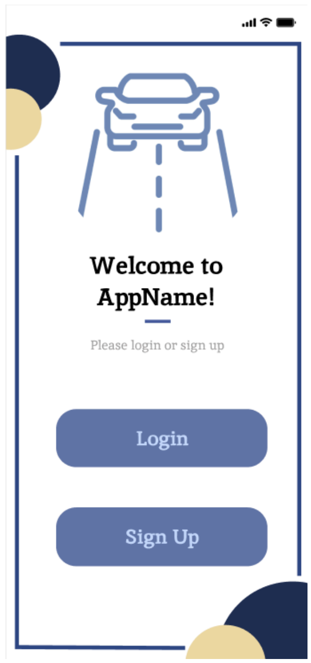



Figure 04: Homepage UI

The Sign-Up UI is displayed in Figure 05. Through the Sign Up Portal (a), the user may register as either a physician (b) or a patient (c).

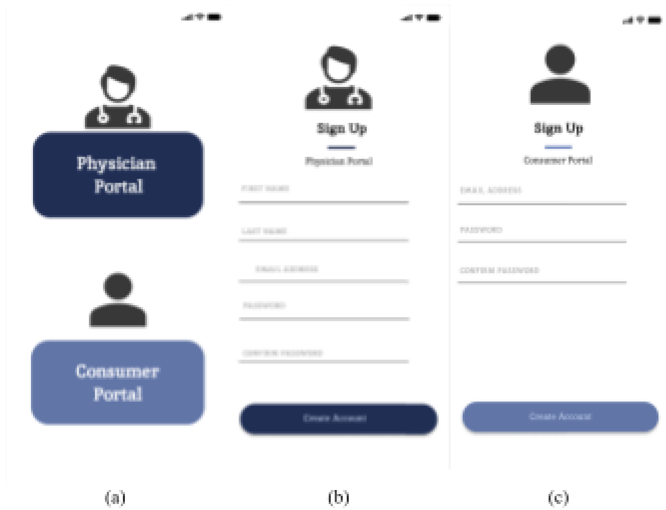
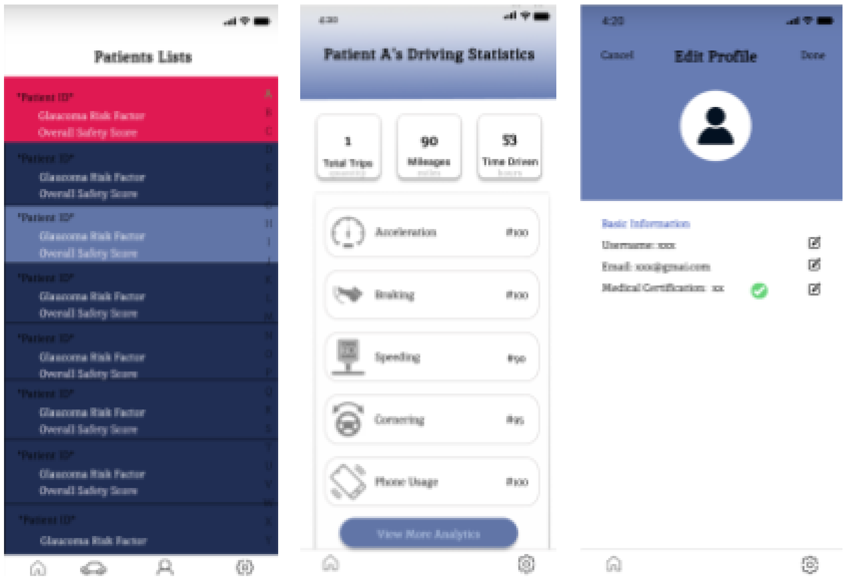



Figure 05: Sign-Up UI

The Patient Homepage UI simply has text to indicate that the app is tracking their drive. Also provided is a button to redirect the patient to their account settings, where they can update their credentials and request the collected raw sensor data (Figure 06).


Figure 06: Patient Homepage UI

The Physician Homepage UI allows the physician to select from a list of patients and view each individual's driving statistics. The physician may also navigate to their account settings to update their account credentials.




(a) (b) (c)

Figure 07: Physician Homepage UI

## S. Glossary

**Advanced Encryption Standard (AES) 256:** Symmetric cipher that generates a 256-bit key to encrypt and decrypt data

**California Consumer Privacy Act (CCPA):** State law that grants consumers rights over personal information collected and requires businesses to inform consumers about the collection, use, and retention of their personal information

**Comma-separated Values (CSV):** Text file format where tabular data data is stored in plain text where a data record is represented in a single line

**Institutional Review Board (IRB):** Appropriately composed group formally assigned to review and monitor biomedical research involving human subjects

**Damoov:** Telematics infrastructure that provides a software development kit for processing smartphone-sensor-collected driving data and configuration to internal online data storage platform DataHub

**Dart:** Programming language developed for app development

**DataHub:** Damoov's online data storage platform that acts as the backend configuration for products using the Telematics software development kit

**Digital Phenotyping:** Moment-by-moment quantification of human phenotype using personal digital device data

**Figma:** Industry-standard, collaborative web application for designing interfaces

**Flutter:** Open-source user interface software development kit created by Google for cross-platform development

**Glaucoma:** General term for a group of eye diseases that damage the optic nerve and leading cause of blindness for individuals over the age of 60

**Gyroscope:** Measuring device in smartphones that measures orientation and angular velocity

**Health Insurance Portability and Accountability Act (HIPAA):** Federal law requiring national standards to protect medical information from being disclosed without a patient's knowledge or consent

**JavaScript Object Notation (JSON):** Text-based, data-interchange format that can be structured as a list of a collection of name/value pairs or an ordered list of values

**Magnetometer:** Measuring device in smartphones that measures the magnetic field using the axes of motion for orientation sensing

**Software Development Kit (SDK):** Collection of software development tools

**Sound Null Safety:** This feature guarantees that when a program and all its libraries are migrated, variables are not unintentionally null to prevent errors

**Stateful Live Reload:** This feature allows for inserting edits to files and refreshing the whole application with changes

**Triaxial Accelerometer:** A measuring device in smartphones that measures acceleration using the axes of motion compared to gravity

**Unique Identifier (UID):** A identifier that is unique to devices.