User-centered design

FOR BETTER, SAFER MEDICAL DEVICES

Establishing a framework to successfully and quickly collect, distill, and make user perspective actionable is important for medical devices.

BY BORIS SAVIC AND DON GOETZ | JULY 2023

In even the most traditional and change-averse verticals, there's a growing understanding among product development teams that a user-centric approach to interface (UI) design is essential to building a successful device. When it comes to a precise, heavily regulated vertical such as medical devices, the ability to fully integrate the end user into the product development process is critical not just to the creation of the design, but to its validation as well.

In industries and use cases where they aren't driven to it explicitly by regulatory requirements, manufacturers often sacrifice the user experience (UX) and user validation – viewing them as nice to have instead of critical components of a successful product. As a result, user testing and validation are among the first elements to fall off the to-do list when the pressures of project delivery deadlines ratchet up.

When it comes to medical devices, that isn't an option. The regulatory process requires robust user observation, participation, and testing in order to validate the conformity of the product to the usage requirements. Therefore, establishing a framework to successfully (and relatively quickly) collect, distill, and make the user perspective actionable is paramount.

Integrate user perspective

Structuring how and when the user perspective is collected and used is a matter of meticulous planning and must conform to regulatory requirements and a project's overall regulatory timeline.

This means software designers must work to gain understanding of users' existing workflows, pain points, habits, and usage
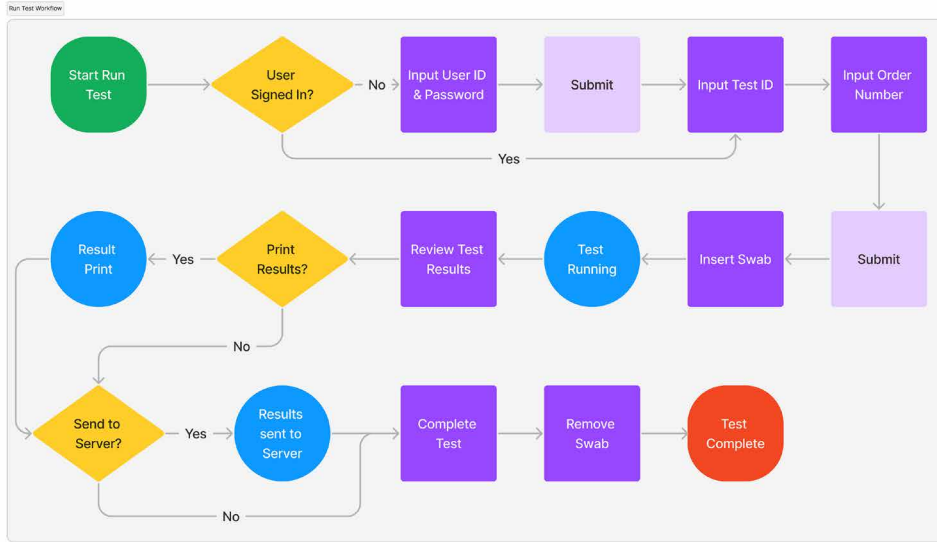
context in order to make informed and thoughtful decisions on the UI design. The challenge is amplified in the case of medical devices because they typically have more than one type of user, each with their own nuanced needs and variables. To achieve product success, designers need to understand and account for these needs. Proven UX design tools and techniques, including user personas, information architecture, and prototypes, allow designers to learn and document this essential information.

User interviews, personas

Talking to real users is indispensable in understanding their current workflows, preferences, and pain points. Typically, a

UX researcher would work with stakeholders to create a consistent script ahead of time and organize sessions by user types. It's critical to have sufficient test subjects for each category of user type for the results to be above the risk of statistical anomaly.

Though user testing results can be summarized in a variety of formats, doing so as user personas is a good way to paint a vivid picture as they give designers a better understanding of how the users will behave.

## Information architecture, workflows, diagrams

An information architecture (IA) is the blueprint for an application. In diagram

form, it's a visual representation of the structure of an application. It shows how the different sections and content are organized, and how users can navigate between them. For example, this is the IA for an Internet of Things (IoT)-connected COVID testing device.

These IA diagrams and workflows are an important part of the design process for any digital product. They help designers think through the structure of the product and help ensure that it's easy for users to find the information they need.

At Boston UX, our design team frequently (but not exclusively) leverages workflows to map out user testing. We typically keep things loose at this stage to stimulate conversion and definition.

A workflow diagram helps us determine how a user will use an application. They are step-by-step guides to how we would assume the user will perform the specific task illustrated in the workflow.
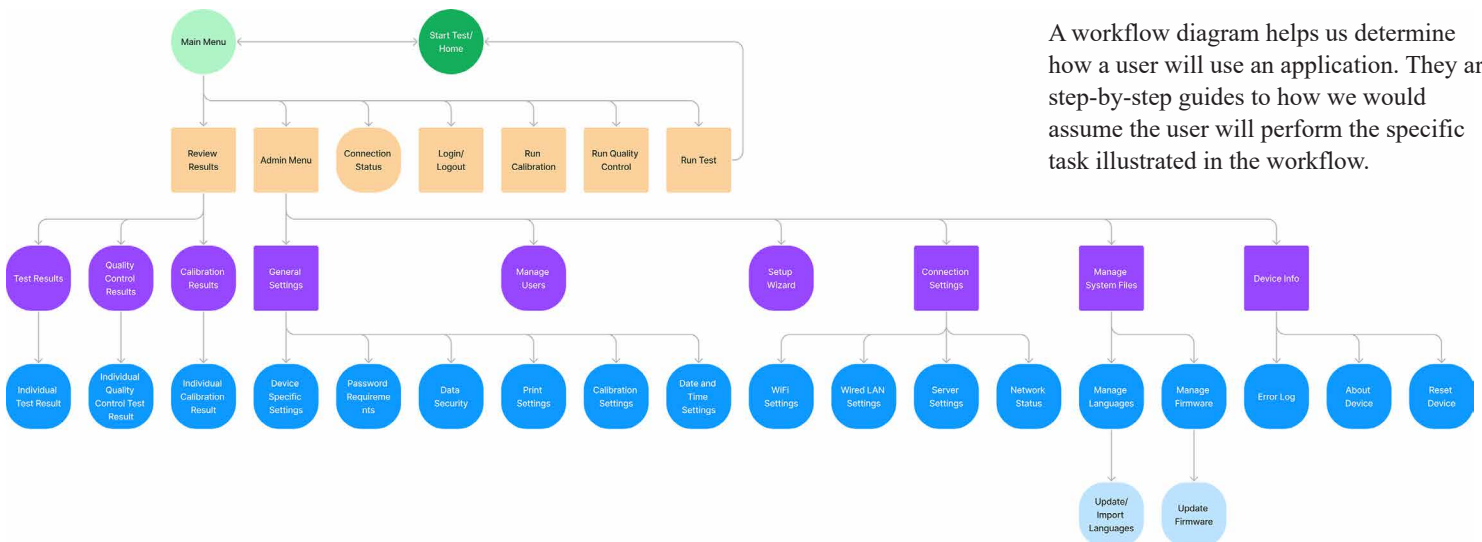
We want to tackle this step quickly at first with the understanding that the workflow will keep evolving with feedback from both stakeholders and users.

Prototypes, formative tests

One of the most effective ways to get critical user data is to create early prototypes to test interactions and elicit feedback. Prototypes are interactive versions of either the wireframes or fully designed screens that can be used to easily convey to either the stakeholders or developers how the application would work. Prototypes are typically simulations that allow for some basic click-through of scenes but do not usually include more advanced features.

One important thing to mention is along with planning tests, it's crucial to also plan how the results will find their way into the improvements to the user interface.

If there exists no mechanism for adding this newfound knowledge meaningfully back into the product design process to make improvements, the design team isn't maximizing the value of the test. Rather, designers are just paying lip service to the end user – and that's unacceptable.

UX touches everything

What makes design for medical devices different from the analogous process in other industries is the regulatory structure medtech projects must abide by. This structure affects not only the documentation produced, but also the design process itself. When it's working at its best, this process proactively flushes out errors and inefficiencies in the UI, leaving behind a trail of how it was done.

The fact is, UX design is an organizing science effective at documenting and expanding use cases and features in a way that defines scope and identifies a clear path forward. In cases where product requirements are insufficiently defined, the UX process is vital in filling those gaps and sharing that knowledge with the adjacent practices (visual design, regulatory, development).

By getting involved early in the product ideation and design of medical devices, UX designers can maximize their value and use

their skillset to unlock the whole team's ability to collaborate more effectively. Boston UX prioritizes UX and purposefully leverages the natural tendency of UX to deconstruct and document everything around the current and intended operation of a particular system.

This information drives the shared understanding of the product vision and details on behalf of the whole team. It also exposes areas that need more discussion and resolution. In regulated verticals such as medical devices, the path to validation is clear: not only come up with the right solution, but also meticulously document the process and pay off those solutions against very specific regulatory asks.

The takeaway is: Best practices-based UX design is a project's connective tissue. It gives product teams control over their own vision and data in a way that's both concrete and actionable.

ABOUT THE AUTHORS

Boris Savic | Director of User Experience at ICS and Boston UX

Don Goetz | Associate Director of User Experience at ICS and Boston UX

Integrated Computer Solutions (ICS)
https://www.ics.com

Boston UX
https://www.bostonux.com/