Personalised Health Monitoring and Decision Support Based on Artificial Intelligence and Holistic Health Records

D8.8 - Standardisation, IPR management and Ethics in iHelp I

WP8 Communication and Exploitation

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Executive summary

This report is the first from a deliverable series of two deliverables, i.e, D8.8 – "Standardisation, Intellectual Property Rights (IPR) management and Ethics in iHelp I" due on M24, and D8.9 – "Standardisation, Intellectual Property Rights (IPR) management and Ethics in iHelp II" due on M36, and will detail all engagement with standardisation bodies or similar fora and the corresponding potential contributions for standardisation, IPR management and consideration for relevant ethical principles.

In Section 2 of this deliverable, we present the standards landscape that are relevant to iHelp, the motivations that lead to using these standards, and what are the standardization activities performed within the project. Also, as stated by the EU data governance act, which is a regulatory framework that facilitates the way companies and public institutions exchange data, one of the provision of data intermediation services include: "*the obligation of interoperability with other data intermediation services, inter alia, by means of commonly used open standards"*.

Taking this into consideration, Section 3 treats the concept of open-source developments in iHelp, we identified the open-source libraries used in the project, the open-source products created in this project as well as the innovations that are subject to public dissemination. Exploiting open source contributes to the economic growth and provides more rapid advancements with transparent and equal access for the benefit of researchers, healthcare professionals, and citizens.

On the other side, Intellectual Property (IP) is one of the most important assets of any company or consortium. Managing this asset necessitates time, effort, and money, and its important because it protects the ideas, the new discoveries. The management of intellectual properties is depicted in Section 4, where we identify the assets within the iHelp project, the access rights issue, the protection, and exploitation of these assets.

The management of projects from scientific area has certain requirements that, when applied, assure the fulfilment of the ethical principles. In Section 5, we identified the potential ethical issues in pilots, the ethic concept in AI research, especially in establishing the trustworthiness of an AI system.

Finally, in Section 6, we present the conclusions from this deliverable and potential other investigation for the future in the areas covered in this document.

High priority is given to the appropriate protection and exploitation of data and results in the various work packages (WPs) of the project. It is important to note that the purpose of the current report is to give a general overview of the guiding principles and key components of IPR that will be applied by the consortium partners to both newly generated results and the implemented open-source solutions. It also addresses how and when to convey results in an honest and ethical manner. It does not, however, replace any existing agreements, such as the Consortium Agreement (CA), Grant Agreement (GA), or any EU project implementation and documentation guidelines. In particular, the CA serves as a primary reference document on data management concerns, outlining the rights and responsibilities of all beneficiaries about the following matters: dissemination of project results and data; ownership of results; protection of results; and access rights.

1 Introduction

1.1 Objectives

This deliverable, i.e., D8.8 – "Standardisation, IPR management and Ethics in iHelp I" is related to T8.3 – "Standardisation, IPR and Ethics Management" and oversees handling IPR developed and brought in throughout the iHelp project, as well as standardization activities (use, compliance, adoption, contributions, etc.). This covers both the intellectual property rights (IPR) of the iHelp building blocks and the IPRs created during the planning and completion of the pilots. It also covers the handling and upholding of ethical standards when offering customized healthcare solutions. The development and use of iHelp solutions will raise the IPR issues described in Section 4. IPR Management, notwithstanding the iHelp partners' commitment delivering open-source solution(s) through the iHelp initiative. To guarantee that all stakeholders adequately handle the business possibilities and resolve the IPR issues in the most effective way, the IPR management in this work will rely on consultations and the use of established IPR management principles. Furthermore, iHelp project aims to uphold and carry out open-source availability of solutions derived from the project.

Following, contributing to, promoting, and ensuring usage of the corresponding relevant standards, while also supporting the liaison and collaboration activities with other EC funded related projects and initiatives. Is considered.

This deliverable also discusses the ethical issues surrounding the use of personal data. The tasks of this deliverable will ensure that the partners are aware of the pertinent rules, regulations, and ethical standards and that the necessary safeguards are put in place to ensure compliance during project development and pilot operations.

1.2 Document structure

The current deliverable is organized as follows: Section 1 establishes the context, summarizes D8.8's primary goals, and describes how it relates to other deliverables.

Standardization-related information is covered in Section 2, while information on the Open-Source technologies utilized in the iHelp project is covered in Section 3.

Strategies for IPR Management are discussed in Section 4, and Ethics handling is covered in Section 5. In Section 6, final conclusions are drawn.

1.3 Connection to other deliverables

The identification, analysis, and plan of the innovation potentials within iHelp has been performed within D1.6 – "Innovation Potential: Plan & Activities I" (G., O., W., +21) and D1.7 – "Innovation Potential: Plan & Activities II" (G., F., K., +22). For the respective innovations, establishing clear IPR guidelines along with the management of IPR issues facilitate a successful exploitation of projects' outcomes, as this deliverable entails.

With respect to ethics, the D1.3 – "Periodic Management Report I" (K., M., M., +21) and its follow-up versions, D1.4 – "Periodic Management Report II" (M24) and D1.5 – "Periodic Management Report III"

(M36) report and assure the ethics legal basis for data use and data protection, while the present D8.8 mention the Ethical Committees' approvals within Section 5.

In this context, also D1.9 – "Ethical Issues Related to the Involvement of Humans in iHelp" (F., 21) describes the initial procedures and criteria have been developed by all pilot partners explaining how human participants are being identified and recruited, the informed consent procedures that will be implemented and the templates that will be used in iHelp project. While D1.10 – "Ethical Issues Related to the Protection of Personal Data" (M., M., 21) treats the general legal, regulatory, and ethical issues which the development of the iHelp platform may face about the protection of personal data that will be used during the project. The project partners have put their best efforts in providing details regarding the data protection mechanisms that will be used in the project. Moreover, D1.11 – "Ethical Issues Related to the Involvement of Non-European Countries" (M., S., M., +21) describes ethical issues which concern the development of the iHelp platform, especially with regards to the involvement of non-European countries. These general concerns were applied to specific situations, with respect to the TMU pilot in which a non-European country is involved, to the extent that information was available as of the date of this deliverable. The project partners have put their best efforts in providing details regarding ethical, legal, and regulatory issues with regards to the Ethical requirements concerning the participation of non-European countries in iHelp.

The use of human cells/tissues is a very important ethical aspect and D1.12 – "Ethical Issues Related to the Human Cells/Tissues" (F., 21) provides an overview of the pilot activities in iHelp, that relate to this matter. Only one pilot conducts activities related to this matter, so protocols for blood sample collections, consent formulas have been presented in this report.

All the above-mentioned deliverables describe the methods or technologies that have been tested as regards to the safety of participants and the impact of the expected results on fundamental rights or research integrity. Furthermore, this deliverable will analyse what are the assets created within the iHelp platform to explore what are the potential risks and the effective measures that will mitigate them and will lay out the requirements to the consortium, with respect to rules, regulations, and ethical standards that are required to ensure compliance during project development.

D1.13 – "Ethics Guidelines for Trustworthy AI in iHelp" (F., K., A., +21) presented the guidelines for trustworthy and transparent AI, and how can AI frameworks can be framed in EU laws. The conclusion of this deliverable will be further extended and developed in the section 5.2.1 of this deliverable.

D2.4 – "Conceptual model and reference architecture-I" (M., A., C., +21) and D2.5 "Conceptual model and reference architecture-II" (M., P., A., +22) provide a preliminary picture of the overall concept architecture and model of the iHelp platform. It highlights key components, interconnections, key capabilities and provides some details on the infrastructure and approach to building the platform. Having this overview of the architecture of the process, it was more facile to discover what are the modules participating in the iHelp framework and thus identify the potential exploitable assets, which have been treated in this deliverable in Section 3.

The specifications introduced in the context of D3.7 – "Standardisation and Quality Assurance of Heterogenous Data I" (M., W., D., +21) and D3.8 – "Standardisation and Quality Assurance of Heterogenous Data II" (M, K., M., +22) were used and revised for the realization and implementation of this holistic mechanism, including its main functionalities in terms of ensuring the accuracy of received data, integrity

and quality, data interoperability, automatic transformation of data into the HHR model and their aggregation, defined in deliverable D3.1 – "Data Modelling and Design of Integrated Medical Records and Open Specification I" (K., D., P., +21), into unique turnkey offers. In addition, these reports describe the basic technologies adopted and sub-mechanisms developed to ensure an effective contribution to the standardization and quality assurance of health data.

Further standards are explored in Section 2 of this deliverable, covering Information and Communications Technology (ICT) standards within the eHealth, wearable technology, data interoperability and AI domains. The specific data processing standards are related to those that were used in modules such as Data Validator, Data Cleanser, Data Verifier, Data Qualifier, and Data Harmoniser, which assure that data that is processed in iHelp, is delivered to the model creation pipeline in a heterogenous way and thus, quality is always assured.

In this context, a thorough data review of modern AI/ML models and algorithms for rapid information verification and evaluation has been presented in this paper. Due to the lack of real information at this stage of the project, the relevant literature has been studied, and in deliverables D5.1 – "Techniques for early risk identification, predictions and assessment I" (K, G, K, +21) and D5.2 – "Techniques for early risk identification, predictions and assessment II" (K., L, G, +22), are included the tools that are the most suitable to be utilized in the next phase of the project. The literature is not extensive when it comes to AI / ML for PC, however there are many methods that can be used as a basis for rapid identification and information.

Beyond standards, this deliverable D8.8 – "Standardisation, IPR management and Ethics in iHelp I" and the following version D8.9 – "Standardisation, IPR management and Ethics in iHelp II" will also refer to standard procedures, guidelines, good practices, and policies. With respect to the policy making process, the deliverable series of T5.4 – "Social Analytics for the Study of Societal Factors and Policy Making (RDF)", i.e., D5.8 – "Social Analytics for the study of societal factors and policy making I" (R., W., G, +22), D5.9 – "Social Analytics for the study of societal factors and policy making II" (R., P., L., +22) and D5.10 – "Social Analytics for the study of societal factors and policy making III", due on M16, M22 and M36 respectively, elaborate further the Social Media Analyzer asset for the purpose of policy making.

Moreover, deliverables D8.5 – "Exploitation plan I" (K., A., K., +21) and D8.6 – "Exploitation plan II", due on M12 and M24 respectively, are a preliminary utility plan, offering consumption strategies, shared usage mechanisms as well as renewal partners' individual plans. The utilization strategy follows a 3-step approach and is defined along with a list of key activities, considerations and IPR prevention practices. In its first year, the project completed the first of three phases, followed by an innovation management activity (T1.3 Quality and Risk Management) linked to the WP8 exploitation activity (T8.2 Exploitation Strategy and Plan), capturing the project's exploitation potential.

The IPR management treated in the present D8.8 deliverable paves the way for exploitation methodologies that are enclosed in the respective D8.5 (K., A., K., +21) and D8.6 (Exploitation plan-I, -II) deliverable series.

In the context of IPR management, only products and innovations are considered, while scientific articles and dissemination do not make part of the present deliverable D8.8 and are treated within task T8.1 "Dissemination and Communication" with its associated reports series, D8.2 "Communication and Collaboration Plan and Activities I" (M12) (M, A. K, +21), D8.3 (M24) and D8.4 (M36).

2 Standardisation

Standards are a common reference system agreed upon individuals and institutions which creates the basis upon which technology can evolve and fosters a rapid technological progress. In the iHelp project standards related to healthcare are considered, standards related to the data handling are of interest (M., W., D., +21). In this deliverable we will explore all the standards that could have an impact on the platform development.

2.1 State of the Art landscape analysis

Existing European Standards (ENs) in the market were screened utilising public repositories and observatories[1], and published information from the well-known standardization organizations, like: IEEE Standards Association (IEEE SA)[2], International Organization for Standardization (ISO)[3], International Electrotechnical Commission (IEC)[4], International Telecommunication Union (ITU)[5], European Committee for Standardization (CEN)[6], European Committee for Electrotechnical Standardization (CENELEC)[7], American National Standards Institute (ANSI)[8], European Telecommunications Standards Institute (ETSI)[9], National Institute of Standards and Technology (NIST)[10]. An additional list of existing standards is included in Annex B - Existing standards, while follow-up policies and guidelines for ICT will be provided in the following version of this document.

2.1.1 ICT Standards

Common ICT standards are one of the necessary measures to ensure that European industries are at the pioneers of the development and exploitation of ICT technologies: they ensure interoperability and guarantee that these technologies work smoothly and reliably with together. This will become increasingly more important as many more devices will be connected to each other in the future - from cars and transport systems to appliances and eHealth systems.

2.1.1.1 eHealth

ETSI Technical Committee eHEALTH is responsible for coordinating ETSI's activities in the eHealth domain, identifying gaps where further standardization activities might be required and addressing those gaps which are not the responsibility of other ETSI bodies (C, W, 18).

Standards like ETSI TR 103 477 (ETSI, 20) treat the eHealth use cases and more in depth, the structure of the use-cases, involved actors and roles, performance constrains, forms of interoperability, that play a key role in developing these types of scenarios.

[1] https://www.standict.eu
[2] https://standards.ieee.org/about/
[3] https://www.iso.org/about-us.html
[4] https://www.iec.ch/who-we-are
[5] https://www.itu.int/en/about/Pages/default.aspx
[6] https://www.cencenelec.eu/about-cen/
[7] https://www.cencenelec.eu/about-cenelec/
[8] https://www.ansi.org/about/introduction
[9] https://www.etsi.org/about
[10] https://www.nist.gov/about-nist

Other standards such as ISO 12967:2009[11] Health informatics—Service architecture were introduced in the domain of health informatics to provide guidance on the development of new electronic health systems and support the integration of existing electronic health systems.

Further, standards like ISO 14155[12] Clinical Investigation of Medical Devices provides good clinical practice for the design and executions of clinical investigations carried out on human subjects considering the safety and performance of medical devices.

2.1.1.2 Wearable Technology

The standardization of wearable technology is still in its early stages. However, there is general agreement that only international standardization can reduce the costs and efforts of early industrialization and provide effective guidelines for market stabilization and expansion.

For example, IEC 63203-101-1:2021 (IEC 63203-101, 2021) provides definitions for commonly used terms related to wearable technologies, thus ensuring a common basis for discussing key concepts. Two standards: IEC 63203-204-1:2021 (IEC 63203-204, 2021) and IEC 63203-201-3:2021 (IEC 63203-201, 2021) provide test methods for electronic textiles. IEC 63203-201-3 defines a test method for determining the electrical resistance of conductive fabrics with respect to the temperature and humidity between skin and clothing. IEC 63203-204-1 specifies a test method for measuring the durability of sports and leisure electronic textiles during washing.

2.1.1.3 Data, HL7

In terms of e-health data, standards are developed that enable structured clinical content for the purpose of exchange such as DICOM SR[13], HL7[14], openEHR[15], CEN EN 13606[16] and further initiatives for normalizing healthcare systems, like: the Good European Health Record (GEHR) project, the European Institute for Health Records (EuroRec)[17] or the European Patient Smart Open Services (epSOS)[18] project.

HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing and retrieval of electronic health information. These standard family define how data is collected and communicated from one end to the other, establishing the language, format and types of data required for inter-system connectivity.

[11] https://www.iso.org/standard/50500.html
[12] https://www.iso.org/standard/71690.html
[13] https://dicom.nema.org/dicom/2013/output/chtml/part20/sect_A.3.html
[14] https://www.hl7.org/implement/standards/
[15] https://specifications.openehr.org/
[16] http://www.en13606.org/information.html
[17] https://www.eurorec.org/
[18] https://joinup.ec.europa.eu/collection/ehealth/solution/european-patients-smart-open-services/about

Common standardized formats within e-Health research and HHR: HL7, FHIR[19], CDA[20], CCD[21], X12[22], XML[23], JSON[24], DICOM[25], NCPDP[26], EDI[27], which are further used for the development of Open-Source solutions.

2.1.1.4 Interoperability Framework

This work (EU, 17) provides as set of recommendations and a set of principles intended to establish general behaviours on interoperability. It presents a model which organises in layers the different interoperability aspects to be addressed when designing European public services, outlining a conceptual model for interoperable public services. The model is aligned with the interoperability principles and promotes the idea of interoperability by design' as a standard approach for the design and operation of European public services.

2.1.1.5 AI and trustworthy AI

As the major point for AI standardization within ISO and IEC, the SC 42 program work (ISO/IEC JTC, 22) refers to the entire AI ecosystem. Furthermore, the scope of SC 42 includes guidelines for the implementation of artificial intelligence activities by ISO and IEC committees.

Current program work focuses on standardization in the areas of AI core standards, Big Data, AI reliability, use cases, applications, AI management implications, computational approaches to AI, testing, ethics and social in the field.

The growth of AI development in industry and healthcare sector required the need to have a system able to explain itself for building a trust between humans and intelligent machines. In this sense, the ANSI/CTA-2090 "The Use of Artificial Intelligence in Health Care: Trustworthiness" standard[28] identifies the core requirements and baseline for AI solutions in health care to be deemed as trustworthy.

2.1.2 Open Source & Standards

The advantages of using open-source software (the code is public, free to reuse, adapt and improve; it can be verified for security issues, is independent from vendors so monopoly is excluded, and reaches towards interoperable systems) clearly pinpoint these objectives.

The key objectives of the new European Commission strategy 2020-2023 (EC, 22) regarding the open-source software (ISO/IEC JTC, 22), are to enable the Commission to:

- Progress towards digital autonomy of Europe's own, independent digital approach.
- Implement the European Commission Digital Strategy.
- Encourage sharing and reuse of software and applications, as well as data, information, and knowledge.

[19] https://www.hl7.org/fhir/overview.html
[20] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[21] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=6
[22] https://www.stedi.com/edi/x12
[23] https://www.w3.org/standards/xml/core
[24] https://www.w3schools.com/js/js_json_intro.asp
[25] https://www.dicomstandard.org/
[26] https://www.ncpdp.org/NCPDP/media/pdf/StandardsMatrix.pdf
[27] https://www.edibasics.com/what-is-edi/
[28] https://shop.cta.tech/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090

- Contribute to the knowledge society by sharing the Commission's source code.
- Build a world-class public service.

Some of the concrete actions towards this direction are[29]:

- Set up an Open-Source Programme Office in the Commission.
- Enhance the EU-centric digital government code repository.
- Revise software distribution practices.
- Enable and create innovation with open-source labs.
- Increase outreach to communities.
- Integrate open source in internal IT governance.
- Ensure OSS security.

2.1.3 Data Governance Act

The Regulation (EU) 2022/868 (EU, 22) lays down the conditions for the re-use, within the Union, of certain categories of data held by public sector bodies. For the provision of data sharing services, it states a respective a notification and supervisory framework. Entities which collect and process data, can voluntary registrate via a Union-level framework for fostering international free flow of data. This Regulation (EU, 22) is without prejudice to specific provisions in other Union legal acts regarding access to or re-use of certain categories of data, or requirements related to processing of personal or non-personal data. A sector-specific Union legal act might require the public sector bodies, providers of data sharing services or registered entities that provide data altruism services to comply with specific additional technical, administrative or organisational requirements, including an authorisation or certification regime. In this case, the provisions of that sector-specific Union legal act should also be followed. Further, the Regulation also provides means to treat the definition of data, meta-data, data holder, data access, data sharing and all the services that imply handling data as well as the actors involved in this process. In terms of protection for the public sector bodies, the Act provides regulations for protection on grounds of commercial confidentiality, statistical confidentiality, protection of intellectual property rights of third parties and protection of personal data.

2.2 iHelp standards and specifications

In this section the standards used in iHelp are described in detail. We will treat more categories of standards like data handling standards related to D3.7 – "Standardisation and Quality Assurance of Heterogenous Data I" (M., W., +21) and D3.8 – "Standardisation and Quality Assurance of Heterogenous Data II" (M, K, M, +22), or data modelling standards like the FHIR and HL7, or AI related standards. All the above standards will be described next.

More specifically, in D3.7 – "Standardisation and Quality Assurance of Heterogenous Data I" and D3.8 – "Standardisation and Quality Assurance of Heterogenous Data II" the initial design and specifications of the iHelp Standardisation and Quality Assurance Mechanism was described. The standardization and quality assurance approach will be unified and integrated into three basic sub-components, Data Cleanser, Data Qualifier, and Data Harmonizer with contributions from two more sub-components: Primary Data Mappers and Secondary Data Mappers, which are responsible for providing ledger operations between the raw data

[29] https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/informatics/open-source-software-strategy_en

asset and the Holistic Health Record (HHR) format as has been identified in the context of the project, which is meant to include all health determinants that define a person's health status.

Semantic interoperability uses this format by involving mapping terminology to various valuable medical repositories. State-of-the-art systems use resources embedded in such medical vocabularies to correctly match one specific term to another. To successfully design and run a multicentre clinical trial, the operating software must be compatible with essential medical resources, such as SNOMED CT (B., 12), LOINC (V., 12), and ICD-10 (ICD, 12), OMOP[30]. Other important medical standards are further detailed in the context of D3.1 – "Data Modelling and Integrated Health Records: Design and open specification I" (K., D., P., +21), like ISO TS22220:2011 (ISO/TS 22220) for the identification of subjects of care.

The purpose of the Primary Data Mapper mentioned earlier, is to syntactically transform data coming from a data model into the internal HHR data model defined in deliverable D3.1 – "Data Modelling and Design of Integrated Medical Records and Open Specification I" (K., D., P., +21). The first prototype is based on a specific pilot, HDM (Hospital de Dénia-MarinaSalud). That organization internally uses the OHDSI[31] standard data model OMOP (W., D., R., +19), therefore the module developed in task "Standardization and Quality Assurance of Heterogeneous Data" converted between two standards, OMOP to HHR (based on HL7/FHIR). The current ISO standard relating to the Harmonized data types for information exchange is 21090:2011 (SIST, 2011).

In addition, the Fast Healthcare Interoperability Resources (FHIR) Specification is a standard for exchanging healthcare information and data in an electronically form. Existing logical and theoretical models are being leveraged to make available a consistent and rigorous mechanism for exchanging data. The main goal behind FHIR is to build a set of resources that can satisfy most common use cases as it allows healthcare information, including clinical and administrative data, to be findable. In one hand FHIR can be used as a stand-alone data exchange standard and in the other hand it can be used collaboratively with existing broadly used standards. Although HL7 standards have been producing healthcare data exchange and information modelling standards for over 20 years, FHIR is a new specification based on industry tactics, capitalizing the successes and challenges gained through defining and implementing standards.

The iHelp project seeks to utilize, transform, and harmonize the data into the HHR format based on the FHIR standard for the purpose of the Holistic Health Record and AI models data preparation. The FHIR and OMOP standards are used for clinical data interoperability towards specifying the standardised HHR data format and respective management mechanisms. The data saved in this format will be fed via tools like Advanced Notebook, into ML learning models in order to create new insights for clinicians.

The Advanced Notebook tool proposed is using Jupyter Notebooks and MLFlow utilities, all licenced as open-source publicly available libraries. MLFlow Model is a standard format for packaging machine learning models that can be used in a variety of downstream tools—for example, real-time serving through a REST API or batch inference on Apache Spark. MLflow supports several standard languages that might be useful

[30] https://www.ohdsi.org/data-standardization/
[31] https://ohdsi.org/who-we-are/

in applications, like Python and R functions, H20, Keras[32], MLeap, PyTorch[33], Scikit-learn[34], Spark MLlib[35], TensorFlow[36], and ONNX[37]. For connecting to the LXS database, the standard JDBC and the Spark connectors are used.

In addition, a set of available standards within the consortium can be fructified accordingly in the project results development, related to the AI, ML, data, healthcare, internet of things domains and policy making, as specified in Annex C - Additional available standards.

The data store (Big Data Platform) complies with various standards or implements interfaces of most popular processing frameworks. With regards to the Big Data platform, standard Application Programming Interfaces (APIs) are used, namely JDBC, ODBC, and OData. As concerns the utilized frameworks, the open Apache Spark Connector, Apache Kafka Connector, and Apache Flink Connector are used.

Specifications that are used in the Monitoring Alerting and Feedback Component are divided into two main parts: i) backend Java microservices and ii) front-end utilities. The backend is implemented according to the: Representational State Transfer (REST) standards, SOLID principles, High Cohesion and Low Coupling microservices principle, and Command Query Segmentation (CQRS) design pattern. The front-end is implemented according to the: ECMAScript standards and HOC (Higher-order component) pattern, by following SOLID principles and Composition and provider principles.

HDM has a certification for the Clinical Analysis Laboratory ISO 9001:2015[38].

This International Standard is based on the principles of quality management described first in ISO 9000[39]. The descriptions include a statement of each principle, a justification of why the principle is important to the organization, some examples of benefits associated with the principle and examples of typical actions. to improve organizational performance when the principle is applied.

The principles of quality management are customer orientation, management, people's commitment, process improvement approach, evidence-based decision-making, Relationship management.

2.3 Standardisation activities

This section includes the activities and initiatives taken towards standardization, contributions to open standards developed within iHelp and to detail all engagements with standardization bodies or similar fora and the corresponding potential contributions. Existing standards in the market continuously require optimizations and new contributions in relation to the rapid growth of the technical advancements within the ICT sector, including data formats especially regarding the healthcare domain, and contributions to policy making. While for policy contributions, policy making and social analysis related deliverables, i.e., D5.8 – "Social Analytics for the study of societal factors and policy making I" (R., W., G, +22), D5.9 – "Social

[32] https://keras.io/
[33] https://pytorch.org/
[34] https://scikit-learn.org/stable/
[35] https://spark.apache.org/mllib/
[36] https://www.tensorflow.org/
[37] https://onnx.ai/
[38] https://www.iso.org/standard/62085.html
[39] https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-4:v1:en

Analytics for the study of societal factors and policy making II" (R., P., L., +22), and D5.10 – "Social Analytics for the study of societal factors and policy making III" further treat these aspects.

In this respect, iHelp seek to contribute to:

- standardised HHR format
- help in policy making by providing decision support and social analysis on the design of new screening programs and new guidelines for bringing improvements in clinical, lifestyle and behavioural aspects of fighting Cancer.

The following items are included in the standardization activities' scope:

- **Formal specification preparation**: integrating the study findings into a formal specification to be evaluated and discussed by industry partners.
- **Constituency building**: Stakeholders will identify various constituencies within the standards groups to meet with, to better understand their interests and positions and ask for their support for the project specifications.
- **Conflict resolution**: address any inquiries, issues, and alternative strategies from others outside the consortium regarding the project specifications.
- **Consensus building**: establishing meetings and communication with significant individuals or entities for the targeted standards body's decision-making.

An indicative list of related standards and specifications actions which the project will monitor and actively seek to contribute, in presented below in Table 1, as an update from the GA proposal considering the major bodies and technical committees related to the iHelp sector, such as EPSOS, BDVA, OASIS[40], HL7, OHDSI, OMOP, EMA[41]/ CEN/ CENELEC, OpenML Community.

Table 1: Standardization activities performed by the iHelp consortium.

Relevant Body	Policy Making and Standardization Activity and Expected outcome	Status
EPSOS	Introduction of holistic data in Patient Summary Standards	In plan
Big Data Value Association (BDVA)	BigData PPP and iHelp share the paradigm of a data driven approach for innovative data analysis solutions based on big data. iHelp findings will contribute to the Data Management, Data Processing Architectures, Data Analytics, and Data Visualisation and User Interaction activities within BigData PPP, and contribute to the evolution of BDVAs Strategic Research and Innovation Agenda.	Ongoing
OASIS	Use and customization of the "The Outcome and Assessment Information Set" for the needs of high	In plan

[40] https://www.oasis-open.org/committees/overview.php
[41] https://www.ema.europa.eu/en

	Cancer risk people, including customization for using the dataset in AI-related applications.	
General Medical Council.	Use and Enhancement of Objective Structured Clinical Examination for the construction and evaluation of the mobile and wearable services developed in the project	Ongoing
EMA/ CEN/ CENELEC	Specification of AI as a medical device through a proper whitepaper, including relevant prototype implementations.	Planned
OpenML Community	Integration of ML/AI algorithms used in the project in the community, as a means of boosting their use as defacto analytics standards.	In plan

Continuous sync with the standardization initiatives in the field of AI, Data and Internet of Things (IoT) has been performed within T8.3 – "Standardisation, IPR and Ethics Management". As members of the Big Data Value Association (BDVA), active participation has been accomplished in the Shaping European AI leadership - online conference on March 10th, 2022, organized by AFNOR (French Standardization Association), which addressed the main challenges for AI standardization and innovation. To ensure a beneficial societal development and to address citizens' concerns, Artificial Intelligence should be trustworthy. Views were exchanged with representatives of standardization bodies, public authorities, and companies for producing tomorrow's standards, and fostered participation in the development of AI trustworthiness. Further participation was accomplished in the AI Standards Hub (aistandardshub.org) activities and webinars to keep track of the actions to advance trustworthy and responsible AI with a focus on the role that standards can play as governance tools and innovation mechanisms. The webinar on December 8th, 2022, provided an overview of the most prominent international standardisation initiatives on AI transparency and explainability. The initiative covered the IEEE 7001[42] published standard as well as two standards currently under development (ISO/IEC AWI 12792[43] and ISO/IEC AWI TS 6254[44]), discussing with the relevant IEEE and ISO/IEC working groups by focusing on the differentiation of these standards, and the connections with AI Standards Hub objectives.

The WOOL platform used as a sub-component within the Tailored Conversational Coaching System - Defines its own standard platform for an interactive dialogue definition language, between virtual agents and users. Similar platforms exist, but are (a) not very professionally maintained, and (b) targeted at video games. The "WOOL" Language is based on the "Yarn" dialogue language definition, see (www.yarnspinner.dev).

According to the "Real Decreto 1090/2015": a favourable opinion of the CEIm of the San Carlos Clinical Hospital in Madrid was received by HDM. (B., 15)

[42] https://standards.ieee.org/ieee/7001/6929/
[43] https://www.iso.org/standard/84111.html
[44] https://www.iso.org/standard/82148.html

The standardization contribution refers to an HL7 specification for Healthcare Interoperability. Two HHR Mappers are under creation based on the FHIR standard which were used by ATC. Some FHIR data attributes require new dictionaries to be added.

Another standardization contribution referring to the development of HHR Mappers based on the FHIR standard related to secondary data coming from Healthentia, which are under construction with help from ICE. In this regard, some FHIR data attributes require new dictionaries to be created.

Finally, in the aspect of standardization with respect to AI in healthcare, a collaborative discussion was initiated between the AI expert partners to apply and join towards contributions for the creation of a Technical Working Group (TWG) focused on “AI for eHealth” or “Personalized Recommendations based on AI”.

3 Open Source in iHelp

Utilizing and exploiting open source within iHelp, helps for improving and streamlining science. In this direction, the Science 2.0 approach is targeted which refers to making publicly available on the Web, raw experimental results, claims of discovery and research publications, based on information-sharing and collaboration principles, made possible by network technologies. This initiative contributes to the economic growth and provides broader, faster, more transparent and equal access for the benefit of researchers, industry and citizens.

Further the iHelp quest for contributing to Open Research Data as described in D1.2 – "Data Management Plan" due on M6 and targets the optimization of research and development in iHelp, addressing the lifecycle and public availability of research data generated by the project. The latter facilitates the extraction and creation of additional knowledge.

Considering results dissemination, partners preliminary agreed on open access publishing. However, depending on the type of information to be published, gold or green access for peer-reviewed scientific publications, that might result from the project, can be granted.

3.1 Used Open Source

The open-source model is a decentralized software development model that encourages open collaboration (R., 01), i.e., "any innovation or production system that relies on goal-oriented but loosely coordinated participants interacting to create a product (or services) with economic value that I make available to both contributors and non-contributors to the public". The open-source movement in software began as a response to the limitations of proprietary code. The model is used in projects such as relevant open-source technology (P., 12) and open-source drug discovery.

Open-source frameworks, platforms and software are utilized in the iHelp project, as described below.

More specifically, in the context of T4.2 – "Model Library: Implementation and Recalibration of Adaptive Models" the Advanced Notebook component utilizes the open-source framework MLFlow and the open-source platform, Jupyter Notebook, aided by Docker open-source utility for deployment.

In the context of T4.1 – "Personalized Health Modelling and Predictions" and T5.1 – "Techniques for Early Risk Identification, Predictions and Assessment", the following open-source technologies are used within the related AI Models for Personalized Health Prediction and Predictor and Risk Identifier components (see Table 2):

Table 2: Open-source technologies for AI Models for Personalized Health Prediction and components.

Technology layers	Open-source technologies
Persistence layer	pymongo, redis, pyleanxcale = {version="1.8.24", index="nexusleanxcale"}, sqlalchemy
Data analysis & manipulation/validation	Pydantic, numpy, pandas, openpyxlsparse

ML & NN frameworks	scikit-learn, tensorflow, lightgbm, xgboost, opencv-pythonmiceforest
Data visualization	Seaborn, pydot, yellowbrick, missingno
Explainability frameworks	Shap, Lime
Tuning frameworks	Ray, tune-sklearn
Utility packages	icd9cms, icd10-cm, python-dotenv, dnspython, rq, configparser, requests, pyyaml, tqdm, joblib, uvicorn, fastapi

For the implementation of the Analytic Workbench, as part of T4.2 – "Model Library: Implementation and Recalibration of Adaptive Models", several open-source frameworks are utilized and further described.

With regards to the Model Trainer, a combination of Angular (for the frontend) and Node.js (for the backend) is used for the development of the Model Trainer. Then, the different algorithms listed in the Model Trainer come from open-source libraries such as scikit-learn, H2o.ai or TensorFlow.

To develop the Model Manager, the MLFlow library is used as the core codebase for the management of the different analytic models trained as part of iHelp activities.

In the case of the Execution Engine, the Kubernetes technology is utilized for the orchestration and actual execution of analytical models trained. All these analytical models are packaged using Docker. In addition to this, matplotlib is used as library for plotting the results of the execution of the models

Finally, for the implementation of the Social Media Analyser, as the main component of T5.4 – "Social Analytics for the Study of Societal Factors and Policy Making", Vue.js is used as the main technology for the frontend. Moreover, Feed3, FastAPI and a few other libraries for handling data are also used. Finally, Flink CEP is planned to be implemented within the third year of the project, in relation to Complex Event Processing (CEP) for detecting event patterns in an endless stream of events.

The Monitoring Alerting and Feedback Component implemented in the context of the T5.5 – "Monitoring, Alerting, Feedback and Evaluation Mechanisms" uses Open-Source technology for Backend Java microservices and for frontend implementations. For backend, the microservices are implemented via Spring Boot framework (JDK8), Hibernate ORM, Java Persistence API (JPA), Gradle, Kafka, Docker, Swagger, MariaDB, Java Easy Rules library, while the frontend is implemented via React framework, React Context API, React Hooks, TypeScript, Bootstrap and Nginx.

Finally, with regards to the development activities for the Primary Data Mappers, the following open-source technologies have been utilized

- Spring Boot framework (JDK8)
- Java Persistence API (JPA)
- Docker
- Swagger
- PostgressDB
- HAPI FHIR

- OmopOnFhir

3.2 Open-Source Products

The components that are related to the development of algorithmically solutions fitting the purpose of iHelp objectives, such as “Analytic Workbench”, and “Monitoring Alerting and Feedback” component, plan to release a collection of essential libraries as open source or open specifications regarding AI specifications, following the iHelp exploitation plan for widespread adoption. For project’s algorithms, specific public repositories will be used, such as OpenML for Analytical Models and services like SourceForge for open-source projects. In addition, the AI models developed within the “AI Models for Personalized Health Prediction” component, and the trained models related to Analytical Models will be released to OpenML platform for expanding the knowledge gained in iHelp and perhaps continue the development after the project will end.

3.3 Open-Source Innovations

Most innovations developed as part of this project are to be released as Open Source to the community.

The potential Advanced Notebook and part of the Bounce Mitigation Innovations will be considered as Open Source to the community with licenses such as BSD-3 and Apache 2.0. The Bounce Mitigation platform part is to be exploited as open source, while the method and methodology as IPR.

Furthermore, the AI Models for Personalized Health Prediction, the Analytic Workbench and the Monitoring Alerting and Feedback component will be considered as Open Source following licensing schemes such as Apache 2.0. On the same line, the Social Media Analyzer tool aims to be generated as an Open-Source Intelligence (OSINT) component.

4 IPR Management

This section offers an initial introduction to IPR and issues, and reporting about the Consortium Agreement with respect to access rights to Background and Results, and respective information for results ownership, protection, and exploitation, followed by presenting the overall IPR methodology. The final sub-section briefly presents the identified assets within the project, with more information provided in Annex A - IPR Assets information and status, while a detailed overview of the innovations plans and activities is presented in D1.6 – "Innovation Potential: Plan & Activities I" (K, O, W, +21) and D1.7 – "Innovation Potential: Plan & Activities II" (M24) (O, F, K, 22), and the corresponding exploitation methodologies in D8.6 – "Exploitation plan II", due on M24.

The Management of Intellectual Property Rights related to iHelp innovations aims (i) to identify the pre-existing knowledge (background) and the specific limitations and conditions for its implementation, (ii) to help the contributors respect the guidelines for Access rights to the background and the results, (iii) to offer support in defining the Ownership of the results and support for actions needed towards results protection and further for exploitation processes, all following the rules and guidelines described in the CA. Overall, this supports partners to disclose knowledge and ideas safely, prove ownership, profit from commercial exploitation and prevent or discourage unauthorized use.

The T8.3 – "Standardisation, IPR and Ethics Management" handles the ongoing IPR issues following the defined rules and guidelines to facilitate the success of project's exploitable outcomes.

In this context, a survey has been conducted between M15 and M23 to gather information on components and status of the development, on the corresponding Standards and Standardization activities, on IPR – aiming to differentiate between results and patentable ideas, on any IPR issues and concerns raised, and on ethics problems that appeared during the project towards the management of these issues. The extracted information has been included in this document.

Amongst the IPR issues that we've identified are the interpretability of the novelty of the assets which could be potentially mitigated by performing a more excessive SotA for similar approaches.

UNIMANs proprietary rights and borderlines considering the use of components/algorithms developed in previous projects are a subject to further analyse, by verifying legal documents already signed.

Another issue to be mentioned is the developed code and its sharing amongst partners in the consortium.

4.1 Basic information – Definitions

Basic information and definitions related to the notions included in this section are described in the following.

Consortium Agreement (CA): establishes a legal framework for the project in order to provide clear regulations for issues within the consortium related to the work, IP-Ownership regarding innovations and any other project outcomes.

Associated entities: businesses or other bodies that are connected to each other in some way.

Background: results brought into the project from previous efforts (data, know-how or information that is needed to implement the action or exploit the results), as defined within CA.

Further Background: Any Party may add further own Background to Attachment 1 in CA during the project by written notice to the other parties or can modify or withdraw existing background with approval of the Project Coordination Committee.

Foreground/New Result: results that are generated under the Project, including information, (raw) data, know-how and materials, regardless of whether are protected by IP Rights. The new results can refer to the ones extended from background, partially or completely developed within iHelp.

Access rights: i.e., licences and user rights to background or results. Access Rights to the background have been granted and detailed in the CA.

Joint ownership: when is not possible to separate the collaborative inventions, partners will jointly own such results.
Joint exploitation: when parties jointly exploit a productive asset.

Technology Readiness Level (TRL) of outcome(s) at the end of the project: What is a realistic TRL for the end of the project and how can this be further developed to a higher level, after the end of the project grant. It comprises the followings: i) TRL 1 – basic principles observed; ii) TRL 2 – technology concept formulated; iii) TRL 3 – experimental proof of concept; iv) TRL 4 – technology validated in lab; v) TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies); vi) TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies); vii) TRL 7 – system prototype demonstration in operational environment; viii) TRL 8 – system complete and qualified; ix) TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).

4.2 IPR Methodology in iHelp project

The **IPR Methodology** aims to define the detailed road map for the IPR analyses' evaluation.

In the iHelp project, the knowledge management procedure is broken down into several steps: first, the information will be obtained and processed. Then it will be correctly disseminated after being indexed. An appropriation phase, which allows to produce new knowledge, will follow.

The ideation process comprises several phases which were described below:

- Identify intellectual property assets
- Capturing the confidential information (NDA, trade secrets, restricted access)
- Likelihood of intellectual property protection (identify the category that should protect one asset, whether is patentable or design-like, or copyright, etc)
- Partnerships: identify if the partner(s) have other potential partners to collaborate with in the development and commercialization of the idea/concept

The iHelp **Intellectual Property Rights (IPR) Strategy** is the following: the CA and task T8.3 Standardisation, IPR and Ethics Management, are both the responsible for the IPR strategy and exploitation management. The project's IPR strategy is a crucial component of its exploitation strategy because valid IPR agreements must be in place before partners can proceed with technology adoption, commercialization, and licensing agreements.

The internal results will be discussed during project meetings with the aim of identifying key concepts and establishing a unique positioning strategy for these concepts in the standardization and commercialization processes.

Intellectual property rights include patent, trademark protection, design protection and copyright. An intellectual property rights strategy helps the entrepreneur manage these intangible assets in a professional manner to maximize business benefits. Questions you can ask yourself about your IPR strategy include: What innovations can we patent? Do we have patents that can be licensed or sold? How should we use our other intellectual property rights? How can we market them and financially benefit? What protection does our trademarks need?

These types of questions have been asked by the T8.3 leaders and the Innovation Manager in an organized manner during the WP8 meetings, IPR workshops and online surveys.

The results of all these questions have been compiled in Table 3.

4.3 Identified Assets within iHelp project

Following the development and projects results, a summary of the identified IPR assets and their status can be found in Table 3, with further details in Annex A - IPR Assets information and status. These IPR relate to the Innovation Potentials identified in D1.6 – "Innovation Potential: Plan & Activities I" (K, O, W, +21) and D1.7 – "Innovation Potential: Plan & Activities II" (O, F, K, 22) documents. IPR Assets' information and innovation components are analytically described in the following sections.

Table 3: Exploitable assets within iHelp.

Asset name	Partner name	Summary	Sector of application	Status
AI Models for Personalized Health Prediction	ATC, ICE, UNIMAN	AI/ML analytical models trained from pilot's health related datasets	Artificial Intelligence	Current state: Under development Final state: Proof of concept (POC)
Analytic Workbench	ICE	AI/ML model trainer, management, and execution tool	Business Intelligence, Data Science and Machine Learning Platform, Healthcare, Industry	Current state: Under development Final State: Expected to be integrated with the iHelp Platform
Big Data Platform	UNIMAN	Big Data Platform based on LeanXcale datastore and database	Data Platform	Current state: TRL6, demonstrated in relevant environment during review (TRL6), and under

				development for TRL 7 Final state: TRL7, with the actual demonstration in operational environment on the pilots' premises
Social Media Analyser	FPG	Tool to analyze social media posts for the creations of policies	Policy Makers engagement	Current state: Under development Final State: Expected to be integrated with the iHelp Platform
Monitoring Alerting and Feedback Component	KOD	An advanced rule-based engine	Remote patient monitoring	Current state: Prototype Finals state: Proof of concept (POC)
Holistic Health Record	ATC	Extend FHIR standard	Information Technology	Current: Mapper working for HDM data. All others are under development
Tailored Conversational Coaching System	iSPRINT	Big data platform for the collection of Real-World Data	Healthcare	Currently in progress, expected to be demonstrated in operational environment
Offline Model Learning Service	iSPRINT	Patients' application for the collection of their RWD and the provision of alerts, feedback, and virtual coaching	Healthcare, Data Science and Machine Learning	Currently in progress, expected to be validated in relevant environment
Advanced Notebook	SIE	Machine learning model management tool	Data Science and Machine Learning Platform, Healthcare, Industry,	In progress. The final development is expected to be integrated with the iHelp Platform and used for a Pilot usecase to demonstrate functionality and possible usage
Bounce Mitigation	SIE	Tool to analyze the user engagement	Patient Engagement, Solutions, Healthcare, Industry	Current: concept. The final development: prototype with pilot usecase.

4.3.1 AI Models for Personalized Health Prediction

The AI models for Personalized Health Predictions will apply state of the art algorithms for the iHelp solutions, with evaluating the explainability aspects of the models and utilizing the knowledge gathered from the accumulated retrospective data of all pilots. In this context, several models will be designed and implemented within the project to solve and address distinct healthcare use-cases.

4.3.2 Analytic Workbench

The Analytic Workbench is based on ICE AI & Analytics and the Advanced Notebook. The Analytic Workbench is composed by four modules:

- Model Trainer, where several AI/ML algorithms can be selected for modelling data
- Advanced Notebook, which is one script deployment for open-source tools that foster faster AI/ML experiments
- Model Manager, which is the model library itself, where all trained models can be accessed for deployment, execution, and retraining
- Execution Engine, which is the runtime engine where the analytical models can be executed

4.3.3 Big Data Platform

The LeanXcale datastore, which has an ultra-scalable database and supports both OLAP and OLTP workloads, is the foundation of the Big Data Platform. It permits full ACID transactions to support the flow of record insertions and updates, and it also enables real-time execution of analytical queries on top of that operational data. It moreover provides polyglot capabilities by supporting several datastores, enabling integration with other datastores that might be set up independently of the iHelp platform.

4.3.4 Social Media Analyser

The Social Media Analyser tool will help the policy makers gather and analyse streams of social media through multiple platforms and draw meaningful information with the aim of helping in creating a new health policy or improve on the existing health policies. The social media analyser tool will apply state of the art techniques i.e., Complex Event Processing (CEP), Sentiment Analysis (SA), Natural Language Processing (NLP) to the gathered datasets and present the results. The results of this information will be furnished on an intuitive dashboard integrated within the project to draw significant conclusions that will assist them to create policies regarding Pancreatic Cancer.

4.3.5 Monitoring Alerting and Feedback Component

The Monitoring Alerting and Feedback component provides a mechanism for remote patient monitoring, real time processing of Holistic Health Records (HHR), gathered via user-centric applications and rule-based evaluation of health data and lifestyle metrics. The Alerting functionality enables decision support for Healthcare Practitioners, as well as risk mitigation and lifestyle improvements for patients. This component allows a wide range of configurations and customization of personalized recommendations. The flexibility allows the adoption of custom way of working for each pilot, hospital or other type of patient engagement.

4.3.6 Holistic Health Records (HHRs)

The (existing) HHRs will be enriched by incorporation data from iHelp, that follow the FHIR standard. In terms of components that will be implemented within the project, are the Primary and Secondary Data Mappers. In total 5 mappers will be created addressing the different pilot use cases and scenarios that have

been identified in the context of the project. All these mappers will be part of the project's data ingestion pipeline and are integrated with the Data Harmonizer in the context of the T3.4 – "Standardisation and Quality Assurance of Heterogeneous Data".

4.3.7 Tailored Conversational Coaching System

iSPRINT is planning to exploit this as part of their main product, Healthentia. This smart service will be activated in the Healthentia accounts of healthcare organizations using Healthentia that request it. The system uses the WOOL platform sub-component (to which iSPRINT is co-maintainer), which is a Dialogue Language and Platform targeted specifically at eHealth applications, with very stable language definition. Is available as open source (under unrestrictive MIT License).

4.3.8 Offline Model Learning Service

iSPRINT is planning to exploit this as part of their main product, Healthentia. This smart service will be activated in the Healthentia accounts of healthcare organizations using Healthentia that request it.

4.3.9 Advanced Notebook

A tool developed by SIE which is one script deployment for open-source tools that foster rapid AI/ML experiments, based on MLFlow and Jupyter Notebooks open-source platforms, which help researchers interact with the data via web-based notebooks, access the ML models metadata, artifacts, and performance indicators via browser.

4.3.10 Bounce Mitigation

A user engagement analysis tool for predicting users that are of risk of quitting the enrolled health plan proposed to be followed and the reasons behind quitting.

4.4 Access Rights

Granting access rights to background and results are described below, as specified in the CA, according to Article from the GA-EU model:

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

- informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or
- agreed with the other beneficiaries that access would not be on a royalty-free basis.

In this section we will define what are the access rights to the background for each partner and what are the access rights to results for each partner.

4.4.1 Access Rights to Background

This section serves to provide information on access rights to background, to reiterate CA and assure the detailed principles regarding access right to background are followed, and to track any changes to the already reported background.

In Attachment 1 of CA, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions

or limits. Access rights will respect the General Principles detailed in the CA. Access rights to background if needed for exploitation of a partner's own results, including for research on behalf of a third party, shall be granted on fair and reasonable conditions and can be made up to twelve months after the end of the Project. During the project, any party may add further own Background to Attachment 1 of CA, by written notice to the other parties, or with approval of the Project Coordination Committee in the case of modifications or withdraws of the Background.

The included background is mentioned in Table 4, with more details in Annex A - IPR Assets information and status.

Table 4: Background items.

Partner name	Asset name	Asset description
LXS	Leanxcale Database Software	LeanXcale is a SQL database with fast key-value data ingestion and linear horizontal scalability. It is optimal for data pipeline acceleration and real-time analytics.
iSPRINT	Healthentia eClinical Platform	an eClinical Big Data platform that is used for capturing and processing of RWD. Is a proprietary platform, receiving continuous updates and improvements
iSPRINT	Healthentia Mobile App	Companion application given to patients for the collection of their RWD and the provision of alerts, feedback, and virtual coaching
ICE	INFORMATION CATALYST SL	any product, services, and components from ICE. ICE solution portfolio is composed of advance tools for master data management, business intelligence, process orchestration and analytics.
UNIMAN	pilot study	The University of Manchester is carrying out pilot study and collecting primary data for iHelp, directly from the University of Manchester
FPG	Patient data	Patient Data from the FPG Datawarehouse

Access to the background brought to the project by partners follows the methodology described in the CA. To this moment, no further background has been added or modifications to the existing background, and no additional separate written agreements have been made as subject to third parties' rights.

4.4.2 Access Rights to Results

Access Rights to Results if needed for exploitation of a party's own results will be granted on fair and reasonable conditions. Access rights to Results for internal research and teaching activities are granted on a royalty-free basis. A request for Access Rights may be made up to twelve months after the end of the Project or, or if it's the case, after the termination of the requesting party's participation in the project.

Access rights to the results from SIE, ATC, ICE, UNIMAN, LXS, KOD, follows the methodology described in CA, as reminded above.

With respect to the AI Models for Personalized Health Prediction asset, the ICE part, access rights to results follows the CA methodology, co-dependent on the integrated components access rights: "Advanced Notebook" – SIE, "Big Data Platform" – LXS, "Holistic Health Record" – ATC and "Decision Support System" – UPM.

For iSPRINT assets and results, namely "Tailored Conversational Coaching System" and "Offline Model Learning Service" – iSPRINT is granting access via the Healthentia SaaS to the authorized users of the service, since the system is an integral part of Healthentia. Any 3rd party wishing to access Healthentia should request a quotation by iSPRINT. Privileged pricing applies to consortium partners.

4.5 Results

Parties can use the project results for publicity and marketing communication reasons provided that the rules on confidentiality and other matters are not broken, as stated in CA.

4.5.1 Ownership

According to the Horizon 2020 Rules for Participation and the methodologies defined in CA/GA, the partner who generates the results or patentable innovations, owns them, following each partner's national laws or intellectual property policy. Where several partners have jointly carried out work generating results (Joint ownership of the results) and if, it is not possible to separate such joint contributions, partners shall have joint ownership of such results or innovations. The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('joint ownership agreement'), to ensure compliance with their obligations.

In the case of such a co-ownership agreement, Parties will negotiate and define:

- the proportion in which each Party shall hold the ownership of the Result set;
- the conditions for the request for protection, maintenance and exploitation of the joint Result and of the rights over them, including conditions for non-exclusive licensing;
- the conditions for the assignment of the joint Result to third parties or between the Co-owners parties;
- the publication of the joint Result.

The joint ownership holders can choose to transfer the results under fair and reasonable conditions, or consider the results non-transferable, non-exclusive, royalty-free and fully paid-up license, without the right to grant sub-licences.

The individual ownership holders of the iHelp results identified up to this point are ATC, ICE, UNIMAN, LXS, KOD, iSPRINT, SIE and UPM and are presented in Table 5. For the moment, no joint ownership holders have been identified.

Table 5: iHelp results and ownership holders.

Assets	Ownership
AI Models for Personalized Health Prediction	ATC, ICE, UNIMAN: Individual Ownership for each party, since the models will be distinct and individually developed
Analytic Workbench	ICE: Individual Ownership
BigData Platform	LXS: Individual Ownership
Social Media Analyser	ICE: Individual Ownership
Monitoring Alerting and Feedback Component	KOD: Individual ownership
Holistic Health Record	ATC: Individual Ownership
Tailored Conversational Coaching System	iSPRINT: Individual Ownership
Offline Model Learning Service	iSPRINT: Individual Ownership
Advanced Notebook	SIE: Individual Ownership
Bounce Mitigation	SIE: Individual Ownership
Decision Support System	UPM: Individual Ownership

4.5.2 Protection

As reported in article 42 of the Horizon 2020 Rules, results produced within a funded project can be protected, in order to ensure their effective commercial exploitation. Therefore, Intellectual Propriety Rights (IPR) are private legal rights that protect, in a reasonable and justified way for an appropriate period of time and, in a suitable territory, the creation of the human mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. They are commonly divided into two categories: i) Industrial Property Rights (e.g., patents, trademarks, industrial designs, geographical indications); and ii) Copyright and Related rights (e.g., rights of the authors/creators and those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programmes). The definition of the most adequate type of IP protection (its duration and geographical coverage) depends on the result itself (exploitation plan, consortium partners' interests).

IP protection is vital for a prospective commercial or industrial exploitation on the other hand it is not always mandatory Each beneficiary must examine the possibility of protecting its results and must European IPR Helpdesk Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if: (a) the results can reasonably be expected to be commercially or industrially exploited and (b) protecting them is possible, reasonable and justified (given the circumstances). When deciding on protection, the

beneficiary must consider its own interests and the interests (especially commercial) of the other beneficiaries.

The type of protection depends firstly on the subject matter (F., 14), as presented in Table 6.

Table 6: Protection types based on subject matter.

Subject Matter	Patent	Utility Model	Industrial Design	Copyright	TradeMark	Confidential Information
Invention (e.g. device, process, method)	X	X				X
Software	X	X		X		X
Scientific article				X		
Design of a product			X	X	X	
Name of a technology/product					X	
Know How	X	X				X
Website			X	X	X	X

Depending on its type, the corresponding IPRs requires or not registration (F., 14), as indicated in Table 7.

Table 7: Protection by IPR.

IPR	What for	Registration
Patent	New inventions	Registration is required
Utility model	New inventions	Registration is required, but conditions are less stringent than for patentability
Trademarks	Distinctive signs	Registration is required
Industrial Design	Appearance of products	Registration is usually required, but it is possible to acquire an unregistered design right
Copyright	Literary, artistic, and scientific works	Not required, but it can be registered in some countries
Confidentiality	Confidential business	Not required, but internal protection measures needed (i.e., NDAs)

	information/trade secrets	

Copyright and trademarks are to be marked with IPR symbols (©, ™ and ®), indicating that it is protected by one or more different IPRs. The protection types can cover not only commercial exploitation, but also as open-source licenses or copyright. For open-source sharing, the asset can be a Software, Scientific article, Design of a product or a website.

Any technical innovation can be granted a **patent**, that is an industrial right to ownership, for a set amount of time (typically 20 years). An innovation must meet three requirements to be patentable: it must be original, include an inventive step, and have an industrial application. A patent grants the owner the legal authority to forbid unauthorized production, use, or sale of the invention. Technical inventions in Europe can either be protected by national patents issued by the relevant national authorities or by European patents issued centrally by the European Patent Office (EPO). The iHelp project will most likely use patents as its primary form of IP protection.

A patent-line intellectual property right called a **utility model** was established to safeguard inventions. Similar to a patent, this type of protection has a shorter term (often 6 to 15 years) and less rigorous restrictions. Since this type of right is covered under the Paris Convention for the Protection of Industrial Property, countries that protect utility models are required to abide by regulations like national treatment. Like a patent, a utility model is an exclusive right that grants the inventor ownership rights to the invention for a set length of time. The prohibition against exploiting the invention for commercial purposes without the right holder's consent, however, makes this different from a patent. This property is frequently referred to as a "short-term patent" or "small patent."

Industrial design is a process applied to physical products that are to be manufactured by mass production. It’s the creative act of conceiving and defining a products shape and features, which will impact how the product will be manufactured. Generally, the designers create these concepts in small scale design of complex systems. Industrial designers don’t usually design gears and apparels that make machines move, but they work with engineers and other professional categories that focus on the functional aspects of the product, assuring thus functionality and manufacturability.

Although the process of design may be considered 'creative,' many analytical processes also take place. Some of the development processes that are usually used, are research, sketching, model making, prototyping, and testing.

Copyright is a type of intellectual property rights (IPR) that covers creative and scientific works like books, poems, paintings, or films as well as software, advertisements, and technical drawings.

The essential aspect of copyright protection is the method the author(s) convey their ideas, whether it be in writing, art, or other tangible form. This sort of protection does not apply to the concepts found in artistic works, scientific content, or technical content.

While copyright law is not all-encompassing, other laws, such as patent and trademark laws, may impose additional sanctions.

Trademarks are a type of intellectual property consisting of a recognizable sign, design, or expression that identifies products or services from a particular source and are easy to distinguish them from others.

Trademark laws protect material that is used to distinguish an individual's or corporation's work from another entity. These materials include words, phrases, or symbols—such as logos, slogans, and brand names—which copyright laws do not cover.

Confidentiality involves a set of rules, or a promise usually executed through confidentiality agreements that limits the access or places restrictions on certain types of information.

Protection, use and dissemination of iHelp results refer to results capable of industrial or commercial application must be protected considering legitimate interests. For each result or innovation, this is described in the following.

The AI Models for Personalized Health Prediction – by ATC, ICE, UNIMAN, is considered as a Software and to be protected by copyright, via open-source licensing, Apache 2.0

The Analytic Workbench – ICE: is considered as a design of a technology/product regarding subject matter, and is to be protected by Copyright, using open-Source licenses, or to be registered as a trademark or industrial design, depending on the development

The Big Data Platform – LXS is the product owner, and the asset will be used for commercializing, to be licensed with DBaaS.

The Social Media Analyser – ICE: is considered as a design of a technology/product regarding subject matter and is to be protected by Copyright using open-source licenses, or to be registered as trademark or industrial design.

The Monitoring Alerting and Feedback Component – KOD, is considered as a Software and to be protected by open-source licensing.

The Holistic Health Record of ATC, will be fructified in a standard, therefore protected by copyright.

The Tailored Conversational Coaching System and the Offline Model Learning Service – where iSPRINT is the sole developer and full owner of each, the services will be licensed within their product Healthentia via SaaS.

The Advanced Notebook of SIE is considered as a design of a technology/product regarding subject matter, and is to be protected by Copyright, however by Open-Source licenses, e.g., BSD-3, Apache 2.0

The Bounce Mitigation of SIE is considered as a design of a technology/product regarding subject matter and is to be protected by Copyright via Open-Source licenses like BSD-3, Apache 2.0. Based on the development, the respective method and algorithm used within the technology could have the potential of an Invention method which could be considered towards a Patent application, while the architecture is exploited as open source.

As described above, the majority of innovations are considered to be distributed via open-source agreements, namely: AI Models for Personalized Health Prediction, Analytic Workbench, Social Media Analyser, Monitoring Alerting and Feedback Component, Holistic Health Record, Advanced Notebook and part of the Bounce Mitigation. Some components, as the BigData Platform, the Tailored Conversational

Coaching System, the Offline Model Learning Service are proprietary components and also part of the Bounce Mitigation will be considered as IPR and protected by Commercial Licenses or Patent Applications. The mentioned innovations are important components within the business exploitation and worth to be considered for commercialization purposes. In this context, market competition will further drive innovation and leverage those ideas to grow. In addition, an Open-Source initiative in this regard will not ensure a trusted, verified and standardized application, hence a patent registration will benefit of a thorough peer-review process towards the assets' exploitation.

4.5.3 Exploitation

The Table 8 summarizes the actions to be taken towards exploitation, while the detailed exploitation plan and strategies are defined further in the respective series of deliverables related to T8.2 – "Exploitation Strategy and Plan", i.e., D8.5 – "Exploitation plan I" (K., A., K., +21), D8.6 – "Exploitation plan II", and D8.7 – "Exploitation plan III".

Table 8: Exploitation summary of assets.

Asset name and holders	Exploitation summary
AI Models for Personalized Health Prediction: ATC, ICE, UNIMAN	Using it in further research activities
Analytic Workbench – ICE	Two main uses: a) using it in further research activities, and b) direct exploitation by selling or servicing
Big Data Platform – LXS	Selling: on cloud or on premise
Social Media Analyser – ICE	Two main uses: a) using it in further research activities, and b) direct exploitation by selling or servicing
Monitoring Alerting and Feedback Component – KOD	Use in further research activities
Holistic Health Record – ATC	further research activities and standardization activities
Tailored Conversational Coaching System – iSPRINT	i) Offer as part of the standard Healthentia SaaS. ii) Use in further research activities.
Offline Model Learning Service – iSPRINT	i) Offer as an extension to the Healthentia SaaS to interested organizations. ii) Use in further research activities.
Advanced Notebook - SIE	using it in further research activities or in standardization activities
Bounce Mitigation - SIE	developing, creating, or marketing a product/service

4.5.4 Towards open-source routes

The iHelp project has several developments oriented towards the open-source concept.

In deliverables D2.1 – "State of the Art and Requirements analysis I" (A., C., C., + 21), D2.2 – "State of the Art and Requirements analysis II" (A., C., C., + 21), and D2.3 – "State of the Art and Requirements analysis III" (A., C., C., + 22) the project's overall methodology for collecting the user and technical requirements of the project, which helped to create a list of scenarios for each pilot. From this initiative, we started a state-of-art analysis of the base technology sectors where iHelp is involved, leading to potential exploitation of a list of baseline technological tools incorporated in the platform.

An example of such tool is described in deliverable D5.9 – "Social Analytics for the study of societal factors and policy making II" (R, P, L, +22), where the Social Media Analyser tool has been developed beyond its conceptual model.

The development of this tool was obtained with the support of several workshops and brainstorming sessions. As a result of this effort, partners concluded that this tool could add a lot more value to policy making process. More than that, this tool could potentially become an exploitable asset developed within the iHelp project and could further be commercialised beyond the project.

The deliverable showcases how this development could go beyond the state-of-the-art to become a specialised Open-Source Intelligence (OSINT) gathering component.

In deliverables D3.7 – "Standardisation and Quality Assurance of Heterogenous Data I" (G., W., D., +21) and D3.8 – "Standardisation and Quality Assurance of Heterogenous Data II" (M, K, M, +22), the main purpose is to describe the main data processing components of the project. The corresponding software prototypes of the Standardisation and Quality Assurance Mechanism are described. In this respect, five different subcomponents have been identified in total and have been detailed in these two deliverables, including the interfaces, as well as the baseline technologies that have been utilized. These prototypes are built upon open-source technologies that have been developed by solid communities.

A work tangent to the exploration of open-source directions is deliverable D8.5 – "Exploitation plan I" (K, A, K, +21) which is the first iteration of the exploration plans, and it is the preliminary exploitation plan that presents the exploitation strategy, the joint exploitation approach, as well as the individual plans of the partners. The exploitation strategy which follows a 3 phases-approach, is described with a list of key tasks, considerations and IPR handling practices.

5 Handling of Ethics issues

Given the broad spectrum of countries represented within the project's consortium, the consortium is well aware of the international legislation, guidelines and codes that regulate management of data:

- The Nuremberg Code (1947) addressing volunteer consent and proper acting (Nuremberg, 47);
- The Revised Declaration of Helsinki in its last version of 2013[45];
- The General Data Protection Regulation 2018[46], see below;
- Opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991-1997) (UNSPECIFIED, 1993)[47] and the European Group on Ethics in Science and New Technologies (as from 1998)[48];
- The New Brunswick Declaration: A Declaration on Research Ethics, Integrity and Governance resulting from the 1st Ethics Rupture Summit, Fredericton, New Brunswick, Canada (2013)[49];
- The Respect Code[50] focused in socio-economic research.

General Data Protection Regulation (GDPR)

Under this scope pilot partners of WP6 – "iHelp Validation and Pilot Studies" have already been organised and have started the procedures for the signing of specific declarations and approvals with their Ethical Committees.

Establishment of Ethics Boards

The iHelp project has formed an Ethics Board with relevant independent expertise to oversee the handling of any ethical issues that may arise throughout the course of the project. Its primary goal is to ensure that any contractual, legal, ethical, and gender equality concerns associated with the project study are correctly taken into account, as well as any pertinent conventions. The EB also has three members who represent three different organizations and have extensive training in the field of ethics. The Board assessed all the ethics-related deliverables that were provided during the project's M3 during this first reporting period. The Board, formed by experienced medical ethical experts, additionally met with the pilot partners before the first technical prototypes were released in the next months.

Ethics Report

The legal basis for processing previously gathered data from the Ethical Framework are followed-up and confirmed within D1.3 – "Periodic Management Report I" (K., M., M., +21), due on M12, and its follow-up versions, D1.4 – "Periodic Management Report II", due on M24, and D1.5 – "Periodic Management Report III", due on M36, along with the assurance that the necessary organizational and technical safeguards are in place to protect the rights of the data subjects, including e.g., the requirement for a Data Protection Impact Assessment (DPIA) with respect to biological data. Under this scope, pilot partners have already organized themselves in the context of WP6 – "iHelp Validation and Pilot Studies" and have begun the

[45] https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
[46] https://commission.europa.eu/law/law-topic/data-protection/eu-data-protection-rules_en
[47] http://aei.pitt.edu/44347/
[48] https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vk66hky9lrxh
[49] http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf
[50] https://embassy.science/wiki/Resource:80d5a629-c748-4cf8-b9c8-7be4c01c8b82

processes for obtaining their Ethical Committees' approvals and signing relevant declarations mentioned in sub-section 5.1 Ethical Issues in Pilots.

The consortium considers ethics and data protection standards and limits in all project phases and activities throughout the duration of the project. At all stages of the project, specific actions should be taken to encourage an Ethics aware mindset in all partners. Therefore, within T8.3 meetings or in the online surveys, ethical concerns have been gathered and reported below.

Reported ethics concerns - ethics problems that appeared within the project and management of these issues:

- ICE (Social Media Analyzer): Concerns about how the social media data is stored, treated, and analyzed might be tackled.
- HDM: Work with personal and health data owned by patients, hence the respective ethical agreements will be set in place.

Equality, non-discrimination, and solidarity is one of the AI development guidelines and principles indicated by EU. As argued in D1.13 – "Ethics Guidelines for Trustworthy AI in iHelp" (F., K., A., +21), the AI solutions developed in the iHelp project will adhere to this principle, considering the moral worth and dignity of all human beings. The design of AI solutions within the iHelp will be inclusive, and the selection of process participants will be conducted in a transparent manner to pay attention to people from different groups, including vulnerable groups, ethnic minorities, or others at risk.

5.1 Ethical Issues in Pilots

This subsection describes the agreements with Human Ethics Committees and updates from previous deliverables D1.9 – "Ethical Issues Related to the Involvement of Humans in iHelp", D1.10 – "Ethical Issues Related to the Protection of Personal Data", D1.11 – "Ethical Issues Related to the Involvement of Non-European Countries", D1.12 – "Ethical Issues Related to the Human Cells-Tissues", and the corresponding WP6 deliverables. The ethical issues related to pilots were addressed in D1.9 – D1.12 documents.

5.1.1 UNIMAN: Risk based community early detection and cancer prevention

The ethic approval of UNIMAN pilot id is referenced: 2022-13644-23283 date 09/05/2022.

The pilot focuses on genomic and epigenomic markers for early assessment of pancreatic cancer risk. The objective of the UNIMAN pilot is (i) to provide individuals with information about risk factors for future diseases is an important public health approach; (ii) to raise awareness of health conditions and educate people about how to prevent life-threatening diseases such as pancreatic cancer. To implement this pilot, UNIMAN will recruit pilot subjects through the UK National Health Service - health check and other community engagement opportunities. Subject criteria included age over 50 years and no history of cancer.

5.1.2 FPG: Interventional Monocentric Study based on Patient Reported Outcomes

The approval of FPG pilot with ID 4820 was received from FPG's Ethical Committee on 23/06/2022.

The pilot focuses on single-centre interventional analysis based on patient-reported outcomes. The FPG pilot study in iHelp aims to define personalized therapeutic strategies that maximize their effectiveness and reduce offside risks in patients affected by Pancreatic Cancer and bring significant improvements in the Quality of Life (QoL) of high-risk individuals. Patients affected by pancreatic cancer with an indication for neoadjuvant, exclusive or adjuvant radiotherapy or chemoradiation will be enrolled according to the inclusion criteria.

5.1.3 HDM: Description of Ambiental factors implicated in the development of pancreatic cancer and its usefulness as predictive factors

The HDM pilot has received the approval from the Ethical Committee on 3/10/2022, with the ID: C.I. 22/531-E.

The pilot focuses on Lifestyle Choices on Elevating the Risk Factors for Pancreatic Cancer. The HDM pilot will be targeted on the studying the effects of lifestyle choices on the risks associated with Pancreatic Cancer.

5.1.4 MUP - Study of Risk, Personalised Recommendations and Measures to Raise Awareness of Relevant Factors

The MUP pilot focuses on Risk, Personalised Recommendations and Measures to Raise Awareness of Relevant Factors. The MUP pilot will analyse and measure the healthcare awareness regarding the risk factors that increase the probability of malignant Pancreatic processes development.

The MUP Scientific Ethical Committee meeting for the protocol, the agreement on the iHelp platform and the approval for survey and inclusion of patients in iHelp, was held on 13/10/2022, the protocol signed on 21/10/2022, and the final document was issued on 11/11/2022, under no. P-2507, as “Statement of the MUP Scientific Ethical Committee on Scientific-Research Project iHelp - Pilot 4 - Study of Risk, Personalised Recommendations and Measures to Raise Awareness of Relevant Factors, part of the WP6 – “iHelp Validation and Pilot Studies”.

5.1.5 TMU - Study of Improved Risk Prediction Models and Targeted Interventions that can Delay the Onset of Cancer

The TMU pilot focuses on Improved Risk Prediction Models and Targeted Interventions that can Delay the Onset of Cancer. TMU aims to develop machine learning algorithms that can be tuned to predict high risk individuals for pancreatic as well as liver cancer for early management of modifiable risk factors (lifestyle, behaviour) among these individuals.

TMU have received the approval for Liver cancer and Digital Trial, and the Institutional Review Board (IRB) approval for pancreatic cancer is still under review, as Table 9 depicts:

Table 9: Ethical approvals for TMU Pilot.

Sr. No.	IRB Type	Approval ID	Approval Date
1	Liver Cancer	N202206086	July 01, 2022

2	Digital Trial	N202210048	November 28, 2022
3	Pancreatic Cancer	Under Review	

5.2 AI and Ethics

EU policies and priorities are translated into calls for proposals for subsequent EU-funded projects. The EC's approach to AI and ethics includes elements aimed at:

- Creating the conditions for the development and use of artificial intelligence ensures the commercialization and market entry of artificial intelligence-related research.
- Develop digital skills and promote a human-centric approach to AI.
- Build strategic marketing and management in high-impact sectors.

Data processing is a crucial task in AI model creation. When constructing new structures using the current health record, but information about fitting parameters will also be included, and an important aspect of this process is the modelling of primary and secondary data. These parameters include health-related characteristics such as lifestyle, well-being, etc., and social parameters such as behaviour, relationships, interactions, etc., both major categories of sensitive data. The meaning of the term "personal data" presupposes that its qualification includes the value of the term "personal" as strictly referring to a natural person. What personal data means is a natural person and, in the case of iHelp, a patient who knows the strict relationship between value and person. Therefore, because of the relationship that intrinsically connects information with each natural person, it creates an additional value that must be preserved. The information to be provided will be anonymised through industry-related procedures according to D1.10 (Ethical Issues Related to the Protection of Personal Data). Sensitive patient information, which will only be retained for processing and verification purposes, will be stored in trusted and reliable well-managed repositories.

5.2.1 Trustworthy AI

On M3 of the project the D1.13 – “Ethics Guidelines for Trustworthy AI in iHelp” (F., K., A., +21) presented the guidelines for trustworthy and transparent AI, while D5.1 – “Techniques for early risk identification, predictions and assessment I” (K, G, K, +21), and D5.2 – “Techniques for early risk identification, predictions and assessment II” (K., L, G, +22) also covered an overview of SotA in relation to XAI.

iHelp will produce AI based techniques and algorithms to enable early identification of Pancreatic Cancer.

These algorithms aim to reveal hidden patterns and trends in real-time/prospective data, to make predictions and also perform assessment of relevant identified risks. The purpose is to develop data analytic techniques to enable early risk identification, assessment, and mitigation of measures, through the development of personalized models.

Due to the correlation of the implementation of AI techniques and the work, the examination of the applicability of the ethical guidelines for trustworthy AI, is of undisputed value.

As stated in the “Ethics Guidelines for Trustworthy AI” document, written by the High – Level Expert Group on AI (HLEG) on April 2019, Trustworthy AI is based on three pillars (T., L., S., 21). Each one separately, should be met throughout the whole system’s life cycle. The first one refers to the lawful obedience of the system, including compliance with regulations. The legal sources include the EU primary and secondary law,

the UN Human Rights treaties, and the Council of Europe conventions, as well as numerous EU Member State laws. The second pillar refers to the ethical perspective, including compliance with ethical principles and values. Under that scope, the European Group on Ethics in Science and New Technologies (EGE) proposed 9 basic principles.

Four of the ethical principles/ ethical imperatives that have derived from the proposed ones, are: a) respect for human autonomy, b) Prevention of harm, c) Fairness and c) Explicability. Among others, the "ethical for human autonomy" principle includes the securing of human oversight over work processes in AI systems. More specifically, AI systems should not unjustifiably subordinate, coerce, deceive, manipulate, condition or herd humans. Regarding the 'prevention of harm' principle, it entails the protection of human dignity, mental and physical integrity, as well as the protection of natural environment and all living beings. Moreover, the 'principle of fairness' refers to both the sustainable and procedural dimension, meaning commitment to ensuring equal distribution of benefits and costs, as well as equal opportunities in terms of education, goods, and services. The "principle of explicability" refers to the transparency and "explainability" of the information of who is/will be affected directly or indirectly. Finally, the third pillar is based on the robustness in terms of technical and social perspective." Following the ethical principle of fair AI refers to openness about algorithmic principles and description of the nature of the dataset used for extracting hidden information-such as group of patients, age, geography, diseases patterns etc. The New England Journal of Medicine been discussed that AI tools developed based on one group of patients may not be applied on other groups (F., +21). To treat this challenge, it's important to include and verify safety checklists and perform mitigation strategies (F., 19). concerns about applicability of AI-solution across populations of patients''

A recent report from the European Parliament on Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts (Q., 22) analyze the potential risks of AI in healthcare and suggest mitigation actions, through risk self-assessment or clinical evaluation of AI solutions. For the latest, clinicians need to:

- employ standard definitions of clinical tasks (like disease definition) to enable objective community-driven evaluations;
- define performance elements beyond accuracy, such as for fairness, usability, explainability and transparency;
- subdivide the evaluation process into stages of increasing- complexity (i.e. to assess feasibility, then capability, effectiveness and durability);
- promote external evaluations by independent third-party evaluators;
- and employ standardised guidelines for reporting the AI evaluation results to increase reproducibility, transparency and trust.

In the recent years, a mechanism emerged namely ethics-based auditing (M., F., 21), used for organizations to control or influence the behaviour of their AI systems. It assesses the entity's behaviour for consistency with relevant principles or norms, in order to bridge the gap between principles and practice in AI ethics. Besides the legitimate and robust properties that AI has to fulfil, the aim is to assure its functionality does not go above the existing regulation. Instead of codifying ethics, ethics-based auditing helps to identify, visualise, and communicate the normative values that are embedded in the system. Although standards have yet to emerge, different types already exist, such as: i) functionality audits focusing on the rationale

behind the decision, ii) code audits entailing reviewing the source code, and iii) impact audits investigating the effects of an algorithm's outputs. Policymakers are encouraged to consider ethics-based auditing within holistic approaches to manage the ethical risks posed by AI. The traditional compliance mechanisms could still be followed; however, ethics-based auditing of AI can complement and enhance human oversight, certification, and regulation.

The capabilities of AI and Big Data coupled with the pervasiveness of devices and sensors of the IoT can change in a multidimensional level the materiality of healthcare, not just in the sense that independently given the possibility to stakeholders deploy new tools and models, but also how evidence-based decisions and care plans unfold and how they can protect fundamental rights and values from possible negative and multifaceted effects on individuals. In addition, the utilization of AI and Big Data is incongruent with human rights (C, I., 21) and if these technologies are governed incorrectly, then many challenges are posed about the citizens' rights and values. Warning examples have shown that if ethical and social implications are disregarded, AI can inflict significant harm on the people (G., B., 20). To this end, fundamental elements of human rights, as well as the respect for human dignity, freedom, equality, democracy, and the rule of law must be safeguarded, and individuals should be protected from the negative impacts of AI & Big Data to realize the opportunities presented by the utilization of these technologies. In this direction, these challenges are considered major pillars towards a successful implementation of EU's vision for fostering excellence in AI and strengthen the uptake, investment, and innovation in AI, as reflected in the EU's AI strategy[51], Regulatory framework proposal[52] and the "White Paper on Artificial Intelligence – a European approach to excellence and trust"[53]. Hence, regulated, ethical-framed and individual-centered AI has the potential to "greatly improve the delivery of healthcare and other services that advance well-being, if it is validated by the authorities, accepted and supported by the Healthcare Professionals and Healthcare Organizations and trusted by patients"[54]. To this end, AI has profound potential to transform health care for the better (K., Q., G., +22), (D., 19). Through a trusted, and fair development, deployment and utilization of AI and Big Data (R., 22), many opportunities will rise to digitize healthcare administrations, automate policies and decisions workflows, strengthen regulatory frameworks, and enhance personalized recommendations and treatments. Overall, without transparent, trusted, and unbiased AI, modern healthcare organizations cannot survive. Putting rules, trustworthiness, regulatory, and accountability frameworks and solutions in place, while also raising the awareness of stakeholders will reassure them that AI is being leveraged responsibly and ethically.

In line with efforts of the European Commission (EC), AI ethics scholarship focuses increasingly on converting abstract principles into actionable recommendations (K., B., S., +16). In order to bring some clarity and define a general framework for the use of AI, the EU's High Level Expert Group on AI (HLEG AI) has published ethics guidelines for trustworthy[55]. These guidelines are aimed at a variety of stakeholders, especially guiding practitioners towards more ethical and more robust applications of AI[56].

[51] https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence
[52] https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai
[53] https://ec.europa.eu/info/sites/default/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf
[54] https://www.medtecheurope.org/resource-library/the-socio-economic-impact-of-ai-in-healthcare-addressing-barriers-to-adoption-for-new-healthcare-technologies-in-europe/
[55] https://ec.europa.eu/digital-single-market/en/high-level-expert-group-artificial-intelligence
[56] https://ec.europa.eu/research/ege/pdf/ege_ai_statement_2018.pdf

According to HLEG AI, an AI to be trustworthy needs to be i) ***lawful***—respecting all applicable laws and regulations, ii) ***robust***—both from a technical and social perspective, and iii) ***ethical***—respecting ethical principles and values. The HLEG AI defines four ethical principles rooted on fundamental rights: 1) respect for human autonomy, 2) prevention of harm, 3) fairness, and 4) explainability.

Based on these four principles, the HLEG AI sets out seven requirements for AI systems to be deemed trustworthy and which assist the process of self-assessment. These key requirements are further introduced in the final Assessment List for Trustworthy Artificial Intelligence (ALTAI)[57].

- Human agency and oversight: all potential impacts that AI systems may have on fundamental rights should be accounted for and that the human role in the decision-making process is protected.
- Technical robustness and safety: AI systems should be secure and resilient in their operation in a way that minimizes potential harm, optimizes accuracy, and fosters confidence in their reliability.
- Privacy and data governance given the vast quantities of data processed by AI systems, this principle impresses the importance of protecting the privacy, integrity, and quality of the data and protects human rights of access to it.
- Transparency: AI systems need to be understandable at a human level so that decisions made through AI can be traced back to their underlying data. If a decision cannot be explained it cannot easily be justified.
- Diversity, non-discrimination, and fairness: AI systems need to be inclusive and non-biased in their application. This is challenging when the data is not reflective of all the potential stakeholders of an AI system.
- Societal and environmental wellbeing: in acknowledging the potential power of AI systems, this principle emphasizes the need for wider social concerns, including the environment, democracy, and individuals to be considered.
- Accountability: this principle, rooted in fairness, seeks to ensure clear lines of responsibility and accountability for the outcomes of AI systems, mechanisms for addressing trade-offs, and an environment in which concerns can be raised.

However, the implementation of AI and Big Data based solutions for data-driven and evidence-based decisions is associated with a host of various challenges, which have not been yet adequately addressed and involve not only how these technologies are being developed, but also their interaction with people and organizations, giving rise to leadership, policy, and administration challenges. Thus, modern AI approaches should be developed in the context of the moral values of individuals and rather than viewed as technical, “black-boxed” and value-neutral tasks of developing components and mechanisms that meet functional requirements formulated by clients and users.

In that context, the utilization of Explainable AI (XAI), and Bias Detection tools and techniques can increase the transparency, the trustworthiness, and the robustness of the AI algorithms and tools of the project. These techniques will boost the transparency and interpretability of AI-based public policy management and policy recommendations. Moreover, novel quantitative XAI tools can balance explainability vs. performance trade-offs. These tools will enable Healthcare Clinical Professionals (HCPs) to develop and

[57] https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment

deliver trusted and unbiased decisions and recommendations to their patients. While also helping them to understand, interpret and evaluate the outcomes of AI-based decisions and recommendations.

In line with these guidelines the iHelp project has introduced the Explainable Dashboard Hub (EDH). A tool for not only explaining and enhance the understanding of the HCPs on the underlying AI models, but also, for fostering the bias detection within the project. This hub facilitates the extraction, simulation, evaluation, and optimization of enhanced evidence-based decisions, including XAI, Causal inference, SHapley Additive exPlanations (SHAP) and What-If analysis techniques for transparent, unbiased, and discrimination-free AI applications. The design and implementation of the EDH play a vital role on the enhancement of the interpretability and explainability of the developed AI models within the iHelp project. Several dashboards are used to monitor metrics and outcomes of the AI models, and they provide easy-to-understand approaches of visualizing both the data and the insights derived from the utilization of different AI models. More specifically, HCPs would be able to select multiple models for numerous cases, to view numerous different visualizations and model comparisons. This will help the HCPs to enhance their knowledge and understanding on models' outcomes.

5.2.2 EU AI Act

The EU AI Act[58] (COM/2021/206 final, 21) aims to implement the second objective for the development of an ecosystem of trust by proposing a legal framework for trustworthy AI. This document is based on EU values and fundamental rights and has the purpose to provide people the confidence to use AI-based solutions, while encouraging business to develop them.

This proposal responds to requests from the European Parliament (EP) and the European Council, which have repeatedly called for legislative actions that have to provide regularized functioning internal market for artificial intelligence systems ('AI systems') where both benefits and risks of AI are adequately addressed at Union level.

Against this political context, the Commission presents the proposed regulatory framework on Artificial Intelligence with the following specific objectives:

- To ensure that AI systems placed on the Union market and used are safe and respect existing law on fundamental rights and Union values.
- To ensure legal certainty to facilitate investment and innovation in AI.
- To enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems.

To facilitate the development of a single market for lawful, safe, and trustworthy AI applications and prevent market fragmentation.
With respect to the point 5, The direct applicability of a Regulation, in accordance with THE Consolidated version of the Treaty on the Functioning of the European Union [2020] Article 288 (TFEU), will reduce legal fragmentation and facilitate the development of a single market for lawful, safe, and trustworthy AI systems.

[58] *Disclaimer:* The EU AI Act is still in a draft state. Various aspects of it may therefore change until it is finally approved.

In “ETHICS GUIDELINES FOR TRUSTWORTHY AI” (HLEGAI, 19) there are a set of guidelines that help projects in developing frameworks that achieve Trustworthy AI.

Trustworthy AI has three major components, which should be completed throughout the system's entire life cycle: (1) it should be lawful, complying with all applicable laws and regulations (2) it should be ethical, ensuring adherence to ethical principles and values and (3) it should be robust, both from a technical and social perspective since, even with good intentions, AI systems can cause unintentional harm. Each component is necessary but not sufficient for the achievement of Trustworthy AI.

The document (HLEGAI, 19), provides the seven key requirements needed for a system to be AI trustworthy:

Human agency and oversight: AI systems should empower human beings, allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which can be achieved through human-in-the-loop, human-on-the-loop, and human-in-command approaches

Technical Robustness and safety: AI systems need to be resilient and secure. They need to be safe, ensuring a fall-back plan in case something goes wrong, as well as being accurate, reliable and reproducible. That is the only way to ensure that also unintentional harm can be minimized and prevented.

Privacy and data governance: besides ensuring full respect for privacy and data protection, adequate data governance mechanisms must also be ensured, considering the quality and integrity of the data, and ensuring legitimised access to data.

Transparency: the data, system and AI business models should be transparent. Traceability mechanisms can help achieving this. Moreover, AI systems and their decisions should be explained in a manner adapted to the stakeholder concerned. Humans need to be aware that they are interacting with an AI system and must be informed of the system’s capabilities and limitations.

Diversity, non-discrimination, and fairness: Unfair bias must be avoided, as it could have multiple negative implications, from the marginalization of vulnerable groups to the exacerbation of prejudice and discrimination. Fostering diversity, AI systems should be accessible to all, regardless of any disability, and involve relevant stakeholders throughout their entire life circle.

Societal and environmental well-being: AI systems should benefit all human beings, including future generations. It must hence be ensured that they are sustainable and environmentally friendly. Moreover, they should consider the environment, including other living beings, and their social and societal impact should be carefully considered.

Accountability: Mechanisms should be put in place to ensure responsibility and accountability for AI systems and their outcomes. Auditability, which enables the assessment of algorithms, data and design processes plays a key role therein, especially in critical applications. Moreover, adequate an accessible redress should be ensured.

In order to treat the various requirements within the act and build a bridge between a legal vocabulary and the technical domain, standards are requested to be created. Currently there is an ongoing standardization request for harmonized standards, for all High Risk Requirements in Article 9 to 15 of the AI Act. On the

basis of the standards to be established and the necessary adjustments, the Act is estimated to come into force in beginning of 2025.

6 Conclusion

This deliverable, i.e., D8.8 – "Standardisation, IPR management and Ethics in iHelp I" is the first iteration with regards to the report of the standardisation, IPR management and ethics activities within the iHelp project and it will be followed by one more iteration, the D8.9 – "Standardisation, IPR management and Ethics in iHelp II" due on M36. This report presents the existing standards that impact the iHelp project, the open-source concepts that must be considered when developing the modules in iHelp project.

Further developments that will be delivered in the next version, entitled D8.9 – "Standardisation, IPR management and Ethics in iHelp II", will be focused on the monitoring of the IPR issues, and on the support offered to the innovators to address and solve the encountered issues.

A gap analysis will be performed and reported in the next iteration of this series of deliverables. This analysis is referred to as a needs analysis and is of use for measuring any type of organizational performance. From a development point of view, it allows companies or consortiums to determine what is the status and where they want to be in the future.

What is more, in the context of this deliverable an introduction in IPR issues and the access rights to Background and Results was performed. On top of this, a detailed review of the results ownership, protections and exploitation was performed, followed by a presentation of the overall IPR methodology.

In the next version of this series of deliverables, mode details on the innovation components will be provided. Consecutively, the reported issues along with the licensing details describe how the platform and assets developed using the platform can provide access for commercial exploitation.

The activities described in this deliverable are meant to ensure that the relevant guidelines, ethical principles, and regulations are known to the partners and relevant measures are put in place to ensure compliance in project development and pilot activities. A study has been conducted to extract all the ethical issues relevant for the iHelp project and are further detailed and described in the context of this deliverable.

The associated and affiliated entities will be investigated and described in the following report version.

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List of Acronyms

ACID	Atomicity, Consistency, Isolation, Durability
AFNOR	French Standardization Association
AI	Artificial Intelligence
ALTAI	Assessment List for Trustworthy Artificial Intelligence
ANSI	American National Standards Institute
API	application programming interface.
ATC	Athens Technology Centre
BDVA	Big Data Value Association
CA	Consortium Agreement
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CDM	Common Data Model
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEP	Complex Event Processing (CEP)
D	Deliverable
DICOM	Digital Imaging and Communications in Medicine
DPIA	Data Protection Impact Assessment
DSS	Decision Support System
EC	European Commission
EDI	Electronic Data Interchange
EGE	European Group on Ethics in Science and New Technologies
EHD	Explainable Dashboard Hub
EHR	Electronic Health Record
EMA	European Medicines Agency
ENG	Engineering Ingegneria Informatica SpA
ENs	European Standards
EP	European Parliament
EPO	European Patent Office
epSOS	The European Patient Smart Open Services
ESO	European Standards Organization
ETSI	European telecommunications standards institute
EuroRec	European Institute for Health Records
FHIR	Fast Healthcare Interoperability Resources
FPG	Agostino Gemelli University Policlinic
GDPR	General Data Protection Regulation
GEHR	Good European Health Record
GPL	Gnu Public License
HCPs	Healthcare Clinical Professionals
HDM	Hospital de Dénia-MarinaSalud
HHR	Holistic Health Record
HL7	Health Level Seven
HLEG AI	High Level Expert Group on AI
ICD-10	International Classification of Diseases 10th Revision

ICE	Information Catalyst for Enterprise
ICT	Information and Communications Technology
IEC	International Electrotechnical Commission
IEEE SA	IEEE Standards Association
IHC	International Health Continuum
IoT	Internet of Things
IP	Intellectual Property
IPR	Intellectual Property Rights
IRB	Institutional Review Board
ISO	International Organization for Standardization
iSPRINT	Innovation Sprint
ITU	International Telecommunication Union
JDBC	Java Database Connectivity
JSON	JavaScript Object Notation
KI	Karolinska Institutet
KOD	KODAR Systems
LOINC	Logical Observation Identifiers Names and Codes
LXS	LeanXcale
ML	Machine Learning
MUP	Medical University Plovdiv
NCPDP	National Council for Prescription Drug Programs
NIST	National Institute of Standards and Technology
NLP	Natural Language Processing
OASIS	Organization for the Advancement of Structured Information Standards
OData	Open Data Protocol
ODBC	Open Database Connectivity
OHDSI	Observational Health Data Sciences and Informatics
OLAP	Online Analytical Processing
OLTP	Online transaction processing
OMOP	Observational Medical Outcomes Partnership
OS	Open Source
OSINT	Open-Source Intelligence
SA	Sentiment Analysis
SaaS	Software as a service
SHAP	SHapley Additive exPlanations
SIE	Siemens
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SoA	State of the Art
TC	Technical Committee
TFEU	Treaty on the Functioning of the European Union
TMU	Taipei Medical University
TRL	Technology readiness level
UNIMAN	University of Manchester
UPM	Universidad Politécnica de Madrid
UPRC	University of Piraeus Research Centre
WP	Work Package

XAI	Explainable Artificial Intelligence
XMP	Extensible markup language

Annex A - IPR Assets information and status

Table 10: IPR assets information and status.

IPR Asset Name	Owner / Partner	Asset Short Description	Asset Type* (Background / New result)	WP tasks	Estimated TRL (1-9)	Current and expected final state of the Asset development	License Type (Commercial: SaaS, … / Open Source: Apache 2.0, CC, GNU[59]…)	Related iHelp components **
Primary data collection from pilot study	UNIMAN	Primary data	Background	T6.3	N/A	N/A	N/A	External Data Providers
Patient Data from the FPG Datawarehouse	FPG	Patient data	Background	T6.3	N/A	N/A	N/A	External Data Providers
Patient data from the HDM Datawarehouse	HDM	Patient data	Background	T6.3	N/A	N/A	N/A	External Data Providers
AI Models for Personalized Health Prediction	ATC, ICE, UNIMAN	AI/ML models trained on HDM and TMU datasets	New result	T4.1	7	Current state: Under development Final state: Proof of concept (POC)	Apache 2.0	Personalized Health Predictor
Analytic Workbench	ICE	AI/ML model trainer, management and execution tool	Improved background	T4.2	7	Current state: Under development Final State: Expected to be integrated with the iHelp Platform	Apache 2.0	Analytic Workbench

[59] http://www.gnu.org/copyleft/gpl.html

LeanXcale Database Software	LXS		Background	T4.4	7	N/A	N/A	Big Data Platform
BigData Platform	LXS	Big Data Platform Supporting mixed OLAP and OLTP workloads	Improved background	T4.4	7	Current state: TRL6, demonstrated in relevant environment during review (TRL6), and under development for TRL 7 Final state: TRL7, with the actual demonstration in operational environment on the pilots' premises	Commercial, part of DBaaS	Big Data Platform
INFORMATION CATALYST SL (ICE ES) – any product, services and components from ICE	ICE		Background		N/A	N/A	N/A	
Social Media Analyser	ICE	Tool to analyze social media posts for the creations of policies	Improved background	T5.4	7	Current state: Under development Final State: Expected to be integrated with the iHelp Platform	Apache 2.0	Social Media Analyser
Monitoring Alerting and	KOD	An advanced rule-based engine executed on certain configurable	New Result	T5.5	7	Current state: Prototype	Apache 2.0, OTN License	Monitoring and alerting

Feedback Component		time intervals (daily, weekly, or monthly) that will read holistic health records from the Big Data Platform. Next, the mechanism will evaluate the data and will compare certain target values defined in the personalized recommendation against real values. In addition, there is an alerting module for distribution of evaluation messages based on different escalation policies and threshold values from a decision matrix.				Final state: Proof of concept (POC)	Agreement for Java SE, BSD	
Holistic Health Record	ATC	Creation of mappers components for transforming the available data into a common HHR format, following the FHIR standard	New Result	T3.1	N/A	Current: Mapper working for HDM data. All others are under development	Standardization	Data Mapper
Healthentia eClinical platform	iSPRINT	Big data platform for the collection of Real-World Data from the everyday setting of patients and general population	Background, Improved background	T3.3	9	Developed outside of project, provided to iHelp for secondary data collection	Commercial, part of the Healthentia SaaS	Monitoring & alerting
Healthentia mobile app	iSPRINT	Companion application given to patients for the collection of their RWD and the provision of alerts, feedback and virtual coaching	Background, Improved background	T3.3 & T5.3	9	Developed outside of project, provided to iHelp for secondary data collection and feedback provision	Commercial, part of the Healthentia SaaS	Monitoring & alerting
Tailored Conversational	iSPRINT	Service to provide virtual coaching	New result	T5.3	7	Currently in progress, expected to be	Commercial, part of the	Monitoring & alerting

Coaching System						demonstrated in operational environment	Healthentia SaaS	
Offline Model Learning Service	iSPRINT	Service to be deployed at Healthentia platform or at the edge to learn ML models, following a zero-code approach	New result	T5.1	5	Currently in progress, expected to be validated in relevant environment	Commercial, part of the Healthentia SaaS	Monitoring & alerting
Advanced Notebook	SIE	One script deployment for open source tools that foster faster AI/ML experiments, offering fast prototyping, and ML models metadata, artifacts and performance indicators management	New result	T4.2	4	In progress. The final development is expected to be integrated with the iHelp Platform and used for a Pilot usecase to demonstrate functionality and possible usage	Open Source, e.g., BSD-3, Apache 2.0	Analytic Workbench
Bounce Mitigation	SIE	Open source tool, based on Advanced Notebook, for predicting users that are of risk of quitting the enrolled healthcare plan, find the reasons behind quitting and take actions to reduce the quitting rate.	New result	T5.5	3	Current: concept. The final development: prototype with pilot usecase.	Open Source, e.g., BSD-3, Apache 2.0	Monitoring and Alerting

** results brought into the project from previous or current efforts*

*** main components or sub-components the asset relates to, referring to iHelp architecture components described in D2.4 – "Conceptual model and reference architecture I"*

Annex B - Existing standards

Table 11: Existing standards.

Domain and Standard	Description
A. AI	
SC 42 WD 23053	Framework for Artificial Intelligence Systems Using Machine Learning
IEEE P2247.1	Standard for the Classification of Adaptive Instructional Systems
IEEE P2247.3	Recommended Practices for Evaluation of Adaptive Instructional Systems
IEEE IC20-027	Responsible Innovation of AI and the Life Sciences
IEEE P2840	Standard for Responsible AI Licensing
IEEE P2841	Framework and Process for Deep Learning Evaluation
IEEE P7000	Model Process for Addressing Ethical Concerns During System Design
IEEE P7003	Methodologies to address algorithmic bias in the development of AI systems
IEEE P2801	Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence
IEEE P7002	Standard for Data Privacy Process
IEEE P7006	Standard for Personal Data Artificial Intelligence (AI) Agent
IEEE P7010	Wellbeing metrics standard for ethical artificial intelligence and autonomous systems
ISO/IEC DTS 4213	Information technology — Artificial Intelligence — Assessment of machine learning classification performance
ISO/IEC AWI 5338	Information technology — Artificial intelligence — AI system life cycle processes
ISO/IEC AWI 5339	Information Technology — Artificial Intelligence — Guidelines for AI applications
ISO/IEC AWI 5392	Information technology — Artificial intelligence — Reference architecture of knowledge engineering
ISO/IEC AWI TS 25058	Artificial intelligence — Quality evaluation guidelines for AI systems
ISO/IEC DTR 24027	Information technology — Artificial Intelligence (AI) — Bias in AI systems and AI aided decision making
ISO/IEC TR 24029-1:2021	Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview
ISO/IEC AWI 24029-2	Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
ISO/IEC AWI TR 24368	Information technology — Artificial intelligence — Overview of ethical and societal concerns
ISO/IEC CD 24668	Information technology — Artificial intelligence —Process management framework for Big data analytics
ISO/IEC AWI 25059	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI-based systems

B. DATA	
ISO/IEC AWI 5259-1	Data quality for analytics and ML — Part 1: Overview, terminology, and examples
ISO/IEC AWI 5259-2	Data quality for analytics and ML — Part 2: Part 2: Data quality measures
ISO/IEC AWI 5259-3	Data quality for analytics and ML — Part 3: Data quality management requirements and guidelines
ISO/IEC AWI 5259-4	Data quality for analytics and ML — Part 4: Data quality process framework
C. Health Informatics	
IEC 63203-101-1:2021	Wearable electronic devices and technologies. Part 101 - Electronics (Vocabularies)
IEC 63203-204-1:2021	Wearable electronic devices and technologies. Part 204 - Smart textiles
IEC 63203-201-3:2021	Wearable electronic devices and technologies - Part 201 - Smart textiles
ISO 12967:2009	Health informatics—Service architecture
ISO 14155	International Standard for Clinical Investigation of Medical Devices
ISO/TS 22220:2011	Health informatics -- Identification of subjects of health care

Annex C - Additional available standards

Table 12: Additional available standards.

Domain and Standard	Description
A. AI	
ANSI/CTA-2090	The Use of Artificial Intelligence in Health Care: Trustworthiness
ISO/IEC 38507	Information technology — Governance of IT — Governance implications of the use of artificial intelligence by organizations
ISO/IEC TR 29119-11	Software and systems engineering - Software testing - Part 11: Guidelines on the testing of AI-based systems
ISO/TR 14639-1	Health informatics - Capacity-based eHealth architecture roadmap - Part 1: Overview of national eHealth initiatives
ISO/TR 14639-2	Health informatics - Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model
ISO/IEC TR 24029-1:2021	Artificial Intelligence (AI) - Assessment of the robustness of neural networks - Part 1: Overview
IEEE 7010	IEEE Recommended Practice for Assessing the Impact of Autonomous and Intelligent Systems on Human Well-being
ISO/IEC 23053	Framework for artificial intelligence systems using machine learning
ISO/IEC TR 24028	Information technology. Artificial intelligence. Overview of trustworthiness in artificial intelligence
B. Health Informatics	
ISO/HL7 10781	Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2
ISO/HL7 16527	Health informatics - HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)
ISO/HL7 21731	Health informatics - HL7 version 3 - Reference information model - Release 4
ANSI/HL7 VMR CDSLM, R2	HL7 Virtual Medical Record for Clinical Decision Support (vMR-CDS) Logical Models, Release 2
ANSI/HL7 V3 DSS, R2	Decision Support Services, Release 2 / revision and redesignation of ANSI/HL7 V3 DSS, R1-2011
ANSI/HL7 CDAR2 PHMRPTS, R1	HL7 CDA (R)R2 Implementation Guide: Personal Healthcare Monitoring Reports, Release 1
ANSI/HL7 EHR, R2.1	HL7 Electronic Health Record System Functional Model, Release 2.1 / revision and redesignation of ANSI/HL7 EHR, R2-2014
ANSI/HL7 PHRSFM, R 1	HL7 Personal Health Record System Functional Model, Release 1
ANSI/HL7 PRIVECLASSSYS, R 1	HL7 Healthcare Privacy and Security Classification System, Release 1
ANSI/HL7 SAIF CANON, R2	HL7 Service-Aware Interoperability Framework: Canonical Definition Specification, Release 2
ANSI/HL7 TEMPLATES, R1	HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1
ETSI TR 102764 V 1.1.1	eHEALTH - Architecture - Analysis of user service models, technologies and applications supporting eHealth
ETSI TR 103477 V 1.2.1	eHEALTH - Standardization use cases for eHealth
ITU-T X.1080.1	e-Health and world-wide telemedicines - Generic telecommunication protocol
SA HB 137	E-health Interoperability Framework
SA HB 138	E-health architecture principles

ISO/TS 10303-1486	Industrial automation systems and integration - Product data representation and exchange - Part 1486: Application module: Decision support
ISO 13606-1	Health informatics - Electronic health record communication - Part 1: Reference model (EHR interoperability)
ISO 13606-2	Health informatics - Electronic health record communication - Part 2: Archetype interchange specification
ISO 13606-3	Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists
ISO 13606-4	Health informatics - Electronic health record communication - Part 4: Security
ISO 13606-5	Health informatics - Electronic health record communication - Part 5: Interface specification
C. Internet of Things (IoT)	
ITU-T Y.4117	Requirements and capabilities of the IoT for support of wearable devices and related services
ITU-T Y.4908	Performance evaluation frameworks of e-health systems in the IoT
D. Data	
ISO/HL7 27931	Data Exchange Standards - Health Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments
ISO/HL7 27932	Data Exchange Standards - HL7 Clinical Document Architecture, Release 2
ISO/IEC TR 20913	Information technology - Data centres - Guidelines on holistic investigation methodology for data centre key performance indicators
ISO 37155-2	Framework for integration and operation of smart community infrastructures - Part 2: Holistic approach and the strategy for development, operation and maintenance of smart community infrastructures
ITU-T Y SUPPLEMENT 50	Use case and application scenario for big-data driven networking
EUEMPF 2020/518	Commission Recommendation (EU) 2020/518 of 8 April 2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID- 19 crisis, in particular concerning mobile applications and the use of anonymised mobility data
DIN EN 14484	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy
ISO/IEC 20547	Information technology — Big data reference architecture — Part 1: Framework and application process
ISO/IEC TR 20547-2	Information technology — Big data reference architecture — Part 2: Use cases and derived requirements
ISO/IEC 20547-3	Information technology — Big data reference architecture — Part 3: Reference architecture
ISO/IEC 20547-4	Information technology – Big data reference architecture - Part 4: Security and privacy
ISO/IEC TR 20547-5	Information technology — Big data reference architecture — Part 5: Standards roadmap
ANSI/HL7 FHIR OBS R1	HL7 FHIR R4 Observation, Release 1
ANSI/HL7 FHIR R4 INFRASTRUCTURE R1	HL7 FHIR® R4 Infrastructure
ANSI/HL7 FHIR R4 PATIENT R 1	HL7 FHIR R4 Patient, Release 1

ANSI/HL7 FHIR R4 TERMINOLOGY R 1	HL7 FHIR R4 Terminology & Conformance
E. Clinical	
AS/HB 307	Guide to the principles and desirable features of clinical decision support systems
EUB 2020/437	Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC
CAN/HSO 13001	Palliative Care Services
F. Policy Making	
CEN-CENELEC-GUIDE 30	European Guide on Standards and Regulation - Better regulation through the use of voluntary standards - Guidance for policy makers
CEN-CENELEC GUIDE 8	CEN-CENELEC guidelines for implementation of the common policy on patents (and other statutory intellectual property rights based on inventions)