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## Accelerating product development with clinical experts

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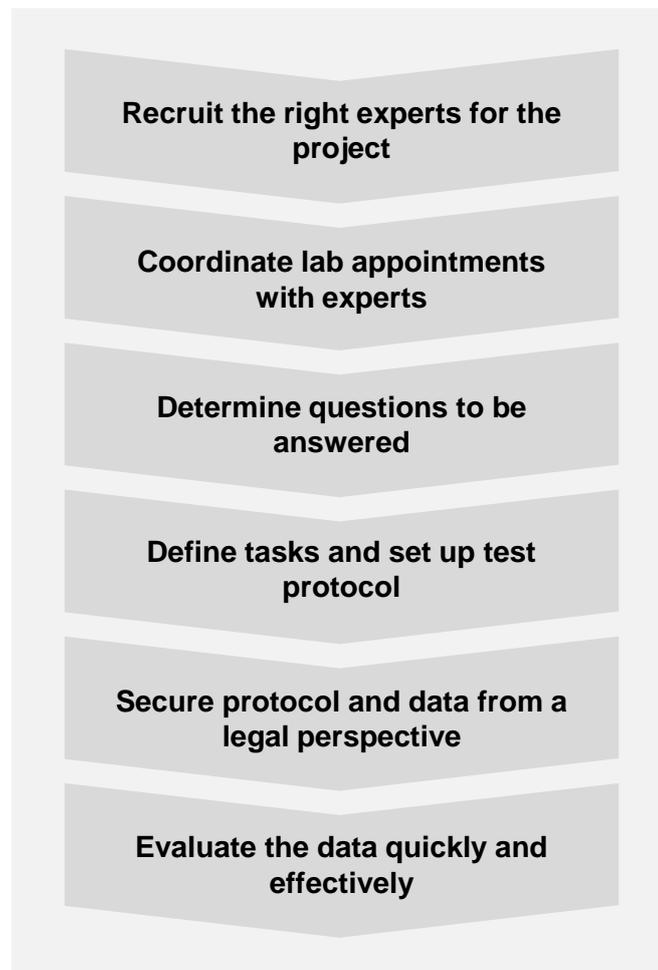
### Executive summary

Developing medical devices can be a complex and challenging task. Applying the principles of agile development and implementing key user panels at an early stage helps optimize your product to meet crucial customer requirements. Two major challenges in implementing usability tests into the development are upfront costs as well as difficulties in acquiring and consolidating clinical feedback. In the mid- and long run, however, the effort pays off with an estimated ROI of up to 10:1<sup>1</sup>. This paper discusses strategies to meet these challenges through agile integration of clinical experts.

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### The M3i strategic approach to user testing

In order to gain valuable and high quality feedback, various aspects need to be considered: regulatory requirements, patients' needs, customers' desires and cost restraints. Firstly, the right planning steps are key:



**Six steps towards high quality user feedback**

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<sup>1</sup> <https://www.mddionline.com/return-investment-human-factors>

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**Best practices in implementing user testing**

Secondly, these following aspects are crucial for a successful acquisition of the right feedback for your product:

**Choosing a representative sample of experts.** Selecting and acquiring the right experts makes a considerable difference in the quality of received feedback. Limiting the sample only to one functional user group can be critical if other user groups perform different tasks with the product, be it operating, cleaning, etc. Likewise, only recruiting experts from one particular medical field will also decrease the feedback quality. In order to avoid missing out on valuable insights a representative sample is essential.

**Gathering data in a structured way.** To make sure that the interviews and testing procedures reveal the right type of information, it is important to operationalize the topics of interest in a measurable way. Furthermore, it is helpful to have a system that allows a quick extraction of the key findings. This will help implement the changes faster.

**Adapting testing procedures for the development phase.** Each phase in the development process requires a different type of testing. In an early stage, expert interviews are a powerful tool to create ideas and move the project forward. In later stages, prototypes will be tested in increasingly complex scenarios.

**Improving the issues until they are settled.** When a feature request is brought up during an early phase of the product development process, it should not only be integrated into the design process, but retested during later test procedures, to make sure users approve of the implementation.

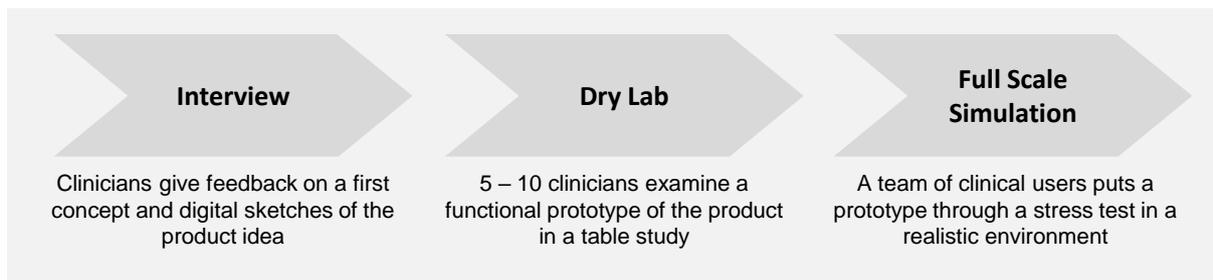
**Meeting compliance and confidentiality criteria.** Sensitive information might be handled between multiple parties during the process. This means, relevant processes and protocols need to be in place, to make sure that experts are free to share their thoughts and are legally bound to keep information confidential.

**Preparing data and testing protocols according to regulatory requirements.** Setting up tests scenarios in a way that they comply with regulatory requirements speeds up the authorization process and saves additional resources, since tests will not have to be repeated to meet the notified bodies' criteria.

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**Ensuring high quality and valid feedback**

While a growing number of medical technology companies understand the importance of integrating user feedback into the development process, it is often not easy to implement the input in practice. The key to overcoming these challenges is to acquire the right type of feedback at the right time and to implement procedures to derive valid data.



### The M3i innovation process with stage specific user feedback

#### Generating valid data by emphasizing the correct test set-up

**Unique and immersive testing lab.** To maximize the benefits of user integration, it is crucial to set up realistic simulation environments. Many studies, however, only include a high level handling of a prototype, without taking environmental factors into account. While a dry lab, or table study, is extremely helpful in a certain stage of the process, it should not be the sole source of user feedback. The key is to set up a realistic use environment, including fully functioning equipment, a sufficiently prepared dummy patient and case-specific material and data (e.g. x-ray images). Only then will the simulation provide the insight needed to improve the product's performance and usability.

**Scientifically validated results about improved safety or speed.** A live observation and recording of a simulated procedure provides invaluable user feedback and insight. To maximize the beneficial effect of the user engagement, preparation and post-procedure analysis are as important as the simulation itself.

**Careful preparation as an element of success.** Usually, an incoming team of practitioners is introduced to the simulation lab, the patient case and the device tested. To test the intuitiveness of an interface or the seamlessness of a workflow effectively, the team should not receive too much information upfront. Deciding what kind of and how much information a team will receive beforehand is already an integral part of a successful simulation test.

**Post-procedure interviews for in-depth insight.** During the procedure, the practitioners are being observed from the control room as well as recorded from various angles, for later analysis. Still, the information gained through this part of the examination can be enhanced by interviewing the practitioners about their experience afterwards, either in-person or by questionnaire. This way, designers can get valuable additional insight into e.g. what a person thought during a moment of distress or confusion.

**Integrate the whole team.** For a realistic simulation of how the device would be integrated into real usage scenarios, it is best to put complete teams to work. In our simulation lab, we frequently have teams visiting who actually work together in real life. This provides insight into how different roles interact with the device – e.g. a doctor might find it convenient to use, while an assisting nurse might have trouble reaching over or finding the right information quick enough.

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**Key advantages of user feedback**

Three of the biggest advantages of implementing customer feedback and usability tests include significant cost savings, shorter time to market periods and higher customer satisfaction. In order to fully utilize these benefits, M3i can support you in the following ways:

**Saving Costs.** Researching and acquiring the right experts as well as coordinating their lab appointments are lengthy and costly efforts. Given the complex nature of this process, a successful outcome is not always guaranteed. With M3i as a partner, you will benefit from access to an extensive pool of experts as well as years of expertise in the set-up of user tests that are designed to move your project forward while complying with regulatory requirements.

**Shortening time to market.** Successfully developing an excellent medical device requires a tight sequence of iterations alternating between development phases and testing. Knowing how and what to test for is key to strategically develop the roadmap towards a product that fulfills customer needs and regulatory requirements. With clear instructions derived from high quality test results, the design team can reach its goal significantly faster.

**Higher customer satisfaction.** Implemented user feedback leads to a better user experience. Focused user feedback reveals which features are desired and which should be removed. The consolidated results can be translated into a more effective and appealing product.

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**Conclusion**

Including user feedback into your product development process offers the opportunity to add value to your product. The key is to implement user feedback of the right type, at the right time and the right way to optimize your product and improve its user experience.

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If you are interested in learning more about how M3i can support you in your product development, please get in touch with our Managing Director, Dr. med. Simon Weidert at [sw@m3i-muenchen.de](mailto:sw@m3i-muenchen.de).

M3i is Germany's biggest Industry-in-Clinic Platform. Our mission is to provide medtech innovators with easier and faster access to clinical experts and infrastructures. Through our services 'InnoCheck', 'SimOP' and 'MedOSS' we offer a broad portfolio of resources for every stage of the development process.

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