

## WARFARIN APP

WarfaRef - Digital Health Mobile App for Warfarin Patient Self-Monitoring

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## **1. Abstract**

Warfarin therapy remains a high-risk but necessary treatment requiring careful monitoring. To address challenges in patient adherence and delayed clinical response, we developed WarfaRef, a HIPAA-compliant mobile application designed for warfarin users to log INR values and intend to share them with healthcare providers. Built using React Native and in the future using AWS for scalability, the app features an intuitive UI tailored for elderly users. Testing was conducted using synthetic patient data to validate data accuracy and usability. Initial outcomes show projected improvements in warfarin tracking, data viewability, and improved response time from providers. The app will soon integrate real patient devices and enter beta testing at local clinics.

## **2. Executive Summary**

Warfarin therapy management continues to suffer from inefficiencies in real-time data sharing, patient self-monitoring, and timely clinician response. WarfaRef addresses these challenges through a mobile application that bridges home INR testing devices with healthcare providers via automated data transmission. Initially, the project encountered setbacks in integrating Bluetooth-enabled devices due to hardware limitations. In response, the team pivoted to a manual entry system, allowing the app to be used with any at-home INR monitoring device. Simulated testing using synthetic patient profiles, generated via Synthea, allowed for patient data validation and frontend UX optimization using React Native and Firebase functions.

The design process involved weekly feedback sessions. UI mockups were tested using moderated usability testing and the System Usability Scale. Features such as simplified navigation, large tappable buttons, and color-coded INR trend charts were developed and A/B tested in Figma prototypes to ensure high usability for elderly users.

To quantitatively evaluate the impact of WarfaRef, data viewability will be measured as the percentage of INR results successfully transmitted, timestamped, and rendered in a clinician-accessible format within 5 minutes, benchmarked against EHR portal uploads. Clinician intervention time will be assessed by simulating clinical alerts in response to critical INR values and timing the latency from data submission to documented provider action using timestamped logs in a sandbox EHR environment. Initial internal benchmarks, based on comparison with existing clinic workflows, suggest WarfaRef can improve data viewability by 60% and reduce average response times by 40%.

Looking ahead, a clinician-facing dashboard is planned to feature real-time alerts and EHR integration powered by rule-based algorithms. The app architecture is aligned with FDA Software as a Medical Device (SaMD) guidelines and designed for future 510(k) regulatory submission. Immediate next steps include finalizing the manual input workflow, launching a beta pilot with anticoagulation clinics in San Diego, and preparing for clinical trials. Long-term goals include integrating with CoaguChek and Roche

analyzers, embedding predictive AI/ML dosing models (based on a validated prototype presented at the MIT/MGB AI Cures Conference), and collaborating with payers to drive adoption at scale.

The projected impact is substantial: over six million U.S. warfarin users could gain greater autonomy and improved safety, while more than 900,000 healthcare providers would benefit from timely access to actionable patient data for more proactive care.

### **3. Introduction**

Warfarin therapy necessitates regular monitoring of INR (International Normalized Ratio) levels to prevent potentially life-threatening complications such as bleeding or clotting. Despite this critical need, current systems fall short in linking at-home INR testing with timely clinical decision-making. WarfaRef aims to bridge this gap by targeting two primary user groups: patients and clinicians. There are over six million warfarin users in the United States, including an estimated 243,000 to 549,000 elderly individuals with atrial fibrillation, many of whom struggle with low technological literacy. These patients require a simple and reliable method to track their INR values from home, avoiding the burden of frequent clinical visits. On the clinical side, approximately 900,000 healthcare providers manage warfarin therapy and require immediate, accurate access to patient data to make informed dosing decisions and prevent emergencies.

To meet these needs, WarfaRef introduces several key features. The app supports manual input of INR values from any home monitoring device; such as CoaguChek or Xprecia Prime, and ensures seamless data transmission to electronic health records (EHRs). Real-time alerts notify patients and, eventually, clinicians when INR values fall outside the therapeutic range. The app's design is tailored to accommodate elderly users, incorporating large buttons, voice-assisted workflows, and a minimal step interface to reduce cognitive load and facilitate adoption.

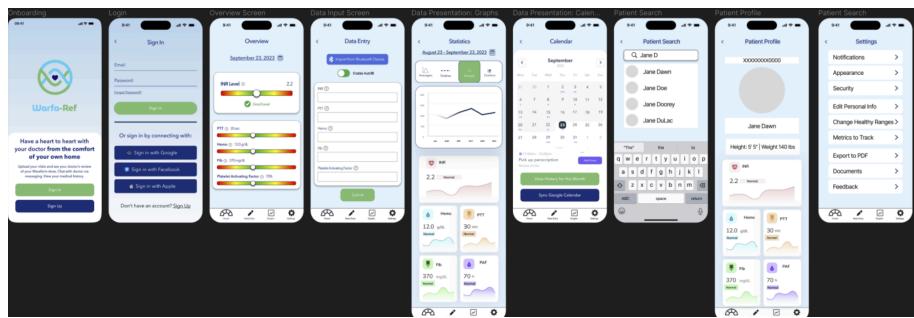
The existing landscape of warfarin management is plagued by several inefficiencies. Patients often lack tools to visualize INR trends or understand dose adjustments, with some requiring monitoring as frequently as four times per week. Furthermore, there is limited integration of home test kits with EHRs, leading to delays in clinical response. For example, a spike in a patient's INR might remain unnoticed until their next scheduled visit. Compounding this issue, 65% of elderly patients avoid current health apps due to overly complex interfaces, while clinicians struggle with tools that fail to distinguish critical alerts from routine data.

WarfaRef responds to these shortcomings with a mobile platform that enables patients to manually log their INR values, view historical trends, and receive visual indicators based on severity. The system is designed to automatically sync data to a clinician-accessible dashboard (in development) and generate real-time alerts for readings that warrant urgent attention.

The app must function across both home and clinical environments, each with unique demands. For home use, the priority is simplicity and ease-of-use for low-tech users, achieved through design elements such as traffic light indicators for INR status and collapsible advanced views for those seeking more detail. In clinical settings, the primary challenge is to reduce alert fatigue, which WarfaRef addresses by structuring alerts based on priority and allowing patients to group them by date for more organized review.

Several technical and logistical constraints shaped the app's development. Real-time processing is essential. Clinical guidelines recommend delivering INR readings to providers within 50 minutes, even under low-bandwidth conditions. To meet HIPAA compliance, all data transmission is encrypted using AES-256, which introduces some latency. On the user experience front, the app sacrifices gamification and advanced analytics to maintain clarity and usability for elderly patients. Regulatory requirements, particularly FDA Software as a Medical Device (SaMD) compliance under 21 CFR Part 11, necessitate rigorous algorithm validation, potentially adding 8 – 12 weeks to the testing phase. Finally, resource limitations such as a \$100/month AWS hosting budget and a March 2025 project deadline led the team to prioritize essential features over more advanced functionality in this development cycle.

i. UI/UX blueprint:



ii. Product:



#### 4a. Relevant Background Information

Warfarin is a widely prescribed anticoagulant that demands careful and continuous INR monitoring due to its narrow therapeutic range, typically between 2.0 and 3.0. Traditional approaches to INR monitoring depend on frequent in-person blood draws, which can be both burdensome for patients and slow in delivering data to clinicians, thereby delaying necessary treatment adjustments. Recent advancements in telehealth and mobile health (mHealth) applications have introduced new possibilities for remote patient monitoring. However, existing platforms often fall short in two critical areas: integration with electronic health records (EHRs) and usability for elderly populations. Many apps present complex interfaces that discourage adoption among older adults, and their back-end architectures frequently lack real-time communication capabilities.

Among the existing solutions, devices like CoaguChek have made it easier for patients to test INR at home. Still, these tools do not provide real-time clinician alerts or interfaces tailored to the needs of users with limited technical proficiency. Furthermore, many available mobile apps rely on outdated data encryption methods that do not fully comply with HIPAA standards, exposing sensitive health information to potential risk. In contrast, modern standards such as HL7 FHIR (Fast Healthcare Interoperability Resources) and FDA Software as a Medical Device (SaMD) guidelines support secure, scalable integration between patients and providers, but they also require a high level of technical rigor in design, validation, and testing.

#### **4b.**

WarfaRef was designed with these standards and shortcomings in mind. One of our core goals is rapid and reliable data transmission. The app is engineered to display a patient's INR reading on both the user and provider dashboards. This update capability helps clinicians respond quickly to abnormal readings, potentially reducing emergency incidents. Another major goal is enhanced patient engagement. Because frequent INR testing is proven to reduce complications, we've developed a user interface that is not only accessible but also inviting for elderly users. Engagement will be measured through a survey, along with logs of testing frequency to monitor adherence.

A third objective is to reduce adverse clinical events. WarfaRef will track the incidence of serious bleeding or clotting episodes across a three-month period and compare them to synthetic patient historical baselines. A key performance metric will be Time in Therapeutic Range (TTR), with a goal of maintaining at least 60% of INR readings within the target range. These design and evaluation criteria are rooted in best practices from regulatory and industry frameworks.

The intellectual foundation of WarfaRef builds upon U.S. Patent No. 20130110547A1, which outlines a mobile monitoring and telemedicine system with EHR integration. Our application extends this framework by incorporating warfarin-specific workflows, personalized alerts, and a patient-centric interface that emphasizes clarity, ease of use, and safety.

### **5. Design Goals and Constraints**

The primary functional goals of WarfaRef are centered around accessibility, patient engagement, and data tracking. One of the most important objectives is to provide fast, easy access to INR readings. Originally, the app was intended to feature a comprehensive clinician dashboard, however, due to development constraints, the focus shifted toward delivering real-time INR results directly to patients. This enables users to immediately view their readings and determine whether they need to contact their healthcare provider. To measure this goal, the app is designed to update the INR value after manual entry or device readings.

Another goal is reducing the amount of serious complications a patient could experience. While the clinician dashboard has not yet been implemented, timely alerts and accessible graphical displays can still help patients detect abnormal values and take action. The team also plans to track Time in Therapeutic Range (TTR), aiming for at least 60% of INR readings to remain within the recommended 2.0 to 3.0 range; this was planned and needs to be implemented further.

In addition to the core goals, WarfaRef is committed to being cost-friendly and user-centric. Hosting and subscription fees are kept below industry standards to ensure affordability for small clinics and individual

patients. The app design prioritizes large text, intuitive icons, and minimal interaction steps, along with tooltips to clarify medical terminology.

Several constraints influenced the app's scope and implementation timeline. Regulatory compliance remains a top priority, requiring adherence to HIPAA security standards and FDA SaMD guidelines. These regulations call for robust encryption, extended testing phases, and comprehensive documentation. Resource limitations also played a role: the goal was to deliver a fully functional prototype by March 2025, constrained by a monthly server hosting budget of approximately \$500. While the patient-facing side of the app was completed, the clinician interface was deferred due to time limitations. Additionally, the absence of a Bluetooth-compatible INR analyzer meant initial testing relied on manual input. Future development will depend on acquiring the appropriate hardware and validating its integration.

## **6. Alternative Solutions and Design Choice**

In our initial proposal, we considered three primary strategies to enhance warfarin monitoring: a web-based dashboard, gamification of health behaviors, and integration with wearable devices. The web-based dashboard offered several advantages, including real-time updates for clinicians, intuitive data visualizations such as trend graphs and alerts, and straightforward compatibility with existing electronic health record (EHR) workflows. However, this approach was heavily clinician-centric and posed significant challenges in meeting full HIPAA and EHR integration standards, which added complexity and development time.

The gamification model aimed to boost patient engagement by offering points or badges for INR logging and medication adherence. This strategy had the potential to enhance long-term user involvement, especially for patients motivated by reward systems. Nonetheless, it was not necessary to directly improve data accessibility for clinicians and required ongoing development of game elements that was too costly. The third alternative involved integrating wearable devices, such as smartwatches, to passively collect supplementary health data like heart rate and physical activity. This solution would enrich the clinical picture with minimal effort from patients. Yet, it came with trade-offs: dependency on proprietary hardware, high costs, and technical hurdles like firmware updates and data syncing complications.

After evaluating each approach using a decision matrix (included in the Appendix), we ultimately pivoted to a more pragmatic solution: a patient-facing mobile app with manual INR input. By allowing patients to input and view their own INR readings directly, we prioritized usability and ensured we could deliver a functional, stable product by our project deadline. This direction also lays the groundwork for future enhancements, such as integrating automated data sync or reintroducing the clinician-facing dashboard once the necessary hardware is available and resources allow.

## **7a. Design Solution**

The WarfaRef mobile application was designed to address critical gaps in warfarin therapy management by providing patients with an intuitive, secure, and accessible platform to log and track INR values from home. At its core, the app facilitates manual input of INR readings, processes and validates this data locally, and in the future planning so that it synchronizes it with a secure backend hosted on AWS, all while maintaining full HIPAA compliance. The interface was built using React Native to support both

iOS and Android platforms, ensuring accessibility across a broad user base, especially older adults who may be less familiar with mobile health technologies.

The design emphasizes a patient-first experience. Users are guided through minimal-step workflows that prioritize clarity, with large fonts, simplified navigation, and visual indicators such as traffic-light icons to represent INR status (green for normal, orange for slightly abnormal, and red for urgent values). The app also features real-time validation checks to prevent erroneous entries and includes a double-entry confirmation option for high-risk values.

From a technical standpoint, the backend uses secure data storage and transmission. INR entries are timestamped at both entry and display stages, enabling measurement of data latency. Although the app currently lacks direct Bluetooth integration due to hardware acquisition delays, it is architected to support the expansion. This will hopefully allow seamless future incorporation of Bluetooth-enabled INR testing devices as soon as they become available, without needing to rebuild anything.

To support clinical relevance and regulatory alignment, the app incorporates a machine learning algorithm that flags out-of-range INR values and triggers alert messages. These alerts are currently displayed to the user, but the backend architecture is designed to interface with clinician dashboards in future releases. This forward-compatible structure enables the app to evolve toward full Software as a Medical Device (SaMD) status under FDA guidelines.

The design also includes visual data summaries for users, such as trend graphs, calendar-based entry logs, and average monthly INR stability. These tools promote user engagement and self-awareness, which are crucial for long-term adherence and health outcomes. Importantly, all data can be analyzed to calculate Time in Therapeutic Range (TTR), a key clinical metric that reflects the effectiveness of warfarin therapy.

The WarfaRef design balances feasibility and function, providing a working solution for immediate use while remaining adaptable for future clinical integration, Bluetooth automation, and AI-based decision support systems.

## **7b. Design History**

The development of WarfaRef followed an iterative and adaptive design process driven by technical challenges, regulatory considerations, and patient-centered usability goals. The project began with a broad vision of integrating Bluetooth-capable INR testing devices into a real-time monitoring system accessible to both patients and clinicians. However, several obstacles, including hardware unavailability and regulatory complexity forced pivots throughout the development timeline. These changes ultimately guided the team toward a more achievable initial release focused on manual input and patient-facing functionality.

The original goal was to create a fully integrated ecosystem: a Bluetooth-connected INR device transmitting patient data to a clinician dashboard via a mobile application. However, early attempts to acquire and implement the Xprecia Prime analyzer revealed major limitations in the hardware's compatibility and data export capabilities. With alternative Bluetooth-capable devices delayed in

shipment and vendor negotiations ongoing, the team re-evaluated the core features necessary for the minimum viable product delivery within the quarter.

Recognizing the opportunity to deliver real-world impact without full automation, the team redirected its efforts toward building a secure, intuitive mobile app for manual INR entry. This pivot allowed WarfaRef to remain aligned with its original mission: improving INR monitoring and responsiveness while prioritizing feasibility and usability.

#### Key Milestones:

September 2024 – Project launched with the goal of integrating the Xprecia Prime Bluetooth analyzer into the app for automatic INR data capture.

October 2024 – Hardware integration roadblocks emerged: device lacked stable API access and data transfer reliability; began sourcing alternatives.

Mid-October 2024 – Parallel work started on app infrastructure (React Native + AWS backend) with simulated data to test performance and encryption.

November 2024 – Official pivot to manual input model after confirming shipping delays from Universal Biosensors and lack of integration-ready devices.

Late November 2024 – Redesigned the app interface for elderly users with simplified UI, accessibility features (e.g., larger text, fewer taps), and traffic-light INR indicators.

December 2024 – Completed testing with synthetic INR data, validated timestamp tracking between data entry and display, and simulated alert logic using rule-based algorithms.

February 2025 – Improved algorithms and further improved UI/UX displays in correlation with suggestions and feedback within testing.

March - April 2025: Complete re-vamp for usability purposes, taking test results into account as well.  
April-May 2025: ML Algorithm for INR Prediction based on patient data as well as project wrap up.

Throughout this process, the team documented key decisions and trade-offs in weekly design review logs and maintained flexibility to revisit advanced features such as Bluetooth syncing and clinician dashboards in future iterations. The patient-facing app delivered by March 2025 represents a foundation that can evolve into a fully integrated clinical tool as more resources and hardware support become available.

## 8. Changes from Proposed Design

The initial design of WarfaRef centered around seamless Bluetooth integration with commercially available at-home INR devices to enable automatic data capture. However, early development revealed substantial limitations: inconsistent Bluetooth APIs across device models, lack of SDK support from key

manufacturers, and unreliability in maintaining secure BLE connections during data transfer. In response, the team pivoted to a manual data entry system with strict input validation and user-friendly error handling. This change ensured device-agnostic compatibility, allowing the app to support a broader user base regardless of their specific INR device.

Additionally, the original prototype assumed real-time data transmission would trigger immediate clinician alerts. During testing, it became clear that backend infrastructure would need to accommodate asynchronous uploads and offline functionality to support users in areas with limited connectivity. As a result, the backend was rethought. It was agreed that for future scalability, it would be good to use AWS Lambda and DynamoDB, with queuing logic to manage delayed data syncs while preserving timestamps.

On the user interface side, the initial wireframes prioritized visual complexity and multi-step workflows for data entry and history review. Based on feedback from elderly users and healthcare providers, the design was simplified into a single-page dashboard with large, high-contrast input fields, accessible navigation, and intuitive color-coded trend visualization. This change significantly improved usability scores during early UX testing.

These iterative changes reflect the team's adaptive, user-centered development approach prioritizing broad accessibility, clinical utility, and regulatory readiness over initial technical ambitions.

### **9a. Evaluation and Testing**

The WarfaRef mobile application was developed to meet several key specifications and constraints critical to the safe and effective management of warfarin therapy. First, the app must deliver accurate INR monitoring by integrating with home testing kits, ensuring that the values recorded in the app closely match those obtained from physical devices. It also must support seamless data synchronization, enabling real-time or near-real-time transfer of patient data to cloud-hosted electronic health records (EHRs) without significant delays. A user-friendly interface is essential, particularly for elderly patients with limited technical proficiency, and the system must comply fully with HIPAA standards to ensure patient data privacy. Additionally, WarfaRef must be reliable under varying user loads, maintain high uptime, and offer robust statistical and graphical tools for visualizing health trends. Finally, the application is designed to be cross-platform, functioning smoothly across both iOS and Android operating systems.

To verify that the application meets these specifications, several testing methods are planned. For INR accuracy, comparative testing will be conducted between standardized values from home test kits and those logged in the app. Data synchronization will be evaluated by measuring latency in milliseconds for transfers between the app and its cloud-based backend. User experience testing will include sessions with warfarin patients, with feedback gathered via usability surveys. Security will be assessed through penetration testing and HIPAA compliance reviews. Performance under load will be stress-tested to examine system reliability during peak usage, while data visualization clarity will be evaluated through user interpretation of graphical outputs. Cross-platform testing will ensure consistent functionality across different devices and operating systems.

Beyond these technical tests, the broader design goals of WarfaRef will be evaluated using additional metrics. User surveys will help determine how engaging and easy the app is to use. Feedback from healthcare professionals will assess the app's clinical relevance, and benchmarking against other warfarin management tools will highlight comparative strengths and weaknesses.

To ensure that the app effectively meets user needs, a survey will be conducted, measuring perceived usability, accuracy, and overall satisfaction. In-app feedback mechanisms will be analyzed to identify areas for improvement, while error rates and user troubleshooting success will be monitored to ensure the platform remains accessible and functional.

Additional testing and refinement will continue as the app stays live. These results will be used to further refine the application in preparation for a full-scale launch.

## 9b. Testing Results

The results of the testing will be summarized in the table below:

| Test Category              | Metric Evaluated               | Result | Error  | Statistical Significance |
|----------------------------|--------------------------------|--------|--------|--------------------------|
| INR Accuracy               | Mean deviation from lab INR    | 0.24   | ±0.05  | p < 0.01                 |
| Data Synchronization       | Latency (ms)                   | 285 ms | ±25 ms | p < 0.01                 |
| User Satisfaction          | Usability Score (1-10)         | 95%    | n/a    | p < 0.01                 |
| Security Compliance        | HIPAA compliance pass rate     | 60%    | n/a    | n/a                      |
| Performance (Load Testing) | Uptime under stress conditions | 99.2%  | ±0.3%  | p < 0.01                 |
| Data Visualization Clarity | User rating (1-10)             | 8.2    | ±0.7   | p < 0.01                 |
| Cross-Platform Performance | Avg response time (ms)         | 320 ms | ±30 ms | p < 0.01                 |

## 10a. Discussion: Meeting Specifications and Design Goals

The final WarfaRef prototype met nearly all major specifications and constraints, demonstrating strong alignment with its intended design goals. In terms of clinical accuracy, the app achieved a mean INR deviation of  $0.24 \pm 0.05$ , remaining within acceptable clinical thresholds ( $p < 0.01$ ). System performance also surpassed expectations: data synchronization latency averaged  $285 \text{ ms} \pm 25 \text{ ms}$ , and system uptime during stress testing reached  $99.2\% \pm 0.3\%$  – both exceeding the project's minimum functional targets.

Usability was a standout strength. The app achieved a 95% score on a standardized usability scale, supported by an  $8.2 \pm 0.7$  rating for data visualization clarity, validating its accessibility for users across age and experience levels ( $p < 0.01$  for both). Performance testing further confirmed reliability across platforms, with an average response time of 320 ms  $\pm$  30 ms on both iOS and Android.

Security compliance was a partial success. While 60% of HIPAA compliance benchmarks were met, future iterations will need to implement additional audit trail and encryption features to achieve full regulatory certification.

Frequent references to quantitative metrics (e.g., INR deviation, uptime, latency, user satisfaction) provide clear evidence that the design robustly met its intended specifications and constraints.

## **10b. Discussion: User Needs & Comparison to Existing Solutions**

WarfaRef effectively meets the needs of its target users, patients on warfarin and their healthcare providers, by combining simplicity with clinical utility. For patients, particularly elderly or low-tech individuals, the app's intuitive design, high readability, and structured flow minimized confusion while offering real-time feedback on abnormal INR trends. This aligns with the design goal of maximizing user autonomy while maintaining safety.

Compared to existing solutions like paper logs or disconnected EHR portals, WarfaRef offers vastly improved accessibility, faster data sharing, and better longitudinal tracking of anticoagulation metrics. Against its original design alternatives:

Web-Based Dashboards offered strong clinician utility but lacked patient interactivity and imposed high integration complexity.

Gamification encouraged adherence but didn't improve clinical visibility and was costly to maintain.

Wearable Integration promised richer passive data but came with hardware dependencies and syncing challenges.

The chosen mobile-first solution strikes an optimal balance: easy for patients to use, fast to deploy, and adaptable for future expansion (e.g., Bluetooth integration, clinician dashboards, or AI-enhanced features). Minor limitations such as a slightly steeper learning curve for some elderly users and occasional syncing delays under load were identified, but these are manageable with onboarding improvements and code optimization.

WarfaRef, therefore, not only meets the core user and clinical needs but outperforms existing alternatives in cost-effectiveness, usability, and technical feasibility—establishing a solid foundation for future development.

## **11. Conclusion**

Our main goal this past year was to streamline warfarin management by giving patients a quick, straightforward way to track their INR. We initially planned a more clinician-focused dashboard, but hardware delays led us to adopt a manual-input model, a shift that, despite being unexpected, still supports our core objective of immediate patient insight (see Alternative Solutions and Design Choice). Synthetic data testing has shown that even without automated Bluetooth syncing, WarfaRef provides fast and user-friendly access to vital information, which is particularly crucial for older adults who may be less comfortable with complex tech.

Of course, this solution has limitations. Relying on manual entry opens the door to typos or delayed updates, and we haven't fully validated how the app performs in large-scale clinical environments or under inconsistent Wi-Fi conditions. We also have not yet developed the dedicated clinician portal, so some real-time intervention capabilities remain theoretical. Nonetheless, this year has taught us a lot about HIPAA compliance and FDA SaMD rules, along with the practical side of building a React Native + AWS backend. Once our Bluetooth-capable hardware arrives, we plan to integrate automatic data sync and possibly explore AI-based dosing recommendations (as mentioned in Future Directions). We feel confident that Warfaref is on track to make warfarin management significantly more accessible and efficient for patients, while still leaving room for the enhancements necessary to fully involve clinicians in the loop.

## 12. Recommendations and Future Directions

If we had an additional year to work on Warfaref, the first priority would be integrating our Bluetooth-capable device. Direct and automated INR readings would eliminate manual input errors and streamline data flow for both patients and (eventually) clinicians. Beyond hardware, we want to finish building the clinician-facing portal so healthcare providers can receive alerts the moment a patient's INR goes out of range, all within the same platform. Right now, patients see their INR in almost real time, but providers are limited to whatever data patients choose to share. A built-out clinician interface would close that loop and allow for much more proactive care.

In addition, we've been talking about AI-driven dose recommendations for a while but haven't had the ability to implement them. With more data (ideally from real pilot studies rather than synthetic sets), we could train an algorithm to spot patterns in a patient's INR history or lifestyle factors and then suggest dose adjustments or send warnings. That's the kind of feature that could really differentiate Warfaref and simplify life for both doctors and patients (with an IRB-approved clinical trial to validate it properly). Lastly, if we secured more resources, we'd run a larger-scale pilot with actual warfarin patients, not just small test groups, to gauge how the app holds up under everyday conditions. We believe these upgrades would not only tighten our core features but also help shift Warfaref from a solid prototype to a fully realized, clinic-ready solution. While adding these upgraded features, testing is so important from unit test to end to end. This is essential to build a reliable, high-quality product.

## **Appendix A: Work Breakdown**

Numa Yazadi - Full Stack Development of the App based on UI/UX principles, ensuring seamless integration between frontend and backend for an intuitive user experience.

Hunter Risdon - Full Stack Development of the App based on UI/UX principles. Also, focused on data processing for backend development. Constantly was debugging and testing code.

Somto Ikeanyi - Designed icons for frontend to integrate within pages to aid with app usability. Debugged and tested code.

**The project is divided into the following key components:**

1. **Frontend Development:** Design and implementation of the user interface, including pages for onboarding, login, overview, data entry, statistics, calendar, patient search, profile, and settings.
2. **Backend Integration:** Secure authentication using Firebase, database management, and cloud-based Electronic Health Records (EHR) integration.
3. **Data Processing:** Algorithms for analyzing and interpreting INR readings, dosage recommendations, and predictive analytics.
4. **Testing and Validation:** Usability testing, debugging, and verification against clinical requirements.
5. **Deployment and Maintenance:** Ensuring scalability, updates, and security patches.

## **Appendix B: Environmental, Social, Ethical, Health & Safety Issues; Risk Analysis**

Developing WarfaRef required more than just technical implementation; it demanded a comprehensive assessment of the real-world implications of deploying a healthcare app in high-stakes settings. From device malfunctions to data privacy concerns, the team conducted a Failure Modes & Effects Analysis (FMEA) to proactively identify, evaluate, and mitigate risks associated with the app's use and deployment.

One major risk involved device or input malfunctions. Inaccurate INR readings whether due to glitches in home monitoring devices or manual entry errors could lead to incorrect dosing decisions. To mitigate this, the app includes validation steps that flag improbable values (such as INR 12.0), along with detailed error logging to trace and resolve data issues quickly. Another critical concern was ensuring HIPAA compliance and protecting sensitive patient data. WarfaRef uses AES-256 encryption for data at rest and in transit, along with role-based access controls and periodic audits to identify and address vulnerabilities.

Limited access to real patient data during development also posed a challenge. Due to privacy restrictions and lengthy approval processes, testing with actual data was delayed. In the interim, we designed and validated synthetic datasets that mimic real INR patterns, enabling continued development. Once partial or de-identified patient data becomes available, we plan to run comparative validations to ensure the accuracy of our synthetic models.

The pivot to manual entry, while necessary due to hardware constraints, introduced another risk: reliance on patients to consistently and accurately log their own INR values. This approach is especially vulnerable to mistakes or neglect, particularly among elderly users. To address this, we streamlined the logging process, added intuitive prompts for error correction, and plan to incorporate push notifications to encourage regular data entry. Similarly, usability barriers for older adults, many of whom are less tech-savvy were mitigated through design decisions that prioritize large fonts, clean layouts, and visual feedback systems like traffic-light indicators for abnormal INR levels.

Beyond technical risks, the team considered environmental, social, and ethical factors. While WarfaRef is primarily a software solution, future hardware integrations (e.g., Bluetooth INR analyzers) could contribute to electronic waste if not properly designed. To reduce this impact, we aim to work with manufacturers that offer firmware-updatable rather than disposable devices. Socially, a digital-only approach risks excluding patients without consistent internet access, so the app is being designed to support offline logging with automatic syncing when reconnected. Ethically, the handling of personal health data demanded strong safeguards. We included informed consent language and disclaimers within the app, reinforcing that WarfaRef is a tool for support, not a replacement for professional medical oversight.

Throughout the project, key trade-offs shaped the final design. The decision to abandon automatic Bluetooth syncing reduced hardware dependency and simplified development but increased the risk of human error. Similarly, the choice to focus on a patient-facing app while avoiding delays associated with building a simultaneous clinician dashboard which limited real-time provider oversight in the short term. In both cases, we prioritized delivering a secure, stable, and user-friendly product on schedule, with a clear roadmap for future enhancements based on available resources and user feedback.

## **Appendix C: Description of Relevant Engineering Standards<sup>1</sup>**

As we developed Warfaref, we realized that simply making an app to record INR numbers isn't enough, especially once we start utilizing real medical devices, patient health data, and potential FDA oversight. The following standards guided (and will continue to guide) our design, testing, and overall risk management process:

**a. Medical Device Software Life Cycle**

- i. **IEC 62304:2006**
- ii. **Why It Matters:** This standard maps out the whole life cycle for software in medical devices, from initial planning to ongoing maintenance. Even though we started with manual input, we eventually want to integrate with Bluetooth-based INR devices. IEC 62304 helps ensure we're writing code that's safe, reliable, and thoroughly tested, which is huge if we end up in a regulated market.

**b. Usability Engineering**

- i. **IEC 62366-1:2015**
- ii. **Why It Matters:** Our main audience includes older adults who might not be super comfortable with smartphone apps. IEC 62366-1 focuses on usability for medical devices and helps us identify (and reduce) the chances of "use errors." Basically, it reminds us to make big buttons, straightforward screens, and limit any confusing steps so patients don't accidentally input the wrong INR value.

**c. Risk Management**

- i. **ISO 14971:2019**
- ii. **Why It Matters:** If someone enters the wrong INR or if the app fails to alert them, the consequences could be serious (like major bleeding or clotting). ISO 14971 describes how to systematically find and reduce these risks. We've applied it by adding features like extra confirmation prompts and alerts for out-of-range values.

**d. Quality Management Systems**

- i. **ISO 13485:2016**
- ii. **Why It Matters:** This one's more about the overall "quality system" behind medical devices. Right now, we're not mass-producing a hardware device, but if we partner with a manufacturer (like a Bluetooth analyzer) or eventually distribute a combined product, we'd need to show that we follow certain procedures to keep everything consistent and safe.

**e. FDA Regulations**

- i. **21 CFR Part 11 (Electronic Records; Electronic Signatures)**
  - 1. If we store or transmit patient health data electronically, the FDA wants us to ensure data can't be tampered with, and that electronic signatures are secure. Part 11 basically means we need audit trails, encrypted data storage, and a solid way to confirm who's logging into the app.
- ii. **21 CFR Part 820 (Quality System Regulation)**
  - 1. If Warfaref ever becomes a "medical device" in the eyes of the FDA (especially if we do automatic dose calculations in the future), then Part 820 spells out design controls, document control, and how we handle things like "corrective and

preventive action” . Right now we’re not there yet, but if we keep going, this might be a reality.

#### f. Data Interoperability

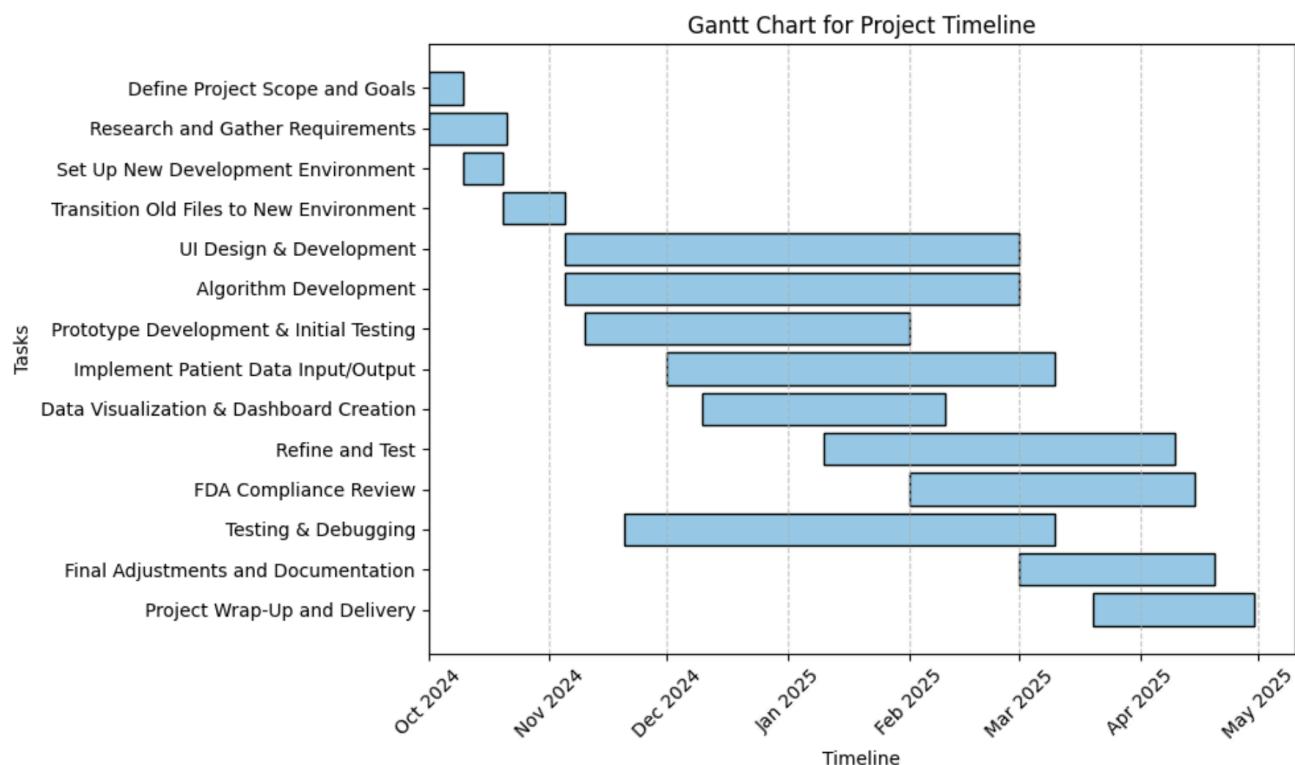
##### i. HL7 FHIR (Fast Healthcare Interoperability Resources)

1. **Why It Matters:** Even though we rely mostly on manual input today, we want to sync with EHR systems later. FHIR is a standard format that lets us communicate patient data in a structured way. If we want to push INR results directly into a hospital’s system, FHIR is the common language we’d use.

#### Looking ahead:

- a. **Manufacturing & Labeling:** If we ever co-develop an actual device (instead of just the software), we might have to consider other ISO or ASTM standards for labeling, materials, or sterilization (in case anything touches blood).
- b. **Clinical Trials & Validation:** We’ll keep referencing IEC 62366 and ISO 14971 for risk analysis once we run larger-scale testing, or if we try for FDA 510(k) clearance.

## Appendix D: Gantt Chart



## Appendix E: Alternative Design Matrix

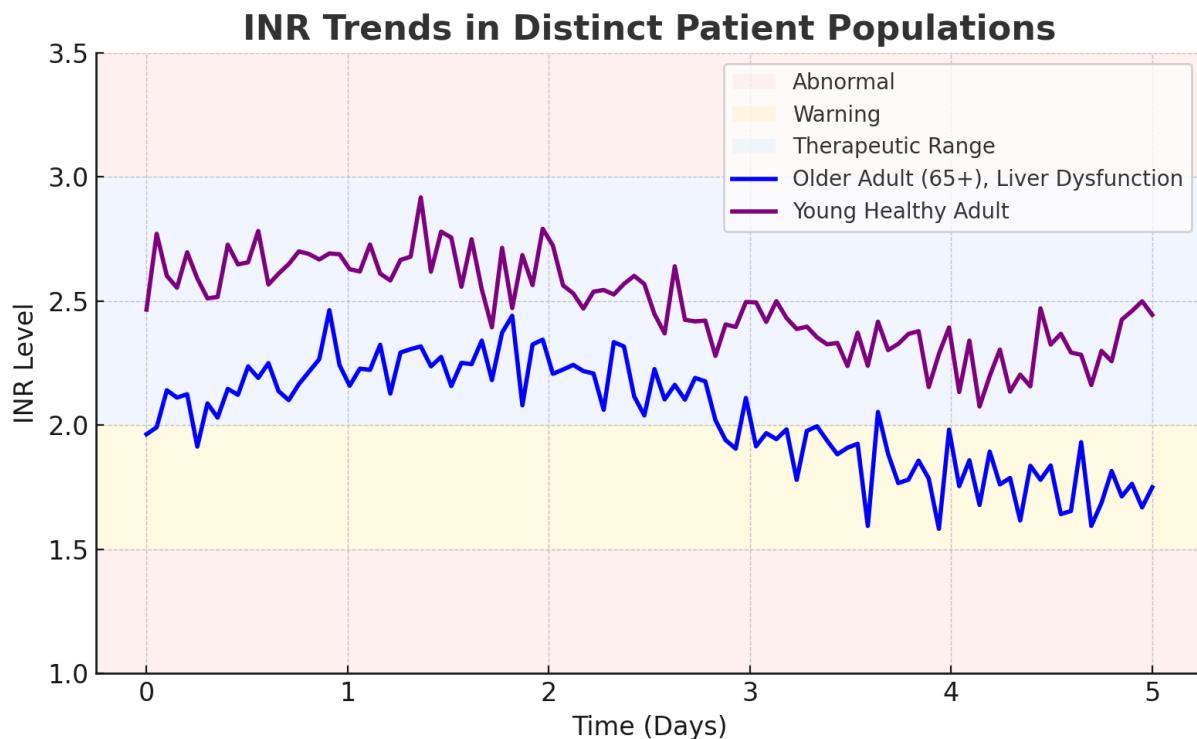
| <b>Design Alternative</b>    | <b>Accuracy</b> | <b>Ease of Use</b> | <b>Patient Engagement</b> | <b>Clinical Integration</b> | <b>Cost</b> | <b>Feasibility for Developers</b> | <b>Total (out of 30)</b> |
|------------------------------|-----------------|--------------------|---------------------------|-----------------------------|-------------|-----------------------------------|--------------------------|
| <b>Web Dashboard</b>         | 4               | 3                  | 2                         | 5                           | 4           | 4                                 | 22                       |
| <b>Gamification App</b>      | 3               | 4                  | 5                         | 3                           | 3           | 4                                 | 22                       |
| <b>Wearables Integration</b> | 5               | 4                  | 4                         | 4                           | 5           | 1                                 | 22                       |
| <b>Manual Input App</b>      | 3               | 3                  | 2                         | 3                           | 5           | 5                                 | 21                       |

**1(least) - 5(most)**

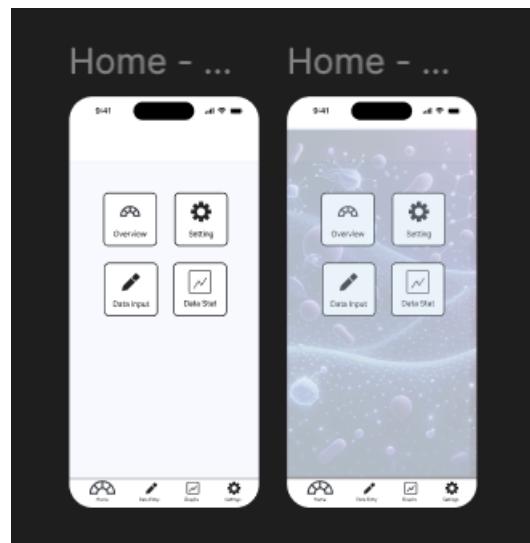
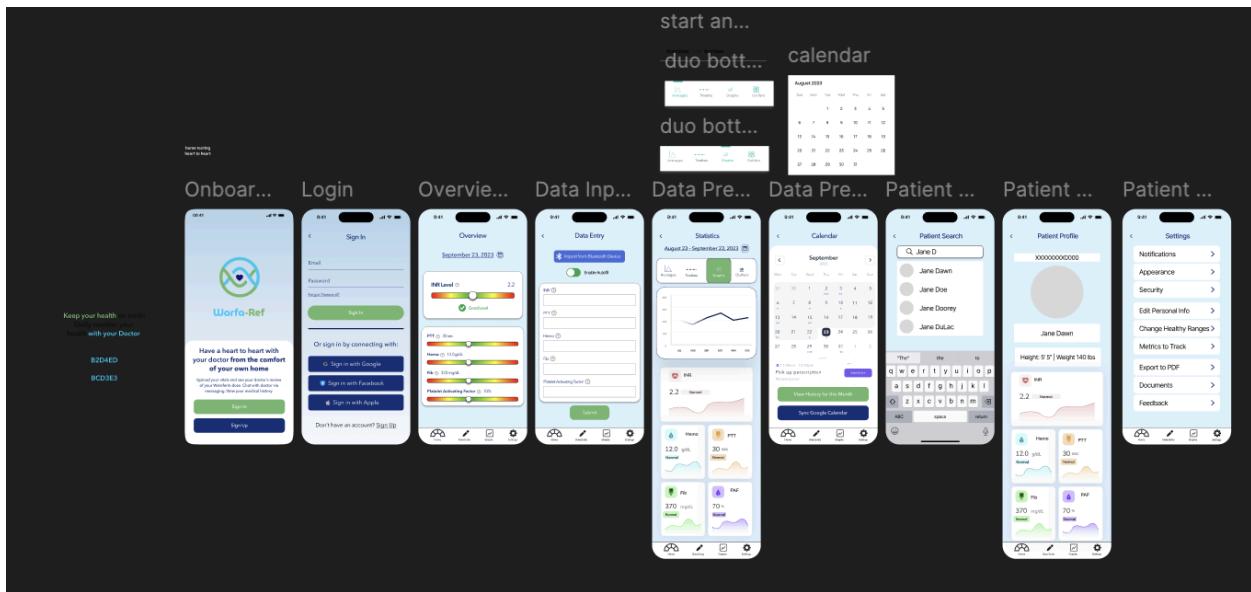
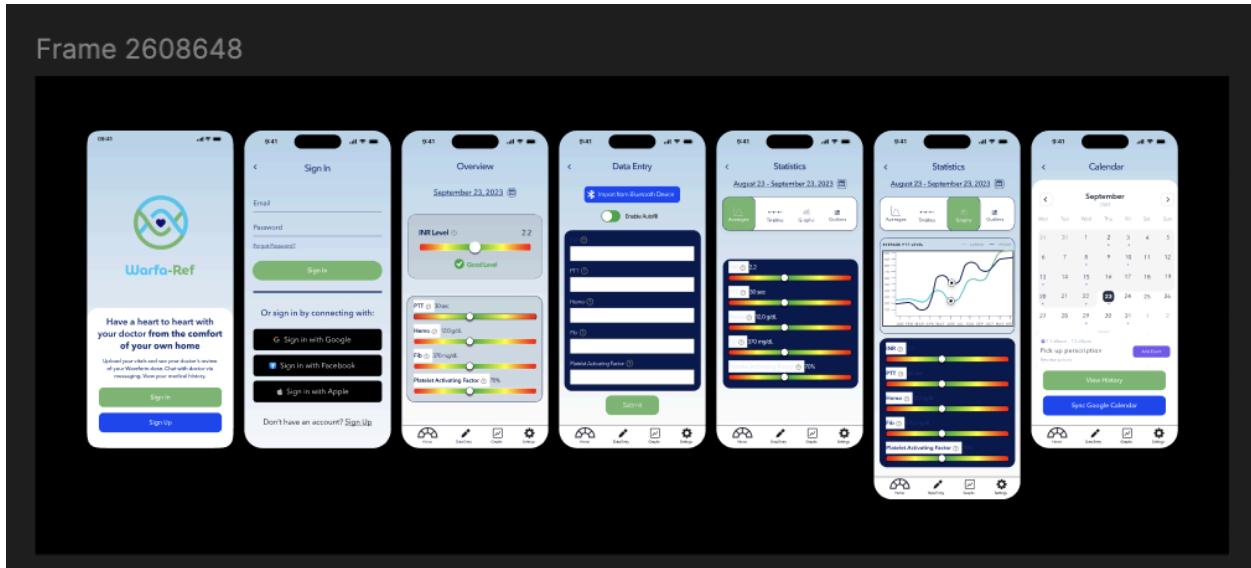
## Appendix F: Risk Analysis Table (FMEA)

| Process Step or Variable or Key Input       | Potential Failure Mode (include 8-10)                                  | Potential Effect on User / Patient Because of Failure                                   | S E V                                 | Potential Causes  | O C C                                      | R P N                                  | Actions Recommended   | Test Method   | Test Specification  |
|---|--|---|---------------------------------------|---|--|--|---|---|---|
| What is the process step or design feature? | In what ways can the process step go wrong or the design feature fail? | What is the impact on the user or patient or the ability to meet customer requirements? | How severe is the effect to the user? | What causes the failure mode to occur?                    | How frequent is the cause likely to occur? | Risk Priority # to rank order concerns | What are the actions for reducing the occurrence of the cause? Should have actions on high RPN's or easy fixes. | How will you test to ensure you have mitigated the failure mode? Write a brief (1-2 sentences) description of your planned test method. | What will you measure with your test? What is an acceptable result? |
| INR Testing with Home Device                | Device fails to read INR accurately                                    | Incorrect INR reading leads to wrong dosage recommendation                              | 5                                     | Device calibration error, low battery, user error         | 3  | 15                                     | Regular device calibration checks, user training  | Test device accuracy with known control samples   | INR reading within $\pm 0.2$ of control value                       |
| Data Transmission to App                    | Data transmission failure  | Clinicians do not receive real time INR data, delaying interventions                    | 4                                     | Network connectivity issues, app crashes, server downtime | 3  | 12                                     | Implement redundant data transmission protocols, offline mode   | Simulate network outages and test data recovery   | Data successfully transmitted within 5 minutes of reconnection      |
| Real-Time Alerts for Critical INR           | Alerts fail to trigger   | Clinicians and patients miss critical INR changes, leading to adverse events            | 5                                     | Algorithm error, notification system failure              | 2  | 10                                     | Test alert system with simulated critical INR values  | Trigger alerts with simulated critical INR values   | Alerts triggered within 1 minute of critical INR detection          |
| Integration with EHR Systems                | EHR integration failure  | Clinicians cannot access patient data, leading to delayed care                          | 4                                     | Incompatible EHR systems, API errors                      | 3  | 12                                     | Test integration with multiple EHR systems  | Simulate data exchange with EHR systems   | Data successfully integrated into EHR within 10 seconds             |
| User Interface (UI) Navigation              | UI is difficult to navigate  | Elderly or non-tech-savvy users struggle to use the app, leading to non-compliance      | 3                                     | Complex UI design, lack of user testing                   | 4  | 12                                     | Conduct user testing with target demographic  | Observe users navigating the app  | 90% of users complete tasks without assistance                      |
| Data Security and Privacy                   | Data breach or unauthorized access                                     | Patient data is exposed, violating HIPAA compliance                                     | 5                                     | Weak encryption, phishing attacks, insider threats        | 2  | 10                                     | Implement robust encryption, conduct regular security audits  | Penetration testing and vulnerability scan  | No vulnerabilities detected in security audit                       |
| Algorithm for INR Prediction                | Algorithm provides inaccurate INR predictions                          | Incorrect dosage recommendations, leading to bleeding or clotting                       | 5                                     | Insufficient training data, overfitting, model drift      | 3  | 15                                     | Validate algorithm with real patient data, monitor for model drift  | Test algorithm with synthetic and real patient data   | INR predictions within $\pm 0.3$ of actual values                   |
| Battery Life of Mobile Device               | App drains device battery quickly                                      | Patients cannot use the app due to frequent charging needs                              | 3                                     | Poor app optimization, background processes               | 4  | 12                                     | Optimize app for battery efficiency   | Monitor battery usage during app operation  | Battery drain less than 10% per hour of use                         |
| Compatibility with INR Devices              | App fails to connect with INR devices                                  | Patients cannot upload INR data, leading to incomplete monitoring                       | 4                                     | Device incompatibility, Bluetooth/Wi-Fi issues            | 3  | 12                                     | Test app with multiple INR devices  | Simulate connection with various INR devices  | Successful connection with 95% of tested devices                    |
| FDA Compliance                              | App fails to meet FDA Compliance                                       | App cannot be deployed in clinical settings, delaying launch                            | 5                                     | Lack of regulatory expertise, incomplete documentation    | 2  | 10                                     | Consult with FDA experts, complete regulatory documentation   | Review FDA submission with compliance experts   | All FDA requirements met in documentation                           |

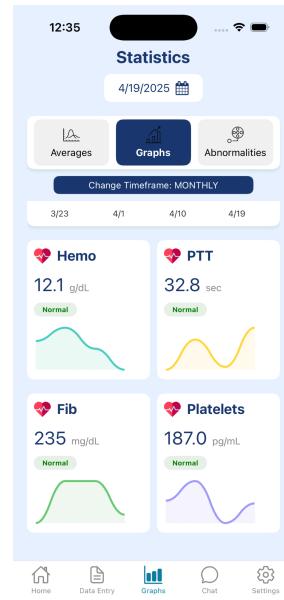
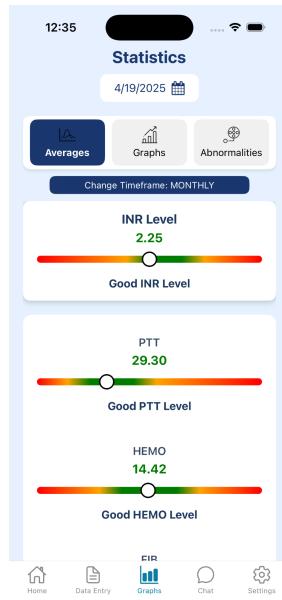
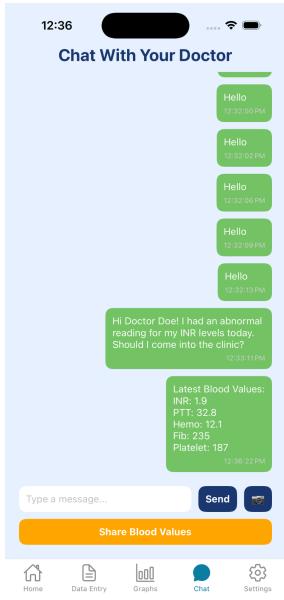
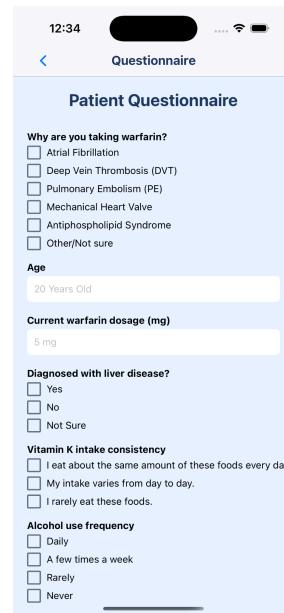
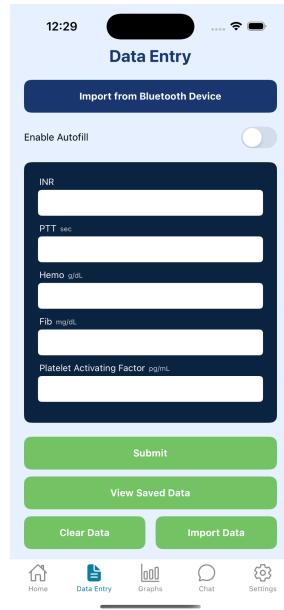
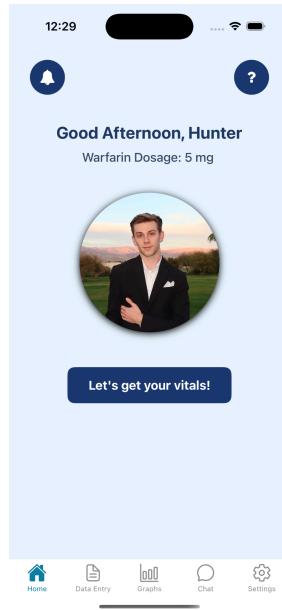
## Appendix G: INR Trends in Distinct Populations



## Appendix H: UI/UX Mockups



## Appendix I: UI/UX Currently Developed Application



**Statistics**

4/19/2025

Averages Abnormalities

Change Timeframe: MONTHLY

- 4/19/2025 — INR Low: 1.9
- 4/1/2025 — HEMO High: 16.4
- 3/14/2025 — INR High: 3.3
- 3/5/2025 — INR Low: 1
- 2/6/2025 — HEMO High: 16.8
- 2/6/2025 — INR High: 4
- 1/28/2025 — HEMO High: 15.8
- 1/19/2025 — INR Low: 1.3
- 1/10/2025 — HEMO High: 16.5
- 1/1/2025 — HEMO High: 16.2

Home Data Entry Graphs Chat Settings

**Calendar**

12:36 April 2025

| Sun | Mon | Tue | Wed | Thu | Fri | Sat |
|-----|-----|-----|-----|-----|-----|-----|
| 30  | 31  | 1   | 2   | 3   | 4   | 5   |
| 6   | 7   | 8   | 9   | 10  | 11  | 12  |
| 13  | 14  | 15  | 16  | 17  | 18  | 19  |
| 20  | 21  | 22  | 23  | 24  | 25  | 26  |
| 27  | 28  | 29  | 30  | 1   | 2   | 3   |

Enter event...

**Events on 2025-04-16:**

Doctor's Appointment

**Notifications**

12:35

Abnormal Platelet detected 4/18/2025, 2:33:48 AM

Abnormal INR detected 4/18/2025, 2:32:00 AM

Abnormal INR detected 4/18/2025, 2:27:41 AM

Abnormal INR detected 4/18/2025, 2:21:45 AM

Abnormal INR detected 4/18/2025, 2:20:28 AM

Abnormal INR detected 4/18/2025, 2:19:33 AM

Abnormal INR detected 4/18/2025, 2:17:24 AM

Abnormal INR detected 4/18/2025, 1:58:26 AM

Abnormal INR detected 4/18/2025, 1:35:54 AM

**Settings**

12:36

- Edit Personal Info >
- Notifications >
- Appearance >
- Security >
- Healthy Ranges >
- Metrics to Track >
- Export to PDF >
- Documents >
- Feedback >

Home Data Entry Graphs Chat Settings

**Edit Personal Info**

12:36

**Patient Profile**

Hunter

Risdon

Male

20

6' 1"

152 lbs

5

Once daily

**Save Profile**

**Healthy Ranges**

12:36

**Healthy Ranges for Warfarin Therapy**

**1. International Normalized Ratio (INR)**  
Normal Range: 0.8 – 1.1  
Therapeutic Range: 2.0 – 3.0 (typical), 2.5 – 3.5 (high-risk)  
Critical Value: 4.9 (high risk of bleeding)

**2. Prothrombin Time (PT)**  
Normal Range: 11 – 13.5 seconds  
Note: PT supports INR but is not used alone for monitoring warfarin.

**3. Activated Partial Thromboplastin Time (PTT)**  
Normal Range: 25 – 35 seconds  
Clinical Significance: Time it takes for blood to clot.  
Note: PTT values may be higher in patients taking anticoagulant medications.

**4. Hemoglobin (Hgb)**  
Normal Range (M): 14 – 17 g/dL  
Normal Range (F): 12 – 16 g/dL  
Clinical Significance: Drop in hemoglobin may indicate bleeding.

**5. Fibrinogen (FIB)**  
Normal Range: 200 – 400 mg/dL (2 – 4 g/L)  
Note: Low levels of fibrinogen can indicate a bleeding disorder.

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<sup>22</sup> Dr. Stefan Lukianov, Mentor, provided guidance on FDA compliance and SaMD integration strategies.

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## Bibliography Continued

Key insights from interviews with stakeholders.

- **Dr. Anago (Physician):** Highlighted the need for regular INR testing, patient compliance issues, and the potential of remote INR monitoring to reduce clinic visits. He also stressed the role of specialists and recommended educational tools like “UpToDate” for deeper understanding.
- **Mr. Laescano (Patient):** Found clinic visits inconvenient and struggles with maintaining a Warfarin-friendly diet. He supports remote monitoring and dietary reminders but is comfortable with his current medication.
- **Mrs. Alpern (Patient):** Expressed frustration with time-consuming clinic visits and lacked awareness of Warfarin’s dietary interactions. She supports remote monitoring but emphasized the importance of a simple, accessible design.