Definitions of the foundational criteria clusters

Criteria Cluster	Definition
1- Technical aspects	Assesses whether the tool is functioning accurately and rapidly, is reliable and available at all times and can handle high levels of traffic and usage, provides adequate and user-friendly training resources for end users, and it is easy and obvious to access technical help when needed.
2- Clinical utility and safety	Assesses whether the tool's clinical effectiveness is supported by strong research with adequate statistical power conducted by credible sources, warns about potential risks when necessary and properly handles potentially "dangerous" information entered by a patient, and differentiates between clinical and technical feedback, and clearly channels clinical feedback that may pose a health risk through the proper channels.
3- Usability and human centricity	Assesses whether the tool's usability and acceptability has been rigorously trialed and tested in a real world setting, learning to use the tool is easy and does not require a lot of time, the visual design is appealing and has a harmonious look and feel, is well structured, and important information is clear and stands out, there's evidence for co-creation and collaboration with users in the tool's development, provides appropriate ongoing feedback and appropriate call to action based on the user's state and activities (when applicable), its content and design are appropriate for the target audience and accessible to vulnerable populations, and has the ability to foster the interaction between the health care professionals and their patients (when applicable).
4- Data management	Assesses whether the tool has a clear privacy policy and informs the users on how their data will be kept confidential and secured and how the data may be used, respects informed consent and allows the user to opt out of data collection, its data can be accessed at any time and on different platforms and operating systems, and it explicitly and easily enables users to delete their data.
5- Functionality	Assesses whether there is clear information about the tool's features and appropriate ways to utilize it, the functionality of each element is clearly identifiable, the tool has specific, measurable and achievable goals (desired outcomes) that are specified/obvious within the tool itself, and interactive features such as reminders, push notifications, and prompts are customizable and not overwhelming.
6- Content	Assesses whether health-related content is accurate, complete, consistent, and timely; is provided in a clear and appropriate way for the target audience; there is sufficient information throughout the tool without any omissions, over-explanations, or irrelevant data; the content has been reviewed by patients to ensure readability and acceptability; the tool contains high quality information from credible and legitimate sources; has been reviewed by (or originated from) healthcare professionals with the most updated evidence-based practice of medicine, and contents are relevant to the underlying objective and likely to be effective in achieving the specified purpose in the specific intended population.
7- Endorsement	Assesses whether the tool has been verified, given a good review, or endorsed by a legitimate/reliable source such as a health organization, health authority, scientific/medical society (e.g., APA; FDA in the US; NIH; NHS in the UK; NICE in the UK) or recommended by trusted Healthcare Professionals.
8- Maintenance	Assesses whether the tool gets periodic updates and maintenance both from technical and content perspectives (e.g., last update not older than xx months depending on the use case, the content is periodically updated with the new findings in the medical field).
9- Developer	Assesses whether the tool's provider respects ethical conduct, clinical responsibility, and the rules and regulations protecting patient's rights and societal interests; interaction quality between the tool's provider and the users, including responsiveness, after sales services, and customer orientation is high; and the tool's provider demonstrates a proactive approach to the assessment of user needs, and continuous learning.

Source: Jacob et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. npj Digit. Med. 6, 232 (2023). <u>https://doi.org/10.1038/s41746-023-00982-w</u>