ISO/TS 82304-2:2021 (E)

Health software — Part 2: Health and wellness apps—Quality and reliability

Contents

5.2.3.1 Are ethical challenges of the health app assessed with intended users and health professionals?
5.2.3.2 Is the health app approved by an independent ethics advisor or ethics advisory board?
5.2.4 Health benefit
5.2.4.1 Describe the health benefit of using the app.
5.2.4.2 Are potential customers and users made aware of the health interventions applied to achieve the health benefit?
5.2.4.3 Are potential customers and users made aware of all financial costs to achieve the health benefit?
5.2.4.4 Are potential customers and users made aware of the need for support of a health professional to achieve the health benefit?
5.2.4.5 Is evidence available to support the health benefit of using the app?
5.2.4.5.1 Does this evidence include peer reviewed research involving the use of this health app?

5.2.4.5.2 Is the level of the evidence appropriate?
5.2.4.6 Is there a maintenance process for the health information in the app?
5.2.4.6.1 Are all sources for the health information in the health app disclosed to potential customers and users?
5.2.4.7 Are all sources of funding of the health app disclosed to potential customers and users?
5.2.4.8 Is the use of advertising mechanisms in the health app disclosed to potential customers and users and are these advertisements clearly distinguishable?
5.2.5 Societal benefit
5.2.5.1 Is evidence available of a societal benefit of using the app?
5.2.5.1.1 Does this evidence include peer reviewed research involving the use of this health app?

5.3 Easy to use
5.3.1 Accessibility
5.3.1.1 Is the health app WCAG 2.1 AA or AAA compliant?
5.3.1.1.1 Are WCAG 2.1 AA compliant measures taken to ensure that all intended users can perceive all relevant information and user interface components of the health app and related documents?
5.3.1.1.2 Are WCAG 2.1 AA compliant measures taken to ensure that all intended users can operate all relevant user interface and navigation components of the health app and related documents?
5.3.1.1.3 Are WCAG 2.1 AA compliant measures taken to ensure that all intended users can understand all relevant information and user interface components of the health app and related documents?
5.3.1.2 Is the health app age-appropriate?
5.3.2 Usability
5.3.2.1 Is the health app design based on an explicit understanding of users, tasks and environment?
5.3.2.2 Are intended users involved throughout design and development of the health app?
5.3.2.3 Is the design of the health app driven and refined by user-centred evaluation?
5.3.2.4 Are measures in place to avoid use error and reasonably foreseeable misuse of the health app?
5.3.2.5 Are potential customers and users provided with adequate product information about the health app?
5.3.2.6 Are instructions for use readily available for users?
5.3.2.7 Are appropriate resources available to adequately help users who experience problems with the health app?
5.3.2.8 Is relevant data on the usability of the health app systematically gathered throughout its entire lifetime, in order to make regular improvements?
5.4 Secure data
5.4.1 Privacy
5.4.1.1 Does the health app process Personally Identifiable Information (PII)?
5.4.1.1.1 Does the health app process health related PII?
5.4.1.1.2 Is data minimization applied in the health app?
5.4.1.1.3 Is an appropriate retention policy established to erase or review the data stored?
5.4.1.1.4 Is a privacy statement readily available to potential customers and users of the health app?
5.4.1.1.4.1 Does the privacy statement start with an accessible overview of less than 150 words?

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