|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ITU Logo | INTERNATIONAL TELECOMMUNICATION UNION  **TELECOMMUNICATION STANDARDIZATION SECTOR**  STUDY PERIOD 2017-2020 | | FG-AI4H-J-041-R01 | |
| **ITU-T Focus Group on AI for Health** | |
| **Original: English** | |
| **WG (s):** | | Plenary | E-meeting, 30 September – 2 October 2020 | |
| **DOCUMENT** | | | | |
| **Source:** | | Editor | | |
| **Title:** | | Updated DEL03: AI4H requirement specifications | | |
| **Purpose:** | | Discussion | | |
| **Contact:** | | Pradeep Balachandran Technical Consultant (Digital Health) India | | Email: [pbn.tvm@gmail.com](mailto:pbn.tvm@gmail.com) |

|  |  |
| --- | --- |
| **Abstract:** | This document contains the draft version 3.0 of the project deliverable FG-AI4H DEL03 "AI4H requirement specification" and supersedes the previous version of the document (FG-AI4H-I-033). |

**CONTENTS**

| Page |
| --- |
| [1 Introduction 4](#_Toc52197312)  [1.1 Purpose 4](#_Toc52197313)  [1.2 SyRS scope 4](#_Toc52197314)  [2 References 4](#_Toc52197315)  [3 Definitions 5](#_Toc52197316)  [4 Acronyms, abbreviations 5](#_Toc52197317)  [5 Document conventions 5](#_Toc52197318)  [6 SyRS overview 6](#_Toc52197319)  [7 Intended use and high-level specification 7](#_Toc52197320)  [8 System functions 9](#_Toc52197321)  [9 User types /classes and characteristics 11](#_Toc52197322)  [10 Operating conditions / environment 13](#_Toc52197323)  [11 Design and implementation constraints 14](#_Toc52197324)  [12 System interface requirements 16](#_Toc52197325)  [13 Non-functional requirements 20](#_Toc52197326)  [14 System design requirements 25](#_Toc52197327)  [15 System deployment requirements 36](#_Toc52197328)  [16 User documentation / training requirements 38](#_Toc52197329)  [17 Assumptions and dependencies 38](#_Toc52197330)  [18 Quality process compliance 39](#_Toc52197331)  [19 Risk management requirements 40](#_Toc52197332)  [20 Change management requirements 41](#_Toc52197333)  [21 System validation requirements 42](#_Toc52197334)  [22 AI4H topic description to AI4H system requirements traceability matrix 44](#_Toc52197335) |

**List of Tables**

| Page |
| --- |
| [Table 1: Intended use and high levelrequirements 7](#_Toc52196467)  [Table 2: Functional requirements 9](#_Toc52196468)  [Table 3: User type/class requirements 11](#_Toc52196469)  [Table 4: Operating environment requirements 13](#_Toc52196470)  [Table 5: Design and implementation constraints 14](#_Toc52196471)  [Table 6: System interface requirements 16](#_Toc52196472)  [Table 7: Non-functional requirements 20](#_Toc52196473)  [Table 8: System design requirements 26](#_Toc52196474)  [Table 9: System deployment requirements 36](#_Toc52196475)  [Table 10: User documentation and training requirements 38](#_Toc52196476)  [Table 11: Assumptions and dependencies 38](#_Toc52196477)  [Table 12: Quality assurance requirements 39](#_Toc52196478)  [Table 13: Risk management requirements 40](#_Toc52196479)  [Table 14: Change management requirements 41](#_Toc52196480)  [Table 15: System validation requirements 42](#_Toc52196481)  [Table 16: TDD requirements traceability matrix template 45](#_Toc52196482) |

**List of Figures**

| Page |
| --- |
| **No table of figures entries found.** |

FG-AI4H DEL03

AI4H requirement specifications

# Introduction

## Purpose

* The purpose of this document is to define the System Requirement Specifications (SyRS) that explains the informational, functional, behavioural and operational aspects a generic AI for health (AI4H) system.
* SyRS serves as the basis and helps to create system design, system verification and validation plans and procedures
* System requirements analysis methodology follows a collaborative team-oriented approach, involving all the working groups and topic groups of AI4GH FG, to help the project team identify, control and track various requirements and changes to those requirements during the AI4H system development lifecycle

## SyRS scope

* SyRS scope includes a requirements model that defines the informational, functional, behavioural and operational aspects of the AI4H system under consideration.
* SyRS is configured as a quality assessment tool to support requirements auditing or requirements traceability analysis of AI4H topic description documents (TDD)
* This SyRS is generic in nature and shall be applicable across all domain specialties/ topic groups of AI4H FG. It may be modified, customized or extended appropriately to include the specific requirements and needs of the particular topic group under consideration
* The intended audiences of this SyRS include System Analysts, System Designers, System Developers, System Testers, Product Managers, Quality Assurance Auditors / Managers, etc.
* SyRS shall be subjected to periodic review and evaluation as per the requirements management process for verification of its coverage and completeness
* Revisions to SyRS shall follow a formal change management process defined under the quality management system (QMS) of the system / product manufacturer. Revisions shall be performed in an iterative manner based on a rapid incremental delivery (agile process) model to elicit the emergent requirements of the system under consideration as AI systems continue to evolve over time to attain progressive maturity levels

# References

[ISO/IEC/IEEE 29148] ISO/IEC/IEEE 29148:2018, "Systems and software engineering – Life cycle processes – Requirements engineering"

[IEEE STD 830-1998] IEEE STD 830-1998, "IEEE Recommended Practice for Software Requirements Specifications"

[ISO/IEC/IEEE 15288] ISO/IEC/IEEE 15288:2015, "Systems and software engineering – System life cycle processes"

[ISO/IEC/IEEE 12207] ISO/IEC/IEEE 12207:2017, "Systems and software engineering – Software life cycle processes"

# Definitions

**System requirements specification** [ISO/IEC/IEEE 29148]: The structured collection of the requirements [functions, performance, design constraints and other attributes] for the system and its operational environments and external interfaces

# Acronyms, abbreviations

|  |  |
| --- | --- |
| AI | Artificial intelligence |
| AI4H | Artificial intelligence for health |
| DAISAM | Data and AI Solution Assessment Methods |
| FDA | Food and Drug Administration |
| GDPR | General data protection regulation |
| HIPAA | [Health insurance portability and accountability act](https://en.wikipedia.org/wiki/Health_Insurance_Portability_and_Accountability_Act) |
| SaMD | Software-as-a-medical device |
| SiMD | Software-in-a-medical device |
| SOP | Standard operating procedure |
| SyRS | System requirement specification |
| QMS | Quality management system |
| TDD | Topic description document |

# Document conventions

This document shall conform to the following standard convention of specification language syntax for every requirement specifications statement to indicate its particular significance / compliance level.

|  |  |
| --- | --- |
| **Term** | **Meaning** |
| "SHALL" | states a **mandatory** requirement of this policy |
| "SHOULD" | states a**re commended** requirement of this policy |
| "MAY" | states an **optional** requirement |

|  |  |
| --- | --- |
| **Requirement 'Risk Levels'** | LOW MEDIUM HIGH |

|  |  |
| --- | --- |
| **Format used for Requirement Specification ID (REQ-ID)** | <R><hyphen><Acronym for Requirements Type/Sub-Type>< Serial Number> |

# SyRS overview

* System requirements specifications are developed following a generic 'requirements modelling framework' defined under the quality management system (QMS) to guide the process of organizing, promising and tracing the requirements
* System requirements specifications are broadly organized in terms of (a) Functional Requirements, (b) External Interface Requirements, and (c) Non-Functional Requirements
* Requirement specifications are defined in terms of different formats including use cases, graphical methods, mathematical models, documentation, etc. or combination of these format.

# Intended use and high-level specification

Table 1: Intended use and high-level requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-PD1 | System SHALL have specification for the intended health intervention use case for which the AI4H software is used | e.g. health intervention use cases   * Public health   + Health service   + Health systems   + Health expenditure   + Health inequities   + Health surveillance   + Health emergencies   + Life expectancy and mortality   + Cause-specific mortality and morbidity   + Communicable diseases   + Non-communicable diseases   + Civil registration and vital statistics   + Other * Clinical Health   + Prevention   + Screening   + Diagnosis   + Treatment   + Research   + Other * Non-clinical Health   + Personal care   + Wellness   + Education   + Other |  |
| R-PD2 | System SHALL have specification for the intended AI-benchmarking class type / AI-Task/ AI-intervention type for which the AI4H software is used | e.g. AI-benchmarking tasks   * Classification * Regression/Prediction * Clustering * Association rule learning * Decision Support / Virtual Assistance / Recommendation systems * Matching * Labelling * Detection * Segmentation * Sequential data modelling * Anomaly detection and Fraud Prevention * Compliance Monitoring / Quality Assurance * Process optimization / Automated planning & scheduling * Other |  |
| R-PD3 | System SHALL have specification for the intended use of AI4H software within the health workflow | Describe how the AI4H software fits into the intended health intervention workflow  e.g. as autonomous tool, assistive tool, augmentative tool, etc   * as add-on unit to existing system/workflow * as replacement unit for existing system/workflow component * as new standalone system/subsystem/device |  |
| R-PD4 | System SHALL have specification for product category /type of AI4H software as released in the market | e.g.   * Software-as-a-Medical Device (SaMD) * Software-as-a-Medical Service (SaMS) * Software-in-a-Medical Device (SiMD) * Mobile Medical Applications (MMA) * Medical Device Data Systems (MDDS) * Other |  |
| R-PD5 | System SHALL have specification for the operation mode of AI4H software | e.g. fully automatic, semi-automatic |  |

# System functions

Table 2: Functional requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-SF1 | System SHALL list the 'functional use cases' for the AI4H software | Functional Use Cases can be identified in terms of the main functional objectives as stated in the respective AI4H Topic Description Document (TDD). e.g.   * TDD -Cardiovascular disease risk prediction * TDD-Outbreak detection * TDD-Symptom assessment * TDD-Dental diagnostics, etc. |  |
| R-SF2 | System SHALL have description for 'functional use cases 'for the AI4H software | Use case description / diagram shall include information on:   * System/ Subsystem services /methods * Primary and secondary actors / users * Goals of primary and secondary actors / users * Tasks/ Functions performed by primary and secondary actors / users   System Data / information acquired, produced or changed by primary and secondary actors / users |  |
| R-SF3 | System SHALL have specification for data elements for each functional use case | Data elements include:   * data type * data unit * data representation format * data precision/accuracy * data range |  |
| R-SF4 | System SHALL have description for data flow for each functional use case | Data flow description / diagram include information on:   * Input/ Output data validity checks * Input/ Output data sequence of operations * Input/ Output data conversion formulas/ rules * Data Error/Exception handling and recovery * Data response time |  |
| R-SF5 | System SHALL have description for process flow for each functional use case | Process flow description / diagram include information on:   * Input validity check * Input (stimulus) * Process Algorithm / Formulas * Output (Response) * Process Error/Exception handling and recovery * Process response time |  |

# User types /classes and characteristics

Table 3: User type/class requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-UC1 | System SHALL have specification for the primary & secondary user types/classes/groups for the AI4H software | Primary user types include:   * Physician, clinician, lab technician, nurse, pharmacist, domain specialist, data scientist/engineer, business /program /product manager, chief information Officer, other   Secondary user types include:   * Software developers, software testers, regulatory affairs and quality managers, risk managers, usability engineers, medical device consultants, service technicians (e.g. update, upgrade, configuration, installation, capturing audit logs, etc.), support staff, other |  |
| R-UC2 | System SHALL have specification for educational level of primary & secondary user types/classes/groups for the AI4H software |  |  |
| R-UC3 | System SHALL have specification for target domain experience level of primary & secondary user types/classes/groups for the AI4H software | e.g. experience with target domain, product type, process tools, technology, etc. |  |
| R-UC4 | System SHALL have specification for technical expertise / technical skill sets of primary & secondary user types/classes/groups for the AI4H software |  |  |
| R-UC5 | System SHALL have specification for roles of primary & secondary user types/classes/groups for the AI4H software | Primary use roles include:   * Physician, clinician, lab technician, nurse, pharmacist, domain specialist, medical expert, data scientist/engineer, computer scientist, business /program /product manager, chief information officer, other   Secondary use roles include:   * Software developers, software testers, regulatory affairs and quality managers, risk managers, usability engineers, medical device consultants, service technicians (e.g. update, upgrade, configuration, installation, capturing audit logs, etc.), support staff, other |  |
| R-UC6 | System SHALL have specification for system security privilege levels of primary & secondary user types/classes/groups for the AI4H software |  |  |
| R-UC7 | System SHALL have specification for training needed for primary & secondary user types/classes/groups for the AI4H software |  |  |

# Operating conditions / environment

Table 4: Operating environment requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-OC1 | System SHALL have a standard operating procedure (SOP) for operations site integration of AI4H software within deployment IT infrastructure |  |  |
| R-OC2 | SOP for operations site integration SHALL specify the run-time environment | e.g. mobile platform, desktop, web/cloud platform, other |  |
| R-OC3 | SOP for operations site integration SHALL specify the modes of operation | e.g.   * programming mode * test mode * troubleshooting mode * monitoring mode * other |  |
| R-OC4 | SOP for operations site integration SHALL specify the workflow/ clinical protocols |  |  |
| R-OC5 | SOP for operations site integration SHALL describe the data processing support functions | e.g. ability to collect and analyse real-time patient data |  |
| R-OC6 | SOP for operations site integration SHALL describe the backup and recovery operations |  |  |
| R-OC7 | SOP for operations site integration SHALL specify the hardware platform configuration & versions |  |  |
| R-OC8 | SOP for operations site integration SHALL specify the operating system configuration & versions |  |  |
| R-OC9 | SOP for operations site integration SHALL specify the operating site energy efficiency rating |  |  |
| R-OC10 | SOP for operations site integration SHALL specify the installation and acceptance procedure |  |  |

# Design and implementation constraints

Table 5: Design and implementation constraints

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-DIC1 | System SHALL list all the 'regulatory policy' / 'regulatory standard' related constraints, if any | e.g. Regulatory compliance with country/region /jurisdiction specific data policies, AI geopolitical implications, etc. |  |
| R-DIC2 | System SHALL list all the 'implementation platform' related constraints, if any | e.g. IT infrastructure implications |  |
| R-DIC3 | System SHALL list all the 'database' related constraints, if any |  |  |
| R-DIC4 | System SHALL list all the 'network/communication protocol' related constraints, if any |  |  |
| R-DIC5 | System SHALL list all the 'hardware limitations', if any | e.g. timing requirements, memory requirements |  |
| R-DIC6 | System SHALL list all the 'external interfaces' related constraints, if any |  |  |
| R-DIC7 | System SHALL list all the 'safety and security 'related constraints, if any |  |  |
| R-DIC8 | System SHALL list all the 'cost 'related constraints, if any |  |  |
| R-DIC9 | System SHALL list all the 'accounting & auditing procedures ' related constraints, if any | e.g. Design considerations related to AI transparency, I trustworthiness, etc. |  |
| R-DIC10 | System SHALL list all the 'data sharing / replication policy ' related constraints, if any | e.g. patient consent (GDPR), AI gender and race representation, data privacy, trust, ethical and legal considerations, data ownership, data custodianship, data retention policy, etc. |  |
| R-DIC11 | System SHALL list all the 'technical accuracy to clinical effectiveness mapping' related constraints, if any | e.g. Interpretable AI constraints, explainable AI constraints, algorithmic risk assessment implications |  |
| R-DIC12 | System SHALL list all the 'business model sustainability ' related constraints, if any |  |  |
| R-DIC13 | System SHALL list, the 'areas of stakeholder conflict', if any |  |  |
| R-DIC14 | System SHALL list all the 'internationalization and/or localization needs' related constraints, if any |  |  |
| R-DIC15 | System SHALL list all the 'specific technologies and/or tools ' to be used in the case of AI4H software |  |  |
| R-DIC16 | System SHALL list all the 'non-clinical data availability 'constraints, if any | e.g. availability of behavioural data, environmental data, patient reported data |  |

# System interface requirements

Table 6: System interface requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| **User interface (UI) requirements specification** | | | |
| R-UI1 | System SHALL have description for User Interface (UI) | e.g. GUI features and formats |  |
| R-UI2 | System SHALL have specification for UI input & output valid range |  |  |
| R-UI3 | System SHALL have specification for UI input & output accuracy |  |  |
| R-UI4 | System SHALL have specification for UI input & output tolerance |  |  |
| R-UI5 | System SHALL have specification for UI input & output -units of measure |  |  |
| R-UI6 | System SHALL have specification for UI input & output timing |  |  |
| R-UI7 | System SHALL describe the UI relationships to other inputs/outputs | e.g. Source of input or destination of output |  |
| R-UI8 | System SHALL list the UI screen formats/ window layout constraints |  |  |
| R-UI9 | System SHALL have specification for UI data formats |  |  |
| R-UI10 | System SHALL have specification for UI command format |  |  |
| R-UI11 | System SHALL define the standard UI widget elements and functions |  |  |
| R-UI12 | System SHALL define the UI standards / style guides |  |  |
| R-UI13 | System SHALL define UI keyboard shortcuts | e.g. programmable function keys |  |
| R-UI14 | System SHALL define the UI error message display standards |  |  |
| **Hardware interface (HI) requirements specification** | | | |
| R-HI1 | System SHALL have description for Hardware Interface (HI) |  |  |
| R-HI2 | System SHALL specify HI supported device types |  |  |
| R-HI3 | System SHALL specify the HI source of input |  |  |
| R-HI4 | System SHALL specify the HI destination of output |  |  |
| R-HI5 | System SHALL specify the HI data types |  |  |
| R-HI6 | System SHALL specify the HI control protocols |  |  |
| R-HI7 | System SHALL specify the HI communication protocols |  |  |
| **Software interface (SI) requirements specification** | | | |
| R-SI1 | System SHALL have description for Software Interface (SI) |  |  |
| R-SI2 | System SHALL specify the SI source of input |  |  |
| R-SI3 | System SHALL specify the SI destination of output |  |  |
| R-SI4 | System SHALL specify the SI input & output data items valid range |  |  |
| R-SI5 | System SHALL specify the SI input & output data items accuracy |  |  |
| R-SI6 | System SHALL specify the SI input & output data items tolerance |  |  |
| R-SI7 | System SHALL specify the SI input & output data items -units of measure |  |  |
| R-SI8 | System SHALL specify the SI input & output data items timing |  |  |
| R-SI9 | System SHALL specify the SI operating systems used |  |  |
| R-SI10 | System SHALL specify the SI tools and libraries used |  |  |
| R-SI11 | System SHALL specify the SI third-party/ commercial components |  |  |
| R-SI12 | System SHALL specify the SI services offered |  |  |
| R-SI13 | System SHALL specify the SI communication protocols |  |  |
| R-SI14 | System SHALL specify the SI application programming interface (API) protocols |  |  |
| R-SI15 | System SHALL specify the SI data sharing mechanism |  |  |
| **Data interface (DI) requirements specification** | | | |
| R-DI1 | System SHALL have description for Data Interface (DI) |  |  |
| R-DI2 | System SHALL have specification for the database | e.g.   * data schema/ structure * data entities and their relationships * accessing capabilities * data integrity constraints * data retention requirements |  |
| **Communication interface (CI) requirements specification** | | | |
| R-CI1 | System SHALL have specification for the web browser used |  |  |
| R-CI2 | System SHALL define network server communications protocols |  |  |
| R-CI3 | System SHALL define the communication standards |  |  |
| R-CI4 | System SHALL have specification for the communication security / encryption mechanisms |  |  |
| R-CI5 | System SHALL have specification for the data transfer rates and synchronization mechanisms |  |  |
| **Memory interface (MI) requirements specification** | | | |
| R-MI5 | System SHALL have specification for the primary and secondary memory configurations / limits |  |  |

# Non-functional requirements

Table 7: Non-functional requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| **Performance requirements specification** | | | |
| R-PER1 | System SHALL have specification for the static performance parameters |  |  |
| R-PER2 | System SHALL have specification for the dynamic performance parameters | e.g. amount of data to be processed within specified time periods for   * normal workload conditions * peak workload conditions |  |
| R-PER3 | System SHALL have specification for the number of terminals to be supported |  |  |
| R-PER4 | System SHALL have specification for the number of concurrent users to be supported |  |  |
| R-PER5 | System SHALL have specification for the amount of information to be handled |  |  |
| R-PER6 | System SHALL have specification for the type of information to be handled |  |  |
| R-PER7 | System SHALL have specification for the AI algorithmic performance on data types-images, videos, text and natural language |  |  |
| R-PER8 | System SHALL have specification for the AI computational efficiency: accuracy-computational cost trade-offs |  |  |
| R-PER9 | System SHALL have specification for the accuracy standards / acceptable algorithm accuracy rates based on use cases /domain specialization | e.g.   * The system shall have a sensitivity of 97% * The system must be able predict the strength of the plaques in the blood to 0.2 mm, etc. |  |
| R-PER10 | System SHALL have specification for the metrics for continuous improvement | e.g.   * workflow impact * patient safety impact * care quality impact * provider/patient satisfaction impact |  |
| **Safety requirements specification** | | | |
| R-SAF1 | System SHALL have specification for the applicable safety standards |  |  |
| R-SAF2 | System SHALL have specification for the applicable safety certifications |  |  |
| R-SAF3 | System SHALL have specification for the protocols for safety alarms, safety alerts |  |  |
| **Security requirements specification** | | | |
| R-SEC1 | System SHALL define the data vulnerability classification procedure |  |  |
| R-SEC2 | System SHALL define the data validation techniques |  |  |
| R-SEC3 | System SHALL define the data encryption/‌decryption techniques | e.g. state-of-the-art cryptographic techniques |  |
| R-SEC4 | System SHALL define the data integrity verification schemes | e.g. Checking data integrity for critical variables |  |
| R-SEC5 | System SHALL define the user authentication schemes | e.g. Multifactorial User Authentication |  |
| R-SEC6 | System SHALL define the user data privacy certifications | e.g. measures adopted to ensure compliance with existing data privacy and management best practices and regulations |  |
| R-SEC7 | System SHALL define the data access control functions | e.g. authentication, authorization, monitoring logging and auditing of health data registries / repositories |  |
| R-SEC8 | System SHALL define the audit logs | e.g. for viewing, creation, modification, validation, copying, import, export, transmission, reception, etc |  |
| R-SEC9 | System SHALL define the data persistence/storage schemes | e.g. safe and secure data storage measures used, data repository compliance with applicable laws |  |
| **Quality requirements specification** | | | |
| R-QTY1 | System SHALL define 'reliability' measures and metrics of AI4H software |  |  |
| R-QTY2 | System SHALL define 'availability' measures and metrics of AI4H software |  |  |
| R-QTY3 | System SHALL define 'adaptability' measures and metrics of AI4H software | e.g. How the AI solution can be generalised to desired range of population with particular consideration of particular class of people (covering diverse backgrounds, cultures and disciplines, etc.) |  |
| R-QTY4 | System SHALL define 'accountability ' measures and metrics of AI4H software | e.g.   * accounting formats & procedures, auditing formats & procedures for different role-based responsibilities * accountable governance practices in compliance with ethical standards |  |
| R-QTY5 | System SHALL define 'accuracy ' measures and metrics of AI4H software |  |  |
| R-QTY6 | System SHALL define 'flexibility ' measures and metrics of AI4H software | e.g. How the AI tool will integrate into existing system / workflow  flexibility of final decision-making capability by the health practitioner taking into account other factors including patient history, options and preferences |  |
| R-QTY7 | System SHALL define 'interoperability' measures and metrics of AI4H software |  |  |
| R-QTY8 | System SHALL define 'reusability ' measures and metrics of AI4H software |  |  |
| R-QTY9 | System SHALL define 'testability ' measures and metrics of AI4H software | e.g. Requirements Vs Test Plan traceability matrix |  |
| R-QTY10 | System SHALL define 'usability ' measures and metrics of AI4H software | e.g. Human Factors design  Logical Visual Flow charts, Event based Alerts/Alarms/Notifications, etc |  |
| R-QTY11 | System SHALL define 'robustness ' measures and metrics of AI4H software |  |  |
| R-QTY12 | System SHALL define 'resiliency ' measures and metrics of AI4H software |  |  |
| R-QTY13 | System SHALL define 'maintainability ' measures and metrics of AI4H software |  |  |
| R-QTY14 | System SHALL define 'portability ' measures and metrics of AI4H software | e.g.   * use of portable programming language * use of compiler or language subset * use of operating system |  |
| R-QTY15 | System SHALL define 'explainability ' measures and metrics of AI4H software | e.g. a documented procedure on how a medical practitioner explains   * how the AI based decision making / result can impact patient care including the limitations of the AI tool * what hardware, software settings, data pre & post processing techniques were used for data sensing modalities (e.g. MRI imaging hardware and software settings) * how the 'ground truth' was established for the training data * how data integrity was verified * with what accuracy was data labelling done * how the AI tool performance was tested and under what all conditions including appropriateness to the target patient group * conditions under which the AI tool was not tested * whether model attained 'saturation' condition during learning phase * whether compliance with regulatory approval requirements achieved or not |  |

# System design requirements

Table 8: System design requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| **AI data design** | | | |
| R-DD1 | System SHALL state applicable regulations and policies related to data handling | e.g. Policies on data management, data acceptance, data protection, data sharing, copyright, privacy laws, patient consent and confidentiality, Ethics board approved consent procedures for sharing patient data, retention of raw data etc. |  |
| R-DD2 | System SHALL have specification for 'data provenance' | e.g.   * Data acquisition protocol for reproducibility (Who, When, Where, How, etc.), * Digitization, Data migration to other databases, etc * Hardware and Software configuration of Data Acquisition/ Data Processing Device /App: Sensor type, Sampling Rate, OS version, firmware version, etc |  |
| R-DD3 | System SHALL define input data source formats | e.g. real & synthetic data sources   * Electronic Health Records (Anonymised) * Medical Images * Vital signs signals * Lab test results * Photographs * Non-medical data-Socioeconomic, Environmental, etc) * Questionnaire responses * Free Text (Discharge / Summary, Medical History / Notes, etc.) * PACS, * Web Portal * mHealth App * Medical Device * Other |  |
| R-DD4 | System SHALL have details of the data collectors | e.g.   * Medical personnel (physician/ clinician / nurse /pharmacist/ etc.) * Support personnel * Patient (or proxy person) * Machine-generated |  |
| R-DD5 | System SHALL define input data types | e.g.   * Real valued * Integer-valued * Categorical value * Ordinal value * Strings * Dates * Times * Complex data type * Other |  |
| R-DD6 | System SHALL define input data formats | e.g.   * DICOM PS3.0 (latest versions)- for Diagnostic Image (X-Ray, CT, MRI, PET, other pathological slides, etc) * JPEG / PNJ – for Static Image * MP3 / OGG – for Audio: * MP4 / MOV- for Video * SNOMED – for clinical observations/terminology * LOINC- for laboratory observations * WHO ICD-10 for disease classifications * RxNORM for Medication Code * Other |  |
| R-DD7 | System SHALL define output data types | e.g.8   * Binary/Class output (0 or 1) as in case of classification problems * Probability output (0-1) as in case of classification problems * Continuous valued output as in case of regression problems |  |
| R-DD8 | System SHALL have specifications for the data encoding-decoding formats | e.g. |  |
| R-DD9 | System SHALL have specifications for the compression and encryption techniques | e.g. Lossy compression / Non-lossy compression techniques, Homographic encryption |  |
| R-DD10 | System SHALL have specifications for the annotation/labelling of ground truth/ reference output data | e.g.   * Standards for health data vocabulary / labelling for training and test data   + Standards for clinical terminology   + Laboratory observations   + Disease mapping   + Procedure mapping   + Messaging   + Clinical data format   e.g. coding standards (e.g. SNOMED, LOINC, ICD-10, HL7-FHIR, etc)   * procedure – to establish the reference or ground truth for the training data (whether based on objective measures, expert group consensus, etc) * labelling accuracy calculation technique * labelling error estimation technique |  |
| R-DD11 | System SHALL have defined 'data completeness' verification techniques used | e.g.   * Data cleaning and correction for ranges, variations, outliers, missing values, etc * Data bias minimization techniques used * Data variance minimization techniques used * Data normalization method- for Data Preparation phase-to account for data variability in terms of data sensing hardware, data sensing software settings, sensor device model and device configuration * Data representativeness : Data to represent different types of population covering diverse backgrounds, cultures and disciplines, vulnerable persons, persons with disabilities, ethnic minorities, women, children, geriatric, refugees and other categories facing risk of exclusion, discrimination, stigmatization, prejudice, abuse, human rights violations, torture, inhumane treatment and marginalization |  |
|  | System SHALL define 'data de-biasing' techniques used |  |  |
| R-DD12 | System SHALL have specifications for the 'data integrity' mechanisms used | e.g. RAID, Mirroring, Checksum, Digital Signature, etc |  |
| R-DD13 | System SHALL have specifications for the 'data privacy' mechanisms used | e.g.   * patient consent obtained * ethics board approval * anonymization & de-identification methods used * secure data disposal policy / agreement |  |
| R-DD14 | System SHALL have specifications for the 'data safety & security' mechanisms used | e.g.   * Access Control Functions (Authentication, Authorization, Monitoring, Logging and Auditing) * Audit Logs for viewing, creation, modification, validation, copying, import, export, transmission, reception, etc. based   + on Blockchain Technology   + Merkle Trees, etc * Data Repositories compliance with ISO 7498-2 Security Model and other allied standards for best practice recommendations on information security management * Data sharing through secured channels * Data flow control mechanisms within practice boundaries * Implementing Security Standards based on Digital Certificate, SSL, SHA-256, etc |  |
| R-DD15 | System SHALL have specifications for the 'data interoperability' mechanisms used | e.g.   * Data formats * Messaging Coding Standards * APIs/web services for data exchange, data loading/importing * Protocols and tools to collect and integrate diverse data |  |
| R-DD16 | System SHALL define the 'data preparation' methods used | e.g.   * Descriptive Statistical Methods used to summarize the distribution and relationships between variables using visualizations such as charts, plots, and graphs * Statistical methods for data cleaning such as Imputation- for rectifying corrupt or missing values * Data modelling using statistical techniques- Encoding, Scaling, Transforms etc. |  |
| R-DD17 | System SHALL define the data splitting criteria for the training, validation, and testing data sets | e.g. independent data sets to be used for each of the training, validation, and testing phases of model development |  |
| **AI model design** | | | |
| R-MD1 | System SHALL define the type of AI model | e.g. 'Static Model' or 'Continuous/Incremental Learning Model? |  |
|  | System SHALL define the algorithm selection method for AI model training | e.g. Algorithm Selection – for Optimization, Specialization, Generalization |  |
|  | System SHALL define the choice of particular machine learning method used for AI model training | e.g.   * Active Learning method- for performance improvement for new data points * Reinforcement learning method -to solve decision-making problems * Genetic Algorithms and Simulated Annealing - for optimization problems * Online / Incremental Learning method- for streaming data * Additive Tree method- for AI model interpretability * Federated Learning, Dynamic Thresholding- for AI Model Performance Improvement * Long Short-Term Memory (LSTM) and Gated Recurrent Units (GRU) for resource-constrained, low memory devices, Convolutional Neural Networks - to handle multi-dimensional datasets * Collaborative Filtering method –for Recommender Systems * Transductive learning method |  |
| R-MD2 | System SHALL define the AI model selection criteria | e.g. specific machine learning algorithm and its configuration that is applied on the training dataset in order to learn the model   * Supervised Learning based algorithms * Linear Regression * Logistic Regression * k-nearest neighbours * Decision Trees * Random Forest * Gradient Boosting Machines * XGBoost * Support Vector Machines (SVM) * Neural Network * other * Unsupervised Learning based algos * k means clustering * Hierarchical clustering * Neural Network * other * Reinforcement Learning based algos * Association rule learning based algos * Apriori algorithm * Eclat algorithm * Deep learning based algos * Convolutional Neural Network (CNN) * Recurrent Neural Networks (RNNs) * Long Short-Term Memory Networks (LSTMs) * Stacked Auto-Encoders * Deep Boltzmann Machine (DBM) * Deep Belief Networks (DBN) * other |  |
| R-MD3 | System SHALL have specification for test data set design | e.g.   * criteria to ensure proportionate mix of True/ False Positives and True/False Negatives and data disjoint from training set * Algorithmic accountability * Split tests * Multiple split tests * Cross validation * Multiple cross validation * Statistical significance validation * Uncertainty estimation * other |  |
| R-MD4 | System SHALL define the AI model evaluation metrics used | e.g.   * Model Accuracy (%) * Model Accuracy -Mean & Standard Deviation * Model Accuracy –Box Plot Summarization * Root Mean Squared Error (RMSE) * Sensitivity (True Positive Rate) * Specificity (True Negative Rate) * F1-Score (class wise performance determination) * Confusion matrix * K-fold Cross-validation * Gain and Lift Charts * Kolmogorov Smirnov Chart * Gini Coefficient * Log [Loss](https://developers.google.com/machine-learning/crash-course/descending-into-ml/training-and-loss) * [Area under the ROC curve (AUC)](https://developers.google.com/machine-learning/crash-course/classification/roc-and-auc) * Concordant – Discordant Ratio * Jaccard coefficient * Pearson Correlation * Other |  |
| R-MD5 | System SHALL define the AI model optimization techniques used | e.g.   * Adding or deleting Features /Attributes of the input data * Aggregating or Decomposing Features /Attributes of the input data * Tuning Model Hyper-parameters * Normalization & Standardization of input data * Changing the learning rate of the algorithm * Examining the Statistical Significance of results * Recruiting Ensemble Methods for combining / augmenting the prediction scores of multiple models * Monitoring and tracking API response times and Computational Memory requirements of the serving infrastructure * Procedure to detect whether AI model attained 'saturation' point of learning or not * other |  |
| R-MD6 | System SHALL have specification for the AI model card / sheet format | e.g.   * assumptions, constraints, dependencies on the algorithm used * current performance figures * expected / optimal performance * major risk conditions * model version * other |  |
| R-MD7 | System SHALL have specification for the AI model Accuracy, Specificity & Sensitivity, Latency |  |  |
| R-MD8 | System SHALL have specification for the AI model software implementation framework | e.g.  AI Model training tools, toolkits and software libraries |  |

# System deployment requirements

Table 9: System deployment requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-DPY1 | System SHALL have specification for the AI4H software deployment / run-time environment configuration | e.g.   * IT infrastructure requirements for network, storage and computing resources- * Processor (manufacturer, speed, and features), RAM (memory size), hard disk size, communication, display interface, sensors, energy sources, safety features, etc |  |
| R-DPY2 | System SHALL have 'assembling and testing ' procedure for the AI4H software deployment / run-time environment |  |  |
| R-DPY3 | System SHALL have specifications for the AI4H software delivery packaging | e.g.   * executable software * support data files * support documentations * installation scripts for different computing configurations-hardware, operating system, peripheral devices, networking interfaces * technical support (for functions and features, troubleshooting guidelines, training materials) * product version * optimal operating condition * optimal configuration * efficiency rating (if applicable) * standards compliance/ certification (if any) |  |
| R-DPY4 | System SHALL have specifications for the distributed computing environment of AI4H software | e.g.   * data workflows, pipelines, and Extract, Transform and Load (ETL) processes * production pipelines for training, retraining, data analytics, data visualization, network connectivity, storage, security and scalability |  |
| R-DPY5 | System SHALL have specifications for the high-performance production environment of the AI4H software | e.g.   * Software Container (Docker) Architectures for Benchmarking Platforms-e.g. CrowdAI, Kaggle, etc. * API response times and Computational Memory configurations * Versioning of code/model/data |  |
| R-DPY6 | System SHALL define the service levels for the AI4H software deployment environment |  |  |
| R-DPY7 | System SHALL define the AI service utilization metrics for the AI4H software deployment environment |  |  |

# User documentation / training requirements

Table 10: User documentation and training requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-UD1 | System SHALL define the user documentation delivery formats / standards | e.g.   * User tutorial * Technical guide * User safety guide * Online help |  |

# Assumptions and dependencies

Table 11: Assumptions and dependencies

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-DPN1 | System SHALL state the assumptions, if any, on the selection of the Machine Learning Algorithm based on the available input dataset | e.g. potential vulnerabilities, risks or biases |  |
| R-DPN2 | System SHALL list the unintended consequences, if any, applicable to the AI4H software | e.g.  Unintended consequences due to   * technology * patient safety issues * workflow disruptions * inadvertent biases |  |
| R-DPN3 | System SHALL state third-party / commercial components / licenses used, if any |  |  |
| R-DPN4 | System SHALL list the components reused from other projects, if any |  |  |
| R-DPN5 | System SHALL state the vendor-neutral interoperability standards, if any |  |  |

# Quality process compliance

Table 12: Quality assurance requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-PRO1 | System SHALL define the primary quality metrics of the AI4H software | e.g. patient safety, quality of care, workflow efficiency, etc |  |
| R-PRO2 | System SHALL define a Project Management Process for AI4H software development as per QMS | e.g. for AI model development phase- to oversee implementation and monitoring of system performance and use |  |
| R-PRO3 | System SHALL define a Data Management process for AI4H software development as per QMS | e.g. for data management practices during data preparation phase- for representing, accessing, storing and transferring health data |  |
| R-PRO4 | System SHALL define a Regulatory Audit Process for AI4H software development as per QMS | e.g. for AI model validation phase -to ensure use of AI and practice is in compliance with regulatory, ethical principles and standards |  |
| R-PRO5 | System SHALL define a Software Delivery Process for AI4H software as per QMS | e.g. building and packaging of AI APIs and Web services |  |
| R-PRO6 | System SHALL define a Quality Audit Process for AI4H software development as per QMS | e.g. AI model validation phase -for quality assurance related to quality management, risk management, reporting standards, training |  |
| R-PRO7 | System SHALL define a Regulatory, Quality and Security Certification Process, if applicable |  |  |

# Risk management requirements

Table 13: Risk management requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-RIM1 | System SHALL define the procedure and metrics for risk assessment | e.g.   * Risk identification and characterization * Risk analysis * Risk assessment criteria |  |
| R-RIM2 | System SHALL define the procedure and metrics for risk control | e.g.   * Risk reduction * Risk acceptance |  |
| R-RIM3 | System SHALL define the procedure and metrics for risk communication |  |  |
| R-RIM4 | System SHALL define the procedure and metrics for risk review |  |  |

# Change management requirements

Table 14: Change management requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-CHM1 | System SHALL define a change management plan and procedure | e.g. based on stakeholder change requests, gaps identified, feedback analysis. Supporting data include   * Approval/ Authorisation formalities in case of any modification to the original deployed model * Usage traceability record - information on software version, date and time of use, use environment and the patient to whom it was applied * User skill traceability record * User Experience Surveys and User Satisfaction Ratings record * Workload Demand and AI Operational Efficiency record * Cost-Benefit-Patient Outcome analysis report * Software up gradation / change request to meet clinical change management requirements * Service Utilization & Service Compliance report (Periodic / Term-wise) * other |  |
| R-CHM2 | System SHALL define a change implementation plan and procedure | e.g.   * timeline and schedule * stakeholder capacity building and training * stakeholder communication and feedback mechanisms * other |  |

# System validation requirements

Table 15: System validation requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **REQ. ID** | **Requirement Specification** | **Description** | **Risk level** |
| R-VDN1 | System SHALL define test plan and procedure for functional testing |  |  |
| R-VDN2 | System SHALL define test plan and procedure for performance testing | e.g. based on   * Feature Engineering * Ensample methods * Algorithm Tuning * Minimizing Model Variance-Bias trade-off |  |
| R-VDN3 | System SHALL define test plan and procedure for Hardware & Software platform testing | e.g. based on multi-vendor equipment |  |
| R-VDN4 | System SHALL define test plan and procedure for Hardware & Software interface testing |  |  |
| R-VDN5 | System SHALL define test plan and procedure for Data Interface / Interoperability testing | e.g. with other health information systems / databases |  |
| R-VDN6 | System SHALL define test plan and procedure for Data Quality testing | e.g. for Data Integrity, Data Completeness, Data Bias |  |
| R-VDN7 | System SHALL define test plan and procedure for Data Access Control testing | e.g. for Authentication, Authorization, Monitoring, Logging and Auditing |  |
| R-VDN8 | System SHALL define test plan and procedure for Workflow / Protocol Integration testing | e.g.to ensure proper AI solution interoperability with clinical workflow setting |  |
| R-VDN9 | System SHALL define test plan and procedure for Safety and Security controls testing | e.g.   * assessment of the likelihood of a threat, vulnerability in case of device functionality * assessment of the likelihood of a threat, vulnerability in case of user safety * estimation of the type and probability of risks (for device, environment of use and user) * verification of security controls for device (software, hardware, firmware) * verification of security controls for data repositories * verification of security controls for data channels * verification of security controls for environment of use * verification of security controls for user |  |
| R-VDN10 | System SHALL define test plan and procedure for User Group testing | e.g. to ensure the user has adequate and appropriate knowledge, skills and competency level to the use/operate AI system in the given role |  |
| R-VDN11 | System SHALL define test plan and procedure for Usability testing | e.g. usability assessment report for different user groups |  |
| R-VDN12 | System SHALL define test plan and procedure for User-Interface testing |  |  |
| R-VDN13 | System SHALL define test plan and procedure for Installation testing |  |  |
| R-VDN14 | System SHALL define test plan and procedure for Stress testing |  |  |

# AI4H topic description to AI4H system requirements traceability matrix

* For the purpose of auditing the coverage of technical requirements for the benchmarking process that are defined in the topic description documents (TDD), AI4H requirements specifications are configured as a requirements verification tool.
* This tool partially serves as a DAISAM quality assessment tool for the benchmarking process under the AI4H assessment platform.
* The tool is implemented as a 'traceability matrix' that represents a mapping between the TDD (technical sub-topics) and their corresponding AI4H system requirements.
* A template for the traceability matrix is shown in Table 16. The first column in the matrix describes the 'question from TDD. The second column represents the actual ' requirements traceability attribute', that we want to verify for its coverage, completeness and correctness. This traceability analysis will be performed for the different TDDs and results shall be tabulated against their respective TG columns in the matrix

Table 16: TDD requirements traceability matrix template

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AI4H Topic Description to AI4H System Requirements Traceability Matrix-Template** | | | | |
| **AI4H TDD Description** | **AI4H Requirements Tractability Attribute** | **TG-Symptoms**  **(verification status)** | **TG-Ophthalmology**  **(verification status)** | **TG-xxx** |
| **TDD Section 1.1.5 Definition of the AI task** | | ✓ | ✓ | x |
| What kind of AI task is implemented? | * Classification |  |  |  |
| * Prediction |  |  |  |
| * Matching |  |  |  |
| * Libelling |  |  |  |
| * Detection |  |  |  |
| * Segmentation |  |  |  |
| * Anomaly detection and Fraud Prevention |  |  |  |
| * Compliance Monitoring / Quality Assurance |  |  |  |
| * Process optimization / Automation |  |  |  |
| Which input data are fed into the AI model? | * Electronic Health Records (Anonymised) |  |  |  |
| * Medical Images |  |  |  |
| * Vital signs signals |  |  |  |
| * Lab test results |  |  |  |
| * Photographs |  |  |  |
| * Non-medical data-Socioeconomic, Environmental, etc) |  |  |  |
| * Questionnaire responses |  |  |  |
| * Free Text (Discharge / Summary, Medical History / Notes, etc.) |  |  |  |
| **TDD Section 1.1.6 Current gold standard** | | | | |
| Are there any numbers describing the performance of the current state-of-the-art? | * Intra-annotator labelling accuracy |  |  |  |
| * Editable automatic pre-annotation tool |  |  |  |
| * Annotation tool labelling accuracy |  |  |  |
| * Coding standard (e.g. SNOMED, LOINC, ICD-10, HL7-FHIR, etc) |  |  |  |
| * Gold standard method-objective measure |  |  |  |
| * Gold standard method- expert group consensus |  |  |  |
| **TDD Section 1.1.7 Relevance and impact of an AI solution** | | | | |
| Which impact of deploying such systems is expected | * Risk-benefit-ratio |  |  |  |
| * Faster patient diagnosis / treatment |  |  |  |
| * Percentage reduction in clinician cognitive workload |  |  |  |
| * Degree of automation / semi-automation introduced |  |  |  |
| * Degree of smartness/intelligence augmentation |  |  |  |
| * New knowledge discovery |  |  |  |
| * Replacement or redefinition of existing gold standard |  |  |  |
| **TDD Section 1.2 Ethical considerations** | | | | |
| How is the privacy of personal health information protected? | * Data privacy /protection policy |  |  |  |
| * Data sharing policy (HIPAA) |  |  |  |
| * Patient consent (GDPR) |  |  |  |
| * Individual vs. administrative consent |  |  |  |
| * electronic informed consent |  |  |  |
| * Ethics board approval |  |  |  |
| * Anonymization & de-identification method |  |  |  |
| * Secure data disposal policy / agreement |  |  |  |
| * Data protection officer |  |  |  |
| How do we ensure that benchmarking data are representative and that an AI offers the same performance and fairness? | * Proportionate sample size of different classes |  |  |  |
| * Subpopulation considered relevant and appropriate to your use case: (a) diverse demographics, (b) cultures and disciplines, (c) vulnerable persons, (d) persons with co-morbidities and contra-indications (e) persons with disabilities, (f) ethnic minorities, (g) women, (h) children, (i) geriatric, (j) persons facing risk of any kind of exclusion, discrimination, and marginalization in the social status and educational status |  |  |  |
| * Subpopulation data (age-group, gender, ethnicity, etc) distribution descriptive statistical methods' to summarize the distribution and relationships between variables (e.g. Histograms) calculation of distributions (histograms), mean / average values, quartiles, joint distribution of features, correlation, etc. |  |  |  |
| * Measurement / sampling bias error |  |  |  |
| * Data bias minimization / de-biasing technique used |  |  |  |
| * Data variance minimization technique |  |  |  |
| * Data Partitioning / Splitting Method |  |  |  |
| * Ground truth labelling error |  |  |  |
| * Data inclusion /exclusion/rejection criteria |  |  |  |
| * Equal true positive rates and also False-positive/negative rates on 'protected population subgroup' as compared to that for the 'entire population group' |  |  |  |
| **TDD Section 1.3.4 Regulatory considerations** | | | | |
| How will the development process of the benchmarking be documented in an effective, transparent, and traceable way? | * SOP (configuration and version control) process   (for libraries and frameworks) |  |  |  |
| * Versioning systems DREAD and CVSS |  |  |  |
| * Name / ID of software libraries and frameworks |  |  |  |
| * Software libraries and frameworks version |  |  |  |
| * User tutorial version |  |  |  |
| * Technical guide version |  |  |  |
| How will the risk management be implemented? | * Lookup Table for risks (with related probabilities of occurrence with magnitude of severities and tolerance rates) |  |  |  |
| Failure Mode and Effects Analysis for Risk Communication: lack of availability / robustness   * slow response times * interoperability problems * software using more CPU, GPU, RAM, I/O, bandwidth than specified |  |  |  |
| * Procedure and metrics for risk assessment |  |  |  |
| * Procedure and metrics for risk control |  |  |  |
| * Procedure and metrics for risk communication |  |  |  |
| * Procedure and metrics for risk review |  |  |  |
| * Risk-based tool validation |  |  |  |
| * Risk-based SOUP validation |  |  |  |
| * Risks related to client server architecture |  |  |  |
| * Risks related to (de)serialization of data |  |  |  |
| * Risks related to format and protocol conversions |  |  |  |
| * Risks related to multiple API versions and API gateways |  |  |  |
| * Risk related specifically for programming language |  |  |  |
| * Risks related to compiler and compiler settings |  |  |  |
| How is the test data quality ensured (e.g., the process of harmonizing data of different sources, standards, and formats into a single dataset may cause bias, missing values, outliers, and errors)? | * Data pre-processing statistical method or (cleaning) tool |  |  |  |
| * Data integrity verification protocol |  |  |  |
| * Data access control protocol |  |  |  |
| * Data sequence of operations |  |  |  |
| * Data conversion formulas/ rules |  |  |  |
| * Data error/exception handling and recovery rules |  |  |  |
| * Data communication security / encryption mechanisms |  |  |  |
| * Data transfer rates |  |  |  |
| * Data encryption/decryption technique |  |  |  |
| * Data quality assessor |  |  |  |
| How is data privacy in the context of data protection regulations ensured, considering regional differences | * Data Ethical Clearance/ Patient Consent obtained |  |  |  |
| * Estimates (type and probability) of data safety risks |  |  |  |
| * Distributed and federated ML model learning |  |  |  |
| * Training over encrypted data (homomorphic encryption) |  |  |  |
| * Security protocols /controls for device (software, hardware, firmware) |  |  |  |
| * Security protocols / controls for data repositories |  |  |  |
| * Security protocols / controls for data channels |  |  |  |
| * Security protocols / controls for environment of use |  |  |  |
| * Security protocols / controls for user |  |  |  |
| **TDD Section 3.2 Benchmarking by AI developers** | | | | |
| Which scores and metrics have been used? | * Performance metrics |  |  |  |
| * Robustness metrics |  |  |  |
| * Explainability metrics |  |  |  |
| * Fairness metrics |  |  |  |
| * Safety metrics |  |  |  |
| How did they approach the acquisition of test data? | * Protocols and tools to collect and integrate diverse data |  |  |  |
| * Data acquisition / sensing modality |  |  |  |
| * Data acquisition / sensing device type |  |  |  |
| * Sensor device-OS version, firmware version |  |  |  |
| * Data collection place |  |  |  |
| * Data collection time |  |  |  |
| * Data collector |  |  |  |
| * Data sampling rate |  |  |  |
| * Data update version |  |  |  |
| * Device identifiers and attributes |  |  |  |
| * Device Authentication protocol (Multiple Levels) |  |  |  |
| * Device synchronization protocol |  |  |  |
| * Data ownership/controller |  |  |  |
| **TDD Section 4.2.2.1 Benchmarking system architecture** | | | | |
| How does the architecture look? | * Software Container (Docker) Architecture -Technology stack |  |  |  |
| What are the most relevant components and what are they doing? | * Data workflows, pipelines, and Extract, Transform and Load (ETL) processes |  |  |  |
| * Production pipelines for training, retraining, data analytics, data visualization, network connectivity, storage, security and scalability |  |  |  |
| * Modes of operation (test mode, troubleshooting mode, monitoring mode) |  |  |  |
| * Application safety control mechanism |  |  |  |
| * User safety control mechanism |  |  |  |
| * APIs/Web services for data exchange, data loading/importing |  |  |  |
| * Data interface ability to collect and analyse real-time patient data |  |  |  |
| * Hardware platform configuration & versions |  |  |  |
| * Operating system configuration & versions |  |  |  |
| * Database configuration |  |  |  |
| * Network/communication protocol |  |  |  |
| * External interfaces |  |  |  |
| * Internationalization and/or localization protocols |  |  |  |
| * Primary and secondary memory configurations |  |  |  |
| * Real time machine learning based threat malware classification |  |  |  |
| What underlying technologies and frameworks have been used? | * SQL |  |  |  |
| * Hadoop |  |  |  |
| * Apache Kafka |  |  |  |
| * SaS |  |  |  |
| * Julia |  |  |  |
| * Python |  |  |  |
| * Spark |  |  |  |
| * Tensorflow |  |  |  |
| * Keras |  |  |  |
| * PyTorch |  |  |  |
| * GPU |  |  |  |
| * Google Analytics |  |  |  |
| * QlikView |  |  |  |
| * Tableau |  |  |  |
| **TDD Section 4.2.2.2 Benchmarking system dataflow** | | | | |
| How do benchmarking data access the system? (data interfaces) | * Data workflows, pipelines, and Extract, Transform and Load (ETL) processes |  |  |  |
| * Data Formats |  |  |  |
| * Messaging Coding Standards |  |  |  |
| * APIs/Web services for data exchange, data loading/importing |  |  |  |
| * Data access control functions e.g. authentication, authorization, monitoring logging and auditing |  |  |  |
| Where and how (data format) are the data, the responses, and reports of the system stored? | * Syntactic level File formats (XML, JSON, PDF, docx, CSV, DICOM, HL7) |  |  |  |
| * Semantic level standards-taxonomies e.g. LOINC (e.g. laboratory values), ATC (drugs), ICD (diagnoses), UCUM (units) and the organizational level (IHE) |  |  |  |
| * Semantic standards-nomenclatures e.g. LOINC |  |  |  |
| * Database -data schema/ structure |  |  |  |
| How are the data sent to the AI systems? | * Data Interface protocols -OSI-Protocols such as TCP/IP, HTTPs, SFTP, CAN, RS232, USB |  |  |  |
| * Data Interface-Bus-Systems such as CAN, USB |  |  |  |
| **TDD Section 4.2.2.3 Safe and secure system operation and hosting** | | | | |
| What safety control measures were taken to manage risks to the operating environment? | * Security protocols / controls for device (software, hardware, firmware) |  |  |  |
| * Security protocols / controls for data repositories |  |  |  |
| * Security protocols / controls for data channels |  |  |  |
| * Security protocols / controls for environment of use |  |  |  |
| * System security privilege levels of primary & secondary user |  |  |  |
| * Lookup Table for 'hazards and related harms' specification with related probabilities of occurrence with magnitude of severities |  |  |  |
| How is the hosting system itself protected against attacks? | * MDR, IVDR, other standards compliance for IT security,   compliance with national safeguards |  |  |  |
| * Encryption protocol (for Data at Rest, Transmission, Use) |  |  |  |
| * Restriction of permitted IP and MAC addresses and physical access protection |  |  |  |
| * Check for incorrect file length, completeness, incorrect character set, unexpected characters, data sent multiple times, outdated/late data, unexpected or incorrect formats, no well-formed XML, invalid JSON files, incorrect data types, XML that does not correspond to the specified schema), other character sets, values that are not included in the intended value range (e.g. in the classification or encoding system), wrong time zone, wrong number format, impossible data |  |  |  |
| * Development tools, development environments and libraries (SOUP, OTS components) loaded only from approved sources classified as secure |  |  |  |
| * Libraries checked for malware before use |  |  |  |
| * Configuration data for the devices, user data (in particular access data), keys, software certificates, program code (including SOUP/OTS) |  |  |  |
| * Definition of who (e.g. user, notified body, authority) to be informed and procedure on how to inform |  |  |  |
| * Network/interfaces (bandwidth, availability, ports, IP ranges, latencies, encryption, firewalls etc.), virus protection, operating systems, physical access permissions |  |  |  |
| * Installation, connection to network, evaluation of audit logs, deletion of unneeded users, exchange of keys or certificates, deletion of temporary files |  |  |  |
| * Consent - primary and secondary data usage |  |  |  |
| * Data Processing Impact Assessment: A Data Protection Impact Assessment (DPIA) to identify and minimize the data protection risks of a project. |  |  |  |
| * Principles of privacy by design incorporated |  |  |  |
| * Data repositories security model |  |  |  |
| * Data flow control mechanism |  |  |  |
| * Security standards based on digital certificate, SSL, SHA-256, etc |  |  |  |
| How are the data protected against data loss (e.g., what is the backup strategy)? | * RAID |  |  |  |
| * Mirroring |  |  |  |
| * Checksum |  |  |  |
| * Digital Signature |  |  |  |
| * Rounding error rate |  |  |  |
| * Compression, decompression error rate |  |  |  |
| * Noise reduction, filtering error rate |  |  |  |
| * Normalization, transformation error rate |  |  |  |
| * Re-sampling error rate |  |  |  |
| How is it ensured that the correct version of the benchmarking software and the AIs are tested? | * SOP for configuration and version control process. |  |  |  |
| * Name of software |  |  |  |
| * Version of software with date and time stamp |  |  |  |
| * Version of data is aligned with corresponding software versions (software for processing and product) |  |  |  |
| How are automatic updates conducted (e.g., of the operating system)? | * Approval/ Authorization formalities in case of any modification |  |  |  |
| * Algorithm update trigger actions (update of risk analysis and re-evaluation of risk-benefit analysis, re-training of algorithm, product recall, implementation of better risk mitigation measures) |  |  |  |
| * Threshold values for trigger actions |  |  |  |
| * Algorithm update frequency / period |  |  |  |
| How and where is the benchmarking hosted and who has access to the system and the data (e.g., virtual machines, storage, and computing resources, configurational settings)? | * IT infrastructure requirements for network, storage and computing resources-Processor (manufacturer, speed, and features), RAM (memory size), hard disk size, communication, display interface, sensors, energy sources, safety features, etc |  |  |  |
| * User role and access privilege |  |  |  |
| * Access Control Functions (Authentication, Authorization, Monitoring Logging and Auditing) |  |  |  |
| How is the system's stability monitored during benchmarking and how are attacks or issues detected? | * Protocols for safety alarms |  |  |  |
| * Risk alert for input data not meeting the requirements |  |  |  |
| * Risk alert for inability of the system to meet the non-functional requirements |  |  |  |
| * Risk alert for ML algorithms not meeting the quality metrics |  |  |  |
| * Risk alert for adversarial attacks |  |  |  |
| * Risk alert for software bugs |  |  |  |
| Risk alert for hardware related risks:   * CPU, RAM, I/O, hard disk space not as specified * memory, CPU, GPU flaws * hard disk full * RAM, CPU, I/O overutilization by other applications. |  |  |  |
| Risk alert for software related risks:   * other type or version of operating system, browser, virtualization layer (.NET, JRE, VM), libraries * software patches not installed * Software bug. |  |  |  |
| Risk alert for network related risks:   * bandwidth, latency not as specified * Endpoints, protocols not supported or blocked |  |  |  |
| Risk alert for interface related risks:   * Unspecified data volumes * Wrong data inputs |  |  |  |
| * Self-tests verifying/validating the implementation and effectiveness of risk mitigation measures |  |  |  |
| How are issues (e.g., with a certain AI) documented or logged? | * Audit Logs for (viewing, creation, modification, validation, copying, import, export, transmission, reception, etc.) based on Blockchain Technology, Merkle Trees, etc |  |  |  |
| Failure Mode and Effects Analysis for Risk Communication   * lack of availability / robustness * slow response times * interoperability problems * software using more CPU, GPU, RAM, I/O, bandwidth than specified |  |  |  |
| **TDD Section 4.2.3** **AI input data structure for the benchmarking** | | | | |
| What are the general data types that are fed in the AI model? | * Data types (images, audio, videos, text and natural language, time series, sensor, etc) |  |  |  |
| * Computational data types (real valued, integer-valued, categorical value, ordinal value, strings, dates, times, complex data type, other |  |  |  |
| How exactly are they encoded? | * Syntactic level File formats (XML, JSON, PDF, docx, CSV, DICOM, HL7) |  |  |  |
| * Semantic level standards-taxonomies e.g. LOINC (e.g. laboratory values), ATC (drugs), ICD (diagnoses), UCUM (units) and the organizational level (IHE) |  |  |  |
| Meta data description   * Filename, * file format * URL * domain * keywords * type, dataset size, * % of missing cells * license * release date * collection range |  |  |  |
| The exact data format with all fields and metadata | * MP3 / OGG – for Audio |  |  |  |
| * MP4 / MOV- for Video |  |  |  |
| * DICOM PS3.0 for X-Ray, CT, MRI, PET |  |  |  |
| * JPEG / PNJ – for Static Image |  |  |  |
| * File formats (XML, JSON, PDF, Docx, CSV) |  |  |  |
| * Data version |  |  |  |
| * Data processing software version |  |  |  |
| * Data source |  |  |  |
| * Number of data sources |  |  |  |
| * Data collection place |  |  |  |
| * Data collection time |  |  |  |
| * Data collection author(s) |  |  |  |
| * Data directory structure |  |  |  |
| * Data backup repository |  |  |  |
| * Number of data updates |  |  |  |
| * Data registry |  |  |  |
| Resolution and data value ranges (e.g., sizes, resolutions, and compressions) | * Data Resolution / Precision |  |  |  |
| * Data Value Range |  |  |  |
| Data size and data dimensionality | * Data Sample Size |  |  |  |
| * Data dimensionality |  |  |  |
| * Data Dimensionality Reduction Technique |  |  |  |
| * Data Compression Format |  |  |  |
| * Train: Validation (Tuning): Test Dataset Partitioning Ratio |  |  |  |
| **TDD Section 4.2.4** **AI output data structure** | | | | |
| What are the general data output types returned by the AI and what is the nature of the output (e.g., classification, detection, segmentation, or prediction)? | * Binary/Class output (0 or 1) |  |  |  |
| * Probability output (0-1) |  |  |  |
| * Continuous valued output |  |  |  |
| How exactly are they encoded? Discuss points like: | * Syntactic level File formats (XML, JSON, PDF, docx, CSV, DICOM, HL7) |  |  |  |
| * Semantic level standards-taxonomies e.g. LOINC (e.g. laboratory values), ATC (drugs), ICD (diagnoses), UCUM (units) and the organizational level (IHE) |  |  |  |
| The exact data format with all fields and metadata (including examples or links to examples) | * File formats (XML, JSON, PDF, Docx, CSV) |  |  |  |
| What types of errors should the AI generate if something is defective? | UI output display (warning, alert) in case of   * Output data validity checks * Output data sequence of operations * Output data response time |  |  |  |
| * System 'RESET' option specification |  |  |  |
| * Data Error/Exception handling and recovery protocol |  |  |  |
| **TDD Section 4.2.4 AI output data structure** | | | | |
| What general criteria have been applied for selecting scores and metrics | * Performance metrics |  |  |  |
| * Robustness metrics |  |  |  |
| * Explainability metrics |  |  |  |
| * Fairness metrics |  |  |  |
| * Safety metrics |  |  |  |
| What scores and metrics have been chosen/defined for robustness? | * Explanation of limitations and residual risks |  |  |  |
| * Risk tolerance rate estimation for resource overload |  |  |  |
| * Risk tolerance rate estimation for runtime errors |  |  |  |
| * Risk tolerance rate estimation for adversarial attack errors |  |  |  |
| * User control for 'algorithm change protocol ' |  |  |  |
| * User option settings to reject, delay or roll-back an algorithm change |  |  |  |
| What scores and metrics have been chosen/defined for medical performance? | * Sensitivity (True Positive Rate) |  |  |  |
| * Specificity (True Negative Rate) |  |  |  |
| * F1-Score (class wise performance determination) |  |  |  |
| * Area under the ROC curve (AUC)-operating threshold (classification tasks) |  |  |  |
| * Prevalence, Type 1, Type 2 errors, Precision and Confidence Interval specifications |  |  |  |
| What scores and metrics have been chosen/defined for non-medical performance? | * Risk-benefit ratio |  |  |  |
| * Patient Benefit estimation |  |  |  |
| * Patient Care Cost estimation |  |  |  |
| * Case Interpretation Efficiency estimation * Decision curve analysis |  |  |  |
| * Model- False Positive referral rate |  |  |  |
| * Specification for 'average time of interpretation' (Clinician Versus Model) |  |  |  |
| * Model development cost |  |  |  |
| * Model deployment cost |  |  |  |
| * Model utilization cost, |  |  |  |
| * Model maintenance and support cost, |  |  |  |
| * Cost involved in establishing patient safety, quality of care, workflow efficiency, etc, |  |  |  |
| * Faster patient diagnosis / treatment |  |  |  |
| * Percentage reduction in clinician cognitive workload |  |  |  |
| * Degree of automation / semi-automation introduced |  |  |  |
| * Degree of smartness/intelligence augmentation new knowledge discovery |  |  |  |
| * Enabling replacement or redefinition of existing gold standard, etc |  |  |  |
| What scores and metrics have been chosen/defined for model explainability? | * Textual or Visual display formats for Model prediction interpretation through LIME (Local Interpretable Model-Agnostic Explanations), LRP (Layer-wise Relevance Propagation) explanation graphs |  |  |  |
| * Super pixels explanations for the predicted classes (Google's Inception network, highlighting positive pixels) |  |  |  |
| * Features that contribute towards the prediction (in one colour code) and non-contributing features (in another colour code) |  |  |  |
| * 'General features' learned from pre-trained' network & the new 'Transfer leaned features' from transition and prediction layers of the network |  |  |  |
| * Features that are globally relevant/significant and that are locally relevant /significant |  |  |  |
| * Learning curves to illustrate the impact of hyperparameter and epochs on quality metrics |  |  |  |
| * Data pre-conditions (met / not met) indicator (in case of data leakage scenario, incomplete data sets or data drift, malicious input data, etc.) |  |  |  |
| * Data (protected / not protected) verification status |  |  |  |
| * Directed Acyclic Graph (DAG) for indicating feature dependencies |  |  |  |
| * Algorithm change (performed / not performed)' |  |  |  |
| * Risk communication indicators in case of non-specified user type, non-specified use environment |  |  |  |
| * Model prediction decision thresholds chosen |  |  |  |
| * Visualization of the dependency (strength, direction) of the prediction of the feature values: 'Counterfactual' explanation, Sharpley-Values, ICE-Plots, Partial Dependency Plots (PDP |  |  |  |
| * Class Activation Mapping-Heat maps plot |  |  |  |
| * Heat map- spatial resolution specification |  |  |  |
| Does it use some kind of approach for correcting dataset bias (e.g., the test dataset usually has a different distribution compared to the distribution of a condition in a real-world scenario. For estimating the real-world performance, metrics need to compensate this difference) | * Selection of subject data |  |  |  |
| * Selection of study method |  |  |  |
| * Selection of efficacy evaluation standard |  |  |  |
| * Clinician consensus determination |  |  |  |
| * Fatigue, perceptual bias, cognitive bias error estimation |  |  |  |
| * QUADAS-2 Tool Test Report |  |  |  |
| * Subject / Control group data size calculation formula (statistical hypothesis based) |  |  |  |
| * Control study-medical device specifications |  |  |  |
| * Success Criteria for Evaluation Results |  |  |  |
| * Comparison report of patient outcomes (for patients on whom the AI model is applied) versus (patients on whom the AI model is not applied) |  |  |  |
| * Bias and Fairness risk estimation |  |  |  |
| * PROBAST Tool test report |  |  |  |
| * FairML tool test report |  |  |  |
| * 'Pre-trained' model verification (GoogLeNet, ImageNet, AlexNet, VGGNet-16, ResNet-50 for CNN architectures) |  |  |  |
| * Verification of the type of regression method used when (number of variable) is greater than the (number of observation) Lasso regression, Ridge regression |  |  |  |
| * Verification status that distinct populations are not inappropriately combined |  |  |  |
| * Verification status that no inappropriate performance metric was selected |  |  |  |
| **TDD Section 4.2.7** **Test dataset acquisition** | | | | |
| How have the data been collected/generated (e.g., external sources vs. a process organized by the TG)? | * Combined databases |  |  |  |
| * Federated learning (e.g. Pooling data from primary, secondary and tertiary hospitals) |  |  |  |
| Have the design goals for the benchmarking dataset been reached (e.g., please provide a discussion of the necessary size of the test dataset for relevant benchmarking results, statistical significance, and representativeness)? | * Verification of exclusion of predictors with high correlation |  |  |  |
| * Verification of exclusion of predictors with degenerate distribution or variance close to zero |  |  |  |
| * Data Leakage detection |  |  |  |
| * Verification status for exclusion of variables that allow the algorithm to identify the outcome (acting as proxy for the outcome) |  |  |  |
| * Distributed and federated ML model learning |  |  |  |
| * Data Leakage detection |  |  |  |
| * Verification status for exclusion of variables that allow the algorithm to identify the outcome (acting as proxy for the outcome) |  |  |  |
| * Descriptive Statistics plots for data dimensionality and variance calculation of distributions (histograms), mean / average values, quartiles joint distribution of features, correlation, etc. |  |  |  |
| * Verification for data transformation (flip, rotate, colour map, scale, etc.) done to match/reflect the real-world clinical data consistency profile |  |  |  |
| Were they collected in an ethical-conform way?  What kind of data anonymization or deidentification has been applied? | * Data privacy /protection policy |  |  |  |
| * Data sharing policy (HIPAA) |  |  |  |
| * Patient consent (GDPR) |  |  |  |
| * Individual vs. administrative consent |  |  |  |
| * Electronic informed consent |  |  |  |
| * Ethics board approval |  |  |  |
| How is the bias of the dataset documented (e.g., sampling or measurement bias, representation bias, or practitioner/labelling bias)? | * Selection of subject data |  |  |  |
| * Selection of study method |  |  |  |
| * Selection of efficacy evaluation standard |  |  |  |
| * Clinician consensus determination |  |  |  |
| * Fatigue, perceptual bias, cognitive bias error estimation |  |  |  |
| * Subject / Control group data size calculation formula (statistical hypothesis based) |  |  |  |
| * Control study-medical device specifications |  |  |  |
| * Adherence to regulatory compliance with country/region specific data policies on data protection, data sharing, copyright, privacy laws, patient consent and confidentiality |  |  |  |
| * Measurement bias introduced due to selection of data or samples that do not represent the true parameters/ distribution of the population of interest |  |  |  |
| * social / representation bias introduced in people-based data sources collected from services/ surveys/ social media etc. that are subject to inherent bias due to historic decisions, outdated laws, cultures and disciplines, ethnic minorities, human rights violation, etc |  |  |  |
| * Practitioner / labelling bias introduced as a result of subjective bias by practitioners during project design, analyses, or interpreting outputs, etc. |  |  |  |
| * subjective practitioner bias arising out of differences in experience in technology application, experience in medical domain, competencies, skill sets, physical and cognitive prerequisites & limitations, cultural & social characteristics, etc. |  |  |  |
| * Training data algorithmic bias: biased data results in biased model |  |  |  |
| * Algorithmic focus bias refers to the selection or rejection of certain types of input data |  |  |  |
| * Transfer context bias: a model trained on data generated within a specific context shall not exhibit optimal performance when the same model is applied on a different contextual data |  |  |  |
| * Algorithmic tuning: bias introduced as a result of tuning or modifying the parameters of the ML algorithm leading to over-fitting or vice-versa |  |  |  |
|  | * Bias risk estimation |  |  |  |
| Have any scores, metrics, or tests been used to assess the quality of the dataset (e.g., quality control mechanisms in terms of data integrity, data completeness, and data bias)? | * Data completeness validation protocols- Data cleaning and correction for ranges, variations, outliers, missing values, etc |  |  |  |
| * Data integrity validation protocols Integrity mechanisms- RAID, Mirroring, Checksum, Digital Signature, etc |  |  |  |
| How were the data submission, collection, and handling organized from the technical and operational point of view (e.g., folder structures, file formats, technical metadata encoding, compression, encryption, and password exchange)? | * Data Interface protocols -OSI-Protocols such as TCP/IP, HTTPs, SFTP, CAN, RS232, USB |  |  |  |
| * Data Encryption protocol (at Rest, Transmission, Use) |  |  |  |
| * Data Access Control Functions (Authentication, Authorization, Monitoring Logging and Auditing) |  |  |  |
| * Data Compression format |  |  |  |
| * Data Privacy & Confidentiality Protocol |  |  |  |
| * Data Security Protocol |  |  |  |
| * Data Encoding/ Decoding Protocol |  |  |  |
| * Data Interface Protocol |  |  |  |
| * Data Digitization Tool & Protocol |  |  |  |
| * Data Migration Tool & Protocol |  |  |  |
| * Data Porting Tool & Protocol |  |  |  |
| * Security protocols / controls for data repositories |  |  |  |
| * Security protocols / controls for data channels |  |  |  |
| * Database configuration |  |  |  |
| * Database -data schema/ structure |  |  |  |
| * APIs/Web services for data exchange, data loading/importing |  |  |  |
| Which scores, metrics, and thresholds were used to assess the label quality and the need for an arbitration process? | * Intra-annotator labelling accuracy |  |  |  |
| * Annotation tool labelling accuracy |  |  |  |
| * Eligibility criteria of annotation specialists |  |  |  |
| * Perceptual errors and bias estimates |  |  |  |
| * Ground truth or reference standard establishment method |  |  |  |
| How have inter-annotator disagreements been resolved (i.e., what was the arbitration process)? | * Adjudication process leading to consensus grading by specialists |  |  |  |
| Were metadata on the annotation process included in the data (e.g., is it possible to compare the benchmarking performance based on the annotator agreement)? | * Standard health data vocabulary / labelling for training and test data |  |  |  |
| * Standards for clinical terminology |  |  |  |
| * Clinical history |  |  |  |
| * Physical body exam results |  |  |  |
| * Laboratory observations |  |  |  |
| * Disease mapping |  |  |  |
| * Procedure mapping |  |  |  |
| * Clinical data messaging formats |  |  |  |
| * Data anonymisation/pseudonymisation formats for training and test data |  |  |  |
| * Labelling accuracy / error calculation and reporting for training data |  |  |  |
| * Intra/inter annotator reliability measurements (with practitioner levels of experience) |  |  |  |
| How was access to test data controlled (i.e., to ensure that no one could access, manipulate, and/or leak data and data labels)? Please address authentication, authorization, monitoring, logging, and auditing. | * Access Control Functions (Authentication, Authorization, Monitoring Logging and Auditing) |  |  |  |
| * Audit Logs for viewing, creation, modification, validation, copying, import, export, transmission, reception, etc. based on Blockchain Technology, Merkle Trees, etc |  |  |  |
| * Data sharing through secured channels |  |  |  |
| * Implementing Security Standards based on Digital Certificate, SSL, SHA-256, etc |  |  |  |
| * Data integrity validation protocols: RAID, Mirroring, Checksum, Digital Signature |  |  |  |
| * "Break glass", i.e. an option to bypass the authorization strategy in order to be able to access important data immediately |  |  |  |
| **TDD Section 4.2.7.1 Data sharing policies** | | | | |
| Roles and responsibilities | * Data provider |  |  |  |
| * Data protection officer |  |  |  |
| * Data controllers |  |  |  |
| * Data processors |  |  |  |
| * Data receivers |  |  |  |
| Which legal framework was used for sharing the AI? | * GDPR, HIPAA |  |  |  |
| **TDD Section 4.2.10 Result** | | | | |
| What overall performance of the AI systems concerning medical accuracy, robustness, and technical performance (minimum, maximum, average etc.) has been achieved? | * Model Accuracy (PA) estimate - Confidence Interval (e.g. With X % Confidence, PA lies in the interval [lower bound, upper bound] |  |  |  |
| * Model Accuracy -Mean & Standard Deviation |  |  |  |
| * Model Accuracy –Box Plot Summarization |  |  |  |
| * Root Mean Squared Error (RMSE) |  |  |  |
| * Sensitivity (True Positive Rate) |  |  |  |
| * Specificity (True Negative Rate) |  |  |  |
| * F1-Score (class wise performance determination) |  |  |  |
| * Confusion matrix |  |  |  |
| * Gain and Lift Charts |  |  |  |
| * Kolmogorov Smirnov Chart |  |  |  |
| * Gini Coefficient |  |  |  |
| * Log Loss |  |  |  |
| * Area under the ROC curve (AUC) |  |  |  |
| * Concordant – Discordant Ratio |  |  |  |
| **TDD Section 4.2.11** **Discussion of the benchmarking** | | | | |
| How was the performance of the AI system compared to the baseline? | * ML model selection, ML model metric selection and optimal hyper-parameter setting guided on the basis of the cost estimates of ML model errors |  |  |  |
| * Model performance fairness estimation on bias relevant population subgroups (females, ethnic subgroups, age) |  |  |  |
| * Estimation of statistical measures of significance and uncertainly |  |  |  |
| * Specification for 'confidence intervals' and 'metric variation' (error bars) |  |  |  |
| * Algorithm augmentation verification (Lagrangian Approach) |  |  |  |
| * Algorithmic tuning / decision thresholds used for differential diagnosis based on age, gender, ethnicity, etc |  |  |  |
| * 'Demographic Parity' verification |  |  |  |
| * Equal Opportunity' verification |  |  |  |
| * 'Verification Status' - that model makes positive prediction on a 'protected population subgroup' as same as that for the 'entire population group' |  |  |  |
| * 'Verification Status' - that model makes equal true positive rates and also False-positive/negative rates on 'protected population subgroup' as those for the 'entire population group' |  |  |  |
| * Verification to ensure that higher model coefficients are penalized to lower the model complexity |  |  |  |
| * Selection of significant features from 'variable importance chart' |  |  |  |
| * Intended user verification (verification of input data distribution for target patient population representativeness |  |  |  |
| * Cost estimation for wrong clinical decision making / if outputs do not meet the specified 'quantitative quality criteria' |  |  |  |
| * Lookup Table for Risk Acceptance criteria specification (Clinical Risk & Cost of Risk) |  |  |  |
| * ML model sensitivity analysis for subsets of the population including vulnerable, marginalized and other sensitive categories of the population |  |  |  |
| * ML model failure analysis for any subsets of the population |  |  |  |
| * Hyper-parameter tuning of ML models to reduce the variance-bias tradeoff |  |  |  |
| * ML model selection on the basis of finding a balance between model accuracy and model simplicity or interpretability |  |  |  |
| * ML model's unacceptable failure rates for any of the subsets of the population |  |  |  |
| * ML model's influence by relevant inputs from the target user / domain experts |  |  |  |
| * Level of interpretability of the ML model meets the expectation of the target user or not |  |  |  |
| * Factors that significantly influenced ML model performance |  |  |  |
| * ROC discrimination threshold' estimation (for mapping the output probabilities to binary predictions) |  |  |  |
| * Estimation of measure that indicates the response predicted by a model on adding independent variables -Residual deviance value |  |  |  |
| * Estimation of measure that indicates percent of variance in a predictor which cannot be accounted by other predictors (multi-co linearity)-'Tolerance' value (reciprocal of Variance Inflation Factor (VIF)) |  |  |  |
| * Algorithm update cycle estimation (time & the amount of change is quantified) to enforce, prevent, delay or roll-back changes to algorithms |  |  |  |
| Algorithm update specifications with respective time stamps:  In cases of Neural Networks,   * fit parameters such as weights of neurons or cut-off of activation function * hyperparameters such as numbers of neurons per layer and number of layers * Optimizer specification (Stochastic gradient descent (SGD), Adam, Adadelta, Adagrad, L-BFGS, etc.) |  |  |  |
| * Estimation of fitness measure which penalizes model for the number of model coefficients-AIC (Akaike Information Criteria) value |  |  |  |
| * Conditions under which the ML model was not tested |  |  |  |
| * Cost estimation of ML model errors |  |  |  |
| * Estimation of the risk probabilities associated with model performance variability due to adversarial attacks (e.g. with manipulation of selected pixels in images) |  |  |  |
| * Risk probabilities associated with model performance variability w.r.t change in hardware and software configurations of model development environment |  |  |  |
| * Estimation of the risk probabilities associated with model performance variability when tested against the following conditions: (a) patients other than those specified, (b) non-specified use environment, (c) patients of different age, sex, race, co-morbidities, (d) patients with different severity of disease type |  |  |  |
| * Model effectiveness re-assessed / re-evaluated/ re-calibrated for multiple clinical settings of different health environments (e.g. with variability in workflow, demographics, etc) |  |  |  |
| * Model generalizability consideration- verification of input data representative of variations in data acquisition and reconstruction parameters, target population, operating time scales. |  |  |  |
| Are there any technical lessons? | * Training over encrypted data (homomorphic encryption) |  |  |  |
| * Prevalence in test database' may not reflect ' real-world prevalence'. addressing by provisioning of combined databases, federated learning (e.g. Pooling data from primary, secondary and tertiary hospitals) |  |  |  |
| * Multi-core training offers a measurable benefit on your system |  |  |  |
| * K-nearest neighbour model to select those instances of the training set that are most similar to the test set. |  |  |  |
| * Different modelling pipelines that result in different sets of predictions, scoring the predictions, then making changes to the pipeline that are expected to result in an improved score |  |  |  |
| * Maintaining consistency of model performance parameters w.r.t to change in hardware and software configurations of AI model development environment |  |  |  |
| * Traceability matrix to link together design, implementation, testing, and risk management |  |  |  |
| * Selection of ML algorithms based on a set of assumptions about the underlying distribution of the input variable |  |  |  |
| * Cost and Loss functions of ML Algorithms |  |  |  |
| * ML Algorithm Hyper-parameter tuning and configuration through reinforcement learning |  |  |  |
| * Inverse relationship between the performance (of AI systems) and the level of explainability and trust |  |  |  |
| * Algorithm Tuning & Ensembles Methods for performance improvement |  |  |  |
| * Re-sampling techniques like k-fold cross-validation to estimate the performance of the model when making predictions on data not used during training |  |  |  |
| How was the performance and operational efficiency of the benchmarking itself (e.g., how long did it take to run the benchmarking for all AI models vs. one AI model; was the hardware sufficient)? | * Average time taken for the model in assigning class labels for the test data |  |  |  |
| * Response time specification as a function of number of users, number of transactions, frequency and amount of input data etc |  |  |  |
| * API response times and computational memory configurations |  |  |  |
| * Number of cores available to support multi-core training |  |  |  |
| * Cost of energy and computation |  |  |  |
| * CPU load greater than x%, a data traffic greater than y MB/s, a storage medium that is using than z% of its capacity, more than n login attempts within m minutes, and so on |  |  |  |
| * Server operating environment configuration (e.g. Linux server with 'x' Titan X GPUs) |  |  |  |
| * Heat map generation time |  |  |  |
| * 'System Availability' specification in terms of percentage of time, percentage of usages or as meantime between failure |  |  |  |
| **TDD Section 5** **Discussion** | | | | |
| Did the AI system perform as predicted relative to the baselines? | ML model summary in terms of:   * explainability * trust * quality of service * generalizability * context applicability * efficiency * safety Implication * risks * limitations * user rating (scale) * recommendations * extensibility to other settings |  |  |  |
| * Patient safety impact (e.g. early detection and lowering of disease severity levels, increased coverage under screening programs) |  |  |  |
| * Care quality impact (e.g. workflow efficiency, reliability and reproducibility of outcomes, increased accessibility, affordability, increased patient and clinician satisfaction) |  |  |  |
| * Interpretability-performance trade-off observed (e.g. lack of model interpretability Vs model performance statistical gains |  |  |  |
| * Comparison of model inferential capabilities with that of the user (clinician) |  |  |  |
| * Level of tolerance that the clinical setting allows to the misdiagnoses/mis-predictions of the model based on the particular use case |  |  |  |
| * Patient 'benefits (demonstrable improvements in patient outcomes like)' outweighs the 'risks' involved |  |  |  |
| * Clinical improvements made by the model outweighs the cost of any work changes that it necessitates |  |  |  |
| * Acceptable risk-benefit-ratio |  |  |  |
| * Predicted benefit actually correspond to clinically observed benefit |  |  |  |
| * Model performance comparable to the performance scores or the level of competence of the clinician/specialist/user in the clinical setting |  |  |  |
| * Conditions under which model renders most confusions about output label classes and performs poorly |  |  |  |
| * Conditions under which the model outperforms the clinician/specialist/user classification performance |  |  |  |
| * Conditions under which the model performs worse than that of the clinician/specialist/user |  |  |  |
| * Conditions under which the performances of both the model and clinician/specialist are comparable |  |  |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_