7 Components of Successful Usability Testing in Medical Device Development

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1. Formative and validation tests
Formative testing

Formative usability testing is *an exploration*. Its purpose is to:

- Identify user needs and potential hazards
- Design out use errors while the design can still be modified
- Test “early and often”
Usability validation

Usability validation is *the proof*. Its purpose is to:

- Demonstrate intended users can safely and effectively perform critical and essential tasks
- Test the final design with intended users in real or simulated environment
Market research

Market research is useful for measuring opinions, attitudes, and speculation, but should not be confused with usability testing.

Usability testing is primarily about risk mitigation. User preference or acceptance is secondary. Usability testing shouldn’t be limited to subjective rating scale surveys (e.g. Likert).
Dual purpose

Often research efforts involve both usability testing and market research to serve two purposes:

Risk mitigation
Find interface problems leading to use error

Product enhancement
Improve ease of use, look and feel, desirability
Is testing required?

Formative testing is not explicitly required by law. However, failure to perform formative testing is a “red flag” to the FDA, and bad business practice. It is appropriate to scale the exercise based on risk and complexity.

Usability validation is required per 21 CFR Part 820
2. Planning for tests
Scheduling testing

Build usability tests into the development schedule early, especially since recruitment of participants takes time.

Testing can actually shorten the overall schedule by:
- Finding issues early when they are easier to fix
- Helping teams make decisions and move forward
Pilot testing

Especially for validation testing, it is wise to perform pilot testing to fine tune the test protocol before collecting data that counts. Pilot testing provides an opportunity to:

- Adjust scenarios and questions
- Check equipment
- Rehearse roles
- Review test schedule
If a project schedule or budget limits formative testing, a “quick and dirty” test can answer some basic design questions.

Whether the effort can be called a formative test depends on methods and recruitment. At minimum, describe the test and results in a memo to receive “credit.”
Unalterable designs

Even if a design is already “frozen,” formative testing is still worthwhile. Critical issues that arise may cause reconsideration. Even if design changes are not pursued, adjustments could be made to learning aids, training, or marketing strategy.
3. User groups and participants
User groups

User groups are distinct populations that interact with the device differently.

They perform different tasks or understand treatment or device operation differently.

Some high level categories are:
- Professional caregivers
- Home or "lay" users
- Pediatric users
User groups

When recruiting participants:

• Be inclusive of variability in user abilities relevant to device use

• Incorporate worst case users if they represent a consistent portion of the user population

• If a disease being treated affects device use, only test people with the disease
How many participants?

For each distinct user group, use a minimum of 5-8 participants for formative testing or 15 for validation.

The goal is to find problems! 5-8 participants reveal 80-90% of problems. Additional participants offer diminishing returns.

Recruit extra participants to account for “no-shows.”
Internal participants

Use of “internal participants” is often suggested to save time and money, but rarely makes sense. They are not members of the user group, and know too much about the project to be unbiased.

A formative test may present an exception if it solely examines physical ability and the internal participants fit the physical user profile.
Group tests

Group usability tests are often proposed for time/cost savings, but should be avoided unless a team approach reflects actual use.

It is important to measure individual performance, and shield participants from the influence of others.

Individual tests may be run concurrently to save time if it is feasible.
4. Moderating usability tests
Internal moderators

There are advantages and disadvantages to having team members conduct tests of their own designs.

**Pro**
- In-depth product knowledge
- Cost savings

**Con**
- Difficult to be objective and avoid unintentional bias
Moderating tests

If moderating a usability test, try to be clear and unbiased in your interaction with participants.

Common mistakes include:

- Talking too much
- Leading or biasing
- Assisting
- Rushing
- Losing track of time
Providing assistance

If participants have difficulty completing tasks, promote perseverance and let them struggle.

Assistance should only be provided at a true impasse. Time limits may help to make that decision. Assistance may ramp up as needed from a hint (e.g. “have you checked the IFU?”) to explicit directions.
5. Use scenarios, prototypes, and training
Usability testing must involve representative use, with tasks selected and prioritized based on risk:

- Critical tasks with a potential for harm
- Essential tasks required for medical benefit

State the selection rationale using preliminary analyses and formative testing.
Use scenarios

Usability testing involves observing participants in use scenarios, groups of tasks with a realistic flow (not “do task 1, now do task 2”).

Use scenarios should include critical and essential tasks. They may be crafted to repeat tasks for closer evaluation, and force difficult or atypical situations as needed.
Prototype fidelity

Formative testing usually involves iterative prototypes to examine use errors mitigated or induced by design features.

Usability validation must be performed with equivalent units.
Training

Thought should be given to training users during usability testing. Formative tests can explore how much (if any) training to provide, while validation must be consistent with the training actual users would receive.

Provide any learning tools that would be available (e.g. instructions for use), and build in a decay period after training.
Training

If actual users receive training, withholding it to show intuitiveness can be counterproductive:

- Testing may fail to expose issues with training
- The project team may see the added challenge as sabotage

Also consider that optimizing a device for intuitiveness can hurt long term ease of use.
6. The test environment
Environment fidelity

Test environments should be representative of actual use environments to the extent that is necessary and practical. Increased fidelity (e.g. noise, distraction) should be guided by preliminary analyses.
7. Test results
Objective data

Objective data must be gathered during usability validation. Count and explain performance failures for critical and essential tasks. These include:

- Actions (or inactions) that would cause harm or make treatment ineffective
- Confusion, difficulty, and close calls that could lead to harm
Subjective assessment

Subjective data must also be gathered during usability validation through interview-based retrospective analysis. Inquire about:

• Each failure, close call, or difficulty
• Any difficulties not noted by the observer
• Thoughts on all critical and essential tasks
Key takeaways

• Usability testing is about optimizing the user interface to ensure safety. User preference or acceptance is secondary.

• Explore risks with formative (early/often before design freeze), and prove safety with validation.

• Adjust test fidelity as needed per preliminary analyses.

• Avoid internal participants, group tests, and subjective rating scales.

• Don’t exclude subjective assessment portion of validation: Validation is not just a list of failures, but an analysis of why.
Bibliography and references


FDA. *Applying Human Factors and Usability Engineering to Medical Devices to Optimize Safety and Effectiveness in Design*. 2011.


We enjoy a good challenge. Let’s start the conversation.

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