1. Summary and Project Objectives:

This project intends to help improve chronic disease management of patients with Type I and Type II diabetes through the integration of continuous glucose monitor data within EHR systems to answer the research question: *can the integration of continuous glucose monitoring systems within EHR systems lead to better disease management for diabetic patients?*

The main goals of this project are to develop successful integration and create an interface with dashboards, notification alerts, and navigational options that will allow patients and providers to easily visualize and monitor changes in glucose levels and respond in a timely manner. Our target audience includes healthcare providers who actively care for diabetic patients. This may involve primary care providers who monitor and continuously care for diabetic patients throughout their lifetime, and urgent care or emergency department providers who may treat diabetic patients in diabetic emergencies. Additionally, patients with type I or type II diabetes are part of our target audience, as this integration actively impacts their care and chronic disease management. The technologies we intend to use are continuous glucose monitors and an interface for EHR systems.

Our project focuses on objective measurements including glucose levels obtained from a continuous glucose monitor. Improvement in disease management as a result of our proposed integration can be visualized by improvement in control of glucose levels over time (i.e., less extreme spikes or drops in glucose levels, more consistent levels, etc.).

2. Target Audience

This project seeks to improve chronic disease management within a diabetic patient population and plans to target both diabetic patients and their care providers. Patients of focus are those who have been diagnosed with Type I or Type II diabetes and utilize or plan to utilize a continuous glucose monitor for diabetic management. Care providers may include the primary care provider who manages the patient's overall healthcare plan or urgent care/emergency department providers who may see a patient in a diabetic crisis (hypo- or hyperglycemia).

A successful integration of CGM with EHR systems provides the benefit of streamlining care and providing real-time data to providers to allow them to make timely and informed decisions regarding patient care. This would hopefully result in better patient care and outcomes of better-managed diabetes. Providers would be notified immediately of out-of-range glucose levels and allow for timely interventions leading to better long-term control of diabetes. Additionally, primary care providers can visualize individual data points as well as trends over time and initiate data-driven conversations with their patients to better educate the patient and develop a more personalized care plan. Finally, this may provide a reduced burden on the healthcare provider and healthcare system. Patients can be monitored and receive interventions remotely, allowing the provider to save appointment times for other patients who cannot be treated remotely. Additionally, better-managed diabetic patients and patients who feel confident in receiving remote care from their primary care providers will likely need less emergent treatment, thereby reducing the burden on urgent care or emergency departments.

3. Stakeholder Interviews:

Two healthcare professionals were interviewed for this project. Our questions began with demographic information, including job position titles, years of experience, background both educational and professional, and experience in treating diabetic individuals. The interviews continued with questions regarding continuous glucose monitoring systems and diabetic management. We inquired about how diabetic management and treatment have evolved during their time in healthcare, perceived patient challenges with CGMs and diabetic management, and intervention for patients with sudden spikes or drops in glucose levels. Moving on, we asked questions regarding EHR systems to obtain insights into how this integration may impact patient care and provider workflow. We inquired about usability, desired features of an interface, and challenges with the integration of new EHR features.

The first healthcare professional who was interviewed was a PA currently working in a primary care setting. She has approximately 20 years of experience in healthcare, the majority of which has been spent in a primary care setting. She initially began her career in a rural primary care clinic, before moving to the central Iowa area. After she moved, she worked part-time in urgent care allowing for flexible time to care for her twins. After her twins began kindergarten, she transitioned back into a full-time primary care provider role. She has experience treating diabetic patients both in a primary care role and when experiencing diabetic crises (hyper- or hypoglycemia). We discussed that early in her career most diabetic patients were treated based on finger prick blood testing, but over the years she has seen an increase in use of the continuous glucose monitor. Additionally, we discussed A1c levels, which is the measurement of average

glucose levels over a 2-3 month period and is traditionally used to understand diabetic control over time.

She was interested in our proposed integration of CGM within EHR as a more accurate way to visualize a patient's glucose levels both at an individual time point versus trends over time. However, she discussed concerns about patient adherence and IT capabilities. She discussed generically that some patients who historically have poor disease management are usually resistant to change and poor treatment adherence, and she raised concerns about their willingness to adapt to continuous glucose monitoring and remote interventions from their providers. However, she was hopeful that our proposed integration would provide improvement in management for a majority of the diabetic population she treats. She raised concerns about the capabilities of her IT team at the clinic she works in. The IT team for her clinic is sometimes difficult to reach and can take a significant amount of time to complete tasks, which presents special concerns when providers are trying to perform real-time interventions for their patients.

The second healthcare professional that was interviewed was a nurse working in an OB emergency department. She is a recent nurse graduate and has about 8 months of working in this setting, but she did complete clinical rotations throughout nursing school in various patient care settings. She has plans to continue her education to become a nurse practitioner in the near future. She was interested in an interface between glucose monitors and EHR systems but noted that it may not directly impact her work. She was excited about how this may pave the way for future integration of other wearable devices and EHR systems that may allow for better patient care.

She provided insights about how diabetes management can impact the patient population she typically interacts with. She highlighted pregnancy complications common for diabetic patients, especially those with poorly controlled diabetes, including both maternal and fetal complications, such as preeclampsia, preterm birth, increased risk of miscarriage or stillbirth, birth defects, and many more. She emphasized that patients who have better control of diabetes significantly decrease the risk for complications and was hopeful that our proposed integration of CGMs and EHR systems would allow for better control of diabetes before pregnancy.

Part of her role in the OB ED focuses on triaging–prioritizing the higher risk or emergencies. Due to this, one feature she recommended was triaged notifications for providers. This could look like red alerts for emergencies that require immediate intervention, yellow alerts for situations that require intervention but are not immediate life-or-death situations, and green alerts for situations where the provider should consult with the patient for purposes such as re-education or minor adjustments to the treatment plan. Similar to the PA we interviewed, this nurse raised concerns about IT capabilities and being able to successfully implement our project into existing workflows.

Overall, both healthcare professionals provided insights into diabetic care and had an interest in our proposed integration of CGMs within EHR systems. Despite concerns regarding IT teams' abilities to successfully implement, both the PA and nurse were hopeful that this integration would provide improved outcomes for patients. These interviews highlight the importance of creating an easy-to-implement and user-friendly interface and confirm the potential benefits.

4. Scope

The primary focus area for our project is the integration of continuous glucose monitoring within an EHR for chronic management of Type I and Type II diabetes. Our inclusions are sample health data collected from glucose monitors. We'll also include the factors that impact chronic diabetes management such as age, BMI, pregnancy, family history, etc. to integrate this data into an EHR better to facilitate chronic diabetes management. In terms of exclusions, we will not be focusing on the actual development of a continuous glucose monitor nor will we focus on the creation, development, or implementation of the EHR system as it is assumed that healthcare providers have access to an established EHR system. Additionally, part of our exclusions include the actual diabetes diagnosis, and while our project aims to help guide treatment plans, the actual development of a patient's treatment plan will be left to the healthcare professional.

5. Functional Requirements

For our user interface features, we will include several dashboards, input forms, and navigation menus that will be essential for the EHR integration system. For patients, there will be a summary dashboard that will feature blood glucose readings by range. One end of the range will be very low with the other end of the range will be very high and in the middle of the range will be target blood glucose level. We plan to organize the data by mean and standard deviation (SD). We also want to include a section for trends with comparisons, patterns, and best days of blood glucose levels for

the patients. These trends will showcase the highs, lows, target range, and average blood glucose levels over a selected time period.

Our selected glucose monitoring device will use application programming interfaces (APIs) that allow the patient's EHR to securely access and retrieve patient data. The same dashboards where patients can see comparisons, patterns, and trends for their blood glucose level healthcare providers will also have the same access. This synchronization will enhance workflow efficiency since healthcare providers won't need to log into another system to access a patient's CGM data. As a result, healthcare providers will be able to save time since they're able to access blood glucose data more consistently which will help them improve their data analysis for more informed decision-making.

For security measures, we'll include several integrated security protocols to protect patients' sensitive health information. We plan to use multi-factor authentication for the patient to gain access to their smart glucose monitoring device. In addition to inputting their password, we also plan on having a code sent to their phone as well as using biometric authentication such as a fingerprint or facial recognition. Robust encryption will be integrated within the EHR to protect patient data both in transit to the healthcare provider and when it's stored. We also plan on implementing robust data backup and recovery plans in case the EHR encounters a system failure.

6. Non-functional Requirements

For usability standards, the goal is to establish strong engagement and maintain high adherence rates from patients. To do this, we plan to use non-technical language

with Google Sites so that patients can easily understand what's presented on their wearable monitoring device. Patients should also have an easy time navigating between dashboards for user satisfaction. Furthermore, the continuous glucose monitor on the patient's wearable monitoring device needs to be synchronized with the healthcare provider's EHR. Alerts and notifications should be integrated within the smart glucose monitoring device, especially for those who have limited technical experience with digital health tools, to help patients with their low or high blood glucose levels.

There are a few errors that have to be managed for patients to ensure that patients use the smart glucose monitoring device effectively. Healthcare providers need to address issues such as sensor failures and inaccurate readings. In the event of a sensor error, the smart glucose monitoring device should display error messages such as "Sensor Failed" or "Replace Sensor" and those alerts should be sent to healthcare providers. It's crucial for patients who are experiencing errors on their smart glucose monitoring devices to have them fixed immediately, otherwise, patients are unable to determine a sudden spike or dip and that could lead to health complications for them.

The only metric that's relevant to our reliability requirements is what's been mandated by the Food and Drug Administration (FDA). [1]The FDA requires that 95% of readings must be within ±15% of a reference method, and 99% within ±20% of a reference method, regardless of glucose levels. For security measures, healthcare providers must be compliant with HIPAA. In particular, they need to follow both the privacy rule and the security rule. Healthcare providers should ensure confidentiality In the event of an unauthorized breach, they have to notify patients when the breach

occurred and what data was compromised. They must also clear and purge patient data if necessary to protect patient privacy and security.

7. Use Cases

Use Case 1: Real-time Glucose Monitoring and Alert System
Summary: The system continuously monitors patients' glucose levels from CGM devices and generates alerts when readings fall outside established thresholds.
Background Information:

- **System:** CGM-EHR integration platform
- **Primary actor:** Healthcare providers (physicians, nurses, diabetes educators)
- **Secondary actor:** Patients with diabetes and automated monitoring system
- **Goals:** Enable continuous monitoring of glucose levels with automated alerts for critical readings
- **Stakeholders:** Hospital administration, clinical care teams, patients and their families
- **Preconditions:** Patient has diabetes diagnosis, prescribed CGM device, and EHR record
- **Triggers:** Patient registration in the system or glucose readings outside established thresholds

Scenarios:

- **Basic flow:** The healthcare provider registers the patient's CGM device in the EHR system and establishes personalized glucose thresholds. The system begins continuous monitoring, storing readings in the patient's EHR record. When readings exceed thresholds, the system automatically generates alerts that are delivered to providers via their preferred notification method. The provider reviews the alert, contacts the patient if necessary, and documents any interventions in the EHR.
- **Alternate flow 1:** The system detects a severe hypoglycemic event below the critical threshold. A high-priority alert is immediately generated and sent to the assigned healthcare provider. If the provider doesn't acknowledge within a reasonable timeframe, the system escalates the alert until a response is received.
- **Alternate flow 2:** The system fails to receive scheduled data from a high-risk patient's CGM device. After three unsuccessful reconnection attempts, the

system generates a connectivity alert for the provider and technical support team.
- **Alternate flow 3:** Multiple patients trigger alerts simultaneously during off-hours. The system prioritizes alerts based on severity and patient risk factors, distributing them to available on-call providers. A summary dashboard helps the clinical team manage multiple concurrent alerts.

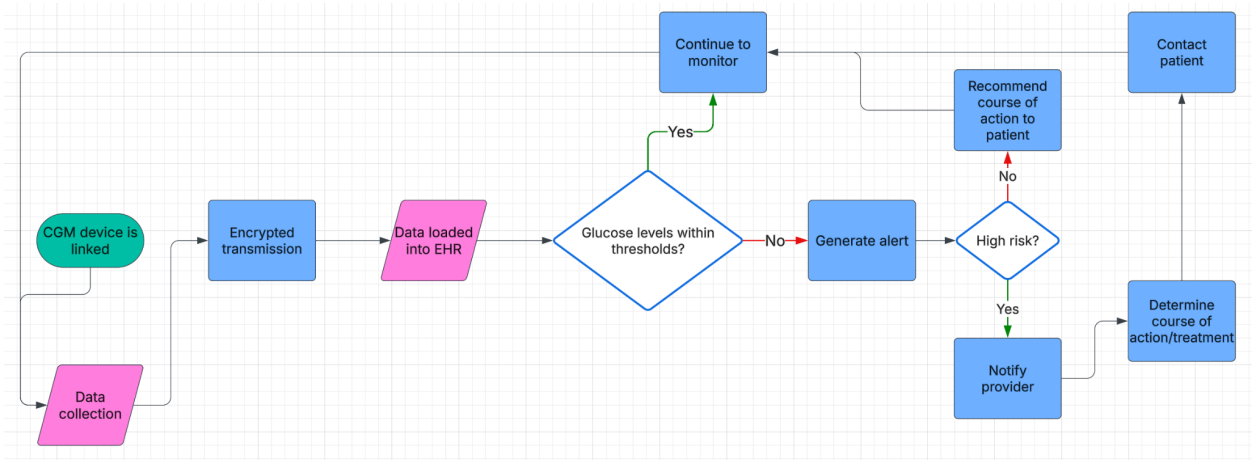
Use Case 2: Clinical Decision Support and Treatment Optimization
Summary: The system analyzes CGM data to provide clinical decision support to healthcare providers, identifying patterns and suggesting treatment adjustments.
Background Information:

- **System:** CGM-EHR integration platform with analytical capabilities
- **Primary actor:** Healthcare providers
- **Secondary actor:** Clinical decision support system and patients with diabetes
- **Goals:** Analyze patient data patterns to enable informed treatment decisions
- **Stakeholders:** Clinical care teams, quality improvement specialists, hospital administration
- **Preconditions:** Patient has used CGM device for enough days where sufficient data has been collected
- **Triggers:** Scheduled patient appointment, provider-initiated analysis, or automated detection of significant pattern changes

Scenarios:

- **Basic flow:** The provider accesses the patient's CGM dashboard within the EHR, viewing visualizations of glucose trends. The system generates evidence-based insights and treatment recommendations, which the provider reviews, selects appropriate options for the treatment plan, and discusses with the patient during their appointment.
- **Alternate flow 1:** During analysis, the system identifies potential data anomalies, such as rapid fluctuations that suggest device malfunction. The provider flags these and schedules a CGM device check before making treatment decisions.
- **Alternate flow 2:** The system correlates insulin delivery data with glucose readings, identifying differences between insulin dosing and expected glucose levels. This reveals potential issues with insulin absorption sites or pump malfunction. The provider then may recommend pump site rotation rather than dosage changes.

8. Data Flow Diagram



9. API Integration Plan

Integrating continuous glucose monitoring (CGM) data with Electronic Health Records (EHRs) revolutionizes diabetes care by connecting daily patient monitoring with clinical systems. The HL7 FHIR framework provides standardized protocols for real-time data exchange between these previously separate systems. This technological bridge enables more responsive care and improves outcomes for diabetic patients by giving providers continuous insight into glucose patterns beyond periodic appointments.

Our plan proposes two key mHealth integrations with EHR systems. First, continuous glucose monitoring integration enables healthcare providers to access up-to-the-minute glucose readings from devices like Dexcom G6/G7 and FreeStyle Libre, receive alerts when readings fall outside patient-specific thresholds, and view historical trends to inform treatment decisions. This integration eliminates the gap between appointments, giving providers insight into patients' day-to-day glucose management and enabling timely interventions for dangerous glucose excursions.

Second, integrating patient-facing diabetes management applications with EHRs brings valuable contextual information into the clinical workflow, including patient-recorded meal timing, physical activity logs, and medication administration

tracking. This integration empowers patients with greater engagement in their care while giving providers critical context for interpreting glucose patterns and optimizing treatment plans.

To facilitate secure and reliable data exchange, our integration will implement strong protocols and authentication measures. The FHIR standard provides modern, web-based technologies that support efficient and standardized data exchange, including RESTful API architecture for consistent data, and push notifications for real-time alerts. These technologies create a similar interface across differing systems, which ensures that glucose and related health data remain consistent throughout the exchange process.

Protecting sensitive health information requires a strong approach to security, including secure authentication using 2FA, encryption for all data in transit, and role-based access controls. These security measures create a trusted environment for health data exchange while following industry best practices for protecting patient information.

10. Timeline

Our project has been moving forward through our 16-week timeline as planned. We have completed much of the planning phase, including our project proposal, feasibility analysis and now this requirements specification. Moving forward, we will be developing a risk management plan that evaluates health data privacy and discusses mitigation strategies to prevent common security threats associated with digital health

technologies. We will plan to complete this portion of the planning phase in week 10. We will then move on to the development phase, creating wireframes and a prototype using Google Sites, which will be completed within week 12. Next, we will be performing usability testing to gather feedback and guide improvements for our prototype, which will be completed by week 14. Finally, we will be working on the final version of our product for implementation and creation of our final report, which will be complete by week 16.

11. Resources

Our team members, Julius, Gabrielle, and Mario, are vital to this project creation. We plan to use Lucid for our whiteboard to create diagrams or process mapping. We will design our systems utilizing Google Sites, optimizing layout and visualization for our proposed interface. We plan to test data and interface integration with an EHR system in a testing environment, which can be acquired potentially through interactions with stakeholders. Our data will be acquired from Kaggle, including diabetic and non-diabetic patients, as discussed in our initial project proposal. Expertise from healthcare professionals, patients, and stakeholders from healthcare systems will be utilized through usability feedback to optimize our system.

12. Feasibility

While there may be technical challenges in combining multiple data sources while maintaining security and interoperability, our project is technically feasible using the existing technology we plan to utilize. The technology we plan to utilize includes

CGM monitors, such as Dexcom G6 or G7 or FreeStyle Libre, Kaggle demographic data, “sandbox” data, Google Sites for the initial prototype, and standardized HL7 FHIR.

We believe that this project is operationally feasible as the integration of CGM data into existing EHR systems will allow providers to assess and treat in real time. This can drastically improve workflows and enhance patient care. The integration would allow for streamlined data transfer, reduction of time spent reviewing patient data, and as a result, strengthening patient-provider relationships. One operational challenge to consider would be time spent training, but this can adequately be addressed by developing a user-friendly interface that integrates well into existing EHR systems and is similar to tools healthcare professionals are already used to using.

CGMs can vary in cost ranging from $1,200 to $7,000 per year depending on the type of monitor and insurance coverage. There are also costs to consider with developing and implementing our interface for integration of the CGM data into EHR systems. However, we believe that the benefits of utilizing these monitors as well as the integration within EHR systems overall outweigh all of these costs. These benefits we considered include reduction of diabetic complications (i.e., hypoglycemia, retinopathy, neuropathy), lower hospital admissions, and decreased length of hospital stays. Overall, the cost associated with diabetic complications or hospital stays are much greater than the cost of a CGM or technical development implementation of the interface.

We also considered scheduling feasibility and concluded that development of our interface could be reasonably achievable within a given 16-week timeframe. After a thorough analysis of the technical, operational, cost/economical, and schedule components, it is believed that the project is overall completely feasible.

13. Risk Management:

The two largest risks with our project are data quality and security. Data quality will be a large issue since our smart glucose monitoring device is contingent on patients' engagement rates. There are oftentimes a variety of factors that affect adherence rates. Technological literacy and comfortability are the biggest factors that will determine if a patient chooses to engage with our smart glucose monitoring device. Furthermore, data quality is dependent upon the physical condition of the patient. If one patient is more susceptible to dips or spikes in blood glucose levels compared to another patient, then the former patient will naturally have more variability in data. Diet is a crucial part of managing blood glucose levels and both Type I and Type II require different approaches to diet that will naturally affect their blood glucose levels.

Security is another large risk with our project, simply because healthcare providers are working with a large amount of data from patients who use our smart glucose monitoring device. First, healthcare providers need to engage in HIPAA-compliant practices that will uphold and safeguard patient data. Through robust encryption, secure access controls, and regular audits healthcare providers can ensure that they're managing patient data with the utmost respect and discretion. It's also crucial that patients are provided with informed consent from the time they first start using our wearable device and throughout the lifecycle of a patient's engagement with it. Lastly, healthcare providers would have to inform patients of any changes in UI or dashboard layout if it affects how they interact with the wearable device.

14. Ethical Considerations:

The key ethical considerations for this project would be data privacy and security for the patient. This is crucial since Type I and Type II diabetics can suffer from discrimination due to their having a pre-existing condition. Their patient data has to be secured at all times since they can be victims of an unauthorized breach which could not only compromise the quality of healthcare that they would receive but it would also increase the gaps in the digital divide for patient health outcomes. To mitigate these concerns, we've previously identified that healthcare providers need to employ several tactics to protect patient data including robust encryption, secure access controls, and regular audits. We'll break down more specifically how we plan to accomplish this in a detailed risk management plan over the next couple of weeks.

15. Evaluation:

For our success criteria, we'll define it quantitatively by the time of duration of use for the device and qualitatively by the subjective experiences of the patients who use our smart glucose monitoring device. We would want to test our smart glucose monitoring device for a short window of time (anywhere from 48-72 hours) to see if it's properly calibrated for patients, obtain initial feedback from them, and collect a small window of blood glucose data for healthcare providers to analyze. To measure these criteria we'll conduct surveys and interview questions to gather initial feedback from patients. By capturing contextual insights from them, we can gain a better understanding of their unique experiences with using our device. In particular, we can better understand if there were any pain points that they went through when they used

our device, then take that input to iterate our wearable device so that it can better serve the needs of patients in the future. Ultimately, we define success as if patients see our smart glucose monitoring device as a useful tool that empowers them to become more proactive in taking better care of managing their diabetes.

16. Individual Contributions:

Our team consists of Julius Miller, Gabrielle Holmes, and Mario Loyd Galvão-Wilson. Throughout the last month and a half, our team has maintained constant contact and scheduled meetings to discuss parts of our project. We have each collaborated on the project and divided work evenly, despite our busy schedules and time differences. For the requirements specification, Mario and Julius collectively developed 20 interview questions. Gabrielle's connections with multiple healthcare professionals provided an opportunity to conduct interviews and gain insights on diabetic disease management, continuous glucose monitoring, EHR challenges, and feedback regarding the possible integration of our project into real-world use.

Moving forward with the requirements specifications, Gabrielle summarized our projects and objectives, the target audience, and how this project can benefit chronic diabetic management in a real-world setting, as well as completing a summary of the interviews conducted and insights provided by two healthcare professionals with varying experience and job duties. Julius completed the scope, discussing the goals and focus of the project as well as what information would be included versus the information that would be excluded. Julius also contributed to the functional and non-functional requirements of the project. Mario completed several use cases, developed a data flow

diagram as well as an API integration plan. The timeline, resources, and overall feasibility were summarized and completed by Gabrielle. Julius evaluated risk, ethical considerations, and a plan for the evaluation of the success of this project. We all collaborated well for this portion of our overall course project, reviewing each other's contributions, providing feedback, ensuring all information was included, and editing for grammatical errors, conciseness, and overall flow of the document.

Source:

1) Katz, L. B., Stewart, L., King, D., & Cameron, H. (2020). Meeting the New FDA Standard for Accuracy of Self-Monitoring Blood Glucose Test Systems Intended for Home Use by Lay Users. *Journal of Diabetes Science and Technology*, *14*(5), 912–916. https://doi.org/10.1177/1932296820906184