Diabetes SaMD: Important Considerations for Developing Successful Interoperable Solutions

Diabetes is a condition that requires significant management. It is this extraordinary workload that has many people with diabetes turning to high-tech devices to help them manage their health and keep their blood sugars within a more normal range. This trend toward a greater reliance on personal medical technology is growing throughout the medical industry. In fact, MarketsandMarkets has projected that the Internet of Medical Things (IoMT) market will grow at a compound annual rate of 30.86% between 2017 and 2022. The Software as Medical Device (SaMD) niche, specifically, will see a large portion of this growth and is predicted to grow at a rate of 28.5% during this same period.[1]

The importance of developing user-friendly interoperable software capable of working with a wide range of medical devices is quickly becoming the only path forward in the long-term treatment of type 1 diabetes. This trend has led to diabetes hardware/device companies with limited software-focused resources developing SaMD without a wholistic understanding of the considerations that must go into creating and launching a successful software product. ***After all, software is not the core business of these diabetes companies, yet it is extremely important to succeed in developing innovative, interoperable software technologies in order to engage their customers and garner greater global market share***. Diabetes companies often struggle to satisfy customer desires and fail to meet interoperability standards from regulatory agencies such as the United States Food and Drug Administration (FDA). Those that are successful in meeting these requirements often do so while overspending and failing to minimize risks during the development process.

Before investing time and money to develop new SaMD for people with diabetes, companies must consider what customers need and want from these devices, what the FDA and other regulatory bodies require, and how to develop software that addresses the inherent risks of interoperable medical devices while allowing for the inclusion of multiple technologies.

Meeting customer desires

The most effective and intelligent SaMD will fail in the marketplace if it does not meet the basic needs of the end user. These devices need to be safe, intuitive, fast, and able to work on multiple platforms. SaMD for people with diabetes must go beyond even these basic tenants. It must allow for interoperability between a variety of devices from pumps, insulin pens, and continuous glucose monitors (CGMs) to meters, smartwatches, and more. Devices that offer the most to the user, including choices for mixing and matching, a simple user interface, and compatible software, will outperform anything on the market that falls short of meeting these customer desires.

The appeal of closed-loop systems

The first hybrid closed-loop insulin pump system was approved in the US in 2016.[2] In four short years, the choices for automated insulin dosing (AID) systems have grown, and the accuracy of these devices continues to improve. This incredible rate of evolution can be seen in the numbers, with the global AID market expected to grow by a compound annual rate of 6% between 2019 and 2027.[3]

The success of such devices reflects the desires of people with diabetes. AID systems greatly reduce the burden of disease management while achieving more stable blood sugars to decrease the risk of diabetic complications and improve patient quality of life.[4] The abilities of these devices are only expected to grow, with many companies promising new models capable of automated bolus and correction dosing. Some of these promised capabilities are already available through open source “looping” apps including do-it-yourself (and not FDA approved) algorithms meant to turn outdated diabetes tech into sophisticated AID systems.

While it is difficult to know how many people with diabetes are using AID systems (specifically, the non-approved systems) to manage their diabetes, the popularity of looping groups, including a Facebook group that has 25,000 members internationally, speaks to their appeal. These apps, which automate almost all aspects of diabetes management, serve as a representation of what consumers desire and what companies should be trying to deliver and surpass in their own systems. But achieving such lofty goals within the confines of government regulations is more difficult.

Important app features

Whether SaMD is developed for use with an AID system or as another form of burden-reducing tech, there are several key features that should be included to meet the needs and wants of the consumer.

Software must be compatible with a range of consumer platforms. Dual Android and iOS compatibility is now a must. Regardless of what platform the software is used on, it must be easy to navigate. This requires an intuitive interface that customers can trust with their own health and safety. The ability of companies to perform secure, remote software updates is another feature tech-savvy consumers have come to expect, but it is also one that companies need to investigate fully before pursuing. Developing software capable of undergoing safe and secure remote updates can be expensive in both the short and long term. These additional costs must be weighed against the benefits of this type of system for each individual product. Finally, and of increasing relevance, these systems must secure private information and protect data from outside attacks.

As the market grows more saturated with SaMD for people with diabetes, these types of features will become more important for attracting customers and, in turn, gaining market share and growing revenue. But developing software capable of meeting these customer desires requires a significant investment by the company. And even then, there are certain aspects that cannot be achieved without the right experience and knowledge.

Interoperability standards

In an effort to improve patient care, reduce errors, and encourage the development of innovative medical technology, the FDA in the United States has become increasingly supportive of interoperable medical devices.[5] This sentiment is shared by the European Medicines Agency (EMA) and other regulatory bodies throughout the world. Medical devices that have received the FDA's interoperable designation are able to exchange information with, and use information from, other interoperable devices developed by other organizations. This special component designation allows for consumers to mix and match their diabetes tech based on their specific needs, promoting more consistent engagement in a patient's own diabetes management and increasing the odds of a positive outcome.[4]

Promotion and regulations

Regulatory bodies, such as the FDA, hold the security and safety of interoperable devices above all other characteristics. The belief is that these types of devices can be developed and produced in a manner that meets these concerns while helping foster innovation to allow for more rapid medical technological advancements. The FDA, with guidance from the International Medical Device Regulators Forum (IMDRF), has issued regulations on the use of standardized architectures and communication protocols as well as non-standard interface requirements and labeling characteristics.[5] Additional guidance on cybersecurity and interoperability has come from many organizations including the National Institute of Standards and Technology (NIST) and the Institute of Electrical and Electronic Engineers (IEEE).[4]

Understanding and abiding by these guidelines and successfully developing SaMD that has a low risk of malfunction while remaining secure should be a major focus for all companies hoping to develop interoperable diabetes devices.

Industry trends

Currently, the only diabetes-related devices that have received the FDA's interoperable component designation are two automated glycemic controllers, two alternate control enabled insulin pumps, and one integrated continuous glucose monitor. All current cleared devices are used to create a mix-and-match AID system. At this time, there are also a number of other algorithms, CGMs, and pumps in development seeking interoperable component designations. All current market efforts are focused on creating choices within closed-loop systems. It is not difficult to see how interoperable innovation could also be applied to the smart insulin pen market, as well.

While the FDA has shown support for the increased development of interoperable devices, most products are not being approved for this special designation as there are specific regulatory requirements that must be met. Companies must work hard to assess all possible risk factors and prove that their product meets or exceeds set component-specific special controls. A complete understanding of this clearance process and the ability to work closely with these regulatory bodies early in development can help ease the burden of obtaining regulatory clearance and commercializing the products.

Difficulties of bringing solutions to market

Meeting regulatory requirements for device clearance is difficult. In the case of interoperable devices, meeting regulatory guidelines by combining devices from different manufacturers can make the process of clearance by regulatory bodies even harder. While the FDA's special controls are fairly concrete, there is room for interpretation. This creates uncertainty within the development process. To overcome such uncertainty, device manufacturers need the experience of a partner who has a deep familiarity with what it takes to receive regulatory clearance.

Once clearance is granted, interoperable devices face a second challenge in gaining reimbursement coverage through insurance providers. Customers and diabetes technology companies continue to embrace the use of mix-and-match medical technology, but health insurance providers often subvert this process by offering exclusive contracts. Even when exclusive contracts aren't in place, providers may require long-term outcomes data to establish the reliability of a new product before they choose to cover it. Understanding how insurance companies assess the risks associated with new devices and use similar established products to assign reimbursement preferences can help companies navigate the difficulties imposed by insurance providers.

Considerations during SaMD development

In order to meet customer desires and avoid delays getting products to market, companies must consider a wide range of factors during the development process. With regard to interoperability, these considerations are not just limited to the risks of a single device or software, *but to all compatible devices*. To find success, diabetes companies must understand all the risks associated with their product, how to minimize these risks, and how to expand this process across multiple devices and multiple organizations. This requires the expertise and neutrality of a third-party partner.

Risks

Opening the lines of communication between two separate devices exposes one of the greatest risks of interoperability. Minimizing the risk of cyberattack or interference starts with a focus on securing each device on its own. Expanding this security to the entire set of interoperable technologies requires external resources with experience and expertise that spans a multitude of devices and SaMD. Additionally, companies must be capable and willing to continue strengthening and updating security protocols after a product has gone to market to combat new threats as they arise.

Creating SaMD that functions as expected and reduces unintended outcomes relies heavily on complete and accurate data exchange. During the development of SaMD, it is important that real-world data, which is inherently messy when coming from medical devices, be complete. This data must also be accurate, meaning there must be checks in place to ensure no values are being altered or modified before being reported to the SaMD. Understanding the complexities of real-world medical device data and how this data must be reported to the SaMD in order for devices to function and respond properly is the most important factor in risk mitigation and requires expert consideration during development.

Lastly, each of these considerations needs to be applied to the entire set of interoperable devices. It should be expected that some devices will require longer development periods than others, a factor that can greatly increase risk to the company if agreed upon timelines begin to diverge. Accounting for all possible risks while keeping development on track for market clearance and release requires experience and oversight that most companies cannot accomplish alone.

Incorporating multiple technologies

The biggest challenge faced by any company developing interoperable diabetes technology is that there are multiple pieces of the final product puzzle that are not being developed by them. Often, the narrow scope of each company on their own device can paralyze progress toward a complete working system due to the lack of experience and expertise with other technologies. As each company deals with their own changing priorities and product updates, the larger picture can be forgotten, resulting in expensive delays and products that fail to meet market needs.

Having a neutral third party to assist in scaling, testing, and integration of each piece of the system greatly reduces the risks for every company involved. By focusing on these solutions as they pertain to the overall system, a neutral outside influence can free each company up to focus on their own product without disrupting the larger scope of the project. The outside partner can also help ensure each party has intellectual property (IP) protections and act as gatekeepers to respect the separation of devices while simultaneously ensuring compatibility and functionality of the overall system.

The importance of a diabetes-focused technology partner in SaMD development

The successful development of SaMD for people with diabetes requires a focus on customer needs and desires, a thorough understanding of standards for regulatory clearance and subsequent market trends, extensive knowledge of risks inherent to interoperable devices, and the ability to minimize these risks while assuring a smooth integration of technologies developed by multiple companies.

Due to the nature of developing SaMD, it is incredibly difficult for any one company to achieve success in all these areas on their own. Partnering with an experienced third party with a focus on software development and a thorough understanding of regulatory risks and quality requirements for medical technology allows companies to concentrate on the design and function of their own product while enlisting an expert to assist in bringing the fully functional multi-device, interoperable system to market.

Sequenex is one such partner: A platform and product development company focused on mobile, cloud and IoT development specifically for the diabetes industry. Sequenex provides consulting services, product development and project-specific staffing augmentation to support our customers in expediting product to market. Our deep domain and regulatory experience allows us the unique ability to rapidly develop and deploy interoperable and innovative systems that align to US and global regulatory requirements, while maintaining focus on a positive user experience. Sequenex has assembled a team with decades of experience in the diabetes ecosystem – from product design and development to quality/regulatory and even post-market maintenance and management.

Sequenex understands what people with diabetes want and need in their technologies; and, we have the knowledge, skillset, and ability to develop highly capable software that is intuitive to use and compatible with multiple platforms. But knowledge of market desires and demand is nothing without the experience and focus necessary to meet regulatory standards for interoperability. This experience also positively correlates with the ability to predict industry trends and Sequenex is consistent in developing and designing flexible frameworks with the future in mind. We work closely with regulatory bodies before the submission process to ensure a smooth transition from development to clearance to market.

Sequenex understand the risks inherent to a broad range of diabetes medical devices and SaMD. We understand and implement both validation and verification testing strategies to assure risk minimization and check that data being exchanged is both complete and accurate. We work with our customers as a neutral third party to oversee the development of the entire interoperable system and pull all involved organizations together to focus on moving solutions forward – propelling products to market, safely. We have expedited Software Development Kit (SDK) development related to interoperable products for multiple global diabetes companies. It is always our goal to protect the investment of each individual company through development, distribution, and ongoing maintenance. Our focus on the larger project allows us to scale costs to provide competitive pricing to everyone involved.

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