Summative Usability Evaluation

What do you need to do? Your checklist

Are you unsure about one of the sub-items?

Take a look at our article on the checklist. We have explained each point there. You can also get in touch with us at any time using our contact form. We look forward to your feedback.

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Inhalt

1 Are you properly prepared?

- ☐ Are you planning the right process? (User Interface of Unknown Provenance for existing products, the complete usability engineering process according to IEC 62366-1 for new products)
- ☐ Have you found the right partner for the implementation?
- ☐ Have you defined all the important factors relating to your medical device?
  - ☐ The use specification
  - ☐ The right user groups
  - ☐ All characteristics of the user interface that are related to its safety
  - ☐ The list of all potential usage errors
  - ☐ A Use Related Risk Analysis has been performed
- ☐ Are there specific MDCG guidance documents for your product?

2 Formative usability testing no longer reveals critical use errors?

- ☐ Is the user interface of your product safe?
- ☐ Does it meet the performance requirements set by the MDR?
- ☐ Have you ensured that your IFUs and instructions accompanying the product are easy to understand by the target group?
- ☐ Have you ensured safe and error-free use across all operating phases?
- ☐ Have you minimized all risks of your product?
  - ☐ The risks due to ergonomic features
  - ☐ The risks of considering the abilities of the intended users

3 You have recruited the right users and enough of them?

- ☐ Do the recruited users correspond to your Intended User Group?
- ☐ The recruited users are a representative sample of the respective group?
- ☐ Have you planned for over-recruitment?

4 You have prepared the UX labs correctly?

- ☐ Is the right equipment available and prepared?
- ☐ Are the right premises available for the tests? Do the premises allow you to create a realistic usage environment for the tests?
- ☐ Have you checked the completeness of the equipment for the recordings and the stream for example?

5 If necessary: Have you trained your users properly?

- ☐ Have you trained according to your IFUs and trainings?
- ☐ Have you considered a realistic time interval between training and use

6 Do you have the appropriate personnel to carry out the summative usability evaluation?

- ☐ The people carrying out the evaluation are not involved in the development of your product?
- ☐ Do you have sufficiently qualified usability researchers for your study?
- ☐ You have appointed a "person responsible for regulatory compliance"?

7 Is your product ready for summative evaluation?

- ☐ Is your product available in pilot series or as a product equivalent device?
- ☐ Are your IFUs and instructions available in final form?

8 The summative evaluation is carried out in accordance with the MDR or IVDR?

- ☐ Have you created realistic conditions of use?
- ☐ You avoid questions during the implementation?
- ☐ The hazard-related use scenarios are tested?
- ☐ Are you considering that knowledge tasks must also be queried?
- ☐ Are you planning post-hoc interviews, i.e. follow-up surveys after use?

9 You have done the follow-up and data analysis?

- ☐ You have collected the data from your summative usability evaluation and would like to analyze it?
- ☐ Have you carried out a root cause analysis?
- ☐ Have you created a summative report?
- ☐ Have you checked your evaluation for completeness?
- ☐ You have fulfilled the previously defined criteria that your medical device must meet in order to no longer cause unacceptable risks during use?

10 Are you still looking for the right service provider?

We will be happy to help you tick off the checklist and support you with the following steps:

- ☐ The entire usability engineering process according to IEC 62366-1 from the Use Specification to the submission of the documents.
- ☐ In the planning and implementing the summative usability evaluation, including the recruitment and training of users and a descriptive evaluation.
- ☐ Preparing your documentation for the authority.

We wish you success in planning, implementing, and the follow-up of your summative usability evaluation!

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