WHY USABILITY ENGINEERING IS IMPORTANT

The value of Usability Engineering

Focusing on and prioritizing Usability Engineering activities will generate numerous cascading benefits:

- Medical devices that can be used safely and effectively
- Fewer late-stage changes in the development, ultimately leading to faster time-to-market
- Regulatory compliance – Even though not always submitted, documentation is still required and can be requested by authorities
- Simpler and more intuitive product user interfaces
- Minimized need for training and support
- Improved user satisfaction leading to improved sales
- Improved market life and customer loyalty
- Minimized risk of liability claims and product market withdrawals

This list clearly illustrates that even though Usability Engineering activities take time and resources, it is definitely an investment worth making.

Save time and money by focusing on Usability Engineering

For some, it might seem obvious that for a product to be successful, the User Interface needs to be easy, safe and effective for the users to use, which requires a dedicated focus on designing and evaluating the interface. For others, it might seem excessive to spend a lot of resources involving users – *"we know how the users will interact with the product"* – seems to be the opinion.

However, our experience is that there is great value and potential savings in both time and money in focusing on Usability Engineering when developing Medical Devices.

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Why plan your Usability Engineering activities?

What is User Interface Evaluation planning and why should you make an evaluation plan in the beginning of your project?

Most larger projects begin with a detailed plan, which is then updated as the project progresses.
This is an important tool to ensure progress and movement in the right direction throughout the project.
Similarly, it is very valuable to make a User Interface Evaluation plan, which gives an overview of the activities related to Usability Engineering throughout the project.

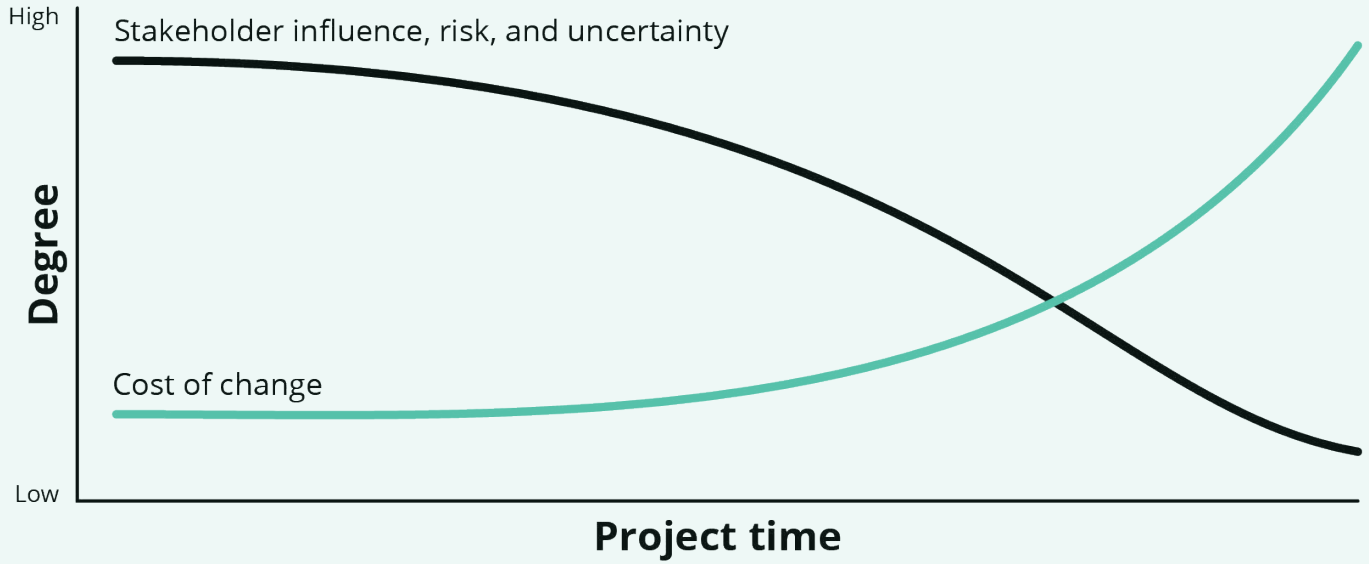
Naturally, this can be integrated in the project plan, but more details can be put in a separate plan. This plan can then enable execution of user research and user interface evaluation activities and ensure agreement on activities and dependencies involving potential usability issues across the R&D disciplines.

Integrating User Interface evaluation early on

There are multiple reasons to prioritize formative UI evaluation activities in the early development stages. A few are described below:

The formative UE activities performed can and should support the final summative evaluation documentation. IEC 62366-1:2015 is a process standard, requiring you to show the process of how you have optimized the user interface and mitigated the use related risks and the FDA expects this too.

It makes sense to start the UE activities to get valuable design input in the early development stages. This will allow for much quicker and cheaper design changes as illustrated in the graph below. For instance, it is crucial to select the right User Interface design concept from the beginning, as this can be expensive, time-consuming and almost impossible to change at a late stage. This is when the product gets more defined and multiple dependencies start to shape the final product.



We find that it is often more time consuming to patch a flawed UI design concept late in the development process than to spend time selecting the right one from the beginning. This includes defining the division of tasks between the user and the device. Careful considerations can save a lot in the later Usability Engineering work and validation activities. Remember, if you can verify that a use risk is eliminated by design, you do not have to validate it.

Launch strategy & Usability Validation

An important input to the User Interface Evaluation plan is which countries the product will be marketed in and in what sequence. For instance, if the product is to be launched in the US, the summative usability evaluation must be performed in the US as the participants should reside in the US. This is often time consuming and expensive for none US companies, but the test will be valid both in the US and the rest of the world.

However, if the product will not be put on the US market, it often makes sense to conduct the summative test in Denmark (i.e. the country of residence of the legal manufacturer). This will lower the cost and is both easier and faster for the Usability Engineering team to set up and conduct. In addition to this, the US FDA's expectation of 15 test participant per user group, even though reasonable, is not a requirement in the EU. For this reason, to get on the market in the EU quickly, it sometimes makes sense first to conduct the summative test in the EU and postpone the summative test in the US to when the product is to be marketed there.

It is important to note that a summative validation test conducted outside the US, is not likely to be accepted by the FDA.

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