The V3+ Usability Validation Glossary

Are you new to the field of usability validation?

Keep this glossary handy.

"Establishing a common language to describe evaluation standards is critical to streamline trustworthy product development and regulatory oversight"

- Jennifer Goldsack *et al* in the original V3 framework, *NPJ Digital Medicine* 2020

Abnormal use: Intentional reckless use or sabotage, beyond the scope of the *use-related risk analysis*. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Actionability: The extent to which *users* of diverse backgrounds, languages, and varying levels of health literacy understand the actions or *user tasks* they should complete in response to clinical data or other information presented to them, typically assessed in a *knowledge task study*. Reference: Shoemaker *et al.* 2014

Clinical utility: The extent to which implementing an sDHT leads to improved health outcomes or provides useful information about the diagnosis, treatment, management, or prevention of a disease. Reference: BEST Glossary

Cognitive walkthrough: A *formative evaluation* in which A) *usability* experts break down *user tasks* and identify possible *use-errors* and/or B) usability experts guide *users* through user tasks while encouraging users to think aloud. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Context of use: A statement that fully and clearly describes how the sDHT is to be used and the purpose of the use. Reference: BEST Glossary

Contextual inquiry: Observation of *users* interacting with a functional sDHT in the intended *use environment*, with staff asking questions during or after use. References: FDA Guidance, MHRA Guidance

Critical task: A *user task* that, if not performed or performed incorrectly, would or could lead to serious harm. References: FDA Draft Guidance, FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Ease of use: The ease with which a *user* is able to perform *user tasks*, captured through self-report (such as the mental demand or effort required to complete a task) or objective measures (such as the number of actions, number of attempts, or time required to complete a task. Reference: Nielsen Norman Group

Efficiency: The *ease* with which a *user* is able to perform *user tasks* after having learned how to use the sDHT. Reference: Nielsen Norman Group

End-user: A *user* from whom sDHT-derived clinical data are captured; that is, the patient or participant.

Error recovery: The ability of a *user* to make a correction following a *use-error* in order to complete a *user task*. Reference: Nielsen Norman Group

Fit-for-purpose: A conclusion that the level of validation associated with an sDHT is sufficient to support its *context of use*. Reference: BEST Glossary

Formative evaluation: A research study or activity undertaken to evaluate *usability* of a prototype sDHT, with the goals of understanding *user* interactions with the sDHT and gathering information to inform design modifications. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Gap analysis: A systematic approach to comparing two or more statements or scenarios. For the *usability validation* component of V3+, a gap analysis will identify differences between the *intended use* and *context of use* statements.

Human factors: The application of knowledge about human behavior, abilities, limitations, and other characteristics of *users* to the design and development of an sDHT to optimize *usability* within a defined *intended use* or *context of use*. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Human-centered design: An approach to interactive systems that aims to make systems usable and useful by focusing on the *users*, their needs and requirements, and by applying *human factors* and *usability* knowledge and techniques. Reference: ISO 9241-210:2019

Indications for use: A statement that describes the disease or condition the sDHT is designed to diagnose, treat, prevent, cure, or mitigate, including a description of the patient or participant population for which the sDHT is intended. Reference: FDA Guidance

Intended use: A statement that describes the specific clinical circumstance or purpose for which an sDHT is being developed, including the *indications for use*. Reference: FDA Guidance

Knowledge task study: A study undertaken to assess *understandability* and *actionability*. Reference: FDA Draft Guidance, FDA Guidance

Learnability: The *ease* with which a *user* is able to perform *user tasks* during their first encounter with the sDHT. Reference: Nielsen Norman Group

Memorability: The *ease* with which a *user* is able to perform *user tasks* after a period of non-use assessed in a test-retest paradigm. Reference: Nielsen Norman Group

Production-equivalent: A sample sDHT of the final design assembled in a way that differs from, but is equivalent to, the manufacturing processes used for the marketed sDHT. Reference: ISO 13485:2016

Sensor-based digital health technologies: Connected digital medicine products that process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function, also referred to as biometric monitoring technology. Reference: V3 framework

Summative evaluation: A research study undertaken on a *production-equivalent* or marketed sDHT, including all components of the *user interface*, with the goal of demonstrating *usability* amongst a representative sample under conditions reflecting the *intended use* or *context of use,* referred to by the FDA as 'human factors validation.' References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Technical specification: A comprehensive description of the sDHT dimensions and materials; the units of the sampled data, sampling frequency and the sampling range of each sensor; battery life; data storage; data transmission protocols; environmental limits; and other technical information.

Understandability: The extent to which *users* of diverse backgrounds, languages, and varying levels of health literacy understand the clinical data or other written information (such as instructions, cautions, warnings, and contraindications) presented to them, typically assessed in a *knowledge task study*. Reference: Shoemaker *et al.* 2014

Usability: The extent to which an sDHT can be used to achieve specified goals with *ease*, *efficiency*, and *user satisfaction* within a defined *intended use* or *context of use*. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated), ISO 9241-210:2019

Usability validation: Evaluation and demonstration of *usability*.

Use environment: The setting(s) in which the sDHT is intended to be used. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Use-error: An action or lack of action may result in a *use-related hazard*. "Use-error" is preferable to "user-error" as it avoids the implication that the user is at fault. Reference: FDA Draft Guidance, FDA Guidance

Use-related hazard: A source of potential harm resulting from a *use-error*. Use-related hazards are those associated with *user* interactions, rather than issues associated with sDHT technical performance or hazards such as sharp edges, unsafe operating temperatures, or non-biocompatible materials. Reference: FDA Guidance

Use-related risk analysis: A living document describing reasonably foreseeable risks associated with using an sDHT and a detailed plan to mitigate those risks. References: FDA Draft Guidance, FDA Guidance, MHRA Guidance

Use scenario: Rich descriptions of several likely *use environments* and how interactions with the sDHT might differ between them. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

Use specification: A living document containing detailed descriptions of all *user* groups, all *use environments*, and all aspects of the sDHT *user interface*. Reference: MHRA Guidance

Usefulness: The extent to which a *user* finds the sDHT, or its specific features/functions, to be valuable, productive, and/or helpful. Reference: Schnall et al. 2015

User: Any individual who may interact with an sDHT as part of normal use, including the *end-user* and their carepartner(s), as well as individuals acting in a professional capacity, such as those in clinical, research, and/or administrative roles. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

User interface: All points of interaction a *user* may have with the sDHT as a holistic system, including hardware, software, all components and accessories, packaging, instructions for use and other documentation, and user training. References: FDA Guidance, MHRA Guidance, NMPA Guidance (translated)

User satisfaction: The extent to which a *user* finds the sDHT to be pleasant to use, which may reflect trust, comfort, aesthetics, engagement, desirability, emotional response/s, and other considerations. Reference: Nielsen Norman Group

User Task: An action or set of actions performed by a *user* to achieve a specific goal, often referred to simply as a 'task.' Reference: FDA Draft Guidance, FDA Guidance

Are you looking to do a deep dive into regulatory guidance and industry standards related to usability?

Check out our Library of Human Factors Resources for Digital Health Technologies.