Supplementary Material

A: Evidence Standards for DHTs developed by NICE

Standard	Tier
Standard 1: the digital health technology (DHT) should comply with relevant safety and quality standards	A, B and C.
Standard 2: incorporate intended user group acceptability in the design of the DHT	A, B and C.
Standard 3: consider environmental sustainability	A, B and C.
Standard 4: consider health and care inequalities and bias mitigation	A, B and C.
Standard 5: embed good data practices in the design of the DHT	A, B and C.
Standard 6: define the level of professional oversight	A, B and C.
Standard 7: show processes for creating reliable health information	B and C.
Standard 8: show that the DHT is credible with UK professionals	B and C.
Standard 9: provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled	B and C
Standard 10: describe the intended purpose and target population	A, B and C
Standard 11: describe the current pathway or system process	A, B and C
Standard 12: describe the proposed pathway or system process using the DHT	A, B and C
Standard 13: describe the expected health, cost and resource impacts compared with current care or system processes	A, B and C
Standard 14: provide evidence of the DHT's effectiveness to support its claimed benefits	C
Standard 15: show real-world evidence that the claimed benefits can be realised in practice	A, B and C
Standard 16: the company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time	A, B and C.
Standard 17: provide a budget impact analysis	A, B and C
Standard 18: for DHTs with higher financial risk, provide a cost-effectiveness analysis	A, B and C
Standard 19: ensure transparency about requirements for deployment	A, B and C
Standard 20: describe strategies for communication, consent and training processes to allow the DHT to be understood	A, B and C.
Standard 21: ensure appropriate scalability	A, B and C.

B: domains, description and orientative questions of AQUAS assessment framework

1 Description of the health problem		8 Ethical Aspects
Item	Description	
Description and context	Definition and description of the health problem (prevalence and incidence, physiopathology, etc.) and of the target population among which the intervention is applied or expected to be applied (average age, risk factors, needs, etc.) and information regarding the standard therapeutic approach (diagnosis, treatment, etc.) and the specific context to which it is applied.	Assessment of the ethical concerns of the care model and/or technology from the point of view of all stakeholders, and the context in which it is implemented or intended to be used.
Associated dimensions and subdimensions	NA	Equity and fairness: Assessment of the inequalities that can be produced or reduced (e.g., improved access to a given service) due to the non-face-to-face care model or technology. Control, user autonomy and contestability: Description: Evaluation of the degree of control and autonomy the user has over the technology (e.g., contradicting a given result). Responsibility: Description: Assessment of the degree to which those responsible for implementing and managing the non-face-to-face care model or technology are explicitly informed.

		Minimal intervention: use of as little user data as possible for the intended purpose of the intervention. Transparency, explainability and interpretability: Assessment of the degree to which users are informed of how the system works and how their data are used.
Orientative questions	What are the main characteristics of the health problem? What is the incidence and prevalence of the health problem? What are the main characteristics and needs of the population? Which therapeutic approach is standard or recommended by clinical practice guidelines?	Are there ethical concerns regarding the implementation of the non-face-to-face model of care or the technology? Does the non-face-to-face model of care or technology reduce or accentuate inequalities in access to care? Does the user of the technology have control over the technological system? Can they challenge or contradict the results reported by the system? Can the person(s) responsible for the implementation and management of the non-face-to-face care/digital health technology model be identified?

2 Description of the technology		9 Legal and regulatory aspects
Item	Description	
Description and context	Description of the main characteristics that define the model of non-face-to-face care or digital health technology, the needs it aims to cover, the regulation or licenses required, the requirements of the technology (e.g., basic material or human resources, space, training, etc.) or the potential added value with respect to existing alternatives (23, 50, 53, 64, 65) aimed at improving the prevention, diagnosis, treatment, monitoring and management of health-related problems, and for the monitoring and management of lifestyles or habits that have an impact on health.	Assessment of the degree to which the non-face-to-face care model or technology complies with the regulations and standards of the country and region (e.g., autonomous community) in which it is planned to be implemented.

Associated dimensions and subdimensions	Credibility and reputation: information on the legitimacy of the company or development team, financing of the technology, evidence of its use in the healthcare system and/or the perception of professionals and users. Scientific basis: the developer indicates that the development of the technology has been carried out in accordance with scientific evidence and provides quality information regarding its usefulness and effectiveness. Technical evaluation and validation: information related to technical evaluation, validation or certification processes that the solution has undergone. Adoption (use and integration): refers to the number of healthcare facilities or users using the technology or those expected to use it. Information management: information on the data collected by the solution, the methodologies used for this purpose, how it is stored and exchanged, who has access or what protection measures the system uses to ensure data privacy (18, 56). Intent of use: information reported by the technology developer regarding intended (and unintended) use. Novelty: uniqueness of the solution and added value compared to existing solutions (18).	Privacy: Evaluation of the degree of compliance with current privacy and data protection legislation. Transparency: Evaluation of the degree to which technology users are informed about the use of their data, the people who have access to it and the potential risks. Accountability: Assessment of the degree to which those responsible for implementing and managing the non-face-to-face care model or technology, and the consequences of its implementation, are explicitly informed.

Orientative questions	What are the main characteristics of the technology? What are the novelties or differentiating features with respect to existing alternatives? Does the company or developer have credibility and reputation? Has the technology been developed in accordance with the available scientific evidence? Has the technology been validated or has it undergone any certification process? How many healthcare facilities or users are currently using the technology? How many are expected to benefit from it? How is the information managed? Are there mechanisms to ensure user privacy?	Does the non-face-to-face care model and/or technology comply with existing standards and regulations of the region where it is to be implemented? Is user privacy ensured? Are users informed about the processing of their data and about the potential risks? Is it reported who is responsible for the implementation and management of the non-face-to-face care model or technology?
3 Content		10 Organisational Aspects
Item	Description	
Description and context	Evaluation of the adequacy, completeness, accuracy, personalisation and timeliness of the content, in terms of written, visual and auditory information, as well as of the therapeutic intervention in question for the individual user of the technology. Evaluation of the scientific evidence on which the content is based or which supports it.	Evaluation of the organisational impact of the non-face-to-face care model or of the technology (e.g., changes in workflows or professional functions). The infrastructure and resources needed to implement the technology (human resources, training, etc.) should also be considered in this area.

Associated dimensions and subdimensions	Adequacy of information: Assessment of the validity, completeness, and scientific evidence on which the information accessible through the solution is based and the appropriateness for the target population (64). Adequacy of the intervention: Assessment of the validity, appropriateness, and evidence of the intervention delivered by the solution for the achievement of the therapeutic goal (65, 149).	NA
Orientative questions	Is the information clear, logical and correct? Is it based on scientific evidence? Is the information comprehensive while concise? Is the language correct so that the information can be understood by the target population? Is the intervention based on the available scientific evidence? Is it adequate to achieve the established therapeutic objective? Can the intervention be personalised or tailored to the patient?	Could the implementation of the non-face-to-face care model or technology change the organisational structure? Could it require mobilisation of available resources or the incorporation of new resources? Implementation of the care model or the digital health technology may change care algorithms, workflow, or practitioner workloads? Implementation of digital health care model or technology may result in infrastructure changes? Does the implementation of the digital health care or technology model involve the training of the professional team? Is the implementation of the non-face-to-face digital health care model or technology applied by the same team that develops it?

4 Safety		11 Technical Aspects
Item	Description	
Description and context	Identification and assessment of risks, harms and unwanted side effects arising from the use of the intervention that may be inherent to the technology or to external factors (e.g., inappropriate user or misuse).	Evaluation of the technological elements that shape and characterise the technology, such as usability and ease of use, adaptability (e.g., interoperability), design, technical stability, generic and reproducibility, interpretability and personalisation.
Associated dimensions and subdimensions	Clinical safety: Identification and evaluation of risk, undesired collateral consequences and/or physical and psychological harm that may be derived from the use of technology, in either patients, family members and healthcare professionals. Technical safety: Identification and evaluation of the risk and undesirable collateral consequences that may arise from the use of the technology, for patients, their families and healthcare professionals in terms of privacy or quality of information (e.g., bias or loss of clinical data).	Usability: Evaluation of the degree to which the system facilitates the user to interact with it and navigate through its interface to perform certain actions or achieve certain objectives (e.g., information consultation). Standardisation and reuse of data: Ability to systematically use the data collected by these applications by other information systems. This dimension is made up of the following sub-dimensions: data accessibility and level of standardisation. Adaptability (interoperability, scalability, data integration, transferability): Evaluation of the ability of a given technology to be integrated or used in different technological environments or in conjunction with other technologies, health problems or contexts. Within adaptability are the following subdimensions: interoperability, scalability, data integration, transferability. Interoperability refers to the capacity of technological solutions to exchange information

		with other technologies and to interpret the information they receive. Scalability is the possibility of expansion of the technology to a wider context than initially envisaged. Data integration is related to the ability of the technology to incorporate and use data from other sources. Transferability refers to the possibility that the results or impact of a technology observed in a given population may be produced in another population with different characteristics. Quality: Measurement of compliance with standards and requirements and meeting or exceeding expectations. Design (persuasive design): Evaluation of the appropriateness of the elements that make up the design with respect to the target population. Technical stability: Evaluation of the ability of the technology to maintain performance over time. Ease of use: Assessment of the degree to which users can interact with the technology and perform a given action or achieve a specific objective with ease. Accessibility: Evaluation of the proportion of potential users who are able to use the technology in question and of the accessibility elements, options and functionalities incorporated in the system (font magnifiers, screens, colour contrast, voiceover, etc.).

		Efficacy or technical performance (reliability, validity, accuracy, precision, sensitivity, feasibility): Evaluation of how accurately the technology or system executes the intended functions and the degree of precision with which it performs them. Within this dimension, the subdimensions of reliability, validity, accuracy, precision, sensitivity and feasibility are considered. Reliability correlates with the consistency of the system with respect to performance and intended functions (60,66,67). Technology validity is related to clinical validity and information validity, and refers primarily to the assessment of the appropriateness of the data and methodologies used for the intended purpose (66,67). Accuracy refers to the assessment of precision when technology plays a role (e.g., measurement) (20). Sensitivity refers to the probability of correctly classifying a given measurement as positive. Feasibility assesses whether the technology performs as expected in a given context. Generalisability and reproducibility: Evaluation of the ability of a given system to operate in uncontrolled or different contexts from those intended with the same degree of accuracy. Interpretability: Evaluation of the degree to which a given algorithm or the result derived

		from its application can be understood by the person using it.
Orientative questions	Are there risks or possible undesirable effects that could cause physical or psychological harm to patients, family members or professionals? What are they? What is their magnitude (reversible or non-reversible)? Are the risks inherent or external to the technology? Could there be a loss of privacy or reputation of the patient, family member and/or professional? Could there be a loss of or bias in clinical information (e.g., miscalibration of monitoring sensors)?	Does the technology present an adequate degree of usability? Are the design elements used in a logical manner? Does the design of the technology pose any difficulty for the user? Does it incorporate accessibility elements? Is the technology interoperable with other systems and can it be integrated and scaled in other systems or contexts? Is the performance of the technology as expected, and does this performance persist over time?

5 Clinical efficacy and effectiveness		12 Environmental Aspects
Item	Description	
Description and context	Evaluation of the clinical benefits and impact on quality of life of the technology under controlled (efficacy) or uncontrolled (effectiveness) conditions. That is, assessment of the degree to which the technology contributes to improving the health status and quality of life of the users in relation to the use of the technology and the expected benefit.	Assessment of the direct and indirect environmental impact associated with the development and implementation of the non-face-to-face care model and/or technology. Measurement of the environmental impact can be the estimated carbon emissions, use of raw materials, energy consumption, among others, as well as the environmental benefits derived.
Associated dimensions and subdimensions	NA	NA
Orientative questions	What are the clinical benefits and quality of life impact of the technology, and are the benefits superior to those of existing alternatives?	What is the carbon footprint of the technology? What is the amount of raw materials and energy required for its development and implementation? What waste does it produce?
6 Economic aspects		13 Post-deployment monitoring
Item	Description	
Description and context	Evaluation of the economic costs of acquisition, maintenance and use both at the patient and health system level and cost-benefit ratio compared to existing alternatives.	Description of the mechanisms established for post-deployment assessment of the performance of the non-face-to-face care model or the technology by its developers or those responsible for its management.

Associated dimensions and subdimensions	Costs: Cost analysis oriented to the comparison of acquisition, maintenance and utilisation costs compared to existing alternatives (21-23,49,50,58,60,62,63,68). Efficacy - economic evaluation: Comparative evaluation of costs and health consequences to determine the efficacy of any type of digital health technology intervention and types of analysis: cost minimisation, cost-effectiveness, cost-benefit, cost-opportunity and cost-utility analyses (22,23,49,52 55,61,63). Resource use and efficacy: Evaluation of the resources required with indirect economic impact (e.g., space required, human resources, time required, etc.) (49, 68) compared to existing alternatives (60).	NA
Orientative questions	What are the costs of acquiring, maintaining and using the technology at the patient and health system level? What is the relationship between the cost of the technology and its impact, and compared to existing alternatives? What resources (material and human) are required? Does the technology reduce the utilisation (number of visits, time of visits, etc.) of the service?	Do the developers or those responsible for developing and implementing the non-face-to-face care model or the technology foresee mechanisms to assess its performance and impact? What are they? Can post-deployment monitoring lead to an iteration in the non-face-to-face care model or technology?

7 Human and sociocultural aspects	
Item	Description
Description and context	Evaluation of the human and sociocultural aspects that may have an impact on the use of the technology (e.g., acceptability, ease of use, digital health literacy, commitment to the intervention, perceived benefit, patient empowerment, etc.) and evaluation of the sociocultural impact that the technology may have (e.g., accessibility to the service or health care, changes in workflows and roles, modification in the doctor-patient relationship, etc.)
Associated dimensions and subdimensions	User experience: Evaluation of subjective perceptions regarding the use of technology (e.g., ease of use, perceived enjoyment). Accessibility: Assessment of whether technology users with functional diversity can access it and whether they have sufficient capacity to be able to use it as expected. Acceptability: Acceptability of patients and professionals to use or be served through a given model of non-face-to-face care or technology. Engagement: Assessment of adherence to intervention and the ratio of expected to actual use. Perceived benefit: Evaluation of the degree to which the user considers that the technology in question improves their health status or condition.
Orientative questions	Do patients, families and professionals accept the non-face-to-face model of care or the use of technology? What is the user experience?

	Are users able to access the technology or the non-face-to-face model of care? Are users able to interact with the system in the way that is expected? Do patients find that technology improves their quality of life and health condition?

C: Elements of the HAS methods guidance (dossier submission)

Purpose	Data	Model	Functional characteristics	
	Description of samples used for initial model learning or relearning	Description of training, validation, and testing, before and after MD deployment	Performance and qualification	System robustness
1 Note the claimed use and the envisaged scope of the medical device (MD) including one or more machine learning algorithms	5 Specify the characteristics of the population on which the initial model learning or relearning data are based	18 Describe the type of learning used	26 Describe and justify the choice of metrics used to measure performance…	33 Specify the tools in place to generate antagonistic examples in the performance evaluation and qualification phase
2 Specify the benefit of the information provided or decisions made by machine learning processes	6 Specify the characteristics of each sample used for the initial model learning or relearning data	19 Describe the type of task automated by the algorithm	27 Describe the processing operations applied which have had a substantial impact on performance	34 Specify the tools in place to monitor the performances of the smart system after its deployment
3 Note the characteristics of the target population and, where applicable, the characteristics for which use of the MD is unsuitable, due to	7 Specify the methodology for separating or segmenting samples	20 Specify the update frequency	28 Describe the identified risks of over- and under-learning and the methods in place to remedy this	35 Specify the thresholds selected (limit values, maximum error rate, etc.) for tracking model degradation and/or concept drift and explain the choice of these thresholds

Purpose	Data	Model	Functional characteristics	
	Description of samples used for initial model learning or relearning	Description of training, validation, and testing, before and after MD deployment	Performance and qualification	System robustness
non-indication, contraindication, or factors influencing the product result				
4 Describe the operating environment of the smart system	Description of input data involved in initial model learning or relearning	21 Describe the model selection criteria	29 Specify whether the system returns a confidence rating for each of its decisions	
	8 Specify the characteristics of the variables (variable type, distribution, etc.)	22 Describe the various training, validation, and test phases, prior to MD deployment	30 Describe the qualification methods of the machine learning system	
	9 Indicate the method of acquisition of the variables and their origin during the learning process	23 Describe the training, validation and test strategies for updates, if applicable	31 Indicate the performance measurement results on the different data sets	
	10 Describe the pre-processing applied to the data.	24 Describe how parties involved in system development are referenced	32 Specify the performance thresholds selected (limit values, maximum error rate, etc.) and explain the choice of these thresholds	
	11 Indicate the proportion of missing	25 Where applicable, state in which cases a		

Purpose	Data	Model	Functional characteristics	
	Description of samples used for initial model learning or relearning	Description of training, validation, and testing, before and after MD deployment	Performance and qualification	System robustness
	data, among the raw data, and describe their management.	human being is involved in the re-training process		
	12 Explain the procedures in place to detect and manage outliers, where applicable			
	13 Justify the representativeness of the samples used for the initial learning (training, validation, and testing) of the algorithm in relation to the data to which this algorithm will be exposed once deployed			
	14 Specify the characteristics of the variables (type, distribution, etc.)			
	15 Indicate the method of acquisition of the			

Purpose	Data	Model	Functional characteristics	
	Description of samples used for initial model learning or relearning	Description of training, validation, and testing, before and after MD deployment	Performance and qualification	System robustness
	variables and their origin			
	16 Describe the pre-processing applied to the data used for decision-making			
	17 List the output variables (model prediction objects) and their characteristics (type, unit, etc.)			

D: Questions of the DIGI-HTA framework for rapid assessments

Domain	Criteria	Domain	Criteria
Company information	1. Contact information of company. 2. What is the company's business model? 3. Are quality management systems in use? Which ones?	Effectiveness	1. Does the product provide clinical benefits? What are they? 2. Does the product provide benefits to the end users by improving their behaviour related to their own health? How so? 3. Does the product provide benefits to the organization (like improving care processes)? How so? 4. What kind of evidence is available for effectiveness (case studies, randomized controlled trials, Cochrane reviews, etc.)? 5. Are there any ongoing studies to investigate the product's effectiveness? 6. Does any institution like the Duodecim Current Care Guidelines recommend the use of the product?
Product information	1. The name of the product. 2. Short description of the product. 3. What is the product's readiness level (TRL levels 1–9)? 4. Which platforms and platform versions of the product are available?	Clinical safety	1. Are there any risks, possible side effects, or other undesirable effects associated with using the product? 2. Is there any research evidence available related to clinical safety? 3. Have any product-related adverse events been reported or identified?

	5. Does the product have CE and/or FDA approval? 6. Is the product a medical device, and what classification does it have? 7. Is the product classified according to MDD or MDR requirements? 8. Does the product meet the electrical safety requirements for medical devices (if applicable)? 9. Does the use of the product require registration or login? 10. Does the use of the product require strong identification? 11. Does the company have any plans for post-market surveillance of the product? 12. What kind of product support does the company offer? 13. What is the intended use of the product? 14. What are the intended user groups? 15. What problem in the healthcare system is the product trying to solve? 16. Is the aim of the product to replace any existing healthcare services? 17. Does the introduction of the product cause any changes to the premises, information systems, or care processes? 18. Is the product already in use elsewhere in Finland or worldwide? Where, and for how long? 19. What kind of support does the end user need to use the product?		4. What is the company's process to handle adverse events? 5. Has the product undergone a risk analysis? 6. Are there any undesirable effects associated with misuse of the product? 7. Are the error conditions of guidelines removed, or is their realization unlikely? 8. Is the company aware of the product register and Manufacturer Incident Report supervised by the National Supervisory Authority of Welfare and Health? 9. Who is the responsible person in the company for handling Manufacturer Incident Reports?

	20. If users need training, who organizes it? When? What is the language of training? 21. Does the company have instructions (e.g., a project plan) for healthcare service providers to ensure fluent introduction of the product?		
Technical stability	1. What is the company's testing process? 2. What is the company's process for handling error messages? 3. Does the company have the capacity to roll back to previous versions of the product? 4. Does the company have a process to proactively monitor the running of systems and system components to automatically identify faults and technical issues? 5. Does the company have a plan for decommissioning the product? 6. Has there been any downtime or impairment time in the use of the product during the last six months?	Data security	1. Detailed criteria are defined in the following documents: 2. Data Security and Protection Preliminary Task 3. Information Security and Data Protection Requirements
Cost	1. What are the costs of using the product for a healthcare customer? 2. If the use of the product is free, what is the source of the company's income? 3. What kind of initial costs (estimated minimum and maximum values in detail) does the introduc-tion of the product impose on the organization, including changes to buildings or facilities, a need	Usability and accessibility	1. Have all user groups been taken into account in product design, like people with visual or hear-ing impairments? 2. Has the product been tested with real user groups? 3. What kind of accessibility testing has been performed on the product?

	for new devices and software, as well as needed training? 4. What are the maintenance costs (estimated minimum and maximum values) to the organization for the use of the product? 5. How often must devices or software versions related to the product be renewed? 6. Which uncertainties apply to these cost estimates?		4. Has the functionality of the product been tested with screen readers or other assistive technol-ogies? 5. How have the product's users been taken into account in the product's text (clear, concrete language; the avoidance of professional language)? 6. How have the product's users been taken into account in the design of its textual content (headings, lists, and images)? 7. How does the company continue to collect feedback from users and make changes to the product based on this feedback? 8. What changes have been made to the product based on user feedback? 9. How is the company going to continue to evaluate and develop accessibility? 10. Is the product compatible with the following usability guidelines (if applicable)? 11. WCAG 2.0/ WCAG 2.1 12. Papunet Design Guide for Websites 13. EN 301 549 section 11-Software 14. Design guidelines for native application 15. Design guidelines for progressive web application 16. Does the application support OS accessibility features?

Interoperability	Does the product have interfaces into the website or other software? Does the product have interfaces into the following healthcare services? Electronic patient records (which ones?) Finnish Kanta PHR Other (what?) Are proprietary formats used to store and transfer data? Are the definitions of the original proprietary formats openly available? Does the product have interfaces for other companies' services? Can the data contained in the product be exported in a commonly used or standard format? Does the product use data from other systems via interfaces? If yes, can the data produced by others be separated in the system? Does the product connect with health or wellness devices? If yes, is it compatible with ISO/IEEE 11073 Personal Health Data (PHD) Standards?	Artificial Intelligence	1. Exactly what defined problem is going to be solved by the AI? 2. What is the classification of AI? Visualization only, AI–assisted (e.g., diagnosis/classification/decision), or solely AI–controlled? 3. Could the problem be solved without the AI solution? 4. Is the solution based on machine learning or a neural network? 5. Do the staff have sufficient capacity to understand the operational logic of AI (e.g., do they need additional training)? 6. Are the conclusions and decisions of the AI solution transparent, i.e., can medical staff understand what the decisions are based on? 7. Is the AI solution validated in the environment in which it will be used? 8. What are the data sources for the AI solution? 9. Are the data sources used in the training of AI solutions relevant to a final use case (e.g. are the age and gender

Robotics	Is there any possibility that using the robot could create safety risks for healthcare personnel or customers (e.g., forces that could be destructive or collision with people)? How have those risks been avoided in the robot's design? What kind of arrangements are needed to teach or program the robot to operate? If the robot is battery-operated, what are the operating, idle, and charging times?		composition of training groups comparable to that of real user groups)? 10. Are the access rights required for the use of the data in order, and have data protection (e.g., GDPR) and security issues been taken into account? 11. When it comes to classifier teaching, are there enough data relative to the size of the smallest class? 12. Can the AI solution use incomplete data? 13. Can the AI solution use noisy data? 14. Is retraining possible for the AI solution? 15. What are the data sources for retraining? 16. How is it ensured that the system is not taught with irrelevant data? 17. How many tests or results are needed for the AI model? 18. Is the algorithm purchased software as a service (SaaS) or its own design? 19. What performance criteria are used? 20. Does the AI solution change care processes? How? 21. When does the AI solution propose an action? How, and who will actually implement it? 22. Is staff's approval needed for action proposed by the AI?

E: AI-checklist developed by HTW

DOMAIN 1: TRAINING	
1.1 Have the authors identified the type of machine learning model used?	Y/PY/PN/N/NI/U
1.2 Is information on the training dataset provided or easily available?	Y/PY/PN/N/NI/U
1.3 Is the training dataset representative of the true population?	Y/PY/PN/N/NI/U
1.4 Are any population exclusions from the training dataset appropriate?	Y/PY/PN/N/NI/U
1.5 **IF PN/N TO 1.4** – Are patients who would usually be seen in the clinical pathway excluded?	Y/PY/PN/N/NI/U
1.6 Is the comparator appropriate / reflective of Welsh standard practice?	Y/PY/PN/N/NI/U
1.7 Has the AI output been cross-checked by a qualified human?	Y/PY/PN/N/NI/U
1.8 Are sensitivity, specificity, NPV, PPV etc. properly reported?	Y/PY/PN/N/NI/U
1.9 **IF N TO 1.6** – is the alternative used appropriate and properly reported?	Y/PY/PN/N/NI/U
Comments on uncertainties regarding the training of the AI:	

DOMAIN 2: CLINICAL SETTING AND USE	
2.1 Is it clear where in the clinical pathway the AI fits in?	Y/PY/PN/N/NI/U
2.2 Is it clear who would be using the AI?	Y/PY/PN/N/NI/U
2.3 Is support from other local departments / systems needed?	Y/PY/PN/N/NI/U
2.4 Is it clear which patient groups / clinical settings the AI would work in?	Y/PY/PN/N/NI/U
2.5 Is the setting appropriate for what is standard in Wales?	Y/PY/PN/N/NI/U
2.6 Would the AI be an 'extra step' in standard practice?	Y/PY/PN/N/NI/U
2.7 **IF Y TO 2.6** – Is it acceptable to the user?	Y/PY/PN/N/NI/U
2.8 Is training required for users to interact with the AI?	Y/PY/PN/N/NI/U
2.9 **IF PATIENT FACING** – could the use of AI increase inequalities?	Y/PY/PN/N/NI/U
2.10 Have the developers demonstrated that the AI performs as expected with input data of varying quality?	Y/PY/PN/N/NI/U
Comments on uncertainties regarding the clinical setting and use of the AI:	

DOMAIN 3: OUTPUTS	
3.1 Is it clear what information the AI gives to the user?	Y/PY/PN/N/NI/U
3.2 **IF Y TO 3.1** – is it clear to the user what should be done with this information?	Y/PY/PN/N/NI/U
3.3 Is AI feedback given in real time?	Y/PY/PN/N/NI/U
3.4 Is the use of AI appropriate for the clinical pathway?	Y/PY/PN/N/NI/U
3.5 Does the AI present clinical benefit if implemented?	Y/PY/PN/N/NI/U
Comments on uncertainties regarding the outputs of the AI:	

DOMAIN 4: ONGOING SUPPORT	
4.1 Have the developers indicated that the AI will be updated over time?	Y/PY/PN/N/NI/U
4.2 Is the pricing model appropriate for the clinical setting?	Y/PY/PN/N/NI/U
4.3 Is it clear what ongoing support is available for adopters?	Y/PY/PN/N/NI/U
4.4 **IF Y TO 4.3** – Is it clear what this support would cost?	Y/PY/PN/N/NI/U
4.5 Is it clear how the AI will be monitored?	Y/PY/PN/N/NI/U
4.6 Is it clear whether/what data is being collected by the AI?	Y/PY/PN/N/NI/U
4.7 **IF Y TO 4.6** – Is it clear what happens with that data?	Y/PY/PN/N/NI/U
4.8 **IF Y TO 4.6** – Can patients opt out of this data collection?	Y/PY/PN/N/NI/U
4.9 Is it clear what processes are in place to monitor and evaluate outputs?	Y/PY/PN/N/NI/U
4.10 Is any additional technology needed to run the AI?	Y/PY/PN/N/NI/U
Comments on uncertainties regarding ongoing support for the AI:	