Technical Annex

to the AEQUITAS AI Regulatory Model

Supporting documents

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Annex 1: Glossary of Key Terms and Definitions

Annex 2: AI System Dossier Template

Annex 1: Glossary of Key Terms and Definitions

A. Regulatory / Legal Architecture Terms

- **AI Act (High-Risk AI System)**

  The European Union Artificial Intelligence Act is a risk-based regulatory framework governing AI systems. “High-risk AI systems” are those that may significantly affect health, safety, or fundamental rights. In healthcare, this typically includes clinical decision-support systems, diagnostic tools, and risk prediction algorithms. High-risk systems are subject to obligations on risk management, data governance, transparency, human oversight, and post-market monitoring.

- **Deployer / Provider**

  Provider refers to the entity that develops or places an AI system on the market or puts it into service under its name or trademark, and is responsible for conformity and system design.

  Deployer refers to the entity that uses the AI system under its authority (e.g., hospitals). Deployers are responsible for correct use, human oversight, monitoring, and compliance with operational obligations during use. The distinction is central to accountability allocation.

- **MDR / IVDR**

  The Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) are EU legal frameworks governing medical devices and diagnostic tools, including software. They establish requirements for clinical evaluation, safety, performance, and post-market surveillance. Many healthcare AI systems fall within their scope when they perform diagnostic or clinical support functions.

- **Fundamental Rights Impact Assessment (FRIA)**

  An assessment required under the AI Act for certain high-risk systems, aimed at identifying and mitigating risks to fundamental rights, including equality, non-discrimination, and human dignity. In healthcare, it includes evaluation of potentially affected patient groups and analysis of mitigation measures for inequitable impacts.

- **Data Protection Impact Assessment (DPIA)**

A requirement under the General Data Protection Regulation (GDPR) for processing activities likely to result in high risks to individuals. In healthcare AI, DPIAs assess risks related to the processing of sensitive health data, including privacy, security, and data misuse concerns.

- **CE Marking / Conformity Assessment**

  A CE mark indicates that a product complies with applicable EU legislation, including safety, health, and environmental requirements. In the context of AI-enabled medical devices, conformity assessment involves formal evaluation of compliance with MDR/IVDR requirements, often conducted by notified bodies for higher-risk systems.

B. Governance Model Terms

- **Lifecycle Governance**

  A regulatory approach in which oversight of AI systems is applied across all stages of their lifecycle: design, development, procurement, validation, deployment, monitoring, modification, and decommissioning. It ensures continuous risk and performance management rather than one-time approval.

- **Safety Management System (SMS)**

  An organisation-wide framework originally developed in aviation for managing safety risks. It includes hazard identification, risk assessment, mitigation, monitoring, and continuous improvement processes.

- **AI Safety Management System**

  An adaptation of the SMS model for AI systems in healthcare. It integrates technical safety controls with equity considerations, including monitoring for performance disparities across gender and racial or ethnic groups, incident reporting, and corrective action mechanisms.

- **AI-vigilance**

  A post-deployment monitoring system for AI in healthcare inspired by pharmacovigilance. It enables systematic reporting, analysis, and escalation of AI-related incidents, including safety issues and inequities affecting specific population groups.

- **Change-Control Policy**

A governance mechanism defining how modifications to AI systems (e.g., model updates, retraining, workflow changes, or integration changes) are evaluated, approved, documented, and monitored. It includes assessment of potential impacts on safety and equity before implementation.

- **Post-Market Monitoring**

  Continuous oversight of AI systems after deployment to ensure ongoing safety, performance, and compliance. It includes detection of performance degradation, safety incidents, and emerging disparities in outcomes across population groups.

C. Technical AI Governance Terms

- **Model Drift / Performance Drift**

  A change or degradation in AI system performance over time due to shifts in data distribution, population characteristics, clinical practices, or operational environments. Drift may disproportionately affect certain disaggregated population groups.

- **Disaggregated Analysis**

  The evaluation of AI system performance across disaggregated population groups (e.g., gender, race, ethnicity) to identify differences in accuracy, error rates, or outcomes.

- **Stratified Performance Evaluation**

  A form of evaluation in which AI system performance metrics are disaggregated by relevant demographic or clinical disaggregated population groups to detect disparities or unequal outcomes.

- **Bias / Algorithmic Bias**

  Systematic and repeatable errors in an AI system that produce unfair or unequal outcomes across groups. In healthcare, this may result in differences in diagnosis, treatment recommendations, or risk predictions across gender, racial, or ethnic populations.

- **Representativeness (in Datasets)**

  The extent to which training, validation, or operational datasets accurately reflect the population on which the AI system is deployed, including distribution across relevant demographic groups such as gender, race, and ethnicity.

❖ **Validation / Revalidation**

Validation refers to systematic evaluation of an AI system before deployment to assess performance, safety, and suitability for intended use.

Revalidation refers to repeated evaluation triggered by significant changes (e.g., updates, new deployment sites, or population shifts) or evidence of performance drift.

D. Institutional Roles & Artefacts (CSO-Relevant)

❖ **Civil Society Organisation (CSO) Role in AI Governance**

CSOs are independent non-governmental organisations participating in oversight, auditing, and rights-based monitoring of AI systems in healthcare. They do not have operational control but provide independent assessment of fairness, transparency, and compliance with fundamental rights principles.

❖ **Equity and Rights Audit**

A structured assessment of whether an AI system complies with fundamental rights obligations, including equality and non-discrimination. It evaluates disaggregated performance, identifies disparities, and assesses mitigation measures and residual risks.

❖ **Technical Audit vs Equity Audit**

A technical audit focuses on system performance, robustness, cybersecurity, and regulatory compliance.

An equity audit focuses on fairness, disaggregated population group disparities, and fundamental rights impacts, including gender and racial or ethnic bias. Both are complementary components of the governance framework.

❖ **AI System Dossier**

A document maintained for each AI system within a healthcare institution. It consolidates key information including intended use, validation results, clinical integration details, disaggregated performance metrics, oversight arrangements, and known limitations.

❖ **AI Impact Assessment**

A standardised evaluation of the potential effects of an AI system prior to deployment, including safety, ethical, legal, and social implications. In healthcare, it includes assessment of risks to patient groups and potential disparities in outcomes across demographic disaggregated population groups.

Annex 2: AI System Dossier Template

Introduction

The AI System Dossier is a standardised, bias-aware document maintained for each AI system prior to deployment within a healthcare organisation. It provides a formal overview of the system's purpose, validation, performance, and equity considerations, ensuring that pre-deployment decisions explicitly account for potential risks to gender and racial equity. The dossier supports transparency, internal governance, and regulatory oversight, and feeds directly into monitoring, auditing, and accountability processes.

The AI System Dossier serves as a comprehensive record of each AI tool deployed within a healthcare organisation, providing a clear and structured overview of its intended clinical purpose and integration within existing workflows. It summarises validation results, including overall performance metrics and detailed analyses along gender and racial or ethnic lines, highlighting any known disparities and the mitigation measures applied during development. The dossier also clarifies human oversight arrangements, specifying which decision points remain under clinician control to ensure safe and equitable use. By consolidating this information, the dossier supports internal governance, enables compliance with regulatory requirements under the AI Act, MDR, and IVDR, and facilitates cross-site learning and accountability, ensuring that gender and racial equity considerations are systematically documented and monitored throughout the AI lifecycle.

Implementation Notes

The AI System Dossier should be treated as a living document, updated whenever new validation results, performance metrics, or bias-mitigation strategies are available. By maintaining an explicit focus on gender and racial disaggregated analyses, the dossier ensures that equity risks are clearly visible, actively assessed, and appropriately mitigated before deployment. Serving both operational and governance purposes, the dossier informs hospital staff about system functionality and limitations, supports regulatory inspections and audits, and provides a structured record that can feed into continuous monitoring, equity and rights audits, and cross-site learning initiatives.

Implementation proportionality and minimum requirements

This template is designed to support bias-aware and rights-based governance of AI systems in healthcare organisations with varying levels of technical and organisational capacity. To facilitate broad implementation, template fields are divided into:

A) Mandatory minimum requirements necessary to support safe, transparent, and accountable deployment of AI systems in line with applicable obligations under the AI Act, MDR/IVDR, and fundamental rights principles; and
B) Recommended or advanced practices, which strengthen continuous monitoring, equity assessment, and organisational learning where resources and technical capacity permit.

Healthcare organisations are encouraged to progressively implement advanced practices over time, particularly for high-risk AI systems or systems deployed in contexts affecting disadvantaged populations.

Core Sections

1. System Overview

Purpose: Provides a clear, succinct description of the AI system, its context, and regulatory status, forming the starting point for bias-aware governance and pre-deployment assessment.

Template Fields and Guidance:

- **Name, version, and release date of the AI system**

Minimum requirement: *Specify the official system name, version number, and release date.*

Recommended: *Include prior versions where relevant to support traceability over time. This enables linkage between system versions and disaggregated performance or bias assessments.*

- **Developer/provider details (internal or external)**

Minimum requirement: *Identify the organisation or individual responsible for development and indicate whether the system is internally developed or externally sourced.*

Recommended: *Describe the roles of involved parties in maintenance, updates, and bias mitigation. Where applicable (external providers), include contact details for reporting bias incidents or requesting additional performance data.*

- **Intended clinical purpose and workflow integration**

Minimum requirement: *Describe the clinical use case (e.g. diagnostic support, triage, prognosis, treatment planning, or workflow assistance). Specify how the system integrates into existing clinical processes, EMRs, or other IT systems. Identify points where human oversight is required and clarify which decisions remain under clinician control.*

Recommended: *Include considerations on whether the intended population includes diverse gender and racial groups, and whether the system's design explicitly accounts for potential differences in performance or impact across these groups.*

- **Regulatory classification**

Minimum requirement: *Specify whether the system qualifies as medical device software under the MDR/IVDR and indicate the risk category under the AI Act (high-risk vs. lower-risk). Include references to relevant MDCG guidance or applicable national rules to justify the classification. Record MDR/IVDR status, AI Act risk category, and supporting references in Table 1.*

Minimum requirement: *Document compatibility with Electronic Medical Record (EMR)/Electronic Health Record (EHR) systems, lab or imaging systems, and key workflow dependencies that may affect implementation or system performance. Use Table 2 to capture these elements, assign responsibilities, and record any technical or workflow constraints.*

Recommended: *Include implications of the regulatory classification for equity oversight, including expected requirements for disaggregated performance evaluation and bias mitigation.*

Recommended: *Consider how classification may influence the level of scrutiny applied to gender and racial equity during procurement, validation, and deployment processes.*

Table 1: Regulatory Classification Table

Regulatory Reference	Purpose	Location / Link	Notes on Equity Implications	Review Date / Version
MDR/IVDR Classification Form	Confirm whether the system qualifies as a medical device	[Link or file path]	Indicates whether performance validation and bias mitigation across gender/racial disaggregated population groups are required	[DD/MM/YYYY or version]
AI Act Risk Assessment Documentation	Determine high-risk vs lower-risk classification	[Link or file path]	Guides level of scrutiny for gender and racial equity in procurement, validation, deployment	[DD/MM/YYYY or version]
MDCG Guidance or National Rules	Justify classification decisions	[Link or file path]	Supports consistent interpretation of obligations related to equity and bias mitigation	[DD/MM/YYYY or version]
Other relevant national regulations	Compliance with local laws	[Link or file path]	Any additional requirements for assessing disaggregated performance or mitigating bias	[DD/MM/YYYY or version]

Table 2: Integration Table

Section	Details / Notes	Responsible Party	Review Date / Version
Clinical Workflow Integration	Describe where the AI system fits within the clinical process; specify decision points, hand-offs, and expected user interactions.	Hospital AI lead / Clinical lead	
EMR / Lab System Compatibility	List the EMR, lab, imaging, or other hospital systems the AI must interface with; note integration requirements or constraints.	IT / Integration team	
Data Input and Output Formats	Specify required input data types, formats, and standards (e.g., HL7, FHIR) and expected output formats.	IT / Data management lead	
Access and User Permissions	Document user roles, authentication mechanisms, and access controls relevant to clinicians and administrators.	IT / Security lead	
Alerts and Notifications	Describe how the system communicates outputs, warnings, or errors within the workflow.	Clinical / IT team	
Training and Support Requirements	Outline necessary training, support contacts, and operational guidance for staff interacting with the system.	AI Governance lead / Provider	
Operational Constraints	Note any environmental, technical, or procedural constraints affecting system deployment or performance.	IT / Clinical lead	

Table 3: Contact information for support

Role / Contact Type	Name	Department / Organisation	Email	Phone
Developer / Provider				
Internal AI Governance Lead				
Clinical Oversight Contact (opt.)				

2. Validation Results and Performance Metrics

Purpose: Provides structured evidence of the system's effectiveness, with detailed analysis of disaggregated performance and documentation of bias mitigation strategies. This section ensures transparency, supports equitable deployment, and allows hospitals and auditors to evaluate compliance with AI Act obligations.

Template Fields and Guidance:

- **Overall system performance**

Minimum requirement: *Include core performance metrics such as accuracy, sensitivity, specificity, AUROC, F1-score, or other clinically relevant measures. Specify the datasets used for evaluation and indicate whether these are internal, external, proprietary, or open-access.*

Recommended: *Include notes on limitations or assumptions affecting generalisability, including any known constraints in the evaluation data that may influence interpretation of performance across different clinical settings or populations.*

- **Disaggregated performance analysis**

Minimum requirement: *Present performance metrics stratified by gender and racial/ethnic groups where such data are available. Highlight any observed disparities or gaps in key performance measures (e.g. accuracy, sensitivity, specificity) between disaggregated population groups.*

Recommended: *Include explanatory notes on potential causes of observed disparities, if known, and document any mitigation measures applied during development or validation. Where feasible, use visual aids (e.g. tables or graphs) and include confidence intervals or statistical significance assessments to support interpretation.*

- **Site-specific performance expectations and equity considerations**

Minimum requirement: *Include any known adjustments or considerations for deploying the system in the specific hospital context. Note relevant differences between validation data and the expected patient population that may affect system performance.*

Recommended: *Address whether the model may underperform for particular demographic groups due to population differences. Where applicable, outline potential mitigation strategies or workflow adjustments to support equitable performance across disaggregated population groups.*

- **Evidence of bias mitigation measures applied during development and testing**

Minimum requirement: *State whether any bias mitigation measures were applied during development or testing. If available, provide a high-level description of the type of approach used (e.g. data-level, model-level, or post-processing).*

Recommended: *Where applicable, document specific techniques used (e.g. data balancing, fairness-constrained training, reweighting, disaggregated evaluation) and reference any testing results demonstrating their effectiveness.*

Recommended: *Include information on whether bias mitigation is ongoing or whether re-evaluation is required during retraining or software updates.*

The table below facilitates the completion of the minimum required information for this section.

Table 4: Validation & Performance Summary Table

Component	Required Information	Dataset / Source	Notes (if applicable)
Overall system performance	[Accuracy, sensitivity, specificity, AUROC, F1-score (or equivalent)]	[Internal / external / proprietary / open-access]	[Specify evaluation context]
disaggregated performance (gender)	[Metrics stratified by gender groups (where available)]	[Internal / external / proprietary / open-access]	[State missing data if not available]
disaggregated performance (racial/ethnic)	[Metrics stratified by racial/ethnic groups (where available)]	[Internal / external / proprietary / open-access]	[State missing data if not available]
Site-specific performance	[Key deployment context adjustments or constraints]	[Local hospital context]	[Brief description only]

Component	Required Information	Dataset / Source	Notes (if applicable)
Bias mitigation (development/ testing)	[Whether mitigation was applied + high-level type]	[Training/validation pipeline]	[Indicate presence/absence]

3. Training Data and Representativeness

Purpose: Documents the origin, composition, and representativeness of all data used to train, fine-tune, or support operational AI models. Ensures hospitals can assess whether the system is likely to perform equitably across gender and racial/ethnic groups, and supports compliance with AI Act and bias mitigation expectations.

Template Fields and Guidance:

- **Summary of datasets**

Minimum requirement: *List all datasets used in development and validation, distinguishing between internal hospital data, external public datasets, and proprietary datasets. Indicate the general type of data used (e.g. imaging, EHR, genomic, laboratory data) and the approximate period of collection.*

Recommended: *Where available, include dataset size, detailed population coverage, and any known limitations such as missing variables, sampling bias, or skewed distributions. Provide additional contextual information on representativeness where relevant.*

- **Demographic composition**

Minimum requirement: *State whether demographic information on the dataset population is available for gender and/or racial/ethnic groups. If available, provide a high-level description of group representation (e.g. balanced, skewed, or partially represented). If not available, explicitly state this limitation.*

Recommended: *Where data are available, provide detailed quantitative breakdowns by gender and racial/ethnic groups. Identify underrepresented groups and describe their proportional representation. Include discussion of potential impacts of imbalances on model performance, and use visualisations (e.g. tables, histograms, charts) where*

appropriate. Where certain groups are absent or minimally represented, include relevant caveats or mitigation considerations for deployment.

- **Data provenance**

Minimum requirement: *Specify the origin of each dataset used, distinguishing between internal, external, proprietary, and non-proprietary sources. Indicate whether datasets are broadly accessible or restricted (e.g. commercial, institutional, or regulated access).*

Recommended: *Where available, include details on licensing conditions, accessibility constraints, and any consent or governance frameworks associated with the datasets. Note any limitations these may impose on independent validation, auditing, or transparency in assessing equity-related performance.*

- **Verification of disaggregated performance / bias mitigation**

Minimum requirement: *State whether disaggregated performance evaluation and bias mitigation checks were performed during development and/or validation. If performed, indicate at a high level whether results were assessed across demographic disaggregated population groups and whether any mitigation measures were applied.*

Recommended: *Where available, describe the specific bias-mitigation strategies used (e.g. reweighting, stratified sampling, fairness-aware algorithms, or post-processing corrections). Include evidence of effectiveness such as test results, performance comparisons across disaggregated population groups, or internal audit outcomes. Indicate whether mitigation measures require re-evaluation during updates, retraining, or deployment changes.*

4. Human Oversight and Use Guidance

Purpose: Ensures that clinicians understand their responsibilities in supervising AI outputs, detecting potential bias, and maintaining equitable patient care. Provides clear procedures for intervention when the AI system exhibits inequitable or unsafe behavior.

Template Fields and Guidance:

- **Description of tasks under clinician control**

Minimum requirement: *Specify which decisions remain under exclusive healthcare professional control and cannot be automated by the AI system. Clearly indicate the boundary between AI-supported outputs and clinician decision-making responsibilities.*

Recommended: *Include concrete examples such as final diagnosis confirmation, treatment selection, or escalation of care pathways. Where relevant, highlight situations where disaggregated performance disparities or uncertainty in outputs may require heightened clinician judgment or additional review.*

- **Guidance on interpreting outputs and identifying bias**

Minimum requirement: *Provide basic instructions for clinicians on how to recognise outputs that may indicate potential bias, including awareness that performance differences may exist across gender or racial/ethnic disaggregated population groups.*

Recommended: *Include examples of potential bias signals (e.g. systematically lower confidence or accuracy for specific disaggregated population groups), visual indicators where applicable, or threshold-based alerts if defined by the system. Where feasible, recommend periodic review of output trends across disaggregated population groups to support early detection of emerging inequities.*

- **Procedures for overriding, stopping, or reporting outputs with equity concerns**

Minimum requirement: *Describe clear procedures for clinicians to override or disregard AI outputs when they appear unsafe or potentially biased. Include basic steps for escalating concerns or reporting outputs through available institutional channels.*

Recommended: *Where available, include structured workflows for temporarily disabling AI recommendations, escalation to specialist review pathways, and submission of reports to formal AI vigilance or incident logs. Emphasize documentation of all interventions and follow-up actions for audit purposes, and describe how these procedures integrate with broader bias mitigation or governance workflows.*

- **Training and competency verification**

Recommended: *Reference any training modules, competency checks, and refresher courses designed to support clinicians in detecting and responding to bias in real-world use. Where applicable, include frequency, case examples, and assessment criteria.*

5. Change Management

Purpose: Ensures that any modifications to the AI system, whether software updates, model retraining, or workflow changes, are assessed for their potential impact on patient safety and equitable outcomes. Maintains transparency and accountability for equity-related risks.

Template Fields and Guidance:

- **Record of updates, retraining, or workflow modifications**

Document each change with date, version, and nature of modification. Guidance: Include whether the update involves data, model architecture, feature engineering, or clinical integration. Specify if changes are triggered by new evidence, regulatory requirements, or performance drift.

- **Assessment of potential impacts on disaggregated performance and equity**

Include analyses of how the update may affect different demographic groups, particularly gender and racial/ethnic disaggregated population groups. Guidance: Compare pre- and post-update performance metrics for all relevant disaggregated population groups, noting improvements or declines. Document any new mitigation measures applied to correct emerging disparities.

- **Evidence of notifications to clinicians or relevant staff**

Track communications regarding changes, including who was informed and how. Guidance: Include summaries of change implications for workflow, risks for disaggregated population risks, and bias mitigation responsibilities. Encourage confirmation that clinicians understand their role in monitoring and responding to equity concerns.

- **Approval and review**

Optional but recommended: Include a section for approval by responsible oversight personnel, e.g., clinical governance committee or AI ethics board. Guidance: Confirm that updates are reviewed not only for safety and regulatory compliance but also for gender and racial equity impacts.

6. Incident Reporting and Mitigation

Purpose: Ensures that all incidents, near-misses, or unexpected outcomes, including those disproportionately affecting gender or racial disaggregated population groups, are systematically captured, analysed, and remediated. Supports continuous improvement and compliance with equity-focused governance requirements.

Template Fields and Guidance:

- **Procedures for capturing incidents or near-misses affecting gender or racial disaggregated population groups**

Minimum requirement: *Document each incident or near-miss involving potential bias or differential impact across gender or racial/ethnic disaggregated population groups. Record the event type, date, system version, and affected disaggregated population group(s). Where applicable, briefly indicate whether the incident involved misclassification, incorrect recommendation, or differential outcomes.*Recommended: *Include structured fields for capturing detailed equity-related concerns, including severity of impact on different disaggregated population groups and contributing factors. Where available, align reporting with internal AI governance or vigilance frameworks to enable*

systematic tracking, aggregation, and analysis of bias-related incidents over time.

- **Summary of prior incidents and actions taken to remediate disparities**

Minimum requirement: *If prior incidents or near-misses have been recorded, provide a brief summary and indicate whether any remediation actions were taken. If no prior incidents exist, explicitly state this.*

Recommended: *Where applicable, maintain a structured log of incidents and associated mitigation strategies (e.g. retraining, model adjustments, workflow changes, or staff interventions). Include evaluation of whether implemented measures reduced disaggregated population group disparities over time, supported by available performance or monitoring evidence.*

- **Integration with hospital-level governance and AI-vigilance processes**

Minimum requirement: *Describe how incident reports are handled within existing hospital governance structures (if applicable), including any links to quality management systems or clinical governance processes. If no formal AI-vigilance or dedicated AI governance structure exists, state how incidents are otherwise escalated or reviewed.*

Recommended: *Where such structures exist, specify how incident reports feed into AI-vigilance logs, equity audits, and governance or oversight committees (including CSO or equivalent roles). Include reference to regulatory notification pathways where applicable, and describe how findings inform procurement decisions, model validation, and change-control processes with consideration of equity impacts.*

- **Follow-up and monitoring**

Recommended: *Document follow-up checks to confirm the efficacy of remediation. Guidance: Track whether subsequent system updates reduce the risk of recurring disparities for affected disaggregated population groups.*

7. Cross-References and Compliance

Purpose: Ensures that the AI system dossier is fully integrated with other governance artefacts and regulatory obligations, creating a clear, auditable trail linking operational information, compliance measures, and equity considerations.

Template Fields and Guidance:

- **Links to FRIA/DPIA assessments, audit reports, and related governance artefacts**

Minimum requirement: *Provide references or links (where available) to any existing governance or compliance documentation relevant to the AI system, such as risk assessments, audit reports, or internal evaluation records. If no such documents exist, state this explicitly.*

Recommended: *Where applicable, include links to FRIA/DPIA packages, disaggregated performance and equity reports, technical audit outputs, change-control records, AI-vigilance logs, and other governance artefacts. Highlight any findings or recommendations related to gender and racial disparities, and indicate whether associated follow-up actions have been completed.*

- **References to AI Act, MDR/IVDR provisions, and internal hospital policies on equity and bias mitigation**

Minimum requirement: *List the main applicable regulatory frameworks relevant to the AI system, such as the AI Act, MDR/IVDR, and any relevant internal hospital policies on equity, non-discrimination, or bias mitigation. Provide a general indication of how these frameworks are considered in system use or oversight.*

Recommended: *Where applicable, specify relevant legal provisions (e.g. AI Act Articles 9–15 for high-risk systems, Article 10 on bias mitigation, MDR/IVDR requirements) and describe how these informed validation, deployment, and monitoring processes. Include cross-references to internal policies explicitly addressing gender and racial equity, and explain how these requirements were operationalised in practice.*

- **Integration with operational oversight**

Minimum requirement: *Describe how responsibilities for monitoring AI system use and compliance are allocated within existing hospital governance or operational structures. Indicate which roles or teams are generally responsible for oversight of system performance and safe use.*

Recommended: *Where applicable, specify formal governance structures such as clinical governance committees, CSO oversight, AI ethics boards, or equivalent bodies. Clarify how*

responsibilities for monitoring compliance with bias mitigation requirements are distributed across teams, and describe accountability mechanisms for ensuring ongoing oversight.

- **Audit and review readiness**

Minimum requirement: *Ensure that key documentation and cross-references related to the AI system can be located and retrieved in a reasonable and structured manner for internal or external review. Indicate where relevant documents or evidence are stored.*

Recommended: *Where applicable, highlight specific locations of evidence related to equity-focused interventions, disaggregated performance analyses, and bias mitigation activities. Describe how documentation is organised to support rapid audit or inspection readiness, including tagging or indexing practices that facilitate retrieval of relevant materials.*

Conclusion

This AI System Dossier provides a structured framework for documenting AI systems in healthcare, supporting compliance with relevant regulatory requirements, including the AI Act and MDR/IVDR, while accounting for varying levels of organisational capacity.

Mandatory fields define the minimum information required for safe and accountable deployment. Recommended fields support enhanced governance, including equity assessment, auditability, and continuous improvement, and may be implemented progressively.

The dossier is intended as a living document to support responsible deployment, ongoing monitoring, and governance across the AI lifecycle.

1st section

Sub-section