Checklist: Essential Usability Validation Questions for sDHT Developers

Are you a researcher or healthcare provider considering implementing a sensor-based digital health technology (sDHT)?

Use this checklist to begin discussing usability validation with the tech developer.

THE BASICS: START HERE

Before you begin these questions, ensure you have developed your context of use statement.

- ☐ What is the sDHT designed to do?
- ☐ Who are the intended users of the sDHT?
- ☐ Where is the sDHT designed to be used?
- ☐ When is the sDHT designed to be used?
- ☐ How should the sDHT be used?

The answers to these questions should be captured in the intended use statement if the sDHT is a regulated medical device. If the sDHT is not a regulated medical device, the tech developer should be able to provide you with answers to each.

How will you use this information? Compare the answers to these questions to your context of use. If there is substantial overlap, the existing usability validation evidence may be sufficient for you to determine that the sDHT is fit-for-purpose. If not, use the gaps to identify areas where additional usability validation evidence will be needed.

QUESTIONS RELEVANT TO THE USE SPECIFICATION

Before you begin these questions, ensure you have developed the first version of your use specification.

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

Remember, the use specification is a living document requiring maintenance and updates throughout the sDHT development process.

☐ Where can I access a detailed description of the sDHT hardware and software?

☐ In what ways does the sDHT design prioritize accessibility?

☐ What sDHT accessories will users interact with? For example, packaging, chargers, or replacement parts.

☐ What written materials are available to users? For example, instructions for use, quickstart guides, or sizing charts.

☐ What training or support is available to users? For example, instructional videos, helpdesk troubleshooting, or in-app chats)?

How will you use this information? Use this information to add more detail to the user interface section in your next use specification version.

QUESTIONS RELEVANT TO THE USE-RELATED RISK ANALYSIS

Before you begin these questions, make sure you have developed the first version of your use-related risk analysis.

Haven't developed your use-related risk analysis yet? Check out our quickstart guide.

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

☐ What cautions, warnings, and contraindications should I be aware of?

☐ What are some of the harms that might result from sDHT use-errors?

☐ Where can I access information about the potential seriousness of those harms?

☐ What are some of the ways users can avoid known risks?

How will you use this information? Use this information to add more detail to the next version of your use-related risk analysis.

QUESTIONS ABOUT EXISTING USABILITY VALIDATION EVIDENCE

Before you begin these questions, ensure you understand the various ways sDHT usability can be measured. Check out our at-a-glance guide.

Many of these questions are captured in the EVIDENCE Checklist.

- ☐ What were each usability validation study's objectives and hypotheses (if applicable)?

- ☐ Which institutional review board or ethics committee approved the study (or granted an exemption), and did participants provide informed consent?

- ☐ Where can I access the protocol of each usability validation study and the clinical trial registration record (if applicable)?

- ☐ What were the characteristics of the end-user study participants?

- ☐ What usability validation evidence is available from other user groups, such as clinicians, researchers, or administrators?

- ☐ How was the sample size of each study determined?

- ☐ Were the usability validation data collected using the same sDHT version (model) currently available? If not, how do the form factor, wear location, and user interface differ between the two models?

- ☐ What usability validation metrics were captured?

- ☐ What use environments were the usability validation evidence collected in?

- ☐ What methods were used to collect the usability validation evidence?

- ☐ What were the statistical analysis procedures?

- ☐ Where can I access the results of existing usability validation studies?

How will you use this information? Use this information to determine the extent to which the existing usability validation evidence is applicable or generalizable to your context of use and the extent to which additional usability validation evidence is required.

HOW CAN RESEARCHERS AND HEALTHCARE PROVIDERS COMMUNICATE AND COLLABORATE WITH THE sDHT DEVELOPER?

☐ What is the best way(s) for my organization to provide usability-related feedback to your organization to incorporate into the design of next-generation sDHTs?

☐ How will sDHT updates and modifications be communicated to my organization for version-control purposes?

☐ Is it appropriate and feasible for our organizations to collaborate on one or more usability validation studies? If yes, how can we arrange that?

It's helpful for a research study sponsor or healthcare provider to consider establishing a collaborative relationship with the sDHT developer to maintain version control and ensure that the tech developer can use feedback from real-world use to improve the usability of the next-generation sDHT.

How will you use this information? Use the information from the tech developer to keep your use specification and use-related risk assessment current.

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