ETHICAI4CARE | ERASMUS+ PROJECT

Self-assessment Tool for Trustworthy AI in Healthcare

EthicAI4CARE - Implementing Ethics by Design in AI: A Training Framework for the Healthcare Sector

Blank fillable assessment

PDF edition 1.1 | Web version 1.1 | Question set 23 September 2026 | Released 26 September 2026 | 147 questions

Assessment details

AI SYSTEM / PROJECT

ORGANISATION

ASSESSMENT DATE

PREPARED BY

REVIEW PERIOD / VERSION

Current implementation stage of the AI tool or use case being assessed

Select one

- ○ Design or planning
- ○ Evaluating third-party solutions
- ○ In development or configuration
- ○ Testing, validation or pilot
- ○ Recently implemented - one month or less
- ○ Fully implemented and in use for more than one month
- ○ Other or mixed stage
- ○ Not sure

FURTHER DETAILS OR A STAGE NOT COVERED ABOVE (OPTIONAL)

About this form

This form helps a team review a healthcare AI tool or use case, document the information available, and identify issues requiring follow-up. It is a discussion aid, not a score, certification, or determination that the tool is compliant, safe, or ready for use. Use it alongside your organisation's usual review processes and seek input from relevant internal or external specialists, including experts in data and AI ethics and governance.

Published 26 September 2026 | Complete with colleagues who understand the system and its context.

Participants and completion guidance

Names are optional. Include only information your organisation is authorised to share.

NAME AND SURNAME (OPTIONAL)	POSITION / ROLE (OPTIONAL)

How to use this form

1. Identify the AI tool and its current implementation stage.
2. Complete the questions with a multidisciplinary team where possible.
3. Choose the response that best reflects the situation today.
4. Use "Don't know / needs input" when evidence or expertise is missing. If you choose "Not applicable," explain why when useful.
5. Use Comments / evidence for context, supporting information and differing views. Mark items that need follow-up.
6. Review the completed form with relevant colleagues and repeat the assessment after material changes.

Keep in mind

- Consider each response in context and use Comments / evidence to explain nuance or uncertainty.
- Respondent names are optional. Include only information your organisation allows you to record and share.
- Use this assessment alongside your organisation's usual review; it does not provide a score or approval.
- Save a copy before closing. Entries stay in this PDF only and do not sync with the online tool.
- Keep comments concise. For longer notes or characters that do not display correctly, use the online tool.

Special instruction for human-oversight status

Question 1.16: 'None', 'Don't know / needs input', and 'Not applicable' are exclusive status choices. If you select any one of them, leave every other choice blank.

Glossary and resources

For the glossary, ethical framework and updated online resources, visit the EthicAI4CARE publications and deliverables page: https://ethicai4care.eu/project-publications-deliverables

ETHICAI4CARE PROJECT PARTNERS

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REQUIREMENT 1 OF 7 | 20 QUESTIONS

Requirement #1: Human Agency and Oversight

AI systems must support healthcare professionals (HCPs) and patients' autonomy and respect their fundamental rights. This means there should be ways for people to check how healthcare AI is working and what it's producing, especially when it comes to making important decisions about healthcare for people who are vulnerable or have rare diseases. Trustworthy healthcare AI systems help healthcare professionals (HCPs) and patients make decisions without taking over their roles.

Human Agency

QUESTION 1.1 HUMAN AGENCY

Does the AI system support healthcare professionals' and patients' decision-making without replacing or undermining them?

◯ Yes ◯ No ◯ In Progress ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.2 HUMAN AGENCY

Are users clearly informed when the system influences a diagnosis, treatment, or health-related recommendation?

◯ Yes ◯ No ◯ Partially ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.3 HUMAN AGENCY

Could any users (e.g., patients, clinicians) mistakenly believe they are interacting with a human when it is actually AI?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Human Agency (continued)

QUESTION 1.4 HUMAN AGENCY

Is there any risk in this regard that the AI system is employing prohibited uses, as listed in the EU AI Act 2024/1689, such as manipulative practices or exploitation of vulnerable groups?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.5 HUMAN AGENCY

Are users notified when the system acts as a conversational agent, triage assistant, or health recommender?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.6 HUMAN AGENCY

Have you put in place safeguards to prevent users from deferring uncritically to AI outputs?

◯ Yes ◯ No ◯ Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.7 HUMAN AGENCY

Can the AI system nudge or bias users' clinical decisions in subtle or unintended ways?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Human Agency (continued)

QUESTION 1.8 HUMAN AGENCY

Are there procedures to minimize unintended influence on patient or provider autonomy?

○ Yes ○ No ○ In Progress ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.9 HUMAN AGENCY

Does the AI simulate empathy, conversation, or emotional rapport that may influence user trust or perception?

○ Yes ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.10 HUMAN AGENCY

Are mechanisms in place to ensure any such simulation supports informed consent and does not mislead users?

○ Yes ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.11 HUMAN AGENCY

Could the system foster emotional attachment (e.g., through continuous interaction or anthropomorphic features)?

○ Yes ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Human Agency (continued)

QUESTION 1.12 HUMAN AGENCY

Have you reviewed or redesigned features to reduce compulsive or dependent use, especially for vulnerable populations?

◯ Yes ◯ No ◯ Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.13 HUMAN AGENCY

Have you planned how to handle distress caused by system unavailability or withdrawal?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.14 HUMAN AGENCY

Could the system inappropriately shape user behavior (e.g., nudging health choices without clinical justification)?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.15 HUMAN AGENCY

Are opt-outs, transparency mechanisms, and ethical limits on persuasive design in place?

◯ Yes ◯ No ◯ In Progress ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Human Oversight

QUESTION 1.16 HUMAN OVERSIGHT

What type of human oversight applies to the system (check all that apply)?

Select all oversight statuses that apply. 'None', 'Don't know / needs input', and 'Not applicable' are exclusive; if selected, leave every other choice blank.

☐ None ☐ Human-in-the-Loop ☐ On-the-Loop ☐ In-Command ☐ Don't know / needs input

☐ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.17 HUMAN OVERSIGHT

Have responsible staff received training for their oversight roles?

○ Yes, extensive ○ Yes, limited ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.18 HUMAN OVERSIGHT

Are there detection and response mechanisms for harmful or unintended AI behavior?

○ Yes ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 1.19 HUMAN OVERSIGHT

Can the system be safely shut down or overridden when needed (e.g., malfunction, risk to patients)?

○ Yes ○ No ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Human Oversight (continued)

QUESTION 1.20 HUMAN OVERSIGHT

If the system is self-learning, are there safeguards to track adaptation and prevent drift or unpredictable behavior?

◯ Yes ◯ No ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 2 OF 7 | 34 QUESTIONS

Requirement #2: Technical Robustness and Safety

Healthcare AI systems must be secure, accurate, and resilient to attacks and errors. These systems must meet accuracy standards and undergo robust validation and safeguard measures to detect and prevent errors. Robust security protections are also essential for protecting data integrity and ensuring patient safety. Transparency around risks and limitations is vital for ensuring that AI supports clinical care.

Resilience & Security

QUESTION 2.1 RESILIENCE & SECURITY

Could the AI system pose risks in the event of design flaws, outages, or attacks?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.2 RESILIENCE & SECURITY

Is the system compliant with HIPAA, ISO 27001, EU Cybersecurity Act, or similar standards?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.3 RESILIENCE & SECURITY

Have you assessed exposure to cyber-attacks in sensitive clinical environments (e.g., EHR)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.4 RESILIENCE & SECURITY

Have attack vectors like data poisoning, evasion, or inversion been evaluated?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Resilience & Security (continued)

QUESTION 2.5 RESILIENCE & SECURITY

Are safeguards in place to ensure system integrity and robustness in clinical settings?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.6 RESILIENCE & SECURITY

Has the system been red-teamed or penetration-tested in healthcare environments?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.7 RESILIENCE & SECURITY

Are users informed about update cycles and how to report vulnerabilities?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.8 RESILIENCE & SECURITY

Are users informed about the existing risks and the back-up systems set up-procedures?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Safety

QUESTION 2.9 SAFETY

Have clinical and operational risks been defined for each use case (e.g., diagnosis, triage)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.10 SAFETY

Is there a process for post-deployment risk monitoring and reassessment?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.11 SAFETY

Have stakeholders been informed of known risks (e.g., false positives, biases)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.12 SAFETY

Have you identified design, technical, or environmental safety threats?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.13 SAFETY

Have you assessed risk of inappropriate use in high-stakes settings (e.g., remote diagnostics)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Safety (continued)

QUESTION 2.14 SAFETY

Are safety-criticality levels defined (impact on health, dignity, well-being)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.15 SAFETY

Are reliability and testing aligned with clinical safety requirements?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.16 SAFETY

Are fallback mechanisms in place (e.g., clinician override, dual systems)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.17 SAFETY

Are safety checks re-evaluated after updates or deployment changes?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Accuracy

QUESTION 2.18 ACCURACY

Could low accuracy cause clinical harm (e.g., misdiagnosis, missed alerts)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.19 ACCURACY

Is training data current, complete, and clinically relevant?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.20 ACCURACY

Is it representative of diverse patients, conditions, and settings?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.21 ACCURACY

Has the system undergone clinical validation before deployment?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.22 ACCURACY

Is performance monitored post-deployment, with recalibration as needed?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Accuracy (continued)

QUESTION 2.23 ACCURACY

Are users informed about accuracy, limitations, and confidence thresholds?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Reliability

QUESTION 2.24 RELIABILITY

Could poor reproducibility undermine care or trust?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.25 RELIABILITY

Are clinical goals (effectiveness, safety) consistently monitored?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.26 RELIABILITY

Have setting- or subgroup-specific reliability limits been assessed?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Reliability (continued)

QUESTION 2.27 RELIABILITY

Are validation studies performed under real conditions?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.28 RELIABILITY

Are inputs/outputs logged for traceability and audit?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.29 RELIABILITY

Is performance drift tracked continuously?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.30 RELIABILITY

Are testing protocols in place across care settings, devices, and software updates?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.31 RELIABILITY

Are fail-safe protocols and governance in place for system failures or alerts?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Reliability (continued)

QUESTION 2.32 RELIABILITY

Is low-confidence output flagged or handled appropriately (e.g., human review, suppressed, qualified)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.33 RELIABILITY

If continual learning is used, are feedback loops, drift, and overfitting risks managed?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 2.34 RELIABILITY

Are validation gates enforced before deploying new learned behavior in clinical workflows?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 3 OF 7 | 19 QUESTIONS

Requirement #3: Privacy and Data Governance

Trustworthy healthcare AI must respect privacy and ensure data protection, especially because sensitive health data requires strict protection. AI systems must comply with GDPR, enable patient control, and use anonymization and secure data sharing. Consent processes should be clear and meaningful.

Privacy

QUESTION 3.1 PRIVACY

Have you assessed the AI system's impact on patients' fundamental rights (privacy, integrity, data protection)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.2 PRIVACY

Does the system protect the confidentiality of medical and sensitive health data?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.3 PRIVACY

Were the medical and sensitive health data obtained with due regard for confidentiality and privacy?

○ Yes ○ No ○ Partially ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.4 PRIVACY

Does the system respect physical and mental integrity in diagnostic/therapeutic contexts?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Privacy (continued)

QUESTION 3.5 PRIVACY

Is the system compliant with GDPR, HIPAA, or local health data laws?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.6 PRIVACY

Have you implemented context-specific privacy measures (e.g., for mental health, genomic medicine)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.7 PRIVACY

Are mechanisms in place for users to flag privacy concerns (e.g., profiling, data misuse)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.8 PRIVACY

Is data usage transparent (purpose, access, sharing, training use)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.9 PRIVACY

Can individuals access to, correct, or delete their health data?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Data Governance

QUESTION 3.10 DATA GOVERNANCE

Was the system developed or trained using sensitive personal data (e.g., health, genetic, mental health)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.11 DATA GOVERNANCE

Have you conducted a DPIA before deployment?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.12 DATA GOVERNANCE

Is a Data Protection Officer involved from early stages?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.13 DATA GOVERNANCE

Are access and processing controls in place (e.g., audit logs, role-based access)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.14 DATA GOVERNANCE

Have you applied privacy-by-design and by-default principles (e.g., pseudonymization, encryption)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Data Governance (continued)

QUESTION 3.15 DATA GOVERNANCE

Is data minimization enforced for sensitive medical data?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.16 DATA GOVERNANCE

Are mechanisms in place to uphold data subject rights (e.g., withdrawal, objection, erasure)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.17 DATA GOVERNANCE

Have you considered data privacy over the full lifecycle (e.g., updates, integration, usage data)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.18 DATA GOVERNANCE

Have you evaluated risks from non-personal data (e.g., re-identification, bias)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 3.19 DATA GOVERNANCE

Is the system aligned with relevant standards (e.g., ISO 27701, 27001, IEEE 7002, national protocols)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 4 OF 7 | 17 QUESTIONS

Requirement #4: Transparency

Healthcare AI systems should be understandable and explainable. This means processes must be traceable, algorithms transparent, and communication clear about system capabilities and limitations. Patients and HCPs must understand how and why an AI system reached a recommendation or diagnosis.

Traceability

QUESTION 4.1 TRACEABILITY

Are mechanisms in place to track AI system behavior across development, deployment, and updates?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.2 TRACEABILITY

Is input data quality regularly assessed (e.g., EHRs, imaging, lab data, real-time feeds)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.3 TRACEABILITY

Can the system trace decisions back to input data and model versions?

◯ Yes ◯ No ◯ Partially ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.4 TRACEABILITY

Are outputs reviewed for consistency with clinical guidelines and judgment?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Traceability (continued)

QUESTION 4.5 TRACEABILITY

Are decision steps (inputs, models, outputs) logged for auditing and regulatory purposes?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.6 TRACEABILITY

Are traceability tools accessible to staff and designed to support error analysis and explainability?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Explainability

QUESTION 4.7 EXPLAINABILITY

Are AI decisions explained in a clinically meaningful way to intended users (e.g., doctors, nurses)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.8 EXPLAINABILITY

Are clinical explanations context-aware (e.g., based on lab results, symptoms)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Explainability (continued)

QUESTION 4.9 EXPLAINABILITY

Are patient-facing explanations available where appropriate, in plain language?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.10 EXPLAINABILITY

Is user comprehension evaluated regularly through testing or feedback?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.11 EXPLAINABILITY

Are usability studies conducted to test understanding, trust calibration, and override behavior?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Communication

QUESTION 4.12 COMMUNICATION

Are users clearly informed when they interact with an AI system, not a human?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Communication (continued)

QUESTION 4.13 COMMUNICATION

Are users informed of the AI system's purpose, logic, and limitations?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.14 COMMUNICATION

Are system benefits (e.g., faster triage, access) communicated transparently?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.15 COMMUNICATION

Are risks (e.g., error rates, misunderstanding complex cases) communicated clearly?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.16 COMMUNICATION

Are training materials or onboarding tools provided for both patients and healthcare staff?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 4.17 COMMUNICATION

Are disclaimers included to reinforce the system's advisory nature and promote human oversight?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 5 OF 7 | 25 QUESTIONS

Requirement #5: Diversity, Non-Discrimination, and Fairness

Trustworthy healthcare AI systems must be bias-free and inclusive. This means ensuring accessibility and fair treatment of all individuals. To avoid biases that could lead to misdiagnosis or unequal treatment, it's crucial for AI in healthcare to be trained on diverse population data, with special regard to data on minorities and rare diseases.

Bias

QUESTION 5.1 BIAS

Have you developed a strategy to address unfair bias across data, model, and outputs?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

QUESTION 5.2 BIAS

Is your training and validation data representative of diverse populations (age, sex, ethnicity, conditions)?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

QUESTION 5.3 BIAS

Are historically marginalized groups included (e.g., disabled, pregnant, elderly, rare diseases)?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

QUESTION 5.4 BIAS

Have you tested for performance disparities across subgroups (e.g., rural, linguistic, gender-diverse)?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

Bias (continued)

QUESTION 5.5 BIAS

Are technical tools used to detect bias (e.g., feature importance, proxies, fairness metrics)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.6 BIAS

Is fairness monitored throughout development, retraining, and deployment?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.7 BIAS

Have your teams received bias-awareness training (clinical, technical, ethical risks)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.8 BIAS

Is there a process to report, review, and correct biased behaviors or outputs?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.9 BIAS

Have all potentially affected populations and stakeholders been identified?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Bias (continued)

QUESTION 5.10 BIAS

Have you considered different fairness definitions and selected context-appropriate ones?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

QUESTION 5.11 BIAS

Were representative communities consulted in defining fairness (e.g., disability groups)?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

QUESTION 5.12 BIAS

Is fairness operationalized using quantitative metrics and built into evaluation criteria?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

Accessibility

QUESTION 5.13 ACCESSIBILITY

Does the system accommodate user diversity in skills, abilities, and preferences?

Yes No Partially / Planned Don't know / needs input Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ADD TO FOLLOW-UP

Accessibility (continued)

QUESTION 5.14 ACCESSIBILITY

Is the interface accessible for users with disabilities or impairments?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.15 ACCESSIBILITY

Are outputs (alerts, explanations) available in accessible, clear formats?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.16 ACCESSIBILITY

Were people with accessibility needs consulted in development and testing?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.17 ACCESSIBILITY

Was Universal Design applied from the start to include all users?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.18 ACCESSIBILITY

Have you evaluated whether any groups may face barriers to using or benefiting from the AI?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Accessibility (continued)

QUESTION 5.19 ACCESSIBILITY

Have underserved or excluded populations (e.g., rare disease patients) been considered?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.20 ACCESSIBILITY

Has the team engaged healthcare providers and patient advocacy groups during development?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.21 ACCESSIBILITY

Have risks of exclusion or harm (e.g., access, treatment changes) been assessed?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Stakeholder Participation

QUESTION 5.22 STAKEHOLDER PARTICIPATION

Is there a process for broad, meaningful stakeholder involvement in all phases?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Stakeholder Participation (continued)

QUESTION 5.23 STAKEHOLDER PARTICIPATION

Have diverse experts and communities been engaged (e.g., clinicians, ethicists, regulators)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.24 STAKEHOLDER PARTICIPATION

Has stakeholder input shaped definitions of fairness, risk, and usability?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 5.25 STAKEHOLDER PARTICIPATION

Is there a mechanism for ongoing consultation and feedback after deployment?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 6 OF 7 | 16 QUESTIONS

Requirement #6: Societal and Environmental Well-Being

Trustworthy healthcare AI should enhance the well-being of people and the environment, and support public health and preventative care. It must reduce disparities, particularly those affecting vulnerable populations, and be ecologically responsible by minimizing its environmental impact and training staff and patients on its use and limitations. Trustworthy healthcare AI must also ensure that decision-making remains human and that any redesign of healthcare workflows and task distributions is transparent, participatory, and sensitive to the needs of workers at all levels.

Environmental Impact

QUESTION 6.1 ENVIRONMENTAL IMPACT

Have you assessed whether the AI system could negatively affect the environment across its lifecycle?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.2 ENVIRONMENTAL IMPACT

Have specific risks like energy use, water use, emissions, or hardware demands been identified?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.3 ENVIRONMENTAL IMPACT

Are mechanisms in place to evaluate environmental footprint (e.g., energy use, data center sustainability)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.4 ENVIRONMENTAL IMPACT

Have you applied strategies to reduce environmental impact (e.g., efficient models, green hardware)?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Environmental Impact (continued)

QUESTION 6.5 ENVIRONMENTAL IMPACT

Is environmental cost weighed against clinical benefit in energy-constrained settings?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Workforce Impact

QUESTION 6.6 WORKFORCE IMPACT

Does the AI system change roles or responsibilities of healthcare professionals?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.7 WORKFORCE IMPACT

Were staff and their representatives informed and consulted before deployment?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.8 WORKFORCE IMPACT

Are role impacts and automation boundaries clearly defined and understood?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Workforce Impact (continued)

QUESTION 6.9 WORKFORCE IMPACT

Do healthcare professionals understand system capabilities and how to override outputs?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.10 WORKFORCE IMPACT

Have you addressed risks of de-skilling through engagement, review, and learning processes?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.11 WORKFORCE IMPACT

Have digital/data skills training and support been provided, including to rural/low-resourced staff?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Societal Impact

QUESTION 6.12 SOCIETAL IMPACT

Could the AI system worsen health inequality or undermine trust in healthcare?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Societal Impact (continued)

QUESTION 6.13 SOCIETAL IMPACT

Have you assessed impact on indirectly affected communities or broader public perceptions?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.14 SOCIETAL IMPACT

Have you taken actions to reduce societal harm and promote equitable access and transparency?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.15 SOCIETAL IMPACT

Are safeguards in place to uphold autonomy, consent, and accountability?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 6.16 SOCIETAL IMPACT

Does the system avoid enabling profiling, surveillance, or discriminatory practices?

○ Yes ○ No ○ Partially / Planned ○ Don't know / needs input ○ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

REQUIREMENT 7 OF 7 | 16 QUESTIONS

Requirement #7: Accountability

Mechanisms must be in place to ensure responsibility and accountability for healthcare AI systems and their outcomes, including auditability, reporting, and redress mechanisms when harm occurs. These procedures should include clear pathways for patients and HCPs to challenge or correct erroneous decisions. The goal is to ensure accountability through both proactive measures and reactive measures.

Auditability

QUESTION 7.1 AUDITABILITY

Are mechanisms in place to ensure the system is auditable to support clinical safety and public trust?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.2 AUDITABILITY

Does auditability span design, data sourcing, deployment, and performance logging?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.3 AUDITABILITY

Are design and training data (origin, criteria) fully documented?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.4 AUDITABILITY

Can the system be audited by external third parties (e.g., regulators, ethics boards)?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Auditability (continued)

QUESTION 7.5 AUDITABILITY

Do audit practices preserve patient confidentiality while enabling transparency?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Risk Management

QUESTION 7.6 RISK MANAGEMENT

Have third-party ethical oversight or auditing bodies been involved across the lifecycle?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.7 RISK MANAGEMENT

Is risk oversight in place during development, integration, and post-market monitoring?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.8 RISK MANAGEMENT

Have stakeholders received training on ethical/legal risks and relevant AI regulations?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Risk Management (continued)

QUESTION 7.9 RISK MANAGEMENT

Is there an internal ethics board or oversight group to advise on ethical conflicts and trade-offs?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.10 RISK MANAGEMENT

Is there a process for continuous evaluation of ethical alignment and principle conflicts?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.11 RISK MANAGEMENT

Are trade-offs and decisions clearly documented during development and updates?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.12 RISK MANAGEMENT

Have governance personnel been trained in legal, ethical, and clinical AI implications?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.13 RISK MANAGEMENT

Is there a reporting channel for clinicians, patients, or partners to flag risks or concerns?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Risk Management (continued)

QUESTION 7.14 RISK MANAGEMENT

Is the feedback loop linked to actionable revision and improvement procedures?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

Redress Mechanisms

QUESTION 7.15 REDRESS MECHANISMS

For sensitive applications, is human review or appeals available to patients?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

QUESTION 7.16 REDRESS MECHANISMS

Are error correction and rights notification procedures clear and in place?

◯ Yes ◯ No ◯ Partially / Planned ◯ Don't know / needs input ◯ Not applicable

COMMENTS / EVIDENCE (OPTIONAL) ☐ ADD TO FOLLOW-UP

What to do next

Please remember that this tool is intended as a first step towards greater awareness and understanding of the ethical and governance issues involved in the responsible and trustworthy use and adoption of AI systems in healthcare. It is not intended to replace expert advice, formal compliance assessments, or other relevant organisational processes. Users are encouraged to consult relevant experts and, where necessary, seek appropriate guidance and expertise from qualified third-party experts in order to assess compliance with applicable ethical, legal, regulatory, technical and other relevant requirements.

Use the assessment to continue the discussion with the people responsible for the relevant areas, including ethical, legal or regulatory (e.g. AI ethics and governance experts), data protection, clinical or quality, cybersecurity or technical, procurement or vendor management colleagues, and affected staff, patients or other users. Check the supporting evidence, agree actions through your organisation's usual processes, seek independent expertise where appropriate, and repeat the assessment when the AI tool or its context changes.

Help improve this tool

EthicAI4CARE welcomes feedback on what worked, what was unclear and what could be improved. Visit **https://ethicai4care.eu/contact.**

Please share feedback about the tool rather than confidential details from your assessment.

How this digital version was developed

This digital self-assessment was adapted from the existing EthicAI4CARE framework through a researcher-led process and based on feedback from project partners. Generative AI was used to support development of the web version of the tool. It was not used to define or revise the underlying framework, assessment requirements, or questions. Responsibility for reviewing and approving the final version remained with the project team.

Ethical framework and official resources

Last checked 23 September 2026

EthicAI4CARE publications and deliverables
https://ethicai4care.eu/project-publications-deliverables

Ethics Guidelines for Trustworthy AI
https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

Assessment List for Trustworthy Artificial Intelligence (ALTAI)
https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment

European Commission AI Act overview
https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai

AI Act Service Desk
https://ai-act-service-desk.ec.europa.eu/en

Official AI Act text (EUR-Lex)
https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng

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