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| ITU Logo | INTERNATIONAL TELECOMMUNICATION UNION**TELECOMMUNICATIONSTANDARDIZATION SECTOR**STUDY PERIOD 2017-2020 | FG-AI4H-G-203 |
| **ITU-T Focus Group on AI for Health** |
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| **Title:** | DEL03: FG-AI4H-G-203- AI4H requirements specifications |
| **Purpose:** | Discussion |
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| **Abstract:** | This document contains the draft version 1.0 of the project deliverable DEL03 "AI4H requirements specification". |

# Introduction

## Purpose

* The purpose of this document is to define the System Requirements Specifications (SRS) that explains the informational, functional, behavioral and operational aspects a generic AI for health (AI4H) system.
* Revisions to SRS shall be performed in an iterative manner based on an incremental delivery 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
* 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

## SRS Scope

* SRS scope includes a requirements model that defines the informational, functional, behavioral and operational aspects of the AI4H system under consideration. Specific objectives include the following:
	+ Best practices for defining the AI software requirements and the task that the AI should solve without any ambiguity. This includes a clear description of the intended use
	+ Procedure to classify AI4H software vis-a-vis existing health interventions. Important considerations include, among others: Does the AI4H software replace components in existing health intervention workflows? Does it represent a new type of intervention?
	+ Risk management guidelines
* This SRS 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
* Requirement specifications may be defined in terms of use cases, graphical methods, mathematical models, documentation, etc. or combination of these

## 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
* This standard convention follows the ‘specific terms’ rules defined in the guidance document- FG-AI4H-F-103- ‘Data Acceptance and Handling Policy’

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| **Term** | **Meaning** |
| "Shall" | states a **mandatory** requirement of this policy |
| "Should" | states a **recommended** requirement of this policy |
| "May" | states an **optional** requirement |

* “TBD” (to be determined) shall be used as a placeholder term for pending information

## Definitions

## Acronyms, Abbreviations

## SRS Overview

* System requirements specifications are developed following a generic ‘requirements modeling framework’ 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

# System Description

* Application domain / topic group affinity/ healthcare speciality
* AI system / product objective
* AI task / service (prevention, screening, diagnosis, treatment, education, self-management, etc.)
* AI system/product category( clinical , non-clinical (personal care & wellness) apps
* AI system /product grade( medical grade product, commercial grade product
* AI operation mode (fully automatic, semi-automatic)
* AI intervention mode ( assistive tool, augmentative tool, etc)
* AI deployment mode

# System Functions

## Functional Requirement 1

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## Functional Requirement N

# User Types /Classes and Characteristics

* Primary user type
* Secondary user type
* User execution requirements

# Operating Conditions / Environment

* Operations site integration requirements
* Operation site adaptation requirements

# Design and Implementation Constraints

* Design considerations /constraints
* Data sharing / replication policy
* Technical accuracy to clinical effectiveness mapping
* Business model sustainability
* Areas of stakeholder conflict
* Regulatory and Policy issues
* Regulatory compliance with country/region specific data policies
* Data privacy, trust, ethics, and ownership considerations
* Internationalization requirements
* Localization requirements
* Application criticality
* Communication protocols
* Security considerations
* Hardware limitations
* Interfaces to other applications
* Parallel operation
* Language requirements
* Control functions
* Specific technologies to be used
* Specific tools to be used
* Specific databases to be used
* Non-clinical data availability

# External Interface Requirements

* User Interfaces
* Hardware Interfaces
* Software Interfaces
* Communications Interfaces
* Memory Constraints

# Non-functional Requirements

* Performance Requirements
* Safety Requirements
* Security Requirements
* System Quality Requirements

# System Design Requirements

* System Architecture design
* Sub system design
* UI design
* Component level design

# System Implementation Requirements

* Coding Principles
* Coding and Testing procedures
* System Testing

# System Deployment Requirements

* System configuration
* Deployment /run-time environment
* Assembling and testing
* Delivery packaging
* Distributing Computing requirements
* High performance production environments
* AI service utilization metrics
* Service levels
* Service level compliance report for clinical deployment

# User Documentation / Training Requirements

* User tutorial
* Technical guide
* User Safety Guide
* Online help
* User documentation delivery formats / standards

# Assumptions and Dependencies

* Unintended consequences
* Third-party / commercial components / licenses used
* Components reused from other projects
* Vendor-neutral interoperability standards

# Standards Process Compliance

* Project Management Process
* Data Management Process
* Software Delivery Process
* Regulatory Audit Process
* Quality Audit Process
* Regulatory, Quality and Security Certification Process

# Risk Management Requirements

* Risk Assessment
* Risk Control
* Risk Communication
* Risk Review

# Change Management Requirements

# Requirements Validation Requirements

* Functional testing
* Performance testing
* System testing
* Hardware & Software platform testing
* Hardware & Software interface testing
* Data Interface / Interoperability testing
* Data Quality testing
* Data Access Control testing
* Workflow / Protocol Integration testing
* Safety and Security controls testing
* User Group testing
* Usability testing
* User-Interface testing
* Installation testing
* Stress testing

**References**

**Appendix A**-Glossary

**Appendix B-** SRS supporting information (e.g. system feasibility study reports, cost analysis study reports, patient safety reports, user surveys, etc)