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DELIVERABLE

D1.6 – HosmartAI Platform Conceptual Architecture – Final version

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Executive Summary

This document presents the final version of the HosmartAI technical requirements. The functional and non-functional requirements from D1.3 are translated into technical requirements, constraints and specifications, taking into account pilot, or partner provided assets (e.g., software, datasets), which are guiding the development tasks.

Also, the technical requirements described in this document guide the design of the HosmartAI Platform Reference Architecture and the specification of core architectural components and models.

This document also includes the HosmartAI Platform Conceptual Architecture, which was detailed in D1.5 and serves as a common point of understanding between Project partners as it illustrates various components, systems and processes, and encourages the adherence to common standards, specifications and patterns. The alignment of the conceptual architecture with other known architectures as well as with the project pilots is also analysed.

Please note that some parts from D1.5 have not changed in D1.6. For completeness, they have been included in D1.6 and they are clearly marked as not changed in the text.

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Definitions, Acronyms and Abbreviations

Acronym/ Abbreviation	Title
AI	Artificial Intelligence
API	Application Programming Interface
CCDA	Consolidated Clinical Document Architecture
CSP	Cloud Solution Providers
DoA	Description of Action
EC	Ethical Committee
EHR	Electronic Health Record
HHub	HosmartAI Hub
HL7	Health Level 7
FHIR	Fast Healthcare Interoperability Resources
HPC	High Performance Computing
KPI	Key Performance Indicator
PHR	Patient Health Record
RAF	Reference Architecture Framework
RPCA	Robust Principal Component Analysis
SDO	Standards Development Organization
SME	Subject Matter Expert
WP	Work Package

Term	Definition
Cohort	In statistics, marketing and demography, a cohort is a group of subjects who share a defining characteristic (typically subjects who experienced a common event in a selected time period, such as birth or graduation).
Consortium	Group of beneficiaries that have signed the Consortium Agreement and the Grant Agreement (either directly as Coordinator or by accession through Form A).
Pseudonymization	The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual[1]

[1] GDPR Article 4(3b): https://www.privacy-regulation.eu/en/article-4-definitions-GDPR.htm

1 Introduction

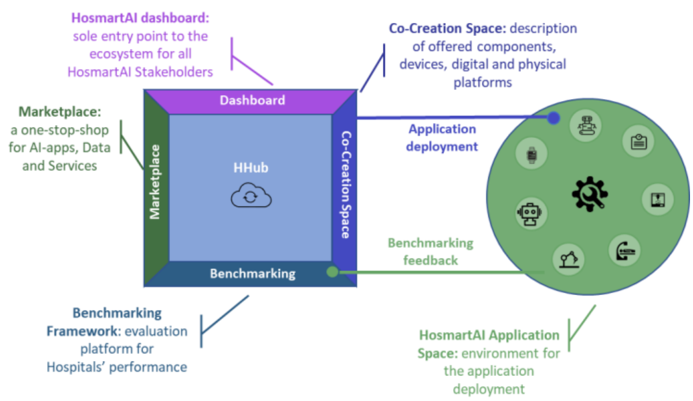
1.1 Project Information

VISION

The HosmartAI vision is a strong, efficient, sustainable and resilient European **Healthcare system** benefiting from the capacities to generate impact of the technology European Stakeholders (SMEs, Research centres, Digital Hubs and Universities).

MISSION

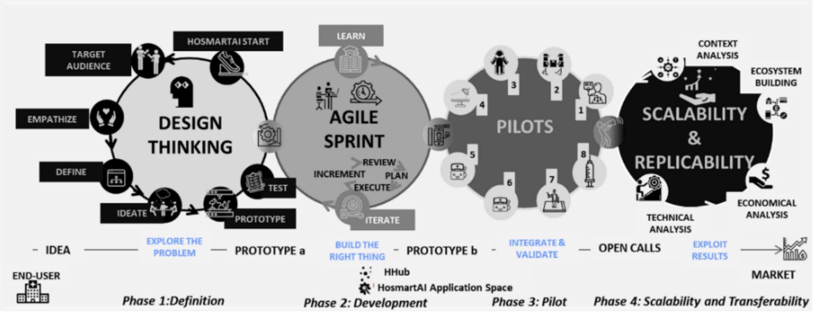
The HosmartAI mission is to guarantee the **integration** of Digital and Robot technologies in new Healthcare environments and the possibility to analyse their benefits by providing an **environment** where digital health care tool providers will be able to design and develop AI solutions as well as a space for the instantiation and deployment of AI solutions.



HosmartAI will create a common open Integration **Platform** with the necessary tools to facilitate and measure the benefits of integrating digital technologies (robotics and AI) in the healthcare system.

A central **hub** will offer multifaceted lasting functionalities (Marketplace, Co-creation space, Benchmarking) to healthcare stakeholders, combined with a collection of methods, tools and solutions to integrate and deploy AI-enabled solutions. The **Benchmarking** tool will promote the adoption in new settings, while enabling a meeting place for technology providers and end-users.

Eight Large-Scale Pilots will implement and evaluate improvements in medical diagnosis, surgical interventions, prevention and treatment of diseases, and support for rehabilitation and long-term care in several Hospital and care settings. The project will target different **medical** aspects or manifestations such as Cancer (Pilot #1, #2 and #8); Gastrointestinal (GI) disorders (Pilot #1); Cardiovascular diseases (Pilot #1, #4, #5 and #7); Thoracic Disorders (Pilot #5); Neurological diseases (Pilot #3); Elderly Care and Neuropsychological Rehabilitation (Pilot #6); Fetal Growth Restriction (FGR) and Prematurity (Pilot #1).



To ensure a user-centred approach, harmonization in the process (e.g. regarding ethical aspects, standardization, and robustness both from a technical and social and healthcare perspective), the

living lab methodology will be employed. HosmartAI will identify the appropriate instruments (**KPI**) that measure efficiency without undermining access or quality of care. Liaison and co-operation activities with relevant stakeholders and **open calls** will enable ecosystem building and industrial clustering.

HosmartAI brings together a **consortium** of leading organizations (3 large enterprises, 8 SMEs, 5 hospitals, 4 universities, 2 research centres and 2 associations – see Table 1) along with several more committed organizations (Letters of Support provided).

Table 1: The HosmartAI consortium.

Number[2]	Name	Short name
1 (CO)	INTRASOFT INTERNATIONAL SA	**INTRA**
1.1 (TP)	INTRASOFT INTERNATIONAL SA	**INTRA-LU**
2	PHILIPS MEDICAL SYSTEMS NEDERLAND BV	**PHILIPS**
3	VIMAR SPA	**VIMAR**
4	GREEN COMMUNICATIONS SAS	**GC**
5	TELEMATIC MEDICAL APPLICATIONS EMPORIA KAI ANAPTIXI PROIONTON TILIATRIKIS MONOPROSOPIKI ETAIRIA PERIORISMENIS EYTHINIS	**TMA**
6	ECLEXYS SAGL	**EXYS**
7	F6S NETWORK IRELAND LIMITED	**F6S**
7.1 (TP)	F6S NETWORK LIMITED	**F6S-UK**
8	PHARMECONS EASY ACCESS LTD	**PhE**
9	TERAGLOBUS LATVIA SIA	**TGLV**
10	NINETY ONE GMBH	**91**
11	EIT HEALTH GERMANY GMBH	**EIT**
12	UNIVERZITETNI KLINICNI CENTER MARIBOR	**UKCM**
13	SAN CAMILLO IRCCS SRL	**IRCCS**
14	SERVICIO MADRILENO DE SALUD	**SERMAS**
14.1 (TP)	FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSITARIO LA PAZ	**FIBHULP**
15	CENTRE HOSPITALIER UNIVERSITAIRE DE LIEGE	**CHUL**
16	PANEPISTIMIAKO GENIKO NOSOKOMEIO THESSALONIKIS AXEPA	**AHEPA**
17	VRIJE UNIVERSITEIT BRUSSEL	**VUB**
18	ARISTOTELIO PANEPISTIMIO THESSALONIKIS	**AUTH**
19	EIDGENOESSISCHE TECHNISCHE HOCHSCHULE ZUERICH	**ETHZ**
20	UNIVERZA V MARIBORU	**UM**
21	INSTITUTO TECNOLÓGICO DE CASTILLA Y LEON	**ITCL**
22	FUNDACION INTRAS	**INTRAS**
23	ASSOCIATION EUROPEAN FEDERATION FOR MEDICAL INFORMATICS	**EFMI**
24	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	**HOPE**

[2] CO: Coordinator. TP: linked third party.

1.2 Document Scope

This deliverable aims at providing a common point of reference for the detailed HosmartAI Conceptual Architecture as well as the first set of Technical Requirements that have been elicited based on the outcome of D1.2 and a technical analysis of stakeholders' requirements. Furthermore, this deliverable provides mappings to the architecture of other platforms, namely AI4EU, GAIA-X, OPEN DEI and DIH-HERO.

1.3 Document Structure

This document is comprised of the following chapters:

Chapter 1 presents an introduction to the project and document.

Chapter 2 contains an overview of standards and projects on which HosmartAI will capitalize.

Chapter 3 contains a technical analysis of the stakeholders' requirements.

Chapter 4 contains the technical requirements and the traceability between user and system requirements.

Chapter 5 contains an overview of the refined conceptual architecture of the HosmartAI platform.

Chapter 6 contains the pilot mapping to the HosmartAI conceptual architecture.

Chapter 7 contains the alignment with other existing solutions.

Appendix A provides the template of the Platform Survey which was executed between October and November 2021 among project partners.

Appendix B contains the used components that were provided as answers to the T1.3 questionnaire. It also includes the template of this questionnaire, which was executed between May and August 2021 among project partners.

2 Related state of the art

The contents of this chapter are also included in D1.5. This chapter is included in D1.6 for completeness.

Covering medical standards for interoperability, general platforms and other relevant standards

2.1 Healthcare standards for interoperability

2.1.1 HL7 and HL7-FHIR

2.1.1.1 HL7

Medical data is being increasingly digitized. As patients and their medical records belong to a healthcare ecosystem, electronic health records (EHRs) must be accessible and understandable by third-party applications. Furthermore, to support automated clinical decision support and other engineering processes, the data must follow a specific structure and standardization. The HL7 standard is the most mature and widely used standard for exchanging information via messages in the healthcare field based on research from both academia and industry. It is owned by the non-profit organization Health Level 7 and has been recognized by many national standardization bodies such as ANSI (USA) and DIN (Germany).

Through the use of the HL7 standard, it is possible to interconnect different applications for the purpose of exchanging medical data, without the need for each application to create different interfaces for interfacing with other applications.

In essence, the HL7 standard creates a universal protocol that allows any organization with the right permission, to access and retrieve information from any other healthcare software system. The HL7 standards serve to improve interoperability between systems, whether they are using old communication systems or APIs. HL7 standards may also fill in as a tool for work process automation in the absence of a comprehensive Electronic Health Record (HER).

By enhancing the correspondence between different clinical associations, more information can be amassed that can later be utilized to improve the quality and productivity of patient care. As more persistent records become available for access, HL7 enables clinicians to access up-to-date information and to get a broader clinical perspective, since information exchange is simplified and accelerated. The standard ensures that clinicians can access data from multiple sources and will have access to synchronized and applicable information. With less need to mention and fill out information physically, the HL7 standard saves time and ensures more precision. Along with providing uniform information exchange among existing clinical frameworks, HL7 protocols also open an array of possibilities for combining that information with other software solutions. In addition to providing a more extensive pool to choose from, it also empowers healthcare organizations to adapt to the latest technologies.

For example, using the standard an analyst in a hospital laboratory can receive direct test orders from clinical departments and return test results to the departments that ordered them automatically. This significantly assists a clinician as he is relieved of the burden of managing a huge volume of medical information, which absorbs significant time and distracts him from his primary purpose, the diagnosis and treatment of his patient.

The data is transmitted via messages. Each message consists of segments in a predefined order. Each segment starts with a header consisting of three capital characters that determines the purpose of the following data stream in the message. Each segment can contain several fields (or composites). The character "|" is used to separate the fields of the segments.

A field can contain other fields or sub-fields. These are separated with "^" characters. Fields and sub-fields can contain any primitive data type such as strings or numbers. These sub-fields can also contain other fields of their own, in which case these sub-sub-fields are separated with the "&" character, and they cannot be further divided. The message can be encoded to XML [REF-01] and other formats.

A new specification and latest version of HL7 is discussed in the next chapter, which is designed specifically for digital interactions as a stand-alone standard for data exchange.

2.1.1.2 HL7-FHIR

Patient Health Record (PHR) as defined by Markle Foundation is "an electronic application through which individuals can access, manage and share their health information, and that of others for whom they are authorized, in a private, secure and confidential environment''. [REF-02]. Patients who try to improve health outcomes by managing their health (e.g., medications, physiological measurements, appointments, etc.) are the main stakeholders of the PHR. However, the patient health data is created and maintained by the providers (e.g., physicians, specialists, nurse practitioners, etc.) using EHR [REF-03]. Patients are expected to have multiple EHRs from various providers however only a single PHR is expected. Thus, a unified representation of electronic health records (EHRs) remains the main issue in the interoperability of electronic health records in general.

FHIR is a promising standard focused especially on healthcare integration and interoperability. Compared to other HL7 approaches towards standardization, the FHIR relates the traditional document-centric approach with a modular approach and represents the atomic/granular healthcare data (e.g., heart rate, procedure, medication, allergies, etc.) as independent modular entities called Resources [REF-04]. FHIR enables the creation, editing, deletion, and exchange of definitions of medical sources for specific profiles such as Patient, Observation, Questionnaire, and more than 140 other types of resources [REF-05]. These FHIR resources are managed (i.e., create, update and share) using APIs and RESTful web services, the backbone of modern web applications. The HL7 FHIR standard is designed using existing HL7 standard/model(s), lessons from their drawbacks and major technological overhaul by leveraging modern web and mobile technologies such as the lightweight HTTP-based REST protocol, JSON, RDF, etc.

With FHIR, there is no single information model. Each resource is a snippet of the larger healthcare information domain. In this way, as outlined in Figure 1 the healthcare domain model is decomposed into smaller, more manageable sub-domains. To ensure consistency and integrity within the resource structures the decomposition framework, outlined in Figure 1, breaks health information model sub-categories into layers based on their degree of commonness. The layers and categories are useful for identifying which parts of healthcare information are the most common and therefore need to be the most consistently defined and tightly governed. The categories at the top layers are the most common and contain the FHIR resources that support the largest number of common healthcare transactions.

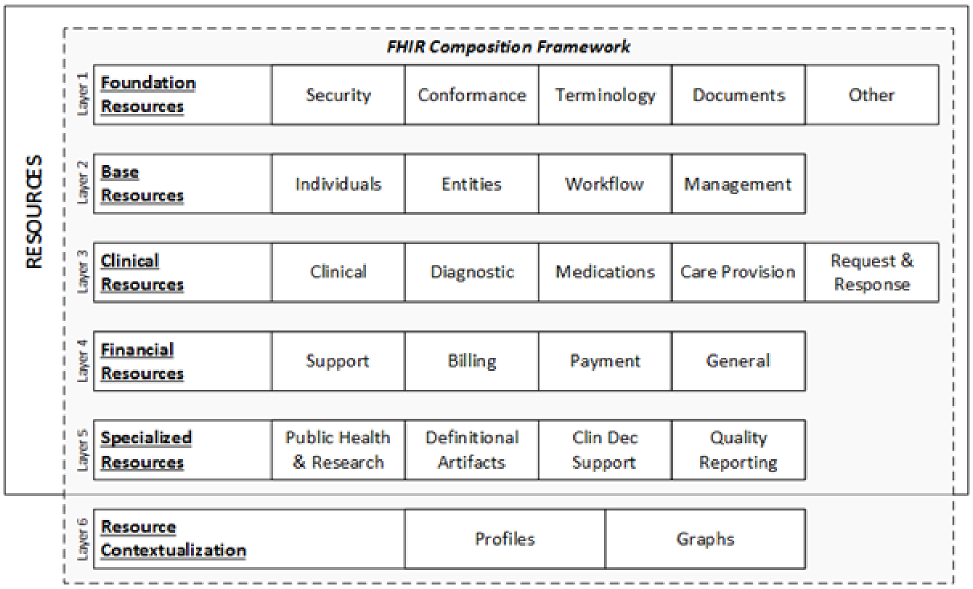


Figure 1: Information Domain of FHIR Resources.

The **Foundation resources** (Foundation module, Figure 2) are the most rudimentary, foundational resources. They are often used for infrastructural tasks. Although not prohibited, they are not always referenced by other resources. The Foundation Module is responsible for the overall infrastructure of the FHIR specification. Every implementer works with the content in the foundation module whichever way they use FHIR. The foundation resources are further decomposed into the following sub-modules:

- *The Security and Privacy Module* describes how to protect a FHIR server (through access control and authorization), how to document what permissions a user has granted (consent), and how to keep records about what events have been performed (audit logging and provenance). FHIR does not mandate a single technical approach to security and privacy; rather, the specification provides a set of building blocks that can be applied to create secure, private systems.
- *The Conformance Module* represents metadata about the datatypes, resources and API features of the FHIR specification and can be used to create derived specifications.
- *The Terminology Module* provides an overview and guide to the FHIR resources, operations, coded data types and externally defined standard and FHIR-defined terminologies that are used for representing and communicating coded, structured data in the FHIR core specification and profiles.

Foundation	Conformance	Terminology	Security	Documents	Other
	CapabilityStatement N	CodeSystem N	Provenance 3	Composition 2	Basic 1
	StructureDefinition N	ValueSet N	AuditEvent 3	DocumentManifest 2	Binary N
	ImplementationGuide 1	ConceptMap 3	Consent 2	DocumentReference 3	Bundle N
	SearchParameter 3	NamingSystem 1		CatalogEntry 0	Linkage 0
	MessageDefinition 1	TerminologyCapabilities 0			MessageHeader 4
	OperationDefinition N				OperationOutcome N
	CompartmentDefinition 1				Parameters N
	StructureMap 2				Subscription 3
	GraphDefinition 1				
	ExampleScenario 0				

Figure 2: The structure of the FHIR Foundation Layer.

Layer two consists of **Base Resources** (Figure 3). These are often the leaf nodes of a resource graph. In other words, they are often referenced by other resources, but don't typically reference other resources themselves. These resources are typically the most commonly used, and therefore require the highest degree of consistency and architectural rigor. Governance is greatest for resources in layers one and two. The resources are further decomposed into the following sub-modules:

- The *Individuals* and *Entities* (#1 and #2) belong to the Administration module. The Administrative module covers the base data that is then linked into the other modules for clinical content, finance/billing, workflow, etc. It is built on the FHIR technology platform modules.
- The *Workflow* module focuses on the coordination of activities within and across systems. This includes three primary aspects: i) How do we ask for another person, device, or system to do something? ii) How do we track the linkages and dependencies between activities - actions to their authorizations, complex activities to individual steps, protocols to plans, orders, etc.? iii) How do we define what activities are possible and the expected order and dependencies of the steps within those activities? i.e., process/orchestration definition
- *Management* aggregates resources from *Administration* and *Foundation* and Clinical Reasoning. The Clinical Reasoning module provides resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts such as clinical decision support rules, quality measures, public health indicators, order sets, and clinical protocols. In addition, the module describes how expression languages can be used throughout the specification to provide dynamic capabilities.

Base	Individuals	Entities #1	Entities #2	Workflow	Management
	Patient N	Organization 3	Substance 2	Task 2	Encounter 2
	Practitioner 3	OrganizationAffiliation 0	BiologicallyDerivedProduct 0	Appointment 3	EpisodeOfCare 2
	PractitionerRole 2	HealthcareService 2	Device 2	AppointmentResponse 3	Flag 1
	RelatedPerson 2	Endpoint 2	DeviceMetric 1	Schedule 3	List 1
	Person 2	Location 3		Slot 3	Library 2
	Group 1			VerificationResult 0	

Figure 3: The structure of the FHIR Base Layer.

Layer 3 focuses on **Clinical Resources** (Figure 4) and includes the resources that are clinical in nature but are also very common across many use cases. This includes resources for clinical observations, clinical treatment, care provision, and medications. These resources can be used by themselves, but typically build on the resources in layer two. For example, an observation resource will reference the patient resource from layer two. These resources are also frequently contextualized when they are referenced by resources in layers three, four and five. The resources are further decomposed into the following sub-modules:

- This *Clinical Module* focuses on the FHIR Resources that represent core clinical information for a patient. The information contained in these Resources are those frequently documented, created, or retrieved by healthcare providers during the course of clinical care. Resources generated during the course of diagnostic studies can be found in the Diagnostics Module, whereas the Resources related to medication ordering and administration process can be found in the Medications Module.
- The *Diagnostics Module* provides an overview and guide to the FHIR content that addresses ordering and reporting of clinical diagnostics including laboratory testing, imaging and genomics.
- The *Medication module* is concerned with resources and functionality in 3 main domains: i) The ordering, dispensing, administration of medications and recording statements of medication use, ii) Recording of Immunizations given (or not given), evaluation of given immunizations and recommendations for an individual patient at a point in time, and iii) The creation or querying for medications as part of drug information or drug knowledge.
- Request & Response module that aggregates resources from *Clinical Reasoning, Workflow and Administration.*

	Summary	Diagnostics	Medications	Care Provision	Request & Response
Clinical	• AllergyIntolerance 3	• Observation N	• MedicationRequest 3	• CarePlan 2	• Communication 2
	• AdverseEvent 0	• Media 1	• MedicationAdministration 2	• CareTeam 2	• CommunicationRequest 2
	• Condition (Problem) 3	• DiagnosticReport 3	• MedicationDispense 2	• Goal 2	• DeviceRequest 1
	• Procedure 3	• Specimen 2	• MedicationStatement 3	• ServiceRequest 2	• DeviceUseStatement 0
	• FamilyMemberHistory 2	• BodyStructure 1	• Medication 3	• NutritionOrder 2	• GuidanceResponse 2
	• ClinicalImpression 0	• ImagingStudy 3	• MedicationKnowledge 0	• VisionPrescription 2	• SupplyRequest 1
	• DetectedIssue 1	• QuestionnaireResponse 3	• Immunization 3	• RiskAssessment 1	• SupplyDelivery 1
		• MolecularSequence 1	• ImmunizationEvaluation 0	• RequestGroup 2	
			• ImmunizationRecommendation 1		

Figure 4: The structure of the FHIR Clinical Layer.

Layer four, **the Financial Resources** (Figure 5), is dedicated to financial resources. Logically, financial resources build on clinical and base resources. For example, a billing resource will reference clinical events and activities as well as base resources like a patient. Thus, the Financial module covers the resources and services provided by FHIR to support the costing, financial transactions and billing which occur within a healthcare provider as well as the eligibility, enrolment, authorizations, claims and payments which occur between healthcare providers and insurers and the reporting and notification between insurers and subscribers and patients. Although further categorized into Support, Billing, Payment and General sub-modules the resources belong either to the **Financial module** or the **Administration.**

	Support	Billing	Payment	General
Financial	• Coverage 2	• Claim 2	• PaymentNotice 2	• Account 2
	• CoverageEligibilityRequest 2	• ClaimResponse 2	• PaymentReconciliation 2	• ChargeItem 0
	• CoverageEligibilityResponse 2	• Invoice 0		• ChargeItemDefinition 0
	• EnrollmentRequest 0			• Contract 1
	• EnrollmentResponse 0			• ExplanationOfBenefit 2
				• InsurancePlan 0

Figure 5: The structure of the FHIR Financial Layer.

Layer five, the **Specialized Resources** (Figure 6) aggregates more specialized resources for less common use cases. These resources almost always reference resources in lower layers. Given that FHIR places priority on satisfying the most common use cases, there are fewer resources in this layer. The resources are categorized into five sub-modules, *Public Health & Research, Definitional Artifacts, Evidence-Based Medicine, Quality Reporting & Testing and Medication Definition*. However, most of the resources also link to Administration, Clinical Reasoning and Medication.

	Public Health & Research	Definitional Artifacts	Evidence-Based Medicine	Quality Reporting & Testing	Medication Definition
Specialized	• ResearchStudy 1	• ActivityDefinition 2	• ResearchDefinition 0	• Measure 2	• MedicinalProduct 0
	• ResearchSubject 1	• DeviceDefinition 0	• ResearchElementDefinition 0	• MeasureReport 2	• MedicinalProductAuthorization 0
		• EventDefinition 0	• Evidence 0	• TestScript 2	• MedicinalProductContraindication 0
		• ObservationDefinition 0	• EvidenceVariable 0	• TestReport 0	• MedicinalProductIndication 0
		• PlanDefinition 2	• EffectEvidenceSynthesis 0		• MedicinalProductIngredient 0
		• Questionnaire 3	• RiskEvidenceSynthesis 0		• MedicinalProductInteraction 0
		• SpecimenDefinition 0			• MedicinalProductManufactured 0
					• MedicinalProductPackaged 0
					• MedicinalProductPharmaceutical 0
					• MedicinalProductUndesirableEffect 0
					• SubstanceNucleicAcid 0
					• SubstancePolymer 0
					• SubstanceProtein 0
					• SubstanceReferenceInformation 0
					• SubstanceSpecification 0
					• SubstanceSourceMaterial 0

Figure 6: The structure of the FHIR Specialized Resources Layer.

Finally, the sixth layer, **Resource Contextualization** does not contain resources. Layer 6 includes profiles and graphs. Profiles are used to extend, constrain, or otherwise contextualize resources for a given purpose. Graphs are compositions of resources, or webs of resources, that contain attributes of their own.

FHIR's development began in 2012 in response to market needs for faster, easier, and better methods to exchange the rapidly growing amount of health data. This growth in the availability of new health data, along with the progressing "app" economy, created the need for clinicians and consumers to be able to share data in a lightweight, real-time fashion using modern internet technologies and standards. The main benefits of the FHIR are:

- FHIR creates a common specification by which healthcare participants can share information.
- FHIR enables the development of applications that benefit from access to high-quality information in a manner that implementers find as easy to use as possible.
- FHIR supports improvements in the delivery of healthcare including new initiatives such as Value-Based care

FHIR has been defined in co-creation and primarily with the following stakeholders in mind:

- Clinical and Public Health Laboratories
- Immunization Registries
- Quality Reporting Agencies
- Standards Development Organizations (SDOs)
- Regulatory Agency
- Payors
- Pharmaceutical Vendors
- EHR, PHR Vendors
- Equipment Vendors
- Health Care IT Vendors
- Clinical Decision Support Systems Vendors
- Lab Vendors
- HIS Vendors
- Local and State Departments of Health
- Medical Imaging Service Providers
- Healthcare Institutions (hospitals, long term care, home care, mental health)

The base FHIR Specification is a platform specification - a specification on which different solutions with different variations of requirements can be built. The FHIR specification focuses on defining capabilities and creating an ecosystem. National standards, vendor consortiums, clinical societies, etc. publish specific "implementation guides" that define how the capabilities defined by the FHIR specification are used in data exchanges, or to solve particular problems. The following table showcases particular adaptations/recommendations where FHIR was modified to fit a specific requirement (sets of requirements). The below guidelines will be considered in the Pilots of HosmartAI project before defining pilot-specific adaptations of FHIR. The full list is available at the **Implementation Guide Registry**[3].

Table 2: List of Implementation Guidelines that can contribute to more efficient FHIR adaptation in HosmartAI.

Recommendation/guideline	Authority	Edition
CCDA on FHIR[4]**:** US Realm Implementation Guide (IG) addressing the key aspects of Consolidated CDA (C-CDA) required for Meaningful Use (MU).	HL7/US	STU1, 1.1 and CI
RCPA Cancer Reports[5]**:** Structured Cancer Reporting Protocols (FHIR adaptation of joint CAP/RCPA protocols)	HL7/AU	R1 Draft, CI
Mobile Care Services Discovery (mCSD)[6]**:** Defines a comprehensive Provider	IHE/UV	R4 Trial

[3] Implementation Guide Registry: http://fhir.org/guides/registry/
[4] CCDA on FHIR: http://hl7.org/fhir/us/ccda/
[5] RCPA: http://fhir.hl7.org.au/fhir/rcpa/index.html
[6] mCSD: https://wiki.ihe.net/index.php/Mobile_Care_Services_Discovery_(mCSD)

Recommendation/guideline	Authority	Edition
Directory including Organization, Location, Services, and Practitioners. Includes IHE-HPD and IHE-CSD use-cases		
Remote Patient Monitoring (RPM)[7]: Provides means of reporting measurements taken by Personal Healthcare Devices in a remote location	IHE/UV	STU3 Trial
Dynamic Care Team Management (DCTM)[8]: Provides the means for sharing care team information about a patient's care teams that meet the needs of many users, such as providers, patients and payers	IHE/UV	STU3 Trail Implementation
Mobile Aggregate Data Exchange (mADX)[9]: Supports interoperable public health reporting of aggregate health data.	IHE/UV	R4 Trial
Patient Reported Outcomes (PRO) FHIR IG: provides the necessary guidance to use FHIR for Patient Reported Outcomes	HL7/US	STU 1 Ballot, CI
FHIR Clinical Guidelines[10]: this implementation guide is a multi-stakeholder effort to use FHIR resources to build shareable and computable representations of the content of clinical care guidelines. The guide focuses on common patterns in clinical guidelines, establishing profiles, conformance requirements, and guidance for the patient-independent, as well as analogous patterns for the patient-specific representation of guideline recommendations	HL7/UV	STU 1, CI
Argonaut Clinical Notes Implementation Guide[11]: This implementation guide provides implementers with FHIR profiles and guidance to create, use, and share Clinical Notes	Argonaut/us	R1, CI
Argonaut Questionnaire[12] Implementation Guide: This IG provides	Argonaut/us	R1, CI

[7] RPM: https://wiki.ihe.net/index.php/Remote_Patient_Monitoring
[8] DCTM: https://wiki.ihe.net/index.php/Dynamic_Care_Team_Management_(DCTM)
[9] mADX: https://wiki.ihe.net/index.php/Mobile_Aggregate_Data_Exchange_(mADX)
[10] FHIR Clinical Guidelines: http://hl7.org/fhir/uv/cpg/
[11] Argonaut Clinical Notes: http://fhir.org/guides/argonaut/clinicalnotes/
[12] Argonaut Questionnaire: http://fhir.org/guides/argonaut/questionnaire

Recommendation/guideline	Authority	Edition
guidance to support the interchange of simple forms based on the Questionnaire and Questionnaire Response resources: it provides implementers with FHIR RESTful APIs and guidance to create, use and share between organizations standard assessment forms and the assessment responses		
FHIR Data Segmentation for Privacy[13]: Guidance for applying security labels in FHIR	HL7/US	STU 1 Ballot, CI
Vital Signs FHIR IG[14]: US Realm Implementation Guide for Vital Signs observations with extensions for qualifying data.	HL7/US	STU 1 Ballot, CI
Making EHR Data MOre available for Research and Public Health (MedMorph)[15]: Making EHR Data More Available for Research and Public Health (MedMorph) Reference Architecture enables clinical data exchange between EHR systems, public health systems/authorities, data repositories, and research organizations. This data exchange utilizes if applicable, knowledge repositories and backend services applications (e.g. FHIR APIs) to determine the triggering event(s) for the data exchange, the process for the data exchange, and validation that the data being exchanged meets a set of rules in order to expedite the data exchange**.**	HL7/US	STU 1 Ballot, CI

2.1.2 DICOM

DICOM[16] (Digital Imaging and Communications in Medicine) is an internationally deployed, non-proprietary standard that establishes rules that allow medical images and associated information to be exchanged between compliant imaging equipment from different vendors, computers, and hospitals. The main areas of interoperability-enabling functionality that the standard is concerned with are: (i) transmission and persistence of images and related data between endpoints, (ii) query and retrieval of files, (iii) implementation of specific actions

[13] FHIR Data Segmentation for Privacy: http://hl7.org/fhir/uv/security-label-ds4p
[14] Vital Signs FHIR: http://registry.fhir.org/package/hl7.fhir.us.vitalsigns|0.1.0
[15] MedMorph: http://hl7.org/fhir/us/medmorph
[16] DICOM: https://www.dicomstandard.org/

such as archiving or printing, (iv) support of digital imaging workflows, and (v) maintenance of consistent, high quality image appearance.

The initial conception of the standard dates back to 1983, when the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) collaborated to develop a standard that would respond to the need for manufacturer-independent digital medical imaging. The DICOM abbreviation was adopted on the third version of the standard, released in 1993. Since its creation, the standard has been continually evolving and adjusting, incrementally achieving a near-universal level of acceptance among medical imaging equipment vendors and healthcare IT organizations.

At its core, DICOM uses an object-oriented abstract data model to organise information about real world objects (i.e., patients, medical procedures, devices, etc). In this model, Information Objects are described as structured collections of Attributes through DICOM Information Object Definitions (IOD). The available Attributes constitute the DICOM Data Dictionary, a list that ensures consistency in attribute naming. Information modelled using IODs can then be transferred and processed across compliant devices or software, termed as Application Entities.

An instance of a real-world Information Object is represented as a Data Set that is constructed of Data Elements. The latter contains the encoded values of Attributes of the object and can be thought of as units of information. A DICOM image is a manifestation of such a Data Set; Apart from the actual pixel data, Data Elements of an image object may contain information related to patient demographics, imaging modality and procedures, technical specifications and more. This grouping of related data items prevents accidental separation of linked or co-dependent pieces of information. For each modality, DICOM precisely defines the Data Elements that are required, optional or required under certain circumstances.

Another central aspect of DICOM is the definition of Services which specify functionality that DICOM applications provide to each other, and regularly involve the transmission of data over a network. An example of a frequently used Service is the DICOM Store service, that enables sending information objects to a Picture Archiving and Communication System (PACS) or workstation. Other common Services include the Query/Retrieve, Print and Structured Reporting services. Overall, DICOM Services provide a standardized framework for capturing, transferring, and processing image data that protects from human error and minimizes the time interlude from image acquisition to evaluation.

For each medical device or system that is intended to be DICOM compliant, a DICOM Conformance Statement document must be elaborated, in which the DICOM functionalities (services) supported by the system are specified. The Statement is an essential technical document, especially relevant when assessing compatibility between different systems or versions of the same system.

2.2 Platforms

Four platform architectures that were the most influential in the refinement process of the HosmartAI Conceptual Architecture are included in this section:

- AI4EU
- GAIA-X
- OPEN DEI
- DIH-HERO

Mappings to the above architectures can be found in 7.2.

2.2.1 AI4EU

The AI4EU consortium was established to build the first European Artificial Intelligence On-Demand Platform and Ecosystem with the support of the European Commission under the Horizon 2020 programme.

The AI4EU Platform [REF-07] brings the stakeholders and resources together in one dedicated place, overcoming fragmentation, so that AI-based innovations will be accelerated. The main principles of the platform are a service-oriented and web platform, which is multidisciplinary and cross-sector, scalable and interoperable, with curated data access, collaborative, social and confidential.

The activities of the AI4EU consortium are:

- The creation and support of a large European ecosystem spanning the 28 countries to facilitate collaboration between all European actors in Artificial Intelligence.
- The design of a European AI on-Demand Platform to support this ecosystem and share AI resources produced in European projects, including high-level services, expertise in AI research and innovation, AI components and datasets, high-powered computing resources and access to seed funding for innovative projects using the platform.
- The implementation of industry-led pilots through the AI4EU platform, which demonstrates the capabilities of the platform to enable real applications and foster innovation:
    - AI-driven attack learning.
    - Air quality monitoring.
    - Crop quality assessment through computer vision.
    - An AI-powered personal assistant for public services.
    - Intelligent performance analytics for industrial robots.
    - AI-Driven digital companion for production facility.
    - Improve quality constancy of medical images reports.
    - AI-Based 3D Generation of animated video.
- Research activities in five key interconnected AI scientific areas (Explainable AI, Physical AI, Verifiable AI, Collaborative AI, Integrative AI), which arise from the application of AI in real-world scenarios.
- The funding of SMEs and start-ups benefitting from AI resources available on the platform to solve AI challenges and promote new solutions with AI.
- The creation of a European Ethical Observatory to ensure that European AI projects adhere to high ethical, legal, and socio-economical standards. The Observatory includes five sections: articles, reports, reviews, centres and networks.

- The production of a comprehensive Strategic Research Innovation Agenda for Europe.
- The establishment of an AI4EU Foundation that will ensure a handover of the platform in a sustainable structure that supports the European AI community in the long run.

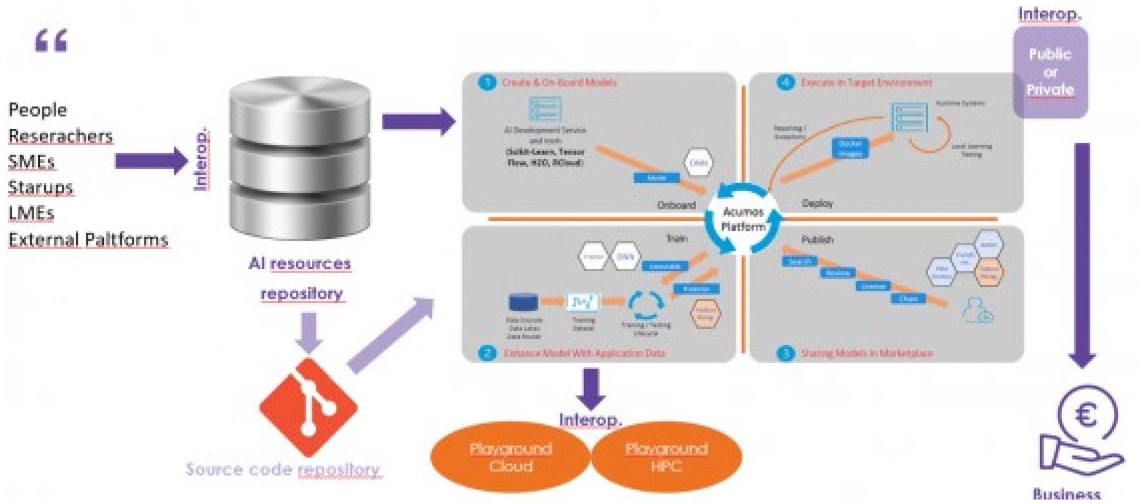


Figure 7: AI4EU Platform, Technical Architecture.

One of the pilots of AI4EU is AI4Healthcare. At the beginning of the AI4EU program, the healthcare pilot aimed to provide brain imaging as reference dataset. The collect phase was planned from March to June 2020. Due to the COVID-19 pandemic, it was proposed to collect chest Computed Tomography (CT scan) datasets from many hospitals. The interpretation of this medical exam is very useful for confirmation of COVID-19 and the usage of AI is key to facilitate the work of radiologists.

2.2.1.1 Acumos AI Platform

It is worth noting that AI4EU uses the Acumos AI Platform, which is an open-source AI platform hosted by the Linux Foundation. Acumos makes it easy to build, share and deploy AI applications among other useful features, such as the following:

- It provides a common API to package toolkits, such as TensorFlow and scikit-learn as well as models.
- It provides a marketplace for sharing AI models either internally or publicly.
- It supports container-based deployment either to public cloud or on-premises environments.
- It provides multitenancy with authentication and access control.

2.2.2 GAIA-X

GAIA-X [REF-08] provides federated services that are based on common standards which ensure transparency and interoperability. GAIA-X achieves that by aligning network and interconnection providers, Cloud Solution Providers (CSP), High Performance Computing (HPC) as well as sector-specific clouds and edge systems. Mechanisms are developed to find, combine and connect services from participating providers in order to enable a user-friendly infrastructure ecosystem. GAIA-X identifies the minimum technical requirements and services necessary to operate the federated GAIA-X Ecosystem.

Technical implementation of these Federation Services focuses on the following areas:

- the implementation of secure federated identity and trust mechanisms (security and privacy by design)
- sovereign data services which ensure the identity of source and receiver of data and which ensure the access and usage rights towards the data
- easy access to the available providers, nodes and services. Data will be provided through federated catalogues
- the integration of existing standards to ensure interoperability and portability across infrastructure, applications and data
- the establishment of a compliance framework and Certification and Accreditation services; and
- the contribution of a modular compilation of open-source software and standards to support providers in delivering a secure, federated, and interoperable infrastructure

GAIA-X is a federated data infrastructure. Each node of the infrastructure forms an independent unit and can be clearly identified and classified by the decentrally administered self-description. A software repository provides components that must or can be used by all providers, depending on their categorization. The components can be provided interoperably across multiple nodes. The necessary interfaces, services and products should be harmonized by standards and be easily identified and used in a central repository for all participants.

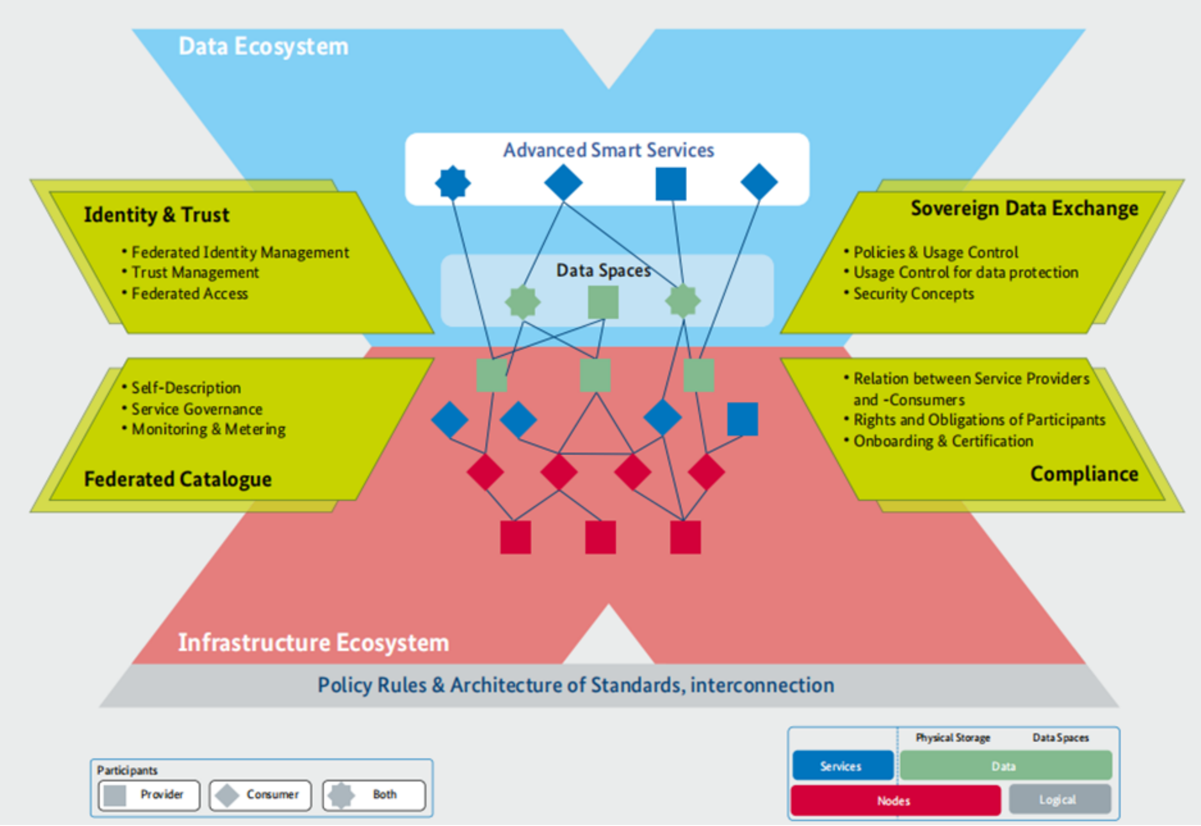


Figure 8: High-level representation of GAIA-X architecture showing the major architecture elements and functions accompanied by the Federation Services.

More than 40 use cases from different domains have already been submitted and presented. The collection has an exemplary character and currently covers the domains 'Industry 4.0/SME', 'Health', 'Finance', 'Public sector', 'Smart living', 'Energy', 'Mobility' and 'Agriculture'. The case studies are intended to show the potential of the data infrastructure on the basis of application patterns that may also be relevant in other sectors.

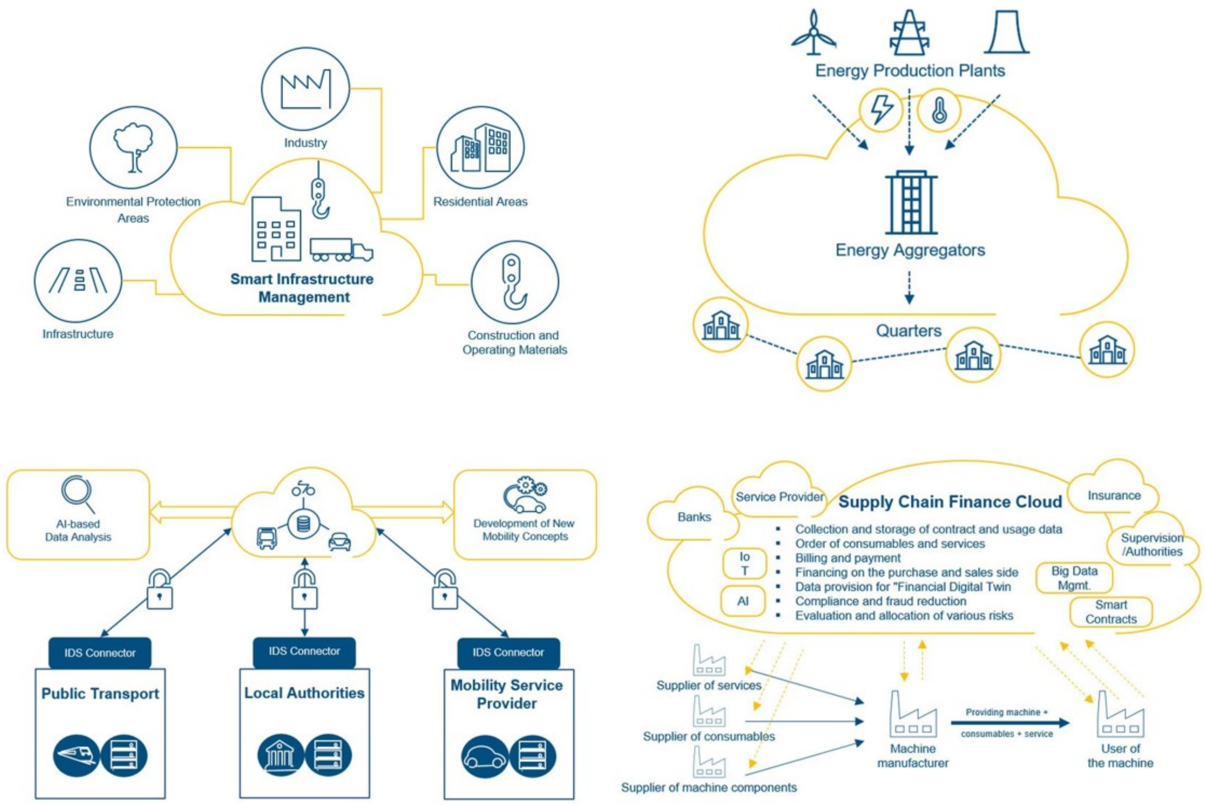


Figure 9: Examples of GAIA-X Use Cases.

2.2.3 OPEN DEI

OPEN DEI [REF-09] supports the creation of common data platforms based on a unified architecture and an established standard in different sectors: manufacturing, agriculture, energy and healthcare, which represent key fields for the deployment of the EU strategy for digitalization. In this framework, the EU-funded OPEN DEI project aims to detect gaps, encourage synergies, support regional and national cooperation, and enhance communication among the Innovation Actions implementing the EU Digital Transformation strategy.

The design and implementation of OPEN DEI Reference Architecture Framework (RAF) [REF-05] was driven by six fundamental principles:

Underlying principle 1: INTEROPERABILITY THROUGH DATA SHARING

Syntactic interoperability between two or more systems is achieved by means of using common data formats and communication protocols. Semantic interoperability between two systems, on the other hand, is achieved when the information exchanged can be interpreted meaningfully and accurately at both ends, producing useful results as defined by the end-users of both systems.

Recommendation 1: OPEN DEI RAF should foster technical interoperability at syntactic and semantic levels, via the use of data sharing mechanisms, grounded on well-established standards and design/implementation patterns.

Underlying principle 2: OPENNESS

In the context of data-driven services, the concept of openness mainly relates to data, data/API specifications and software.

Recommendation 2: OPEN DEI RAF should ensure a level playing field based on open-source datasets/software/standards and demonstrate active and fair consideration of the coverage of functional needs, maturity and market support and innovation

Underlying principle 3: REUSABILITY

Reuse means that system architects confronted with a specific problem seek to benefit from the work of others by looking at what is available, assessing its usefulness or relevance to the problem at hand, and where appropriate, adopting solutions that have demonstrated their value elsewhere. This requires the involved stakeholders to be open to sharing its interoperability solutions, concepts, frameworks, specifications, tools and components with others.

Recommendation 3: OPEN DEI RAF must support reusing and sharing of data and solutions, enabling cooperation in the collaborative development of data models and solutions when implementing Digital Transformation pathways.

Underlying principle 4: AVOID VENDOR LOCK-IN

When establishing Digital Platforms, system architectures should focus on functional needs and defer decisions on technology as long as possible in order to minimize dependencies on vendors, to avoid imposing specific technical implementations or products on their constituents and to be able to adapt to the rapidly evolving technological environment. This requirement relates to data portability - the ability to move and reuse data easily among different applications and systems, which becomes even more challenging in cross-border scenarios.

Recommendation 4: OPEN DEI RAF should foster access and reuse of their digital services and data irrespective of specific technical implementations or products.

Underlying principle 5: SECURITY and PRIVACY

Organizations and businesses must be confident that when they interact with other stakeholders they are doing so in a secure and trustworthy environment and in full compliance with relevant regulations. To establish trust between different security domains requires a common data sharing infrastructure based on agreed standards, policies and rules that are acceptable and usable for all domains. In addition to secure solutions, it is necessary to build a trust ecosystem that includes identification, authentication, authorization, trust monitoring and certification of solutions.

Recommendation 5: OPEN DEI RAF must define a common security and privacy framework and establish processes for digital services to ensure secure and trustworthy data exchange between the involved stakeholders and in interactions with organisations and businesses.

Underlying principle 6: SUPPORT TO A DATA ECONOMY

In a data economy, data becomes a key asset that businesses provide as a way to generate value. And where businesses do not have the exact data that is valuable to their customers, they use their platform base to connect to other platform partners who do have that data. Common data sharing infrastructures should come with marketplace functions enabling data providers to publish their offerings associating terms and conditions which, besides data and

usage control policies to be enforced, may include different formulas for payment: single payment, subscription fees, pay-per-use, etc. In order to support monetization of data, it should also include the necessary backend processes supporting data usage accounting, rating, payment settlement and billing. Standards enabling publication of data offerings across multiple compatible marketplaces will be highly desirable.
Recommendation 6: OPEN DEI RAF must define a data marketplace framework enabling parties to publish open and priced data, supporting the creation of multi-side markets and innovative business models which bring support to the materialization of a Data Economy

The Reference Architecture Framework (RAF) proposed promotes reusability as a driver for interoperability, recognizing that the data-driven services for DT should reuse information and services that already exist and may be available from various sources inside or beyond the organizational boundaries of the adopting organizations. Information and services should be retrievable and be made available in interoperable formats (e.g., adhering to the FAIR principles[17]). To this end, the core reusable Model Building Blocks (MBBs), mainly representing information sources and services, should make their data or functionality accessible through well-defined services supporting data-oriented and event-driven interactions. The reusable building block approach finds a suitable application by mapping solutions against the conceptual building blocks of a Reference Architecture that allows reusable components to be detected, which also promotes rationalization.

The extensive use of sensors and connected devices is a common scenario in the implementation of many Digital Transformation solutions and in many industrial sectors. The huge amount of available data is able to cover many business scenarios. Data-driven pipelines and workflows management is nowadays crucial for data gathering, processing, and decision support. To cope with this complexity OPEN DEI has adopted the following 6C architecture, adapted from the one suggested by the German Industrie 4.0 initiative, and based on the following pillars (using a bottom-up reading):

- **Connection**, making data available from/to different networks, connecting systems and digital platforms, among several IT cultures, and cross organizations' boundaries, start from the capability to make data available from/to different physical and digital assets. Different devices or sensors are used to acquire a variety of IoT data, but also many systems are based on unstructured or multi-media files. Data and information may also come from existing IT systems, using sector-specific protocols or more common standards coming from the Internet of Things (IoT) world used to realize data transfers.
- **Cyber**, modelling and in-memory based solutions to convert data into information, leveraging several information conversion mechanisms. Digital representations (of assets, data and information) will be then shared with the upper layers of the pyramid in order to improve the self-healing properties of the overall system.
- **Computing**, storing and using data on the edge or on the cloud. Many modern digital platforms use a combination of cloud and edge computing models, based on driving factors for establishing a more centralized and powerful computation capabilities, or

[17] https://www.go-fair.org/fair-principles/

faster, connectivity-friendly and secure computing at the edge of the digital networked platform. The forces fuelling the demand for distributing computing technologies are advancing rapidly. This will create a paradigm shift for organizations moving along new digital transformation pathways, with potential changes affecting all players in the target business ecosystem.

- **Content/Context**, correlating collected data for extracting information, creating a digital space for data information continuum, not something to push out to one side of the adopted information architecture. Modern businesses need a holistic approach with the end goal of driving the data (processing) and information needs. However, exploiting data is not as straightforward. So, data needs to be acquired (captured, entered via a data pipeline) and processed with a goal and context in mind, making it information, which essentially is about processed data, before moving to the next levels.
- **Community**, sharing data between people and connecting stakeholders for solving collaboration needs. Networked organizations will be able to collect and share knowledge and opportunities in the widest number of sectors so that their members can make the right decisions. The community around organizations could become increasingly important to collect and share information in a push & pull fashion.
- **Customization**, personalizing allow to add value to data following each own user's perspective and to match their expectations. Multiple strategies can make it possible to address all aspects of the end-user expectations and empower an individual to progress through platform functionalities in a natural way. Democratizing access to data is a promising approach to help unlock the value of data, but even the most advanced technology is of little value if people do not embrace it. This is a lesson that many businesses have learned the hard way; in order to avoid pitfalls, it is paramount to properly understand end-user expectations and build the platform from the ground up while keeping in mind that the intended audience, even within a single organization, can be very diverse and must be properly segmented and with specific and varying needs.

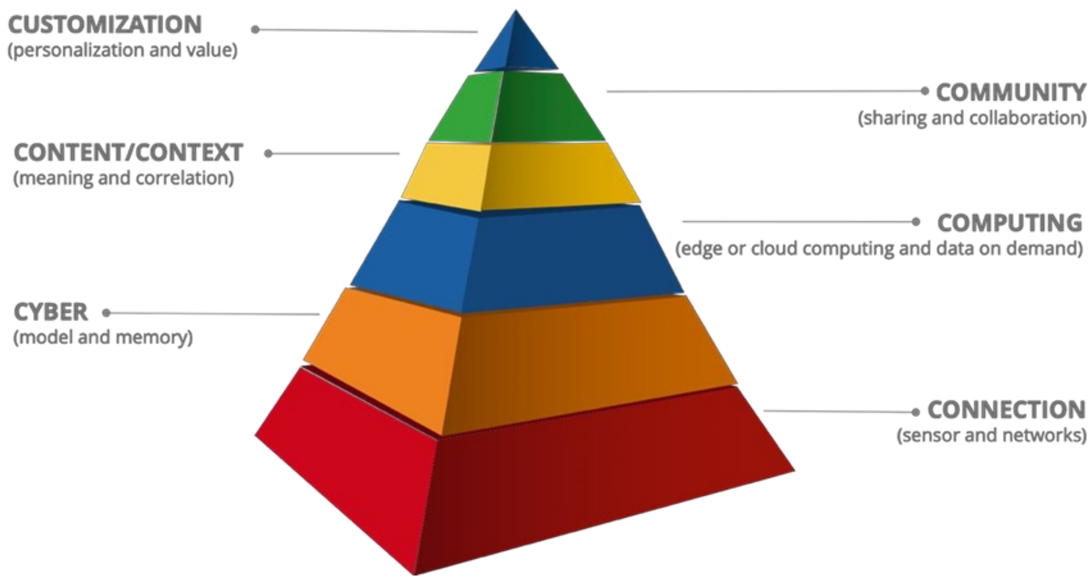


Figure 10: 6C Architectural Model.

The above-mentioned 6C Architecture principles have driven the design of the OPEN DEI RAF, developed around the main concept of Data Spaces in which data is shared (published and accessed), identifying three main different layers described in the following using a bottom-up reading approach:

- **Field Level Data Spaces**: it includes the Smart World Services able to collect data and support the interaction with the IoT Systems (configuration, calibration, data acquisition, actuation, etc.), Automation and Smart Assets (robots, machinery, and related operations) and Human Systems (manual operations, supervision, and control, etc.).
- **Edge Level Data Spaces**: it defines the typical edge operations from the data acquisition (from the logical perspective) to the data processing through the data brokering. The edge services will play a key role also for data analytics (i.e., validating and improving models for data analysis).
- **Cloud Level Data Spaces**: it includes data storage, data integration and data intelligence operations on the cloud. The cloud services will process big data, deploy algorithms, integrate different source platforms and services, provide advanced services such as AI prediction and reasoning.

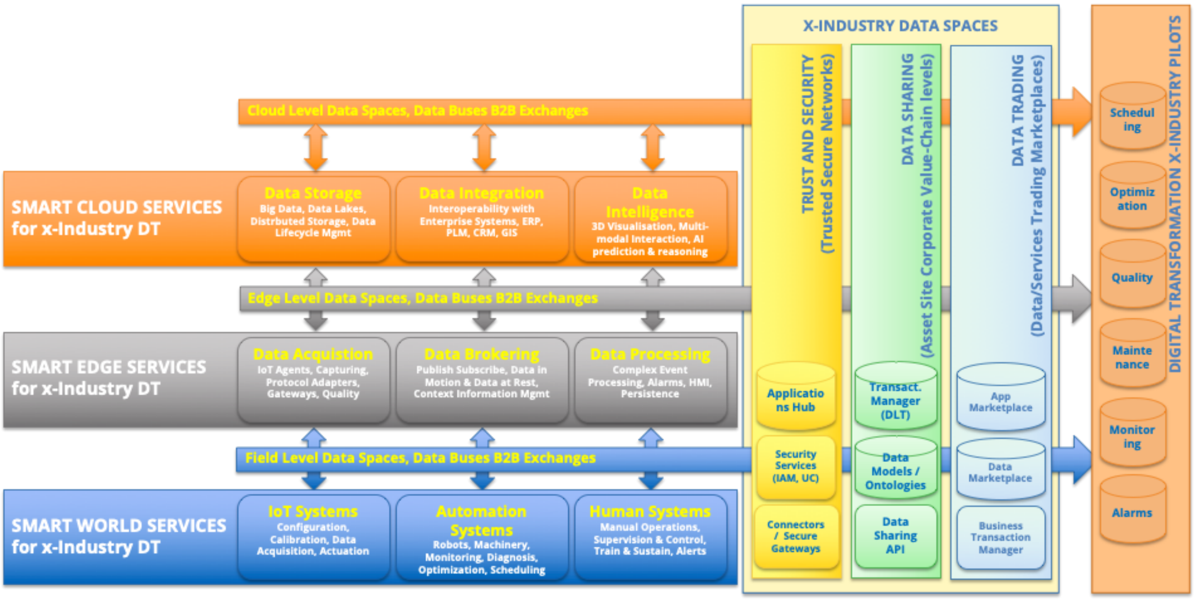


Figure 11: OPENDEI Reference Architecture Framework.

Furthermore, all these horizontal Data Spaces spines will feed the OPEN DEI Reference Architecture Framework a main orthogonal dimension, named **X-Industry Data Spaces**, characterized by the following components:

- **Trust and Security**, incorporating technical frameworks and infrastructures that complements the previous to support trusted and secure exchange, which embraces:
    - **Applications Hub**, an infrastructure which collects the recipes required for the provision of applications (e.g., deployment, configuration and activation) in a manner that related data access/usage control policies can be enforced.
    - **Security Services**, a technical framework to support Identity Access Management, Usage Control and other security services.
    - **Connectors and Secure Gateways**, a technical framework for trusted connection among involved parties.
- **Data Sharing**, incorporating technical frameworks and infrastructures for an effective and auditable data sharing, which more specifically embraces:
    - **Transaction Manager**, a distributed ledger/blockchain infrastructure for logging selected data sharing transactions.
    - **Data Models and Ontologies**, to leverage common standards and information representations.
    - **Data Sharing API**, a technical framework for effective data sharing: a data sharing API.
- **Data Trading**, incorporating technical frameworks and infrastructures for the trading (offering, monetization) of data, which embraces:

- **App Marketplace**, enabling the offering of applications and application building blocks which can be integrated plug & play to enrich existing data spaces.
- **Data Marketplace**, enabling the offerings around data resources with associated terms and conditions including data usage/access control policies as well as pricing schemas.
- **Business Support Functions**, enabling data/applications usage accounting as well as implementing Clearing House, Payment and Billing functions.

All layers mentioned above serve the realization of **Digital Transformation X-Industry Pilots**, for enabling applications (sometimes sector-specific) for supporting business scenarios from experiments. Recent efforts have tried to classify the standards against a reference framework and improve the usability of selected standards:

- An eHealth Interoperability Framework (eEIF) has been defined and its refined version (ReEIF) has been adopted by the eHealth Network in November 2015. This common framework is a means for managing interoperability and standardization challenges in the eHealth domain in Europe.
- A Conformity Assessment Scheme (CAS) for Europe has furthermore been developed. It promotes the adoption and take-up of interoperability testing mechanisms for testing eHealth solutions against standards and profiles defined in the ReEIF.
- The European Interoperability Framework (EIF) supported by the project ISA has also produced 47 cross-domain recommendations for the use of standards and specifications to set up interoperable digital public services.

A set of standards initiatives and bodies in the healthcare domain has been identified which hold a high importance in the healthcare sector.

To support interoperability at the syntactic level:

- HL7-FHIR
- HL7-CDA
- OPEN EHR
- CEN 13606

To support interoperability at the semantic level:

- SNOMED-CT
- WHO classifications (ICD, ICNP, ICF, etc.)
- UCUM, LOINC
- ICPC
- ATC, MedDRA

To support interoperability at the architecture level:

- UniversAAL
- FIWARE
- IDS Reference Architecture

- Continua Health Alliance

To support interoperability testing of use cases:

- IHE profiles

2.2.4 DIH-HERO

DIH-HERO is an independent platform that connects Digital Innovation Hubs across Europe to create a sustaining network for all those who are active in the healthcare robotics sector. The project consortium consists of 17 core partners spread across 11 pan-European countries.

Their primary objective is to accelerate innovation in robotics for healthcare. To connect innovators, providers, businesses, users, and politicians, DIH HERO establishes an open online portal offering multiple services facilitating collaboration on various innovations, emphasizing throughout the value chain. They focus on supporting small and medium-sized enterprises in maximizing their impact and reducing time-to-market.

By connecting businesses and healthcare stakeholders, DIH HERO enables them to develop innovative products and services that are better fitted to the needs of the healthcare systems across Europe. They also engage in necessary standardization for robotics in healthcare, including ethical, legal, and societal issues.

The services they offer are:

- Technology: offering prototyping, research and development, and manufacturing expertise to speed up the development of the product healthcare robotics.
- Certification and Go-to-Market: helping innovators understand customer segments, regulations, and value chains to create a market entry strategy.
- Business Capital and Incubation: Providing access to public and private funding to help in the transformation of innovative ideas into market-ready products.
- Testing facilities and Test Center: enabling product testing and service testing as well as validation in specialized labs and realistic tests environments.
- Training and Education: helping knowledge building for healthcare professionals and technology providers.

In the scope of this deliverable, mostly the technology and testing services will be considered for input.

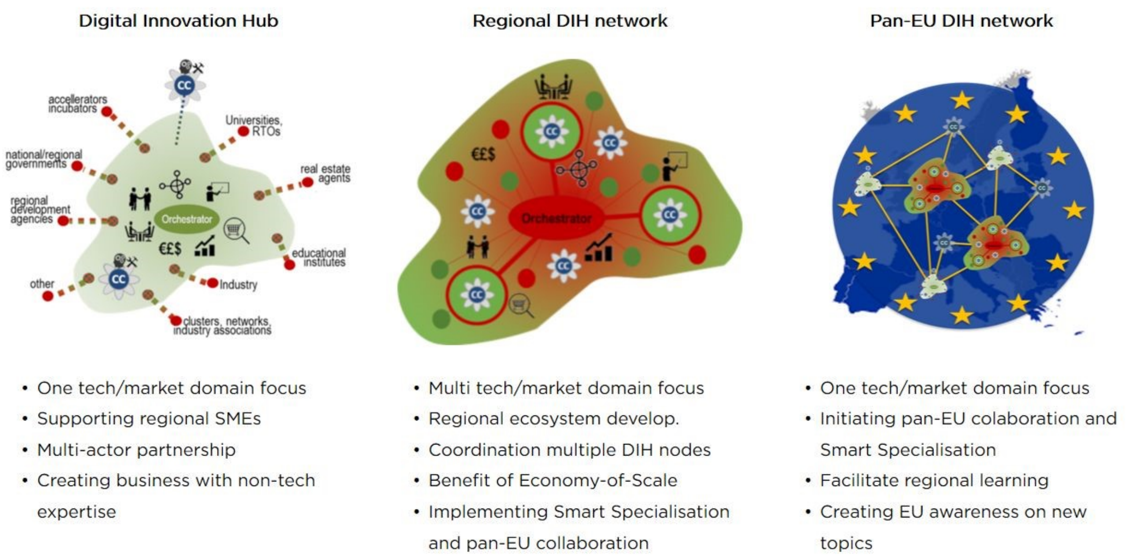


Figure 12: DIH-HERO Platform Schema.

2.3 Other Standards

2.3.1 Health Informatics

The standards used for health informatics are described in the following paragraphs, including two technical committees based on health informatics:

- **ISO 13606-1:2020** – HEALTH INFORMATICS. Communication of the electronic medical record. Part 1: Reference model. (Based on ISO 13606-1:2019)
- **ISO 13606-2:2020** – HEALTH INFORMATICS. Communication of the electronic medical record. Part 2: Archetype exchange specification. (Based on ISO 13606-2:2019)
- **ISO 13606-3:2020** – HEALTH INFORMATICS. Communication of the electronic medical record. Part 3: Reference archetypes and lists of terms. (Based on ISO 13606-3:2019)
- **ISO 13606-4:2020** – HEALTH INFORMATICS. Communication of the electronic medical record. Part 4: Security (Based on ISO 13606-4:2019)
- **ISO 13606-5:2020** – HEALTH INFORMATICS. Communication of the electronic medical record. Part 5: Interface specification (Based on ISO 13606-5:2019)
- **ISO 23903:2021** – HEALTH INFORMATICS. Interoperability and integration reference architecture: Model and framework
- **ISO/HL7 10781:2015** – HEALTH INFORMATICS. EHR FM Release 2
- **CEN/TC 251 HEALTH INFORMATICS**
    - **I:** Information Models.
    - **II:** Terminology and Knowledge Bases.
    - **III:** Security, Safety and Quality.
    - **IV:** Technology for Interoperability.
    - **V:** Force Cards.

- **ISO/TC 215 HEALTH INFORMATICS**
    - **I:** Health Records and Modelling Co-ordination.
    - **II:** Messaging and Communication.
    - **III:** Health Concept Representation.
    - **IV:** Security.
    - **V:** Health Cards.

HL7 (Health Level Seven) refers to a set of international standards to facilitate the electronic exchange of clinical information by the transfer of clinical and administrative data between software applications used by various healthcare providers, please refer to Section 2.1.1.

HL7 International, which is an international standards organization, specifies the number of flexible standards, guidelines, and methodologies by which various healthcare systems can communicate with each other. Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner. These data standards are meant to allow healthcare organizations to easily share clinical information. Theoretically, this ability to exchange information should help to minimize the tendency for medical care to be geographically isolated and highly variable

HL7 standards are grouped into reference categories:

- Section 1: Primary standards - Primary standards are considered the most popular standards integral for system integrations, inter-operability and compliance. Our most frequently used and in-demand standards are in this category.
- Clinical Document Architecture Products - Clinical Document Architecture Products
- Section 1b: EHR – Electronic Health Record – These standards provide functional models and profiles that enable the constructs for the management of electronic health records.
- Section 1c: FHIR – Fast Healthcare Interoperability Resources
- Section 1d: Version 2 - HL7 Version 2
- Section 1e: Version 3 – HL7 Version 3
- Section 1f: Arden Syntax – The Arden Syntax is a formalism for representing procedural clinical knowledge in order to facilitate the sharing of computerized health knowledge bases among personnel, information systems and institutions.
- Section 1g: CCOW – HL7 Clinical Context Management Specification (CCOW) is aimed at facilitating the integration of application at the point of use, as a standard for both internal applications programming and runtime environment infrastructure that complements HL7's traditional emphasis on data interchange and enterprise workflow.
- Section 1h: Cross-paradigm/Domain Analysis Models – Cross-paradigm / Logical Level Standards
- Section 2: Clinical and Administrative Domains – Messaging and document standards for clinical specialties and groups. These standards are usually implemented once primary standards for the organization are in place.

- Section 3: Implementation Guides – This section is for implementation guides and/or support documents created to be used in conjunction with an existing standard.
- Section 4: Rules and references – Technical specifications, programming structures and guidelines for software and standards development.

OPEN EHR is an open standard that describes the management storage of health information in the form of Electronic Health Record (HER) reports. All a person's data is stored in a technology-independent, comprehensive, patient-centric EHR. The standards relevant to Open EHR fall into several categories as follow.

- **ISO/TR 20514** – Health informatics – Electronic health record – Definition, scope, and context.
- **ISO/TS 18308** – Technical specification for requirements for an EHR architecture.
- **OMG HDTF Standards** – General design.
- **CEN EN 13606:2006** – Electronic Health Record Communication
- **CEN HISA 12967-3** - Health Informatics Service Architecture – Computational viewpoint.
- **CEN HISA 12967-2** – Health Informatics Service Architecture – Information viewpoint.
- **CEN ENV 13940** – Continuity of Care.
- **ISO 8601** – Syntax for expressing dates and times.
- **ISO 11404** – General Purpose Data types.
- **HL7 UCUM** – Unified Coding for Units of Measure.
- **HL7v3 GTS** – General Timing Specification Syntax.
- **IETF RFC 2440** – openPGP.
- **CEN EN 13606:2005** – Electronic Health Record Communication.
- **HL7v3 CDA** – Clinical Document Architecture (CDA).
- **HL7v3 messages** – Quality of conversion currently unknown due to flux in HL7v3 messaging specifications and diversity of message schemas.
- **HL7v2 messages** – Importing of HL7v2 message data is technically not difficult and is already used in some openEHR systems.
- **ISO RM/ODP** – Generic Technology Standards.
- **OMG UML 2.0** – Generic Technology Standards.
- **W3C XML schema 1.0** – Generic Technology Standards.
- **W3C Xpath 1.0** - Generic Technology Standards.

2.3.2 AI

The below standard used in AI is published by ISO/IEC:

- **ISO/IEC JTC 1/SC 42** - Standardization around Artificial Intelligence
  - Serve as the focus and proponent for JTC 1's standardization program on Artificial Intelligence
  - Provide guidance to JTC 1, IEC, and ISO committees developing Artificial Intelligence applications

Currently, 31 standards are under the direct responsibility of ISO/IEC JTC 1/SC 42:

1. **ISO/IEC DTS 4213**: Information technology — Artificial Intelligence — Assessment of machine learning classification performance
2. **ISO/IEC AWI 5259-1**: Data quality for analytics and ML — Part 1: Overview, terminology, and examples
3. **ISO/IEC AWI 5259-2**: Data quality for analytics and ML — Part 2: Part 2: Data quality measures
4. **ISO/IEC AWI 5259-3**: Data quality for analytics and ML — Part 3: Data quality management requirements and guidelines
5. **ISO/IEC AWI 5259-4**: Data quality for analytics and ML — Part 4: Data quality process framework
6. **ISO/IEC AWI 5338**: Information technology — Artificial intelligence — AI system life cycle processes
7. **ISO/IEC AWI 5339**: Information Technology — Artificial Intelligence — Guidelines for AI applications
8. **ISO/IEC AWI 5392**: Information technology — Artificial intelligence — Reference architecture of knowledge engineering
9. **ISO/IEC AWI TR 5469**: Artificial intelligence — Functional safety and AI systems
10. **ISO/IEC AWI TS 5471**: Artificial intelligence — Quality evaluation guidelines for AI systems
11. **ISO/IEC AWI TS 6254**: Information technology — Artificial intelligence — Objectives and approaches for explainability of ML models and AI systems
12. **ISO/IEC AWI TS 8200**: Information technology — Artificial intelligence — Controllability of automated artificial intelligence systems
13. **ISO/IEC 20546:2019**: Information technology — Big data — Overview and vocabulary
14. **ISO/IEC TR 20547-1:2020**: Information technology — Big data reference architecture — Part 1: Framework and application process
15. **ISO/IEC TR 20547-2:2018**: Information technology — Big data reference architecture — Part 2: Use cases and derived requirements
16. **ISO/IEC 20547-3:2020**: Information technology — Big data reference architecture — Part 3: Reference architecture
17. **ISO/IEC TR 20547-5:2018**: Information technology — Big data reference architecture — Part 5: Standards roadmap
18. **ISO/IEC DIS 22989**: Information technology — Artificial intelligence — Artificial intelligence concepts and terminology
19. **ISO/IEC DIS 23053**: Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)
20. **ISO/IEC CD 23894.2**: Information Technology — Artificial Intelligence — Risk Management
21. **ISO/IEC DTR 24027**: Information technology — Artificial Intelligence (AI) — Bias in AI systems and AI aided decision making
22. **ISO/IEC TR 24028:2020**: Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence
23. **ISO/IEC TR 24029-1:2021**: Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview

24. **ISO/IEC AWI 24029-2**: Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
25. **ISO/IEC TR 24030:2021**: Information technology — Artificial intelligence (AI) — Use cases
26. **ISO/IEC DTR 24368**: Information technology — Artificial intelligence — Overview of ethical and societal concerns
27. **ISO/IEC DTR 24372**: Information technology — Artificial intelligence (AI) — Overview of computational approaches for AI systems
28. **ISO/IEC CD 24668**: Information technology — Artificial intelligence — Process management framework for Big data analytics
29. **ISO/IEC AWI 25059**: Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI-based systems
30. **ISO/IEC DIS 38507**: Information technology — Governance of IT — Governance implications of the use of artificial intelligence by organizations
31. **ISO/IEC AWI 42001**: Information Technology — Artificial intelligence — Management system

IEEE AI-related standards:

- P2049.1 - Standard for Human Augmentation: Taxonomy and Definitions
- P2049.2 - Standard for Human Augmentation: Privacy and Security
- P2049.3 - Standard for Human Augmentation: Identity
- P2049.4 - Standard for Human Augmentation: Methodologies and Processes for Ethical Considerations
- P2801 Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence
- P2802 Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology
- P2089 - Standard for Age-Appropriate Digital Services Framework - Based on the 5Rights Principles for Children
- P2817 - Guide for Verification of Autonomous Systems
- P3333.1.3 - Standard for the Deep Learning-Based Assessment of Visual Experience Based on Human Factors
- P3652.1 Guide for Architectural Framework and Application of Federated Machine Learning

2.3.3 Robotics and Medical equipment

The main standard used for robotics is the one described below:

- **ISO 13482:2014** - Robots and robotic devices: Safety requirements for personal care robots.

In **ISO 13482**, there are some others documents and norms normatively referenced, becoming indispensable for its application. Some examples of other related norms are:

- **ISO 8373:2012** – Robots and robotic devices.
- **ISO 12100:2010** – Safety of machinery - General principles for design- Risk assessment and risk reduction.
- **ISO 13849-1**– Safety of machinery - Safety-related parts of control systems – Part 1: General principles for design
- **ISO 13850**– Safety of machinery - Emergency stop – Principles for design
- **ISO 13854**– Safety of machinery - Minimum gaps to avoid crushing of parts of the human body
- **ISO 13855**– Safety of machinery - Positioning of safeguards with respect to the approach speeds of the human body
- **ISO 13856**– Safety of machinery - Pressure-sensitive protective devices
- **ISO 13857**– Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs
- **ISO 14118**– Safety of machinery - Prevention of unexpected start-up
- **ISO 14119**– Safety of machinery - Interlocking devices associated with guards – Principles for design and selection
- **ISO 14120**– Safety of machinery - Guards – General requirements for the design and construction of fixed and movable guards
- **ISO 15534**– Ergonomic design for the safety of machinery
- **ISO/IEC 60204-1:2009**– Safety of machinery - Electrical equipment of machines – Part 1: General requirements
- **ISO/IEC 60335-1** – Household and similar electrical appliances – Safety – Part 1: General requirements
- **ISO/IEC 60335-2-29** – Household and similar electrical appliances – Safety – Part2-29: Particular requirements for battery chargers
- **IEC 60417-1** – Graphical symbols for use on equipment – Part 1: Overview and application
- **IEC 60529** – Degrees of protection provided by enclosures (IP Code)
- **IEC 60825-1** – Safety of laser products – Part 1: Equipment classification and requirements
- **IEC 61140** – Protection against electric shock – Common aspects for installation and equipment
- **IEC 61496**– Safety of machinery - Electro-sensitive protective equipment
- **IEC 62061:2012**– Safety of machinery - Functional safety of safety-related electrical, electronic, and programmable electronic control systems
- **IEC 62471** – Photobiological safety of lamps and lamp systems

2.3.4 Security and privacy

General digital security, IT governance, and eHealth:

- **ISO/IEC 27000** - Information Security Management Systems (ISMS) Family of Standards, in particular:

- **ISO/IEC 27001:2013** - Information security management systems — Requirements
- **ISO/IEC 27002:2013** - Code of practice for information security controls
- **ISO/IEC 27003:2017** - Information security management systems — Guidance
- **ISO/IEC 27031:2011** - Guidelines for information and communication technology readiness for business continuity

- **ISO/IEC 38500:2015** – Governance IT for the organization
- **ISO/IEC 31000:2018** – Risk management - Guidelines
- **(EU) 2016/1148** of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (ENISA NIS Directive on security of network and information systems**)**
- **COM/2020/767 final** - Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act)
- **C(2019)800** - Commission Recommendation on a European Electronic Health Record exchange format of 6 February 2019 (EHR)
- **93/42/EEC, Regulation (EU) 2017/745** - European Medical Devices Directive (MDD)
- **ISSAF standard** – OWASP Penetration Testing Methodology

Robotics and AI:

- **2015/2103(INL)** - European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics.
- **COM/2021/206 final** - Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts
- **COM (2018) 237** - Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Artificial intelligence for Europe.
- **COM (2018) 795 final** - Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Coordinated Plan on artificial intelligence.
- **COM (2020) 64 final** - Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics

Privacy:

- **(EU) 2016/679 GDPR** - On the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- **Preliminary Opinion 8/2020** on the European Health Data Space (EDPS, European Data Protection Supervisor)
- **COM (2017) 10 final (ePrivacy Regulation, ePR)** - Regulation of the European Parliament and of the Council concerning the respect for private life and the

protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications)

- **2002/58/EC** of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)
- **2011/24/EU** of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
- **ISO 25237:2017** - Health informatics — Pseudonymization
- **ISO/IEC 20889:2018** on Privacy-enhancing data de-identification terminology and classification of techniques (Anonymization)

Other worldwide standards:

- **HIPAA Standards** for Privacy of Individually Identifiable Health Information (45 CFR parts 160 and164) USA
- **Health Insurance Portability and Accountability Act** of 1996 (HIPAA) USA
- **ISA/IEC 62443** - A series of standards including technical reports to secure Industrial Automation and Control Systems (IACS). Medical Devices (Health), Cybersecurity
- **NEN-7510 (NL)** -This standard provides guidelines and principles for determining, setting and enforcing measures that an organization in the healthcare sector must take to protect the information provision. Cybersecurity (Netherlands)
- **NEN-7512** - Health informatics - Information security in healthcare-Requirements for trusted exchange of health information (NL)It applies to electronic communication in healthcare, between healthcare providers and healthcare institutions and with patients and clients, healthcare insurers, and other parties involved in healthcare. Cybersecurity, (Netherlands)
- **NEN-7513** - Health informatics - Recording actions on electronic patient health records (NL) Cybersecurity (Netherlands)
- **Hébergeurs de Données de Santé (HDS)** - The Hébergeurs de Données de Santé (HDS) certification is required for entities such as Cloud service providers that host the personal health data governed by French laws and collected for delivering preventive, diagnostic, and other health services (Cloud Security France).

3 Technical analysis of stakeholders' requirements

The original data that are analysed in the below sections originate from the answers that the project partners provided to the Platform Survey (Appendix A), the T1.3 Questionnaire (Appendix B.2) and from HosmartAI deliverables that have already been submitted, such as D1.2, D1.3 and D6.7.

3.1 Platform survey analysis

The platform survey contained questions on the topics of application development, deployment orchestration, deployment sites, technologies to be used, AI tools, data storage and data access by consumer applications.

3.1.1 Platform technologies analysis

The following responses were received. These responses were analysed to make deductions on how to facilitate the development and usage of the HosmartAI platform.

Table 3: Application development.

Would you be able to develop new software that supports gRPC or you would like to use another protocol, such as REST?
• Not applicable in our case. The current plan is to develop standalone desktop apps. (SPBTU) • Preferably REST. (iMEDPHYS)
EXYS is developing the security and privacy infrastructure for the HosmartAI project, therefore a "supporting" system. For this REST communication protocol would be preferable, but we remain completely open to other standards (like gRPC or classical XML-based web services, etc.).
A protocol other than gRPC would be preferable.
Up to now, INTRAS does not have experience with gRPC, since we are currently using REST that works appropriately for our applications. Nevertheless, we are open to try new solutions, as gRPC.
I would like to have a REST web services.
Up to now, VIMAR does not have experience with gRPC, since we are currently using REST that works appropriately for our applications. Nevertheless, we are open to trying new solutions, as gRPC.

Based on the above responses, we conclude that gRPC is perceived by partners as a reasonable alternative to more popular protocols such as REST. However, most partners are familiar with REST as they use it in existing technology assets, although they remain open to try gRPC. Consequently, the current plan for the HosmartAI platform is to use REST as the main communication protocol. However, gRPC-based models coming from the AI4EU Catalog and new model onboarding through Acumos will be supported.

Table 4: Deployment orchestration preferences.

Please explain your thoughts on whether a Kubernetes or a plain Docker deployment would be the preferred option when an application that has been created in the HosmartAI Platform needs to run on a Pilot site (if this question is applicable to you).
• We prefer simple Docker. (SPBTU) • We plan to have dockerized services. We can also manage to run our services on a Kubernetes environment. (iMEDPHYS)
• Deployment of the security/privacy infrastructure would be preferably done with simple Docker or Docker Composer. • We have less experience with Kubernetes.
Our Platform is embedded with low capacity and uses ARM processors. Containers are not suitable for that.
INTRAS has no experience with Docker as INTRAS applications so far have not required it. We are not in a position to give an opinion on this matter.
I would prefer to use Docker for orchestration of my developments.
VIMAR has experience with Docker, but not with Kubernetes, thus we cannot evaluate its viability in the HosmartAI platform. However, we do not exclude the possibility to use Kubernetes in our solutions.

In the above responses, we see that Docker containers, or no containers are preferred, although in some cases partners are open to experiment with Kubernetes. Consequently, the current plan for the HosmartAI Platform is to use Docker containers. However, model deployment through Acumos to Kubernetes is supported.

Table 5: Deployment orchestration in Pilots.

Are you aware of Pilot assets where software from the Platform cannot be deployed either in Docker or Kubernetes? Is there a specific method that the assets should be deployed? What is this method?
• At this stage, Docker is considered sufficient for our needs. More complex needs may arise during development. (SPBTU) • Most probably no. (iMEDPHYS)
• Docker is sufficient. • No specific methods are needed by us, at this stage.
We are on the Edge and not in the cloud. The method is to use embedded programming to reduce the energy consumption.
Outside the scope of INTRAS, since the integration with Gradior will be limited to sending the results of the Gradior sessions to the HOSMARTAI platform for subsequent exploitation.
No, we are not aware of assets that cannot be deployed in Docker or Kubernetes.

As we see in the above partners’ responses, most Pilot assets are expected to be compatible with Docker, which is in line with the current plan for the HosmartAI Platform to use Docker containers.

Table 6: Deployment sites.

Would you be able to use the applications that are deployed on the cloud or you will require all applications to be deployed locally? If you cannot use cloud applications in some cases can you explain the reasons and the circumstances?
• All services will be deployed locally since it is not good practice to transfer medical data outside the hospital. (SPBTU) • Back-end of the use case applications will run locally. AI models could run on the cloud (using anonymized data), if needed. (iMEDPHYS)
All applications deployed on the cloud or locally can be monitored in principle by the security infrastructure. However, specific requirements for particular circumstances could arise in more mature stages of the pilots' implementation.
We deploy locally for security, data sovereignty and energy consumption.
The Gradior Cognitive App for the rehabilitation sessions are installed on the user's (patient's) devices: Android Tablet, Windows 10, etc... Gradior apps can be used online / offline.
I would like to deploy my applications on cloud system.
We do not exclude that some situations may require a local deployment of applications, mainly to guarantee the continuity of the service in case of connectivity issues, data privacy and security. For these reasons, we suggest for the applications the possibility to be deployed locally.

Based on the above answers, we observe that most applications will be deployed locally although some of them will use cloud components.

Table 7: Platform technologies.

Which platform technology do you think would be the preferred one? Would Acumos AI Platform be useful as part of the main platform? Can you explain your view based on specific reasons and requirements? Other platforms or technologies that could potentially be better options?
• Acumos could provide an interesting solution for AI model dockerization and deployment, however it is not considered mandatory, as we depend on the FAST framework (https://fast.eriksmistad.no/) for AI model inference purposes. Other interesting technologies that could be of use are NVIDIA Clara (https://developer.nvidia.com/clara) and Jupyter Notebook equipped with package manager such as pip. (SPBTU) • Acumos would be ideal to use for the AI models' deployment. (iMEDPHYS)
Our preferences focus on those platform technologies which can guarantee the most security and privacy.
INTRAS has no experience in this matter so we cannot assess the use of Acumos AI Platform.
VIMAR does not have elements to evaluate if Acumos AI would be a good choice. However, the example of AI4EU suggests that Acumos AI could be a useful tool to provide a uniform and standardized solution.

In their answers above, partners do not strongly recommend any platform technologies in particular and express their agreement with having Acumos AI Platform as an available option.

Table: 8 AI Tools.

Which version of each tool is required? Can it be deployed in the pilot sites? Can you describe the process in which it is required?
• The last stable version of FAST framework provides us all required AI tools. (SPBTU) • Latest stable version of python and pip package manager. Other indicative tools and libraries to be used for development and/or testing purposes are: scikit-learn (https://scikit-learn.org/stable/), pandas (https://pandas.pydata.org/), NumPy (https://numpy.org/), XGBoost Python Package (https://xgboost.readthedocs.io/en/latest/python/index.html), etc. (iMEDPHYS)
Our preferences focus on those tools which can guarantee the most security and privacy.
That will depend on the use case for the robot deployment.
We cannot answer this point since we have not planned to deploy AI tools on the platform.

In the above answers, libraries that can be installed through the Python Package Index are mentioned. This is something that has already been considered and will be supported by the HosmartAI platform.

Table 9: Platform storage.

From the above data (referring to 3.3.1), which (if any) will need to be catalogued in the Platform or its marketplace? How will this data be accessible (REST, SFTP, etc.)? Is there a specific need to store data in the Platform (the Platform in general should not be considered as a data repository)?
The datasets (CAMUS, EchoNet, Kvasir) are already publicly available, so HosmartAI platform can provide a link to the official website of the dataset providers.
Currently not applicable to us. Depending on the details of the Platform implementations, curated security event logs could be generated and stored in the system. In that case, no specific need of accessibility protocol (although we prefer REST) or storage is required.
Yes, in principle from INTRAS we have proposed sending the results of the Gradior sessions to the platform so that they are accessible and available for exploitation.
The above-listed Smart Home Data will be not directly available on the platform.

In the above answers, we see that some data, such as the results of Gradior sessions, will be stored in the platform, while the rest of the data such as publicly available data, do not need to be copied onto the platform.

Table 10: Data access by consumer applications.

How are the data to be consumed exposed to the consumer application? Please describe the expected location of the application and the location of the data that each application uses.
Data will be retrieved from local directories using the file management system (e.g., windows explorer). The app will be installed, and the data will be stored in a local (to the pilot site) computer.
Currently not applicable to us. Depending on the details of the Platform implementations, curated security event logs could be generated and exposed to selected consumer applications. In that case, no specific need of application/data location is required.

The data consumed by the App will be hosted on INTRAS servers. The results of the sessions are sent to the HOSMARTAI platform.
Raw data will be not exposed directly to the consumer application.

From the above answers, it does not seem like data from the platform will need to be consumed from a remote location.

3.1.2 Platform scope analysis

The contents of this section are also included in D1.5. This section is included in D1.6 for completeness.

The partners that participate in HosmartAI gave the below answers to four questions related to which area they perceive as most benefited by HosmartAI.

The first question (Figure 13) puts more emphasis on the interoperability between existing solutions. We observe a high level of agreement between all partners, pilot that HosmartAI will provide interoperability.

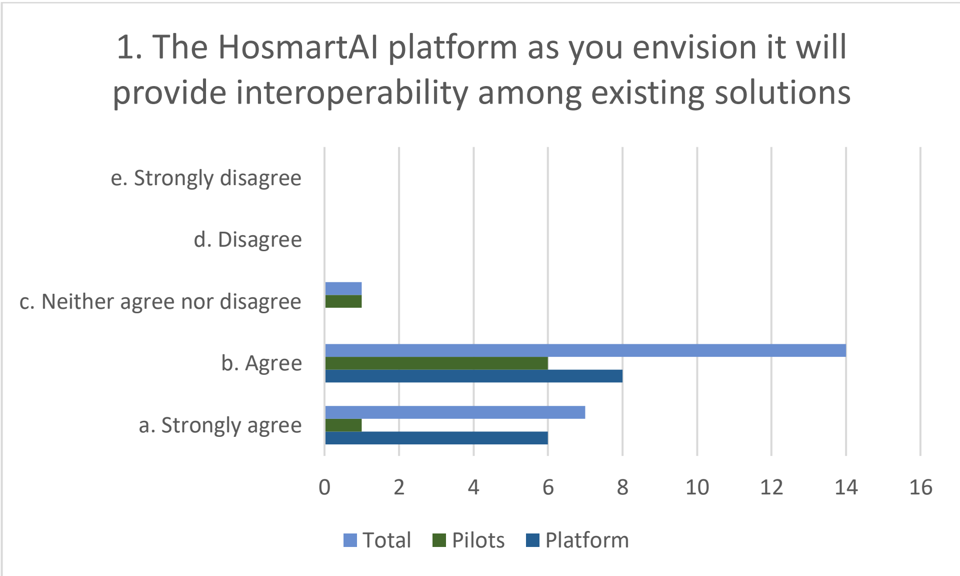


Figure 13: Platform scope question 1.

The second question (Figure 14) is about adding features to existing solutions and it is the one with the strongest level of agreement. Both Pilots and Platform partners demonstrate a similar pattern in their answers, which can be interpreted as a matching view between them.

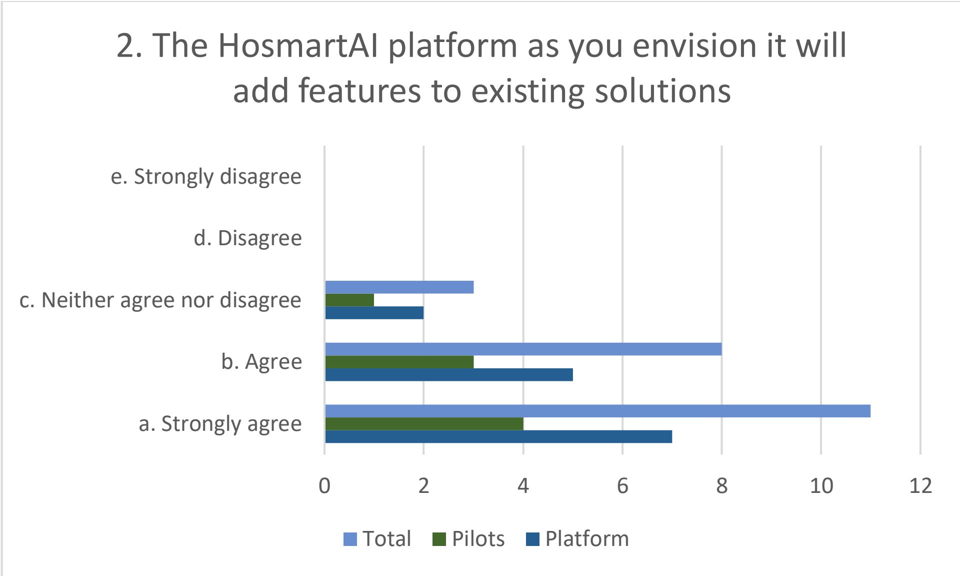


Figure 14: Platform scope question 2.

The third question (Figure 15) is about HosmartAI supporting the development of a new solution, to which most partners answered positively, although “Agree” is clearly ahead of “Strongly Agree”.

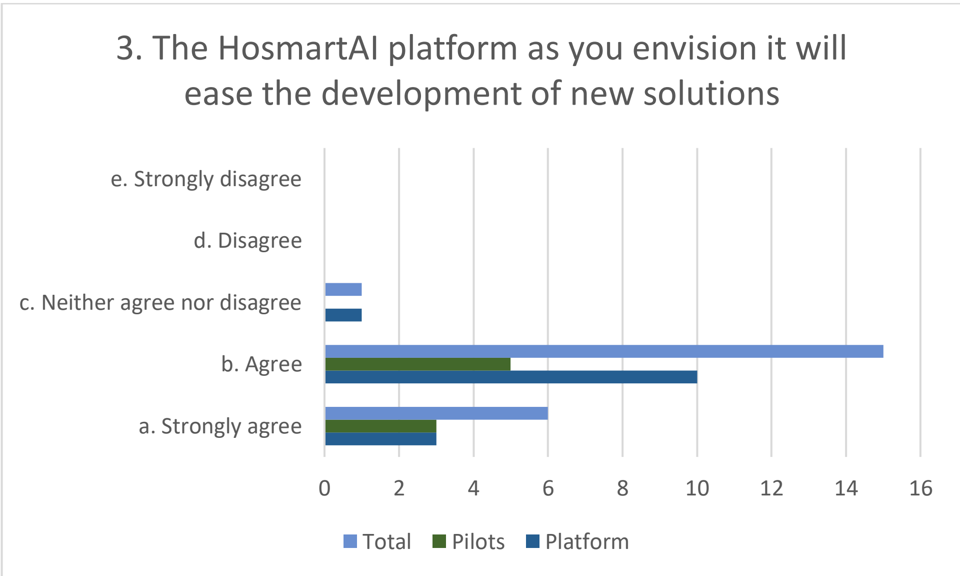


Figure 15: Platform scope question 3.

The fourth question (Figure 16) is about the HosmartAI marketplace evolving into an EU-wide store for AI-powered solutions. Here we observe more “Neither agree nor disagree” than “Strongly agree” answers, although there were no opposing views. This could be translated as indifference to the role of the Marketplace, especially between Pilot partners.

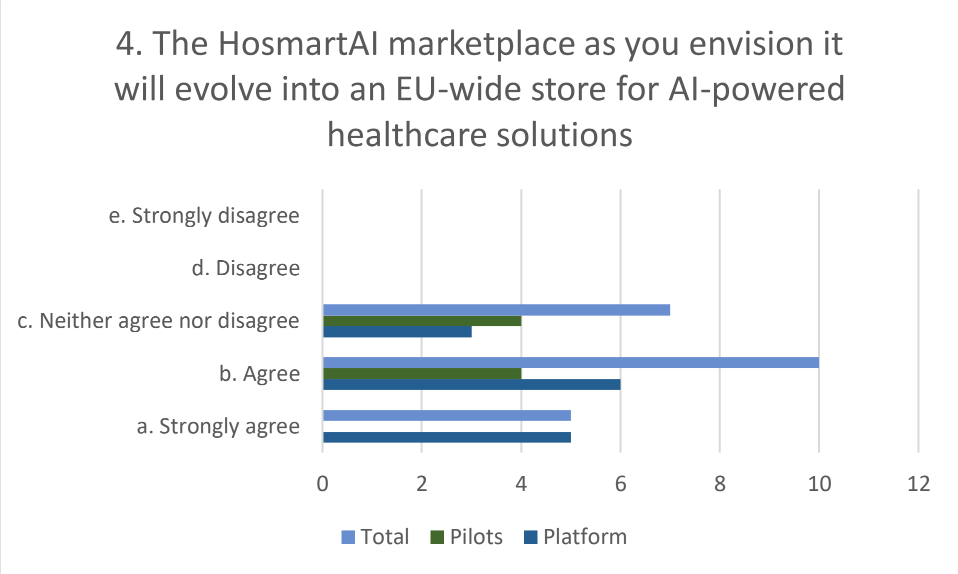


Figure 16: Platform scope question 4.

Overall, we notice that the levels of agreement to the above statements are remarkably high.

Three more open-ended questions were included in the survey. The questions and answers as provided by partners are shown below.

Table 11: Views of HosmartAI as development platform.

How do you envision HosmartAI as a deployment platform?
A cloud-native platform (SaaS) integrated with hospital systems electronic medical records and laboratory equipment, providing actionable analytics during patient analysis and treatment of disease conditions, real-time feedback and guidance during procedures, and assessment of results and outcomes – all generated on the basis of collective intelligence from big data.
Based on the heterogeneity between the pilots' medical scenarios, the platform should be decentralized, so that each partner has the flexibility to develop the tools needed in the wanted way, without burdening the entire platform. Some best practices may need to be adopted, so that there is homogeneity in the architecture of the overall system.
Deploying new personalized solutions will respond more quickly to customer demand with new updates and deliver new features more frequently to drive customer satisfaction, satisfy user needs and take advantage of economic opportunities.
As a valuable resource. HosmartAI in itself will provide an example of what is possible to achieve and will provide manifold components and solutions
The HosmartAI platform should provide live access to the intraoperative data source in the cathlab so that the robotic platform can connect to those data sources.
A full ecosystem intended to support professionals in the healthcare and medical sector, in increasing their qualitative and quantitative performances, integrating information coming from multiple sources, using innovative technological resources (AI, Robotics), meeting state-of-the-art standards and levels of data security and privacy.
HosmartAI will facilitate the deployment of the developed applications on any environment with support of specific and widely used deployment tools. Applications

will appear on a centralized catalog, but the actual development environment can be complemented separated from the platform without making the deployment of the tool any more difficult.
A catalogue of modules and developments, with users, will have high interest of very specific applications and specific equipment. It will allow reusing code to connect new equipment for data acquisition; and integrate data from many heterogeneous sources, responding to mostly to care-centre-specific situations.
A marketplace with AI solutions/technologies separated per disease area, or multiple disease areas and each stakeholder (hospital/healthcare sector/department etc.) will be able to download/plug in the AI technologies of interest.
The platform is an environment for stakeholders to design and develop AI-enabled solutions jointly based on their needs and challenges. The platform will extend the coverage of interoperability across the data, existing platforms, digital/ physical services, and connecting various Healthcare stakeholders and advisors with providers of ICT/AI-based solutions. The platform will provide a possibility to analyze and identify cost-benefit evidence of already deployed solutions through benchmarking within similar environments. It will also create knowledge exchange related to process optimization crucial for decision-makers and let third-party developers deploy their AI-based solution via Open Calls.
Sort of modern typical mobile app store type
HosmartAI platform should be a flexible environment encouraging the development of new ideas and solutions. The platform would provide know-how and data to promote the development of innovative solutions and smart devices while ensuring European standards for medicine and software.
We believe that the deployment of the HosmartAI platform could be done through the intermediary of a service provider which would facilitate a module from the HosmartAI platform to the module of a specific client.
HosmartAI platform should be a flexible environment encouraging the development of new ideas and solutions. The platform would provide know-how and data to promote the development of innovative solutions and smart devices while ensuring European standards for medicine and software.
The HosmartAI platform should provide live access to the intraoperative data source in the cathlab so that the robotic platform can connect to those data sources.
In general, beyond the marketplace, it should not be centralized, but edge-based and modifiable per requirements of specific real use (or more cases)
We envision HosmartAI platform with direct access for the health care ecosystem. Any organization could access its features and find what is more relevant to it according to its profile (marketplace, benchmarking module, knowledge manager, challenges to develop and implement, development frameworks, etc) and create cooperation networks to take the developments/pilots further. It is important to develop a marketing strategy that promotes HosmartAI as a single-entry point to easily offer/find opportunities to collaborate in AI based tools and pilots, also enabling the demand and the offer to meet. The decision-making process based on evidence and data and benchmarking is a must, and we should attract public health systems to it trying to involve them in order to boost AI regional policies that are favourable to the growth and deploy of HosmartAI.
The platform can be a kind of app store containing AI-based applications. Deployment will typically require tuning since the applications have been developed for a particular clinical area.

Initially by connecting to existing solutions, later by integrating them and making solutions more broadly useable. Also, help with adhering to European medical standards for software.

Table 12: Views of HosmartAI regarding AI solutions.

How do you envision HosmartAI replacing existing solutions with AI-powered ones? Can you provide examples?
As an example, of cardiac ablation, AI will be used to enhance electrocardiac mapping, add a continuous time function, and predict outcomes on the basis of intended procedures/ablation areas prior to such procedure being implemented. Ultimately AI powered algorithms will be able to create indicative electrocardiac maps without any interventions, and possibly generate further intelligence that can better identify the source of erratic electric activity in the heart, such as atrial fibrillation. AI models, such as k-neighbours, can further be used over big data databases of large patient pools to create patient cohorts and applicable disease and treatment differentiation, ultimately narrowing the scope of treatment on the basis of specific patient characteristic typical of a cohort, finally leading to the limits of personalized patient treatment or precision medicine. In cardiology and EP specifically, this is especially achievable and attractive because of the vast amount of data and research databases available, as the number of devices and procedures that obtains these data points routinely is highly prevalent and extremely frequent through countries, including the most remote areas (via remote patient monitoring).
An important characteristic of AI-powered solutions is the potential to continuously improve by leveraging new data, generated as time progresses. In this sense, data stemming from existing procedures will enable the development of robust AI models that may replace or enrich existing pipelines. AI-assisted diagnostic tools (Pilot 1) can help improve time and resource efficiency, reduce fatigue and decision variability among specialists, while maintaining high accuracy and reliability.
Starting from existing solutions, adding the “learning from experience” from multiple sources processes
HosmartAI should provide live access to the intraoperative data with low latency so that the robotic solution can use those data to use them intraoperatively to control our robotics systems.
The AI solution provided by HosmartAI will encompass a broader healthcare domain than the one usually covered by existing solutions.
HosmartAI can be used for developing components with continuous collaboration leading to gradually replacing more and more existing solutions and processed with AI-powered ones. Also, new data added to the HosmartAI platform could accelerate the improvement of AI-powered solutions. Medical procedures is one area that HosmartAI can be used to create many new AI-powered solutions.
The AI solutions will enable using more data as inputs, providing more precise and holistic solutions.
The AI technologies will offer speed, consume less resources and process information in time 0.

The E-health solutions will be faster than their existing counterparts and operate in real-time timescales – the measurements that were done previously physically will be automated, resulting in substantial time-saving benefits for medical staff. Digital optimization of treatment appointment process taking into account complex and continuously changing criteria will ensure the best possible utilization of medical (treatment) recourses. Data received from the treatments/ clinical analyses/medical device tests /drug prescriptions will be safely stored and accessible for healthcare providers for the future patient treatment plans, no risk to lose the data, all stored in one place.
AI has the capability of dynamically adapting to new solutions and new data. This peculiarity gives the possibility of developing personalized and adaptable solutions. In the field of Neurological disease rehabilitation, AI would provide support for clinicians monitoring patients and ensure patients' safety, even in their homes.
The scheduling of appointments in the radiotherapy department is currently carried out by coordinators who must avoid harming a group of patients when one of them requires a change of appointment. Thus, a solution with an AI-powered ones could partially or completely replace the coordinators
AI has the capability of dynamically adapting to new solutions and new data. This peculiarity gives the possibility of developing personalized and adaptable solutions. In this sense, data stemming from existing procedures will enable the development of robust AI models that may replace or enrich existing pipelines. In the field of Neurological disease rehabilitation, AI would provide support for clinicians monitoring patients and ensure patients' safety, even in their homes.
HosmartAI should provide live access to the intraoperative data with low latency so that the robotic solution can use those data to use them intraoperatively to control our robotics systems.
As a complementary role. i.e. support tool in clinical decision making (i.e. XAI), providing extra engagement in nursing (nor replacing per see)
We think that this important question should be treated at the time of designing the business model of HosmartAI. Addressing market entry barriers is essential since at least in our country (Spain)the innovation/technology reluctance organizational culture in the health care sector and social-health care is prominent (e.g. it is one of the last sectors in the digitization process). Convincing the future clients and policy makers in this kind of investments will be one of the hardest tasks. However, HosmartAI can help them in an evidence-based decision-making, taking as a reference what other regions/care organizations are implementing, measured by KPIs, etc. The open solutions are also a competitive advantage to convince and attract clients
AI has the potential to improve existing applications, but it will only be able to do so if the applications have been trained with sufficient amounts of high quality, balanced data.
The widest scope for AI is in our view in i) integrating patient information and ii) using AI to analyze the data to obtain a more holistic view towards diagnosis, as well as treatment.

Table 13: Views of HosmartAI platform regarding interoperability.

How could the HosmartAI platform improve interoperability between existing platforms?
Interoperability means an ability to integrate existing patient electronic records and other patient data together with medical devices that are used for obtaining information as well as performing procedures. This can be further extended by integrating patient data with large databases of other patients and relevant patient cohorts to leverage AI in defining treatments on personalized patient basis. AI can further improve interoperability by narrowing the translation burden/communication barriers between systems, as it can be used for complex event processing and real-time data transformation to match existing platforms without the need for innate adoption within each platform. AI modules can be used as extremely fast and extremely efficient translation and communication layers among a vast variety of data standards and varying devices/device types.
The common semantic data model will employ standardization strategies to facilitate the exchange of mutually beneficial information across heterogenous platforms, enabling interoperability and reuse. In addition to data, platforms may make functionality openly available through a common interface, reducing the need to develop tools that already exist or allowing for cross-platform validation of common methodologies. This could greatly streamline and accelerate the future development of more sophisticated and feature-rich solutions.
Providing specific interfaces, finding the intersection of standards between processes
By taking up and building on standards that are emerging, aligning with standards of existing platforms
Defining standard to have live access to the intraoperative data. At the moment most of the standard (e.g. DICOM) is used to store the data postoperative and do not provide live access during the procedure.
Interoperability between existing platforms will be eased, improved and extended by the vast set of functionalities that the HosmartAI solution will provide, both in terms of AI methodologies/algorithms and robotics services.
Integration of multiple IoT devices and services from various vendors via a single platform
The HosmartAI applications will use common interfaces that other existing platforms already utilize.
It will facilitate the reuse of interoperability solutions and adapt them to include other systems and thus facilitate interoperability of an ever-increasing number of equipment and other data sources. HosmartAI's catalogue will be a large inventory of solutions that enable wide data acquisition from heterogeneous sources, and additionally provide AI tools using these data.
Interoperability could be achieved by identifying the common operating items of each platform/technology. All technologies/platform need at the end of the day/project to use "common" language.
Interoperability among different existing platforms will give substantial amount of data to utilize while developing AI-tools (low-cost & short-time solutions) and optimizing internal processes/logistics
By using open standards and well-defined interfaces

HosmartAI platform would be standardized and open, thus its architecture would promote collaboration among groups and even different platforms. Furthermore, adherence to medical and software standards would ensure interoperability between different use cases.
The solution should be generic and applicable to other concepts. In addition, Pilot # 2 has a conversational robot system (chatbot) which requires interoperability with the AI solution.
The common semantic data model will employ standardization strategies to facilitate the exchange of mutually beneficial information across heterogenous platforms, enabling interoperability and reuse. In addition to data, platforms may make functionality openly available through a common interface, reducing the need to develop tools that already exist or allowing for cross-platform validation of common methodologies. This could greatly streamline and accelerate the future development of more sophisticated and feature-rich solutions. HosmartAI platform would be standardized and open, thus its architecture would promote collaboration among groups and even different platforms. Furthermore, adherence to medical and software standards would ensure interoperability between different use cases.
Defining standard to have live access to the intraoperative data. At the moment most of the standard (e.g. DICOM) is used to store the data postoperative and do not provide live access during the procedure.
In clinical setting and non-clinical setting with standardization of data formats
The HosmartAI Pilots experience should represent a first step in achieving a significant interoperability. Lessons learned can be taken to expand this interoperability framework to achieve further applicability with other selected platforms.
Difficult to answer this question since I lack the insights about other existing platforms. Which ones do you mean here? In general, a platform that will facilitate data sharing will be valuable since this is essential for the development of AI-based applications.
Providing technical support, identifying interoperability issues and solutions

3.2 Used components analysis

The following table defines the different components that are used on the pilots. In this table, information can be found about the name of the component, the different pilots where the component can be used, a small description of the main functionalities/purpose of the component and additional information about requirements needed to integrate the component with the platform, other components or other functional requirements.

Id	Pilot	Title	Functionalities	Integration
1	1, 3, 6	iPrognosis application	Remote Monitoring of Parkinson symptoms - Automatic collection of data (**APP**) - Automatic machine learning on the **cloud** **- Generation of biomarkers** indicating the severity of the disease	- **Cloud infrastructure API** (To transfer and/or process the data) - **Potentially a Virtual Machine**

Id	Pilot	Title	Functionalities	Integration
2	1, 3, 6	iPrognosis Motor Assessment Tests	Remote assessment of Parkinson disease motor capacity - **Camera** sends input to the **cloud**, - **Cloud** processes the data, Comparing user vs expert movements	- **Cloud infrastructure API** (To transfer and/or process the data) - **Potentially a Virtual Machine**
3	2	**Scheduler optimization**	Scheduler for radiotherapy **- User Interface for patient and doctors**	- FHIR and DICOM - Automatic and dynamic Information
4	3	**Connected Gateway**	Exposes the local framework to the **user app through VIMAR cloud** **- Bluetooth technology Wi-Fi device** **- Dialogue with wireless devices and voice assistants** **- Configuration, supervision, system diagnostics**	- VIMAR cloud connection - Socket connection
5	3	**Connected 2-way switch**	**- Electronic connected switch** Switch mechanism via - on-board push button, **- wireless connection** - a traditional remote push button	- Wireless connection to Gateway
6	3	**Connected rolling shutter mechanism**	**- Mutually exclusive activation of the relays with a minimum interlocking time.** Control the roller shutter/slat via - the on-board keys **- wireless connection**. **- Internet connected.**	- Wireless connection to Gateway
7	3	**Connected actuator**	**-** Protect against overcurrent by cutting off the load when the threshold value is exceeded. - Relay operation: two-position stable or one-position stable with current meter - One-position stable activation time - Set up using the **View Wireless App.** - Load reactivation from the front push button - Load reactivation using **the View App.** - View the instant power consumed with **the View App**	- Wireless connection to Gateway
8	3	**Monophase IoT energy meter**	- measure the consumption/production of instantaneous electricity and	- Wireless connection to Gateway

Id	Pilot	Title	Functionalities	Integration
			consumption **logs** with an **hourly, daily, monthly and annual resolution** - Energy consumption/production **- Monitoring** of instant power consumption/ production **- Monitoring** of instant energy consumption/ production	
9	3	**NFC/RFID smart card landing reader**	**- Grants access** only if the smart card associated with it is read and recognised - Controlled and configured by using View **Wireless App** - Recognition of the smart card (that triggers the door opening) - Anomaly detection on the reader - Do Not Disturb signalling - "Crossover relay" option for combined operation with card reader pocket	- Wireless connection to Gateway
10	3	**NFC/RFID smart card reader pocket**	- Activation of utilities only if the **wireless** smart card associated with it is read and recognised - Controlled and configured by using View **Wireless App** - Recognition of the smart card (with toggle off if card removed) - "Crossover relay" option for combined operation with card landing reader	- Wireless connection to Gateway
11	3	**Ultra Wide Band (UWB)**	**- Detect human movement/presence** without using Fresnel lens - People Presence/absence - Micro movements detection - Load activation - Area/volume of detection parametrization	- Wireless connection to Gateway
12	3	**Cloud View**	**- high-performance infrastructure to handle real-time data, based on AWS services.** - Resources **monitor** - Security monitor - Audit log – compliance **- Data storage**	- Cloud Infrastructure - Gateway connection
13	4	**Mobile Robotic Magnetic Navigation Platform**	- robotic system to control magnetic catheter and magnetic endoscope by generating an external magnetic field	Ethernet socket to connect to the robotic platform to send desired magnetic field.

Id	Pilot	Title	Functionalities	Integration
14	5	**Robot Pepper**	- Interaction - Data Visualization - Collection of PROs - Games and digital activities	CE Certification
15	5	**Multimodal sensing network**	- Collection of objective biomarkers; we consider: physical biomarkers collected medical grade telemonitoring platforms measuring and blood pressure, heart rate - Collection of subjective biomarkers; we consider: speech-related and acoustic biomarkers, face related and language-related features expressed during interaction and classification of symptoms of psychological distress (depression)	GPU enabled hardware
16	5	**Speech Recognition System SPREAD**	**- Speech to text** - Spoken language understanding	GPU enabled hardware
17	5	**Speech Synthesis System PLATOS (DNN version)**	**- Speech synthesis**	GPU enabled hardware
18	5	**Chatbot (DNN version)**	- Engage with patients	- Audio-Video enabled hardware
19	5	**EVA Framework to generate non-verbal gestures**	- Define co-verbal gestures	- Audio-Video enabled hardware
20	5	**Nvidia Jetson (Nano, TX2 or Xavier NX to be decided)**	- GPU aided processing power - Mobile and autonomous computation unit - Compatibility with most popular frameworks in AI	- Framework to run Image processing and AI libraries
21	5	**TensorFlow 2**	- Out of the box popular models - Several kinds of neural network layers already implemented - Support for GPU acceleration - Convenient features for developing and deploying new architectures	- GPU enabled hardware
22	5	**OpenCV**	- Efficient implementation of filters and convolutions - Several well-known hand-made feature extractors - Algorithms for pattern recognition - Convenient image manipulation	- GPU enabled hardware
23	6	**An AI and Big Data diagnosis support system**	**- Real time** capture data. **- Storage data** in Bigdata Cassandra Database.	- At least **3 VMs** for fault tolerance and scalability of **Cassandra Database**.

Id	Pilot	Title	Functionalities	Integration
			- **Security access** (encryption, authentication, authorization).	- **One VM for web services** for the communication integration.
24	6	**Suite Gradior (cognitive stimulation)**	- **Real time** capture data. - Data **analysis** for **monitoring** and follow-up (AI) - **Security access** (encryption, authentication, authorization).	- HosmartAI common **data model** - **Cloud** infrastructure API
25	7	**Cathlab Assistant**	- **Data analysis** - **User interface**	- To be agreed upon with UZB
26	8	**Cytoscape**	- Genomics instrumentation and related bioinformatics, see http://www.brightcore.be/	- **Connection to centralised database**
27	8	**PRIMUZ**	- Integrated **storage** of patient records/information, https://www.uzbrussel.be/web/primuz	- **Connection to other hospital databases**
28	8	**PACS/RIS**	- **Storage** of patient images (MRI, PET, …)	- **Connection to centralised database**
29	8	**REDCAP or XNAT**	- **Storage** of integrated patient data for research	- Pseudonymization of patient records

3.3 Used Data analysis

In the following two sections, we can find the important data sources as they have been identified and provided by partners, as input to the corresponding section of the Platform Survey (A.4) and an overview of the used data that were referenced more extensively in other deliverables, such as D6.7.

3.3.1 Important data sources

The template to be used for the partner's input was provided in the Platform Survey (A.4).

Data source name	CAMUS - Cardiac Acquisitions for Multi-structure Ultrasound Segmentation
Data Short Description	Dataset consisting of clinical cardiac ultrasound examination videos from approximately 500 patients, paired with semantic annotations of cardiac structures (left ventricle, left ventricle myocardium, left atrium) at specified video frames corresponding to the end-systole and end-diastole phases of the cardiac cycle. For each patient, the sex, age, as well as end-systolic and end-diastolic volumes are given, along with the left ventricular ejection fraction. For each video, an indication of image quality is given.
Dataset Type	Medical imaging dataset
Purpose in Pilot	The dataset is used for training and validation of left ventricle and left ventricle myocardium segmentation deep learning models.
Dataset Owner	
Dataset Provider	https://www.creatis.insa-lyon.fr/Challenge/camus/databases.html
Access License	

Access rights for HosmartAI		
Dataset Access		
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format	Images and image sequences are stored in .raw and .mhd file pairs. Accompanying information is stored in .cfg text files.	
Encryption	None	
Data structure description	The ultrasound videos from each patient are stored in a separate folder. In each folder, the files corresponding to the videos are stored.	
For unusual format, tool to read it	SimpleITK python library	
Remote accessibility	*Yes/No*	No
	Protocol	
	Message format	
	Pull/Push	
	Provided interface	
If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	
	If no, how the data has been generated?	The full dataset was acquired from GE Vivid E95 ultrasound scanners (GE Vingmed Ultrasound, Horten Norway), with a GE M5S probe (GE Healthcare, US). No additional protocol than the one used in clinical routine was put in place. For each patient, 2D apical four-chamber and two-chamber view sequences were exported from EchoPAC analysis software (GE Vingmed Ultrasound, Horten, Norway). These standard cardiac views were chosen for this study to enable the estimation of left ventricle ejection fraction values based on the Simpson's biplane method of discs.
Data Sample link	https://www.creatis.insa-lyon.fr/Challenge/camus/databases.html	

Data source name	EchoNet-Dynamic database
Data Short Description	The EchoNet-Dynamic database includes 10,030 labeled echocardiogram videos and human expert annotations (measurements, tracings, and calculations) to provide a baseline to study cardiac motion and chamber sizes.

Dataset Type	Medical imaging dataset	
Purpose in Pilot	The dataset is used for training and validation of deep learning models for left ventricle segmentation and left ventricular ejection fraction estimation.	
Dataset Owner	Stanford AIMI	
Dataset Provider	Stanford AIMI	
Access License	Stanford University Dataset Research Use Agreement	
Access rights for HosmartAI		
Dataset Access		
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format	The videos are stored in .avi files. Accompanying information is stored in .csv files.	
Encryption	None	
Data structure description	A single folder contains all the videos. Accompanying .csv files contain the rest of the information.	
For unusual format, tool to read it		
Remote accessibility	*Yes/No*	No
	Protocol	
	Message format	
	Pull/Push	
	Provided interface	
If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	
	If no, how the data has been generated?	The dataset contains apical-4-chamber echocardiography videos from individuals who underwent imaging between 2016 and 2018 as part of routine clinical care at Stanford University Hospital. In addition to the video itself, each study is linked to clinical measurements and calculations obtained by a registered sonographer and verified by a level 3 echocardiographer in the standard clinical workflow.
Data Sample link	https://stanfordaimi.azurewebsites.net/datasets/834e1cd1-92f7-4268-9daa-d359198b310a	

Data source name	Kvasir-Capsule Dataset	
Data Short Description	Kvasir-Capsule is a large video capsule endoscopy dataset collected from examinations at Hospitals in Norway. Kvasir-Capsule consists of 117 videos which can be used to extract a total of 4,741,504 image frames. Labelling and medical verification of 47,238 frames with a bounding box around detected anomalies from 14 different classes of findings has been performed. In addition to these labelled images, there are 4,694,266 unlabelled frames included in the dataset.	
Dataset Type	Medical imaging dataset	
Purpose in Pilot	The dataset is used for training and validation of deep learning models for detection and classification of small intestine abnormalities.	
Dataset Owner		
Dataset Provider	Open Science Framework	
Access License	Creative Commons Attribution 4.0 International	
Access rights for HosmartAI		
Dataset Access		
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format	Images are stored as .png files. Bounding box information for medical findings is stored in a .csv file.	
Encryption	None	
Data structure description	The labeled images are stored in single folders corresponding to the class they belong to. Unlabeled images are stored in a separate folder. Bounding box information is stored in a separate file.	
For unusual format, tool to read it		
Remote accessibility	*Yes/No*	No
	Protocol	
	Message format	
	Pull/Push	
	Provided interface	
If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	
	If no, how the data has been generated?	The VCE videos were collected from consecutive clinical examinations performed at the Department of Medicine, Bærum Hospital, Vestre Viken Hospital Trust in Norway. The examinations were conducted between February 2016 and

		January 2018 using the Olympus Endocapsule 10 System including the Olympus EC-S10 endocapsule and the Olympus RE-10 endocapsule recorder.
Data Sample link	https://osf.io/dv2ag/wiki/home/	

Data source name	Suite Gradior (cognitive stimulation)	
Data Short Description	Neuropsychological evaluation and rehabilitation system for carrying out training programmes supporting people with cognitive deficits or impairment. It allows working adults Attention, Perception, Orientation, Memory, Calculation, Executive Function, Language and Reasoning. The system consists of a website (aimed at professionals) and an app for the execution of intervention sessions by users.	
Dataset Type		
Purpose in Pilot	Results of the rehabilitation sessions with Gradior and care plans for the follow-up and monitoring of the users.	
Dataset Owner	INTRAS	
Dataset Provider	INTRAS	
Access License		
Access rights for HosmartAI	The access to the Gradior results will be defined according to the need of the project.	
Dataset Access	API REST	
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format	JSON/XML	
Encryption	Security access (encryption, authentication, and authorization).	
Data structure description	Personal data Sociodemographic data Clinical data Results of treatment sessions (% hits and misses, reaction times)	
For unusual format, tool to read it		
Remote accessibility	*Yes/No*	Yes
	Protocol	HTTPs
	Message format	JSON/XML
	Pull/Push	Pull/Push
	Provided interface	API REST
If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	Yes
	If no, how the data has been generated?	
Data Sample link		

Data source name	Smart home data	
Data Short Description	Consumption/production of instantaneous electricity and consumption logs, Human presence/access control, Devices' activation and connected loads, AI-based virtual sensors	
Dataset Type		
Purpose in Pilot	Collected data will help to monitor patients' health, safety, and activities	
Dataset Owner	Data belongs to the owner of the domotic system. The owner defines access to the data	
Dataset Provider	VIMAR	
Access License		
Access rights for HosmartAI	The owner defines access to the data	
Dataset Access	API REST	
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format	JSON	
Encryption		
Data structure description		
For unusual format, tool to read it		
Remote accessibility	*Yes/No*	Yes
	Protocol	KNX IoT third party
	Message format	JSON
	Pull/Push	Pull/Push
	Provided interface	API REST
If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	Yes
	If no, how the data has been generated?	
Data Sample link		

3.3.2 Overview of used data

The contents of this section are also included in D1.5 as Section 3.3. This section is included in D1.6 for completeness.

Pilot	Functionality	Types of Data, Sources, and Uses
Pilot 1 - A	Computer-aided cardiac function assessment using portable ultrasonics	There are two sources of the data, 1) a portable ultrasound (US) device which broadcasts the acquired sequence of frames and 2) a Picture Archiving and Communication System (PACS) where previously acquired ECHO clips are stored.
Pilot 1 - B	Computer-aided diagnosis of small intestine pathology in capsule endoscopy	Videos acquired from capsule endoscopy systems to automatically detect and categorise suspicious findings.
Pilot 2	Development of an intelligent algorithm that allows the scheduling of medical appointments in the most efficient way.	Patient information • Id, Scale of emergency, Time preferences, Vital status, Hospital localization, Cancer's localization, Weight of patient, Irradiation localization Treatment information. Electronic records: • Appointment's nutritionist, dentist, cardiologist, surgeon, chemotherapy, other appointments; Nº of Sessions/visits; Availability of medical staff, Availability of machines. Mosaiq machine • Time treatment, Simulation
Pilot 3	Develop a set of “treatment & rehabilitation technologies” by collecting data to monitor and control the environment.	Data used will come from 1. Environmental sensors 2. Virtual Sensors 3. Smart rehab and wearable devices 4. Other clinical parameters collected during medical examinations In more detail, the sources of data are the following: • Sensors providing information about human presence in the environment (Ultra Wide Band, access control) and monitoring the status of the building. Data will be used also to develop AI-based virtual sensors to provide additional information for caregivers and residents. • Therapeutic devices and sensors, and clinical information from IRCCS. • The iPrognosis android smartphone application by AUTH that collects keystroke dynamics data to produce a bradykinesia and a rigidity severity score, inertial measurement unit (IMU) data during phone calls to detect tremor, and voice recording data during phone calls to classify the speaker as having Parkinson’s disease or not. • The iPrognosis Motor Assessment Tests (iMAT) solution by AUTH that acquires 3D video data of patients performing pre-specified movements and

Pilot	Functionality	Types of Data, Sources, and Uses
		employs human pose estimation to produce a score that quantifies similarity of the patient's movement to a reference movement performed by an expert.
Pilot 4	Building an application that allowed for (semi-)automatic catheter navigation for cardiac ablation procedures, using AI-driven analytics to support clinical decisions.	• Patient data derived from implanted and external monitoring devices • Electronic medical record data and other historical health records • Research data (from clinical studies) and other data from historical patient procedures • Real-time data derived during interventional cardiac procedures (e.g., Ablation mapping) • Magnetic fields at specific positions in the workspace during ablation / cardiac ablation mapping.
Pilot 5	AI-solutions to Explore the clinical data (existing and new) during Grand rounds, A Robotic unit to collect patient data and engage with patients to deliver non-value-added nursing services	Patient Clinically Relevant Information Collected: Patient-id, Age, Sex, Weight/Height, Conditions and Diseases, Medication, Depression/Anxiety Symptoms and Mood, Temperature, Heart rate, Respiration rate, Oxygenation – Pulse oximetry, VAS Score, Laboratory Results, other Robot-generated/scanned patient information to identify and link patients to their EMR
Pilot 6-A	A neuropsychological evaluation and rehabilitation system for carrying out training programmes in people with deficits and/or cognitive impairment.	Using intervention sessions, patient data related to the following areas will be collected: Attention, Perception, Orientation, Memory, Calculation, Executive Function, Language and Reasoning.

Pilot	Functionality	Types of Data, Sources, and Uses
Pilot 6-B	A digital phenotyping mobile application intended for detecting and/or assessing Parkinson's Disease (PD) symptoms.	The application collects keystroke dynamics data to produce a bradykinesia and a rigidity severity score, inertial measurement unit (IMU) data during phone calls to detect postural tremor, and voice temporal and spectral features during phone calls to classify the speaker as having Parkinson's disease or not.
Pilot 6-C	A Personal Health Record - PHR application with telemedical capabilities where health data and information related to the care of a patient is maintained.	The health data collected include patient-reported outcome data, lab results, and data from integrated medical devices such as wireless glucometer, SPO2, Non-invasive blood pressure meter, urine analyzer, weight scale, spirometer temperature & other data collected via a mobile app.
Pilot 7	A Cath lab SW application that automates reporting for cardiac interventions by tracking each step of the procedure, logging relevant events and actions, and auto-populating reports with images and measurements acquired during the clinical procedure.	Images and measurements captured during Cath lab procedures, including CT scans, Echos, MRIs, other biomarkers and measurements, coupled with clinical data from various sources, including EMR, Lab Systems, external patient records etc.
Pilot 8	Create a digital health research platform to: 1. Integrate clinical data for glioma, 2. Create a research platform for digital health and AI-driven analytical modelling, 3. Support clinical decisions with visualization and predictive analytics	• Date of diagnosis • Tumor type (histopathology) • Tumor location (frontal/temporal/parietal/occipital/central/posterior fossa/other) • MRI characteristics (volume on T1+/- Gd, volume of FLAIR hyperintensity) • FET-PET characteristics (maximum metabolic activity, maximum TBR (Tumor-to-background ratio), tumor volume (area of TBR>1.6)) • Spatial genomics data, including mutations related to cancer and their effect at the protein level • Former medical history • Clinical symptoms at diagnosis • Physical neurologic exam at diagnosis (abnormal findings) • Treatment (surgical, medical, radiotherapy) at first diagnosis • Treatment at (first, second, etc) progression

3.4 User requirements analysis

The analysis carried out within D1.2 "Stakeholders requirements and analysis report", provided a recompilation of the user requirements of the platform and the 8 lighthouse pilots to be executed within the HosmartAI Project. In the present section, we resume the analysis performed and advance the next steps.

A total of 124 user requirements were distributed in the following way: 10 user requirements for the HosmartAI Platform; 12 user requirements for Pilot 1; 10 user requirements for Pilot 2; 18 user requirements for Pilot 3; 4 user requirements for Pilot 4; 30 user requirements for Pilot 5; 32 user requirements for Pilot 6; 3 user requirements for Pilot 7; and 5 user requirements for Pilot 8.

As mentioned in D1.5 "HosmartAI Platform Conceptual Architecture – First version", the prioritization process is a crucial step for this development.

As described in D1.3 "Stakeholders requirements and analysis report – second version", the user requirements elicitation process is being carried out and partners have assigned an initial score value and risk implementation (see Figure 17 and Figure 18). Within the user requirements value, there is a predominance of requirements that represent a high value for the platform, close to 70%. Within the risk of implementation, the requirements that represent a high implementation risk account for only 19% of the total, compared to 49% of low risk and 32% of medium risk.

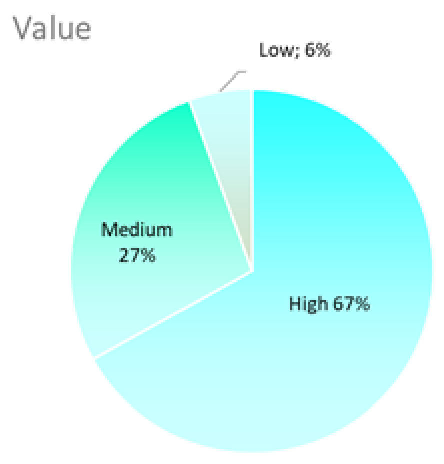


Figure 17: User Requirements prioritization – value.

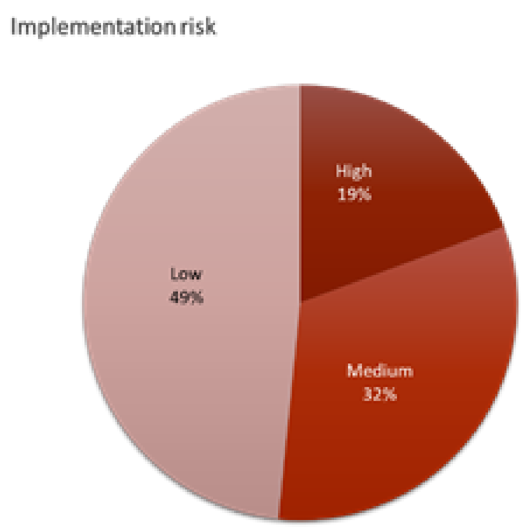


Figure 18: User Requirements prioritization - Risk of implementation.

The results obtained in this process can be consulted in D1.3 "Stakeholders requirements and analysis report – second version".

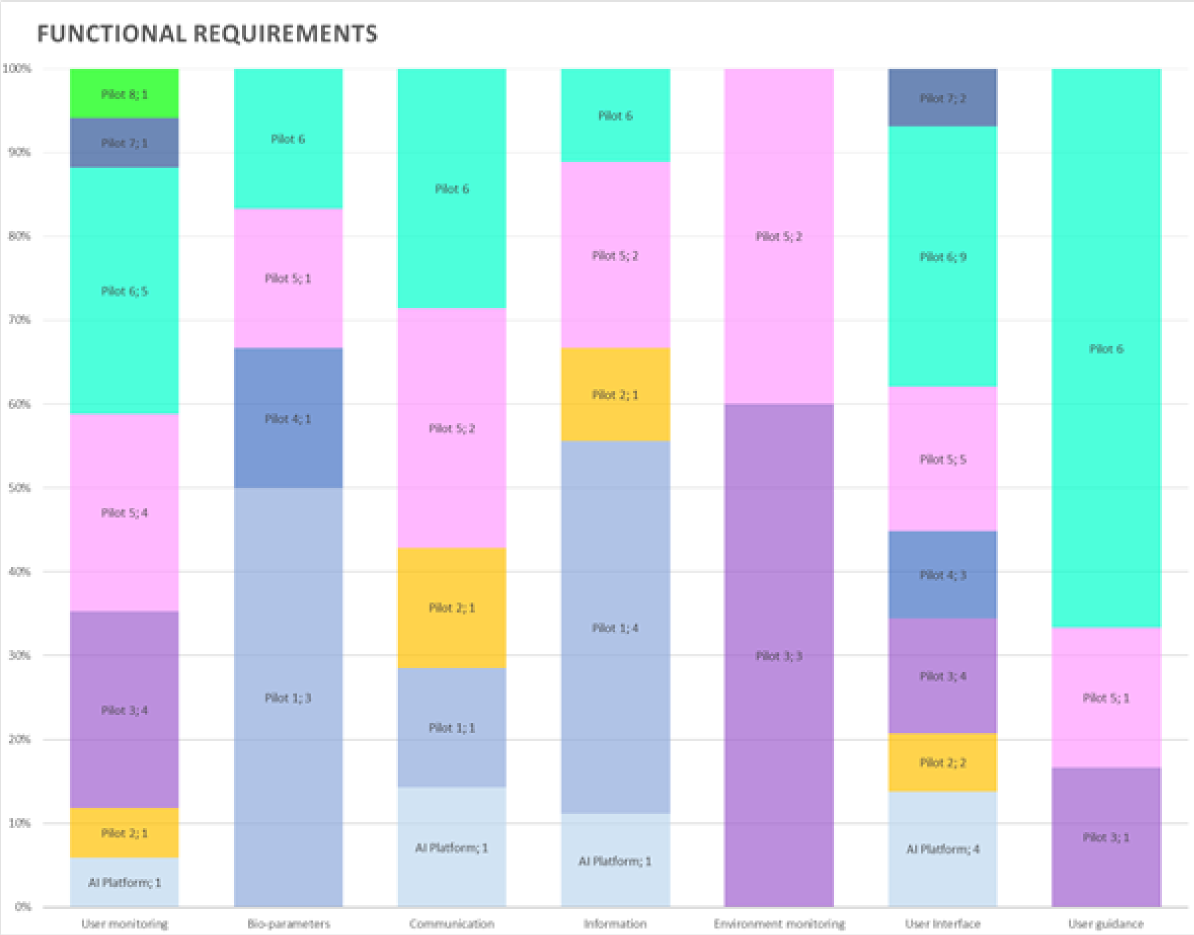


Figure 19: Functional user requirements.

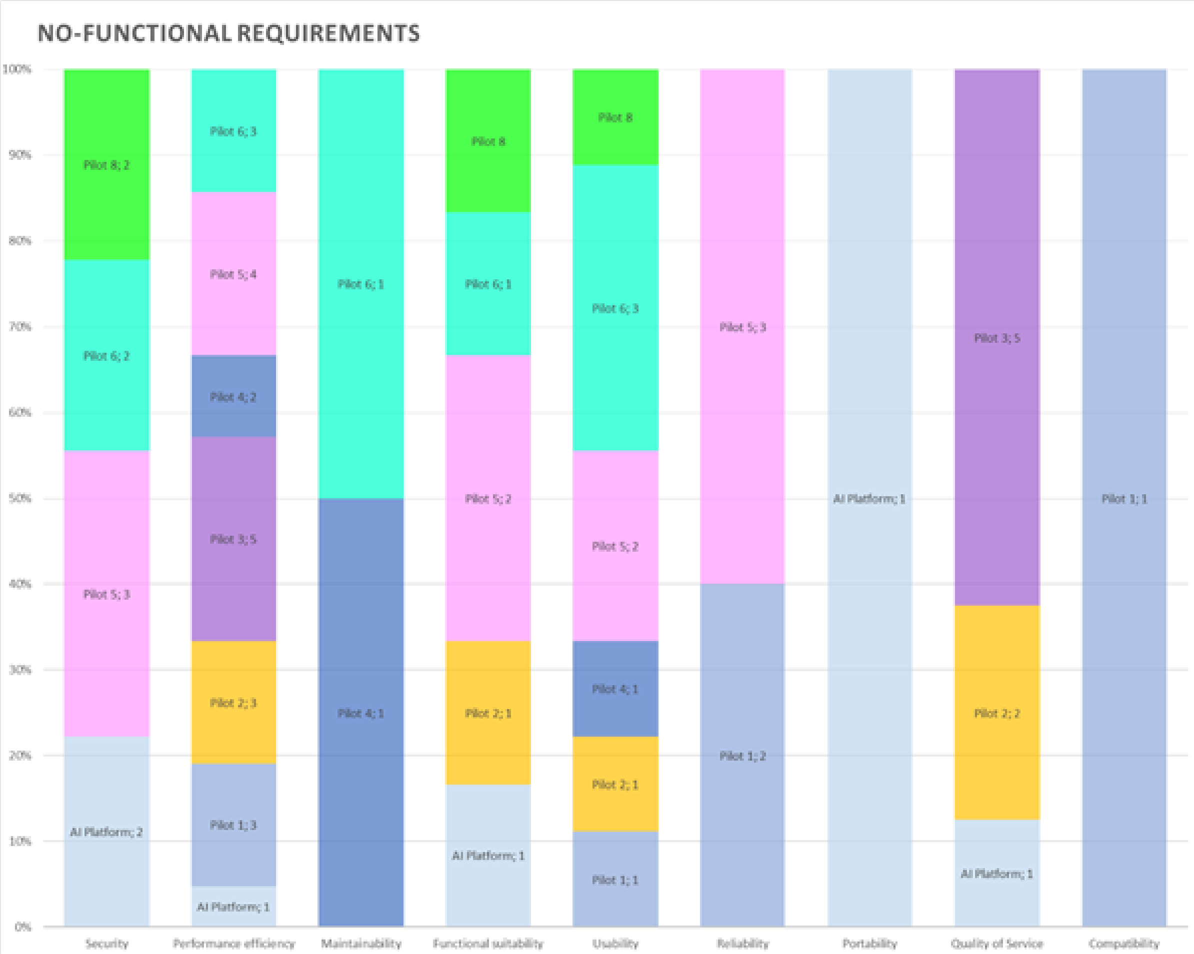


Figure 20: Non-functional user requirements.

As planned, JIRA software is being used as a backlog and will continue its purpose throughout the HosmartAI lifetime.

In Sprint 1, requirements were revised and new functionalities emerged (see Figure 19 and Figure 20). Updated value and risk scores were given considering the feedback from stakeholders. Table 14 presents the overall score obtained in the rough estimation's calculation for the prioritization process.

Table 14: Overall score calculation.

	Initial	Sprint 1	Overall score
Value	3	3	3
Implementation Risk	3	2	2.3

Table 15: JIRA - User Requirement example.

[URE-117] Privacy Created: 01/Sep/21 Updated: 09/Sep/21	
Status:	Proposed
Project:	User Requirements
Components:	None

Affects versions:	None		
Fix versions:	None		
Type:	User Requirement	**Priority:**	Medium
Reporter:	HosmartAI_regular_user	**Assignee:**	HosmartAI_regular_user
Resolution:	Unresolved	**Votes:**	0
Labels:	None		
Remaining Estimate:	Not Specified		
Time Spent:	Not Specified		
Original estimate:	Not Specified		
Issue links:	**Relates**		
	relates to TR-28 Privacy Proposed		
	relates to TR-29 Secure computing environment Proposed		
	relates to TR-36 Monitoring of the research data datasets Proposed		
	relates to TR-41 Data filtering and limiting Proposed		
	relates to TR-42 Integrity verification of research da... Proposed		
	relates to TR-44 Monitoring of digital events (event l... Proposed		
	relates to TR-46 Open source tools for security, privacy... Proposed		
	relates to TR-47 Open source tools for processing the ... Proposed		
	relates to TR-48 Compliance of the security, privacy a... Proposed		
	relates to TR-49 Scalability in regard with the security... Proposed		
	relates to TR-50 Encryption of communication over publ... Proposed		
	relates to TR-51 System continuity Proposed		
Value:	High		
Implementation Risk:	Medium		
Requirement Type:	Non-functional		

Non-functional Requirements Category:	Security
Most important actor involved:	Patients
Related Pilot (or Platform):	Pilot 6
Rank:	0|i000sf:
All collected information should be unobstructed and users should be able to withdraw themselves and their data at any time from the system for any reason.	

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4 Technical Requirements

The User Requirements described in the previous Section 3.4 were used to elicit Technical Requirements, which are presented in the following pages in categories that correspond to relevant tasks in the Project.

Each Technical Requirement has an ID that matches the one generated by JIRA at the time it was entered into the system. As shown in the previous section the relationship between the entries of a User Requirement and a Technical Requirement provides forward and backward visibility into the activity surrounding each requirement. An example follows in Table 16.

Table 16: JIRA - Technical Requirement Example.

[TR-5] Give recommendations in Hospital performance aspects Created: 14/Jul/21 Updated: 05/Sep/21			
Status:	Proposed		
Project:	Technical Requirements		
Components:	None		
Affects versions:	None		
Fix versions:	None		
Type:	Technical Requirement	Priority:	Medium
Reporter:	HosmartAI_regular_user	Assignee:	Unassigned
Resolution:	Unresolved	Votes:	0
Labels:	None		
Remaining Estimate:	Not Specified		
Time Spent:	Not Specified		
Original estimate:	Not Specified		
Issue links:	**Relates** relates to URE-3 Benchmarking Proposed relates to URE-4 Catalog of AI Applications Proposed		
Reporter (e.g. ITCL):	Makis (INTRA)		
Related pilots (Optional):	None (Platform)		
Relevant project Tasks:	T2.2, T2.3, T4.4		
Source:	DoA (1.3.1.4 HosmartAI Platform scenarios)		
Last changed:	05/Sep/21 4:30 PM		
Rank:	0|i0001p:i		

Description

The common database benchmarking performance framework will be developed following all precautions regarding data safety and anonymity as imposed by GDPR guidelines optimizing data processing and minimizing risk related to data management (cyber, loss, deterioration, etc.). The common database benchmarking performance framework will be able to give recommendations in Hospital performance aspects such as:

1. management efficiency analysis: Hospital's productivity and organization.

2. technical efficiency analysis: data of processes, equipment; and best practices/balanced score cards and other performance indicators.

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4.1 Common data models and semantic interoperability

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-197	FHIR client setup	Setup a client which will invoke main management operations on the FHIR server.	TR-196	All	T2.1	Consultation with pilot leaders, user requirements, DoA, D6.7
TR-196	FHIR server setup and configuration	Setup and configure a FHIR server capable of processing, validating, and storing pilots' healthcare data in a standard format.	TR-109, TR-197	All	T2.1	Consultation with pilot leaders, user requirements, DoA, D6.7
TR-129	FHIR Resources	A FHIR Version that supports an efficient implementation of resources such as: ▪ care plan, ▪ composition, ▪ task, ▪ condition, ▪ diagnostic report, etc...	URE-71 , URE-70 , URE-149 , URE-80 , URE-150 , URE-152 , URE-147	Pilot 5	WP2 (T2.1), WP4	
TR-128	FHIR Server	FHIR Server capable to ingest and aggregate new data and supporting clients for visualization of the data during the clinical routine.	URE-71 , URE-70 , URE-149 , URE-80 , URE-150 , URE-152	Pilot 5	WP2 (T2.1)	

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-110	HosmartAI semantic interoperability	HosmartAI common semantic data model will be designed and developed in a form of an ontology.	TR-109	ALL	T2.1	Consultation with pilot leaders, user requirements, DoA, D6.7
TR-109	Clinical variables mapping procedure	HosmartAI clinical variables will be mapped to existing standards, ontologies and/or vocabularies. Custom classes and properties will be created to fill gaps that may arise.	TR-196, TR-110	ALL	T2.1	Consultation with pilot leaders, user requirements, DoA, D6.7

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-106	Access to different data types	EMR, medical imaging, genomics, and physiological monitoring data. For example: Variables to be collected are: 1. Tumour type (histopathology) 2. Tumour location (frontal/temporal/parietal/occipital/central/posterior fossa/other) 3. MRI characteristics (volume on T1+/- Gd, volume of FLAIR hyperintensity) 4. FET-PET characteristics (maximum metabolic activity, maximum TBR (Tumour-to-background ratio), tumour volume (area of TBR>1.6)) 5. Spatial genomics data, including mutations related to cancer and their effect at the protein level 6. Former medical history 7. Clinical symptoms at diagnosis 8. Physical neurologic exam at diagnosis (abnormal findings) 9. Treatment (surgical, medical, radiotherapy) at first diagnosis 10. Treatment at (first, second, etc) progression 11. Date of progression (progression-free survival) (first, second, etc) 12. Date of death (overall survival) 13. Date of diagnosis	URE-130	Pilot 8	T3.6, T2.1	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-104	Better access to clinical data for research	The system should enable research within legal parameters to help advance healthcare. The legal requirements that the research-based tools need to adhere to, especially with regard to accountability in clinical decision support, and compliance with principles and obligations outlined inter alia in the EU General Data Protection Regulation and Belgian Framework on Data Protection, will be included. A secure integrated data system with controlled user roles and data access will enable researchers to access only the data designated by study parameters.	URE-126	Pilot 8	T3.6, T2.1, T4.1	Platform and cross-components requirements study based on D1.2

4.2 Common AI pillars

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-180	Support AI4EU applications	The system should provide interoperability with AI4EU models. Through the usage of the Acumos AI Platform, AI4EU provides various resources such as data sources, AI applications, algorithms and pipelines. These resources have been onboarded onto AI4EU as Acumos models. When exported, another deployment of Acumos AI Platform can also fully utilize them, or they can be deployed in a Kubernetes cluster.	TR-47 , URE-2 , TR-178 , TR-177 , TR-176 , TR-175	Platform	T2.2	Input from INTRA Technical Team

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-179	Provide environment to run AI algorithms	The system should provide an environment that supports the execution of AI algorithms. This can be done through Notebooks that support the execution of Python code that imports various AI Libraries, such as TensorFlow and scikit-learn, as well as client libraries to other tools, such as Apache Spark. An example of a platform that has the ability to provide Notebooks that support Python to users is JupyterHub.	TR-47 , URE-2 , TR-178 , TR-177 , TR-176 , TR-175	Platform	T2.2	Input from INTRA Technical Team
TR-178	Support AI Applications that use Keras	The system should support AI applications that use Keras	TR-180 , TR-47 , URE-2 , TR-179	Platform	T2.2	Input from INTRA Technical Team
TR-177	Support AI Applications that use Pandas	The system should support AI applications that use Pandas	TR-180 , TR-47 , URE-2 , TR-179	Platform	T2.2	Input from INTRA Technical Team
TR-176	Support AI Applications that use scikit-learn	The system should support AI applications that use Scikit-Learn	TR-180 , TR-47 , URE-2 , TR-179	Platform	T2.2	Input from INTRA Technical Team
TR-175	Support AI Applications that run on Apache Spark	The system should support AI applications that run on Apache Spark	TR-180 , TR-47 , URE-2 , TR-179	Platform	T2.2	Input from INTRA Technical Team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-19	Algorithms for the radiotherapy flow	The system should be able to support developing and evaluating models and algorithms used to automatically create radiotherapy treatment schedules	URE-37 , URE-43	Pilot 2	T2.2	Common AI Pillars study on D1.2
TR-18	AI platform to automate patient flow	An intelligent platform that can manage and automate patient flows, events and tasks, moving hospitals from a reactive to a proactive healthcare system.	URE-36	Pilot 2	T2.2	Common AI Pillars study on D1.2
TR-16	Support for Chatbots	The system should be able to support tools that provide the functionality of a chatbot. Many of these tools for example require a persistent HTTP connection.	URE-22 , URE-21	Pilot 2	T2.2	Common AI Pillars study on D1.2
TR-10	Provide space with AI Application description and benchmarking results	Create space where a description for each AI Application will be available. Also, the benchmarking results for each application should be reachable from that space.	URE-3	Platform	T2.2	DoA (1.3.1.4 HosmartAI Platform scenarios)
TR-8	Support AI Applications that run on TensorFlow	The system should support AI applications that run on TensorFlow	TR-47 , URE-2	Platform	T2.2	DoA (1.3.1.4 HosmartAI Platform scenarios)
TR-5	Give recommendations in Hospital performance aspects	The common database benchmarking performance framework will be developed following all precautions regarding data safety and anonymity as imposed by GDPR guidelines optimizing data processing and minimizing risk related to	URE-3 , URE-4	None (Platform)	T2.2, T2.3, T4.4	DoA (1.3.1.4 HosmartAI Platform scenarios)

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		data management (cyber, loss, deterioration, etc.). The common database benchmarking performance framework will be able to give recommendations in Hospital performance aspects such as: 1. management efficiency analysis: Hospital's productivity and organisation; 2. technical efficiency analysis: data of processes, equipment; and best practices/balanced score cards and other performance indicators.				
TR-3	Store KPIs of solutions	Store data to assess innovative solutions. These will be used by the benchmarking framework to give insights on the impact on resources, staff training and existing practices. E.g., • educational impact • cost efficiency • acceptability for secondary users (Health institutions)	URE-3	Platform	T2.2	DoA (1.3.1.4 HosmartAI Platform scenarios)

4.3 The HosmartAI Benchmarking Framework

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-190	API to get data from Benchmarking	Implementation of an open API with the Integration of the Benchmarking and Marketplace access and share of data.	URE-159		T2.3, T4.3, T4.1	
TR-174	Collect and share KPI data in benchmarking framework	Sharing clinical data relevant to KPI measurements collected from sensors. The system will be built with a tool for receiving Pilots data (inputs and KPI) through FHIR protocol of communication. It would be a possibility the use of Kafka because it includes different features for fault tolerance. A background system will be always running to process new data received in each topic and new topics from new or other pilots. The process saves the data on NOSQL database.	URE-48 , URE-56 , URE-141 , URE-3 , URE-54	Pilot 3	T3.3, T2.3	
TR-33	Benchmarking database driver	The system should be able to support connection to relevant databases in order to obtain the input data of the benchmark. The Benchmarking Framework will be able to process data from kafka and save on NOSQL Database like Cassandra and Mongo. Data will be labeled with each pilot ID	URE-3	Platform	T2.3	D1.2

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
		for later use during processing.				
TR-32	Development of a benchmarking user interface	Development of a user-friendly interface for the correct interaction of the user with the system for the selection of the KPIs to study. For the improvement of the use the benchmarking interface, the use of JupyterLab system will be pursued. JupyterLab is the latest web-based interactive development environment for notebooks, code, and data. Its flexible interface allows users to configure and arrange workflows in data science, scientific computing, computational journalism, and machine learning. A modular design invites extensions to expand and enrich functionality.	URE-3	Platform	T2.3	D1.2
TR-31	Development of Python benchmarking libraries	Development of custom AI Python libraries to generate different KPIs studies to any given input. Benchmarking library will include algorithms for transform (scale and normalise) data, pre-processed relevant feature, use different cross-validation techniques. Algorithms will be included in the library: • **Feature selection** ○ ICC	URE-3	Platform	T2.3	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		○ MI ○ mRMR • **Cross Validation** ○ 10Kfolder ○ 5*2 K folder ○ LOO • **Pilot's specific algorithm**				
TR-5	Give recommendations in Hospital performance aspects	The common database benchmarking performance framework will be developed following all precautions regarding data safety and anonymity as imposed by GDPR guidelines optimizing data processing and minimizing risk related to data management (cyber, loss, deterioration, etc.). The common database benchmarking performance framework will be able to give recommendations in Hospital performance aspects such as: 1. management efficiency analysis: Hospital's productivity and organization; 2. technical efficiency analysis: data of processes, equipment; and best practices/balanced score cards and other	URE-3, URE-4	None (Platform)	T2.2, T2.3, T4.4	DoA (1.3.1.4 HosmartAI Platform scenarios)

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		performance indicators.				

4.4 Tools and services for secure applications, data protection, privacy, traceability and governance

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-147	Tools for data anonymization and measurement of risks of reidentification	Anonymization of medical data collected and evaluation of risks of re-identification. Should be integrated into benchmarking so that hospitals can assess possible FAIR (Open) data sharing. This reflects primarily	URE-80 , URE-68	Pilot 5	WP2 (T2.4)	
TR-105	Environments that ensure data security	The system should be able to protect patient information, by supporting full de-identification when it is required. The integrated data system enables de-identification of data when required, in relation to the study parameters, so that patient identity cannot be extracted from them. This includes removing personal information, but also reducing data content when necessary (e.g., genetic fingerprint of amino acid variants in genome).		Pilot 8	T3.6, T2.4	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-68	Patient QRCode Recognition	It is crucial for the robot to recognize the patient. In the hospital each patient gets a bracelet with a QR/BAR code which she/he wears and the same on the bed. The robot should be, as part of the computer vision recognize that, to properly store data from the prospective study and to recollect the retrospective data.	URE-148 , URE-67	Pilot 5	T2.4	Development and Deployment Tools for AI study based on D1.2
TR-57	Edge Cloud environment	An edge cloud is created by a set of edge network nodes deployed in facility and which computing capacity is federated to host AI services at the edge, near end-user and devices. An edge cloud is autonomous from datacenter although it can interact with it. Thus, local data remains local.	TR-28 , TR-29	Pilot #6	WP2 (T2.4)	
TR-51	System continuity	System continuity should be guaranteed: 1. attacks on one component shall not disrupt functionality of the other components of the system; 2. the system will be resistant against falsified or corrupted data observed; 3. the system will be resilient from physical damaging of one or more of its components.	TR-28 , URE-117 , TR-29		T2.4, T6.5	DoA, D2.1, D6.7

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-50	Encryption of communication over public networks	Communication over public network within the system and between the system and its users will be encrypted when necessary. This must be applied to the HHub and to the pilots' infrastructure as well.	TR-28 , URE-117 , TR-29 , URE-129		T2.4, T6.5	DoA, D2.1, D6.7
TR-49	Scalability in regard with the security, privacy and traceability	The system will be scalable in regard with the security, privacy and traceability needs. This means, that the security, privacy and traceability tools and methods implemented should be as less sensitive as possible to changes in the system's size.	TR-28 , URE-127 , URE-117 , TR-29 , TR-45		T2.4, T6.5	DoA, D2.1, D6.7
TR-48	Compliance of the security, privacy and traceability subsystem with regulations	The security, privacy and traceability subsystem will comply with applicable laws and regulations of the EU and Member States, as well as other regulations and standards if required.	TR-28 , TR-27 , URE-117 , TR-29 , URE-129 , TR-45		T2.4, T6.5	DoA, D2.1, D6.7
TR-47	Open source tools for processing the collected data	Processing of the collected data within the system will be performed using open-source tools. (NFR)	TR-28 , URE-117 , TR-29 , URE-129 , TR-46 , TR-180 , TR-179 , TR-178 , TR-177 , TR-8 , TR-176 , TR-175		T2.4, T6.5	DoA, D2.1, D6.7
TR-46	Open source tools for	The security, privacy and traceability subsystem	TR-28 , URE-		T2.4, T6.5	DoA, D2.1, D6.7

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
	security, privacy and traceability subsystem	will use, where possible, open-source software. (Traceability tools will also include T2.5 blockchain deployments). (NFR)	117 , TR-29 , URE-129 , TR-45 , TR-47			
TR-45	Data traceability	Point-to-point traceability of exchanged and shared data must be guaranteed. Envisioned means: • Traceability of data and aggregated datasets through validation of the single systems. • Common criteria (e.g.; common data field, etc) to maintain minimum origin of aggregated data.	TR-49 , TR-46 , TR-48 , TR-58 , URE-8		T2.4, T6.5	DoA, D2.1, D6.7
TR-44	Monitoring of digital events (event logs)	Provide real-time awareness in facing cyber-attacks and to promptly apply adequate countermeasures, by monitoring digital events at various levels (infrastructure, core, services). Event logs are also required to get information and statistics for post-events analyses. Envisioned means: • Native infrastructure logging system • Syslog • Ad-hoc agents to be installed on	TR-28 , URE-117 , TR-29 , URE-129		T2.4, T6.5	DoA, D2.1, D6.7

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		monitored infrastructure • SSL based connections (AMQPS, ...) • SIEM: data collection and analysis system. • Development of a set of analysis to be carried out by the SIEM system. • Definition of thresholds and development of alerts. • Detection of system anomalies.				
TR-43	Validation of the origin of data	Validation of the origin of data is required to avoid illicit data access and data forgering (injection of malicious code), and to increase system robustness vs. resiliency to errors. Envisioned means: • Adequate use of access control methods: • RBAC (role-based access controls). • Login (for M2M data communication). • Multi factor authentication for user logins. • Token-based communication (e.g., OAuth, OpenID, Keycloak, …)	TR-29 , URE-129		T2.4, T6.5	DoA, D2.1, D6.7

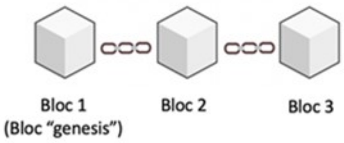
Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		• MAC/IP based acceptance criteria. • FW-based endpoint protection (insert authentication device in front of unsecured system nodes). • Use of secure ad-hoc encrypted communication tunnels.				
TR-42	Integrity verification of research datasets	Research datasets need integrity verification methodologies and, for the privacy issues, pseudonymization (or anonymization) techniques, depending on the case. Envisioned means: • Data path and traceability, definition of plausibility criteria. • Increase in robustness and resiliency to errors. • Use of hashing techniques to guarantee anonymization and integrity. • Possible use of Blockchain techniques (T2.5) to guarantee data integrity over time.	TR-28 , URE-117		T2.4, T6.5	DoA, D2.1, D6.7

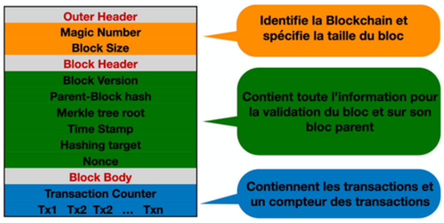
Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-41	Data filtering and limiting	Necessity to filter out and limit the data exported. The more data is exchanged, the more the likelihood for them to be stolen or to undergo any attempts of damaging. Envisioned means: Design and application of Filtering Policies based on: • requester services • specific API endpoint (RESTfull protocol)	TR-28 , URE-117		T2.4, T6.5	DoA, D2.1, D6.7
TR-36	Monitoring of the research data datasets	Research dataset, at the infrastructure level, should be constantly monitored and submitted to audit sessions, in order to ensure their quality in relation to security and privacy. This should be applied to both HHub and to pilots. Envisioned means: • Audit campaigns on pilot infrastructures. • Application of OSSTMM techniques. • Other procedures based on recognized standards (NIST, SANS, ITIL, ISO2700x, ...),	TR-28 , URE-117 , TR-29 , URE-129		T2.4, T6.5	DoA, D2.1, D6.7

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		adequately applied				

4.5 Data integrity and trustworthy data sharing, blockchain approach

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-61	Blockchain Resilience to Split & Merge	The different nodes that contain a copy of the Blockchain are connected to each other through a network. Those nodes could reboot, shutdown, have bad radio link, make mobility… All those actions will remove some nodes from the network during an interval of time. In this interval, the other nodes may validate blocks in the blockchain and when the node comes back again to integrate the network, we will have a problem because the Blockchain will lose a main propriety where some nodes don't have the same copy of the blockchain. The developed blockchain in the project should answer the question of Split and Merge of the Blockchain nodes.	TR-58	Pilot #6 ; Pilot#5	T2.5	
TR-60	Blockchain Network	To function properly, the nodes that maintain the blockchain must be able to communicate with each other, through a network. In the project, this network is formed by a mesh network composed of nodes communicating with each other using wired or wireless technology such as Wi-Fi. However, the communications between the nodes could be done through an infrastructure network such as a fixed Wi-Fi access point or 4G. In the first case, nodes move relative to each other, which can lead to multiple networks with no communication between them, and in the extreme case, a network can consist of only one node. When	TR-58	Pilot #6 ; Pilot#5	T2.5	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		separate networks are formed, they may join each other or only some nodes may join another network. Many different scenarios are possible and represent what happens in different use cases. The performance of the links is extremely variable depending on their distance from each other until they can no longer communicate.				
TR-59	Blockchain Hardware	The secure management of the blockchain requires the use of cryptographic algorithms. The nodes must have sufficient computing resources to support the procedures of signing, hashing and eventually encrypting/decrypting the data blocks.	TR-58	Pilot #6 ; Pilot#5	T2.5	
TR-58	Blockchain	A blockchain is a data structure where information is recorded and collected in a block. This block of data is then added to the blockchain by linking it to the most recent block already present. The latter is then considered as the "parent block" of the former. Cryptographic fingerprinting and digital signature mechanisms ensure that the blockchain cannot be modified by the nodes that maintain it.  The above figure shows a blockchain with three blocks. The first block is the "genesis" block which is the beginning of the chain. The "genesis" block does not have a "parent block". A block is created to contain information in the form of transactions to be recorded in the database. The number of transactions in a block is variable and depends on each application. As time goes on,	TR-171 , TR-45 , TR-59 , URE-69 , URE-8 , URE-68 , URE-143 , TR-60 , TR-61	Pilot #6 ; Pilot#5	T2.5	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		new blocks are created to contain new transactions. When a new block is added to the blockchain, it points to the last block in the chain. This link is made by a "hash" value. That is, the new block that joins the chain contains the "hash" of the "parent" block.  The above figure shows the structure of a block which is composed of three parts: an outer header, an inner header (the main header of the block) and the body of the block. The outer header contains the block identifier and specifies the size of the block. The block header contains, among other things, the hash of the "parent" block and the time stamp of the block. The body of the block contains transactions which are user information in the distributed database. The objective of this section is to examine the requirements for a blockchain to be implemented on a distributed network. Properties The following properties represent the reasons why we want to use a blockchain in the project. It should be noted, however, that the performance of these properties will depend mainly on the implementation choices that are made and the priorities that are set. • Decentralization: Most applications implementing a blockchain employ a				

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		distributed architecture where each node stores a complete copy of the database. These nodes are commonly referred to as "miners". The particular structure of the blockchain allows these miners to cooperate even when trust between them cannot be guaranteed. By setting rules algorithmically, each miner can individually verify the validity of updates made by other nodes. This ensures that all miners have an equal impact on the database. This solves the problems associated with the existence of a single point of failure usually encountered with traditional databases. Finally, since the nodes can all act on the blockchain individually, a consensus algorithm must be used to synchronize them in order to avoid conflicts that could be caused by simultaneous modifications. This algorithm must respect the same decentralization constraints to ensure that all miners can add blocks. • Integrity: With the ability to check the history and data already in the blockchain, nodes can verify that all new data entered into a block is consistent with that in previous blocks. Thus, the blockchain allows to ensure with a high level of guarantee, the consistency, the reliability and the relevance of the data that are recorded. • Immutability: The cryptographic techniques of fingerprints and digital				

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
		signatures guarantee that the data contained in a block cannot be modified by a third party. In addition, the link between blocks is made in such a way that if a miner modifies the data of a block that he could have added to the blockchain, this modification would invalidate all the subsequent blocks of the chain and would make the attempt to corrupt the database detectable by the other nodes. • Transparency: Since the blockchain is duplicated among all the miners who participate in its maintenance, these miners can consult its contents at any time to ensure its integrity. This property is particularly important in the case where the members of the network do not trust each other (open network, risk of compromise, ...). • Irrefutability: The immutability and integrity of the blockchain allow data and metadata (originating node, date, digital signature, etc.) to be permanently recorded and verified. Thus, if a mechanism is in place to uniquely identify the nodes in the network, they cannot refute any additions they may make to the blockchain. This ensures the traceability of data.				

4.6 Diagnosis Revolution tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-195	Applications front-end development	Front-end (client side) development will primarily provide appearance, structure, behavior and content management for both applications separately.	TR-113 , TR-112 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements
TR-153	VCE: Ability to render content overlayed on and adjacent to CE video	The software should be able to render informational content overlayed on rendered CE video, or adjacent to it. Such content may refer to explanatory visualizations, such as localization bounding boxes around detected abnormalities, or other results of automatic processing, such as identified classes of abnormalities in text form.	URE-14 , URE-13	Pilot 1	T3.1	Technical requirements refinement after the first sprint
TR-152	VCE: Ability to read and write supplementary information	The software should be able to read and write supplementary information files, i.e., results of automatic processing, for the purpose of long-term storage and recovery.	URE-14	Pilot 1	T3.1	Technical requirements refinement after the first sprint
TR-151	ECHO: Left Ventricular Ejection Fraction estimation from ECHO videos of the apical 4-chamber cardiac view	Given an ECHO video depicting the apical 4-chamber cardiac view, the software should be able to estimate the Left Ventricular Ejection Fraction.	URE-9 , URE-11 , URE-10	Pilot 1	T3.1	Technical requirements refinement after the first sprint

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-150	ECHO: Semantic segmentation of cardiac morphological structures	Given an ECHO video depicting one of the three apical cardiac views, the software should be able to automatically segment and discriminate between image regions that correspond to cardiac morphology of interest, i.e., the left ventricle endocardium and myocardium.	URE-9 , URE-11	Pilot 1	T3.1	Technical requirements refinement after the first sprint
TR-149	ECHO: Ability to render content overlayed on and adjacent to ECHO video	The software should be able to render informational content overlayed on rendered ECHO video, or adjacent to it. Such content may refer to explanatory visualizations, such as computed segmentation images of cardiac morphological structures, or other results of automatic processing, such as calculated metrics of cardiac function either in text form or in graphical plots.	URE-14 , URE-13 , URE-11	Pilot 1	T3.1	Technical requirements refinement after the first sprint
TR-148	ECHO: Ability to render ECHO video in native framerates	The software should be able to render ECHO video in its native framerate.	URE-14 , URE-13	Pilot 1	T3.1	Technical requirements refinement after the first sprint
TR-123	Unaffected performance	Applications should be able to operate unaffected and to the maximum in cases of increased data volume.	TR-111	Pilot 1	T3.1	DoA, user requirements

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-122	Ease of use	Applications must be designed considering the users level of knowledge and familiarity regarding the use of electronic systems and applications. The design must be user-friendly, with clear work screens, containing user guidance messages or warnings, where necessary, in order to achieve the exchange of necessary information in the most comprehensible way.	TR-111	Pilot 1	T3.1	
TR-121	Future expandability	Both applications should ensure that it is able, if required, to be upgraded, offering new functionalities and tools to the end-users.	TR-111	Pilot 1	T3.1	DoA, user requirements
TR-120	System availability	Within the project, procedures (physical and electronic) must be applied regarding the continuous availability of data and unimpeded access to them (e.g. use of online back-up servers, data disaster recovery servers, etc.).	TR-111	Pilot 1	T3.1	DoA, user requirements

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-119	Data integrity	Unauthorized modification, accidental loss or destruction of recorded patients' data could cause a number of serious problems, directly affecting the proper applications' functionality. For this purpose, encryption algorithms and controlled access based on the "need-to-know" principle will be applied.	TR-111	Pilot 1	T3.1	DoA, user requirements
TR-118	Security and privacy	Applications must implement security and privacy guidelines in line with European and international standards. Due to sensitive personal data (medical data) handling, special attention must be paid to the systems' compliance with the General Data Protection Regulation – GDPR.	TR-111	Pilot 1	T3.1	DoA, user requirements
TR-117	Predictive models' integration	Predictive models must be integrated into the respective applications for each medical scenario and necessary APIs must be developed.	URE-19 , URE-18 , TR-116 , TR-115 , TR-114 , URE-20 , TR-112 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-116	Identification of cases with obstructive coronary artery disease	Development of an AI-based model that will be able to classify patients based on the presence and extend of obstructive coronary artery disease (CAD).	URE-18 , TR-117 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements
TR-115	Identification of cases complicated by fetal growth restriction	Development of an AI-based model that will predict, with an acceptable percentage of certainty, whether each case will be complicated by fetal growth restriction.	TR-117 , URE-20 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements
TR-114	Identification of cases with symptoms of preterm labour	Development of an AI-based model that will predict, with an acceptable percentage of certainty, whether each pregnant woman with symptoms of preterm labour, might give birth prematurely.	URE-19 , TR-117 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements
TR-113	Applications' core functionalities development	For both applications it will be necessary to develop a set of services and tools that will serve their core functionality (tabs for recording essential medical data, ability to record / enter data of medical examination results, etc.).	TR-195 , URE-19 , URE-18 , URE-20 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-112	Patient profiles management	Both applications must allow the user/physician to create and manage patient profiles/accounts, therefore the corresponding functionality should be integrated in both applications.	TR-195 , URE-19 , URE-18 , TR-117 , URE-20 , TR-111	Pilot 1	T3.1	Consultation with medical team, user requirements
TR-111	Applications back-end development	Back-end development based on the proposed conceptual architecture model for both applications separately. The development will primarily focus on applications' databases, back-end logic, APIs, and servers that will be required for the smooth operation of the applications.	URE-19 , URE-18 , TR-119 , TR-118 , TR-117 , TR-116 , TR-115 , TR-114 , TR-113 , TR-112 , TR-123 , URE-20 , TR-122 , TR-121 , TR-120 , TR-195	Pilot 1	T3.1	Consultation with medical team, user requirements, DoA
TR-84	VCE: Summarization of CE videos into sections of diagnostic interest	Given a CE video recording, the software should be able to segment it into sections of successive normal frames, and sections of successive abnormality-containing frames.	URE-15	Pilot 1	T3.1	Consultation with participating medical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-83	VCE: Localization and classification of suspicious abnormalities in CE videos	Given a CE video recording, the software should be able to identify video frames that contain suspicious abnormalities, localize the abnormalities, and classify them into pre-determined classes.	URE-17 , URE-16 , URE-15	Pilot 1	T3.1	User requirements on D1.2
TR-82	VCE: Ability to read CE video files	The software should be able to read video files created during Capsule Endoscopy (CE) examinations.	URE-15	Pilot 1	T3.1	User requirements on D1.2
TR-81	ECHO: Left Ventricular Global Longitudinal Strain calculation from single and multiple ECHO videos	Given a single ECHO video of the apical 2-chamber, 3-chamber or 4-chamber view, the software should be able to calculate the Left Ventricular Global Longitudinal Strain (LV GLS). Given multiple videos of a different view each, the software should be able to calculate the average LV GLS across views.		Pilot 1	T3.1	Consultation with participating medical team
TR-80	ECHO: Left Ventricular Ejection Fraction estimation from ECHO videos pair of the apical 2-chamber and 4-chamber cardiac views	Given a pair of successively acquired ECHO videos of the apical 2-chamber and 4-chamber cardiac views, the software should be able to estimate the Left Ventricular Ejection Fraction.	URE-9 , URE-11 , URE-10	Pilot 1	T3.1	User requirements on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-79	ECHO: Real-time recognition of the three apical cardiac views from ECHO video	The three apical cardiac views in echocardiography refer to different cross-sections of the heart and are known as the apical 2-chamber, 3-chamber, and 4-chamber views. Given an ECHO video, the software should be able to recognize whether it depicts one of the three apical views and identify which one. Upon recognition, the software should be able to estimate a measure of distance to the reference view, reflecting the quality of the video in terms of structural resemblance to a properly acquired view.	URE-12	Pilot 1	T3.1	User requirements on D1.2
TR-78	ECHO: Ability to read and write DICOM ECHO video and supplementary information	The software should be able to read and write ECHO video recordings in accordance with the DICOM standard. The software should also be able to read and write supplementary information files, i.e., results of automatic processing, for the purposes of long-term storage and recovery.	URE-9 , URE-14 , URE-12	Pilot 1	T3.1	User requirements on D1.2

4.7 Logistic Improvement tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-40	Chatbot human-machine interaction AI tools (NLP)	Development of all the necessary AI tools to make the best interaction between the user and the chatbot. These tools will make easier • the conversation in natural language between the patients and the scheduler. • the conversation in natural language between the patients and the Robotic Nurse – Restricted Domain Conversation, Treated Story Lines to ensure patient safety	URE-71 , TR-140 , URE-68 , TR-74 , URE-67 , URE-21 , TR-71 , TR-132 , URE-61 , URE-72 , URE-147 , TR-72	Pilot 2, Pilot 5	T3.2, T3.5, T4.2, T4.4	D1.2
TR-39	Chatbot coaching system	Integration with EPIONE ™ System to obtain access to the chatbot features.	URE-22	Pilot 2	T3.2, T4.2, T4.4	D1.2
TR-38	Patient data exchange	Integration with InteropEHRate to ease the exchange of sensitive medical data, using highly secure channels. Databases: • Mosaiq machine • Omnipro	URE-24	Pilot 2	T3.2, T4.4	D1.2
TR-37	Mobile application	Development of a mobile application in order to bring the user the possibility of visualize all the proposed appointments and chat-bot to interact with the scheduler	URE-23	Pilot 2	T3.2, T4.4	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-35	Patient data sources	Obtain and store all the patient-related variables in order to interconnect all the data and have valuable reports.	URE-29 , URE-28 , URE-27 , URE-26 , URE-25 , URE-35 , URE-34 , URE-33 , URE-32 , URE-31 , URE-30	Pilot 2	T3.2, T4.4	D1.2
TR-34	Scheduler backend	Development of the algorithm that should be able to show and use the restrictions given by the medical staff to auto-generate new appointments for each patient.	URE-38 , URE-37 , URE-36 , URE-44	Pilot 2	T3.2, T4.2, T4.4	D1.2

4.8 Treatment Improvement tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-174	Collect and share KPI data in benchmarking framework	Sharing clinical data relevant to KPI measurements collected from sensors. The system will be built with a tool for receiving Pilots data (inputs and KPI) through the FHIR protocol of communication. It would be a possibility the use of Kafka because it includes different features for fault tolerance. A background system will be always running to process new data received with each topic and new topics from new or other pilots. The process saves the data on NOSQL database.	URE-48 , URE-56 , URE-141 , URE-3 , URE-54	Pilot 3	T3.3, T2.3	
TR-126	Collecting data from the components GRADIOR	The GRADIOR server will collect data from the management infrastructure layer and App.	URE-89 , URE-95	Pilot 6	T3.3	Input by INTRAS technical team
TR-125	Clinical management interface	Clinicians will need proper and usable interface to handle different types of data (graphics, dashboards, statistics, etc.).	URE-88 , URE-99 , URE-112 , URE-101	Pilot 6	T3.3	Input by INTRAS technical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-124	UIs of the GRADIOR monitoring tools will conform to modern design principles and accessibility requirements	The user interfaces of the GRADIOR monitoring tools will be simple, clean, and easy to understand, effectively communicating information to the user.	URE-82 , URE-105 , URE-106 , URE-117 , URE-118 , URE-108 , URE-87 , URE-98 , URE-111 , URE-113 , URE-83	Pilot 6	T3.3	Input by INTRAS technical team
TR-93	Interface for clinical data	Clinicians and physiotherapists will need proper and usable interface to handle different types of data (graphics, dashboards, statistics, etc.). • Graphical interface will be provided to clinicians and physiotherapists to visualize different types of data (graphics, dashboards, statistics, etc.)	URE-137 , URE-138 , URE-139 , URE-48 , URE-47 , URE-140 , URE-56 , URE-142 , URE-134 , URE-135 , URE-136	Pilot 3	T3.3	User requirements on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-92	Collecting data from the components	IRCCS server will collect data coming from infrastructure layer, tele-rehabilitation devices, iPrognosis and AI-based virtual sensors. VIMAR Cloud and IRCCS server will interact and exchange information and data.	URE-48 , URE-140 , URE-56 , URE-141 , URE-142 , URE-54 , URE-53 , URE-52 , URE-134 , URE-135 , URE-51 , URE-136 , URE-137 , URE-138 , URE-139	Pilot 3	T3.3	User requirements on D1.2
TR-91	Domotics and remote environmental control	Caregivers and medical staff can access data from domotics devices installed at San Camillo Hospital in Venice. • The integration among different sources of data will be handled by developing a solution based on API Rest and on KNX IoT 3rd party to allow data exchange. Further more, there will be the possibility to register to receive asynchronous notifications related to changes in data.	URE-48 , URE-140 , URE-56 , URE-55 , URE-142 , URE-53 , URE-52 , URE-134 , URE-135 , URE-51 , URE-136 , URE-50 , URE-137 , URE-138 , URE-139	Pilot 3	T3.3	User requirements on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-90	AI-based virtual sensors	AI will provide the tools to develop "virtual sensors", i.e. additional recommendations for users or technicians related to their system. These virtual sensors will enhance the patients' monitor capability, both in the hospital and remotely. Beyond boosting the functions of an existing system, it is also a useful means of support for the elderly and people with restricted mobility.	URE-48 , URE-56 , URE-55 , URE-142 , URE-54 , URE-53 , URE-52 , URE-134 , URE-51 , URE-136 , URE-50 , URE-137 , URE-138	Pilot 3	T3.3	User requirements on D1.2

TR-89	Ultra Wide Band (UWB) presence sensor	Development of an Ultra-Wide Band sensor capable of detecting human presence. The sensor will act as a radar for the high-bandwidth communication. UWB sensors are installed to detect any informative behaviour, including risks associated with mobility when therapists or caregivers are not in the room while monitoring and analysing domotic based events. • The UWB technology will be introduced in a new domotic devi ce that will provide reliable data on the presence of subjects in a room. The device will allow the collection of data on the human presence, useful to analyze human behaviour in the monitored environment. Its high detection accuracy will allow the falling detection functionality, to identify potentially dangerous situations where a person is alone in the room laying on the ground.	URE-137 , URE-138 , URE-48 , URE-56 , URE-55 , URE-142 , URE-53 , URE-52 , URE-134 , URE-51 , URE-136 , URE-50	Pilot 3	T3.3	User requirements on D1.2
TR-88	UIs of the iPrognosis monitoring tools	The user interfaces of the iPrognosis monitoring tools will be simple, clean,	URE-138 , URE-139 ,	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
	will conform to modern design principles and accessibility requirements	and easy to understand, effectively communicating information to the user.	URE-48 , URE-47 , URE-56 , URE-87 , URE-52			technical team
TR-87	Data transmitted from the iPrognosis monitoring tools will be processed on the servers and results will be stored there in JSON format following the HL7 FHIR standard.	Processing of the data acquired with the iPrognosis technologies will be performed on the receiving servers. The results will also be stored on the same servers, formatted as JSON, following the HL7 FHIR standard.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-86	iPrognosis monitoring tools will transmit data to servers in JSON format following the HL7 FHIR standard	In cases where data acquired via the iPrognosis monitoring technologies is transferred to servers for storage or processing purposes, the data will be formatted as JSON, following the HL7 FHIR standard.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-85	iPrognosis monitoring tools will transmit data to servers over HTTPS	In cases where data acquired via the iPrognosis monitoring technologies is transferred to servers for storage or processing purposes, transmission will be securely conducted according to the HTTPS protocol.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-20	Telerehabilitation kit	Patients might need caregivers' support to manage the telerehabilitation service from home. System should allow access from the relevant sites.	URE-49 , URE-48 , URE-47 , URE-56	Pilot 3	T3.3	Platform and cross-components requirements study based on D1.2

4.9 Surgical Support tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-184	Registration of patient's anatomy and the catheter in the world coordinate frame	This will help the operator to understand the catheter's position w/ respect to the anatomy and allow for more intuitive remote control as well as closed loop control	URE-60 , URE-58 , URE-57	Pilot 4	T3.4	
TR-183	Allow remote control of the catheter w/ low latency	The catheter will be controlled remotely. To allow the surgeon to get a good feeling of the mechanical properties of the catheter a low latency is necessary.		Pilot 4	T3.4	
TR-182	Integration of virtual camera at the catheter tip	The pose of the camera tip is tracked w/ respect to the patient's anatomy. This allows us to generate a virtual view at the tip of the camera to simulate a first person view from the catheter's perspective. This has the potential to significantly improve the intuitiveness of the control interface.		Pilot 4	T3.4	
TR-181	Integration of button to stop automated navigation during the procedure at any time	The operating surgeon can stop the automated navigation procedure at any time. This is a crucial safety feature.		Pilot 4	T3.4	
TR-103	User interface to define target location	The user can select a target location inside the patient's heart.	URE-60	Pilot 4	T3.4	D1.2
TR-102	Improved EP map	The user can view an AI-improved 3D electrophysiological map of cardiac structures and electrical signals.	URE-59	Pilot 4	T3.4	D1.2
TR-101	(Semi-)automatic navigation along a trajectory	The operating user can active (semi-)automatic navigation along a pre-defined or AI-generated ablation trajectory.	URE-58 , URE-57	Pilot 4	T3.4	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-100	(Semi-)automatic navigation to target location	The operating user can active (semi-)automatic navigation to a target location inside the patient's heart.	URE-57	Pilot 4	T3.4	D1.2
TR-99	Automatic reporting	Automatic population of key entries in the report, including steps performed during the procedure, stenosis assessment, optimal frames of the pre- and post angio runs. This function should also identify inconsistencies and incompleteness of the report	URE-122 , URE-123	Pilot 7	T3.4	
TR-98	Automatic key event detection	AI-based automatic detection of key intra-procedural events in X-ray image sequence, including balloon inflation, contrast agent injection and device deployment	URE-124	Pilot 7	T3.4	D1.2
TR-97	Coronary tree segmentation	AI-driven automated coronary tree segmentation with indications of stenosis for reporting. The algorithm should recognize the main vessel contours and quantify the degree of the stenosis.	URE-124	Pilot 7	T3.4	D1.2
TR-96	Automatic measurements transfer	Automatically transfer physiology parameters and hemo measurements (i.e. clinical variables like age, BMI, blood pressure, heart rate) from IGT equipment to the report.		Pilot 7	T3.4	D1.2
TR-95	Capture stenosis details	Capture the stenosis details (lesion % indicating the vessel narrowing) used for decision making during procedure into report	URE-124	Pilot 7	T3.4	D1.2
TR-94	Capture Procedure information	Capture procedure information used for decision making during procedure into report	URE-123	Pilot 7	T3.4	D1.2

4.10Assistive Care tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-191	The iPrognosis monitoring tools will be able to transmit raw measurements data and/or results to the e-Pokratis system servers, for processing or presentation/visualisation on the e-Pokratis website	In an effort towards unification of the monitoring solutions, communication between iPrognosis technologies and the e-Pokratis infrastructure will allow accessing the information produced by multiple tools at a single location. For this purpose, periodic, asynchronous transmission of data is required. Transmission of raw measurements data (e.g., keystroke dynamics data, accelerometer or gyroscope data, voice recordings) or results of processing (e.g., bradykinesia and rigidity scores, classification results), from the iPrognosis monitoring tools to the e-Pokratis system servers, will be possible. Raw measurements data will be processed on the servers to produce results. Results will be stored there and made available for presentation and visualization on the e-Pokratis website.	URE-91	Pilot 6	T3.5	Technical requirements refinement after the first sprint

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-189	Activities created with the Activity Plan Editor will comprise a title, description, multimedia, and default recommended frequency	Each activity will have a title and a description, as well as a default recommended repetition frequency, in text form. Additionally, activities may contain multimedia such as example images, videos, or audio information.	URE-154 , URE-155	Pilot 6	T3.5	Input by AUTH technical team
TR-188	Activities created with the Activity Plan Editor will be stored in and retrieved from a suitable database	A database will be the central storage point for all activities created with the Activity Plan Editor. The database will store all information (e.g., text, multimedia) related to each activity. Activities will be retrieved from the database for display or editing purposes.		Pilot 6	T3.5	Input by AUTH technical team
TR-187	The Activity Plan Editor web application will provide functionalities for viewing, editing, and creating activities	In the Activity Plan Editor web application, authenticated users will be able to view a list of the existing activities, edit them, or create new ones, through appropriate graphical user interfaces.	URE-154 , URE-155	Pilot 6	T3.5	Input by AUTH technical team
TR-186	The Activity Plan Editor web application will provide user sign-up and sign-in functionalities	In the Activity Plan Editor web application, new users will be able to register, and existing users will be able to sign-in using their credentials (username and password). The required information for user authentication will be securely stored in an appropriate database.		Pilot 6	T3.5	Input by AUTH technical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-185	The Activity Plan Editor will be hosted on servers of INTRAS	The required server infrastructure for hosting the Activity Plan Editor, including the web application as well as back-end components (e.g., databases) will be provided by INTRAS.		Pilot 6	T3.5	Input by AUTH technical team
TR-172	IoT and robots connectivity	To connect to GC's local Network infrastructure, Robots and IoT devices should use Wi-Fi in client mode.	URE-71 , URE-70 , TR-170 , URE-69 , URE-66 , URE-75 , URE-63 , URE-62	Pilot #6 ; Pilot#5	T3.5	
TR-171	Blockchain	Machines that would like to push data into the blockchain (e.g. robots and IoT) should use the WebDAV protocol.	TR-58 , URE-66 , URE-63	Pilot #6 ; Pilot#5	T3.5	
TR-170	GC local network infrastructure	GC local network is composed of YOI routers communicating with each other using a mesh networking protocol. YOI routers can be displayed in the environment (e.g. walls) with access to power supply and in places where they cannot be unplugged by mistake. Routers should be placed in the wifi range of each other or, if it is not possible, have access to an Ethernet backhaul.	TR-172 , URE-158	Pilot #6 ; Pilot#5	T3.5	
TR-165	Facilitated log in	The log in functionality in the Pilot application should be user-friendly by including pictograms.	URE-153	Pilot 6	T3.5	User requirements on Jira

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-164	Content size and organization being shown in the tablet (small interface)	Tablet size / interface size (reading and interaction facilitated) Older adults generally have difficulties seeing something so small. The robot pepper seems to have a very small tablet. Auto-responsive.	URE-157	Pilot 6	T3.5	User requirements on Jira
TR-146	Data Annoynmization of sensed data	Libraries to ensure proper data anonymization related features extracted from videos.	URE-80 , URE-68	Pilot 5	T3.5 Technical Requirements	
TR-145	M2M Protocol to support distributed Edge-Fog Implementation	Kafka, MQTT, REST protocols to support services and interaction among services.	URE-150 , TR-143	Pilot 5	T3.5 Technical Requirements	
TR-144	Resource allocation and scheduling	Edge v.s. FOG computing paradigm to ensure real-time messaged processing mechanism to achieve proper execution of services	URE-69 , TR-74 , URE-66 , TR-143	Pilot 5	T3.5 Technical Requirements	
TR-143	Data interaction between the robot, services and the edge computing platform	An FSM-based approach towards the activation of control/movement and interaction capacity of the robot. This is due to hardware requirements of the services, i.e. not to overload the robot, and since some data sources and hardware resources might be locked when being accessed	TR-141 , URE-69 , URE-150 , URE-64 , TR-145 , URE-63 , TR-144 , URE-114	Pilot 5	T3.5 Technical Requirements	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-142	Access to Iot Sensor network on the Robot	Since a hybrid slam is envisaged also access to other sensors (i.e. lasers and sonars) must be ensured.	TR-141 , URE-119 , URE-77 , URE-65 , URE-64 , URE-75 , URE-63	Pilot 5	T3.5 Technical Requirements	
TR-141	Simultaneous localization and mapping and robot awareness	Simultaneous localization and mapping (SLAM) is the computational problem of constructing or updating a map of an unknown environment while simultaneously keeping track of an agent's location within it. While this initially appears to be a chicken-and-egg problem there are several algorithms known for solving it, at least approximately, in tractable time for certain environments.	TR-139 , TR-138 , URE-64 , URE-75 , URE-63 , URE-145 , TR-133 , TR-132 , TR-143 , TR-142	Pilot 5	T3.5 Technical Requirements	
TR-140	Voice Activity Detection	VAD must be delivered to enable execution of conversation and to activate speech recognition on demand	URE-144 , TR-40 , TR-72 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-139	Quality of camera input and video signal	Some signal preprocessing might be required to ensure the minimal quality of video signal	TR-141 , URE-78 , TR-66 , URE-77 , URE-64	Pilot 5	T3.5 Technical Requirements	
TR-138	Camera and Mic Streams of the Robot	For edge classification, we require access to the stream.	TR-141 , URE-90 , URE-78 , TR-66 , URE-64 , URE-75 , URE-144 , URE-61	Pilot 5	T3.5 Technical Requirements	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-137	Language Dependency - Resources to train the Algorithms	Some of the algorithms might require additional resources, especially those analyzing the language-dependent features	URE-67 , TR-66 , URE-73 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-136	IR Sensor to enable Remote Temperature Measurements	Minimal distance is 0.5 meters	URE-78 , URE-77 , TR-71 , URE-64 , URE-75	Pilot 5	T3.5 Technical Requirements	
TR-135	Connectable IoT-based Monitor	Connectable vital sign monitors that enable a) autonomous collection of data and b) collection of data on demand. The monitors will be delivered by the Pilot Sponsor	TR-71 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-134	Training Material for Speech Synthesis	Data-Driven DNN-based Speech synthesis required at minimum 40 hours of speech from single speaker	URE-73 , TR-72 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-133	Quality of Sound Source and speech Signal	Minimal requirements and noise within the environment need to be evaluated and the use of amplification and noise reduction applied at the edge	TR-141 , TR-66 , TR-72 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-132	HPC Requirements at the EDGE	Hardware components supporting the inference at the edge using NVIDIA-based technologies	TR-141 , TR-40 , TR-72	Pilot 5	T3.5 Technical Requirements	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-131	Training Material for Speech Recognition	An end-to-end automatic speech recognition (ASR) system takes speech audio waveform and outputs the corresponding text. Approximately 1000 hours of annotated speech	URE-144 , URE-73 , TR-72	Pilot 5	T3.5 Technical Requirements	
TR-130	Kinematic model to Control Pepper	Design of the kinematic model to carry out exercises	URE-151 , TR-74 , URE-65 , URE-61	Pilot 5	T3.5 Technical Requirements	
TR-88	UIs of the iPrognosis monitoring tools will conform to modern design principles and accessibility requirements	The user interfaces of the iPrognosis monitoring tools will be simple, clean, and easy to understand, effectively communicating information to the user.	URE-138 , URE-139 , URE-48 , URE-47 , URE-56 , URE-87 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-87	Data transmitted from the iPrognosis monitoring tools will be processed on the servers and results will be stored there in JSON format following the HL7 FHIR standard.	Processing of the data acquired with the iPrognosis technologies will be performed on the receiving servers. The results will also be stored on the same servers, formatted as JSON, following the HL7 FHIR standard.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-86	iPrognosis monitoring tools will transmit data to servers in JSON format following the HL7 FHIR standard	In cases where data acquired via the iPrognosis monitoring technologies is transferred to servers for storage or processing purposes, the data will be formatted as JSON, following the HL7 FHIR standard.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-85	iPrognosis monitoring tools will transmit data to servers over HTTPS	In cases where data acquired via the iPrognosis monitoring technologies is transferred to servers for storage or processing purposes, transmission will be securely conducted according to the HTTPS protocol.	URE-138 , URE-139 , URE-48 , URE-56 , URE-52	Pilot 3, Pilot 6	T3.3, T3.5	Input by AUTH technical team
TR-75	Automatic scheduling system	A System to automate FHIR CarePlan resource: i.e. a rule based engine to automatically trigger required behavior of the robotic nurse as defined by the clinicians. For instance, to delegate the nurse to execute exercise with Patient A every morning at 6.00 AM. A FSM based or a similar Rule Based Engine is proposed to be deployed	URE-71 , URE-150 , URE-67 , URE-152 , TR-74 , URE-143 , URE-62 , URE-146	Pilot 5	T3.5	D1.2
TR-74	Robot coaching system	Design a series of exercises as exergames executed on the robot to help patient with breathing exercises. Speech and Gestures are supported, if needed also the tablet may be used to provide multidimensional coaching.	URE-151 , TR-75 , URE-120 , URE-121 , TR-144 , URE-74 , URE-156 , URE-62 , TR-40 , URE-61 , URE-147 , TR-72 , URE-114 , TR-130 , URE-81 , TR-67	Pilot 5	T3.5	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-73	Common Data Model to universally store Patient data	Aggregation of new data collected, such as blood-pressure, heart rate, temperature (continuous), Mood/Emotion, Patient Experience, Health Care Quality Measures, User Experience and Patient Engagement with Existing Clinical Data. We propose HL7 FHIR Resources and HL7 FHIR Server interlinked with.	URE-76	Pilot 2	T3.5	D1.2
TR-72	E2E speech recognition and E2E speech synthesis in Slovenian Language	The Robot should be able to deliver a spoken language interface with support for speech and natural language. Example technologies: • Tacatron, WaveGlow • CTC, Jasper	URE-151 , TR-74 , URE-67 , TR-66 , TR-134 , TR-133 , URE-74 , TR-40 , TR-132 , TR-131 , URE-61 , URE-72 , URE-71 , TR-140	Pilot 5	T3.5	Platform and cross-components requirements study based on D1.2
TR-71	Automation of retrospective data collection during Grand Rounds	The robot should automatically recollect the relevant clinical data for the specific patient and visualize it (intuitive interfaces).	URE-71 , URE-148 , URE-70 , URE-149 , TR-67 , URE-150 , URE-67 , TR-22 , TR-136 , TR-135 , TR-40 , URE-147	Pilot 5	T3.5	Platform and cross-components requirements study based on D1.2

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-70	Visualization of the retrospective data from prospective study	An intuitive way to browse, visualize and modify/update FHIR resources (i.e. FHIR Client). Example libraries: • SMART on FHIR • HAPI FHIR • Fhir.NET API • Spark is a public domain FHIR • Snow Owl • Php-fhir • Hearth • Fhir-kit-client	URE-148 , URE-70 , TR-69 , URE-146	Pilot 5	T3.5	D1.1, D1.2
TR-69	Web interface to access clinician's interfaces with mobile and PC-based devices	Access to the dashboard should be via web, using a common browser. The interface must be responsive	URE-148 , URE-70 , URE-132 , TR-70	Pilot 5	T3.5	D1.1, D1.2
TR-67	Libraries for action recognition	Robots need to recognize some basic actions to evaluate proper execution of exercises. If possible we should consider also recognition of proper breathing using vision + acoustic processing.	TR-74 , URE-67 , TR-71 , URE-61 , URE-147	Pilot 5	T3.5	Development and Deployment Tools for AI study based on D1.2
TR-66	Libraries for multimodal classification of emotion/mood and symptoms of depression	In addition to PROs, the robots should be able to sense the user and evaluate hers/his psychological state from conversation exploiting features extracted with multimodal sensing.	TR-139 , TR-138 , TR-137 , TR-133 , URE-61 , URE-147 , TR-72	Pilot 5	T3.5	Development and Deployment Tools for AI study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-40	Chatbot human-machine interaction AI tools (NLP)	Development of all the necessary AI tools to make the best interaction between the user and the chatbot. These tools will make easier • the conversation in natural language between the patients and the scheduler. • the conversation in natural language between the patients and the Robotic Nurse – Restricted Domain Conversation, Treated Story Lines to ensure patient safety	URE-71 , TR-140 , URE-68 , TR-74 , URE-67 , URE-21 , TR-71 , TR-132 , URE-61 , URE-72 , URE-147 , TR-72	Pilot 2, Pilot 5	T3.2, T3.5, T4.2, T4.4	D1.2
TR-29	Secure computing environment	The system should be secure enough to ensure that data is safe from unauthorized eyes in the same space or through the internet.	URE-69 , URE-68 , URE-152 , TR-44 , TR-43 , TR-51 , TR-50 , URE-71 , TR-28 , TR-49 , URE-117 , TR-46 , TR-57 , TR-48 , TR-36 , TR-47	Platform, Pilot 8, Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-28	Privacy	All collected information should be unobstructed and users should be able to withdraw themselves and their data at any time from the system for any reason.	URE-69 , TR-42 , URE-68 , TR-41 , URE-67 , URE-152 , TR-44 , TR-51 , TR-50 , URE-148 , TR-49 , URE-117 , TR-29 , TR-46 , TR-57 , TR-48 , TR-36 , TR-47	Platform, Pilot 6, Pilot 5	T3.5, T4.4	Platform and cross-components requirements study based on D1.2
TR-27	GDPR	The system must be designed and operate in a way that conforms to the country's laws. In the European Union, the system must be compliant with the General Data Protection Regulation7 (GDPR).	URE-148 , URE-107 , TR-48 , URE-68 , URE-67	Platform, Pilot 5, Pilot6	T3.5, T4.4	Platform and cross-components requirements study based on D1.2
TR-22	Libraries for feature extraction from multimodal sensing	Facial, speech and text feature extraction libraries should be supported in development and deployment. Example libraries: • Facial: OpenFace, AUNets • Speech: openSMILE, LibRosa • Text: NLTK, Reldi, Spacy, Stanza • Multi-modal: end2you	URE-67 , TR-71 , URE-74 , URE-61 , URE-147	Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2

4.11 Personalised treatment tools development

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-108	Bring new discoveries into clinical care	Clinical researchers should be able to use advances in diagnosis and treatment, when validated. For example, development of computer-aided clinical decision-support systems: 1. the intuitive visualization of image and molecular patient data 2. personalizing therapeutic recommendations through predictive models of response to treatment and outcome. By combining biological and clinical data, to achieve the highest accuracy in predicting tumour response and follow-up.	URE-130	Pilot 8	T3.6, T5.3	Platform and cross-components requirements study based on D1.2
TR-107	Secure computing environment	Built for data science to enable discovery, within the hospital setting. Secure computing environment like XNAT for structured data management: XNAT is an open-source platform for imaging research. XNAT helps in management, productivity and quality assurance task related mainly to the imaging data and is being commonly used in public datasets management. XNAT provide full dicom image integration and annonymization, secure access to data and fine-grained permission control, integrated search and reporting on the image data. It facilitates complex processing on the data by using high performance computing, search and exploration of large datasets.	URE-130	Pilot 8	T3.6, T4.2	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-106	Access to different data types	EMR, medical imaging, genomics, and physiological monitoring data. For example : Variables to be collected are: 1. Tumour type (histopathology) 2. Tumour location (frontal/temporal/parietal/occipital/central/posterior fossa/other) 3. MRI characteristics (volume on T1+/- Gd, volume of FLAIR hyperintensity) 4. FET-PET characteristics (maximum metabolic activity, maximum TBR (Tumour-to-background ratio), tumour volume (area of TBR>1.6)) 5. Spatial genomics data, including mutations related to cancer and their effect at the protein level 6. Former medical history 7. Clinical symptoms at diagnosis 8. Physical neurologic exam at diagnosis (abnormal findings) 9. Treatment (surgical, medical, radiotherapy) at first diagnosis 10. Treatment at (first, second, etc) progression 11. Date of progression (progression-free survival) (first, second, etc) 12. Date of death (overall survival) 13. Date of diagnosis	URE-130	Pilot 8	T3.6, T2.1	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-105	Environments that ensure data security	The system should be able to protect patient information, by supporting full de-identification when it is required. The integrated data system enables de-identification of data when required, in relation to the study parameters, so that patient identity cannot be extracted from them. This includes removing personal information, but also reducing data content when necessary (*e.g.* genetic fingerprint of amino acid variants in genome).		Pilot 8	T3.6, T2.4	Platform and cross-components requirements study based on D1.2
TR-104	Better access to clinical data for research	The system should enable research within legal parameters to help advance healthcare. The legal requirements that the research-based tools need to adhere to, especially with regard to accountability in clinical decision support, and compliance with principles and obligations outlined inter alia in the EU General Data Protection Regulation and Belgian Framework on Data Protection, will be included. A secure integrated data system with controlled user roles and data access will enable researchers to access only the data designated by study parameters.	URE-126	Pilot 8	T3.6, T2.1, T4.1	Platform and cross-components requirements study based on D1.2

4.12Development and Deployment tools for AI-based solutions

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-158	HosmartAI Platform Application security and code quality	Each HosmartAI Application should pass the defined quality gate in SonarQube (if code is provided) which will include the essential security checks for apps (important security vulnerabilities, issues that might affect functionality, etc.). Also, other checks that might be part of CI/CD should be successful, e.g. checks for compromised passwords, Docker image vulnerabilities, etc.		Platform	T4.2	Input by INTRA technical team
TR-157	GitLab.com repository for Platform components	Platform components should be available in the relevant project in GitLab.com. If code is included, then also the relevant Dockerfiles and build instructions should be available. If code is not included, the docker image should be available to be pulled from a Docker registry. In both of the above cases, the deployment steps should be described in code in the relevant Jenkinsfile.		Platform	T4.2, T4.4	Input by INTRA technical team
TR-154	HosmartAI Platform Application containers	HosmartAI Platform Applications should run inside containers. The required volumes and ports should be documented and in case multiple containers are required, the deployment should be described inside a docker-compose.yml file.		Platform	T4.2, T4.4	Input by INTRA technical team
TR-127	HosmartAI Applications containers	HosmartAI Applications should support deployment based on Docker containers.	URE-5 , URE-4 , URE-83		T4.2, T4.4	Input by INTRA Technical Team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-107	Secure computing environment	Built for data science to enable discovery, within the hospital setting. Secure computing environment like XNAT for structured data management: XNAT is an open-source platform for imaging research. XNAT helps in management, productivity and quality assurance task related mainly to the imaging data and is being commonly used in public datasets management. XNAT provide full dicom image integration and anonymization, secure access to data and fine-grained permission control, integrated search and reporting on the image data. It facilitates complex processing on the data by using high performance computing, search and exploration of large datasets.	URE-130	Pilot 8	T3.6, T4.2	Platform and cross-components requirements study based on D1.2
TR-40	Chatbot human-machine interaction AI tools (NLP)	Development of all the necessary AI tools to make the best interaction between the user and the chatbot. These tools will make easier • the conversation in natural language between the patients and the scheduler. • the conversation in natural language between the patients and the Robotic Nurse – Restricted Domain Conversation, Treated Story Lines to ensure patient safety	URE-71 , TR-140 , URE-68 , TR-74 , URE-67 , URE-21 , TR-71 , TR-132 , URE-61 , URE-72 , URE-147 , TR-72	Pilot 2, Pilot 5	T3.2, T3.5, T4.2, T4.4	D1.2

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-39	Chatbot coaching system	Integration with EPIONE ™ System to obtain access to the chatbot features.	URE-22	Pilot 2	T3.2, T4.2, T4.4	D1.2
TR-34	Scheduler backend	Development of the algorithm that should be able to show and use the restrictions given by the medical staff to auto-generate new appointments for each patient.	URE-38 , URE-37 , URE-36 , URE-44	Pilot 2	T3.2, T4.2, T4.4	D1.2
TR-29	Secure computing environment	The system should be secure enough to ensure that data is safe from unauthorized eyes in the same space or through the internet.	URE-69 , URE-68 , URE-152 , TR-44 , TR-43 , TR-51 , TR-50 , URE-71 , TR-28 , TR-49 , URE-117 , TR-46 , TR-57 , TR-48 , TR-36 , TR-47	Platform, Pilot 8, Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2
TR-23	ROS libraries development	Development should support improving the code of ROS libraries by specific needs in the project (clean environment, hospital, etc.) in Python or C++ code.	URE-65 , URE-76 , URE-62	Pilot 5	T4.2	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-22	Libraries for feature extraction from multimodal sensing	Facial, speech and text feature extraction libraries should be supported in development and deployment. Example libraries: • Facial: OpenFace, AUNets • Speech: openSMILE, LibRosa • Text: NLTK, Reldi, Spacy, Stanza • Multi-modal: end2you	URE-67 , TR-71 , URE-74 , URE-61 , URE-147	Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2
TR-14	Application versions	Applications should be able to have new versions to fix issues or add features.	URE-6	Platform	T4.2	Development and Deployment Tools for AI study based on D1.2

4.13HosmartAI Co-creation and Hub

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-190	API to get data from Benchmarking	Implementation of an open API with the Integration of the Benchmarking and Marketplace access and share of data.	URE-159		T2.3, T4.3, T4.1	
TR-168	HosmartAI Hub user management	HHub should support user login and save parameters that are specific to each user. Co-creation and marketplace should use the specific user context.	URE-98 , URE-100	Platform	T4.3, T4.4	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-167	Co-creation knowledge base	Co-creation should provide tools that can be used to provide a knowledge base, such as a wiki, a recommendation tool based on existing solutions, a wizard based on existing templates, etc.		Platform	T4.3	Input by INTRA technical team
TR-166	Co-creation forum	Co-creation tools should include forum-like tool(s)		Platform	T4.3	Input by INTRA technical team
TR-56	Dashboard implements secure access to underlying APIs and to users	Given that all communication between the Dashboard, the users, and the underlying components such as Marketplace and Benchmarking will be conducted over the Internet, security mechanisms should be in place to ensure privacy, system and data integrity. Apart from common policies such as authentication with credentials, inter-module communication can be secured using token such as JWT.	URE-131	Platform	T4.3	Platform and cross-components requirements study based on D1.2
TR-55	Dashboard expose functionality of underlying components	The Dashboard client API should map to the exposed functions of underlying modules such as Marketplace, Benchmarking, etc. The functionality of the mapped functions should be presented to users.			T4.3	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-54	Implement decoupled Dashboard architecture	In order for the dashboard to communicate with underlying modules, it should employ standard interfaces such as REST and / or gRPC		Platform	T4.3	Platform and cross-components requirements study based on D1.2
TR-53	Ensure accessibility to Hhub Dashboard from all types of devices	Access to the web platform should be irrelevant of Operating System, device type and browser, implementation should be platform and device neutral	URE-132	Platform	T4.3	Platform and cross-components requirements study based on D1.2
TR-52	Provide web interface for Dashboard	Access to the dashboard should be via web, using a common browser. Contending technologies for dashboard implementation include ASPX.NET (DevExpress XAF), Blazor (C# .NET / WebAssembly), PHP (WordPress or other CMS)	URE-132	Platform	T4.3	Platform and cross-components requirements study based on D1.2

4.14 HosmartAI Marketplace and 3rd parties integration

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-163	Contact info in Marketplace items	Author or publisher fields should be included with each item. Organization and/or person name and emails can be provided.			T4.5	
TR-162	Dependencies in Marketplace items	If the use of the item depends on others, the latter should be provided. TBD what specific fields to use for that (links/text).			T4.5	

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-161	Financial info in Marketplace items	Items should include information on the financial model they are offered in a specific field (e.g. under paid license, open source under LGPL). Further details may be provided in links, description or attachment. If there are geographical restrictions on where the items are offered, they should be listed. The addition of a specific field for that is TBD.			T4.5	
TR-65	Types of Marketplace items	The HosmartAI Marketplace should be able to include all components, devices, services, data sources, platforms, etc. that are available for exploitation. Also, components such as data sets that will be useful for application development.	URE-128 , URE-73	Platform	T4.5	
TR-64	Description of Marketplace items	Marketplace items should have descriptions to understand where each one is meant to be used.	URE-13	Platform	T4.5	
TR-63	End user feedback on Marketplace	The feedback received from end users through the Benchmarking tool should be able to be used in the Marketplace for sorting, filtering, recommendation.	URE-7	Platform	T4.5	HosmartAI Marketplace and 3rd parties Integration study based on D1.2
TR-62	Catalog of AI Applications	AI Applications must be available on a web-based catalog, which can be sorted and filtered based on description and benchmarking results.	URE-4	Platform	T4.5	HosmartAI Marketplace and 3rd parties Integration study based on D1.2

4.15Platform and cross-components requirements

Key	**Summary**	**Description**	**Linked Issues**	**Related pilots (optional)**	**Relevant project tasks**	**Source**
TR-190	API to get data from Benchmarking	Implementation of an open API with the Integration of the Benchmarking and Marketplace access and share of data.	URE-159		T2.3, T4.3, T4.1	
TR-160	Application Onboarding	The system should provide a mechanism to onboard applications to a HosmartAI Platform deployment.	URE-5 , URE-4 , URE-83	Platform	T4.1	Input by INTRA technical team
TR-168	HosmartAI Hub user management	HHub should support user login and save parameters that are specific to each user. Co-creation and marketplace should use the specific user context.	URE-98 , URE-100	Platform	T4.3, T4.4	
TR-159	Unit and Integration Tests for HosmartAI Platform Applications	HosmartAI Platform Application should have adequate unit test coverage and integration tests for the endpoints that are expected to be used in integration with other components. Automated unit and integration test execution must be implemented in order to be used in the CI/CD pipelines.		Platform	T4.4	Input by INTRA technical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-157	GitLab.com repository for Platform components	Platform components should be available in the relevant project in GitLab.com. If code is included, then also the relevant Dockerfiles and build instructions should be available. If code is not included, the docker image should be available to be pulled from a Docker registry. In both of the above cases, the deployment steps should be described in code in the relevant Jenkinsfile.		Platform	T4.2, T4.4	Input by INTRA technical team
TR-156	Documentation of application endpoints	Application endpoints that could be used in integration with other apps or to expose user functionality should be documented. The documentation should ideally consist of a YAML or JSON file adhering to the OpenAPI v3 spec that is valid when loaded on Swagger Editor (https://editor.swagger.io/) or used through the Swagger UI.		Platform	T4.4	Input by INTRA technical team
TR-155	HosmartAI Platform Application user authentication	HosmartAI Platform Applications that require user authentication based on credentials should implement support for OAuth 2.0. The integration to an OAuth 2.0 compliant server, such as Keycloak, at a later stage, should be configurable based on configuration files and environment variables.	URE-131	Platform	T4.4	Input by INTRA technical team

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-154	HosmartAI Platform Application containers	HosmartAI Platform Applications should run inside containers. The required volumes and ports should be documented and in case multiple containers are required, the deployment should be described inside a docker-compose.yml file.		Platform	T4.2, T4.4	Input by INTRA technical team
TR-127	HosmartAI Applications containers	HosmartAI Applications should support deployment based on Docker containers.	URE-5 , URE-4 , URE-83		T4.2, T4.4	Input by INTRA Technical Team
TR-40	Chatbot human-machine interaction AI tools (NLP)	Development of all the necessary AI tools to make the best interaction between the user and the chatbot. These tools will make easier • the conversation in natural language between the patients and the scheduler. • the conversation in natural language between the patients and the Robotic Nurse – Restricted Domain Conversation, Treated Story Lines to ensure patient safety	URE-71 , TR-140 , URE-68 , TR-74 , URE-67 , URE-21 , TR-71 , TR-132 , URE-61 , URE-72 , URE-147 , TR-72	Pilot 2, Pilot 5	T3.2, T3.5, T4.2, T4.4	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-39	Chatbot coaching system	Integration with EPIONE ™ System to obtain access to the chatbot features.	URE-22	Pilot 2	T3.2, T4.2, T4.4	D1.2
TR-38	Patient data exchange	Integration with InteropEHRate to ease the exchange of sensitive medical data, using highly secure channels. Databases: • Mosaiq machine • Omnipro	URE-24	Pilot 2	T3.2, T4.4	D1.2
TR-37	Mobile application	Development of a mobile application in order to bring the user the possibility of visualize all the proposed appointments and chat-bot to interact with the scheduler	URE-23	Pilot 2	T3.2, T4.4	D1.2
TR-35	Patient data sources	Obtain and store all the patient-related variables in order to interconnect all the data and have valuable reports.	URE-29 , URE-28 , URE-27 , URE-26 , URE-25 , URE-35 , URE-34 , URE-33 , URE-32 , URE-31 , URE-30	Pilot 2	T3.2, T4.4	D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-34	Scheduler backend	Development of the algorithm that should be able to show and use the restrictions given by the medical staff to auto-generate new appointments for each patient.	URE-38 , URE-37 , URE-36 , URE-44	Pilot 2	T3.2, T4.2, T4.4	D1.2
TR-29	Secure computing environment	The system should be secure enough to ensure that data is safe from unauthorized eyes in the same space or through the internet.	URE-69 , URE-68 , URE-152 , TR-44 , TR-43 , TR-51 , TR-50 , URE-71 , TR-28 , TR-49 , URE-117 , TR-46 , TR-57 , TR-48 , TR-36 , TR-47	Platform, Pilot 8, Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-28	Privacy	All collected information should be unobstructed and users should be able to withdraw themselves and their data at any time from the system for any reason.	URE-69 , TR-42 , URE-68 , TR-41 , URE-67 , URE-152 , TR-44 , TR-51 , TR-50 , URE-148 , TR-49 , URE-117 , TR-29 , TR-46 , TR-57 , TR-48 , TR-36 , TR-47	Platform, Pilot 6, Pilot 5	T3.5, T4.4	Platform and cross-components requirements study based on D1.2
TR-27	GDPR	The system must be designed and operate in a way that conforms to the country's laws. In the European Union, the system must be compliant with the General Data Protection Regulation7 (GDPR).	URE-148 , URE-107 , TR-48 , URE-68 , URE-67	Platform, Pilot 5, Pilot6	T3.5, T4.4	Platform and cross-components requirements study based on D1.2
TR-26	Communication with cloud services	The system should allow communication with cloud services to store data if an application requires it.	URE-95	Pilot 6	T4.4	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-22	Libraries for feature extraction from multimodal sensing	Facial, speech and text feature extraction libraries should be supported in development and deployment. Example libraries: • Facial: OpenFace, AUNets • Speech: openSMILE, LibRosa • Text: NLTK, Reldi, Spacy, Stanza • Multi-modal: end2you	URE-67 , TR-71 , URE-74 , URE-61 , URE-147	Pilot 5	T3.5, T4.2, T4.4	Development and Deployment Tools for AI study based on D1.2
TR-21	Integration with Pepper robot	The system should support communication protocols with Softbank's Pepper robot	URE-69 , URE-66 , URE-65 , URE-62	Pilot 5	T4.4	Platform and cross-components requirements study based on D1.2
TR-17	Access through smartphones	The system should allow smartphones to communicate with HosmartAI applications.	URE-148 , URE-79 , URE-67 , URE-23	Pilot 2, Pilot 5	T4.4	Platform and cross-components requirements study based on D1.2
TR-15	Efficient placement and integration of the software in the clinical setting	The solution should be straightforwardly integrated into the established clinical practice, introducing no obstacles.	URE-14	Pilot 1	T4.4	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-13	Mechanism to convert existing application	Any existing application without special hardware requirements should be able to be onboarded as a HosmartAI application. This mechanism would require the app to be containerized and its input and output parameters declared (e.g. using Protocol Buffers).	URE-5	Platform	T4.4	Platform and cross-components requirements study based on D1.2

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-5	Give recommendations in Hospital performance aspects	The common database benchmarking performance framework will be developed following all precautions regarding data safety and anonymity as imposed by GDPR guidelines optimizing data processing and minimizing risk related to data management (cyber, loss, deterioration, etc.). The common database benchmarking performance framework will be able to give recommendations in Hospital performance aspects such as: 1. management efficiency analysis: Hospital's productivity and organisation; 2. technical efficiency analysis: data of processes, equipment; and iii) best practices/balanced score cards and other performance indicators.	URE-3, URE-4	None (Platform)	T2.2, T2.3, T4.4	DoA (1.3.1.4 HosmartAI Platform scenarios)

Key	Summary	Description	Linked Issues	Related pilots (optional)	Relevant project tasks	Source
TR-104	Better access to clinical data for research	The system should enable research within legal parameters to help advance healthcare. The legal requirements that the research-based tools need to adhere to, especially with regard to accountability in clinical decision support, and compliance with principles and obligations outlined inter alia in the EU General Data Protection Regulation and Belgian Framework on Data Protection, will be included. A secure integrated data system with controlled user roles and data access will enable researchers to access only the data designated by study parameters.	URE-126	Pilot 8	T3.6, T2.1, T4.1	Platform and cross-components requirements study based on D1.2

5 Conceptual architecture

The contents of this chapter are also included in D1.5. This chapter is included in D1.6 for completeness.

5.1 Description

A HosmartAI-enabled application follows the reference architecture depicted in the figure below, consisting of the following layers and taking into consideration Healthcare standards at different levels (functional, syntactic, and semantic).

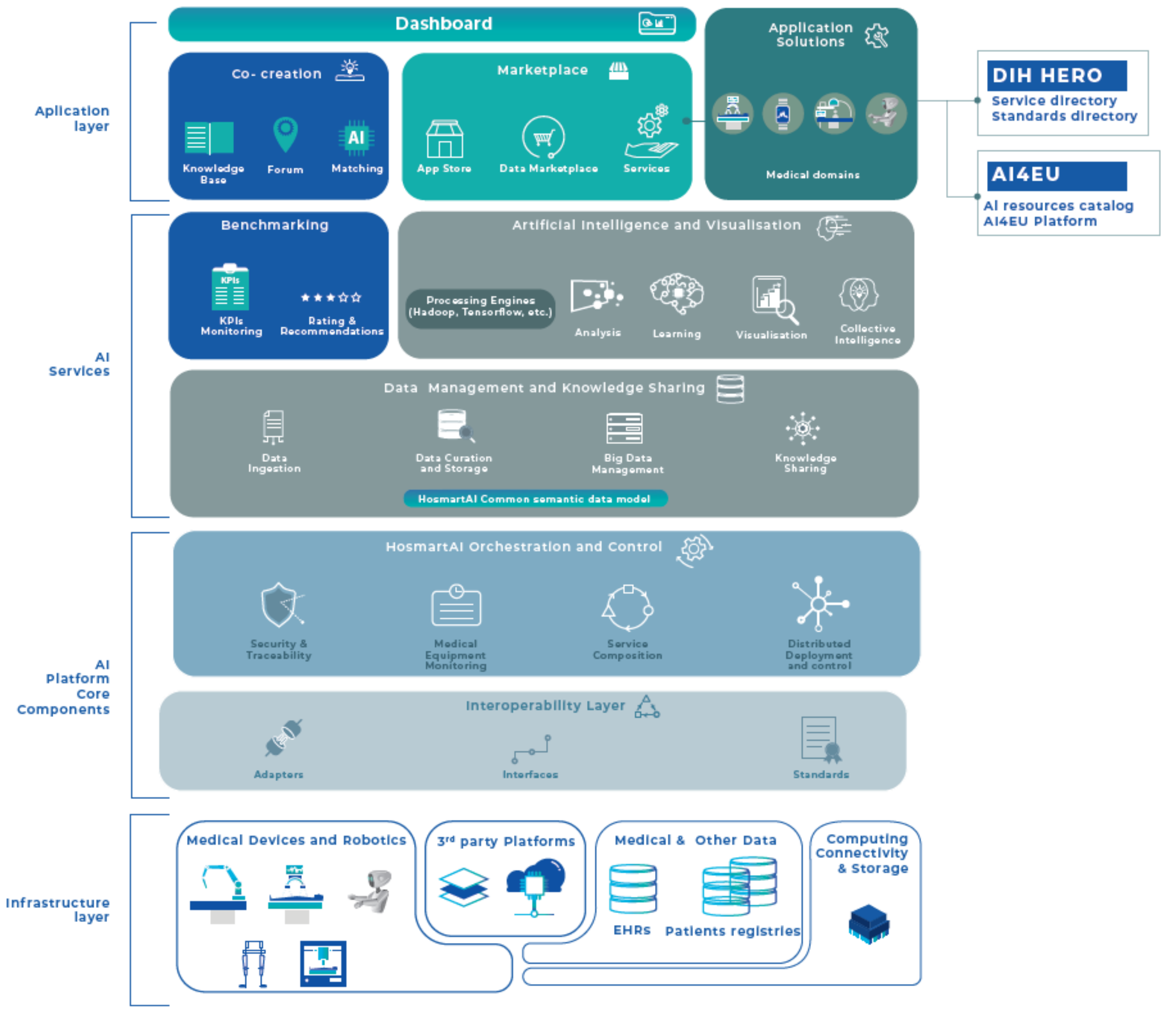


Figure 21: HosmartAI Conceptual architecture.

5.2 Components

The components that comprise the HosmartAI conceptual architecture have been categorised as belonging to four layers:

- Infrastructure layer

- AI platform Core Components layer
- AI Services layer
- Application layer

5.2.1 Infrastructure layer

This layer includes the infrastructure, such as the following:

- Assets that are used to store data as well as train and execute AI algorithms. The data might originate from Electronic Health Records (EHR), Hospital Information Systems (HIS) or other sources of non-clinical data, such as lifestyle and demographics.
- Medical devices and robotics.
- Added value third-party platforms which can offer high-level APIs, extra features and libraries.
- Other computing, connectivity and Big Data storage infrastructure.

5.2.1.1 Medical devices and robotics

In this category of components, we may find devices such as the following, which in many cases can be combined for more accurate results:

- Devices for Capsule endoscopy (CE) imaging, which can be wireless (e.g., Wireless Capsule Endoscopy (WCE) MEDTRONIC PILLCAM SB 3).
- Devices that produce echocardiogram images from which the left ventricular (LV) function can be analysed to quantify ejection fraction (EF). These can be combined with handheld devices (tablets, smartphones, laptops) for portability. Some ultrasound transducers (e.g., Philips Lumify S4-1) can pair with an Android device.
- Devices that support Computerized cardiotocography (CTG) for fetuses (e.g., Monica AN24 fetal heart rate monitor). These can collect fetal ECG data from electrodes placed on the labouring woman’s abdomen.
- CT scanners, e.g., GE Optima CT660 / 168 slices.
- Devices for invasive cardiac electrophysiology, which include 3D mapping systems, Electrophysiology (EP) recording and pacing systems, intracardiac electrocardiography devices, robotic navigation systems, magnetic navigation systems, remote magnetic navigation systems and fluoroscopy systems.
- Social humanoid robots, such as Pepper Robot by Softbank.
- Robotics and sensor-based rehabilitation devices, such as Amadeo®, Omego® and Diego® (Tyromotion GmbH, Graz, Austria), that allow assistive and interactive therapies.
- Virtual reality rehabilitation systems, such as VRRS® (Khymeia Group, Noventa Padovana, Italy), which can be connected to a wide range of specialized peripheral devices.
- Telerehabilitation systems, such as TeleCockpit® (Khymeia Group, Noventa Padovana, Italy), which are dedicated to managing remote and home devices or medical imaging, including streaming activities.
- Home automation systems, such as VIMAR domotics, which can be used for remote environmental control.

- Smartwatch and activity tracker devices, which for example can be used as sensors to detect tremorous events.
- Genomics sequencing equipment, such as the Illumina NovaSeq 6000 parallel sequencing solution.

5.2.1.2 3rd party platforms

Third-party platforms will be used for a variety of reasons.

- Platforms can provide access to data coming from various sources. For example, Ninety One platform will be used to provide access to data sets from remote monitoring of patients with implanted cardiac devices in the USE, EU, and Japan available from Abbott, Biotronik, Boston Scientific, and Medtronic.
- Platforms that provide specialized visualization, such as the MutaFrame online platform that visualizes impact amino acid variants in human proteome (deogen2.mutaframe.com).
- Components from other platforms could be used on HosmartAI. Components coming from the H2O AI Platform or AI4EU could be imported into HosmartAI platform with minor changes.

5.2.1.3 Medical and other data

This can include:

- Data from the previous testing of individuals can be used to identify various predictors that improve the prediction of risk for a disease in an individual patient.
    - Previous testing results of the individual patient will be coming from various medical devices that exist in most hospitals.
    - Datasets that include US images from patients with cardiovascular problems and databases from ongoing projects including clinical, genetic and biological samples of several hundreds of patients with CHD.
- Publicly available datasets, such as the CAD-CAP database and 2126 fetal cardiotocograms available online at UCI repository are also useful in many applications.
- Other datasets might come from software systems, such as the MOSAIQ patient information management system which provides the MOSAIQ Radiation Oncology data sets. [REF-06]
- Datasets from other projects, such as i-PROGNOSIS, will also be used. These can include keystroke timing and pressure data, Inertial Management Units (IMU), voice data, etc.
- Datasets from applications for cognitive therapies, such as GRADIOR which has more than 10.000 users and has been used in more than 50000 sessions.
- Data sets from previous ablation mapping procedures, such as the one at SERMAS, could be used.
- Data sets used in other research such as data related to analysis of ECG (e.g. Mayo study 2020) and Ablation mapping open research data sets.

- Medical data sets used in Cathlab (catheterization laboratories) where narrowing of coronaries arteries and other similar conditions are treated. Related datasets include Philips ISVC dataset, Philips haemodynamic monitoring dataset, PACS dataset, Corpys Registry on anatomy and physiology of coronary artery stenosis.
- Medical data sets used in glioblastoma treatments, such as MRI and histological/tissue data.
- Clinical data warehouses that contain medical records as well as Patient-reported Experience Measures (PREMs) and Patient-reported Outcome Measures (PROMs), such as the data warehouse of PRIMUZ, which provides a patient portal to access this data.
- Data sets used in humanoid robot applications, such as SenticNet, Yale Face Database, RAVDESS, EVA Corpus, CREMA-D, Language resources from CLARIN and CLARIN.SI repositories, AVA Dataset, A2D: Actor-Action Dataset, The RoboTurk Real Robot Dataset, The Awesome Robotics Datasets, The FMP Dataset, The Robot@Home Dataset, MRPT dataset, Depth-included Human Action video dataset, HMDB: a large human motion database, Fall detection Dataset.

5.2.1.4 Computing, Connectivity and Storage

Data collected by medical devices might need to be stored in cloud-based servers to support telehealth consultations. Also, the data from many different devices need to be backed up in a common cloud to avoid information lost in case of hard disk corruption.

Mesh networks can host AI applications and services closer to the end-user for faster data processing and privacy. One such system is the Green PI mesh network: a self-healing internet infrastructure compose of wireless hotspots connected to each other using device-to-device communication. Tiny mesh hotspots can also be wearable or embedded onto robots and Green PI open edge cloud technology.

5.2.2 AI Platform Core Components

This layer consists of:

- A large set of adapters that enable the integration and interoperability of applications for smart hospitals. The specifications for these adapters include:
    - Common interfaces, for example based on OpenAPI
    - Data pipelines utilizing the publish-subscribe pattern to distribute information
    - Common standards
- Security and traceability services enabling privacy preservation that will be embedded throughout the entire operational system lifecycle
- Common tools abstracting the medical device monitoring functionalities
- Tools to compose a microservices-based application
- Tools and environment to deploy and control the microservices-based applications

5.2.2.1 Interoperability Layer

5.2.2.1.1 Adapters

Adapters in smart hospitals can be used to support automated data pipelines. For example, an automated pipeline for interpreting echocardiogram images can provide preliminary interpretation in areas with insufficiently qualified cardiologists.

5.2.2.1.2 Interfaces

Common interfaces allow the integration of various similar devices that provide a similar data format. For example, an adapter and the common interface computerized CTG data can be used in an AI application for the identification of reduced short-term variability in the foetal heart rate.

A format that is expected to be the primary option for creating definitions of APIs in a common format is OpenAPI, and specifically OpenAPI 3.0, which is an open-source format for describing and documenting APIs. One advantage of using this is that there are available tools that support it, such as Swagger Editor (https://editor.swagger.io/), which happens to also provide conversion utilities from previous versions to the latest.

5.2.2.1.3 Standards

HL7 and HL7-FHIR, as presented in the relevant Section 2.1.1, play an important role in interoperability. Various tools that support these standards have been developed, such as HL7 Collector (provided by TMA), which is a collection of features that facilitate integration with healthcare systems for transparent data interchange.

5.2.2.2 HosmartAI Orchestration and Control

5.2.2.2.1 Security and traceability

HosmartAI will utilize security-oriented tools to early detect application vulnerabilities that could result in data leaks or cyberattacks. Monitoring software can be used to detect malicious activity and identify areas for improvements to make the system more secure or less error prone. Intrusion detection systems can be used for additional monitoring of parameters that would indicate suspicious activity and issue alerts when such activity is discovered. Also, the application space can be used to develop new applications to improve security and traceability of healthcare systems.

Blockchain will be used for data integrity and trustworthy communication. A distributed ledger (database), immutable and secure (encrypted), can protect the privacy of medical records, something that stems from its ability to guarantee tracking of events and data transactions as well as anonymization.

5.2.2.2.2 Medical equipment monitoring

HosmartAI should be able to support monitoring through various equipment used for medical purposes. That may vary from CTG devices to domotics devices and smartphones/smartwatches with specialized applications installed. For example, VIMAR's wired and wireless domotic application package and intelligent treatment and rehabilitation technologies can be used to actively control the environment of the treatment and monitor the activities that patients can perform to assess the goals achieved during these activities.

5.2.2.2.3 Service Composition

Composition of many services to create links between them or pipelines will be supported. In many cases, information needs to flow from one service to the other or be collectively assessed at a central point. For example, many services can be combined to support Social Robotic Systems (SRS) in HosmartAI where this robotic system will use AI to i) monitor vital signs through wearables, ii) engage with patients to collect psychological data and motivate the patient, iii) provide companion features through an empathic conversational AI algorithm.

5.2.2.2.4 Distributed deployment and control

HosmartAI applications will be built around the concept of containerization, where each container can support a single functionality that can be implemented and deployed in a microservice-like manner. This results in greater flexibility in deployment and control of the services by orchestrating the service execution and information flow between multiple containers, which can inherently support distributed deployment and orchestration via a relevant tool, such as Kubernetes.

5.2.3 AI Services

This layer includes all the offered services that will be openly accessible through Open APIs. Examples of these are the services that provide the following types of functionality:

- preliminary data quality assessment (e.g., format check, type check, value range check, null check)
- a library of AI models which can be deployed over a variety of processing frameworks and can be trained for AI-enhanced applications
- data lifecycle management activities within a dynamic pipeline to address the first Big Data Vs (volume of data, velocity, variety, veracity) and enable the last V (value)
- a common Semantic data model that facilitates the pipelining and the information flow amongst various components by annotating the data and the messages exchanged between the components
- data translation mechanisms to combine the proposed data model with the respective data translation using standardised solutions such as HL7-FHIR, HL7-CDA
- the benchmarking framework

5.2.3.1 Artificial Intelligence and Visualization

Artificial Intelligence algorithms can be used to automate image processing and analysis of medical data to produce an augmented visualization of data to include analysis results in a way that makes it easy to interpret by medical practitioners. One example is the algorithm to support AI-augmented echocardiography applications and automate image processing and quantitative analysis of Left Ventricular (LV) function.

Also, AI can solve optimization problems, such as the optimization of patient scheduling.

Another example of a field that AI algorithms can be helpful is the navigation of catheters in Remote Magnetic Navigation (RMN) to improve the time needed to reach multiple ablation paths or ablate along a path.

5.2.3.2 Data Management and Knowledge Sharing

The goal of Data Management will be that of addressing and enabling the 5 Big Data Vs, as mentioned above, as well as facilitating knowledge sharing through data translation mechanisms that use common standards. An example of this is the development of tools to map the electrical activity of the heart by companies that record ECG signals with the goal of integrating with various sources and standardizing the data set across different models and device types.

5.2.3.3 Benchmarking

The HosmartAI Benchmarking Framework assessment will help identify ways to improve healthcare services and applications through establishing measurable indicators and putting feedback mechanisms in place.

An application that is available in the HosmartAI Hub and then deployed in the HosmartAI Application Space environment can provide feedback to the benchmarking tool in HHub during operation. Consequently, any application deployed in HosmartAI Pilots can provide feedback data during operation to drive improvements on KPIs that are deemed important.

Participants will receive recommendations based on the framework assessment of similar processes on other sites and will be able to optimise and improve their procedures and outcomes. The KPIs will be Medical, Patient-Reported Outcomes (PROs), Patient Reported Experiences (PREMs), Productivity and Economic.

5.2.4 Application layer

The application layer includes the application solutions that will be developed with the support of HosmartAI Hub. The HHub will support them through the common Dashboard UI, which will offer the Co-creation and Marketplace.

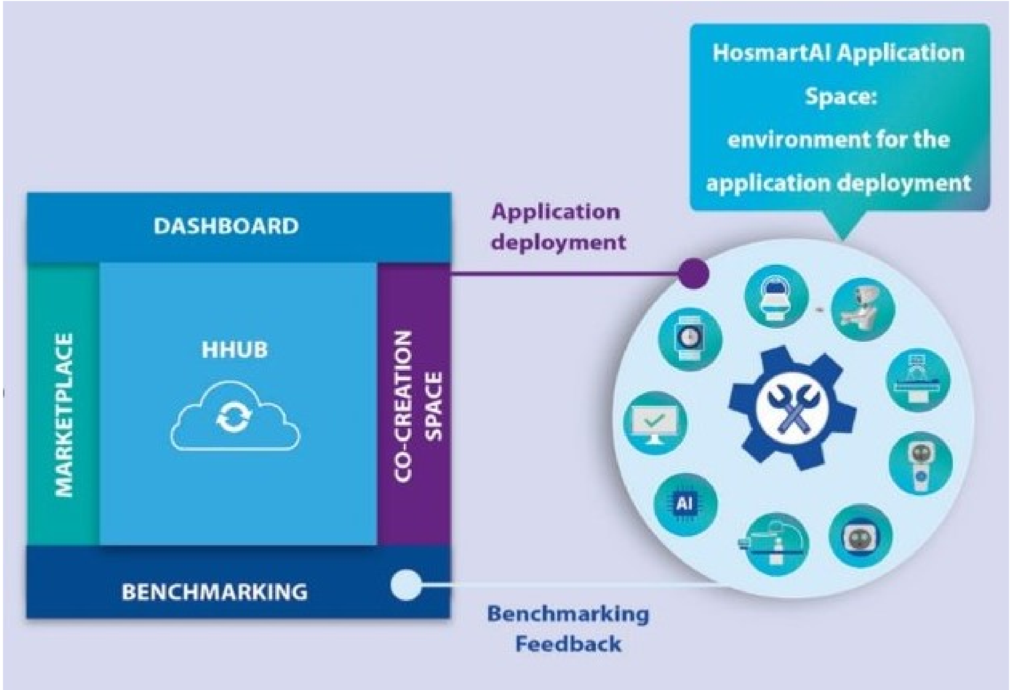


Figure 22: HosmartAI Hub and Application Space.

5.2.4.1 Co-creation

The HosmartAI Co-creation Space is used during the co-creation process, in which healthcare stakeholders, service advisors and providers can select together the most appropriate set of tools, devices, components and data sources. To do this they can also examine the existing ones and their performance through the HosmartAI Benchmarking Framework. Many of those can be already deployed at hospitals, primary care centres and care homes and thus provide valuable information that can be used to set expectations and improvement goals.

Except for the above, the Co-creation Space can be used for the set of standards, APIs, interoperability mechanisms and data models that will be used in the process of creating the HosmartAI-enabled application.

5.2.4.2 Marketplace

The HosmartAI Marketplace includes all components, devices, services, data sources, platforms, etc. that are available for exploitation. The project's marketplace will support the development of applications with access to technologies, but also with training material, documentation and other useful data.

One of the most important assets to support the development and proper execution of AI algorithms is the specific data set to be used by 3rd party developers in Open Calls. The HosmartAI Marketplace will provide those as well as the ability for stakeholders coming from both the demand side and the supply side to participate.

The HosmartAI Marketplace will be able to pull resources from the AI4EU project that will complement the already available ones. Also, the marketplace will provide information about already available services in digital innovation hubs such as DIH-HERO.

5.2.4.3 Dashboard

The HosmartAI Dashboard will provide the main entry point to the HosmartAI platform. The Dashboard will also offer access to each user's personal account and allow them to perform administration tasks to customize their participation to Co-creation, Benchmarking and Marketplace.

5.2.4.4 Application solutions

Application solutions that will be developed will be able to combine different types of tools and frameworks for their main functionality regarding its inner workings, but also interfaces to interact with end-users.

For example, a computer-aided diagnosis (CADx) suite can be developed based on:

i) general-purpose, open-source AI/ML frameworks, such as TensorFlow, Keras, Scikit-learn and Microsoft Cognitive Toolkit and application-specific open-source libraries, such as EchoNet31,
ii) explainable AI open-source packages, such as LIME32 and SHAP33,
iii) custom-built signal/image acquisition and processing application core services
iv) user interfaces to allow for the interaction of the clinicians with the system's outputs.

Another example is a chatbot that can inform patients when a rescheduling in the radiotherapy plan is validated, thus avoiding unnecessary trips to the hospital, or waiting times. Also, the patients can register their questions or get answers from this conversational robot during their treatment.

6 Pilot mapping to conceptual architecture

The contents of this chapter are also included in D1.5. This chapter is included in D1.6 for completeness.

In this chapter, we examine how each Pilot architecture maps to the HosmartAI conceptual architecture.

6.1 Pilot 1

Computer-aided cardiac function assessment using portable ultrasonics

The objective of this application is to acquire echocardiography (ECHO) clips, either online (streaming from a device) or offline (importing from storage), and to automatically calculate metrics related to cardiac function to facilitate prompt and accurate diagnosis. The application will be mainly developed upon the open-source cross-platform FAST[18] framework [REF-11][REF-12][REF-13].

There are two sources of the data: 1) a portable ultrasound (US) device which broadcasts the acquired sequence of frames and 2) a Picture Archiving and Communication System (PACS) where previously acquired ECHO clips are stored. In the first case, i.e., the online data acquisition, the broadcasted stream of frames is grabbed and converted into local variables via a data acquisition API. The usage of such an API requires permission and/or support from the device manufacturer. In the second case, i.e., the offline data acquisition, a PACS is mainly built on Digital Imaging and Communications in Medicine (DICOM) standard; hence, the ECHO data retrieval/storage is made via DICOM services. These APIs are implemented in FAST.

Moreover, to increase the performance of the AI algorithm, focus must be given to the neural network inference. High performance neural network inference requires specialized hardware, e.g., GPUs and FPGAs, which are driven by some inference engine. Currently, there are several inference engines available including Intel's OpenVINO, NVIDIA's TensorRT, and Google's TensorFlow which supports multiple backends, including NVIDIA's cuDNN, AMD's ROCm and Intel's MKL-DNN. These inference engines only work on specific processors and have completely different APIs. FAST has implemented a common interface for all of them and still provides high performance inference.

The functionality of FAST framework has been implemented using a set of core C++ libraries:

- Open Computing Library (**OpenCL**): An open standard for parallel programming on heterogeneous systems, including multi-core CPUs, GPUs, and FPGAs. It is supported by most processor manufacturers including AMD, NVIDIA and Intel.
- Open Graphics Library (**OpenGL**): A cross-platform library for visualization.
- GL Extension Wrangler (**GLEW**): A library for handling OpenGL extensions.
- **Eigen**: A fast cross-platform linear algebra library.

[18] FAST: FrAmework for heterogeneouS medical image compuTing and visualization, https://fast.eriksmistad.no/

- **Boost**: A C++ utility library.
- **Qt**: A cross-platform graphical user interface (GUI) toolkit.

It is worth noting that Python application can also be developed using FAST via provided Python bindings.

Finally, a set of widely used Python packages will be used in different development phases, e.g., AI services development, validation and evaluation. These packages consist of

- **TensorFlow**: an open-source machine learning library. It is a symbolic math library based on dataflow and differentiable programming. It is used for both research and production at Google.
- **PyTorch**: an open-source machine learning library based on the Torch library, used for applications such as computer vision and natural language processing, primarily developed by Facebook's AI Research lab.
- **SciPy** ecosystem: a Python-based ecosystem of open-source software for mathematics, science, and engineering.
- **Scikit-learn**: is a free software machine learning library for the Python programming language. It features various classification, regression, and clustering algorithms.
- **OpenCV**: is a library of programming functions mainly aimed at real-time computer vision.

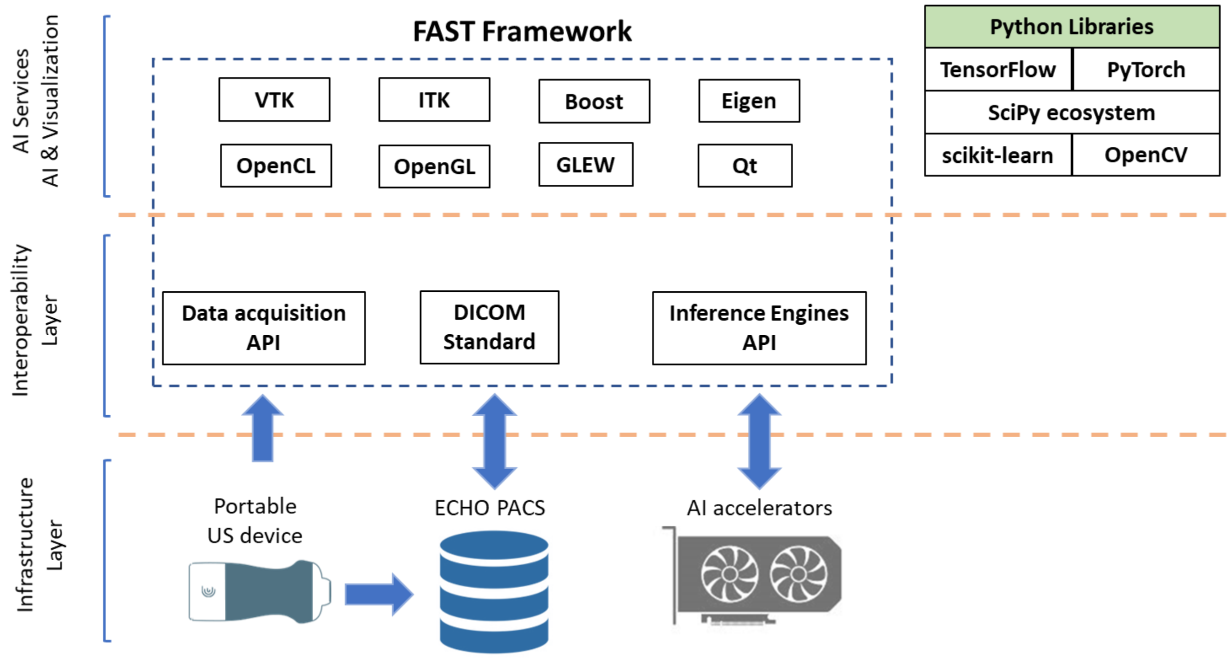


Figure 23: Pilot 1 technical architecture for computer-aided cardiac function assessment.

Computer-aided diagnosis of small intestine pathology in capsule endoscopy

The objective of this application is to process videos acquired from capsule endoscopy systems to automatically detect and categorise suspicious findings. The application will be mainly developed upon the open-source cross-platform FAST framework.

The source of the data for this application is a CE storage system. Given that the videos will be stored in a standardised video format, the application will communicate with the CE storage system using the video import/export APIs implemented in FAST.

The remaining description of the application regards the usage of AI accelerators for enhancing the performance of the AI services, as well as the core programming libraries/packages that are used to develop and deploy the AI services. Since this application will be also developed upon the FAST framework, such a description is the same as the one in the previous section, so it is omitted.

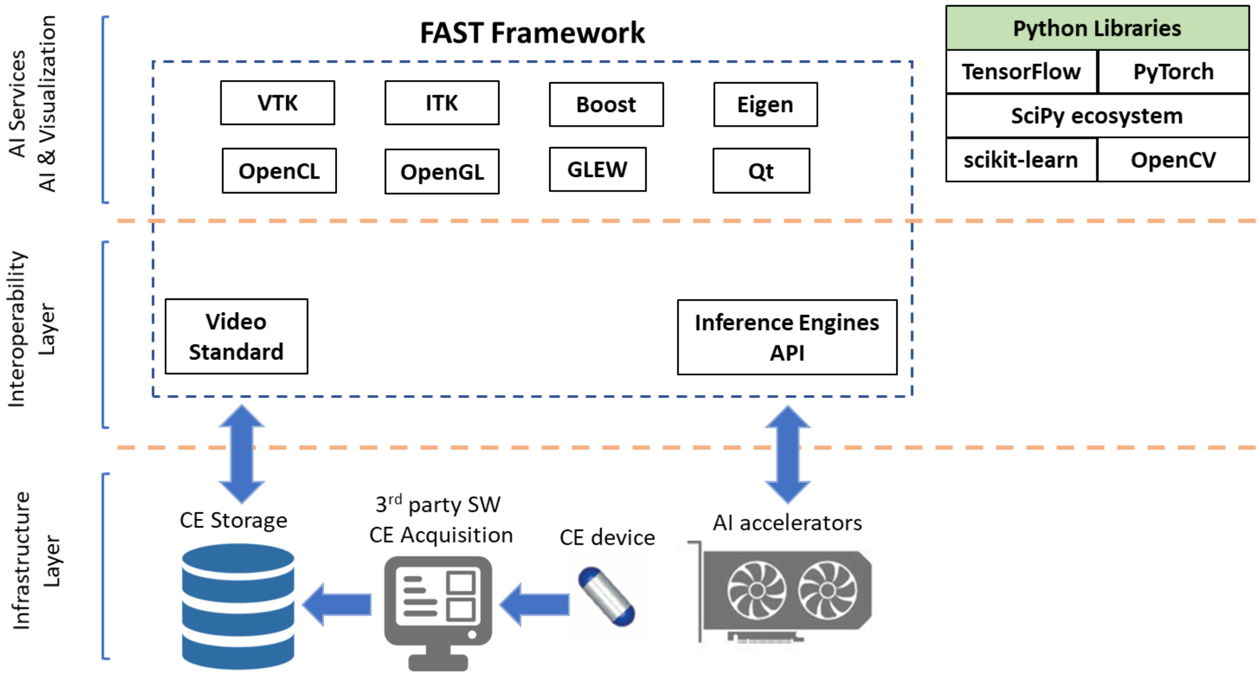


Figure 24: Pilot 1 technical architecture for computer-aided diagnosis of small intestine pathology in capsule endoscopy.

Computer-aided coronary CT angiography and obstetrics scenarios

In the computer-aided coronary CT angiography medical scenario, the platform to be developed aims to support cardiologists to choose individual-tailored therapy/prevention methods, by predicting patients likely to have coronary heart disease (CHD). To this end, clinical and genetic risk factors, lab exams results, coronary artery geometric features, the coronary artery calcium score (CACS), etc. will be analysed and machine learning methods will be used to train an AI-based model that will be able to classify patients based on the presence and extend of obstructive CAD. Coronary CT angiography (CCTA) datasets will be analysed using dedicated software for vessel analysis with tools for semi-automatic quantification of plaque volume. The outcome of the present study will be the presence of obstructive coronary artery disease (CAD) on CCTA, defined as the detection of ≥ 50% diameter stenosis in any of the four major epicardial coronary arteries. On the other hand, in the computer-aided obstetrics medical scenario, the platform to be developed aims to support gynaecologists/obstetricians to identify whether pregnant women with symptoms of preterm labour need to be referred to the region's referral centre, in case neonatal intensive care unit is needed. To this end, computerized cardiotocography (cCTG) analysis results, demographic details and other obstetrical data will be analysed and machine learning methods will be used to train an AI-based model that will be able to classify pregnant women based on the need to be referred.

Both medical scenarios will be based on the same typical web-based conceptual architecture (see Figure 25). The architecture is more or less based on the monolithic model design, which as typical includes the *User Interface Layer*, the *Services Layer (Business Logic)*, the *Data Access Layer*, as well as the application's main database.

Applications' Artificial Intelligence (AI) services constitute a separate component, which communicates with the applications' core services through an API. AI tools and services will be developed mostly in Python, utilizing existing machine learning tools and libraries such as scikit-learn, which is an open-source machine learning library that supports unsupervised and supervised learning and includes a variety of tools and services. AI component will be responsible for analysing data and extracting the respective prediction for each medical scenario. The component will function as an autonomous separate service, that will constantly retrain the predictive model using the new recorded data, thus aiming to increase prediction's reliability. This component, depending on the final architecture of the HosmartAI platform, can also be part of the core services of HosmartAI, while maintaining the same functionality.

Regarding forward compatibility, in case of a future large increase in applications functionality, migration from monolith to microservices model is feasible in case it serves better.

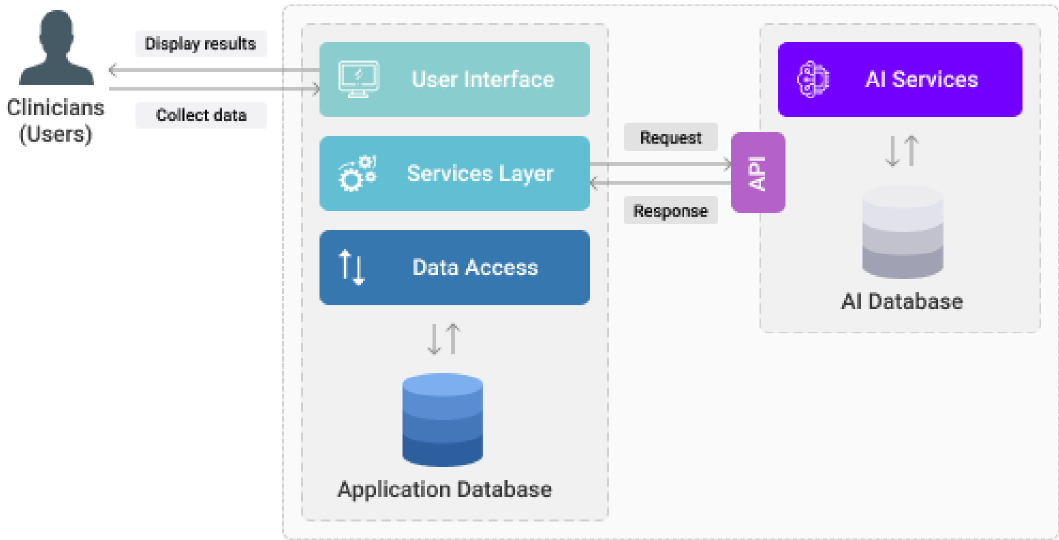


Figure 25: Conceptual architecture for CCTA and obstetrics medical scenario (Pilot 1)

6.2 Pilot 2

The objective of the HosmartAI project is the development of an intelligent algorithm that allows the scheduling of medical appointments in the most efficient way. For this purpose, the identifying data and preferences of each patient and the type of cancer found in patients, will be considered. The number of appointments and the number of specialists that need to be during each treatment, will be determined. The algorithm should optimize the scheduler in order to minimize costs, resources, downtime, etc.

Interoperability

From the first appointment with the doctor, the scheduler will start and create the radiotherapy appointments for each patient, considering their other medical appointments as well as those for laboratory and radiology examinations. A first version of the diagram corresponding to a patient with lung cancer is attached as an example.

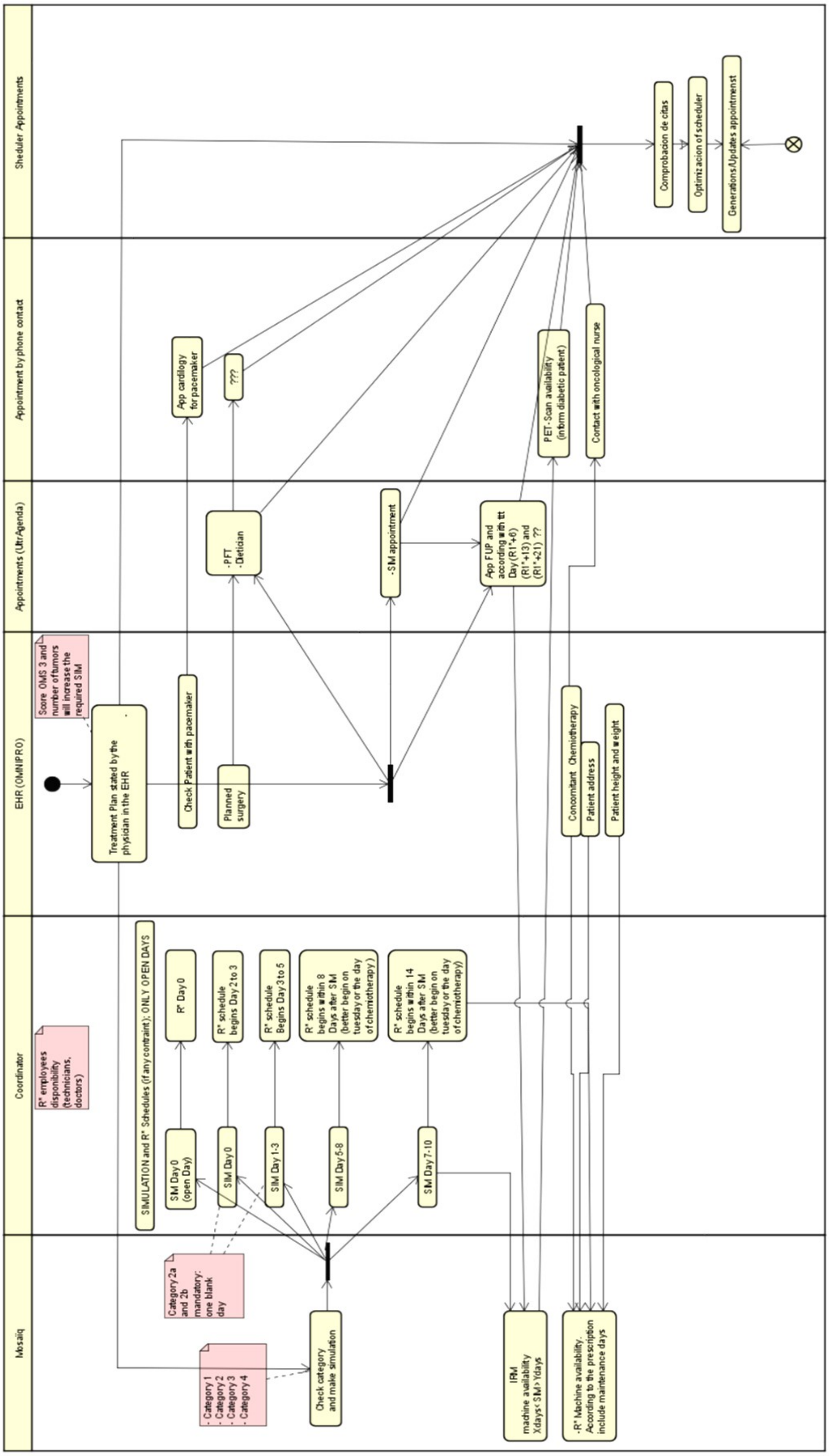


Figure 26: Pilot 2 flow diagram.

Infrastructure layer

Here, we can find in a more detailed way, the architecture data inputs that will be used for Pilot 2:

- Patient information
    - Id
    - Scale of emergency
    - Time preferences
    - Vital status
    - Hospital localization
    - Cancer's localization
    - Weight of patient
    - Irradiation localization
- Treatment information. Electronic records:
    - Appointment's nutritionist
    - Appointment's dentist
    - Appointment's cardiologist
    - Appointment's surgeon
    - Appointment's chemotherapy
    - Other appointments
    - Nº of Sessions/visits
    - Availability medical staff
    - Availability machines.
- Mosaiq machine
    - Time treatment
    - Simulation

AI Services

The AI Services will support the scenarios that will take place in this pilot, which are described below and are all related to tumours and cancers diseases.

- Lung, Breast, Rectal-Colon, Stomach, Esophagus, ENT related tumors, Gynecology related tumors, Urology related tumors, Liquid related cancers, Skin related tumors, Brain related tumors, Bone and Joints related tumors, Endocrinolgy related tumors.

6.3 Pilot 3

Latest studies proved that recent technological improvements could help to boost the treatment and rehabilitation of patients with neurological diseases. These technology-based modalities can provide a great aid for caregivers while improving the quality of care for patients. Pilot 3 aims to develop a set of “treatment & rehabilitation technologies” by collecting data to monitor and control the environment.

The sources of data are the following:

- Sensors providing information about human presence in the environment (Ultra Wide Band, access control) and monitoring the status of the building. Data will be used also to develop AI-based virtual sensors to provide additional information for caregivers and residents. Data will be collected through VIMAR's wired and wireless domotic application package.
- Therapeutic devices and sensors, and clinical information from IRCCS.
- The iPrognosis android smartphone application by AUTH that collects keystroke dynamics data to produce a bradykinesia and a rigidity severity score, inertial measurement unit (IMU) data during phone calls to detect tremor, and voice recording data during phone calls to classify the speaker as having Parkinson's disease or not.
- The iPrognosis Motor Assessment Tests (iMAT) solution by AUTH that acquires 3D video data of patients performing pre-specified movements and employs human pose estimation to produce a score that quantifies similarity of the patient's movement to a reference movement performed by an expert.

Table 17: Pilot 3 sensors and data.

Type of sensors	Type of data	Location of sensors/where data is collected	Where data is stored
Environmental sensors	• Access control • UWB • Building status (lights, energy loads, roller shutters, etc.)	• Rehabilitation Room • Sensorized Rooms • Patients' House	VIMAR Cloud
Virtual sensors	• Additional recommendations for users or technicians related to their system	• Rehabilitation Room • Sensorized Rooms • Patients' House	VIMAR Cloud
Smart rehabilitation devices and wearable devices	• Keystroke dynamics data for bradykinesia and rigidity severity scoring • IMU data for tremor detection • Voice recording data for Parkinson's disease classification • 3D video data for motor assessment via pose estimation • Therapeutic rehabilitation devices • Telerehabilitation systems	• Rehab Room	IRCCS server
TBD	• Clinical parameters	• Collected by clinicians during their medical examinations	IRCCS server

Pilot 3 architecture

Infrastructure layer

- Medical Devices and Robotics
    - Therapeutic devices which can be connected to a wide range of specialized peripheral devices,
    - Telerehabilitation systems which are dedicated to managing either the remote or home devices, including streaming activities.
    - Environmental physical sensors from VIMAR View Wireless and UWB device
    - Devices running the iPrognosis smartphone application and Motor Assessment Tests solution that collect and transmit data.
- Medical and Other Data
    - Clinical data from patients
    - Data collected by medical devices might need to be stored in cloud-based servers to support telehealth consultations. Also, the data from many different devices need to be backed up in a common cloud to avoid information loss in case of hard disk corruption.
- Computing Connectivity & Storage
    - IRCCS server containing patients' information, data from robotics platforms, data correlated to the patients' activity extracted from Vimar Cloud and the estimated parameters provided by smartwatches and activity trackers from iPrognosis technology.
    - VIMAR Cloud infrastructure containing both real-time and time-series data from physical environmental sensors. The asset is also used to train and execute AI algorithms to develop virtual sensors providing additional features.

AI Platform Core Components

One objective of the pilot is to provide a unified and general framework containing data of various nature collected from different sources. These data need to be elaborated to provide a similar and compatible data format.

- Interfaces
    - IRCCS server will collect data coming from the infrastructure layer. A proper interface will be implemented to handle different types of data.
    - VIMAR Cloud and IRCCS server will interact and exchange information and data.
    - User Interface for clinicians and patients/caregivers will be designed. UI will allow clinicians to work according to their usual standards and will allow patients/caregivers to easily access the services of their individual rehabilitation programme.
- Standards
    - Standards have to match the clinical variables mapping results to FHIR Resources for Pilot 3 defined in deliverable 2.1.
    - Further standards will be identified according to the design of new functionalities.
- Security & Traceability

- Transmission of data to the servers will be conducted securely according to the HTTPS protocol.

AI Services

- Visualization and analysis of clinical data.
- User interfaces to visualize the KPIs.
- Storage and processing of data transmitted from devices running the iPrognosis technologies.

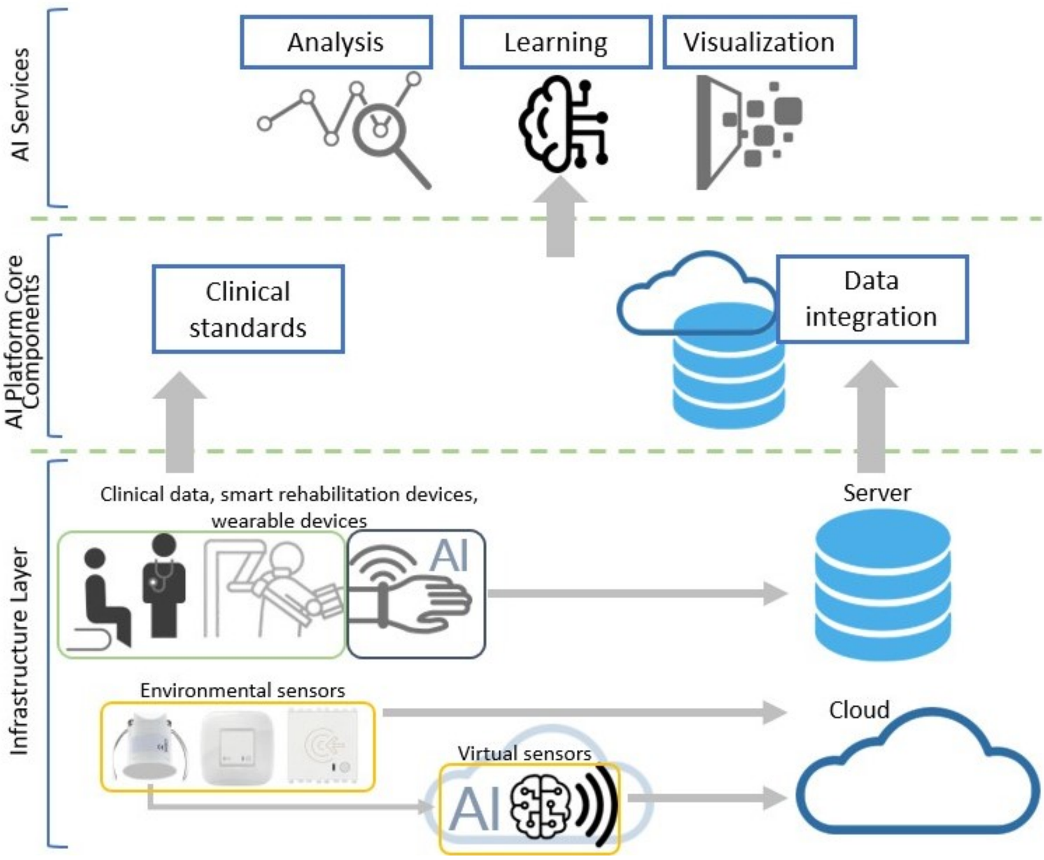


Figure 27: Pilot 3 technical architecture.

6.4 Pilot 4

The purpose of this application is to allow for (semi-)automatic catheter navigation for cardiac ablation procedures. In this application, a catheter with a magnetic tip is positioned inside a magnetic navigation system. The catheter can then be manipulated by controlling the magnetic field in the magnetic navigation system.

The core of this framework is the communication layer which is based on the Robot Operating System (ROS). The communication layer receives sensor feedback from the catheter as well as the magnetic navigation system. This information is then processed in the AI services and visualization layer and fed back to the magnetic navigation system via the communication layer to actuate the catheter.

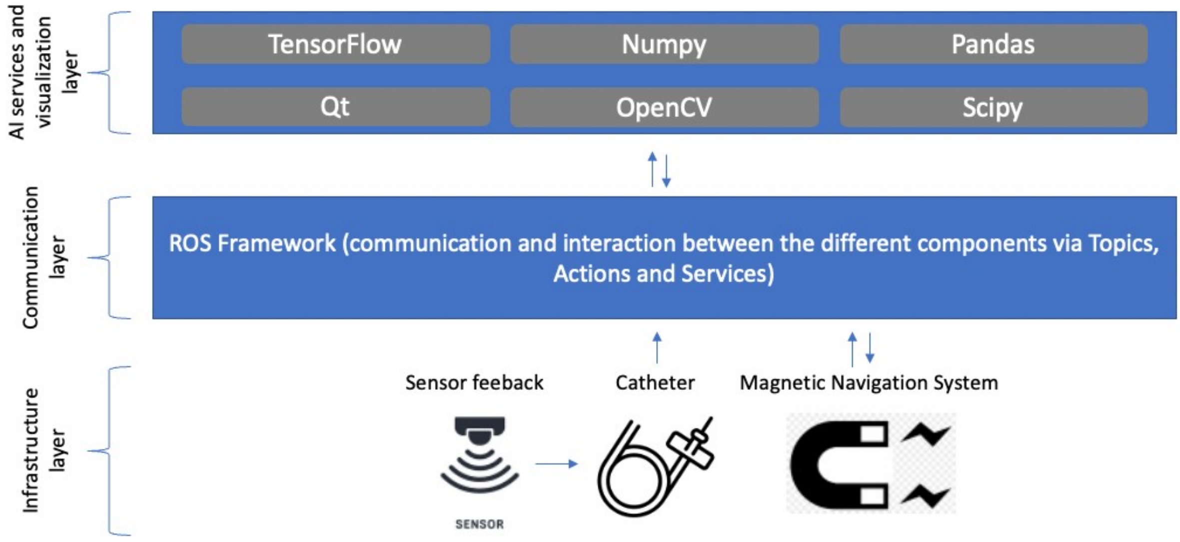


Figure 28: Pilot 4 technical architecture.

In this use case, electro-cardiac mapping data and images will be integrated from various sources, devices, and disease types, and run mathematical modelling with AI to support clinical decisions namely, to drive catheter navigation and increase the precision of ablation.

The objectives are the following:

i. Demonstrate that the combination of RMN and AI can reduce the time to create an EP map;
ii. Demonstrate that the combination of RMN and AI can reduce the time to reach multiple ablation sites or ablate along a path;
iii. Prepare the path to allow future venture to automatize part of an ablation procedure;
iv. Review the available data source in the EP lab and propose standardization;
v. Archive data recorded during EP procedure to create a database that can be leveraged for further research and patient clustering / disease-type patient cohorting.

The types of data used will be:

- Patient data derived from implanted and external monitoring devices
- Electronic medical record data and other historical health records
- Research data (from clinical studies) and other data from historical patient procedures
- Real-time data derived during interventional cardiac procedures (e.g. Ablation mapping)
- Specific location magnetic field data
- Lab results and other related patient information

The architecture of the holistic solution of combining AI-driven analytics and cross-system integration with RMN catheter ablating with full/semi-automation is presented in the next three graphics:

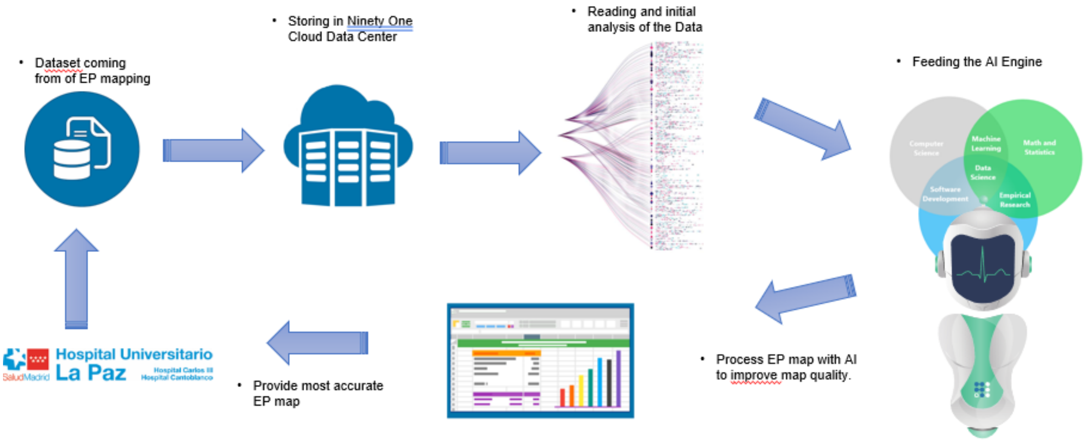


Figure 29: Development of interface for mapping system.

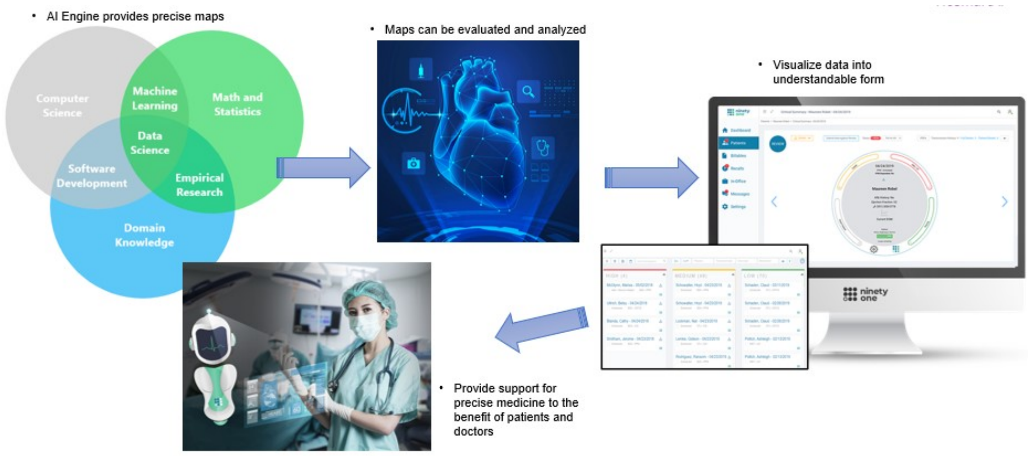
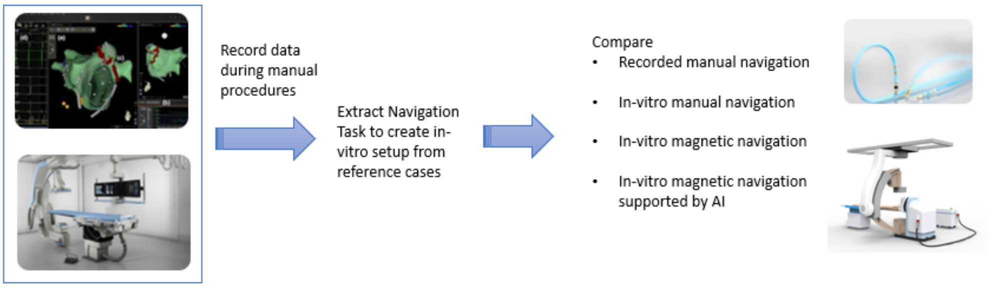


Figure 30: Data Science and AI for mapping system.



- KPI: **User's satisfaction with robotic solution**. Target value: **> 5** (on avg.) on 7-point Likert scale.
- KPI: **Effective time to reach multiple targets along an ablation trajectory**. Target value: **> 25%** decrease in time over manual navigation.

Figure 31: Robotic Magnetic Navigation.

6.5 Pilot 5

<u>Patient Clinically Relevant Information Collected</u>:

Patient-id, Age, Sex, Weight/Height, Conditions and Diseases, Medication, Depression/Anxiety Symptoms and Mood, Temperature, Heart rate, Respiration rate, Oxygenation – Pulse oximetry, VAS Score, Laboratory Results

<u>Population:</u> Patients Treated for Conditions in Cardio-vascular Surgery and Thoracic Surgery Departments

<u>Background:</u> We introduce AI-solutions into care workflow in form of: new clinical observations (PROs, continuous monitoring) integrated into EHRs, A Clinical Support Tool to Explore the clinical data (existing and new) during Grand rounds, A Robotic unit to collect patient data and engage with patients to deliver non-value-added nursing services

<u>Clinician-centred use (a Series of Wizard of Oz Experiments)</u>

1. Robot follows the clinician during Grand Round
2. Upon arriving at the bed, the robot scans for the patient id (face recognition pr BAR/QR Scanner) and loads the clinical data from the hospital's clinical repository and HosmartAI repository
3. The doctors can filter and visualize the data on demand during the grand round

Technology: ASR, Speech Synthesis, FHIR Resource Visualizer and Browser, Image Recognition (bar code scanner), SLAM and algorithm to follow person, Robot's manual control interface

<u>Patient-centred use (a Series of Wizard of Oz Experiments)</u>

1. Robot creates a storyline based on CarePLan FHIR resource
2. Robot is directed to a specific patient where the robot executes a pre-arranged storyline in form of social discourse
3. Robot when needed collects PROs (and possibly PGHD)
4. Robots execute breathing exercises with patients (and possibly action recognition to verify active participation)

5. The activities to be executed can be stored in FHIR CarePlan Resource

Technology: ASR, Speech Synthesis, Robot Gestures, Image/Action Recognition, Gamification of breathing exercises, chatbot, SLAM and object avoidance

6.6 Pilot 6

Within Pilot 6, three technologies will be integrated: GRADIOR, iPrognosis and E-pokratis. Follows a resume regarding these technologies and how the consortium proposes to integrate them.

GRADIOR is a neuropsychological evaluation and rehabilitation system for carrying out training programmes in people with deficits and/or cognitive impairment. It allows working in adults Attention, Perception, Orientation, Memory, Calculation, Executive Function, Language and Reasoning. The system consists of a website (aimed at professionals) and an app for the execution of intervention sessions by users.

In pilot 6, this system will be used as a screening and intervention tool, in order to detect and prevent cognitive deterioration. These functions will be integrated into the home and the clinical centre setting, through a tablet and, in the clinical centre setting, integrate the tablet on the social robot Pepper for a group intervention. The system collects this data through the intervention sessions and designs personalized treatments according to the level of cognitive deterioration.

The **iPrognosis technologies** comprise the **iPrognosis smartphone application** and **iPrognosis Motor Assessment Tests (iMAT)**.

The **iPrognosis smartphone application** is a digital phenotyping mobile application intended for detecting and/or assessing Parkinson's Disease (PD) symptoms. The application collects data passively from smartphone sensors during the natural interaction of users with their device and converts them to digital biomarkers, via Cloud-based machine learning (ML) models. Specifically, the application collects keystroke dynamics data to produce a bradykinesia and a rigidity severity score, inertial measurement unit (IMU) data during phone calls to detect postural tremor, and voice temporal and spectral features during phone calls to classify the speaker as having Parkinson's disease or not.

iMAT is a series of tests exploiting human pose estimation technology to assess the motor capacity of people with Parkinson's disease. Standing in front of a 3D camera (Orbbec Persee), users perform a series of movements displayed on video by an expert. Movements displayed are similar to those performed during the clinical assessment of the patient based on standardised scales such as the Unified Parkinson's Disease Rating Scale Part. At the end of each test, using human pose estimation, a score is produced reflecting the similarity of the movement performed by the user with the one performed by the expert.

In Pilot 6, the iPrognosis technologies will be used for remote and in-clinic monitoring of people with PD receiving pharmacological treatment and/or undergoing rehabilitation for motor symptoms. Longitudinal monitoring of digital biomarkers measured by the tools, is expected to facilitate the assessment of symptoms progression and response to treatment.

Regarding integration, data collected by the tools will be securely transmitted to servers where they will be analysed to produce the relevant outcomes. The latter will be stored on the servers and securely transmitted to the iPrognosis/ iMAT apps and the dedicated HosmartAI experts' platform, serving as feedback to the patient and the healthcare professional, respectively.

e-Poκratis Welfare, is a Personal Health Record - PHR with **telemedical capabilities** where health data and information related to the care of a patient is maintained. The intention of TMA e-Poκratis Welfare is to provide a complete and accurate summary of an individual's medical history which is accessible online by the patient & the authorized (by the patient) medical and paramedical personnel. The health data on e-Poκratis include patient-reported outcome data, lab results, and data from integrated medical devices such as **wireless glucometer, SPO2, Non-invasive blood pressure meter, urine analyser, weight scale, spirometer temperature & more** via e-Poκratis mobile app.

The modular and highly decoupled architecture of e-Pokratis allow the integration with 3rd party systems at different entry points. Within the framework of HosmartAI, the optimal way to achieve integration is by modifying the mobile app to attach to the API of the AI Platform Core layer. Data can be sent from the mobile app either using a REST API or MQTT.

In Figure 32 we can see the HosmartAI Space used for Pilot 6. During the execution of this pilot, we will have three different databases (GRADIOR, I-PROGNOSIS, E-Pokratis) that have to inject their post-processed data to HosmartAI Database with API/REST, MQTT. Later, the deployment of the algorithm will be in charge to predict possible abnormal pattern and give activity action recommendations to robots, so that they can be developed in patients.

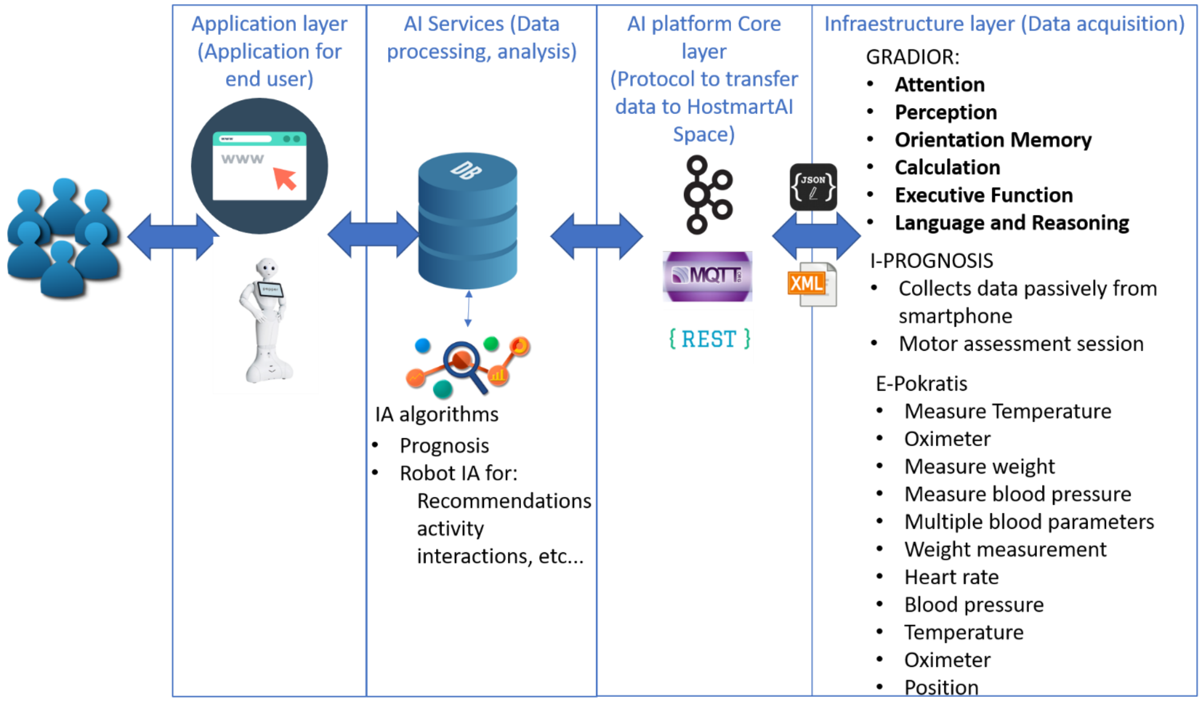


Figure 32: HosmartAI Space for Pilot 6.

In Figure 33 we represent possible activities that a patient could make in clinical centres or hospitals and in their homes with the three systems (GRADIOR, I-PROGNOSIS, E-Pokratis). The flow of the system gives a small view of the connection and action required in each layer of the HosmartAI Space.

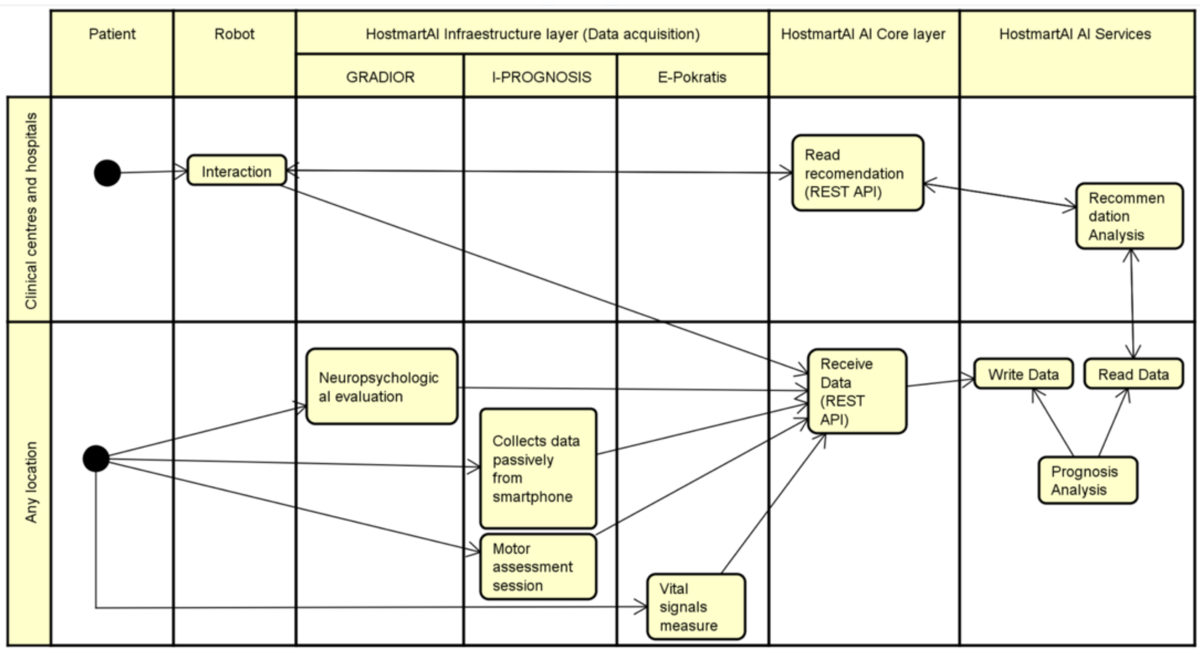


Figure 33: Activities system flowchart for Pilot 6.

6.7 Pilot 7

Pilot 7 is about a cathlab SW application that automates as much a possible the reporting for cardiac interventions by automatically tracking each step of the procedure, logging relevant events and actions, and auto-populating reports with images and measurements acquired during the clinical procedure. The architecture to support this functionality is shown below.

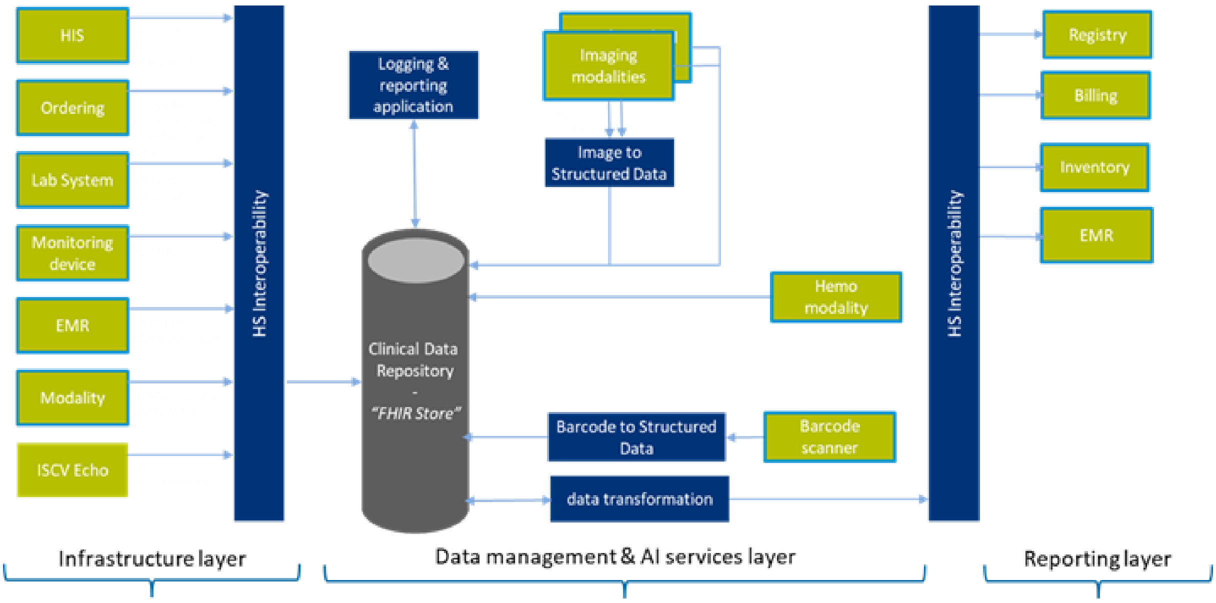


Figure 34: Pilot 7 Technical Architecture.

Data from various relevant sources is captured in the infrastructure layer and stored in a central repository. This information is complemented with structured data which is derived by AI-based analysis of clinical images. AI-based services include automatic key event detection and automatic coronary tree segmentation. These functionalities are part of the data management & AI services layer. Finally, in the reporting layer, the results are transformed into a report that is structured, interoperable and standardized, while being easy and efficient to complete.

6.8 Pilot 8

The expertise and data resources at the VUB and UZ Brussel are pooled in this pilot to enable us to create a digital health research platform, with main technical goals:

1. **Integrate clinical data for glioma**, both UZ Brussel-specific and externally available, at patient, clinical diagnosis, status and evolution, treatment, tumor imaging and molecular (gene/protein) levels, while investigating related legal aspects.

2. **Create a research platform** for digital health where these multifactorial patient data are available for AI approaches, such as deep learning. This will enable us to make connections between molecular events, tumor characteristics, and patient response to treatment.

3. **Support clinical decisions** via intuitive visualization of raw medical data and the results from analysis and predictive models, **including legal aspects**, *i.e.* how AI-created advice can be used.

By addressing these challenges, we will assist clinicians working with solid tumors, while creating a general framework for use by other researchers interested in using clinical data for research.

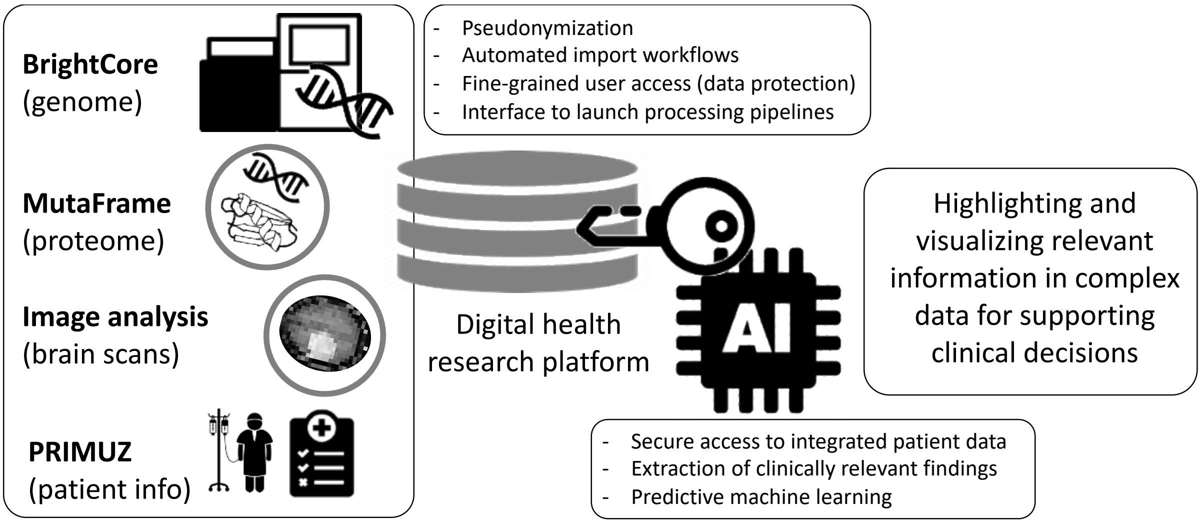


Figure 35: Pilot 8 Conceptual overview of the position of the digital health research platform

The technical components currently used are:

- XNAT for structured data management
- Python for data pipeline conversion/integration scripts
- Jupyter for data analysis, which will be further developed towards an interface to visualize the AI-based analysis of the integrated data
- PyTorch for machine learning/AI

Variables to be collected are:

- Date of diagnosis
- Tumor type (histopathology)
- Tumor location (frontal/temporal/parietal/occipital/central/posterior fossa/other)
- MRI characteristics (volume on T1+/- Gd, volume of FLAIR hyperintensity)
- FET-PET characteristics (maximum metabolic activity, maximum TBR (Tumor-to-background ratio), tumor volume (area of TBR>1.6))
- Spatial genomics data, including mutations related to cancer and their effect at the protein level
- Former medical history
- Clinical symptoms at diagnosis
- Physical neurologic exam at diagnosis (abnormal findings)
- Treatment (surgical, medical, radiotherapy) at first diagnosis
- Treatment at (first, second, etc) progression

- Date of progression (progression-free survival) (first, second, etc)
- Date of death (overall survival)

7 Alignment with other existing solutions

The contents of this chapter are also included in D1.5. This chapter is included in D1.6 for completeness.

In this chapter, the alignment with other existing solutions from Chapter 2 is explained.

7.1 Healthcare Standards for Interoperability

7.1.1 HL7 and HL7-FHIR

HL7 FHIR is already used by some of the HosmartAI partners and it is considered as the most common standard within the project consortium. Building upon the FHIR standard will facilitate the connection of partners' systems and infrastructure with the HOSMARTAI platform, through the HOSMARTAI semantic data model. HL7 FHIR standard was chosen for application in the HosmartAI due to many benefits in comparison with other standards that were tested. Such benefits include:

- A RESTful API-driven architecture makes implementation faster and easier.
- The implementation of customized use cases is easier without having to undergo a massive integration effort, for example, health care analytics, clinical decision support, real-time alerts, and notifications.
- In contrast to earlier standards, the data resources are intuitive and it's possible to incorporate new sources of data (from wearable devices, wearable apps, sensors, and biometric devices) within clinical workflows in a compliant, secure manner.
- It allows for the creation of a health care app ecosystem to leverage resources from various sources

7.1.2 DICOM

The DICOM standard is omnipresent in current healthcare systems, enabling manufacturer-independent integration of devices such as scanners, servers, workstations, printers and network hardware into picture archiving and communication systems (PACS). This wide adoption mandates consideration of DICOM compatibility in HosmartAI use cases that involve the exchange and processing of medical imaging data, to maximise maturity of the developed solutions in terms of compatibility with existing infrastructure. In view of interoperability being a core objective in HosmartAI, following the DICOM standard will greatly facilitate reuse and extension of the diagnostic solutions developed and tested during the pilots, essentially exposing the project’s results to a wider group of stakeholders.

Alignment with DICOM begins with the identification of the standard’s components that are relevant to the functionalities of the systems under development; these may vary significantly, depending on the intended application. Following the identification, the components are implemented. Finally, the latter are systematically described in a Conformance Statement, where additional extensions or specializations of the particular implementations are also specified. HosmartAI will aim to generate solutions that meet the minimum general requirements for DICOM conformance.

7.2 Platforms

7.2.1 AI4EU

The following Figure 36 illustrates how components from the static view of AI4EU Architecture [REF-10] can be mapped to HosmartAI components of the conceptual architecture.

The level of interoperability between AI4EU and HosmartAI is expected to be high:

- The HosmartAI Application space will be able to support AI4EU resources coming from AI4EU experiments marketplace which is based on the Acumos AI platform. This is depicted by the dashed line.
- HosmartAI Dashboard and Co-creation space provide similar functionality to Identity & Access management and Collaboration management components in AI4EU.
- The HosmartAI marketplace is expected not only to resemble the AI4EU functionality, but also to offer support for interoperability by importing AI4EU resources.
- The Orchestration and Infrastructure layer in AI4EU look equivalent to the AI Platform Core Components and Infrastructure layer in HosmartAI respectively.

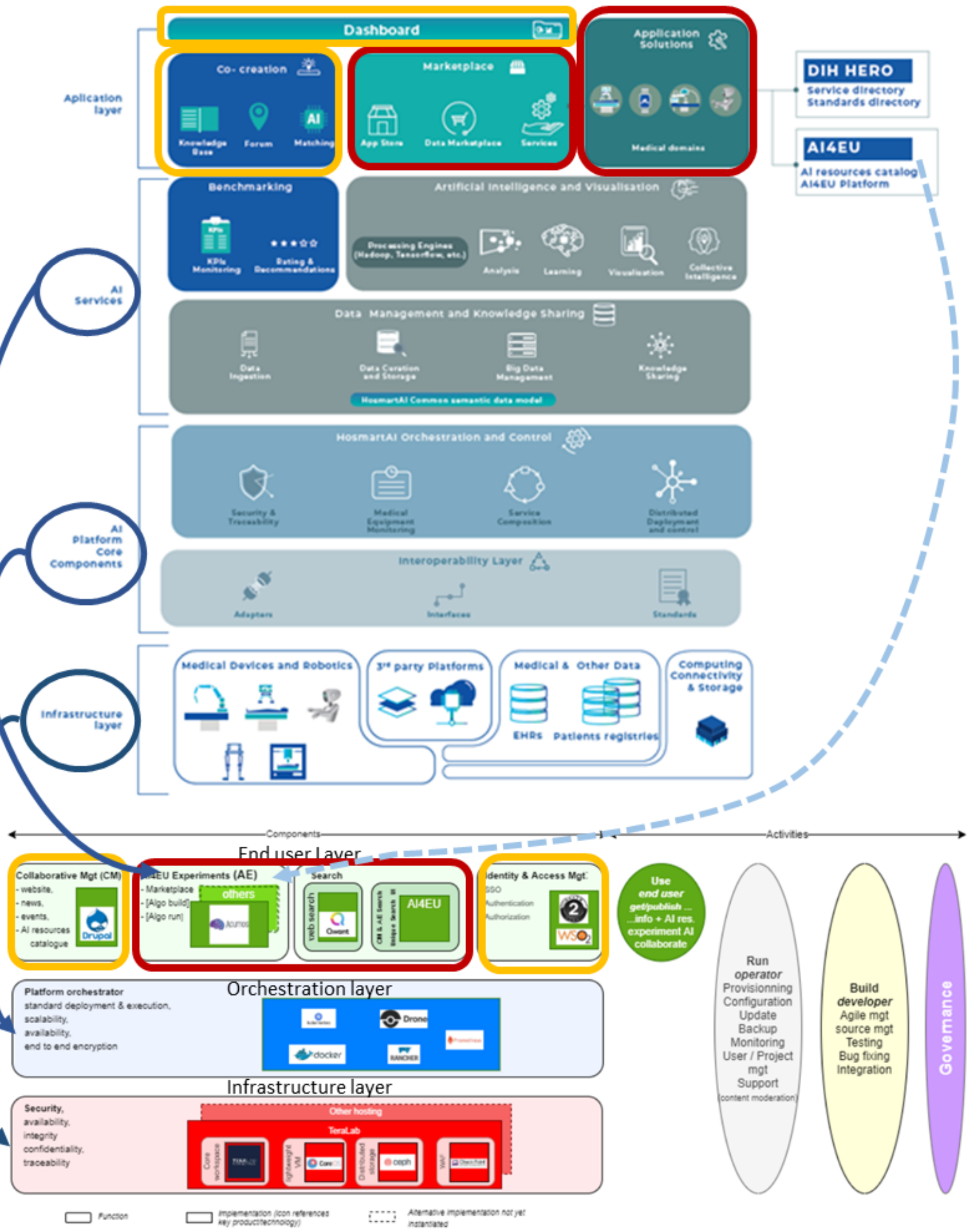


Figure 36: Mapping AI4EU Architecture.

7.2.2 GAIA-X

As shown in the below Figure 37, many layers and components of the HosmartAI conceptual architecture can map directly to the GAIA-X Federation Services and Portal.

As the GAIA-X **Portal** supports the onboarding and Accreditation of participants, it maps to the HosmartAI Dashboard.

The **Federated Catalogue** constitutes an index repository to enable the discovery of Providers and their Service Offerings. Therefore, it maps to the Co-Creation and Marketplace services of HosmartAI.

Compliance includes mechanisms to ensure a Participant's adherence to the Policy Rules in areas such as security, privacy, transparency and interoperability during onboarding and service delivery. This suggests that a suitable match for a mapping to the HosmartAI components would be the HosmartAI Application solutions, which will be compliant with certain rules for security and interoperability.

Data Sovereignty Services enable the data exchange of Participants, which maps to the Data Management and Knowledge Sharing components of HosmartAI.

Identity and Trust maps to the group of HosmartAI components that include Security and Traceability, Medical equipment monitoring and control of the distributed deployment, which appears on Conceptual Architecture as the HosmartAI Orchestration and Control.

Data and Infrastructure layers are located under the services layer which is comprised of all the services mentioned above. We could map the **Data Ecosystem** of GAIA-X to the AI Services and AI Platform Core Components layers, which are the layers of HosmartAI where data is a first-class citizen. Finally, the **Infrastructure** layer of Gaia-X can map to the HosmartAI Infrastructure.

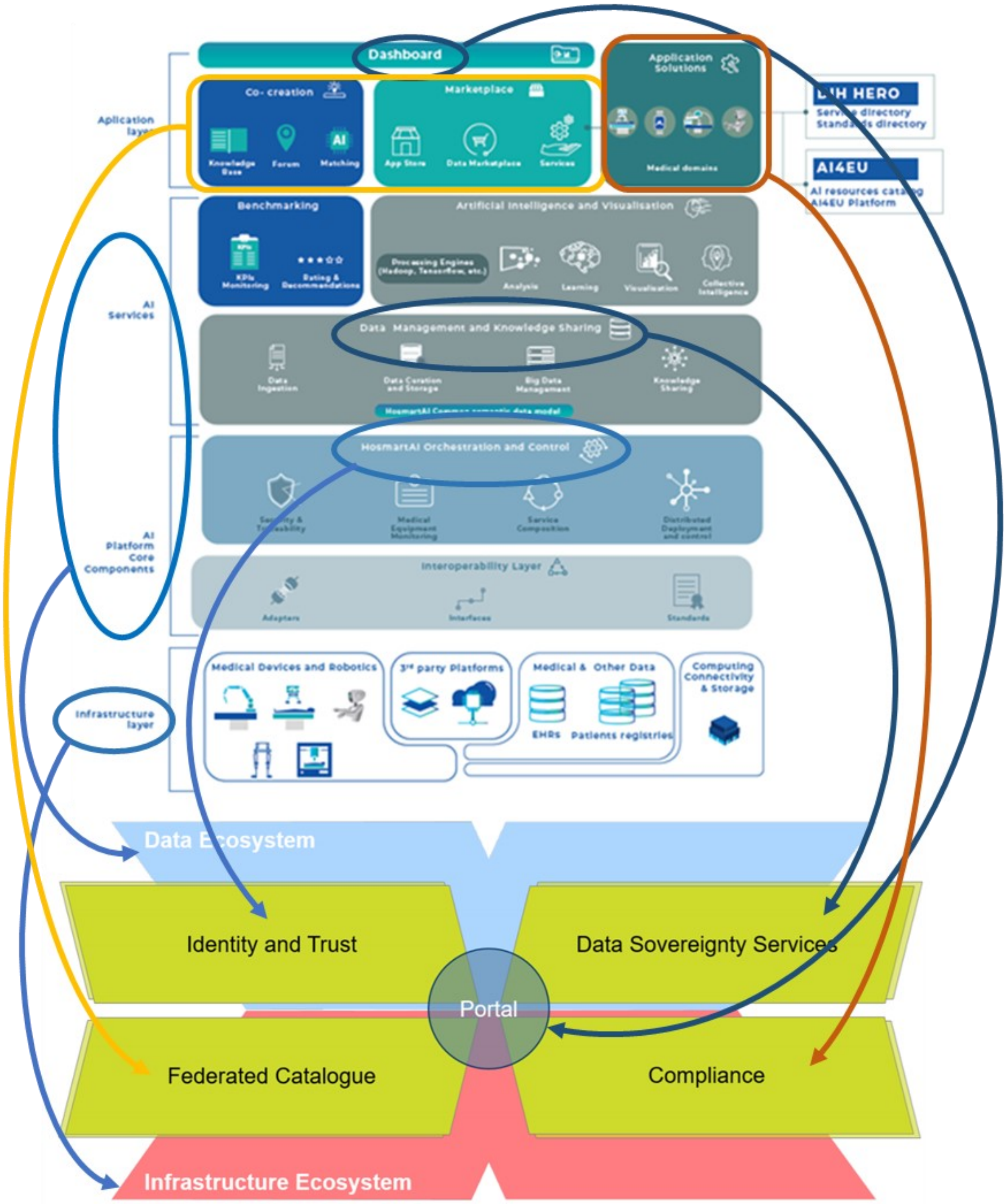


Figure 37: Mapping to GAIA-X Architecture.

7.2.3 OPEN DEI

Below, there is a graphical representation of the high-level mapping of OPEN DEI Reference Architecture Framework to the HosmartAI conceptual architecture.

When comparing the approaches, we see that the AI Services layer of HosmartAI corresponds to the service layers of OPEN DEI RAF, which include smart cloud services, smart edge services and smart world services. What really enables the provisioning of these services is the lower three layers of the conceptual architecture starting from the Infrastructure layer that supports the AI Platform Core Components, which in turn supports the AI services.

Looking at the X-Industry Data Spaces components, we notice the similarities between the below components:

- Data Sharing and Data Trading of OPEN DEI and Co-creation and Marketplace of HosmartAI, that include sharing of data and a marketplace.
- Trust and Security of OPEN DEI and Dashboard of HosmartAI, which include Identity Access Management and embrace an Applications Hub.
- Digital Transformation X-Industry Pilots of OPEN DEI and Application Space of HosmartAI, which enable applications for supporting various scenarios.

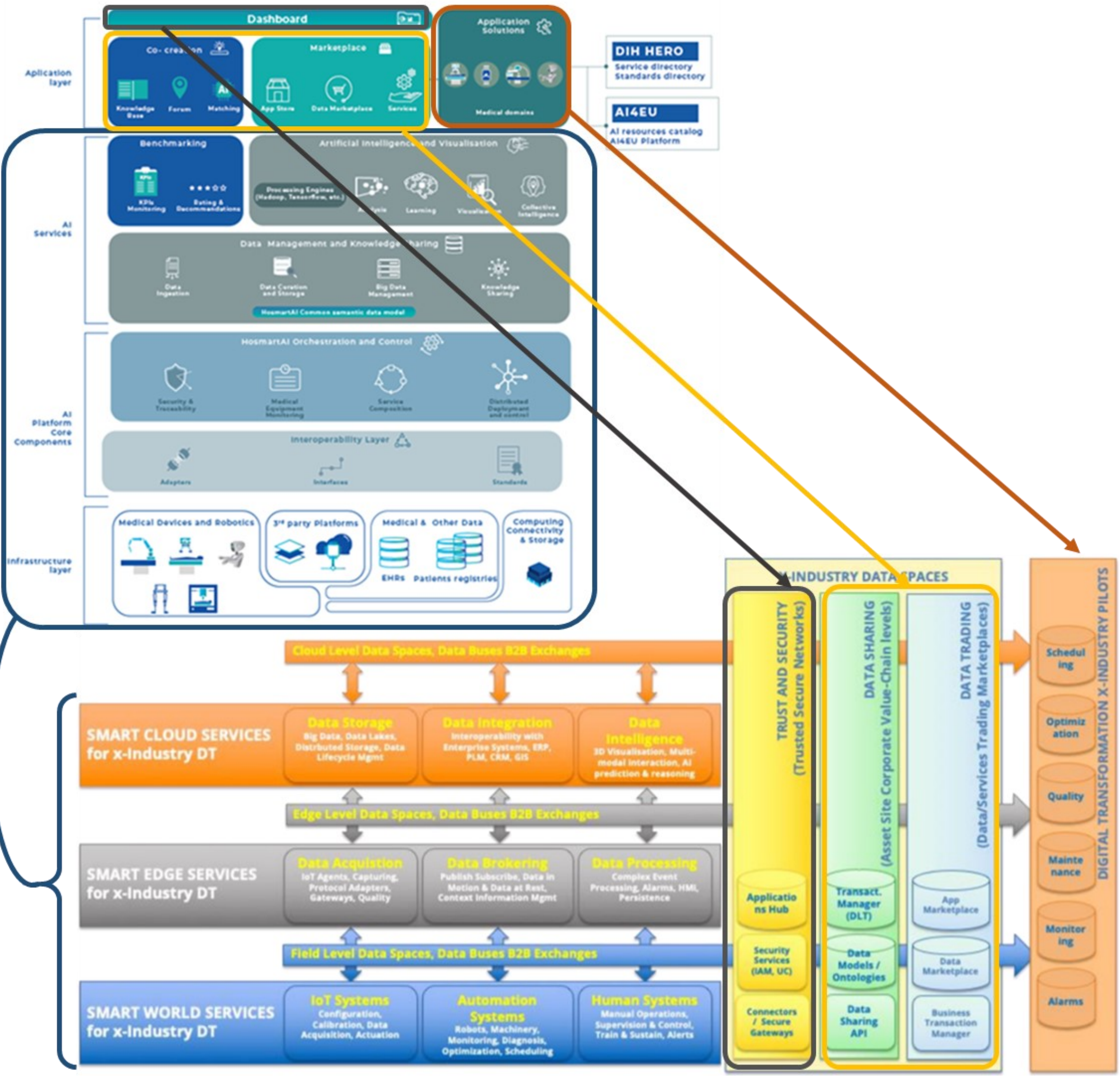


Figure 38: Mapping to OPEN DEI Architecture.

7.2.4 DIH-HERO

DIH-Hero has five robotic domains defined, all of which are covered by the HosmartAI pilots (see Figure 39) and this demonstrates the potential for collaboration.

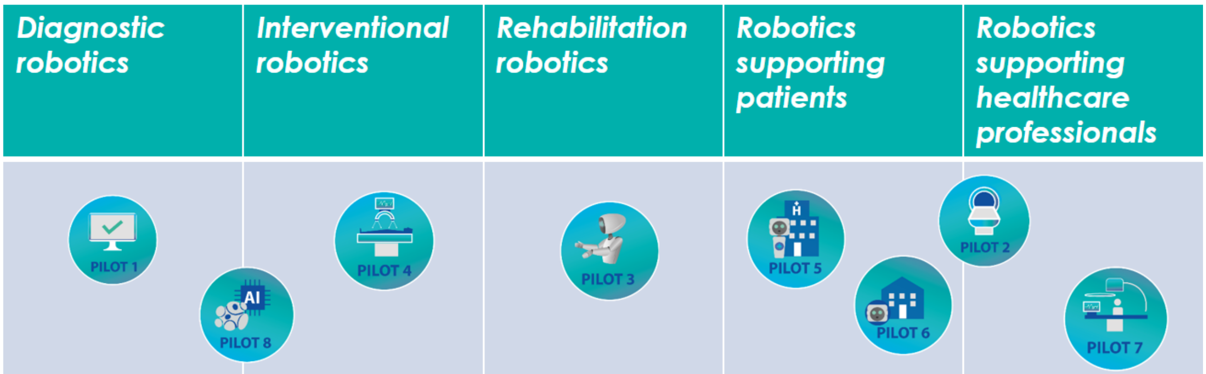


Figure 39: Mapping of the HosmartAI pilots on the DIH-HERO robotic domains.

From DIH-HERO mostly the technology and testing services will be considered for input; the two on the far left in Figure 40. This will be evaluated in course of the project.

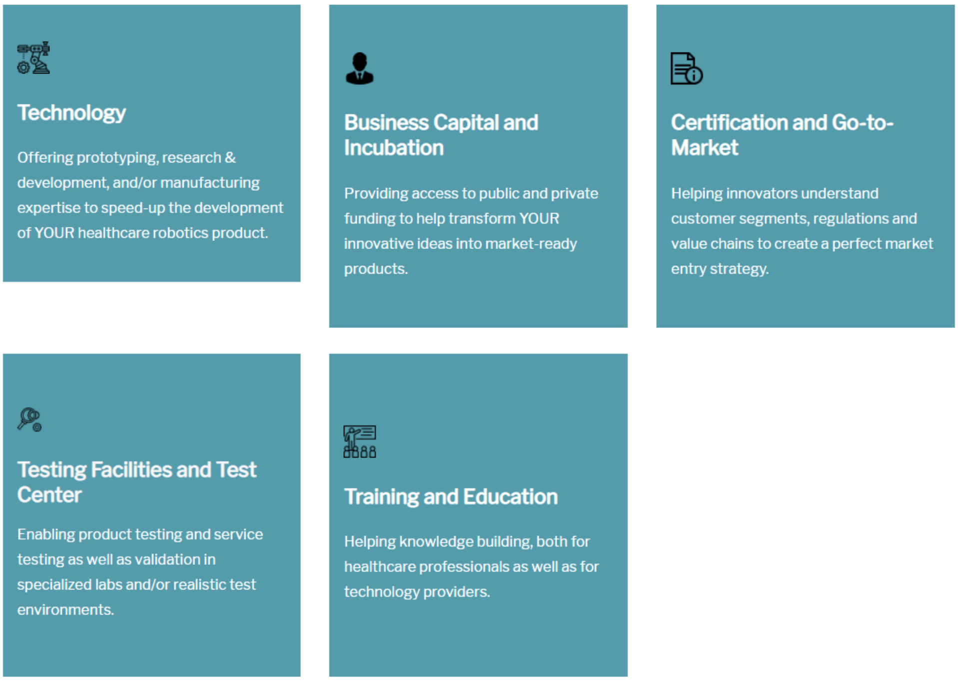


Figure 40: Overview of DIH-HERO services.

7.3 Other Standards

7.3.1 Health informatics

HL7-FHIR and HL7-CDA will work as standardised solutions providing the necessary data translation mechanisms combining the use of the proposed data model along with the respective data translation, management, and mechanisms. The data will be collected in HL7 following the measures in predetermined forms database tables and will be connected to the Hospital’s HL7 database.

7.3.2 AI

The standards that will be the primary focus in the Project are the ones belonging to the first two working groups of SC 42:

- SC 42/WG 1 Foundational standards
  - ISO/IEC 22989: Artificial Intelligence Concepts and Terminology
  - ISO/IEC 23053: Framework for Artificial Intelligence Systems Using Machine Learning
- SC 42/WG 2 Big data
  - ISO/IEC TR 20547-1: Information technology — Big Data reference architecture — Part 1: Framework and application process
  - ISO/IEC 20547-3: Information technology — Big Data reference architecture — Part 3: Reference architecture
  - ISO/IEC 24668: Information technology — Artificial Intelligence — Process management framework for Big data analytics

7.3.3 Robotics and Medical equipment

The standards described in Section 2.3.3, especially '**ISO 13482:2014** - Robots and robotic devices: Safety requirements for personal care robots' concerning safety regulations, must be considered for required compliance for the HosmartAI developments, in particular the ones including robotics.

7.3.4 Security and privacy

The most widespread reference regulation about digital security, concerning in particular the eHealth/medical sector, appropriate for the HosmartAI ecosystem, is the ISO/IEC 27000 - Information Security Management Systems (ISMS) family of standards, while for IT governance is the ISO/IEC 38500:2015 – Governance IT for the organization. For privacy aspects, the reference legislations are, above all, the (EU) 2016/679 GDPR and the two standards ISO/IEC 20889:2018 and ISO 25237:2017 for data anonymization and pseudonymization (see Section 2.3.4).

8 References

[REF-01]	XML encoding rules for HL7 v2 messages. Available online: http://www.hl7.org/documentcenter/public/wg/xml/drafts/v2xmlcb1.pdf (accessed on 2021-09-28).
[REF-02]	Tang, P. C., Ash, J. S., Bates, D. W., Overhage, J. M., & Sands, D. Z. (2006). Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. Journal of the American Medical Informatics Association, 13(2), 121-126.
[REF-03]	Saripalle, R., Runyan, C., & Russell, M. (2019). Using HL7 FHIR to achieve interoperability in patient health record. Journal of biomedical informatics, 94, 103188.
[REF-04]	Saripalle, R. K. (2019). Fast Health Interoperability Resources (FHIR): current status in the healthcare system. International Journal of E-Health and Medical Communications (IJEHMC), 10(1), 76-93.
[REF-05]	Resourcelist—FHIR v4.0.1. Available online: http://hl7.org/fhir/resourcelist.html (accessed on 2021-07-06).
[REF-06]	MOSAIQ Radiation Oncology. Available online: https://www.elekta.com/software-solutions/care-mangement/mosaiq-radiation-oncology/
[REF-07]	AI4EU website https://www.ai4europe.eu/ (accessed on 2021-09-04)
[REF-08]	GAIA-X website https://www.data-infrastructure.eu (accessed on 2021-09-04)
[REF-09]	OPEN DEI website https://www.opendei.eu/ (accessed on 2021-09-04)
[REF-10]	AI4EU Deliverable D2.1 Platform Architecture, Implementation, and day-to-day Operations https://ec.europa.eu/research/participants/documents/download Public?documentIds=080166e5d45546a9&appId=PPGMS (accessed 2021-09-07).
[REF-11]	Smistad, E., Bozorgi, M., & Lindseth, F. (2015). FAST: framework for heterogeneous medical image computing and visualization. International Journal of computer assisted radiology and surgery, 10(11), 1811-1822.
[REF-12]	Smistad, E., Østvik, A., & Pedersen, A. (2019). High performance neural network inference, streaming, and visualization of medical images using FAST. IEEE Access, 7, 136310-136321.
[REF-13]	Documentation. FAST. (n.d.). https://fast.eriksmistad.no/

Appendix A Platform Survey Template

Between October and November 2021, a survey was run among project partners to gather information regarding the HosmartAI platform technologies. The partners that will be affected by the selected technologies were highly encouraged to participate. The results of the Platform Survey are summarized in Section 3.1.1.The below sections (A.1 - A.6) contain the template of the Platform Survey.

A.1 Application development

Would you be able to develop new software that supports gRPC or you would like to use another protocol, such as REST?

A.2 Deployment orchestration

Please explain your thoughts on whether a Kubernetes or a plain Docker deployment would be the preferred option when an application that has been created in the HosmartAI Platform needs to run on a Pilot site (if this question is applicable to you). Is the overhead created by the Kubernetes configuration something that you can manage?

Are you aware of Pilot assets where software from the Platform cannot be deployed either in Docker or Kubernetes? Is there a specific method that the assets should be deployed? What is this method?

A.3 Deployment site

Would you be able to use the applications that are deployed on the cloud or you will require all applications to be deployed locally? If you cannot use cloud applications in some cases can you explain the reasons and the circumstances?

A.4 Important Data sources

Please fill in a copy of the below table for each important data source/dataset that you will use in HosmartAI. If some information is not available, you may leave the corresponding fields empty.

Data source name		
Data Short Description		
Dataset Type		
Purpose in Pilot		
Dataset Owner		
Dataset Provider		
Access License		
Access rights for HosmartAI		
Dataset Access		
Big Data Characteristics (if applicable) BBVA 5 Vs	Volume	
	Velocity	
	Variety	
	Veracity	
	Value	
Data format		
Encryption		
Data structure description		
For unusual format, tool to read it		
Remote accessibility	*Yes/No*	
	Protocol	
	Message format	
	Pull/Push	
	Provided interface	

If data is not yet accessible, how can they be retrieved?	*Describe the architecture and where an agent can be deployed*	
	Agent development requirements	
	Usable software API on device	
Dataset generation	*Was the data monitored in a system with real users?*	
	If no, how the data has been generated?	
Data Sample link		

From the above data, which (if any) will need to be catalogued in the Platform or its marketplace? How will this data be accessible (REST, SFTP, etc.)? Is there a specific need to store data in the Platform (the Platform in general should not be considered as a data repository)?

How are the data to be consumed exposed to the consumer application? Please describe the expected location of the application and the location of the data that each application uses.

A.5 Platform technologies

Which platform technology do you think would be the preferred one? Would Acumos AI Platform be useful as part of the main platform? Can you explain your view based on specific reasons and requirements? Other platforms or technologies that could potentially be better options?

A.6 AI Tools

Which version of each tool is required? Can it be deployed in the pilot sites? Can you describe the process in which it is required?

Appendix B Partners answers to T1.3 Questionnaire

The contents of this chapter are also included in D1.5. This chapter is included in D1.6 for completeness.

Between May and August 2021, a survey was run among all project partners to gather information regarding the HosmartAI platform scope, used components by partners and applied standards. The results of the platform scope are summarized in Section 3.1.2. The standards are presented in Sections 2.1 and 2.3. The first chapter of Appendix B contains the used components as provided by the project partners. The second chapter of Appendix B contains the Questionnaire template that was used to gather information on the intended platform scope, components that will be used and important standards.

B.1 Used components

ID		**ARHM_NOVA_VECTORS**
Responsible partner		91
Component name		ARHM, NOVA, VECTORS
Overall Description		Ninety One's ARHM platform is a high performance, cloud-native application that captures patient data, charts, and processes and renders them in an interactive user interface for medical providers and analysts to view, manage, and process. NOVA is Ninety One's proprietary engine that uses varying concepts in data science, machine learning, and artificial intelligence to process data and big data in order to generate analytics that define relationships between data points, trends, and probabilities of outcomes, and other stratification of data cohorts, path dependent expectations, and assessment of impact from independent or external variables. VECTORS is Ninety One's engine for pivoting big data at exceptionally efficient and high-performance levels in order to establish linear and non-linear/ragged hierarchies and extract search values as required by users of ARHM and other systems that may become interoperable during the project.
Details	*Functionalities offered*	1. Real-time data processing 2. AI powered data analysis and analytics 3. User interface 4. Real-time, big data pivot 5. High scalability 6. **Security** / CyberSecurity (encryption, authentication, authorization)

			7. HIIPA/CE5 standards
	Data input	*Description*	• Patient data derived from implanted and external monitoring devices • Electronic medical record data and other historical health records • Research data (from clinical studies) and other data from historical patient procedures • Real-time data derived during interventional cardiac procedures (e.g. Ablation mapping)
		Format	JSON, XML, HL7, csv, txt, other unstructured data formats
	Data Output	*Description*	• Aggregated health data • Analytics / actionable data points • Projection of data maps / surfaces of data describing expected values for certain variables within patients organs/heart • Stratification and pivoting of data and analytics on patient specific and patient cohorts • Assessment of potential outcomes with probabilistic scales ex-ante during procedures • Assessment of outcome ex-post during procedures
		Format	JSON, XML, csv, other data formats
	Integration requirements		• Several integration methods possible: API, SFTP, HL7, VPN. • Kubernetes, GraphQL, Google HIIPA Cloud, AWS HIIPA Cloud • Cloud servers for interoperability and decision making, coupled with local servers for processing of big data

ID	**MIMT**
Responsible partner	EFMI
Component name	EFMI MIMT - EFMI Medical Informatics multilingual thesaurus
Overall Description	To efficiently and effectively support the overall communication between different actors in the project and make them the users of the products, the EFMI MIMT will evolve from dictionary to thesaurus, will Integrate the MeSH

			concepts into previous EFMI MIMT hierarchy, add on specific EFMI MIMT concepts (e.g. omics, One Health, One Digital Heath,…), add on specific HosmartAI concepts e.g. Artificial Intelligence in Medicine related fields Robotics, Natural Language Processing, Machine Learning, Project Management, Human Machine Interface, Ethics, Regulation/GDPR.
Details	*Functionalities offered*		Access to multilingual communication
	Data input	*Description*	• Concepts, terms
		Format	text
	Data Output	*Description*	• Translated terms, ontologies
		Format	text
	Integration requirements		TBD

ID			**RMN_PLATFORM**
Responsible partner			ETHZ
Component name			Mobile Robotic Magnetic Navigation Platform
Overall Description			The RMN platform is a robotic system to control magnetic catheter and magnetic endoscope by generating an external magnetic field.
Details	*Functionalities offered*		The key capabilities is to generate a magnetic field.
	Data input	*Description*	Desired magnetic field at one specific position in the workspace.
		Format	To be defined, currently custom message in the Robotic Operating System (ROS)
	Data Output	*Description*	Actual magnetic field at different positions in the workspace.
		Format	To be defined, currently custom message in the Robotic Operating System (ROS)
	Integration requirements		Ethernet socket to connect to the robotic platform to send desired magnetic field.

ID		**EXYS7900_SIEM**
Responsible partner		EXYS
Component name		EXYS7900-SIEM
Overall Description		The **EXYS7900** is an enterprise-grade **SIEM** providing real-time analysis of security alerts generated by applications and network hardware, and available at affordable prices.
Details	*Functionalities offered*	The services offered by the EXYS7900-SIEM are

			• Data log collector and indexing engine for several third-party solutions, including Microsoft AD services and network services. • Log management tool implementing event management, data aggregation, alerting and cross correlation to external indicators and databases. • Principles of SIRP (Security Incident Response Platform) and SOAR (Security Orchestration Automation Response) • Flexible big-data indexing system, extensible to interface to alternate platforms used by the customer • Multi-layered GUI studied for use from 3 distinct profiles: administrators, service managers, and service users. • Incident investigation and reporting tool allowing very user friendly and efficient creation of forensic reports. • Extensions for OT event management. • CTI module for definition of ATT&CK matrices for SOC analysts to build comprehensive kill-chain context. • Extensions for the management of binary files detected and isolated viruses, pcap files, ...) on bigdata storage services. • Malware analysis module and reporting tool
	Data input	*Description*	Network logs, viruses
		Format	Binary, pcap, syslog data
	Data Output	*Description*	• Real-time alerts • Security data logs • Periodic reports • Incident reports
		Format	PDF, CSV, JSON
	Integration requirements		TBD

ID		**EXYS9000_EFS**
Responsible partner		EXYS
Component name		EXYS9000-EFS
Overall Description		Endpoint tunnelling and firewalling system, allowing to protect computer networks and data traffic from outside threats.
Details	*Functionalities offered*	The equipment and functionalities coming with the EXYS92000-EFS are • Modules for stateful end-to-end security

			• Secured Data Communication • Authentication, privacy and cryptography • Secure technologies: TLS/SSL, IPSec, GRE, OpenVPN • Data Integrity and Confidentiality • Unified management user interface
	Data input	*Description*	Internet traffic
		Format	Binary, pcap
	Data Output	*Description*	Data logs
		Format	PDF, CSV, JSON
	Integration requirements		TBD

ID			**GREEN_PI**
Responsible partner			GC
Component name			Green PI
Overall Description			Distributed Internet & Edge Cloud Platform
Details	*Functionalities offered*		- Dedicated Internet Infrastructure with various interfaces to connect multiple IoT devices. - Edge Cloud with Edge services for IoT devices management, local communications and collaboration (chat, file sharing system, etc.)
	Data input	*Description*	IoT devices MAC address GPS when enabled
		Format	TBD
	Data Output	*Description*	Display of the data on a network visualization application
		Format	XML file, vCards
	Integration requirements		TBD

ID		**STREAMHANDLER_PLATFORM**
Responsible partner		INTRA
Component name		Streamhandler Platform
Overall Description		INTRA's Streamhandler Platform is a high-performance (low latency and high throughput) distributed streaming platform for handling real-time data based on Apache Kafka. It can efficiently ingest and handle massive amounts of data into processing pipelines, for both real-time and batch processing.
Details	*Functionalities offered*	The key capabilities and features offered by the platform are:

			• **Real-time** monitoring and event-processing • **Interoperability** with all modern data storage technologies and popular data sources • **Distributed** messaging system • High fault-tolerance - Resiliency to node failures and support of automatic recovery • Elasticity - High scalability • **Security** (encryption, authentication, authorization)
	Data input	*Description*	**GPS** and other **sensor data** (incl. fuel level and driver behaviour data) from vehicles (tracks) and their drivers • 1000 vehicles • Supporting **1,5 to 3 million** messages per sec
		Format	Any kind of data typically: CSV, JSON, AVRO, XML
	Data Output	*Description*	• Aggregated GPS and sensor data • Data suitable for ingestion
		Format	Any kind of data typically: CSV, JSON, AVRO, XML
	Integration requirements		• At least 3 VMs to support fault tolerance and scalability. • External connectors will need to use Kafka Connect. • Consumers/producers will be integrated through Kafka Streams API.

ID			**AI_DIAGNOSIS_SUPPORT**
Responsible partner			ITCL
Component name			An AI and Big Data diagnosis support system
Overall Description			Big Data platform system for efficient medical assistance, diagnosis.
Details	*Functionalities offered*		The key capabilities and features offered by the platform are: • **Real time** capture data. • **Storage data** in Bigdata Cassandra Database. • **Security access** (encryption, authentication, authorization).
	Data input	*Description*	Age.

			Body Height. General status. Heartbeat. Oxygen. Blood pressure. Body temperature. Urine. Glucose. Body weight. Stool.
		Format	JSON
	Data Output	*Description*	Medical diagnostic.
		Format	JSON
	Integration requirements		At least 3 VMs to support fault tolerance and scalability for Cassandra Database. One VM for web services for the communication integration.

ID			**JETSON_NANO**
Responsible partner			ITCL
Component name			Nvidia Jetson (Nano, TX2 or Xavier NX to be decided)
Overall Description			A nanocomputer with high-end capabilities specifically designed for embedded AI applications
Details	*Functionalities offered*		• GPU aided processing power • Mobile and autonomous computation unit • Compatibility with most popular frameworks in AI
	Data input	*Description*	• Sensor data captured by the robot (Video, audio, etc) • Data offered by external servers
		Format	JSON, CSV, XML, binary streams, etc.
	Data Output	*Description*	• Actions detected by the system • Predictions performed by the system
		Format	JSON, CSV, XML, binary streams, etc.
	Integration requirements		TBD

ID	**TENSOR2**
Responsible partner	ITCL
Component name	TensorFlow 2

Overall Description			One of the most used deep learning frameworks across the AI field. It gives support for efficient neural network implementations in a convenient manner.
Details	*Functionalities offered*		• Out of the box popular models • Several kind of neural network layers already implemented • Support for GPU acceleration • Convenient features for developing and deploying new architectures
	Data input	*Description*	• Sensor data captured by the robot (Video, audio, etc)
		Format	JSON, CSV, XML, binary streams, etc.
	Data Output	*Description*	Predictions performed by the neural networks.
		Format	JSON, CSV, XML, binary streams, etc.
	Integration requirements		TBD

ID			**OPENCV**
Responsible partner			ITCL
Component name			OpenCV
Overall Description			The reference library for artificial vision related tasks. It provides a vast amount of classical computer vision algorithms.
Details	*Functionalities offered*		• Efficient implementation of filters and convolutions • Several well-known hand-made feature extractors • Algorithms for pattern recognition • Convenient image manipulation
	Data input	*Description*	Video captured by the robot
		Format	binary streams
	Data Output	*Description*	Results of the video analysis performed
		Format	JSON, CSV, XML, binary streams, etc.
	Integration requirements		TBD

ID	**PHE_EASY_ACCESS**
Responsible partner	Pharmecons Easy Access
Component name	Key Performance Indicators (KPIs) / Non engineering KPIs
Overall Description	Pharmecons Easy Access in collaboration with the pilot partners will link the objectives of each

			pilot with measurable outcomes based on specific Key Performance Indicators (KPIs) which have been agreed by all partners and are used in everyday clinical practice by hospitals and healthcare environments.
Details	*Functionalities offered*		8. Guidance on which KPIs to be used per pilot 9. Analysis in case of Patient Reported Outcomes and Patient Satisfaction data 10. The introduction of the KPI metrics to be used in the HOSMARTAI Platform in collaboration with ITCL 11. Creation of HOSMARTAI Patient & physician satisfaction questionnaire 12. Protocol & CRF provision for pilots Include here AI/robotics functionalities, if applicable.
	Data input	*Description*	• Advise on non-engineering objectives and how to measure them (KPIs) • Clinical, Patient Reported Outcome, satisfaction and cost data and any other source of data
		Format	Excel, SPSS or STATA
	Data Output	*Description*	• Support in analysis of any kind of health data regarding non engineering KPIs • Report on KPI Definition • Patient & physician satisfaction questionnaire if approved by pilots
		Format	Excel, Word, or any other interactive way/presentation
	Integration requirements		Integration of respective data in all agreed deliverables.

ID			**PATIENT_SCHEDULER**
Responsible partner			TMA
Component name			Patient Scheduler
Overall Description			Patient Scheduler offers flexible patient scheduling for examination and consultation taking into account various parameters like physicians availability, patient preferences and limitations
Details	*Functionalities offered*		Key features are: - Patient scheduling - Patient medical file - Exam history - Overall schedule view

			- Notifications / reminders - Messaging - Reporting - Calendar
	Data input	*Description*	Patient medical data, exams
		Format	DICOM / HL7 / proprietary
	Data Output	*Description*	Exam schedule
		Format	JSON / proprietary
	Integration requirements		HTTP API, DICOM interface

ID			**CONNECTED_GATEWAY**
Responsible partner			VIMAR
Component name			Connected Gateway
Overall Description			Bluetooth technology Wi-Fi device designed to allow dialogue with wireless devices to permit the configuration, supervision, system diagnostics and its integration with voice assistants. Main device that manages the Bluetooth technology Mesh network. Via the View Wireless App it receives the system configuration through Bluetooth technology. The presence of Wi-Fi connectivity is required to allow the connection to the cloud for supervision and for integrations with the Alexa, Google Assistant and Siri voice assistants.
Details	*Functionalities offered*		Exposes the local framework to the user app through VIMAR cloud
	Data input	*Description*	TBD
		Format	TBD
	Data Output	*Description*	TBD
		Format	TBD
	Integration requirements		TBD

ID	**CONNECTED_2WAY_SWITCH**
Responsible partner	VIMAR
Component name	Connected 2-way switch
Overall Description	The device is equipped with 2 interlocked relay outputs to accomplish the switch function and a front key to control the connected load. It performs the automatic opening of the relay for thermal protection. Switching on zero crossing. The electronic switch can be connected to existing

			wired multi-way/two-way switches to make the load function “connected”.
Details	*Functionalities offered*		The electronic switch mechanism connected is designed to operate a load via on-board push button, through a wireless connection and from a traditional remote push button.
	Data input	*Description*	• Toggle on/off • One-position stable activation time
		Format	TBD
	Data Output	*Description*	• Serial number • LED settings (colour, brightness, etc) • Power on behaviour • Timed behaviour • Switch on time • External button behaviour • Scene activation and delay • Actual load status
		Format	CSV, JSON
	Integration requirements		TBD

ID			**CONNECTED_ROLLING_SHUTTER**
Responsible partner			VIMAR
Component name			Connected rolling shutter mechanism
Overall Description			The device is equipped mutually exclusive activation of the relays with a minimum interlocking time. The front keys of the device control the on-board roller shutter actuator, starting or stopping the slat movement or the rotation. It allows also the recall of a favourite position.
Details	*Functionalities offered*		The device makes it possible to control the roller shutter/slat using the on-board keys and via a wireless connection. It
	Data input	*Description*	• Slat orientation • Roller shutter activation • Preferred position • Movement check • Scenario activation • Status check
		Format	TBD

	Data Output	*Description*	• Serial number • Shutter type • LED settings (colour, brightness, etc) • Move up/down time • Slat move time • Scenarios activation delay • Favourite blind position • Favourite slat position • External button behaviour/scene • Activation time • Generic level status
		Format	CSV, JSON
	Integration requirements		TBD

ID			**CONNECTED_ACTUATOR**
Responsible partner			VIMAR
Component name			Connected actuator
Overall Description			The actuator is equipped with a relay output with a current meter and a front push button with which to reset the load and perform configuration/reset. Its function is to protect against overcurrent by cutting off the load when the thresh-old value set via the View Wireless App is exceeded. Load reactivation, aside from the front push button, can also be done via the View App. The View App also makes it possible to View the instant power consumed.
Details	*Functionalities offered*		• Relay operation: two-position stable or one-position stable with current meter • One-position stable activation time
	Data input	*Description*	• Load cut-off threshold function • Consumption threshold for load cut-off • Load status when the power supply is restored
		Format	TBD
	Data Output	*Description*	• Serial number • LED settings (colour, brightness, etc) • Power on behaviour • Timed behaviour • Activation time • Scene activation and delay

			• Power alarm threshold • Enable power alarm • Connected device name • Active Power and Active Energy (updated when active power changes more than 10W from the previous) • Continuous Active power • Continuous Active energy
		Format	CSV, JSON
	Integration requirements		TBD

ID			**IOT_ENERGY_METER**
Responsible partner			VIMAR
Component name			Monophase IoT energy meter
Overall Description			The device is designed to measure the consumption/production of instantaneous electricity and consumption logs with an hourly, daily, monthly and annual resolution. It should be connected to the single-phase line using the current probe provided. Only one meter for total consumption can be installed in a system.
Details	*Functionalities offered*		• Energy consumption/production • Monitoring of instant power consumption/ production • Monitoring of instant energy consumption/ production
	Data input	*Description*	TBD
		Format	TBD
	Data Output	*Description*	• Serial number • Active power, active energy consumption and production saved with hourly resolution • Power transmission policy • Application meter • Power threshold • Power timer • Continuous Active power • Continuous Active consumption energy • Continuous Active production energy • Dynamic mode
		Format	CSV, JSON
	Integration requirements		TBD

ID			**SMART_CARD_LANDING_READER**
Responsible partner			VIMAR
Component name			NFC/RFID smart card landing reader
Overall Description			Access control is achieved with the combined usage of NFC/RFID smart card landing reader and NFC/RFID smart card reader pocket, both controlled and configured by using View Wireless App. The smart card landing reader device is designed to be installed outdoors and near an entrance and it grants access only if the smart card associated with it is read and recognised.
Details	*Functionalities offered*		• Recognition of the smart card (that triggers the door opening) • Anomaly detection on the reader • Do Not Disturb signalling • “Crossover relay” option for combined operation with card reader pocket
	Data input	*Description*	• Smart card ID
		Format	TBD
	Data Output	*Description*	• Smart card information • Smart card landing time • Crossover relay option • Smart card recognition
		Format	CSV, JSON
	Integration requirements		TBD

ID		**SMART_CARD_READER_POCKET**
Responsible partner		VIMAR
Component name		NFC/RFID smart card reader pocket
Overall Description		NFC/RFID smart card reader pocket allows the activation of utilities only if the wireless smart card associated with it is read and recognised. The two devices are designed to communicate (if associated during configuration) to manage accesses to the same room and ensure greater safety via the “Crossover relay” option.
Details	*Functionalities offered*	• Recognition of the smart card (with toggle off if card removed)

			• "Crossover relay" option for combined operation with card landing reader
	Data input	*Description*	• Smart card ID
		Format	TBD
	Data Output	*Description*	• Smart card information • Smart card insertion time • Smart card removal time • Internal relay timeout • Crossover relay option • Smart card recognition
		Format	CSV, JSON
	Integration requirements		TBD

ID			**ULTRA_WIDE_BAND**
Responsible partner			VIMAR
Component name			Ultra Wide Band (UWB)
Overall Description			This sensor can detect human movement/presence without using Fresnel lens. It employs a military-based radar UWB technology capable of detecting centimetres wide human movements. It has been conceived a recessed version and one to be installed in the ceiling.
Details	*Functionalities offered*		• People Presence/absence • Micro movements detection • Load activation • Area/volume of detection parametrization
	Data input	*Description*	TBD
		Format	TBD
	Data Output	*Description*	• Status of presence/absence
		Format	TBD
	Integration requirements		TBD

ID	**CLOUD_VIEW**
Responsible partner	VIMAR
Component name	Cloud View
Overall Description	Cloud View is a high-performance infrastructure to handle real-time data, based on AWS services.

			Through APIs it provides the possibility to analyse high volumes of data ensuring safety and stability.
Details	*Functionalities offered*		• Resources monitor • Security monitor • Audit log – compliance • Data storage
	Data input	*Description*	• Electricity consumption and production • human presence/access control • Devices activation and connected load
		Format	JSON
	Data Output	*Description*	TBD
		Format	TBD
	Integration requirements		TBD

ID		**IPROGNOSIS**
Responsible partner		AUTH
Component name		iPrognosis application (for Pilots #3, #6)
Overall Description		iPrognosis is a digital phenotyping mobile application intended for detecting and/or assessing Parkinson's disease symptoms. The application collects data passively from smartphone sensors during the natural interaction of users with their device and converts them to digital biomarkers, via Cloud-based machine learning models.
Details	*Functionalities offered*	Key features: Remote, longitudinal monitoring of Parkinson's disease symptoms. Automatic, unobtrusive collection of heterogenous data. Automatic, machine learning-based analysis on the cloud. Production of digital biomarkers indicating the severity of the disease, namely: **A bradykinesia and a rigidity severity score** based on keystroke dynamics data collected during natural typing with the iPrognosis custom virtual keyboard.

			Whether or not **tremor** is detected in motion data captured while users hold their device during a phone call (postural tremor). **Whether the user has Parkinson's disease or not** based on voice spectral and time-domain features extracted from natural speech during phone calls.
	Data input	*Description*	**Time stamps of touch actions** corresponding to key press and release events during typing using iPrognosis custom keyboard **IMU sensor data** during phone call **Microphone stream** corresponding to the initial 75s of phone call
		Format	TBD
	Data Output	*Description*	Bradykinesia and rigidity score, date-time, user ID Flag of tremor detected/not detected in call, date-time, user ID Flag of voice sample corresponding to a person with/without Parkinson's disease, date-time, user ID
		Format	JSON
	Integration requirements		Cloud infrastructure API Possibly a VM

ID	**IMAT**
Responsible partner	AUTH
Component name	iPrognosis Motor Assessment Tests (iMAT) (for Pilots #3, #6)
Overall Description	iMAT is a series of tests exploiting human pose estimation technology to assess the motor capacity of people with Parkinson's disease. Standing in front of a 3D camera, users perform a series of movements displayed on video by an expert. Movements displayed are similar to those performed during clinical assessment of the patient based on standardized scales. At the end of each test, a score is produced reflecting the similarity of the movement performed by the user with the one performed by the expert.

Details	*Functionalities offered*		Key features: Remote, personalized assessment of Parkinson's disease patients motor capacity. Production of scores, quantifying the similarity of the movements performed by the user with the ones performed by the expert.
	Data input	*Description*	**3D video data** of patients performing movements.
		Format	TBD
	Data Output	*Description*	Similarity score with reference skeleton, date-time, user ID
		Format	JSON
	Integration requirements		Cloud infrastructure API Possibly a VM

ID			**SCHEDULER_OPTIMIZATION**
Responsible partner			TMA and CHUL
Component name			Scheduler optimization
Overall Description			Scheduler for optimization of machines, therapy rooms, nurses, waiting times, etc...
Details	*Functionalities offered*		1. Scheduler system for radiotherapy treatments. 2. User interface for patient and doctors.
	Data input	*Description*	Omnipro Health Record System from where anonymised data can be retrieved. • Preference about location hospital. • Type of treatment. • Number of sessions. • etc.... Mosaiq Machine data: • DICOM patient exams • Patient medical history • Patient medication • Medical equipment involved
		Format	Binary, CSV, XML, AVRO, unstructured text
	Data Output	*Description*	Scheduler optimization
		Format	JSON, Binary, XML, CSV
	Integration requirements		Integration with FHIR and DICOM protocols.

			IT have to create the information automatically and dynamically.

ID			**PEPPER**
Responsible partner			UM
Component name			Robot Pepper
Overall Description			An autonomous humanoid robot designed to interact with patients and clinicians in pilot #5.
Details	*Functionalities offered*		1. Interaction 2. Data Visualization 3. Collection of PROs 4. Games and digital activities
	Data input	*Description*	Interaction: Speech, Image Assistive mode: EHRs and PGHD
		Format	TBD
	Data Output	*Description*	Interaction: Speech, Gestures Assistive mode: Visualization on tablet
		Format	JSON, visualization
	Integration requirements		CE Certification

ID		**MULTIMODAL_SENSING_NETWORK**
Responsible partner		UM
Component name		Multimodal sensing network
Overall Description		The conceptual network is designed as an enabler for collection and integration of PGHD. It is built around conversational intelligence enriched with an embodied conversational agent as the tool for data collection and connecting the patient and the patient's care team. The following open libraries will be considered and integrated: openSMILE, LibRosa, OpenFace, OpenPose, Stanza, CLASSLA, spaCy
Details	*Functionalities offered*	1. Collection of objective biomarkers; we consider: physical biomarkers collected medical grade telemonitoring platforms measuring and blood pressure, heart rate 2. Collection of subjective biomarkers; we consider: speech related and acoustic biomarkers, face related and language related features expressed during interaction and classification of symptoms of psychological distress (depression).

	Data input	*Description*	Speech, Image
		Format	Signal and text
	Data Output	*Description*	Extracted features
		Format	JSON
	Integration requirements		GPU enabled hardware

ID			**SPREAD**
Responsible partner			UM
Component name			Speech Recognition System SPREAD
Overall Description			To support Slovenian (Pilot #5) and French (Pilot #2) language, we will deploy the UM's proprietary automatic speech recognition (ASR) System SPREAD. The systems is based on end-to-end connectionist temporal classification- (CTC-).
Details	*Functionalities offered*		1. Speech to text 2. Spoken language understanding
	Data input	*Description*	Speech
		Format	Signal
	Data Output	*Description*	Text, acoustic features
		Format	JSON
	Integration requirements		GPU enabled hardware

ID			**PLATOS**
Responsible partner			UM
Component name			Speech Synthesis System PLATOS (DNN version)
Overall Description			To support Slovenian (Pilot #5) and French (Pilot #2) language, we will deploy the UM's proprietary automatic speech synthesis (TTS) System PLATOS (DNN variant). The systems are Tacotron 2 and flow-based neural network model – WaveGlow
Details	*Functionalities offered*		1. Speech synthesis
	Data input	*Description*	Text
		Format	text
	Data Output	*Description*	speech
		Format	file or audio stream
	Integration requirements		GPU enabled hardware

ID	**UM_CHATBOT**
Responsible partner	UM
Component name	Chatbot (DNN version)
Overall Description	A chatbot to deliver domain restricted conversation. UM will deploy RASA NLU as an open source conversational intelligence; machine learning framework to automate text-and voice-

			based conversations. Rasa enables the delivery of contextual assistants capable of having layered conversations with lots of back-and-forth.
Details	*Functionalities offered*		1. Engage with patients
	Data input	*Description*	Text
		Format	JSON
	Data Output	*Description*	Text
		Format	JSON
	Integration requirements		TBD

ID			**UM_EVA_GESTURES**
Responsible partner			UM
Component name			EVA Framework to generate non-verbal gestures
Overall Description			A framework to deliver non-verbal (i.e. gestures) modality and speech as natural responses. Following UM's proprietary algorithm we will assume the dynamics are addressed mostly by the relation between the temporal distribution of the co-verbal expression (movement-phases) and the spatial configuration of the shapes. Virtual movement can be specified as almost instantaneous, whereas the movement controllers of the robotic unit require longer temporal periods. The responsiveness of the servo-motors (the robot's physical movement controllers) is defined by the motors' maximum angular velocities and by their maximum angular acceleration.
Details	*Functionalities offered*		1. Define co-verbal gestures
	Data input	*Description*	Text/speech signal
		Format	JSON, File
	Data Output	*Description*	EVA SCRIPT based description of conversational behaviour
		Format	XML
	Integration requirements		TBD

ID	**GRADIOR**
Responsible partner	INTRAS
Component name	Suite Gradior (cognitive stimulation)
Overall Description	Neuropsychological evaluation and rehabilitation system for carrying out training programmes in people with deficits and/or cognitive impairment. It allows working in adults Attention, Perception, Orientation,

			Memory, Calculation, Executive Function, Language and Reasoning. The system consists of a website (aimed at professionals) and an app for the execution of intervention sessions by users.
Details	*Functionalities offered*		The key capabilities and features offered by the platform are: • **Real time** capture data. • Data analysis for monitoring and follow-up (AI) • **Security access** (encryption, authentication, authorization).
	Data input	*Description*	Personal data Sociodemographic data Clinical data Results of treatment sessions (% hits and misses, reaction times)
		Format	JSON
	Data Output	*Description*	Results of rehabilitation sessions with Gradior and care plans (editor and patient data)
		Format	JSON
	Integration requirements		HosmartAI common data model Cloud infrastructure API

ID			**CATHLAB_ASSISTANT**
Responsible partner			PHILIPS
Component name			Cathlab Assistant
Overall Description			SW application that analyses coronary angiograms and performs automatic labelling of coronary vessels
Details	*Functionalities offered*		13. Data analysis 14. User interface
	Data input	*Description*	• X-ray image data
		Format	TBD
	Data Output	*Description*	• Coronary vessel labels
		Format	TBD
	Integration requirements		To be agreed upon with UZB

ID	**CYTOSCAPE**
Responsible partner	VUB
Component name	Cytoscape
Overall Description	Gene/protein information

Details	*Functionalities offered*		Genomics instrumentation and related bioinformatics, see http://www.brightcore.be
	Data input	*Description*	Patient cancer samples
		Format	-
	Data Output	*Description*	Gene information on cancer cells
		Format	Variant Call Format (VCF) files
	Integration requirements		Connection to centralised database

ID			**PRIMUZ**
Responsible partner			VUB
Component name			PRIMUZ
Overall Description			Patient information database
Details	*Functionalities offered*		Integrated storage of patient records/information, https://www.uzbrussel.be/web/primuz
	Data input	*Description*	Patient information
		Format	-
	Data Output	*Description*	Integrated patient data files
		Format	APIs
	Integration requirements		Connection to other hospital databases

ID			**PACS_RIS**
Responsible partner			VUB
Component name			PACS/RIS
Overall Description			Patient image data storage
Details	*Functionalities offered*		Storage of patient images (MRI, PET, …)
	Data input	*Description*	Patient images
		Format	-
	Data Output	*Description*	Access to images
		Format	APIs
	Integration requirements		Connection to centralised database

ID			**REDCAP_XNAT**
Responsible partner			VUB
Component name			REDCAP or XNAT
Overall Description			Integrated patient data/image/gene storage
Details	*Functionalities offered*		Storage of integrated patient data for research
	Data input	*Description*	Connection to other databases
		Format	-
	Data Output	*Description*	Integrated data amenable for AI research
		Format	APIs
	Integration requirements		Pseudonymization of patient records

B.2 T1.3 Questionnaire Template

The following sections 0, B.2.2 and B.2.3 were included in a questionnaire addressed to all Project partners to gather the relevant data.

B.2.1 Platform scope questions

Who is this addressed to: All partners

Questions about the envisaged scope of the platform will contribute towards refining and validating HosmartAI conceptual architecture. Each user of the platform has an important perspective which can be utilised to define the shape of the platform.

Please select the more appropriate option for you in the following statements:

The HosmartAI platform as you envision it will provide interoperability among existing solutions

- □ Strongly agree
- □ Agree
- □ Neither agree nor disagree
- □ Disagree
- □ Strongly disagree

The HosmartAI platform as you envision it will add features to existing solutions

- □ Strongly agree
- □ Agree
- □ Neither agree nor disagree
- □ Disagree
- □ Strongly disagree

The HosmartAI platform as you envision it will ease the development of new solutions

- □ Strongly agree
- □ Agree
- □ Neither agree nor disagree
- □ Disagree
- □ Strongly disagree

The HosmartAI marketplace as you envision it will evolve into an EU-wide store for AI-powered healthcare solutions

- □ Strongly agree
- □ Agree
- □ Neither agree nor disagree
- □ Disagree

- ☐ Strongly disagree

Please answer the below questions:

How do you envision HosmartAI as a deployment platform?

How do you envision HosmartAI replacing existing solutions with AI-powered ones? Can you provide examples?

How could the HosmartAI platform improve interoperability between existing platforms?

B.2.2 Used components

Who is this addressed to: All partners having components that will be used in HosmartAI

Please fill in a copy of the below table for each available component you already have and will use in HosmartAI. Examples of such components are:

- *Existing tools that might be used as is or extended in the platform*
- *Third-party platforms*
- *Cloud provider tools*
- *Cloud storage Used datacentres*
- *Special hardware required (GPU, HPC)*
- *Robotics*

ID			**(to be assigned later)**
Responsible partner			PartnerName
Component name			TheNameOfTheComponent
Overall Description			Lorem ipsum dolor sit amet, consectetur adipiscing elit. Cras ut leo efficitur, pellentesque magna a, gravida risus. Praesent tincidunt enim.
Details	*Functionalities offered*		15. Data analysis 16. User interface 17. Etc. Include here AI/robotics functionalities, if applicable.
	Data input	*Description*	• Sensor data from robots • Health data • Etc.
		Format	JSON, XML, etc.

	Data Output	*Description*	• Advise on logistics assignments • Aggregated health data • Etc.
		Format	JSON, XML, etc.
	Integration requirements		ERP, standards, other HosmartAI component, APIs etc.

Example:

ID			
Responsible partner			INTRA
Component name			Streamhandler Platform
Overall Description			INTRA's Streamhandler Platform is a high-performance (low latency and high throughput) distributed streaming platform for handling real-time data based on Apache Kafka. It can efficiently ingest and handle massive amounts of data into processing pipelines, for both real-time and batch processing.
Details	*Functionalities offered*		The key capabilities and features offered by the platform are: • **Real-time** monitoring and event-processing • **Interoperability** with all modern data storage technologies and popular data sources • **Distributed** messaging system • High fault-tolerance - Resiliency to node failures and support of automatic recovery • Elasticity - High scalability • **Security** (encryption, authentication, authorization)
	Data input	*Description*	**GPS** and other **sensor data** (incl. fuel level and driver behavior data) from vehicles (tracks) and their drivers • 1000 vehicles • Supporting **1,5 to 3 million** messages per sec
		Format	Any kind of data typically: CSV, JSON, AVRO, XML
	Data Output	*Description*	• Aggregated GPS and sensor data • Data suitable for ingestion
		Format	Any kind of data typically: CSV, JSON, AVRO, XML
	Integration requirements		• At least 3 VMs to support fault tolerance and scalability. • External connectors will need to use Kafka Connect.

		• Consumers/producers will be integrated through Kafka Streams API.

Empty template:

Standards used/required	Tool…	Pilot…									
HL7 FHIR											
DICOM											
ISO 23903:2021											

ID			
Responsible partner			
Component name			
Overall Description			
Details	*Functionalities offered*		
	Data input	*Description*	
		Format	
	Data Output	*Description*	
		Format	
	Integration requirements		

B.2.3 Standards

Who is this addressed to: All partners offering tools or leading pilots

Please put an "X" in the boxes that apply for the tools you provide or the pilot you are involved. Fill in the tool and pilot names in the column headers. If an important standard is missing, please append it in a new row. Please skip generic standards, such as ISO 9001 and ISO 27000.