Tool details and risk tier

(according to the selected risk tier some criteria may not apply)

Tool name	
Link to the tool's website	
Tool description	*Objectives, use cases, target users, disease area*
Developer information	*Details about the developers and their affiliation (e.g. commercial, NGO, university, unknown...)*
Assessor profile	*E.g. self-appraisal done by the tool devloper, the assessor is a hospital administrator, a clinician...etc.*
Date of the assessment	*Assessments should be periodically revised as eHealth tools are typically often updated and further developed as new technologies emerge*
Risk tier	*Risk tier A, B, or C. Please see guidance below to help define which risk tier the tool you are assessing belongs to (according to the selected risk tier some criteria may not apply)*
Assessor notes	*Any additional notes about the tool or the developer that the assesor(s) would like to add*

Tier A tools are those which have no direct outcome on the patient, but which are intended to save costs or staff time

(e.g. electronic prescribing systems that do not provide advice to patients, complex scheduling software)

Tier B tools are those that assist the public to manage their own health

(e.g. instant messaging apps for healthcare, symptom or mood diaries and programmes to aid weight-loss or better sleep)

Tier C tools are those used for treating and diagnosing medical conditions, with direct health outcomes, and which are likely to be regulated medical devices

(e.g. symptom monitors which share data with care teams, triaging systems that use patient health data to assist with care decisions and devices that perform diagnostic image analysis for making treatment decisions)

Tier C DHTs are further split into four sub-groups, namely those which: inform clinical management, drive clinical management, diagnose a condition and treat a condition

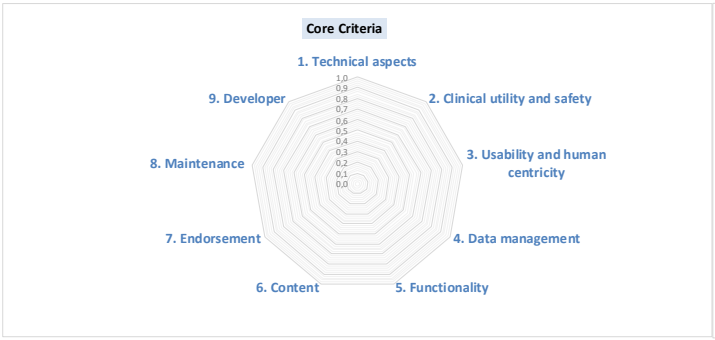
For more info please check the NICE ESF risk classification in this link
https://www.nice.org.uk/corporate/ecd7/chapter/section-b-classification-of-digital-health-technologies

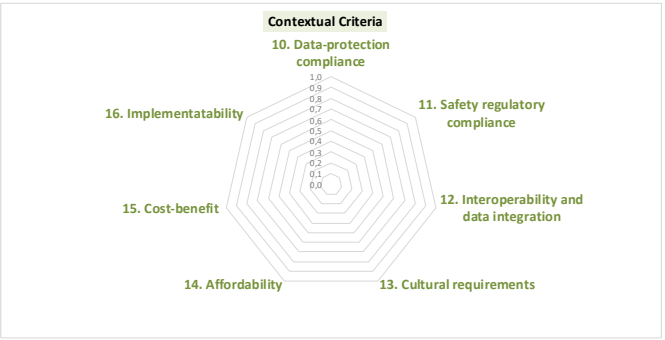
The scorecard will automatically reflect the assessment values entered in the sheets "Core criteria - entry" and "Contextual criteria - entry"

Please scroll to see radar charts

Core	sub-criteria	mean score
1. Technical aspects	1.a. Tool functioning accurately and rapidly, 1.b. Reliable and available at all times, 1.c. Adequate training resources, 1.d. Easy to access help	#DIV/0!
2. Clinical utility and safety	2.a. Clinical evidence, 2.b. Properly handles potentially dangerous information, 2.c. Differentiates between clinical and technical feedback	#DIV/0!
3. Usability and human centricity	3.a. User research, 3.b. Easy to navigate, 3.c. Learnability, 3.d. Visual design is appealing, 3.e. Well structured , 3.f. Evidence for user engagement, 3.g. Ongoing feedback and call to action, 3.h. Design appropriateness and accessiblity, 3.i. Fosters HCP-patient interaction	#DIV/0!
4. Data management	4.a. Clear privacy policy, 4.b. Respects informed consent, 4.c. Data accessibility, 4.d. Enables easy data deletion	#DIV/0!
5. Functionality	5.a. Clear info about features and use, 5.b. Functionality is clearly identifiable, 5.c. Specific, measurable and achievable goals, 5.d. Interactive features are customisable	#DIV/0!
6. Content	6.a. Content is accurate, complete, consistent, and timely, 6.b. Content is appropriate for target audience, 6.c. Sufficient information, 6.e. Content reviewed by patients, 6.f. Quality information from credible sources, 6.g. Content reviewed by HCPs, 6.h. Content relevant for its specified purpose	#DIV/0!
7. Endorsement	7. Verified and endorsed by a health authority	#DIV/0!
8. Maintenance	8. Periodic updates and maintenance	#DIV/0!
9. Developer	9.a. Ethical conduct 9.b. Developer interaction quality 9.c. Proactive approach to user needs	#DIV/0!

Contextual	sub-criteria	mean score
10. Data-protection compliance	10.a. Compliant with applicable privacy laws, 10.b. Complianty allows data sharing	#DIV/0!
11. Safety regulatory compliance	11.a. Gone through the proper certification processes, 11.b. Disclaimer that the tool does not replace HCPs	#DIV/0!
12. Interoperability and data integration	12. Allows data exchange	#DIV/0!
13. Cultural requirements	13. Culturally relevant factors	#DIV/0!
14. Affordability	14. Affordability and business model transparency	#DIV/0!
15. Cost-benefit	15. Cost-benefit analysis	#DIV/0!
16. Implementatability	16.a. Resources required to scale-up, 16.b. Infrastructure readiness	#DIV/0!





Criteria clusters and sub-criteria	Met the criterion (5/5)	Partially met the criterion (2.5/5)	Did not meet the criterion (0/5)	Score	Additional guidance for assessors	Optional	Subjective measure (ensure assessors' diversity)	Requires hands-on trial	May require getting in touch with the developer	Risk tier A	Risk Tier B	Risk Tier C
1. Technical aspects	*The assessor may add cluster-specific comments in this area...*			#DIV/0!								
1.a. Tool functioning accurately and rapidly	The tool is functioning accurately and rapidly, without any error messages, glitches, or crashes (e.g., unexpected stops of running, response time)	The tool is mostly functioning accurately and rapidly, with some error messages, glitches, or crashes (e.g., unexpected stops of running, response time)	The tool is not functioning accurately and rapidly, with many error messages, glitches, or crashes (e.g., unexpected stops of running, response time)		This may sometimes be impacted by local infrastructure like wifi speed - the need here is to assess the tool's technical reliability not that of the infrastructure (which is assessed elsewhere)			x		✓	✓	✓
1.b. Reliable and available at all times	The tool is reliable and available at all times and can handle high levels of traffic and usage, with backup and recovery measures in case of downtime or system failures (e.g. enabling offline functionality, functioning during energy interruption or under difficult environmental conditions)	The tool is reliable and available most of the time (with some exceptions) and can mostly handle high levels of traffic and usage, with backup and recovery measures in case of downtime or system failures (e.g. enabling offline functionality, functioning during energy interruption or under difficult environmental conditions)	The tool is not reliable and available at all times and cannot handle high levels of traffic and usage, with backup and recovery measures in case of downtime or system failures (e.g. enabling offline functionality, functioning during energy interruption or under difficult environmental conditions)					x	x	✓	✓	✓
1.c. Adequate training resources	The tool provides adequate and user friendly training resources for end users (patients and clinicians) to ensure their comfort with basic competencies and skills needed to use the tool effectively (e.g., in the form of training material, tutorials, videos, user guides or documentation)	The tool provides some training resources for end users (patients and clinicians) to ensure their comfort with basic competencies and skills needed to use the tool effectively (e.g., in the form of training material, tutorials, videos, user guides or documentation) but they are not adequate or user friendly	The tool does not provide training resources for end users (patients and clinicians) to ensure their comfort with basic competencies and skills needed to use the tool effectively (e.g., in the form of training material, tutorials, videos, user guides or documentation)							✓	✓	✓
1.d. Easy to access help	It's easy and obvious to access technical help when needed (e.g. hotline, support email, contact form, help section, live chatbot, the technical help needed by a user can be canalized by the HCP to different channels depending on opening hours)	It's not very easy to access technical help when needed (e.g. hotline, support email, contact form, help section, live chatbot, the technical help needed by a user can be canalized by the HCP to different channels depending on opening hours)	It's quite difficult or impossible to access technical help when needed (e.g. hotline, support email, contact form, help section, live chatbot, the technical help needed by a user can be canalized by the HCP to different channels depending on opening hours)		This criterion is about technical support. Clinical support (safety) is addressed elsewhere			x		✓	✓	✓
2. Clinical utility and safety	*The assessor may add cluster-specific comments in this area...*			#DIV/0!								
2.a. Clinical evidence	The tool's clinical effectiveness is supported by strong research (e.g. pre-registered RCTs - Randomised Controlled Trials, observational studies, or large clinical RWE - real world evidence studies) with adequate statistical power conducted by credible sources, in which the tool was found to be superior to an appropriate placebo or equivalent to acceptable evidence-based treatment groups. Interventions should have a positive impact either on how a patient feels, how a patient functions, or how a patient survives.	The tool's clinical effectiveness is supported by some weak research (e.g. pre-registered RCTs - Randomised Controlled Trials, observational studies, or large clinical RWE - real world evidence studies) without adequate statistical power nor conducted by credible sources, in which the tool was found to be superior to an appropriate placebo or equivalent to acceptable evidence-based treatment groups. Interventions should have a positive impact either on how a patient feels, how a patient functions, or how a patient survives.	The tool's clinical effectiveness is not supported by any research (e.g. pre-registered RCTs - Randomised Controlled Trials, observational studies, or large clinical RWE - real world evidence studies), in which the tool was found to be superior to an appropriate placebo or equivalent to acceptable evidence-based treatment groups. Interventions should have a positive impact either on how a patient feels, how a patient functions, or how a patient survives.		The level of evidence will be influenced by how long the tool has been on the market (i.e. tools that have been longer on the market are more capable of showing evidence than newer tools that didn't build the user base yet). In case the tool is still very newly launched, at least a mid-term evidence plan should be presented and re-evaluated after an agreed period of time (e.g. DiGAs in Germany or more recently in France). For further guidance on assessing the quality of clinical evidence and what to look for please consult the Evidence DEFINED framework that provides a standardized approach to assessing evidence for digital health products https://www.nature.com/articles/s41746-023-00836-5				x			✓
2.b. Properly handles potentially dangerous information	The tool warns about potential risks when necessary and properly handles potentially "dangerous" information entered by a patient (e.g. when it is necessary to consult a professional), i.e. avoiding injuries to patients from the care that is intended to help them	The tool warns about some but not all potential risks and does not always properly handle potentially "dangerous" information entered by a patient (e.g. when it is necessary to consult a professional), i.e. avoiding injuries to patients from the care that is intended to help them	The tool does not warn about potential risks and does not properly handle potentially "dangerous" information entered by a patient (e.g. when it is necessary to consult a professional)					x			✓	✓
2.c. Differentiates between clinical and technical feedback	The tool differentiates between clinical and technical feedback, and clearly channels clinical feedback that may pose a health risk through the proper channels (e.g. advising the patient to call their care team, go to the ER....) and reviews them for vigilance and post-market surveillance purposes and, where relevant, notify them to competent authorities		The tool does not differentiate between clinical and technical feedback, and does not clearly channel clinical feedback that may pose a health risk through the proper channels (e.g. advising the patient to call their care team, go to the ER....) and does not review them for vigilance and post-market surveillance purposes					x		✓	✓	✓
3. Usability and human centricity	*The assessor may add cluster-specific comments in this area...*			#DIV/0!								
3.a. User research	The tool's usability and acceptability has been rigorously trialled and tested in a real world setting, and its effectiveness was verified by strong evidence in published scientific literature (e.g. peer reviewed usability studies and user research)	The tool's usability and acceptability has been partially tested in a real world setting, and its effectiveness was verified by weak evidence in published scientific literature (e.g. peer reviewed usability studies and user research)	The tool's usability and acceptability has not been tested in a real world setting, and its effectiveness was not verified by evidence in published scientific literature (e.g. peer reviewed usability studies and user research)		The level of evidence may be influenced by how long the tool has been on the market (i.e. tools that have been longer on the market are more capable of showing evidence than newer tools that didn't build the user base yet). Assessors are advised to have a closer look at such studies to inspect their quality (e.g. sample size, sample diversity, and rigor of the study methodology) For further details, there are also usability standards that the assessor may refer to. E.g. ISO/TC 210 is a standard for quality management and corresponding general aspects for products with a health purpose including medical devices https://www.iso.org/standard/63179.html				x	✓	✓	✓
3.b. Easy to navigate	It is easy to navigate through the tool (e.g. to move from one location to another and to move backwards, and the design is responsive to the screen size used)	It is not always easy to navigate through the tool (e.g. to move from one location to another and to move backwards, and the design is not always responsive to the screen size used)	It is difficult or confusing to navigate through the tool (e.g. to move from one location to another and to move backwards, and the design is not responsive to the screen size used)				x	x		✓	✓	✓
3.c. Learnability	Learning to use the tool is easy and does not require a lot of time, appropriate explanations appear if needed	Learning to use the tool is not very easy and requires some time, appropriate explanations appear if needed	Learning to use the tool is not easy and requires a lot of time, appropriate explanations does not appear if needed				x	x		✓	✓	✓
3.d. Visual design is appealing	The visual design is appealing and has a harmonious look and feel (including colours, and fonts are appropriately sized for the target audience)	The visual design is somewhat appealing and has a harmonious look and feel (including colours, and fonts are appropriately sized for the target audience)	The visual design is not appealing and does not have a harmonious look and feel (including colours, and fonts are not appropriately sized for the target audience)				x	x		✓	✓	✓
3.e. Well structured	To tool's appearance is well structured, and important information is clear and stands out	To tool's appearance is somewhat well structured, and important information is sometimes clear but doesn't always stand out	To tool's appearance is not well structured, and important information is not clear and does not stand out				x	x		✓	✓	✓
3.f. Evidence for user engagement	There's evidence for co-creation and collaboration with users in the tool's development (e.g. a strong and balanced advisory board with clinical/patients/technical team members able to lead the product design and development)	There's evidence for co-creation and collaboration with some users in the tool's development (e.g. advisory board is not balanced with only some but not all relevant stakeholder groups such as clinical/patients/technical team members able to lead the product design and development)	There's no evidence for co-creation and collaboration with users in the tool's development (e.g. there's no advisory board with clinical/patients/technical team members able to lead the product design and development)							✓	✓	✓
3.g. Ongoing feedback and call to action	The tool provides appropriate ongoing feedback and appropriate call to action based on the user's state and activities (e.g. provides guidance based on user-entered information)	The tool partially provides some feedback and call to action based on the user's state and activities (e.g. provides guidance based on user-entered information)	The tool does not provide any feedback and call to action based on the user's state and activities (e.g. does not provide guidance based on user-entered information)		In some limited cases, depending on the tool's objectives and use cases, this criterion may not be applicable	x		x			✓	✓
3.h. Design appropriateness and accessiblity	The tool's content and design are appropriate for the target audience and accessible to vulnerable populations (e.g. adjust text size, text to voice, colourblind colour scheme adjuster, any specificity for use by minors, offline features, left and right handed options). I.e. it takes the user context into account and does not vary in quality because of personal characteristics such as dexterity, disabilities, movement disorders, or vision problems etc.	The tool's content and design are partially appropriate for some but not all target audiences and not always accessible to vulnerable populations (e.g. adjust text size, text to voice, colourblind colour scheme adjuster, any specificity for use by minors, offline features, left and right handed options). I.e. it somewhat takes the user context into account and may partially vary in quality because of personal characteristics such as dexterity, disabilities, movement disorders, or vision problems etc.	The tool's content and design are not appropriate for the target audience and not accessible to vulnerable populations (e.g. adjust text size, text to voice, colourblind colour scheme adjuster, any specificity for use by minors, offline features, left and right handed options). I.e. it does not take the user context into account and varies in quality because of personal characteristics such as dexterity, disabilities, movement disorders, or vision problems etc.				x	x		✓	✓	✓

3.i. Fosters HCP-patient interaction	The tool has the ability to foster the interaction between the health care professionals and their patients (e.g. communication features, feedback options)		The tool does not have the ability to foster the interaction between the health care professionals and their patients (e.g. there are no communication features, feedback options)		In some very limited cases where the tool being assessed is completely autonomous and is not designed to be integrated in the traditional halthcare setting, this criterion may not be applicable	x				✓	✓
4. Data management	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
4.a. Clear privacy policy	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 (e.g., for commercial or research purposes)	The tool has a complex privacy policy and the users are not clearly informed on how their data will be kept confidential and secured and how the data may be used (e.g., for commercial or research purposes)	The tool does not have a clear privacy policy and does not inform the users on how their data will be kept confidential and secured and how the data may be used (e.g., for commercial or research purposes)							✓	✓	✓
4.b. Respects informed consent	The tool respects informed consent and allows the user to opt out of data collection (e.g. ability to configure the settings of their data storage, access, and management)	The tool partially respects informed consent and allows the user to opt out of some but not all data collection (e.g. ability to configure some settings of their data storage, access, and management)	The tool does not respect informed consent and does not allow the user to opt out of data collection (e.g. ability to configure the settings of their data storage, access, and management)							✓	✓	✓
4.c. Data accessibility	The tool and its data can be accessed at any time and on different platforms and operating systems (e.g., Android, iOS…)									✓	✓	✓
4.d. Enables easy data deletion	The tool explicitly and easily enables users to delete their data	The tool enables users to delete their data but not in an easy or explicit way	The tool does not enable users to delete their data							✓	✓	✓
5. Functionality	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
5.a. Clear info about features and use	There is clear information about the tool's features and appropriate ways to utilize it (e.g., adjunct, standalone) and the population it is designed to serve, presented in a concise way not overwhelming to the user	There is some information about the tool's features and appropriate ways to utilize it (e.g., adjunct, standalone) and the population it is designed to serve, but it is presented in an inconcise way and can be overwhelming to the user	There is no information about the tool's features and appropriate ways to utilize it (e.g., adjunct, standalone) and the population it is designed to serve							✓	✓	✓
5.b. Functionality is clearly identifiable	The functionality of each element is clearly identifiable (e.g. if the user must take a specific action, the tool clearly and visually indicates the action to be taken)	The functionality of some, but not all, elements is somewhat identifiable (e.g. if the user must take a specific action, the tool indicates the action to be taken, but not always in a clear way)	The functionality of some elements is not identifiable (e.g. if the user must take a specific action, the tool does not indicate the action to be taken)				x	x		✓	✓	✓
5.c. Specific, measurable and achievable goals	The tool has specific, measurable and achievable goals (desired outcomes) that are specified/obvious within the tool itself	The tool has somewhat specific, measurable and achievable goals (desired outcomes) but they are not specified/obvious within the tool itself	The tool does not have specific, measurable and achievable goals (desired outcomes)							✓	✓	✓
5.d. Interactive features are customisable	Interactive features such as reminders, push notifications, and prompts are customisable and not overwhelming (e.g. users can customise the frequency and timing of reminders to suit their daily routines)	Some, but not all, interactive features such as reminders, push notifications, and prompts are somewhat customisable (e.g. users can customise the frequency or timing of reminders to suit their daily routines)	Interactive features such as reminders, push notifications, and prompts are not customisable							✓	✓	✓
6. Content	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
6.a. Content is accurate, complete, consistent, and timely	Health-related content is accurate, complete, consistent, and timely (e.g. according to state of the art scientific evidence)	Health-related content is somewhat, but not always, accurate, complete, consistent, or timely (e.g. according to state of the art scientific evidence)	Health-related content is not accurate, complete, consistent, nor timely (e.g. according to state of the art scientific evidence)					x		✓	✓	✓
6.b. Content is appropriate for target audience	The tool's content is provided in a clear and appropriate way for the target audience (using an understandable, plain and simple language, with messages adapted to the user profile in terms of linguistic style and level, facilitating user understanding and avoiding using technicalities)	The tool's content is somewhat, but not always, provided in a clear and appropriate way for the target audience (using a somewhat understandable, plain and simple language, with messages somewhat adapted to the user profile in terms of linguistic style and level, and not always avoiding using technicalities)	The tool's content is not provided in a clear and appropriate way for the target audience (does not use an understandable, plain and simple language, and messages are not adapted to the user profile in terms of linguistic style and level, using technicalities, not facilitating user understanding)				x	x		✓	✓	✓
6.c. Sufficient information	There is sufficient information throughout the tool without any omissions, over-explanations, or irrelevant data	There is somehat sufficient information throughout the tool, but there are some omissions, or over-explanations, or irrelevant data	There is no sufficient information throughout the tool, there are clear omissions, or over-explanations, or irrelevant data				x	x		✓	✓	✓
6.e. Content reviewed by patients	The content has been reviewed by patients to ensure readability and acceptability		The content has not been reviewed by patients to ensure readability and acceptability							✓	✓	✓
6.f. Quality information from credible sources	The tool contains high quality information (e.g. text, feedback, charts, measures, references) from credible and legitimate sources (e.g., WHO)	The tool contains sometimes, but not always, high quality information (e.g. text, feedback, charts, measures, references) and sometimes, but not always, from credible and legitimate sources (e.g., WHO)	The tool does not contain high quality information (e.g. text, feedback, charts, measures, references) nor from credible and legitimate sources (e.g., WHO)								✓	✓
6.g. Content reviewed by HCPs	The content has been reviewed by (or originated from) healthcare professionals with the most updated evidence-based practice of medicine		The content has not been reviewed by (or originated from) healthcare professionals							✓	✓	✓
6.h. Content relevant for its specified purpose	The tool's contents are relevant to the underlying objective and likely to be effective in achieving the specified purpose in the specific intended population	The tool's contents are somehow relevant to some of the underlying objective and may be effective in partially achieving the specified purpose in the specific intended population	The tool's contents are not relevant to the underlying objective and not likely to be effective in achieving the specified purpose in the specific intended population					x		✓	✓	✓
7. Endorsement	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
7. Verified and endorsed by a health authority	The tool has been verified, given a good review, or endorsed by a legitimate/reliable source such as a health organisation, 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		The tool has not been verified, nor given a good review, nor endorsed by a legitimate/reliable source such as a health organisation, health authority, scientific/medical society (e.g., APA; FDA in the US; NIH; NHS in the UK; NICE in the UK) nor recommended by trusted Healthcare Professionals		This is an adoption criterion. It is impacted by how long the tool has been on the market (the longer the tool has been on the market, the more likely it will be used and verified or endorsed by health authorities)					✓	✓
8. Maintenance	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
8. Periodic updates and maintenance	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)	The tool partially gets updates and maintenance either from technical or content perspectives (e.g. last update is relatively old, the content is only partially updated with the new findings in the medical field)	The tool does not get periodic updates and maintenance both from technical and content perspectives (e.g. the tools has not been updated in a relatively long time, the content is not updated with the new findings in the medical field)							✓	✓	✓
9. Developer	*The assessor may add cluster-specific comments in this area...*			#DIV/0!							
9.a. Ethical conduct	The tool's provider respects ethical conduct, clinical responsibility, and the rules and regulations protecting patient's rights and societal interests (e.g., the tool was approved or certified by a regulatory body in the case of software as a medical device, GDPR, HIPAA...)	The tool's provider only sometimes, but not always, respects ethical conduct, clinical responsibility, and the rules and regulations protecting patient's rights and societal interests (e.g., the tool was in some cases approved or certified by a regulatory body in the case of software as a medical device, GDPR, HIPAA...)	The tool's provider does not respect ethical conduct, clinical responsibility, and the rules and regulations protecting patient's rights and societal interests (e.g., the tool was not approved or certified by a regulatory body in the case of software as a medical device, GDPR, HIPAA...)							✓	✓	✓
9.b. Developer interaction quality	Interaction quality between the tool's provider and the users, including responsiveness, after sales services, and customer orientation is extremely high (e.g. provider responds to direct requests/messages swiftly and professionally)	Interaction quality between the tool's provider and the users, including responsiveness, after sales services, and customer orientation is acceptable (e.g. provider takes a relatively long time to respond to direct requests/messages, the response is not always very professional)	Interaction quality between the tool's provider and the users, including responsiveness, after sales services, and customer orientation is very low or non-existent (e.g. provider does not responds to direct requests/messages)						x	✓	✓	✓
9.c. Proactive approach to user needs	Demonstration of excellence in a proactive approach to the assessment of user needs, and continuous learning (e.g. provider continuously takes user feedback into account in the periodic updates and iterations of the tool and communicates this to the users)	Demonstration of some engagement in the assessment of user needs, and continuous learning (e.g. provider somewhat takes user feedback into account in the periodic updates and iterations of the tool and sometimes communicates this to the users)	Lack of proactive approach to the assessment of user needs, and continuous learning (e.g. provider does not take user feedback into account in the periodic updates and iterations of the tool)		If this information is not publicly communicated by the tool's provider, the assessor may need to directly ask about how the provider takes user feedback into account and how they communicate the resulting changes to the users				x	✓	✓	✓

Short form	Met the criterion (5/5)	Partially met the criterion (2.5/5)	Did not meet the criterion (0/5)	Score	**Additional guidance for assessors**	Optional	Subjective measure (ensure assessors' diversity)	Requires hands-on trial	May require getting in touch with the developer	Risk tier A	Risk Tier B	Risk Tier C
10. Data-protection compliance	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
10.a. Compliant with applicable privacy laws	The tool explicitly reports being compliant with the relevant data privacy and protection laws (e.g. GDPR, HIPAA...), and the treatment of any personal data is compatible with the Patient Data Act, Personal Data Act, and other applicable privacy laws (flexibility to respect multiple data regulations depending on local context)		The tool does not explicitly report being compliant with the relevant data privacy and protection laws (e.g. GDPR, HIPAA...), and it is not clear if the treatment of any personal data is compatible with the Patient Data Act, Personal Data Act, and other applicable privacy laws (flexibility to respect multiple data regulations depending on local context)							✓	✓	✓
10.b. Compliantly allows data sharing	The tool compliantly allows for data sharing and segregation for research use (including data analytics and reporting, quality improvement initiatives, and clinical trials)	The tool partially allows for some data sharing and segregation for research use (including data analytics and reporting, quality improvement initiatives, and clinical trials)	The tool does not allow for data sharing and segregation for research use (including data analytics and reporting, quality improvement initiatives, and clinical trials)							✓	✓	✓
11. Safety regulatory compliance	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
11.a. Gone through the proper certification processes	The tool's provider clearly identifies the risks that its management may pose for user safety and has gone through the proper certification processes to ensure its safety (e.g. software as a medical device, third-party certification by a medical or governmental organisation)		The tool's provider does not identify the risks that its management may pose for user safety and has not gone through the proper certification processes to ensure its safety (e.g. software as a medical device, third-party certification by a medical or governmental organisation)								✓	✓
11.b. Disclaimer that the tool does not replace HCPs	The tool contains a disclaimer (or a statement of similar implication) that the information provided/content does not replace a health care professional's judgment		The tool does not contain a disclaimer (or a statement of similar implication) that the information provided/content does not replace a health care professional's judgment		In very limited cases, depending on the local laws and the risk level of the tool being assessed, this criterion may not be applicable	x				✓	✓	✓
12. Interoperability and data integration	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
12. Allows data exchange	The tool allows for interoperability, data integration and exchange of data with other apps, e-tools, wearable devices, electronic health records (ability to exchange data with other systems on a technical and policy level, and with other users such as clinicians or care givers)	The tool only partially allows for interoperability, data integration and exchange of data with some but not all other apps, e-tools, wearable devices, electronic health records (ability to exchange data with other systems on a technical and policy level, and with other users such as clinicians or care givers)	The tool does not allow for interoperability, data integration and exchange of data with other apps, e-tools, wearable devices, electronic health records (ability to exchange data with other systems on a technical and policy level, and with other users such as clinicians or care givers)							✓	✓	✓
13. Cultural requirements	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
13. Culturally relevant factors	The tool takes into account culturally relevant factors (e.g. different languages and alphabets, specific religious or cultural requirements or restrictions, gender considerations)	The tool takes into account some but not all culturally relevant factors (e.g. different languages and alphabets, specific religious or cultural requirements or restrictions, gender considerations)	The tool does not take into account culturally relevant factors (e.g. different languages and alphabets, specific religious or cultural requirements or restrictions, gender considerations)							✓	✓	✓
14. Affordability				**#DIV/0!**								
14. Affordability and business model transparency	The tool is affordable taking into account the local socioeconomic context, and it is clear who pays for it and how they pay	The tool is only affordable for some potential users taking into account the local socioeconomic context (e.g. depending on their insurance model), and it is clear who pays for it and how they pay	The tool is not affordable taking into account the local socioeconomic context, and it is not clear who pays for it and how they pay							✓	✓	✓
15. Cost-benefit	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
15. Cost-benefit analysis	A cost-benefit analysis was performed and led to positive results. I.e. the balance between the costs and benefits arising from the tool's utilisation. This refers to the tool's direct costs (purchase price, subscription, licensing…), but may also include costs associated with the tool's selection, staff training, setting up support mechanisms, and appropriate governance		A cost-benefit analysis was not performed and or has led to negative results. I.e. the balance between the costs and benefits arising from the tool's utilisation. This refers to the tool's direct costs (purchase price, subscription, licensing…), but may also include costs associated with the tool's selection, staff training, setting up support mechanisms, and appropriate governance		This will differ depending on the implementation context and the respective payment model in that specific context (e.g. fee for service with focus on efficiency, vs value-based which would consider the outcomes/incremental health benefit)				x	✓	✓	✓
16. Implementatability	*The assessor may add cluster-specific comments in this area...*			**#DIV/0!**								
16.a. Resources required to scale-up	The tool fits well into existing workflows and does not require additional resouces (workforce, hardware, software) to scale-up and to enable it to function properly	The tool does not completely fit into existing workflows but only requires low to medium additional resouces (workforce, hardware, software) to scale-up and to enable it to function properly	The tool does not fit well into existing workflows and requires considerable additional resouces (workforce, hardware, software) to scale-up and to enable it to function properly						x	✓	✓	✓
16.b. Infrastructure readiness	The tool fits well into the existing infrastructure and does not require investment in additional infrastructure to enable it to function properly (This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context)	The tool partially fits well into the existing infrastructure (hardware, software, and network capabilities) and requires low to medium investment in additional infrastructure to enable it to function properly (This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context)	The tool does not fit into the existing infrastructure and requires considerable investment in additional infrastructure to enable it to function properly (This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context)							✓	✓	✓

Short form	Full description	Additional guidance for assessors	Risk tier A	Risk Tier B	Risk Tier C
17. Design	*The assessor may add cluster-specific comments in this area...*				
17.a. Allows different platforms	The tool allows the users to move across different platforms to allow portability of the tool while retaining their data (e.g. mobile app vs web app, iOS vs Android, older smartphones)		✓	✓	✓
17.b. Can be used in real time	The tool can be used in real time (i.e. real-time data tracking), e.g. if the user is experiencing a health issue, reducing waits and sometimes harmful delays for both those who receive and those who give care	This criterion is optional and may not be applicable depending on the specific use case of the tool being evaluated (e.g. asynchronous eHealth tools are not necessarily designed for real-time data tracking)	✓	✓	✓
17.c. Possibility to give instant feedback	The tool allows the possibility to give instant feedback to the developers (e.g., provider messaging to report technical issues or errors, inaccuracies or inconsistent workflows)		✓	✓	✓
17.d. Usability in the intended clinical setting	The tool is usable and accessible in the intended clinical setting (e.g. if it is used by HCPs in a clinical setting, can they use it while wearing gloves, e.g. are buttons big enough and separated)		✓	✓	✓
18. Comorbidities	*The assessor may add cluster-specific comments in this area...*				
18. Considers related health issues	The tool considers multiple health issues and related ones, and sufficiently addresses them to help meet the intended purpose without overwhelming the user (i.e. consider evidence-based comorbidities, and features that may improve overall quality of life, e.g. adding breathing exercises in a remote patient monitoring tool for lung cancer patients)			✓	✓
19. Data definition	*The assessor may add cluster-specific comments in this area...*				
19. Metadata definition, findability, and retrievability	Data findability and retrievability: Metadata definition (including e.g. units used, reference to controlled vocabularies, ontologies) and the ability for users to retrieve data with the same granularity specified by the metadata (up to and including raw data sets)		✓	✓	✓
20. Behavioral and social	*The assessor may add cluster-specific comments in this area...*				
20.a. High quality interactive features	The tool includes high quality interactive features (enables user input and reaction) and is presented in an engaging way (e.g., contains the right mix of video/audio/text/graphics)		✓	✓	✓
20.b. Customisability	The tool is customisable and allows the user to control all the necessary settings and features (e.g., notifications, alerts, sounds, colours, and fonts) except for the features that form an essential part of an intervention (e.g. the tool allows the patients to customise the time of a certain reminder according to their daily routine but doesn't allow them to remove it)		✓	✓	✓
20.c. Persuasiveness and behavioural change	The tool is persuasive and aims at understanding what influences people's behaviour and decision making, and then uses this information to design compelling user interactions by offering relevant and customisable therapeutic activities and encouraging users to complete them (e.g. through incentivization, gamification...) in a way that balances engagement vs tool additction	This criterion is optional and may not be applicable depending on the specific use case of the tool being evaluated		✓	✓
20.d. Possibilities for peer support	The tool provides possibilities for peer support and/or social networking (e.g. anecdotal evidence - a space to share experiences like patient forums, groups etc) and/or supported by patient organisations or advisory groups	This criterion is optional and may not be applicable depending on the specific use case of the tool being evaluated		✓	✓
21. Adoption and implementation	*The assessor may add cluster-specific comments in this area...*				
21.a. Implementation and user base	The tool is implemented and utilised within the target health system under usual care OR a large group of clinicians officially refers patients to utilise it (this can be checked by looking at the unique monthly users and their percentage in relation to the target population in the target health system/market). The size of the target population needs to be evidence based (e.g. if it's pilot or beta how big is a therapeutic area? size of the technology provider? when did they start selling the tool?)	This is an adoption criterion. Meaning that it is impacted by how long the tool has been on the market (the longer the tool has been on the market, the more likely it will rank higher for this criterion)	✓	✓	✓

21.b. Feasibility of implementation planning	Assesses the extent to which the tool can be implemented as intended (i.e., feasibility of implementing the tool at a pre-determined date and time). This can be checked by looking at how long it takes, on average, from the contractual agreement until the tool is fully up and running in a healthcare organisation	This is an adoption criterion and depends on whether the tool requires a high degree of integration (i.e. may be "not applicable" for some tools). It also depends on the business model of the tool being evaluated (e.g. B2B2C can be quite complex)	✓	✓	✓
21.c. Favourable pre-conditions	How favourable are the pre-conditions (strategic, political, and environmental contexts) that influence the scaling up of the eHealth tool. For example, the tool's suitability to the socioeconomic context in question, considerations of foreign languages that the tool needs to support, literacy level, and the local regulatory environment such as standard reimbursement processes for eHealth tools	This is a contextual criterion. Its assessment will be different depending on the context that the tool is being considered for	✓	✓	✓
21.d. Visible users' reviews	The tool's visible and verified users' reviews and ratings are favourable (e.g. a star rating above 4/5 stars in the app store, or the Net Promoter Score - NPS). Using users' perceived value through users' reviews and ratings as a proxy for quality, usefulness, or acceptability and popularity	This is an adoption criterion. Meaning that it is impacted by how long the tool has been on the market (the longer the tool has been on the market, the more likely it will rank higher for this criterion). This criterion is meaningful only when the tool reaches a critical mass (i.e. a large enough number of user reviews)	✓	✓	✓
21.e. Availability of phase-out scenarios	Availability of phase-out scenarios, if the tool's provider stops producing/maintaining the tool		✓	✓	✓
22. Provider details and experience	*The assessor may add cluster-specific comments in this area...*				
22.a. Provider details availability	Contact details of the tool's provider are available, easy to find, and include office address, email, and team members details		✓	✓	✓
22.b. Credentials of those involved in development and funding	Availability of information and credentials of the individuals and organisations involved in the development and funding of the tool (transparency on the involvement of any parties that may lead to conflict of interest, e.g. commercial sponsors and partners, financial disclosure)		✓	✓	✓
22.c. Provider eHealth or healthcare experience	The tool's developer and / or its core team members have specific experience in the eHealth field OR academic institution (e.g., university) OR health care system (or large health providers' organisation). E.g. an experienced medical director that oversees the algorithms / contents / features of the tool		✓	✓	✓