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| **Abstract:** | This document contains the draft version 2.0 of the project deliverable FG-AI4H DEL03 "AI4H requirement specification" and supersedes the previous version of the document (FG-AI4H-G-203). |

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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.
* 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 29148:2018] 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 15288:2015] ISO/IEC/IEEE 15288:2015, “Systems and software engineering — System life cycle processes”

[ISO/IEC/IEEE 12207:2017] ISO/IEC/IEEE 12207:2017, “Systems and software engineering — Software life cycle processes”

# Definitions

**System requirements specification** [SO/IEC/IEEE 29148:2018]: 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

# High-level product specification

Table 1: High-level product 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 stand alone 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 analyze 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 |  |  |
| 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 althea ‘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. AI transparency, black box phenomena, AI 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 althea ‘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 UIrelationships 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 & 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 tradeoffs |  |  |
| 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/de-cryption 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 h/w and s/w 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 define ‘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, trouble shooting 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 |  |  |

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