Quickstart Guide: V3+ Use-Related Risk Analysis

Are you a tech developer looking to get started with your use-related risk analysis?

Are you considering implementing a sensor-based digital health technology (sDHT) for research or clinical care?

This quickstart guide is for you.

Developing a use-related risk analysis is the second step of the usability validation component of V3+, following the development of the use specification.

Haven't developed your use specification yet? Check out our quickstart guide.

The use-related risk analysis is undertaken iteratively and collaboratively to identify foreseeable risks associated with using the sDHT and develop a plan to minimize or eliminate those risks. Keep the focus on user interactions rather than on issues related to sDHT technical performance or hazards such as sharp edges, unsafe operating temperatures, or non-biocompatible materials.

STEP 1. Describe all user tasks

A user task is an action or set of actions a user performs to achieve a specific goal.

Tip: User tasks can be identified during task analysis, heuristic analysis, expert review, systematic searches for known use problems, and by observing end-users interact with the sDHT during formative evaluations.

Remember, **'users'** includes end-users - the patients or participants from whom the sDHT are captured - and any other individuals who interact with the product, including carepartners, clinicians, investigators, and administrators.

For example, consider providing a hypothetical continuous glucose monitor to end-users to adjust the dose of their long-acting insulin medication.

If the goal is to review overnight glucose data, user tasks might include Open app > Click on 'My Data' > Select yesterday's date > Select the preferred measurement units > Click 'Go'.

STEP 2. Describe potential use-errors

A use-error is an action, or lack of action, which may result in harm.

Tip: It is also helpful to capture and describe any user interactions that are different than expected but do not result in harm, as these are likely to impact the overall usability of the sDHT. However, these errors are not typically described in the use-related risk analysis.

The term "**use-error**" is preferable to "user-error" as it avoids the implication that the user is at fault.

For example, *a potential use-error might involve the end-user selecting glucose units of mmol/L when they intended to select mg/dL.*

STEP 3. Describe potential use-related hazards

A use-related hazard is a source of potential harm resulting from a use-error.

Tip: Optimal sDHT design involves minimizing or eliminating all possible use-errors; however, this is particularly important for critical tasks, which are use-errors that may result in serious harm.

The use-related risk analysis is a living document requiring maintenance and updates throughout the entire sDHT development process.

For example, *serious harm might result if the end-user adjusts their insulin dose based on glucose data displayed in mmol/L, when they are more familiar with mg/dL.*

STEP 4. Develop a plan to minimize or eliminate known risks

The ideal approach is for use-errors to be 'designed out,' known as inherent safety by design.

- If this is not feasible, protective measures may be adopted.
- Instructions to avoid use-errors may be provided to users as a last resort.

For example,

- ✔ *The configuration process could be modified to allow only one measurement unit in each region, thereby eliminating the risk.*

- ✔ *A pop-up warning could be programmed to appear before the glucose data are displayed, alerting the end-user that they have selected mmol/L as the measurement unit. This approach is not optimal because the end-user might dismiss the warning without acting on it.*

- ✔ *A warning statement could be added to the instruction manual highlighting the importance of selecting the appropriate units. This approach is insufficient, as end-users may only sometimes read the manual.*

STEP 5. Keep it up to date!

The use-related risk analysis is a living document requiring ongoing updates and maintenance throughout the usability validation process.

What comes next for V3+ Usability Validation?

Check out our at-a-glance guide for incorporating human-centered design into sDHT development.

See the V3+ Usability Validation Glossary for key terms and definitions.