INSIGHTS

into **MedTech Innovation**

MEDACUITY

CREATING SAFE USABLE MEDICAL DEVICE SOLUTIONS

Effective Collaboration is Key

For many manufacturing organizations, medical device development happens at the intersection of technology and business. Typically, technology stakeholders ask, "What can we build?" and business leaders ask, "How can we achieve our goals?"

Often, these two viewpoints fail to take a third, and often more important, viewpoint into account—that of the user. Users are commonly viewed as a monolithic group that can't be effectively engaged due to a lack of time, resources, or access. As a result, assumptions are made about their needs, which sometimes prove to be incorrect in the long run. By putting the effort in early on to include and consistently maintain the user's perspective through close collaboration of designers, developers, and product owners throughout the design and development process, organizations can create an optimal mix of perspectives needed to bring a safe, usable device to market.

This might sound easy in theory but can be challenging to execute. A successful medical device development project—one that launches on-time, within budget, and meets the customer's needs—requires perseverance to keep all stakeholders engaged throughout the entire process. The end result will not only be truly effective and highly adopted devices, but also reduced costs that result from avoiding the need to solve problems late in the process that could have been addressed by closer collaboration at the start.

Avoid Inefficiencies and Rework

Close collaboration between design and development teams is key to communicating the different perspectives each team brings to the process. To bring a highly usable and safe medical device to market requires both the development team's deep understanding of the capabilities and limitations of the device's hardware and software architecture, and the design team's in-depth knowledge of the user's needs. Investing in tools, technologies and processes that enable and facilitate close, continuous collaboration between people and teams pays off significantly in the end.

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When it comes to product development, the design and development teams hold different pieces of a complex puzzle. Each team brings a unique and equally vital perspective to the table. When they operate in isolation, independently of one another, they may discover too late in the process that the pieces don't come together as they should.

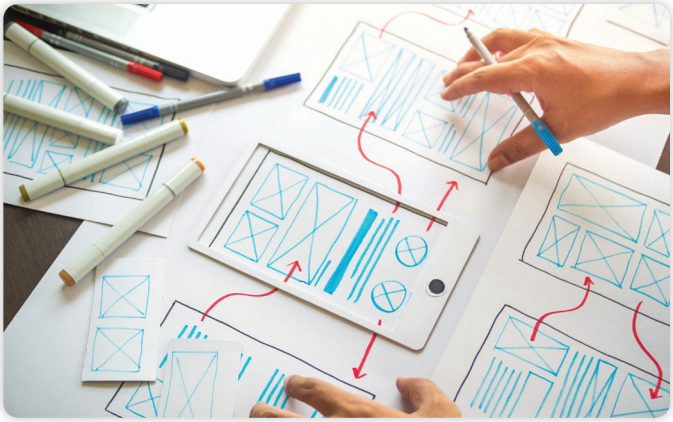
The development team understands the device itself–how it will be built, the hardware that will be used, the capabilities of the UI toolkits. Because of their understanding, they can define what is feasible. The design team, on the other hand, has a perspective on how the device is going to be used, which is essential to the overall success of the project. The give-and-take between software design and UI design is essential so the two remain well-aligned and the intent of the design is effectively captured in the implementation, which will lead to better software, shorter development cycles, and a better overall user-experience. "Close enough implementation" won't suffice in today's competitive medical device market, nor can it when it comes to patient safety.

Expect and Encourage Healthy Tension

Design and development teams may differ in their thought processes and approaches. Despite being in everyone's best interest to collaborate, it's natural for some tension to arise. Healthy tension doesn't have to be a bad thing—it can actually lead to better ideas. Providing an environment where everyone is encouraged to explore and examine ideas, respectfully challenge assumptions, and encourage each other to think in new ways can make for the best final product. Laying some team ground rules that support effective collaboration and ensuring users' needs are always being considered when opinions differ can help keep things positive and constructive.

Start Prototyping Early

It is essential to start gaining user feedback through prototyping as early as possible. Early prototyping allows for the product design to be fine-tuned before development resources have been committed to a design that may not be ideal. The software development process is complex and consumes substantial time and resources, so implementing software for user testing is costly. Some of today's common collaborative design tools, such as InVision, Sketch, Axure, and Figma, allow for fast prototyping and "real" experiences that can yield better, timelier user feedback. Software prototyping efforts should be focused on proof-of-concept testing where there are architectural questions and implementation concerns (feasibility, resource issues, etc.).



Understand and Include Users

While budget and timeline are certainly important, it's even more significant to deliver a safe medical device solution that end users will feel comfortable using and has the functionality they require. Therefore, it's critical to know when and how to solicit feedback from end users. Knowing what "just enough research" looks like for each project is critical to identifying the make-or-break features that are the hallmark of truly effective, highly usable safe medical device solutions.

Up front, it's crucial for all parties involved in design and development to understand who the user is, and to distill what that user is trying to accomplish. Once an initial prototype is created, formative testing should be done with actual users to get their feedback on what is and isn't working before development resources have been committed to a design.

Proxies (who are often from the sales team rather than actual clinicians or prospective patients) may not always understand the real-world use environment—lighting, noise, distractions, use of plastic drapes and gloves, time pressures, user's skill level. Or maybe the proxy has been in the role in the past, but things work differently now. Working directly with users provides the vital situational knowledge that allows both design and development teams to truly innovate. Real-world users should be engaged often in the process to provide input and feedback as concepts and designs are refined. Putting together advisory panels to give 15 to 30 minutes of feedback can be helpful if using the same users for ongoing input.

Conclusion

Projects with close collaboration between design and development that engage with their target users, while providing significant advantages in lower risks and costs, can often face organizational headwinds. Collaboration between teams works best and becomes second nature when it's an organizational mindset evangelized from the top and is supported throughout the development lifecycle. This kind of ongoing collaboration between design and development—before design of the UX/UI, during the design, and after the design—coupled with real user input, greatly increases the likelihood that the UX/UI will be safe and effective for end users; can be implemented within the constraints of the device; and will meet the objectives and goals of business leaders.

ABOUT THE AUTHORS

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Mary directs Fathom Consulting's research capability, diving deep in the design and delivery of quantitative and qualitative research. She's also a veteran user experience practitioner who has focused much of her career on eliciting user needs via research and improving digital experiences via usability evaluations, prototype creation and heuristic reviews.

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As a senior developer and technical lead, Bruce is highly skilled in planning, designing, implementing and delivering complex medical software systems. His passion for medical technology has inspired him to author a number of white papers and articles, and present at technical and industry conferences and webinars.

ABOUT FATHOM CONSULTING

Fathom Consulting is a business and design consultancy with over 20 years' experience in healthcare and health technology. We take a human-centric approach to the design and implementation of products, services, and strategic initiatives. By bringing the essential voices to the table and ensuring collaboration, momentum, and alignment, we help our clients drive change with confidence. With a rich understanding of human factors engineering, Fathom ensures products are designed with users' needs at the forefront. Our areas of practice support clients as they examine concepts, implement device design, test and train users, and prepare for FDA submission. **For more information, visit www.consultfathom.com.**

ABOUT MEDACUITY

MedAcuity is a specialized engineering firm that focuses on medical technology software development. The trusted and experienced firm was founded in 2007 by a team of seasoned software engineers who identified opportunities to fill gaps in the engineering expertise and efficiency facing the medical technology industry. MedAcuity offers extensive experience across the MedTech industry with full life-cycle software development and subspecialties in other areas including tool validation, algorithm development, and cybersecurity. **For more information, visit our website and follow us on LinkedIn and Twitter.**