The V3+ Usability Validation Glossary

Are you new to the field of usability validation? “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 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](https://www.nielsen规范.com)

**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](https://www.bestglossary.com)

**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](https://www.fda.gov), [MHRA Guidance](https://www.mhra.gov.uk), [NMPA Guidance](https://www.nmpa.gov.cn) (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](https://www.fda.gov), [MHRA Guidance](https://www.mhra.gov.uk), [NMPA Guidance](https://www.nmpa.gov.cn) (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](https://www.iso.org)

**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](https://www.fda.gov)

**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](https://www.fda.gov)

**Knowledge task study:** A study undertaken to assess understandability and actionability. Reference: [FDA Guidance](https://www.fda.gov)

**Learnability:** The ease with which a user is able to perform user tasks during their first encounter with the sDHT. Reference: [Nielsen Norman Group](https://www.nielsen规范.com)

**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](https://www.nielsen规范.com)

**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](https://www.iso.org)

**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](https://www.v3framework.org)
**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 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 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 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.