D3.5 - Big Data platform final release and evaluation report

28/02/2023

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Document Abstract	This deliverable describes the evaluation and verification of the complete PERSIST system. It includes the description of the different types of tests performed as well as the definition of the specific test plan developed for this project, which allows to analyse the performance of the PERSIST platform. In addition, it presents the main challenges for PERSIST regarding security and privacy-protection, resulting from an assessment of the PERSIST model and its compliance with GDPR.

DOCUMENT	
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DISCLAIMER

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Acronyms and abbreviations

ACRONYM	TITLE
API	Application Programming Interfaces
ASR	Automated Speech Recognition
CDS	Clinical Decision Support
CDSS	Clinical Decision Support System
CTA	Cohort and Trajectories Analysis
CTC	Circulating Tumour Cell
CtC	Connectionist Temporal Classification
DCD	Disease Centric Discourse
DC4H	Digital Connect 4 Healthcare
DPIA	Data Protection Impact Assessment
ECA	Embodied Conversational Agent
EDPB	European Data Protection Board
EHR	Electronic Health Record
FFE	Facial Feature Extractor
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HL7	Health Level 7
HTTP	HyperText Markup Language
IT	Information Technology
IoT	Internet of Things
JWT	JSON Web Token
LSTM	Long-Short Term Memory

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ML	Machine Learning
MFCC	Mel-/Bark-Frequency-Cepstral Coefficients
MQTT	Message Queuing Telemetry Transport
MRAST	Multimodal Risk Assessment and Symptom Tracking
MSN	Multimodal sensing network MSN
NLTK	Natural Language Toolkit
OHC	Open Health Connect
PGHD	Patient-Generated Health Data
PLP	Perceptual Linear Predictive
PREM	Patient Reported Experiences
PROM	Patient Reported Outcomes
RF	Random Forest
SFTP	SSH File Transfer Protocol
SFE	Speech Feature Extractor
SVM	Support vector machine
TFE	Text/Language Feature Extractor
TTS	Speech synthesis or text-to-speech
UI	User Interface

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1. Executive Summary

This document is intended to provide an evaluation report of the complete platform developed within the PERSIST project. This includes:

- ➔ Description of the different test types used to evaluate the platform.
- ➔ Definition of the test plan, including each of the test types described.
- ➔ Platform evaluation based on the defined test plan.
- ➔ Results.

For this evaluation, the individual components that make up the PERSIST platform as well as the integration between components and the functioning of the complete connected system have been taken into account, in order to ensure that meaningful results are provided to end-users, namely cancer survivors, healthcare professionals and liquid biopsy laboratory technicians.

In addition, the document presents the assessment of the security of processing, ethics and data protection mechanisms in PERSIST technology. The final outcome of this activity addresses five specific challenges that have been spotted in PERSIST technology and will provide tailored insights for future development of the PERSIST proposed care model for cancer survivors.

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2. Technical validation

General Concepts

Testing and evaluating a developed system is a crucial step of the design and development process as it analyses whether the system works as it is supposed to, or whether it needs to be improved or fixed. As general points:

- ➔ It ensures that a system works efficiently and meets the user's needs and expectations.
- ➔ It allows error or bug detection in the system, which allows for fixing them. This helps to ensure that the system works correctly in all its aspects and does not cause problems for the users who use it.
- ➔ It helps to ensure the scalability and performance of a system. As a system is used in different environments and with different data sets, it is important to ensure that it remains stable. Thus, testing allows performance problems to be identified and corrected before they become critical.

In short, testing is important to ensure that the system works correctly, meets the user's needs and has stable performance, which helps ensure reliability and end-user satisfaction. It is an essential step in system development as it helps to avoid costly problems and ensure that the system meets the required quality standards. In a complex system such as the one developed in PERSIST, composed of different modules in which more than one partner is involved, it is very important to develop a rigorous test plan that confirms the functioning of the modules, as well as their integration and joint functioning.

Testing techniques are classified into two main categories: **functional testing and non-functional testing.** Functional tests check each system's function or feature, while non-functional tests check non-functional aspects such as the system's performance, usability, reliability, etc. The former is based on customer requirements, while the latter is based on customer expectations. Within these two main categories, different types of tests are defined and used to evaluate systems from different angles. OBJ OBJ OBJ

Functional testing

In functional testing, similar to a mathematical function with its input and output, a software is considered a function and is conceived in terms of input values and corresponding output values. In other words, a "black box" approach is used in which the internal structure of the software is ignored and tests are built from the functional properties of the program which have been previously specified (W. E. Howden, 1980).

Thus, functional tests are used to verify that a system meets its specified functional requirements. This "black box" approach is based on the execution, review and feedback of previously designed system functionalities. These tests focus on verifying that the system performs the tasks for which it was designed and that it does so as expected, checking only the output of an action and not checking the intermediate states of the system when performing that action.

In a complex system like the PERSIST's one, functional testing is particularly important to ensure that the system works correctly at all levels and in all functions. This ranges from basic functions to advanced functions, such as integration with other systems and applications. They are performed by comparing the actual results with the expected results,

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thus verifying that the system behaves as expected. To perform these tests it is necessary to have a specification of the functional requirements of the system, once these requirements are in place it is possible to create test scenarios that allow the evaluation of the behaviour of the system under different conditions.

In brief, functional tests are essential in a complex system to ensure that the system meets the specified functional requirements and that it works properly in all functions, both basic and advanced. **In the test plan defined for the PERSIST project, functional tests of each of the functionalities specified for each component have been included.**

Functional tests are typically divided into four distinct groups: **unit, integration, system and acceptance testing** (M. A. Jamil et al., 2016). These are executed and validated sequentially, as shown in Figure 1. The definition of these tests are described below.

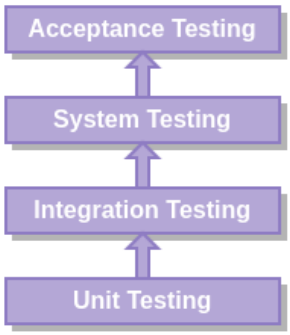

Figure 1 Diagram explaining types of functional tests.

Unit testing

Unit tests are performed close to the source code of a particular module, component or unit prior to its integration with other units (Angelina Samaroo et al., 2015). BCS, Swindon, GBR.). This is a way of ensuring that an application's code works correctly by performing isolated tests on small code units, such as functions or individual methods. These tests focus on verifying that each code unit works correctly independently.

Unit testing is used to detect and fix code errors early and efficiently, as it allows developers to find and correct problems in the individual code units before integrating and testing the overall code. This can help reduce development costs and time, as bugs and errors detected early are easier and cheaper to attach. In addition, unit tests are also useful for maintaining and improving the system code as changes and updates are made. They allow individual code units not to adversely affect other parts of the code, which is really important in projects that are developed in large teams, across different companies or over a long period of time.

To summarise, unit testing is an essential tool in system development, as it helps to ensure code quality and reliability, allowing for to detect and fix errors in an early way, facilitating the maintainability and improvement of the code and ensuring that the code units function correctly independently of each other.

In PERSIST this kind of test is not included as such in the general test plan defined to evaluate the system as the partners themselves have individually tested the different functionalities of their modules, and have made sure of their correct behaviour.

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Integration testing

Integration tests are performed after unit tests have been passed. These tests are used to check that the unitary components that make up a system work together correctly, testing them as a group. These components can be software modules, applications, hardware systems, web services, databases, etc. The purpose of integration testing is to detect integration problems at an early stage of development before the system is fully implemented.

There are several integration testing approaches, such as Big-bang integration, top-down integration, and bottom-up integration testing (Angelina Samaroo et al., 2015).

- **Big-bang integration testing** is performed once all components have been integrated, i.e., it consists of integrating all units at once to build the complete system. With this type of integration, it is sometimes difficult to isolate the errors detected, because no attention is paid to the verification of the connections between pairs of units.
- **Top-down integration testing** is performed in stages. Thus, the system is built starting with components that call other components. Components that call other components are usually placed above those that are called. Top-down integration testing requires that the interactions of each component be tested as it is built. Those lower in the hierarchy may not have been built or integrated yet.
- **Bottom-up integration testing** is an opposite approach to the top-down approach. In bottom-up integration testing, testing is performed from the bottom up. The lowest-level modules are tested first, then the high-level modules are tested, and finally, the high-level modules are integrated at the low level to ensure that the system works as intended.

In summary, integration testing is essential to ensure that the different components of a system work together correctly and that integration problems are detected at an early stage of development, allowing them to be corrected before final implementation. **Integration tests are not included in the PERSIST test plan,** as they, like unit tests, have been carried out between partners as components were integrated in pairs.

System testing

System testing is a type of testing performed on a complete system, which objective is to evaluate the end-to-end system specifications. System tests take as input all integrated components that have passed the integration tests. They are performed with the complete system and under real operating conditions, with real data and workloads.

System testing is used to:

- Testing fully integrated applications and modules, including external peripherals, to analyse the components' behaviour in relation to each other and with the system as a whole.
- Check that each possible action or system input achieves the expected results.
- Test the user's experience with the system.

With respect to system tests, test flows have been described on the PERSIST's test plan for each of the PERSIST systems which are used by the different users: clinicians, patients and liquid biopsy laboratory personnel.

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Acceptance testing

Acceptance tests are specific tests that are carried out to assess the acceptability of the system to users (Miller, R., & Collins, C. T, 2001). These tests aim to verify that the system meets the usability, accessibility and functionality requirements from the users' point of view. They are carried out with real users and under real operating conditions. Similar to functional testing, this type of testing is a black box testing technique where only the functionality is verified to ensure that the product meets the specified acceptance criteria (no design/implementation knowledge required).

Acceptance testing is not considered in the scope of this deliverable, as it is already covered in **D6.2. Data collection and usability clinical study results** and **D6.3. Full clinical study validation results.**

Non-functional testing

Non-functional tests verify requirements based on the operation of a software, not on the functionality itself (QALovers, 2021). This type of test plan is a means of quality control, which is performed to make sure that everything is working correctly and to identify under what circumstances the software may fail.

Thus, non-functional testing allows to know what risks the product runs and tells if it performs poorly or underperforms in production environments. In that sense, non-functional software tests are done in order to obtain information. They allow to explain what the product supports and whether it meets customer expectations.

There are several types of non-functional tests which can be performed on a system such as PERSIST. These include load testing, security testing, performance testing, volume testing, reliability testing, scalability testing and others.

- **Load testing.** They consist of simulating a series of accesses on a system and measuring the result. These tests are performed under expected demand and also under overload conditions.
- **Security testing.** They are related to ethical hacking, detecting vulnerabilities and auditing good practices. They check the security attributes or characteristics of the system, analyse whether it is a secure system or not, whether it can be breached, etc.
- **Performance testing.** They consist of evaluating the behaviour of a system in terms of responsiveness and stability under a given workload. Performance tests are typically run to examine the speed or robustness, for instance.
- **Volume testing. T**hey are a type of test that is performed to test a system with a certain amount of data. The amount used in volume testing could be the size of a database or it could also be the size of an interface file that is the subject of the volume test.
- **Reliability testing.** This type of testing is performed to ensure that the software is performing and functioning consistently in each environmental condition as well as in a specified period.
- **Scalability testing.** It is a type of load testing that measures the ability of a system to scale up or down in reaction to an increase in the number of users. In other words, it tests how the system will perform during a sudden spike or drop in user request loads.

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The platform has managed an important data volume:

- One-shot ingestion process with information to train and test the algorithms.
- Continuous on-line data ingestion process through mHealth application, with data from patients who participated in the clinical study.

Next table shows the data volume managed by the platform during the project:

Table 1 Data volume managed by the PERSIST platform.

Year	Concept	Resources	Disk Space (GB)	Daily Ratio		Comments
2021	Retrospective data	23.874.569	38,10			
	Patients' data	11.138.119	10,28	40.650	39 Mb	Since 30/March/21
	Multimedia files	11.439	97,89	42	364 Mb	Since 07/July/21
2022	Patients' data	4.516.811	4,36	12.409	15 Mb	
	Multimedia files	12.387	55,77	34	208 Mb	
2023	Patients' data	3.798	0,004	100	15 Mb	Till 08/02/2023
	Multimedia files	367	1,68	10	208 Mb	Till 08/02/2023

The services have been up and running during the whole PERSIST project, without any impact on the operations of the data capture and clinical study.

The design of the DC4H (former Open Health Connect) and the deployment of the artificial intelligence models in the cloud will enable the smooth scalability of the PERSIST platform, ensuring that the volume of users and loading of data will not affect the performance and availability of PERSIST services, providing professionals and cancer survivors with meaningful and valuable results.

3. Scope - PERSIST architecture components

DC4H platform (former Open Health Connect - OHC)

Based on the DC4H platform (formerly named as Open Health Connect platform), the main core of the solution consists of an ElasticSearch database in which patient records are stored from different platforms to later apply ML techniques. Around this database, other components have been installed that guarantee the quality of the information and FHIR stu3 standard. Information processing systems have also been implemented so that external systems can access it safely. Added to this, other systems have been deployed to ensure the security of the environment.

In addition, new services have also been included that facilitate the exchange of information and the correct functioning of the application ecosystem.

These are the components deployed in the system:

- ElasticSearch
- Kibana
- Keycloak
- Kong
- FHIR Server

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- ➔ Insights Workbench
- ➔ CDS Hook
- ➔ AI Ready
- ➔ SFTP
- ➔ SPatient

As a schematic of the PERSIST solution, you can refer to the following figure 2. It represents all the platform components and the logic interconnections between them. The main platform is located inside the dot line, leaving the external actors (users, data providers and other components) outside the dot line.

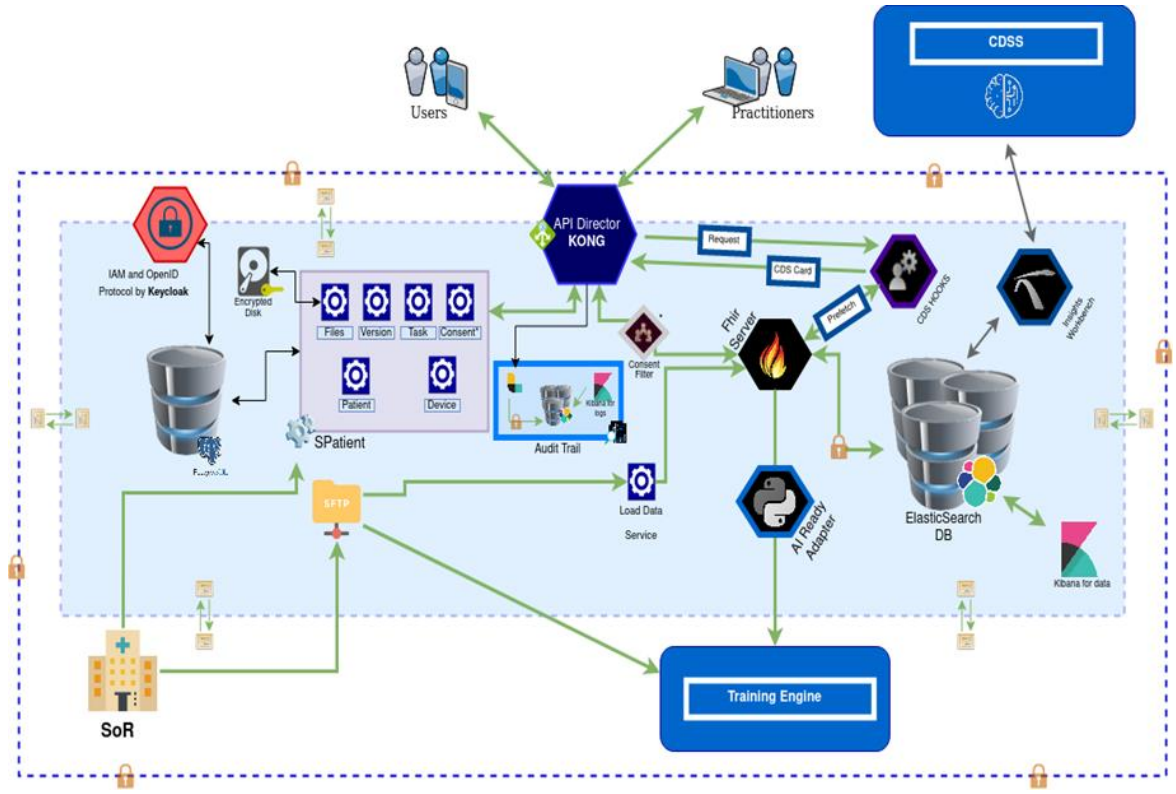

Figure 2 PERSIST solution platform. Representation of the PERSIST solution infrastructure, showing all the components used and their integration with the rest of the systems (internal and external).

ElasticSearch

Elasticsearch is a search engine based on the Lucene library. It provides a distributed, multitenant-capable full-text search engine with an HTTP web interface and schema-free JSON documents.

In order to have more control over the information and to be able to separate clinical data from infrastructure and access tracking data, we decided to set up two clusters with the same characteristics. The only difference will be the access management.

Kibana

Kibana is an open-source data visualisation dashboard for Elasticsearch. It provides visualisation capabilities on top of the content indexed on an Elasticsearch cluster. Users

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can create bar, line and scatter plots, or pie charts and maps on top of large volumes of data.

The deployment provides an anonymized view of the information in order to anticipate possible errors in the tool and to foresee problems with data loading. It also allows us to export follow-up reports on measures or types of data recorded on the platform.

In this way, it is possible to know which regions load the most data into the system, what type of data they record and whether unusual values are being loaded.

Keycloak

Keycloak is an open-source Identity and Access Management solution for modern Applications and Services. All users, roles and other permissions will be managed through this application.

It's the component to manage roles and access based on specific user attributes. In addition, this application allows us to create different clients to manage access from different applications and to assign different attributes to users depending on the client used.

Kong as API Director

Kong is a cloud-native, fast, scalable, and distributed Microservice Abstraction Layer (also known as an API Gateway or API Middleware).

FHIR Server and Consent Filter

The **DC4H FHIR** Server provides an open, industry-standard method for accessing the integrated record. It implements an industry-standard data access layer for client applications to read, update and delete records and avoids proprietary interfaces. It is an open RESTful API implementation of HL7 FHIR format.

This service is not exposed to the internet, and the access requires a valid access token obtained from Keycloak.

Insights Workbench

The **Insights Workbench** generates actionable insights and alerts from automated workflows that monitor real-time data in the integrated record. It allows health organisations to establish monitored pathways which flag alerts when intervention or prevention is necessary. It coordinates workflow through support for CDS-Hooks and FHIR, and it allows users to describe pathways using the open industry BPMN modelling notation.

CDS Hooks

CDS Hooks allows connecting our system with clinical decision support (CDS) systems using an open industry interfacing standard. Clinical Decision Support systems allow decisions to be made and new insights discovered based on real-time data. CDS-hooks allow passing data to clinical decision tools and retrieving back recommendations for clinical actions without interrupting workflows. The CDS Hooks server publishes a REST API, based on the CDS Hooks 1.0 specification, and acts as a proxy that routes requests from the CDS clients to the corresponding CDS service, ensuring that both requests and responses conform to the format defined in the specification.

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Following, there is a diagram which describes the dataflow for a request through CDS-Hooks:

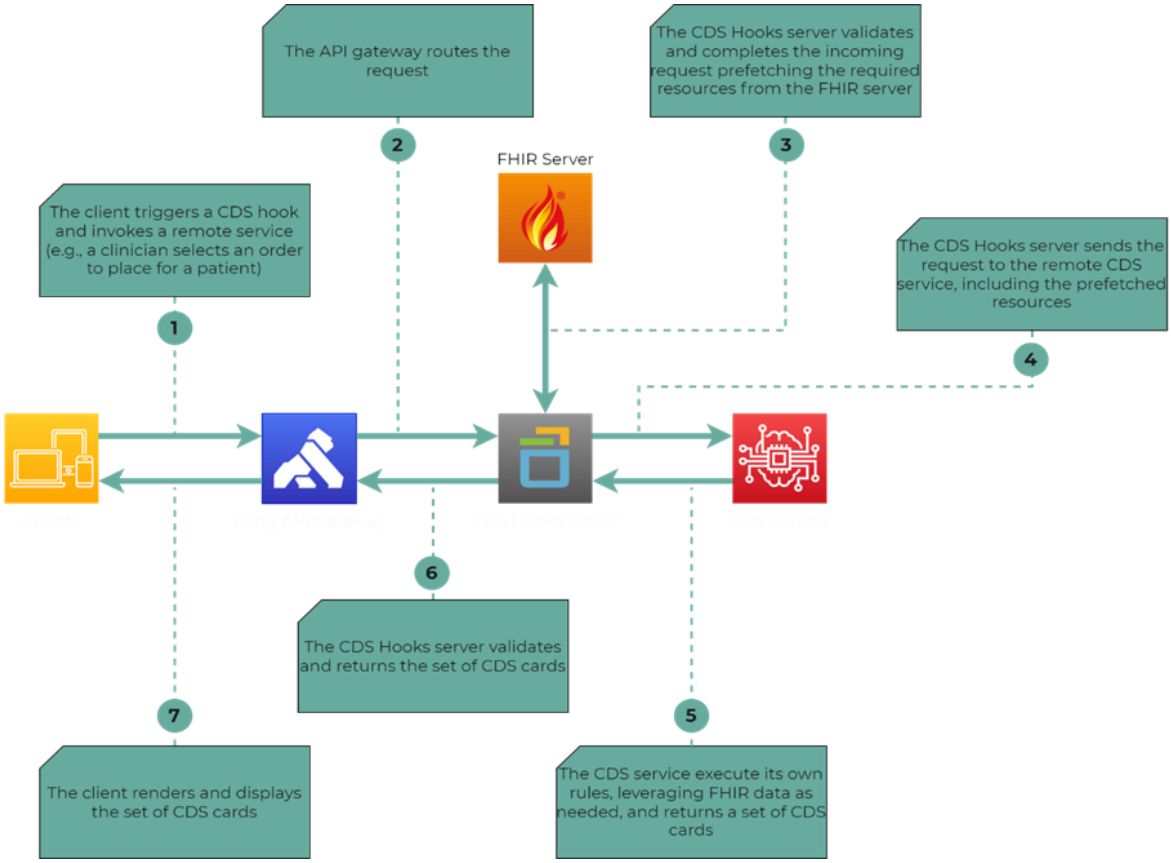

Figure 3 CDS Hook request flow. Diagram representing the flow of information through CDS Hooks after receiving a request.

AI Ready Service

The **AI-Ready** adapter is a pluggable module allowing the system to interoperate with upstream artificial intelligence and machine learning platforms. It allows data from the integrated records to be extracted and optimised for consumption by AI and BI platforms. It supports field and record level encryption allowing data to be obfuscated before being shared with external partners. It honours patient preferences by applying consent permissions to the extract. It flags the presence of patient identifiable data within unstructured text so it can be filtered out.

Currently, supported data sources are:

- ➔ Input connectors: ElasticSearch.
- ➔ Output connectors: ElasticSearch, CSV.

The next diagram shows how this module interacts:

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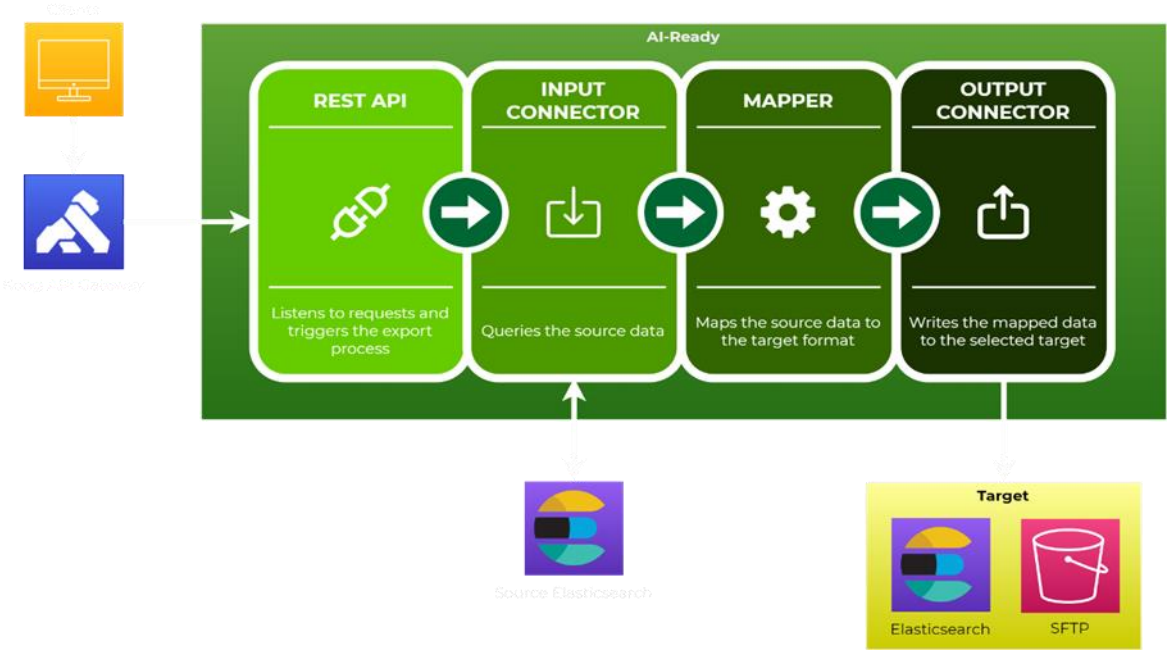

Figure 4 AI Ready Service interactions.

SFTP

A **SFTP** has been deployed as a docker image on development and production servers. Named users and several directories have been created and assigned to each organisation.

Each user only has access to their organisation's directory using SSL certificate. The users cannot read or write anything to another directory.

The main objective of this component was to have an accessible and shared place to upload configuration files or for professionals to work within the platform and share information with each other.

SPatient

SPatient (Solution for patients) is an application developed by Dedalus on Spring Boot and that is made up of several microservices that offer the functionalities required by the project:

- Access certificates.
- Create Patient.
- Register Device.
- Consent.
- Files.
- Scheduler.
- Versioning.

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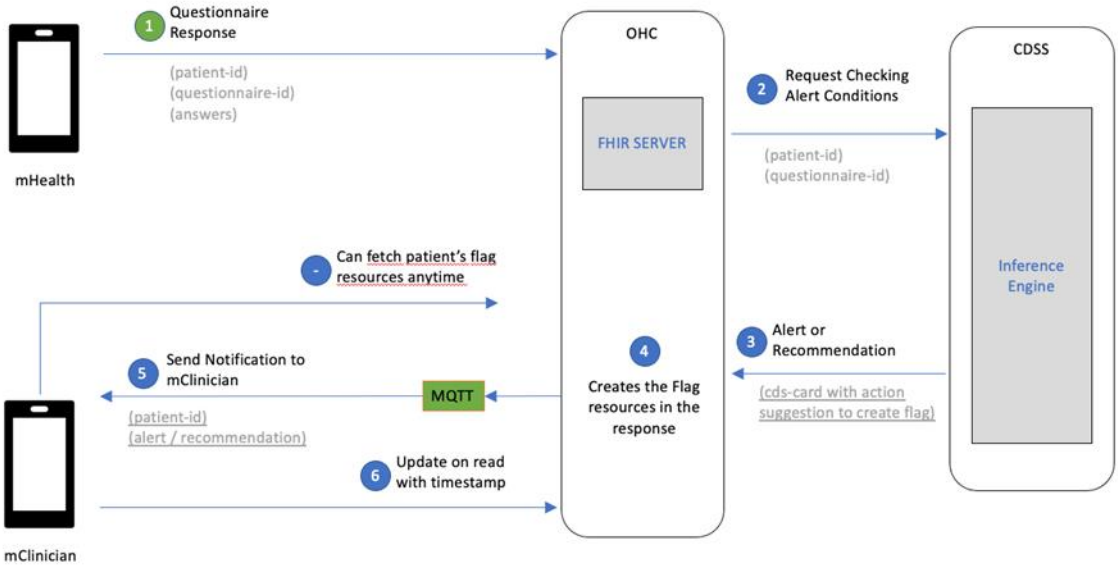

Figure 5 Scheduler. Flowchart representing the logic implemented in the task scheduler service.

More information can be found in D3.3, where the platform is widely described.

mHealth Application

The mHealth application is a mobile app designed for use by patients, with features that support their overall health and wellbeing. The app has several functional and non-functional requirements to enhance the user experience and improve its functionality. Detailed explanation of mHealth application can be found in deliverable **D4.5. Full version of PERSIST mHealth Application.**

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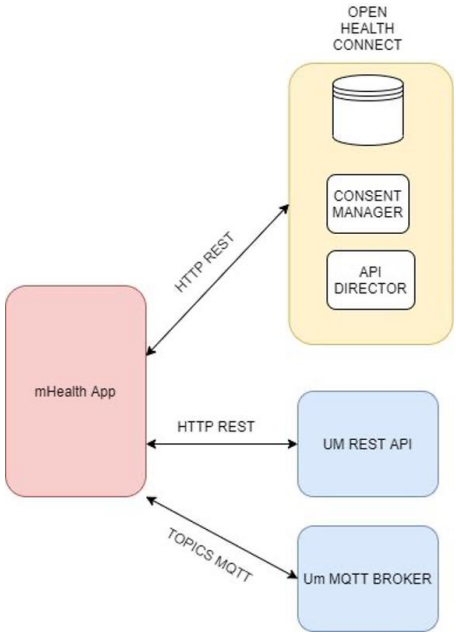

Figure 6 General structure of mHealth App functionality.

The app provides an intuitive interface for users to manage their health and treatment. Users can select their preferred language from a list of available options and register their mobile device by linking it to their patient account using a provided patient ID and code. The registration process ensures security by requiring the user to set a password, receive a certificate from the server to establish secure two-way SSL connections, and log in securely. In the event of password or device loss, the app also supports re-registration.

Once registered, users can accept consent forms and view their treatment plan, as well as other information related to their health. The app also integrates with a smart band that collects data such as heart rate, blood pressure, activity level, and sleep patterns. The collected data is displayed in a summary form and can be tracked over time. In addition, users can record diary entries in the form of text or video and view appointments, goals, and messages from their clinician.

The app is designed to provide a comprehensive health management experience for users. It prompts users to answer questionnaires and provides access to a knowledge bank related to cancer. To ensure the app remains useful even when running in the background, it can respond to incoming MQTT messages from the server and provide app settings.

The app has been updated to include a new feature, the DCD process, which dynamically changes questions based on the input received from a specific MQTT message. This means that the questions that are asked to the user can change in real-time based on the data received from the server. This feature makes the app more flexible and responsive to the user's needs, providing a personalised experience.

The app also features a virtual agent, which is displayed in specific situations such as when the app is opened for the first time or during the completion of questionnaires. The virtual agent acts as a guide for the user, providing helpful information and instructions on how to use the app. The virtual agent tries to enhance the user's experience by providing a visual and interactive element, to make the app more engaging.

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The app utilises two-way SSL connections and secure authentication for user registration. It has high performance and handles large amounts of data efficiently. The app is also compatible with various mobile devices and operating systems and has the capability to run in the background and respond to incoming MQTT messages. Additionally, the app can be updated easily and have a flexible design to accommodate future updates and new features. The app achieves low power consumption to avoid draining the device battery.

mClinician Application

The developed web app is a client-side app without a dedicated backend. It directly connects to the general-purpose backend services that are provided within the project: Keycloak is used for user authentication and receiving a JWT that authenticates the app to the rest of the services and FHIR server is used for storing data. In addition, the app connects to a custom backend service for user registration and a custom proxy for SYMP API that provides standard coded concepts. FHIR server constitutes the main backend where the bulk of the app's data is stored.

The app is developed using the Flutter UI framework. The main purpose of Flutter is the development of mobile applications and the mHealth app that patients use is also developed with it. Flutter applications can also be compiled into web apps in the form of HTML and JavaScript and can work like any other client-side web app. The choice of using Flutter to develop the web app enabled heavy code reuse between the mHealth mobile app and the mClinician web app as they both deal with the same services and data. During the build step, the client-side app is compiled from Flutter code to HTML and JavaScript, two zip archives are produced for dev and prod and sent to DH, which is deployed to the dedicated hosting area in OVH.

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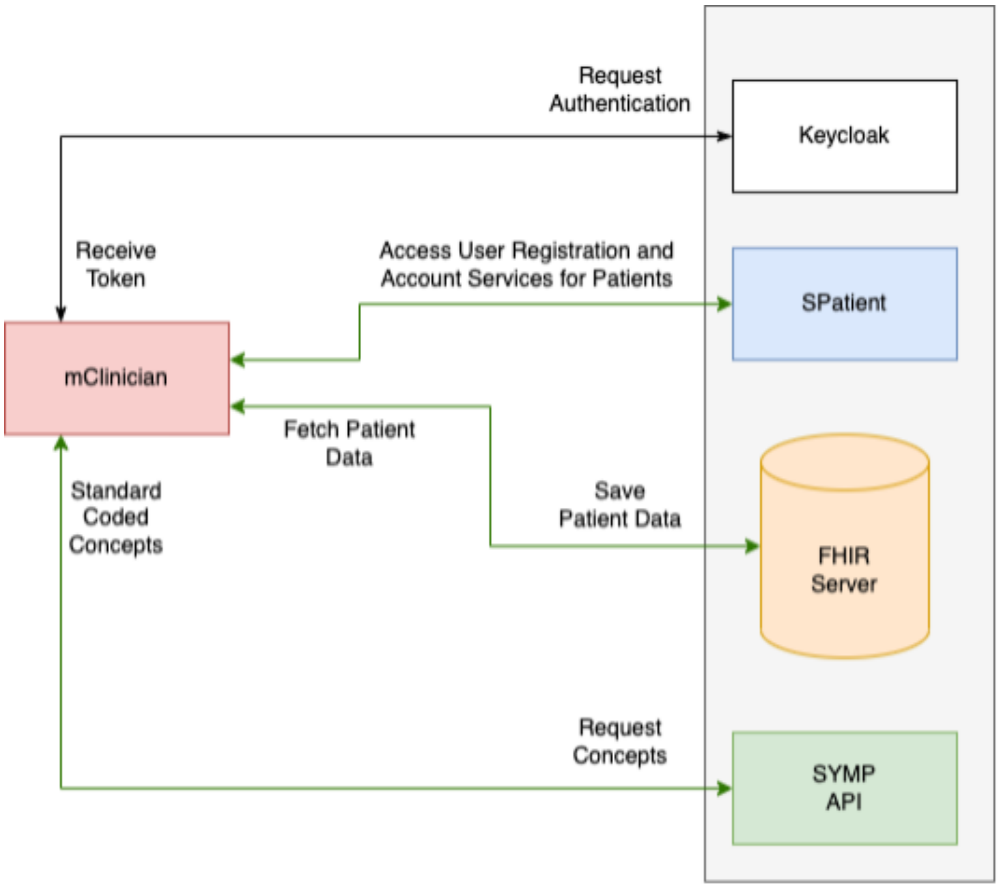

Figure 7 General structure of mCinician App functionality.

The data that the app records include the following that is all represented in the appropriate FHIR records according to the PERSIST FHIR data model. Data fields, which additionally are supported by Symptoma's API to standardize unstructured data to one Ontology. These records are mapped to FHIR resources including Observation, Condition, Encounter, etc. Some records that are displayed as separate concepts in the app are mapped to the same FHIR resource and are differentiated by the values of certain fields of that FHIR resource. For example, Observation FHIR records whose ids are found in the Evidence list field of a Condition record are displayed under the corresponding tumour entry (e.g., histological grade), whereas other Observation records are displayed in general medical history (e.g., weight and height). The EHR records in the app are created and displayed using the user interface elements that are created according to clinicians' requirements and their feedback. The different types of data entry handled by user interface elements (e.g. Item Lists, Nested Records with Lists, Dated Data with Non-Prominent History, Generic Dropdown for FHIR-Compatible Records) are explained in deliverable D5.7.

Components of the Multimodal Sensing Network

The development of the **Multimodal sensing network (MSN)** was explained at different deliverables (D4.2, D4.3, D4.4 and D4.6) throughout the PERSIST project. The D4.2 **(D4.2: Embodied conversational assistant)** describes the implementation of a symmetric model of interaction which targets to improve the quality and sustainability of the collection of patient experiences (PREMs/PROMs) by enabling the natural channels of interaction, i.e., speech and gestures. The goals of D4.2 are to design and implement a wellbeing

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tracking module through PREM and PROM based implementation of chatbot and to design and implement technology to enable generation of multimodal machine outputs represented by an Embodied Conversational Agent. The D4.3 **(D4.3 Alpha version of the sensing network) highlights the technological framework which enables to collect PGHD and Experiences (PREMs/PROMs)** and integrate them into clinical practice. The goals of D4.3 are to deliver a microservice infrastructure to support interoperability between the mHealth App and the clinical IT infrastructure, to deliver microservice supporting data collection from objective and subjective sensors and to deliver a series of ''software'' sensors capturing visual, acoustic, and linguistic features expressed during discourse to further decrease the burden of patient reporting. The D4.4 **(D4.4 Beta version of the sensing network)** defines and describes in detail the software component of the PERSIST Sensing Network, i.e. The Multimodal Risk Assessment and Symptom Tracking (MRAST) framework. The main goal of MRAST is to deliver a novel machine-learning-based framework to recognize individual's risk factors and track disease symptoms by analysing physiological biomarkers, i.e. tumour cells, and by extracting and processing conversational biomarkers, i.e. symptoms of depression and medical concepts as expressed during diary recordings. The D4.6 **(D4.6: Multimodal Sensing Network Final Version)** defines and describes the updates about PERSIST Sensing Network, i.e. the Multimodal Risk Assessment and Symptom Tracking (MRAST) framework which was defined in Deliverable 4.4. D4.6 includes the last technical structures of the depression recognition framework and hand-crafted feature extraction framework; test results of Automated Speech Recognition (ASR), Speech Synthesis (TTS), Embodied Conversational Agent (ECA), Circulating Tumour Cells (CTC), machine learning algorithms and MRAST and the final architecture of the PERSIST Sensing Network.

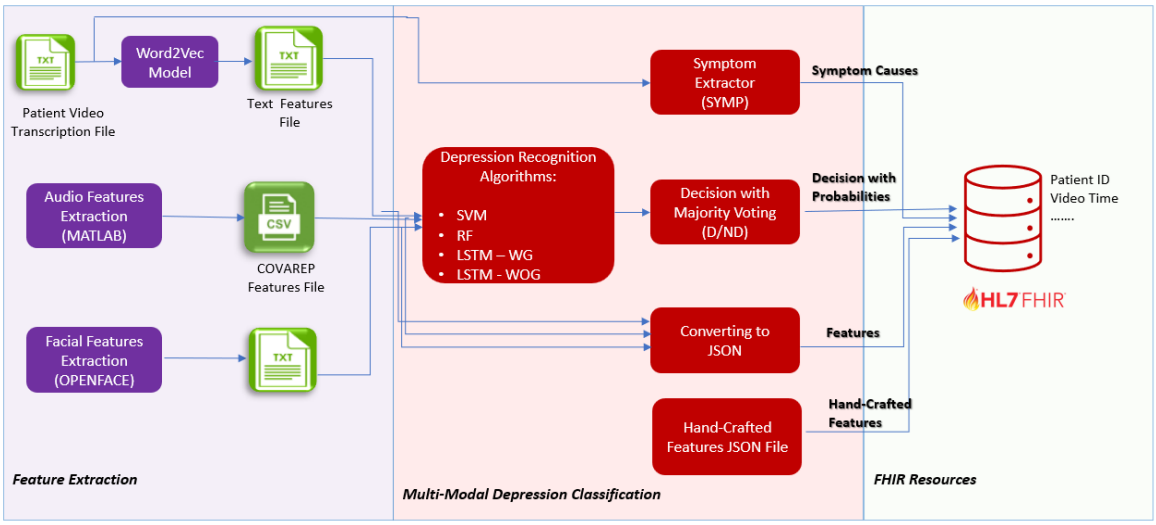

Figure 8 Multimodal Sensing Network's structure.

The final structure of the framework is given in Figure 8. The process starts after getting the patient video as an input. Then, the audio file is extracted from the video and patient transcription is obtained automatically via automatic speech recognition process from the audio file. Also, the audio file is used for audio feature extraction by MATLAB. The process ends with a COVAREP file that includes all audio features. OpenFace library is used for facial features extraction directly from the patient video file. And, the library gives 5 files for different features (action units on face, facial landmarks in 2D and 3D, head pose and eye

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gaze). All feature files are fed into machine learning algorithms (SVM, RF, LSTM with Gating and LSTM without Gating). According to the performance and error metrics, the best algorithm is selected for the decision. After the calculation, all features are stored in json format for the FHIR server.

Symptoma's concept extraction from video diaries has been implemented and tested at UM servers. In the flow, UM extracts the audio from the patient video. That audio is then sent to the automatic speech recognition engine to get the transcription text. Finally, this transcription file is sent to the symptom extractor module to get the possible symptom causes.

Hand-crafted features are implemented for both as complementary features to multi-modal features and to increase the explainability of the results. Observable cues of depressive symptoms (6 language cues, 14 speech cues, and 36 facial expression cues) with artificial intelligence for cancer survivors' depression are defined in D4.4 Deliverable and the information about the technical implementation of above-mentioned observable cues is given with scientific literature references at D4.6 deliverable.

All details of MSN can be found at those deliverables. Here the summary of the last version of each component of MSN will be described with latest results.

Speech Feature Extractor

The aim of this component is to extract the speech features from the audio file (which is extracted from the video file) of the patient by frame energy, CHROMA (octave-warped semitone spectra), CENS features (energy-normalised and smoothed CHROMA), Mel-/Bark-Frequency-Cepstral Coefficients (MFCC) and Perceptual Linear Predictive (PLP) Coefficients. The Munich open-Source Media Interpretation by Large feature-space Extraction (openSMILE) toolkit was used for speech feature extraction in the PERSIST project. The whole pipeline of the extractor, screenshots of the outputs and graphical representation of features were given at **D4.4 Beta version of the sensing network.**

Facial Feature Extractor

The aim of this component is to extract the facial features from the video of the patient by using facial landmarks, head pose tracking, eye gaze tracking and facial action unit recognition. OpenFace library which was originally developed by Tadas Baltrušaitis in collaboration with CMU MultiComp Lab led by Prof. Louis-Philippe Morency was used for facial features extraction in the PERSIST project. We used different combinations of those features to predict the emotional state of the patient. Screenshots of the library, sample images of the face outputs and details of the facial action units can be found at **D4.4 Beta version of the sensing network.**

Text/Language feature extractor

The aim of this component is to extract the language features from the transcription file (which is extracted from the video file by ASR) of the patient by using tokenization, sentence split, lemmatization, dependency parsing and named entity recognition. Natural Language Toolkit (NLTK) which provides easy-to-use interfaces to over 50 corpora and lexical resources such as WordNet, along with a suite of text processing libraries was used for language feature extraction in the PERSIST project. Screenshots of the toolkit, content of the output documents and details about the usage of the toolkit can be found at **D4.4 Beta version of the sensing network.**

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Speech Recognition

The aim of the automated speech recognition (ASR) component is to recognize the transcription of the spoken person via his/her audio file. UM decided to focus on end-to-end Connectionist Temporal Classification (CtC) based models (like the original DeepSpeech model). These models are called end-to-end because they take speech samples and transcripts without any additional information. Some basic information about ASR like development of speech recognition system, speech recognition engine implementation, spelling correction model for end-to-end speech recognition and inference – asr decoder were provided at **D4.3: Alpha version of the sensing network.** On the other hand, the results of training and testing phases for all PERSIST languages (Slovenian, French, English, Latvian, Russian and Spanish) were provided at **D4.6: Multimodal Sensing Network Final Version.**

Mood classifier and condition aware PREM/PROM API

In the mHealth application the patients were provided with the mood wheel where they were able to insert mood how they feel which was collected from them and stored on the FHIR server and available to the clinicians in the mPatient application for better understanding of the patient. PREM/PROM API offered the list of questionnaires on which patients answered when being asked to. PREM/PROM API offered the questionnaires in English, Slovenian, French, Latvian Russian and Spanish. PREM/PROM APIwas running on the top of the Rasa chatbot and was explained in more details in the **D4.2: Embodied conversational assistant.**

Embodied Conversational Agent Service

The aim of the EVA framework was to evoke a social response in human-machine interaction through affective synthetic response generated on arbitrary and unannotated texts. Thus, the EVA behaviour generation model within the EVA framework was data-driven and also driven by the text-to-speech synthesis engine. In the PERSIST project the EVA agent was presented to the patients in the mHealth application while they were answering on the questionnaires and EVA was supported in all languages of the PERSIST project. EVA was presented as a human-like embodied agent that can speak, that is, perform lip synchronisation with the provided audio and make hand gestures beside the speech. Specific deliverable that explains the EVA agent is the **D4.2: Embodied conversational assistant.**

Speech Synthesis

Speech synthesis or text-to-speech (TTS) was the core part to further develop the EVA agent and provide the automatic generation of the arbitrary speech from the text. In the project, with the speech synthesis UM generated the audio files with given text transcription for the EVA agent. The developed TTS engine which runs on the GPUs provided the real-time generation of the speech synthesis for all languages in the PERSIST project. Male and female voices were available for specific language based on the train data that was used to create the flow of the TSS. The **D4.2: Embodied conversational assistant explained the speech synthesis microservice.**

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Chatbot component

Chatbot component was present in the PREM/PROM from the UM side to provide the questionnaires to the patients. Other chatbot component in the project was the one from the SYMPTOMA which was included in the workflow for the DCD where patients received SYMPTOMA questionnaires from the chatbot which was asking patients for any symptoms they did or didn't notice and provided the patient with the information on the possible causes and diseases based on the answers provided from the patients. The chatbot components also supported all PERSIST languages and provided real-time interaction with the patients. Symptoma Chatbot was explained in the **D4.2: Embodied conversational assistant explained the speech synthesis microservice.**

CTC Component

The CTC (Circulating Tumour Cells) component consists of a web application with two main functionalities, whose main objective is to maintain a count of CTCs in liquid biopsy from patients. On the one hand, there is the CTCs monitoring functionality, which allows expert users to keep track of the number of CTCs detected in each patient analysis. On the other hand, there is the automatic CTCs automatic counting functionality. This is implemented by means of a Deep Learning algorithm integrated in a service consumed by the web application itself, and allows CTCs automatic detection in fluorescence microscope images, speeding up and facilitating the manual process. All information related to this component has already been reported under **D4.6: Multimodal Sensing Network final version.**

Components of the Clinical Decision Support System

Cohort and trajectories analysis module

One of the modules of the Clinical Decision Support is the Cohort and Trajectories Analysis (CTA). The goal of the CTA module is to provide predictions and trajectories of a given patient in order to enhance diagnosis, treatment, and prognosis decisions. Moreover, CTA provides a list of feature importance per patient's trajectory, which enriches the set of tools for decision support. CTA is based on statistical and AI-based models, it leverages retrospective and prospective data, enhancing the quality of its predictions. Indeed, in the case of the PERSIST data, the prospective patient population is small and biased. Therefore, CTA (I) learns the embedded model parameters using retrospective data and (II) fine-tunes them using prospective data providing accurate estimations of the patients' trajectories.

Recurrence prediction module

The Recurrence prediction module is a service that allows clinicians to obtain predictions of cancer relapse for their patients. The module uses data, collected by the clinicians via the mClinican app and stored in the FHIR server, to feed the models that calculate these probabilities. It has two components: one is the API, which is used by external components, such as mClinician, to connect to the service and make prediction requests; the second one is the models, which calculate the predictions of relapse. There are two different models, one for breast cancer and one for colon cancer, which use a different subset of the data of the patient in order to calculate the predictions. These models were trained with prospective data of CHU de Liège, as their data was the most comprehensive. The

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specifics of the API and the models have been reported under D5.8: Final version of high risk markers for patient stratification.

EHR Data preparation and Enrichment module

To install Symptoma's analytical toolbox securely and easily onto the PERSIST external server infrastructure, SYMP has developed a container architecture to wrap all required components **(extended details in D5.7).** The first one contains the extraction engine, which is used to find medical concepts in texts, the second container provides a code service to unify codes from different ontologies and the last container contains the main PERSIST EHR application of the enrichment process, which also orchestrates and starts all services, including the creation of statistics to compute the enriched resources.

Inference Engine module

The inference engine module consists of three main parts: the knowledge base, the inference engine and an interface. Knowledge base contains the conditions and relationships of the compiled data in the form of rules that are found in the form of clinical guidelines or generated or updated by clinical experts, as well as cohort and trajectory analysis. These formed rules are developed in the inference engine so they can be executed with current data to create patient-specific outcomes. Inference engine component of a decision support system handles reasoning The rules and relations are processed using inputs from a particular patient data as well as knowledge modules and services. As a result, users, in this case, clinicians and other related system components, are conveniently presented with patient-specific information and knowledge of the patient's current state related to the topic of CDS service.

4. Test cases

The main objective of the PERSIST test plan is the validation of the components of PERSIST Big Data architecture, and the integrations between them after its final release. The proposed test plan follows a dynamic testing approach, in which the programmed code will be validated according to a set of test cases at two levels: integration testing and functional testing. For this purpose, we present the tests included in the test plan designed for each of the components that make up PERSIST.

It is worth mentioning that in the case of the **DC4H platform**, no tests of any of the defined types have been defined, as this is already a commercial product, developed outside the framework of the PERSIST project, and has therefore already been tested prior to its launch on the market.

Functional Testing

mHealth Application

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Table 2 mHealth Application functional tests.

Test case ID	Test case name	Description
mHealth_FT-1	Correct first time login on a device of an authorised user.	A user registered as a Patient is successfully authenticated in the mHealth mobile application for the first time to define a permanent password.
mHealth_FT-2	Correct login of an authorised user.	A user registered as a Patient and logged in and defined a permanent password is successfully authenticated in the mHealth mobile application.
mHealth_FT-3	First time connecting to a smartband.	An already authenticated user opens the application smartband settings screen and successfully connects to selected smartband.
mHealth_FT-4	Automatically connects to a previously connected smartband.	A previously authenticated user launches the application and the previously connected smartband is turned on and close to the mobile phone automatically connects phone and device.
mHealth_FT-5	Successfully saving an application setting to device application storage.	An authenticated user changes an application settings (e.g. Language, manual input option)
mHealth_FT-6	Successfully sending FHIR resource to server for storing.	An authenticated user opens the application to sync measurements from smartband, report emotions or upload a diary recording.
mHealth_FT-7	Successfully fetching FHIR resource to display to user.	An authenticated user opens the application and navigates to a screen that displays data from the server.
mHealth_FT-8	Successfully start listening notifications by setting up MQTT Connection and subscriptions.	A user successfully logins or an already authenticated user opens the application.

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mClinician Application

Table 3 mClinician Application functional tests

Test case ID	Test case name	Description
mClinician_FT-1	Correct login on a device of an authorised user.	A user registered as a Clinician is successfully authenticated in the mClinician mobile application and can access application features.
mClinician_FT-2	Successfully sending FHIR resource to server for storing	An authenticated user opens the application to sync measurements from smartband, report emotions or upload a diary recording.
mClinician_FT-3	Successfully fetching FHIR resource to display to user	An authenticated user opens the application and navigates to a screen that displays data from the server.
mClinician_FT-4	Successfully start listening notifications by setting up MQTT Connection and subscriptions.	A user successfuly logins or an already authenticated user opens the application.
mClinician_FT-5	Successfully exporting usage stats in CSV format	An authenticated user opens the application and navigates to the usage stats screen then exports displayed data in CSV format to download it to the device.

Components of the Multimodal Sensing Network

Speech Feature Extractor

Table 4 Speech Feature Extractor (SFE) functional tests.

Test case ID	Test case name	Description
SFE_FT-1	Successful extraction of audio file.	The audio file is extracted from the patient's video file.

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SFE_FT-2	Obtaining speech features.	Audio file is used as an input to MATLAB Covarep function to get all the required speech features.

Facial Feature Extractor

Table 5 Facial Feature Extractor (FFE) functional tests

Test case ID	Test case name	Description
FFE_FT-1	Face Detection.	The face of the patients is detected frame by frame searching for face locations.
FFE_FT-2	Obtaining facial features.	All facial features are extracted from OPENFACE library as five different files.

Text/Language Feature Extractor

Table 6 Text/Language Feature Extractor (TFE) functional tests.

Test case ID	Test case name	Description
TFE_FT-1	Successful extraction of audio file.	The audio file is extracted from the patient's video file.
TFE_FT-2	Obtaining full transcription of patient.	Extracting the transcription and checking the content of the output.
TFE_FT-3	Obtaining text/language features.	Transcription file (txt) is used as an input to NLTK toolkit to get all the required text/language features.

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Speech Recognition

Table 7 Speech Recognition functional tests.

Test case ID	Test case name	Description
ASR_FT-1	Speech recognition.	This test is performing the transformation of the audio to the text.

Mood classifier and condition aware PREM/PROM API

Table 8 Mood classifier and condition aware PREM/PROM API functional tests

Test case ID	Test case name	Description
PREMPROM_FT-1	PREM/PROM API for questionnaires.	UM Swagger REST API with Rasa chatbot to offer questionnaires to the patients.

Embodied Conversational Agent Service

Table 9 Embodied Conversational Agent (ECA) Service functional tests.

Test case ID	Test case name	Description
ECA_FT-1	ECA EVA agent welcome video.	This test shows virtual agent video inside the mHealth application once the user is starting the app.
ECA_FT-2	ECA EVA agent questionnaire videos.	This test shows virtual agent videos asking the questions from the questionnaire and finalises by showing the ECA video.

Chatbot component

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Table 10 Chatbot component functional tests.

Test case ID	Test case name	Description
CHATBOT_FT-1	CHATBOT for DCD questionnaire.	This test offers patient questionnaires that are triggered by the mHealth application after the analysis of collected causes and diseases from the SYMPTOMA based on the video diaries.

CTC Component

Table 11 CTC component functional tests.

Test case ID	Test case name	Description
CTC_FT-1	Successful login of an authorised user.	The CTCs web application successfully authenticates a user who has enabled access to the CTCs data.
CTC_FT-2	Incorrect login of an unauthorised user.	A user with non-enabled access to CTC data cannot access the CTCs web application.
CTC_FT-3	List of CTC reports for a registered patient.	A user accesses CTC reports relating to a patient registered on the FHIR server.
CTC_FT-4	Error trying to list CTC reports for an unregistered patient.	A user tries to access CTC reports for a patient who is not registered on the FHIR server.
CTC_FT-5	Adding button function.	The adding button (+ icon) correctly changes to the "create a new report" screen.
CTC_FT-6	Fill in the fields of the form to create a new CTCs report.	All fields can be filled in when creating a new CTC report.

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CTC_FT-7	New CTCs report creation.	The CTCs web application correctly sends a report information to the FHIR server when the user clicks on the "save" button.
CTC_FT-8	Edit an existing CTCs report.	An user can edit an existing CTCs report by changing some of the values in the form.
CTC_FT-9	Viewing a PDF report.	The application is able to retrieve from the FHIR server the information related to an attached PDF and allows users to download it by clicking on its name.
CTC_FT-10	Cancel an existing report edition.	An user can cancel the edition of an existing CTC report by clicking on the "cancel" button in the "edit an existing report" screen.
CTC_FT-11	Delete an existing CTCs report.	An user can delete an existing CTCs report from the FHIR server.
CTC_FT-12	Cancel an existing report deletion.	An user can cancel the deletion of an existing CTC report by clicking on the "cancel" button in the delete confirmation pop-up window.
CTC_FT-13	Menu button function.	The top right button (menu) correctly displays a drop-down menu.
CTC_FT-14	Successful automatic prediction screen access.	The "automatic CTCs prediction" option of the drop-down menu displays the automatic prediction screen.
CTC_FT-15	Successful sending of a microscope image to the automatic prediction service.	An user is able to send an image from the file system to the CTCs automatic prediction system.
CTC_FT-16	Error when trying to send no images to the CTCs prediction service.	The CTCs application does not allow sending a request to the automatic prediction service without having uploaded any image.

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CTC_FT-17	Cancel sending a microscope image to the automatic prediction service.	An user can cancel the upload of an image to the CTCs prediction service by clicking on the "cancel" button in the automatic CTC prediction screen.
CTC_FT-18	Successful prediction retrievement screen access.	The "prediction retrievement" option of the drop-down menu displays the prediction retrievement screen.
CTC_FT-19	Successful retrieval of a microscope image's CTCs prediction.	The CTCs web application correctly displays the CTCs automatic prediction service results to the user.
CTC_FT-20	Successful deletion of a predicted CTC from the user interface.	The CTCs web application allows users to delete a predicted CTC from the user interface by clicking on the "delete" button (bin icon) displayed next to the prediction results.
CTC_FT-21	Error trying to list CTC predictions for a non-existent prediction identifier.	A user tries to access CTC prediction for an identifier that has not been returned by the automatic prediction service.
CTC_FT-22	Cancel sending a prediction identifier to the automatic prediction service.	An user can cancel the request of a prediction to the CTCs prediction service by clicking on the "cancel" button in the prediction retrieval screen.
CTC_FT-23	Correct user's logout.	The "exit" option of the drop-down menu logs out the user from the CTCs web application.

Components of the Clinical Decision Support System

Cohort and trajectories analysis module

Table 12 Cohort and trajectories analysis (CTA) module functional tests.

Test case ID	Test case name	Description

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CTA_FT-1	Survival Probability Service: Correct survival probability for colon cancer patients grouped by staging	A user or service makes a well-formed survival probability request to the Survival Probability service for Colon Cancer patients and obtains as a response a JSON allowing to draw the survival probability graph.
CTA_FT-2	Survival probability Service: Correct survival probability for breast cancer patients grouped by staging	A user or service makes a well-formed survival probability request to the Survival Probability service for Breast Cancer patients and obtains as a response a JSON allowing to draw the survival probability graph.
CTA_FT-3	Survival probability service: wrong cancer type	A user or service makes a survival probability request to the Survival Probability service for an erroneous Cancer type and obtains as a response a bad request error.
CTA_FT-4	CPH Service: Correct cph for colon cancer patient	A user or service makes a well-formed request to the CPH service for Colon Cancer patient and obtains as a response a JSON allowing to draw the CPH graph.
CTA_FT-5	CPH Service: Correct cph for breast cancer patient	A user or service makes a well-formed request to the CPH service for Breast Cancer patient and obtains as a response a JSON allowing to draw the CPH graph.
CTA_FT-6	CPH Service: wrong patient ID	A user or service makes a well-formed request to the CPH service for a patient that does not exists and obtains as a response a valid JSON without data
CTA_FT-7	CPH Influence Service: Correct CPH influence for colon cancer patient	A user or service makes a well-formed request to the CPH influence service for Colon Cancer patients and obtains as a response a JSON allowing to plot the influence of each feature on the CPH trajectory.
CTA_FT-8	CPH Influence Service: Correct CPH influence for breast cancer patient	A user or service makes a well-formed request to the CPH influence service for Breast Cancer patients and obtains as a response a JSON allowing to plot the influence of each feature on the CPH trajectory.
CTA_FT-9	CPH Influence Service: wrong cancer type	A user or service makes a well-formed request to the CPH Inflience service for an erroneous Cancer type and obtains as a response a bad request error.

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CTA_FT-10	Risk Service: Correct Risk for colon cancer patient	A user or service makes a well-formed request to the Risk service for colon cancer patients and obtains as a response a json allowing to draw the different graphs
CTA_FT-11	Risk Service: Correct Risk for breast cancer patient	A user or service makes a well-formed request to the Risk service for breast cancer patients and obtains as a response a json allowing to draw the different graphs
CTA_FT-12	Risk Service: wrong cancer type	A user or service makes a well-formed request to the Risk service for an erroneous Cancer type and obtains as a response a bad request error.
CTA_FT-13	Survival Probability Service: missing or no valid authorisation token	An user or service makes a request on Survival Probability Service without a valid authorisation token that results in an unauthorised error.
CTA_FT-14	CPH service: missing or no valid authorisation token	An user or service makes a request on CPH Service without a valid authorisation token that results in an unauthorised error.
CTA_FT-15	CPH Influence Service: missing or no valid authorisation token	An user or service makes a request on CPH Influence Service without a valid authorisation token that results in an unauthorised error.
CTA_FT-16	Risk Service: missing or no valid authorisation token	An user or service makes a request on Risk Service without a valid authorisation token that results in an unauthorised error.

Recurrence prediction module

Table 13 Recurrence prediction module functional tests.

Test case ID	Test case name	Description
RP_FT-1	Recurrence Prediction service: Correct recurrence prediction for a Colon Cancer patient	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Colon Cancer patient that has all necessary data and obtains as a response a JSON with the recurrence prediction value.

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RP_FT-2	Recurrence Prediction service: Correct recurrence prediction for a Breast Cancer patient	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Breast Cancer patient that has all necessary data and obtains as a response a JSON with the recurrence prediction value.
RP_FT-3	Recurrence Prediction service: Missing data for a Colon Cancer patient	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Colon Cancer patient that is missing necessary data and obtains as a response an error message explaining what data is missing.
RP_FT-4	Recurrence Prediction service: Missing data for a Breast Cancer patient	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Breast Cancer patient that is missing necessary data and obtains as a response an error message explaining what data is missing.
RP_FT-5	Recurrence Prediction service: Incorrect patient	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a patient ID that does not exist and obtains as a response an error message explaining that the patient does not exist.
RP_FT-6	Recurrence Prediction service: Incorrect petition	An user or service makes a recurrence prediction request to the Recurrence Prediction service with an incorrect body and obtains as a response an error message explaining that the petition is incorrect.
RP_FT-7	Recurrence Prediction service: missing or no valid authorisation token	An user or service makes a recurrence prediction request without a valid authorisation token and obtains as a response an error explaining that it is not authorised.

EHR Data preparation and Enrichment module

Table 14 EHR Data preparation and Enrichment module functional tests.

Test case ID	Test case name	Description

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EHR-DP&EM_FT-1	EHR Data preparation and enrichment module service: successful authentication.	The PERSIST EHR application successfully authenticates an authorised user to run the service.
EHR-DP&EM_FT-2	EHR Data preparation and enrichment module service: reject invalid credentials.	The PERSIST EHR application successfully identifies an unauthorised user and blocks access.
EHR-DP&EM_FT-3	EHR Data preparation and enrichment module service: verification of containers.	A user verifies that all related containers are active.
EHR-DP&EM_FT-4	EHR Data preparation and enrichment module service: verification of manual start.	A user manually starts the PERSIST EHR application to generate an enriched FHIR dataset.
EHR-DP&EM_FT-5	EHR Data preparation and enrichment module service: review of log file.	Study the log file for inconsistencies.
EHR-DP&EM_FT-6	EHR Data preparation and enrichment module service: Review of CVS files of example resources.	Study output files for inconsistencies and examples.
EHR-DP&EM_FT-7	EHR Data preparation and enrichment module service: Request of example resources by ID.	The PERSIST EHR application correctly sends a resource example by ID.
EHR-DP&EM_FT-8	EHR Data preparation and enrichment module service: verification of annotations in the FHIR data.	A user can verify an existing FHIR enriched data in the application.

Inference Engine module

Table 15 Inference Engine module functional tests.

Test case ID	Test case name	Description

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Inference_Engine_FT-1	Successfully request an inference via inference engine API	A request sent to the inference engine api successfully responded with CDS Card results defined in CDS Hooks documentation.
Inference_Engine_FT-2	Successfully request a risk assessment.	A request sent to the inference engine api successfully responded with non-empty CDS Card results defined in CDS Hooks documentation.
Inference_Engine_FT-3	Successfully request an alert assessment resulting in alert condition.	A request sent to the inference engine api successfully responded with non-empty CDS Card with an action defined in CDS Hooks documentation.
Inference_Engine_FT-4	Successfully request an alert assessment not resulting in alert condition.	A request sent to the inference engine api successfully responded with an empty CDS Card defined in CDS Hooks documentation.

System Testing

mHealth Application

Table 16 mHealth Application system tests.

Test case ID	Test case name	Description
mHealth_ST-1	Successful first time login.	A registered user with first login credentials has already been given enters information and logins to create password.
mHealth_ST-2	Successful login with created password.	A registered user with login credentials is already given enters information and logins with the password created previously on first login.
mHealth_ST-3	Smartband synchronisation.	A logged in user synchronises smart band data.
mHealth_ST-4	Manual vital data input.	A logged in user manually inputs vital data.

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mHealth_ST-5	Emotion report.	A logged in user reports Emotion.
mHealth_ST-6	Switch to Detail tab.	A logged in user switches to detail tab to navigate in details menu.
mHealth_ST-7	Navigating through Detail menu.	A logged in user switches to detail tab to navigate in details menu.
mHealth_ST-8	Display notifications.	A logged in user sees all notifications.
mHealth_ST-9	Display settings.	A logged in user accesses settings menu.
mHealth_ST-10	Change Language.	A logged in user accesses settings menu and changes language.
mHealth_ST-11	Successful Diary Recording.	A logged in user records diary.
mHealth_ST-12	Answer Questionnaire.	A logged in user answers a questionnaire.

mClinician Application

Table 17 mClinician Application system tests.

Test case ID	Test case name	Description

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mClinician_ST-1	Navigating through the application.	A logged in user taps on navigation buttons on main menu and interior menus.

Multimodal Sensing Network

Table 18 Multimodal Sensing Network system tests.

Test case ID	Test case name	Description
MSN_ST-1	MSN flow user testing - Multimodal Sensing Network flow to process the diary videos.	This test includes the whole pipeline for diary videos from getting an access token to storing the results to the server.

CTC Component

Table 19 CTC component system tests

Test case ID	Test case name	Description
CTC_ST-1	CTCs report management.	A CTC counting system's user manages a patient's reports. In this management the user adds, modifies and deletes reports from the system.
CTC_ST-2	Automatic counting of CTCs in fluorescence microscope images.	A CTC counting system's user uses the system's automatic counting to analyse a microscope image.

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5. Test results

Functional Testing

mHealth Application

Table 20 mHealth Application functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
mHealth_ FT-1	Correct first time login on a device of an authorised user.	**N = 2**	**A user registered as a Patient is successfully authenticated in the mHealth mobile application for the first time to define a permanent password.**	-	Passed	01/09/2022	The system should return an access token. The user should access the permanent password form.	The system checked the user and password and returned an access token. The user can access the permanent password form.
		1	mHealth mobile application sends a HTTP POST request to the FHIR server to obtain an access token for a user with enabled access to read/write user's	User has been previously registered and persist id and one-time password is generated.	Passed	01/09/2022	The FHIR server should return an *HTTP 200* response with a valid access token for the user.	The FHIR server returned an *HTTP 200* response with a valid access token for that user.

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			own data					
		2	The access token is verified and permanent password form is displayed.	The FHIR server has returned an HTTP 200 response with a valid access token for that user.	Passed	01/09/2022	Should display permanent password form	The application popped a dialog displaying permanent password form
mHealth_FT-2	Correct login of an authorised user.	**N = 2**	**A user registered as a Patient and logged in and defined a permanent password is successfully authenticated in the mHealth mobile application.**	-	Passed	01/09/2022	The system should return an access token the user should be directed to home screen	The server returned an access token. The user directed to the home screen.
		1	mHealth mobile application sends a HTTP POST request to the FHIR server to obtain an access token for a user with enabled access to read/write user's own data	User has been previously registered set permanent password	Passed	01/09/2022	The FHIR server should return an HTTP 200 response with a valid access token for that user.	The FHIR server returned an HTTP 200 response with a valid access token for that user.

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		2	The access token is verified and access and refresh token is stored in application storage.	The FHIR server has returned an HTTP 200 response with a valid access token for that user.	Passed	01/09/2022	The token information should be stored in application storage for future use.	The token is checked for correctness and the token information is stored and accessible in application storage.
		3	User home screen is displayed.	-	Passed	01/09/2022	User home screen should be displayed	The application switched to the next screen: user home.
mHealth_ FT-3	First time connecting to a smartband.	**N=4**	**An already authenticated user opens the application smartband settings screen successfully connects to the selected smartband.**	-	Passed	08/09/2022	The smartband connection should be established	The smartband connection is established
		1	The app starts scanning nearby devices and the results are displayed in the application.	The bluetooth is enabled on the phone and the smartband is turned on.	Passed	08/09/2022	Found device ids should be listed as interactable buttons	Found device ids are listed as interactive buttons
		2	User taps on one of the listed devices to select for connecting. Selected device id is use to establish a	Smartband to connect is near the phone.	Passed	08/09/2022	Application should start the connection process.	Application starts the connection process.

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			bluetooth connection.					
		4	Device is connected and device id is saved to application storage and the user is informed.		Passed	08/09/2022	Application should connect to the smartband, the connection is displayed as successful.	Application connects to the smartband, the connection is displayed as successful.
mHealth_ FT-4	Automatically connects to a previously connected smartband	**N=2**	**A previously authenticated user launches the application and the previously connected smartbands is turned on and close to the mobile phone automatically connects phone and device.**	User is authenticated previously by logging in. Connected to a smartband successfully before.	Passed	17/09/2022	The smartband connection should be established automatically on launching the application	The smartband connection is established automatically on launching the application
		1	The device id is fetched from the application storage.	The bluetooth is enabled on the phone and the last connected smartband is turned on.	Passed	17/09/2022	The app should get device id information to be used.	Get device id information to be used.
		2	Bluetooth connection is established using the fetched device	Last connected smartband is near the phone.	Passed	17/09/2022	Application should connect to the smartband and	Application connects to the smartband and

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			and the user is informed, the app continues launching.				continue launching.	continues launching.
mHealth_ FT-5	Successfully saving an application setting to device application storage	**N=2**	**An authenticated user changes an application settings (e.g. Language, manual input option)**	User is authenticated previously by logging in.	Passed	17/09/2022	Changed settings should be saved and remembered on future launches.	Changed settings are saved and remembered on future launches.
		1	User navigate to an application setting to change.	-	Passed	17/09/2022	The app should show an interactable interface element to change the setting.	Show an interactable interface element to change the setting.
		2	Changed preference is saved to application local storage and fetched on future launches.	-	Passed	17/09/2022	The setting should be saved and should be retrievable from the storage	The setting is save and retrievable from the storage
mHealth_ FT-6	Successfully sending FHIR resource to server for storing	**N=4**	**An authenticated user opens the application to sync measurements from smartband, report emotions or upload a diary recording.**	-	Passed	17/09/2022	Sent resources should be stored in the FHIR Server	Sent resources are stored in the FHIR Server
		1	The user is informed in the interface that a save process is started.	-	Passed	17/09/2022	Should display an ui element to show progressing	Progress ui element is shown

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		2	mHealth mobile application creates the corresponding FHIR resource for the data to be saved in JSON format and sends a HTTP POST request to the FHIR server to save the created resource.	-	Passed	17/09/2022	The FHIR server should return an *HTTP 201 Created* response with the created resource.	The FHIR server returns an *HTTP 201 Created* response with the created resource.
		3	The user is informed about the completion of the save process.	-	Passed	17/09/2022	Should hide the ui element that showing progress	Progress ui element is hidden and completion message is shown.
mHealth_ FT-7	Successfully fetching FHIR resource to display to user		**An authenticated user opens the application and navigates to a screen that displays data from the server.**	-	Passed	17/09/2022	Requested resources should be fetched successfully and displayed in the interface	Requested resources are fetched successfully and displayed in the interface
			The application sends a HTTP GET request to the FHIR server to query the required resource.	-	Passed	17/09/2022	The FHIR server should return an HTTP 200 response with requested resource in JSON format located in the response body.	The FHIR server returns an HTTP 200 response with requested resource in JSON format located in the response body.

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			The response in JSON format is parsed to models and displayed in the interface.	The FHIR server has returned an HTTP 200 response with a valid resource for the query.	Passed	17/09/2022	The requested data should be displayed in the interface.	The requested data should be displayed in the interface.
mHealth_ FT-8	Successfully start listening notifications by setting up MQTT Connection and subscriptions.		**A user successfully logins or an already authenticated user opens the application.**	-	Passed	17/09/2022	The MQTT server connection should be established and the application should work as a MQTT client and subscribe to predefined channels and receive notifications.	The MQTT server connection is established and the application can work as a MQTT client and subscribes predefined channels and receive notifications.
			mHealth application sends required credentials to connect to MQTT server as a MQTT client	-	Passed	17/09/2022	The MQTT server should return successful MQTT connection state	The MQTT server returns successful MQTT connection state
			mHealth application subscribes to its relevant channels	The MQTT server connected and application can be used as MQTT client	Passed	17/09/2022	MQTT client should start listening the channels an able to receive a triggered notification	MQTT client starts listening the channels an able to receive a triggered notification

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mClinician Application

Table 21 mClinician Application functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
mClinician_FT-1	Correct login on a device of an authorised user.	**N = 2**	**A user registered as a Clinician is successfully authenticated in the mClinician mobile application and can access application features.**	-	Passed	1/09/2022	The system should return an access token. The user should access the main navigation screen.	The system checked the user and password and returned an access token. The user can access the permanent password form.
		1	mClinician mobile application sends a HTTP POST request to the FHIR server to obtain an access token for a user with enabled access to read/write user's own data	User has been previously registered and persist id and password is generated.	Passed	1/09/2022	The FHIR server should return an *HTTP 200* response with a valid access token for the user.	The FHIR server returned an *HTTP 200* response with a valid access token for that user.
		2	The access token is verified and the permanent app main navigation screen is displayed.	The FHIR server has returned an HTTP 200 response with a valid access token for that user.	Passed	1/09/2022	Should display main navigation screen	The application popped a dialog displaying main navigation screen

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mClinician_FT-2	Successfully sending FHIR resource to server for storing	**N=4**	**An authenticated user opens the application to sync measurements from smartband, report emotions or upload a diary recording.**		Passed	1/09/2022	Sent resources should be stored in the FHIR Server	Sent resources are stored in the FHIR Server
		1	The user is informed in the interface that a save process is started.		Passed	1/09/2022	Should display an ui element to show progressing	Progress ui element is shown
		2	mClinician mobile application creates the corresponding FHIR resource for the data to be saved in JSON format and sends a HTTP POST request to the FHIR server to save the created resource.		Passed	1/09/2022	The FHIR server should return an *HTTP 201 Created* response with the created resource.	The FHIR server returns an *HTTP 201 Created* response with the created resource.
		3	The user is informed about the completion of the save process.		Passed	1/09/2022	Should hide the ui element that showing progress	Progress ui element is hidden and completion message is shown.
mClinician_FT-3	Successfully fetching FHIR resource to display to user	**N = 2**	**An authenticated user opens the application and navigates to a screen that displays data from the server.**		Passed	1/09/2022	Requested resources should be fetched successfully and displayed in the interface	Requested resources are fetched successfully and displayed in the interface

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		1	The application sends a HTTP GET request to the FHIR server to query the required resource.		Passed	1/09/2022	The FHIR server should return an HTTP 200 response with requested resource in JSON format located in the response body.	The FHIR server returns an HTTP 200 response with requested resource in JSON format located in the response body.
		2	The response in JSON format is parsed to models and displayed in the interface.	The FHIR server has returned an HTTP 200 response with a valid resource for the query.	Passed	1/09/2022	The requested data should be displayed in the interface.	The requested data should be displayed in the interface.
mClinician_FT-4	Successfully start listening notifications by setting up MQTT Connection and subscriptions.	**N = 2**	**A user successfully logins or an already authenticated user opens the application.**		Passed	1/09/2022	The MQTT server connection should be established and the application should work as a MQTT client and subscribe to predefined channels and receive notifications.	The MQTT server connection is established and the application can work as a MQTT client and subscribes predefined channels and receive notifications.
		1	mClinician application sends required credentials to connect to MQTT server as a MQTT client		Passed	1/09/2022	The MQTT server should return successful MQTT connection state	The MQTT server returns successful MQTT connection state

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		2	mClinician application subscribes to its relevant channels	The MQTT server connected and application can be used as MQTT client	Passed	1/09/2022	MQTT client should start listening the channels an able to receive a triggered notification	MQTT client starts listening the channels an able to receive a triggered notification
mClinician_FT-5	Successfully exporting usage stats in CSV format	**N = 3**	**An authenticated user opens the application and navigates to the usage stats screen then exports displayed data in CSV format to download it to the device.**		Passed	1/09/2022	Requested resources should be fetched successfully and displayed in the interface	Requested resources are fetched successfully and displayed in the interface
		1	The application sends a HTTP GET request to the FHIR server to query the required resources.		Passed	1/09/2022	The FHIR server should return an HTTP 200 response with requested resource in JSON format located in the response body.	The FHIR server returns an HTTP 200 response with requested resource in JSON format located in the response body.
		2	The response in JSON format is parsed to models and started analysing usage data.	The FHIR server has returned an HTTP 200 response with a valid resource for the query.	Passed	1/09/2022	The usage data should begin to be analysed in the background.	The requested data started to be analysed.

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		3	Analyse results are displayed in charts and exported in CSV format	The usage data is successfully fetched.	Passed	1/09/2022	The analyse results should be displayed in the screen and should able to be exported in CSV format	The analysed results are displayed, exported in CSV format, and downloaded into device storage.

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Components of the Multimodal Sensing Network

Speech Feature Extractor

Table 22 Speech Feature Extractor functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
SFE_FT-1	Successful extraction of audio file	1	The audio file is extracted from the patient's video file.	The duration of the video should be a minimum 20 seconds.	Passed	5/02/2023	Audio File which has 20 seconds duration	Audio File
SFE_FT-2	Obtaining speech features	1	Audio file is used as an input to MATLAB Covarep function to get all the required speech features.	MATLAB functions should work under python environment.	Passed	05/02/2023	Speech features as a Covarep file	Speech features

Facial Feature Extractor

Table 23 Facial Feature Extractor functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
FFE_FT-1	Face Detection	**N = 1**	**The face of the patients is detected frame by frame searching for face locations.**	Video should have audio and transcription before face detection.	Passed	5/02/2023	Face locations should be found at any frame of the video.	Face is detected...

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FFE_FT-2	Obtaining facial features	**N=2**	**All facial features are extracted from OPENFACE library as five different files.**	-	Passed	5/02/2023	-	-
		1	Video file is used as an input to OPENFACE library to get all the required facial features.	OPENFACE functions should work under python environment.	Passed	5/02/2023	Facial features are extracted as a single file	Facial features (patient_video.csv)
		2	Single feature file is split into five required files for action units, 2D/3D facial landmarks, gaze and pose vectors.	OPENFACE output as a single feature file	Passed	5/02/2023	Five different feature file (txt) is obtained from the output of OPENFACE library.	patient_facial_CLNF_AUs.txt, patient_facial_CLNF_features.txt, patient_facial_CLNF_features3D.txt, patient_facial_CLNF_gaze.txt, patient_facial_CLNF_pose.txt

Text/Language Feature Extractor

Table 24 Text/Language Feature Extractor functional tests results

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result

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TFE_FT-1	Successful extraction of audio file	1	The audio file is extracted from the patient's video file.	The duration of the video should be a minimum 20 seconds.	Passed	5/02/2023	Audio File which has 20 seconds duration	Audio File
TFE_FT-2	Obtaining full transcription of patient	**N=2**	**Extracting the transcription and checking the content of the output.**	-	Passed	05/02/2023	-	-
		1	Extracting the transcription via Automated Speech Recognition (ASR)	Audio file and running ASR engine	Passed	5/02/2023	Text file that contains the transcription of the audio file	Transcription file (txt)
		2	Controlling the content of transcription file about including text or blank.	Transcription file (txt)	Passed	05/02/2023	The decision about the content of the transcription file	"Audio and text are ok..." or "Audio and text are empty..."
TFE_FT-3	Obtaining text/language features	1	Transcription file (txt) is used as an input to NLTK toolkit to get all the required text/language features.	Transcription file (txt) and NLTK toolkit	Passed	5/02/2023	The output file that contains word2vec model	Text features file (txt)

Speech Recognition

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Table 25 Speech Recognition functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
ASR_FT-1	Speech recognition	**N = 2**	**This test is performing the transformation of the audio to the text.**	-	Passed	05/02/2023	-	-
		1	Prepare format for audio file.	Microservice running and ready to receive the request.	Passed	5/02/2023	Reformat the audio file.	Reformat the audio file.
		2	Get speech recognition result from UM API with language selection.	Have a valid API KEY for the platform.	Passed	05/02/2023	Text of the speech.	Text of the speech.

Mood classifier and condition aware PREM/PROM API

Table 26 Mood classifier and condition aware PREM/PROM API functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
PREMPROM_FT-1	PREM/PROM API for questionnaires	**N =6**	**UM Swagger REST API with Rasa chatbot to offer questionnaires to the patients.**	-	Passed	5/02/2023	-	-

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		1	Get a list of questionnaires from UM API.	Have a valid API KEY for the platform.	Passed	5/02/2023	A list of questionnaires for specific language or all languages.	A list of questionnaires for specific language or all languages.
		2	Restart conversation session for user.	None.	Passed	05/02/2023	Session is restarted for user.	Session is restarted for user.
		3	Start session for user.	Restart conversation session for user.	Passed	5/02/2023	Start the session.	Start the session.
		4	Request the questionnaire.	Start session for user.	Passed	05/02/2023	Get first question for questionnaire.	Get first question for questionnaire.
		5	Answer on question.	Request the questionnaire.	Passed	5/02/2023	Record answer and get new question.	Record answer and get new question.
		6	End of questionnaire.	Answer all questions.	Passed	05/02/2023	Store questionnaire results to the FHIR server.	Store questionnaire results to the FHIR server.

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Embodied Conversational Agent Service

Table 27 Embodied Conversational Agent Service functional tests results

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
ECA_FT-1	ECA EVA agent welcome video	**N = 2**	**This test shows virtual agent video inside the mHealth application once user is starting the app.**	-	Passed	05/02/2023	-	-
		1	Get a list of ECA welcome videos from UM API based on the language.	Have a valid API KEY for the platform.	Passed	5/02/2023	A list of ECA videos for all languages.	A list of ECA videos for all languages.
		2	Show ECA welcome video on the mHealth application.	None.	Passed	05/02/2023	Play welcome video after user start the application.	Play welcome video after user start the application.
ECA_FT-2	ECA EVA agent questionnaire videos	**N = 6**	**This test shows virtual agent videos asking the questions from the questionnaire and finalises by showing the ECA video.**	-	Passed	5/02/2023	-	-
		1	Get a list of questionnaires from UM API.	Have a valid API KEY for the platform.	Passed	5/02/2023	A list of questionnaires for specific language or all languages.	A list of questionnaires for specific language or all languages.

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		2	Restart conversation session for user.	None.	Passed	05/02/2023	Session is restarted for user.	Session is restarted for user.
		3	Start session for user.	Restart conversation session for user.	Passed	5/02/2023	Start the session.	Start the session.
		4	Request the questionnaire with ECA video.	Start session for user.	Passed	05/02/2023	Get first question with ECA video for questionnaire.	Get first question with ECA video for questionnaire.
		5	Answer on question.	Request the questionnaire.	Passed	5/02/2023	Record answer and get new question.	Record answer and get new question.
		6	End of questionnaire and show the ECA video.	Answer all questions.	Passed	05/02/2023	Show the video and store questionnaire results to the FHIR server.	Show the video and store questionnaire results to the FHIR server.

Table 27. Embodied Conversational Agent Service functional tests results.

Chatbot component

Table 28 Chatbot component functional tests results

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result

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CHATBOT_FT-1	CHATBOT for DCD questionnaire	**N = 3**	**This test offers patient questionnaire that are triggered by the mHealth application after the analysis of collected causes and diseases from the SYMPTOMA based on the video diaries.**	-	Passed	05/02/2023	-	-
		1	Trigger MQTT notification to patient.	Have a valid patient id. Have patient symptoms/diseases from 1.	Passed	5/02/2023	Patient is notified to start a SYM questionnaire.	Patient is notified to start a SYM questionnaire.
		2	Send patient answer to SYM and request a new question.	Get an API key for Symptoma REST API.	Passed	05/02/2023	Patient is showed a new question in mHealth app	Patient is showed a new question in mHealth app
		3	At the end of the questionnaire save the DCD questionnaire.	Get an access token from Keycloak for user with consent signed.	Passed	5/02/2023	Store patient questionnaire answers on FHIR server.	Store patient questionnaire answers on FHIR server.

CTC Component

Table 29 CTC component functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result

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CTC_FT-1	Successful login of an authorised user.	**N = 2**	**The CTCs web application successfully authenticates a user who has enabled access to the CTCs data.**	-	Passed	20/01/2023	An access token is returned once the system confirms that the user and password are valid and enabled. The user has access to the web application's subsequent screen.	The system verifies that the user name and password match one of those registered in the FHIR server. The application's main screen, the CTCs report listing screen, is accessed after an access token has been generated.
		1	The CTCs web application sends an *HTTP POST* request to the FHIR server to obtain an access token for a user who has enabled access to CTCs data.	A specific user's password and access to CTCs data have already been enabled on the FHIR server.	Passed	20/01/2023	The FHIR server provides an *HTTP 200 OK* response along with a functional access token for that user.	The FHIR server replies to the application's HTTP POST request with an *HTTP 200 OK* response and an access token.

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		2	The access token is verified and access to the application's main screen is allowed.	The FHIR server has returned an *HTTP 200 OK* response with a valid access token for that user.	Passed	20/01/2023	The token is correct and the application proceeds to the main screen: report listing.	The application successfully switches from the login screen to the main screen (report listing).
CTC_FT-2	Incorrect login of an unauthorised user.	**N = 2**	**A user with non-enabled access to CTC data cannot access the CTCs web application.**	-	Passed	20/01/2023	An authentication error is returned by the system when it determines that the user name and password are incorrect or disabled. The CTCs web application's user cannot access the main screen.	The user is unable to access the application's main screen because the FHIR server verifies that the user and/or password are not registered and sends an unauthorised error.
		1	The CTCs web application sends an *HTTP POST* request to the FHIR server to obtain an access token for a user with non-enabled access to CTCs data.	None	Passed	20/01/2023	The FHIR server returns an *HTTP 401 Unauthorised* response.	The FHIR server responds to the *HTTP POST* request from the CTCs application

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								with an *HTTP 401 Unauthorised* message.
		2	The CTCs application detects that the FHIR server has sent an access error.	The FHIR server has returned an *HTTP 401 Unauthorised* response.	Passed	20/01/2023	The login screen shows an error message informing the user that he/she is not allowed.	The application displays an error to the user indicating that he/she is not authorised to access it.
CTC_FT-3	List of CTC reports for a registered patient.	**N = 3**	**A user accesses CTC reports relating to a patient registered on the FHIR server.**	-	Passed	23/01/2023	The CTC reports related to that patient are displayed in the application's user interface.	The application displays patient-related reports on the screen.
		1	CTCs web application sends a request to the FHIR server to check if the patient is registered in the system.	A user with enabled access to CTCs data has previously successfully authenticated in the application.	Passed	23/01/2023	The FHIR server checks that the patient ID is registered and does not return any errors.	The FHIR server checks that the patient ID exists and allows the search, returning no errors.

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		2	CTC web application sends an HTTP POST request to the FHIR server, sending patient ID as 'subject' parameter, and also "ctc-panel" as 'code'.	A patient has been registered on the FHIR server to track CTCs and the FHIR server has previously confirmed it is.	Passed	23/01/2023	The FHIR server returns a JSON file containing a list with all the DiagnosticReport resources associated with this patient ID that have the "ctc-panel" code.	The FHIR server responds with an *HTTP 200 OK* along with a JSON containing the CTC's DiagnosticReports of the patient whose ID has been sent.
		3	CTCs application analyses the CTCs DiagnosticReports list and displays them in the user interface.	The FHIR server has returned a JSON file containing a list with all the CTCs DiagnosticReport resources associated with a patient ID.	Passed	23/01/2023	The different DiagnosticReports are listed in the user interface, showing the summary information and being sorted by issued date. An edit and a delete button for each report and a general adding button are also displayed.	The patient's CTC DiagnosticReports are displayed on the main screen. In the list they can be seen the summary fields and the reports sorted by issued date. The corresponding buttons are also displayed.
CTC_FT-4	Error trying to list CTC reports for an unregistered patient.	**N = 2**	**A user tries to access CTC reports for a patient who is not registered on the FHIR server.**	-	Passed	23/01/2023	The application displays an error to the user.	The application displays a patient not found error to the user.

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		1	CTCs web application sends a request to the FHIR server to check if the patient is registered in the system.	A user with enabled access to CTCs data has previously successfully authenticated in the application.	Passed	23/01/2023	The FHIR server checks that patient ID is not registered and returns an *HTTP 404 Not Found* error.	The FHIR server returns an *HTTP 404 NOT FOUND* along with a "patient not found" message.
		2	CTC web application analyses the FHIR server response and manages the error in the user interface.	CTC web application has received an *HTTP 404 Not Found* error from the FHIR server.	Passed	23/01/2023	The application displays the NOT FOUND error to the user.	The application displays on the user interface the message received by the FHIR server.

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CTC_FT-5	Adding button function.	**N = 1**	**The adding button (+ icon) correctly changes to the "create a new report" screen.**	DiagnosticReports has been listed in the user interface with the corresponding edit and delete buttons for each one and the general adding button.	Passed	23/01/2023	The application changes the current screen to the "create a new report" screen.	By clicking on the "add" button, the application displays the screen for creating a new CTCs report.
CTC_FT-6	Fill in the fields of the form to create a new CTCs report.	**N = 5**	**All fields can be filled in when creating a new CTC report.**	The user could access the "create a new report" screen.	Passed	23/01/2023	-	-
		1	The user adds information to the text fields displayed in the "create a new report" screen.	-	Passed	23/01/2023	Text fields can be filled and the information is kept on the screen.	The information entered in the text fields is retained in the text fields.
		2	The user can select between the cancer types by clicking on the cancer type selector.	-	Passed	23/01/2023	Cancer types are correctly displayed and the user's selection is kept in the selector field.	The option selected in the cancer type drop-down menu is saved in the field.

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		3	The user can select the issued date in the calendar menu.	-	Passed	23/01/2023	Selected issued date is kept on the menu.	The date selected in the calendar menu is saved in the issued date field.
		4	The user can attach images to the report by clicking on the "new images to upload" button. The application can access the user's file system to allow selection of one or more images.	-	Passed	23/01/2023	The uploaded image's name appears on the screen. Next to it, a "delete" button (a bin icon) is also shown to the user.	The name of the image that has been uploaded to the application is displayed within the attached images along with a button to delete it.
		5	The user can attach PDF files to the report by clicking on the "new PDF report to upload" button. The application can access the user's file system to allow selection of a PDF.	-	Passed	23/01/2023	The uploaded PDF file's name appears on the screen. Next to it, a "delete" button (a bin icon) is also shown to the user.	The name of the PDF file that has been uploaded to the application is displayed within the attached images along with a button to delete it.

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CTC_FT-7	New CTCs report creation.	**N = 2**	**The CTCs web application correctly sends a report information to the FHIR server when the user clicks on the "save" button.**	-	Passed	23/01/2023	The user sees in the reports list screen the new report created together with the previous reports. The correct values are shown in the summary fields and the report appears at the top of the list.	The report is successfully created and on the main screen of the application you can see the new report together with the previously created reports. The report appears at the top of the list.
		2	The CTCs application creates a FHIR DiagnosticReport resource including the information contained in the report creation form and sends it as an *HTTP POST* request to the FHIR server.	All fields could be filled in when creating a new CTC report.	Passed	23/01/2023	The FHIR server saves the new report and returns a confirmation message.	The FHIR server stores the information and returns an *HTTP 201 OK.*
		3	The CTCs web application returns to the listing screen.	The FHIR server has saved the new report and returned a confirmation message.	Passed	23/01/2023	The CTCs web application shows the new report together with the previous ones, located on the top of the list.	The application displays the list of patient reports, which now includes the newly created one. It appears at the top of the list.

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CTC_FT-8	Edit an existing CTCs report.	**N = 4**	**An user can edit an existing CTCs report by changing some of the values in the form.**	-	Passed	23/01/2023	The user sees in the reports list screen the updated report. The correct values are shown in the summary fields.	The report is edited correctly and the changes made in the summary fields are reflected in the list.
		1	The editing button correctly changes to the "edit an existing report" screen.	DiagnosticReports has been listed in the user interface with the corresponding edit and delete buttons for each one and the general adding button.	Passed	23/01/2023	The editing button correctly changes to the "edit an existing report" screen, where the form with the current values of the fields is displayed.	The "edit report" button switches the screen to the editing screen of a specific report, where the current values can be viewed.

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		2	The user is able to edit some fields, for instance, to delete an attached image by clicking on the "delete" button next to the image's name, and change some CTCs class information.	The editing button correctly has changed to the "edit an existing report" screen, where the form with the current values of the fields is displayed.	Passed	23/01/2023	The values of the edited fields change and the new ones remain on the screen.	The new values of the fields can be seen on the screen.
		3	The CTCs web application correctly sends the updated Observation and DiagnosticReport FHIR resources to the FHIR server when the user clicks on the "save" button by sending an *HTTP PUT* request.	The values of the edited fields have changed in the editing form.	Passed	23/01/2023	The FHIR server saves the new report and returns a confirmation message.	The FHIR server updates the resource and sends an *HTTP 200 OK* response mensake.

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		4	The CTCs web application returns to the listing screen.	The FHIR server has saved the updated report and returned a confirmation message.	Passed	23/01/2023	The CTCs web application displays the new report values in the summary fields of the list.	On the main screen, the list of reports is updated and the new values are displayed in the modified report.
CTC_FT-9	Viewing a PDF report.	**N = 1**	**The application is able to retrieve from the FHIR server the information related to an attached PDF and allows users to download it by clicking on its name.**	A user has successfully accessed the "edit an existing report" screen.	Passed	25/01/2023	The PDF report is successfully reconstructed and the user can view it on the screen.	The PDF report is downloaded in a correct format and a user can view it on the screen.
CTC_FT-10	Cancel an existing report edition.	**N = 1**	**An user can cancel the edition of an existing CTC report by clicking on the "cancel" button in the "edit an existing report" screen.**	An user has access to the "edit an existing report" screen and edit some report's fields.	Passed	23/01/2023	The CTCs web application returns to the listing screen and displays the same report values in the summary fields of the list.	Clicking the cancel button does not apply any changes and the application returns to the main screen.
CTC_FT-11	Delete an existing CTCs report.	**N = 3**	**An user can delete an existing CTCs report from the FHIR server.**	-	Passed	23/01/2023	The deleted CTCs report is deleted from the CTCs report list.	

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		1	By clicking on a "delete" button, the application asks the user to confirm the deletion of the resource.	DiagnosticReports has been listed in the user interface with the corresponding edit and delete buttons for each one and the general adding button.	Passed	23/01/2023	A pop-up window with a delete confirmation message and two "confirm" and "cancel" buttons are displayed in the user interface.	Clicking on the delete button shows the user a confirmation pop-up with two buttons.
		2	By clicking on the "yes" button in the delete confirmation pop-up window, the CTCs application sends an DELETE HTTP request for this resource to the FHIR server.	The pop-up window with the delete confirmation message and two "confirm" and "cancel" buttons was displayed.	Passed	23/01/2023	The FHIR server deletes the DiagnosticReport and the attached Observation resources and returns a confirmation message.	The FHIR server deletes the resource and returns an *HTTP 200 OK.*
		3	The CTCs web application receives the delete confirmation message from the FHIR server and refreshes the CTCs reports list.	The FHIR server has deletead a DiagnosticReport and the attached Observation resources and returned a confirmation message to the CTCs web application.	Passed	23/01/2023	The deleted CTCs report has disappeared from the CTCs report list.	The deleted report disappears from the patient's report list.

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CTC_FT-12	Cancel an existing report deletion.	**N = 1**	**An user can cancel the deletion of an existing CTC report by clicking on the "cancel" button in the delete confirmation pop-up window.**	The pop-up window with the delete confirmation message and two "confirm" and "cancel" buttons was displayed to the user when trying to delete a resource.	Passed	23/01/2023	The CTCs web application returns to the listing screen and displays the same reports as it has previously displayed.	Clicking the cancel button does not prompt the FHIR server to delete the report and the application displays the same reports.
CTC_FT-13	Menu button function.	**N = 1**	**The top right button (menu) correctly displays a drop-down menu.**	A user with enabled access to CTCs data has previously successfully authenticated in the application.	Passed	23/01/2023	The drop-down menu is displayed and shows the user the four application options: listing reports, automatic CTC prediction, CTC algorithm predictions retrievement and exit.	Clicking on the upper right button displays the options menu that includes the 4 possible options: report listing, automatic prediction, prediction results retrieval and application exit.
CTC_FT-14	Successful automatic prediction screen access.	**N = 1**	**The "automatic CTCs prediction" option of the drop-down menu displays the automatic prediction screen.**	The drop-down menu has been displayed correctly by clicking on the top right button.	Passed	23/01/2023	The CTCs web application displays the automatic CTC prediction screen where a button appears to upload a new image.	When clicking on the automatic CTC prediction option, the application displays a new screen with a button to upload an image.

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CTC_FT-15	Successful sending of a microscope image to the automatic prediction service.	**N = 3**	**An user is able to send an image from the file system to the CTCs automatic prediction system.**	-	Passed	23/01/2023	The CTCs prediction service performs the prediction on one or several images and returns a prediction identifier to be used to retrieve the results.	The automatic CTCs prediction service processes one or several images sent by the user and sends back to the application, as well as by mail, a prediction identifier to retrieve the results.
		1	The application can access the user's file system to allow selection of one or more images when clicking on the "new images to upload" button in the automatic CTC prediction screen.	An user has been able to access the automatic CTC prediction screen.	Passed	23/01/2023	The names of the uploaded images appear on the screen. Next to them, a "delete" button (a bin icon) is also shown to the user.	The names of the images uploaded by the user can be seen in the application together with a delete button corresponding to each one of them.

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		2	The CTCs application sends a request to the automatic prediction service by clicking on the "upload images" button.	An user has uploaded one or more microscope images to the application on the automatic CTCs prediction screen.	Passed	23/01/2023	The CTCs prediction service performs the prediction and returns a prediction identifier so that the user can retrieve the prediction results.	When clicking on upload images the automatic prediction service returns a prediction identifier.
		3	The CTCs prediction service sends an email to the user with the prediction results.	An user has uploaded one or more microscope images to the application on the automatic CTCs prediction screen and clicked on the "upload images" button to send them to the CTCs prediction service.	Passed	23/01/2023	The user receives an email with sender *ctcpersist@gradiant.org*. On this email it is sent the prediction identifier and the number of CTCs detected by de service.	The recurrence prediction service also sends the identifier by e-mail to the user together with the number of CTCs detected in the image processing.
CTC_FT-16	Error when trying to send no images to the CTCs prediction service.	**N = 1**	**The CTCs application does not allow sending a request to the automatic prediction service without having uploaded any image.**	An user has been able to access the automatic CTC prediction screen.	Passed	23/01/2023	The CTCs web application displays a pop-up window prompting the user to upload any images.	When clicking on submit the application displays the user informing him/her that he/she must upload an image first.

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CTC_FT-17	Cancel sending a microscope image to the automatic prediction service.	**N = 1**	**An user can cancel the upload of an image to the CTCs prediction service by clicking on the "cancel" button in the automatic CTC prediction screen.**	An user has been able to access the automatic CTC prediction screen and may upload some images to the CTCs application.	Passed	23/01/2023	Clicking cancel does not make any request to the recurrence prediction service and the application returns to the main screen.	The CTCs web application successfully returns to the main screen.
CTC_FT-18	Successful prediction retrievement screen access.	**N = 1**	**The "prediction retrievement" option of the drop-down menu displays the prediction retrievement screen.**	The drop-down menu has been displayed correctly by clicking on the top right button.	Passed	23/01/2023	The CTCs web application displays the prediction retrieval screen where a text input field appears together with a "retrieve prediction" and a "cancel" button.	When clicking on the prediction retrievement option, the application displays a new screen with a text field and two buttons.
CTC_FT-19	Successful retrievement of a microscope image's CTCs prediction.	**N = 3**	**The CTCs web application correctly displays the CTCs automatic prediction service results to the user.**	An user has previously asked for a prediction to the automatic CTC prediction service and received a prediction identifier.	Passed	23/01/2023	The CTCs web application displays the service prediction divided into different layers and with slider bars to manage some image parameters, facilitating the visualisation of the predicted CTCs.	

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		1	The CTCs web application sends a request to the CTC automatic prediction service with a correct prediction identifier.	The CTCs web application has returned an identifier when sent one or more images to process.	Passed	23/01/2023	The automatic CTCs prediction service returns a crop of the image for each CTC it has detected, for each of the submitted images. This image's crops have five layers according to the microscope images (one for each CTC component).	The prediction system returns the image slices where it has detected a CTC. These chunks have 5 layers just like the original images that have been sent.
		2	The received image crops are divided into layers to be presented to the user.	The automatic CTCs prediction service has returned some image's crops for the detected CTC. These crops have five layers according to the microscope images.	Passed	23/01/2023	The CTCs web application displays the predicted CTCs in each of the images divided into the five layers. Each layer of each fragment is displayed twice along with a slider bar.	The application displays the detected CTCs divided into the 5 layers. The user is also presented with two slide bars to modify the properties of each layer: in one the brightness and in the other the colour intensity.
		3	The two slide bars work correctly on each image layer.	The CTCs web application has displayed some predicted CTCs and also two slider bars per crop's layer.	Passed	23/01/2023	The application allows for each layer of each detected CTC to adjust the brightness values using the first	The application allows you to tune the properties of image layers using slide bars.

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							slider bar and to apply an intensity filter on the other one.	
CTC_FT-20	Successful deletion of a predicted CTC from the user interface.	**N = 1**	**The CTCs web application allows users to delete a predicted CTC from the user interface by clicking on the "delete" button (bin icon) displayed next to the prediction results.**	The CTCs web application has displayed some predicted CTCs when a user has sent a correct prediction identifier.	Passed	13/02/2023	The CTCs application deletes from the user interface the predicted CTC.	The prediction is removed correctly from the user interface.
CTC_FT-21	Error trying to list CTC predictions for a non-existent prediction identifier.	**N = 1**	**A user tries to access CTC prediction for an identifier that has not been returned by the automatic prediction service.**	An user has been able to access the prediction retrievement screen.	Passed	23/01/2023	The recurrence prediction service returns an *HTTP 404 NOT FOUND* error which is displayed to the user.	The application displays a *NOT FOUND* error to the user.
CTC_FT-22	Cancel sending a prediction identifier to the automatic prediction service.	**N = 1**	**An user can cancel the request of a prediction to the CTCs prediction service by clicking on the "cancel" button in the prediction retrievement screen.**	An user has been able to access the prediction retrievement screen and may upload some images to the CTCs application.	Passed	23/01/2023	The CTCs web application returns to the main screen.	The CTCs web application successfully returns to the main screen.

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CTC_FT-23	Correct user's logout.	**N = 1**	**The "exit" option of the drop-down menu logs out the user from the CTCs web application.**	The drop-down menu has been displayed correctly by clicking on the top right button.	Passed	23/01/2023	The CTCs web application returns to the login screen.	Clicking on the exit option returns the application to the login screen.

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Components of the Clinical Decision Support System

Cohort and trajectories analysis module

Table 30 Cohort and trajectories analysis module functional tests results

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
CTA_FT-1	Survival Probability Service: Correct survival probability for colon cancer patients grouped by staging	1	A user or service makes a well-formed survival probability request to the Survival Probability service for Colon Cancer patients and obtains as a response a JSON allowing to draw the survival probability graph.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the informations required to draw the survival probability plot for colon cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-2	Survival probability Service: Correct survival probability for breast cancer patients grouped by staging	1	A user or service makes a well-formed survival probability request to the Survival Probability service for Breast Cancer patients and obtains as a response a JSON allowing to draw the survival probability graph.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the informations required to draw the survival probability plot for breast cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json

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CTA_FT-3	Survival probability service: wrong cancer type	1	A user or service makes a survival probability request to the Survival Probability service for an erroneous Cancer type and obtains as a response a bad request error.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	The system should return 400 bad request error	The system return a 400 bad request error
CTA_FT-4	CPH Service: Correct cph for colon cancer patient	1	A user or service makes a well-formed request to the CPH service for Colon Cancer patient and obtains as a response a JSON allowing to draw the CPH graph.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to draw the CPH trajectory graph for colon cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-5	CPH Service: Correct cph for breast cancer patient	1	A user or service makes a well-formed request to the CPH service for Breast Cancer patient and obtains as a response a JSON allowing to draw the CPH graph.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to draw the CPH trajectory graph for breast cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-6	CPH Service: wrong patient ID	1	A user or service makes a well-formed request to the CPH service for a patient that does not	The user or service has obtained a valid authorisation	Passed	2/02/2023	The system should return the minimal json that defines axis of the graphs	The minimal json is returned by the system and

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			exists and obtains as a response a valid JSON without data	token.			but no data	it does not contains the data as the patient does not exist
CTA_FT-7	CPH Influence Service: Correct CPH influence for colon cancer patient	1	A user or service makes a well-formed request to the CPH influence service for Colon Cancer patients and obtains as a response a JSON allowing to plot the influence of each feature on the CPH trajectory.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to plot the influence of each features in CPH for colon cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-8	CPH Influence Service: Correct CPH influence for breast cancer patient	1	A user or service makes a well-formed request to the CPH influence service for Breast Cancer patients and obtains as a response a JSON allowing to plot the influence of each feature on the CPH trajectory.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to plot the influence of each features in CPH for breast cancer patient	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-9	CPH Influence Service: wrong cancer type	1	A user or service makes a well-formed request to the CPH Inflience service for an erroneous Cancer	The user or service has obtained a valid authorisation	Passed	2/02/2023	The system should return 400 bad request error	The system return a 400 bad request error

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			type and obtains as a response a bad request error.	token.				
CTA_FT-10	Risk Service: Correct Risk for colon cancer patient	1	A user or service makes a well-formed request to the Risk service for colon cancer patients and obtains as a response a json allowing to draw the different graphs	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to plot the risk graph for colon cancer patients	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-11	Risk Service: Correct Risk for breast cancer patient	1	A user or service makes a well-formed request to the Risk service for breast cancer patients and obtains as a response a json allowing to draw the different graphs	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	A json containing all the information required to plot the risk graph for breast cancer patients	The json is correctly retrieved and a graph can be drawn from the data contained in the json
CTA_FT-12	Risk Service: wrong cancer type	1	A user or service makes a well-formed request to the Risk service for an erroneous Cancer type and obtains as a response a bad request error.	The user or service has obtained a valid authorisation token.	Passed	2/02/2023	The system should return 400 bad request error	The system return a 400 bad request error
CTA_FT-13	Survival Probability	1	An user or service makes a request on Survival	None	Passed	2/02/2023	The system should return 401	The system returned 401

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	Service: missing or no valid authorisation token		Probability Service without a valid authorisation token that results in an unauthorised error.				unauthorised error	unauthorised error
CTA_FT-14	CPH service: missing or no valid authorisation token	1	An user or service makes a request on CPH Service without a valid authorisation token that results in an unauthorised error.	None	Passed	2/02/2023	The system should return 401 unauthorised error	The system returned 401 unauthorised error
CTA_FT-15	CPH Influence Service: missing or no valid authorisation token	1	An user or service makes a request on CPH Influence Service without a valid authorisation token that results in an unauthorised error.	None	Passed	2/02/2023	The system should return 401 unauthorised error	The system returned 401 unauthorised error
CTA_FT-16	Risk Service: missing or no valid authorisation token	1	An user or service makes a request on Risk Service without a valid authorisation token that results in an unauthorised error.	None	Passed	2/02/2023	The system should return 401 unauthorised error	The system returned 401 unauthorised error

Table 30. Cohort and trajectories analysis module functional tests results.

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Recurrence prediction module

Table 31 Recurrence prediction module functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
RP_FT-1	Recurrence Prediction service: Correct recurrence prediction for a Colon Cancer patient	1	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Colon Cancer patient that has all necessary data and obtains as a response a JSON with the recurrence prediction value.	The user or service has obtained a valid authorisation token. The patient exists in the FHIR server and has a Colon Cancer diagnosis. All necessary data for the recurrence prediction is stored in the FHIR server.	Passed	16/01/2023	The user or service obtains a JSON as a response which contains the recurrence prediction value	Obtained a JSON which contains the recurrence prediction value for the patient.
RP-FT-2	Recurrence Prediction service: Correct recurrence prediction for a Breast Cancer patient	1	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Breast Cancer patient that has all necessary data and obtains as a response a JSON with the recurrence prediction value.	The user or service has obtained a valid authorisation token. The patient exists in the FHIR server and has a Breast Cancer diagnosis. All necessary data for the recurrence prediction is stored in the FHIR server.	Passed	22/02/2023	The user or service obtains a JSON as a response which contains the recurrence prediction value	Obtained a JSON which contains the recurrence prediction value for the patient.

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RP_FT-3	Recurrence Prediction service: Missing data for a Colon Cancer patient	1	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Colon Cancer patient that is missing necessary data and obtains as a response an error message explaining what data is missing.	The user or service has obtained a valid authorisation token. The patient exists in the FHIR server and has a Colon Cancer diagnosis.	Passed	16/01/2023	The user or service obtains a response which contains an error message with details about the missing data.	The service responded with a JSON containing an error message that indicates that a parameter is missing
RP_FT-4	Recurrence Prediction service: Missing data for a Breast Cancer patient	1	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a Breast Cancer patient that is missing necessary data and obtains as a response an error message explaining what data is missing.	The user or service has obtained a valid authorisation token. The patient exists in the FHIR server and has a Breast Cancer diagnosis.	Passed	16/01/2023	The user or service obtains a response which contains an error message with details about the missing data.	The service responded with a JSON containing an error message that indicates that a parameter is missing
RP_FT-5	Recurrence Prediction service: Incorrect patient	1	An user or service makes a well-formed recurrence prediction request to the Recurrence Prediction service for a patient ID that does not exist and obtains as a response an error message explaining that the patient	The user or service has obtained a valid authorisation token.	Passed	22/02/2023	The user or service obtains a response which contains an authorisation error.	The service responded with a JSON file containing an error message that indicates that the patient does not exist

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			does not exist.					
RP_FT-6	Recurrence Prediction service: Incorrect petition	1	An user or service makes a recurrence prediction request to the Recurrence Prediction service with an incorrect body and obtains as a response an error message explaining that the petition is incorrect.	The user or service has obtained a valid authorisation token.	Passed	16/01/2023	The user or service obtains a message as a response that indicates that the request is not formed correctly	The service responded with a JSON file that indicates "field missing"
RP_FT-7	Recurrence Prediction service: missing or no valid authorisation token	1	An user or service makes a recurrence prediction request without a valid authorisation token and obtains as a response an error explaining that it is not authorised.	None	Passed	16/01/2023	The user or service obtains a message as a response that indicates that the user or service was not authenticated.	Obtained response from service "invalid token"

Table 31. Recurrence prediction module functional tests results.

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EHR Data preparation and Enrichment module

Table 32 EHR Data preparation and Enrichment module functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
EHR-DP&EM_FT-1	EHR Data preparation and enrichment module service: successful authentication	N = 1	The PERSIST EHR application successfully authenticates an authorised user to run the service	Virtual machine to interface with Dedalus services	Passed	18/11/2022	Dedalus' system confirms that the user and password are valid and enabled. The user has access to the EHR application.	The system verifies that the user name and password match one of those registered in the server. The application's main screen, the persist.symptoma.com screen is accessed.
EHR-DP&EM_FT-2	EHR Data preparation and enrichment module service: reject invalid credentials	N = 1	The PERSIST EHR application successfully identifies an unauthorised user and blocks access	Virtual machine to interface with Dedalus services	Passed	30/01/2023	An error message is returned once the system confirms that the user and password are not valid. The user has no access to the server.	The system verifies that the user name and password don't match one of those registered in the server. Access to the application's main screen, the persist.symptoma.

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								com screen is blocked and an error message appears.
EHR-DP&EM_FT-3	EHR Data preparation and enrichment module service: verification of containers	**N=3**	**A user verifies that all related containers are active**	A user with enabled access to persist.symptoma.com has previously successfully authenticated in the application. The user has permissions set to use the docker command	Passed	31/01/2023	All the containers shows up as running in the overview screen of docker	The system verifies the active status of the containers in the docker screen
		1	Extraction engine		Passed			
		2	Code service		Passed			
		3	Enrichment module		Passed			
EHR-DP&EM_FT-4	EHR Data preparation and enrichment module service: verification of manual start	**N=2**	**A user manually starts the PERSIST EHR application to generate an enriched FHIR dataset.**	All containers are active	Passed	1/02/2023	The cvs statistics and log files related to the enrichment service are displayed in the application's interface	The application displays FHIR enriched-related data on the screen
		1	PERSIST EHR application sends a request to the FHIR server (Dedalus) to read FHIR resources of the patients registered in each	Successful authentication / login to persist.symptoma.com . The user has access	Passed		The application stage is passed without errors	No errors occurred

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			hospital dataset	rights to the service directory on persist.symptoma.com				
		2	PERSIST EHR application analyses the FHIR server response and generates an updated enriched FHIR dataset and automatically disables on success or error service	The PERSIST EHR application correctly sends the updated enriched FHIR resources to the FHIR server	Passed			
EHR-DP&EM_FT-5	EHR Data preparation and enrichment module service: review of log file	N = 1	Study the log file for inconsistencies	Log file has been created by the application	Passed	31/01/2023	The log file is present and contains information about the runtime and processed resources. No critical errors should be found	The log file is present and contains all the relevant information (screenshot)
EHR-DP&EM_FT-6	EHR Data preparation and enrichment module service: Review of CVS files of example resources	N = 1	Study output files for inconsistencies and examples	Output file has been created after successful run	Passed	31/01/2023	The csv data files are present and contain the expected amount of rows and columns.	CSV files were created and adhere to the desired format
EHR-DP&EM_FT-7	EHR Data preparation and enrichment module service: Request of example	N = 1	The PERSIST EHR application correctly sends a resource example by ID	User is in possession of valid credentials for the Dedalus FHIR Service. The service is running and reachable	Passed	31/01/2023	The request returns the respective resource identified by the provided ID as JSON	The resource identified by the respective ID is displayed as JSON

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	resources by ID			from persist.symptoma.com				
EHR-DP&EM_FT-8	EHR Data preparation and enrichment module service: verification of annotations in the FHIR data	N = 1	A user can verify an existing FHIR enriched data in the application.	User is in possession of valid credentials for the Dedalus FHIR Service	Passed	31/01/2023	The user sees in the enriched data reports the timestamp, resource ID, language, extensions incl. code and display	The new extensions of the FHIR resources can be seen on the screen. The enriched data report is correct and all direct identifiers are absent, no risk for re-identification

Inference Engine module

Table 33 Inference Engine functional tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
Inference_Engine_FT-1	Successfully request an inference via inference engine API	**N = 2**	**A request sent to the inference engine api successfully responded with CDS Card results defined in CDS Hooks documentation.**	-	Passed	26/09/2022	The system should return CDS Cards for the requested inference	The system returned CDS Cards for the requested inference.

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		1	An HTTP POST request with a body in JSON and FHIR format is sent to Inference Engine API with information requested for the desired inference.		Passed	26/09/2022	The inference Engine server should successfully process the request.	Sent request was successful.
		2	A CDS Card information in JSON format is returned.	The Inference Engine server has received the request successfully.	Passed	26/09/2022	The Inference Engine server should return an HTTP 200 response with a valid CDS Card.	A CDS Card information in JSON format is returned with HTTP status code 200.
Inference_Engine_FT-2	Successfully request a risk assessment.	**N=2**	**A request sent to the inference engine api successfully responded with non-empty CDS Card results defined in CDS Hooks documentation.**	-	Passed	26/09/2022	The system should return a non-empty list of CDS Cards for the requested inference	The system returned a non-empty list of CDS Cards for the requested inference.
		1	An HTTP POST request with a body in JSON and FHIR format is sent to Inference Engine API with information requested for the desired inference.	-	Passed	26/09/2022	The inference Engine server should successfully process the request.	Sent request was successful.
		2	A non-empty list of CDS Card information in JSON format is returned.	The Inference Engine server has received the request successfully.	Passed	26/09/2022	The Inference Engine server should return an HTTP 200 response with a	A non-empty list of CDS Card information in JSON format is returned with

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							valid non empty list of CDS Cards.	HTTP status code 200.
Inference_Engine_FT-3	Successfully request an alert assessment resulting in alert condition.	**N = 2**	**A request sent to the inference engine api successfully responded with non-empty CDS Card with an action defined in CDS Hooks documentation.**	-	Passed	26/09/2022	The system should return a non-empty CDS Card with an Action to create Flag resource.	The system returned a non-empty CDS Card with an Action to create Flag resource.
		1	An HTTP POST request with a body in JSON and FHIR format is sent to Inference Engine API with information requested for the desired inference.	-	Passed	26/09/2022	The inference Engine server should successfully process the request.	Sent request was successful.
		2	A CDS Card information with an action to create a Flag FHIR resource in JSON format is returned.	The Inference Engine server has received the request successfully.	Passed	26/09/2022	The Inference Engine server should return an HTTP 200 response with a valid CDS Card containing an Action to create a Flag resource.	A CDS Card information with an Action to create a Flag resource in JSON format is returned with HTTP status code 200.

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Inference_Engine_FT-4	Successfully request an alert assessment not resulting in alert condition.	**N = 2**	**A request sent to the inference engine api successfully responded with an empty CDS Card defined in CDS Hooks documentation.**	-	Passed	26/09/2022	The system should return an empty CDS Card.	The system returned an empty CDS Card.
		1	An HTTP POST request with a body in JSON and FHIR format is sent to Inference Engine API with information requested for the desired inference.	-	Passed	26/09/2022	The inference Engine server should successfully process the request.	Sent request was successful.
		2	An empty CDS Card in JSON format is returned.	The Inference Engine server has received the request successfully.	Passed	26/09/2022	The Inference Engine server should return an HTTP 200 response with a valid but empty CDS Card.	An empty CDS Card JSON format is returned with HTTP status code 200.

System Testing

mHealth Application

Table 34 mHealth Application system tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
mHealth_ST-1	Successful first time login	**N=3**	**A registered user with first login credentials has already been given enters**	-	Passed	01/09/2022	-	-

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			information and logins to create password.					
		1	The user enters patient id and password.	User should have an active patient account and own credentials to login	Passed		-	-
		2	The user clicks the button to log in.	The user has entered credentials to login	Passed		-	-
		3	Dialog to define user password is displayed.	The user has entered credentials and tapped login button	Passed		The user should successfully log in and should be shown the password creation dialog.	The user should successfully log in and the password creation dialog is displayed.
mHealth_ST-2	Successful login with created password	**N=1**	**A registered user with login credentials are already given enters information and logins with the password created previously on first login**	-	Passed	01/09/2022	-	-
		1	The user enters his/her password and taps login	User should have an active patient account, previously logged in and created his/her	Passed		Applications main screen with Summary tab open should be displayed	User logged in successfully and directed to the applications main screen

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				password				
mHealth_ST-3	Smartband synchronisation	**N=3**	**A logged in user synchronises smart band data**	-	Passed	01/09/2022	-	-
		1	the user can click on the "measure" button.	The user has successfully logged into the application and accessed the main screen and connected smartband	Passed		Should reveal the start button and synchronisation interface panel.	Start button is available to be tapped and synchronisation details are displayed
		2	The user clicks the start button to trigger synchronisation.	The user has tapped on measure button to reveal start button and synchronisation interface	Passed		Should start synchronisation and display ongoing phase information	Synchronisation is started and relevant information is displayed in the synchronisation panel.
		3	A ui widget showing the progress is displayed with ongoing task information	The user has tapped on the Start button.	Passed		Should display progress with a ui widget and the final report when the process ends	During synchronisation progress icon is displayed and at the end the final report for the synchronisation is

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								displayed
mHealth_ST-4	Manual vital data input	**N=1**	**A logged in user manually inputs vital data**	-	Passed	08/09/2022	-	-
		1	the user can click "pencil icon" to enter vital signs manually	The user has logged in and reached the main screen of the application, but has not connected the smartband	Passed		If user wants to update vital signs user needs to click "measure" button. but if the user has not connected a smart band a text message and a button will be shown to guide the user to enter vital signs manually.	the user successfully updated/entered blood pressure
mHealth_ST-5	Emotion report	**N=3**	**A logged in user reports Emotion**	-	Passed	08/09/2022		
		1	the user clicks "how are you feeling" button to provide emotions report	The user has logged in and reached the main screen of the application.	Passed		Should display emotion report screen	Emotion report screen is displayed
		2	the user enters information using sliders and checkboxes	The user clicked "how are you feeling" button to	Passed			

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				display emotion report screen				
		3	the user taps OK button at bottom to save	the user entered at least one emotion information in emotion report screen	Passed		Should show saving process icon and return to main screen	Icon is displayed and then application returned to main screen
mHealth_ST-6	Switch to Detail tab	**N=1**	**A logged in user switches to detail tab to navigate in details menu**	-		08/09/2022		
		1	the user taps "Detail" button at the bottom of the main screen to reach appointments, diary, messages, trends, treatment plan, knowledge bank, questionnaires	The user has logged in and reached the main screen of the application.	Passed		the use should be directed to detail menu when detail button clicked	user successfully directed to detail menu
mHealth_ST-7	Navigating through Detail menu	**N=6**	**A logged in user switches to detail tab to navigate in details menu**	The user has logged in and tapped on Detail button .	Passed	08/09/2022	-	-
		1	the user can tap on appointments	The user has logged in and tapped on Detail button .	Passed		The user should have access to view their appointments with their clinician	Appointments screen is displayed
		2	the user can tap on diary	The user has logged in and tapped on	Passed		the user should be navigated to diary recording	the user successfully directed to diary

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				Detail button .			menu	menu
		3	the patient can tap on messages	The user has logged in and tapped on Detail button .	Passed		the user should be shown messages from clinician	clinician messages screen is displayed
		4	the patient can access to treatment plan	The user has logged in and tapped on Detail button .	Passed		treatment plan should be displayed	Treatment Plan screen is displayed
		5	the patient can tap on questionnaires	The user has logged in and tapped on Detail button .	Passed		the use should see questionnaires	questionnaires are successfully shown
		6	the patient can tap on Knowledge bank	The user has logged in and tapped on Detail button .	Passed		the use should see knowledge bank interface	Knowledge bank interface is shown
mHealth_ST-8	Display notifications	**N=1**	**A logged in user sees all notifications**		Passed	08/09/2022		
		1	the user can click bell button to see all notifications	The user has logged in and reached the main screen of the application.	Passed		When the user presses the bell button located on the top of the home screen, all notifications should be displayed	Application shows all notifications
mHealth_ST-9	Display settings	**N=1**	**A logged in user accesses settings menu**	-	Passed	08/09/2022	-	-

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		13	the user clicks the settings button to reach the settings menu.	The user has logged in and tapped on Detail button	Passed		user should reach settings menu to make personal changes to application	the user is shown settings menu
mHealth_ST-10	Change Language	**N=2**	**A logged in user accesses settings menu and changes language**	-	Passed	15/09/2022	-	-
		1	the user clicks the settings button to reach the settings menu.	The user has logged in and tapped on Detail button	Passed		Settings screen should be displayed	Settings navigation is displayed
		2	the user can change language by tapping the language button	The user must first navigate to the settings menu	Passed		the language of the application must be changed to the desired language	the language successfully changed
mHealth_ST-11	Successful Diary Recording	**N=6**	**A logged in user records diary**	-	Passed	15/09/2022	-	-
		1	User taps the Diary button	The user has logged in and tapped on Detail button .	Passed		Diary record interface should be displayed	Diary history and record new diary button is displayed
		2	the user taps record a new diary button	User is at diary interface	Passed		A dialog to receive diary summary is displayed with start recording button	Dialog to enter summary is displayed including start and cancel buttons
		3	the user taps start recording	User enters diary summary	Passed		Phone camera should be displayed in selfie mod with a	Phone camera is displayed in selfie mod with a rectangle to

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							rectangle to correspond user's face on the screen	correspond user's face on the screen
		4	user taps on bottom after bringing his/her head into the displayed rectangle	Camera is displayed	Passed		Should start recording	Recording started
		5	user taps on bottom of the screen to finish recording	Already started recording	Passed		Should display option to record again, play and save	Three buttons to trigger the next action is displayed
		6	user taps on add this video to diary	Stopped recording	Passed		Should save diary and go back to diary screen	Saved diary and navigated back to diary screen
mHealth_ST-12	Answer Questionnaire	**N=1**	**A logged in user answers a questionnaire**	-	Passed	15/09/2022	-	-
		1	User navigates to questionnaire list	The user has logged in and tapped on Detail button .	Passed		Available questionnaire list should be displayed	Available questionnaire list is displayed
		2	User taps on a questionnaire	The user is at questionnaire list screen	Passed		Questions in the questionnaires should be displayed one by one as the user responds	Questions are displayed as they are answered

mClinician Application

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Table 35 mClinician Application system tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
mClinician_ST-1	Navigating through the application	**N = 17**	**A logged in user taps on navigation buttons on main menu and interior menus**		Passed			
		1	clinician can see patient list with clicking patient list button	clinician has successfully logged into the application and accessed the main screen	Passed	01/09/2022	when clinician click patient list button clinician should be shown patient list	patient list is successfully shown
		2	clinician can choose a patient with clicking patient names	clinician has successfully logged in and navigate to partner list section	Passed	01/09/2022	selected patients profile should be shown	patient profile is successfully shown
		3	clinician can click Alert button to see patients alert	clinician has successfully navigated to patients profile	Passed	01/09/2022	clinician should see patients alerts	patients alert is successfully shown
		4	clinician can click Archived Alerts to see alert details	clinician has successfully navigated to patients profile	Passed	08/09/2022	clinician should see patients archived alerts	patients alert details are successfully shown
		5	clinician can click Trends to see patients trends	clinician has successfully navigated to patients profile	Passed	08/09/2022	clinician should see patients trends	patient trends are successfully shown

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		6	Clinicians can click on the 'Diary Analysis' button to view the diary analysis of a patient	clinician has successfully navigated to patients profile	Passed	08/09/2022	clinician should see diary analysis of the patient	dairy analysis are successfully shown
		7	Clinician can click on "Ctc Results" button to view Ctc test results	clinician has successfully navigated to patients profile	Passed	08/09/2022	Clinician should view Ctc results	Ctc Results are successfully shown
		8	clinician can click "Request New CDSS" for new CDSS	clinician has successfully navigated to patients profile	Passed	08/09/2022	clinician should go to CDS service list	clinician successfully received new CDSS
		9	Clinician can click "Alerts" button to view active alerts	clinician has successfully logged into the application and accessed the main screen	Passed	08/09/2022	clinician should view active alerts	active alerts are successfully shown
		10	clinician can click "Appointments" button to view appointments	clinician has successfully logged into the application and accessed the main screen	Passed	15/09/2022	clinician should be shown a calendar for appointments	appointments shown successfully
		11	clinician can click "Trajectories" button to go Trajectories section	clinician has successfully logged into the application and accessed the main screen	Passed	15/09/2022	clinician should be shown trajectory section	Trajectories successfully shown
		12	clinician can click "Usage Stats" button to view usage stats	clinician has successfully logged into the application and accessed the	Passed	15/09/2022	clinician should be shown usage stats of patients	usage stats is shown successfully

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				main screen				
		13	Clinician can click "Colon Cancer Recurrence CDS" button to view CDS recommendation	clinician has to successfully navigated to CDS Service List section	Passed	15/09/2022	Clinician should be shown Colon Cancer Recurrence CDS screen	Colon Cancer Recurrence CDS is shown successfully
		14	Clinician can click "Cardiovascular Disease Risk CDS" button to view CDS recommendation	clinician has to successfully navigated to CDS Service List section	Passed	15/09/2022	Clinician should be shown Cardiovascular Disease Risk CDS screen	Cardiovascular Disease Risk CDS screen is successfully shown
		15	Clinician can click "Breast Cancer Recurrence CDS" button to view CDS recommendation	clinician has to successfully navigated to CDS Service List section	Passed	15/09/2022	Clinician should be shown Breast Cancer Recurrence CDS screen	Breast Cancer Recurrence CDS screen is successfully shown
		16	clinician can click "Trajectory" button to view patients trajectory graph	clinician has to successfully navigated to CDS Service List section	Passed	15/09/2022	Clinician should be shown Trajectory screen	Trajectory screen is successfully shown
		17	clinician can click "Recurrence Prediction" to see probability of patients recurrence	clinician has to successfully navigated to CDS Service List section	Passed	15/09/2022	Clinician should be shown Recurrence Prediction	Recurrence Prediction is successfully shown

Multimodal Sensing Network

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Table 36 Multimodal Sensing Network system tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
MSN_ST-1	MSN flow user testing - Multimodal Sensing Network flow to process the diary videos	**N = 5**	**This test includes the whole pipeline for diary videos from getting an access token to storing the results to the server.**	-	Passed	05/02/2023	-	-
		1	Get an access token from Keycloak for user with consent signed.	Have a valid patient id. Have patient symptoms/diseases from 1.	Passed	5/02/2023	A valid access token for that user.	A valid access token for that user.
		2	Download file with the ID returned in the test plan number 1	1. Have an access token. 2. Have practitioner information: firstName, lastName, email, code, hospitalCode, hospitalName and language.	Passed	05/02/2023	The API returns the file ID and the FHIR resource for this file.	The API returns the file ID and the FHIR resource for this file.
		3	Check that you can open this file without problems	Patient voice must be found in the audio of the diary video.	Passed	5/02/2023	The file opens correctly.	The file opens correctly.
		4	Process the downloaded file	Patient voice must be found in the audio of	Passed	05/02/2023	Diary video is processed	Diary video is processed correctly

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				the diary video together with the patient face present in the video.			correctly in the MRAST framework.	in the MRAST framework.
		5	Store generated results from MRAST to the DEV and PROD FHIR server	Get an access token from Keycloak for user with consent signed.	Passed	5/02/2023	Generated data successfully transferred to the FHIR resources and stored on the FHIR server.	Generated data successfully transfered to the FHIR resources and stored on the FHIR server.

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CTC Component

Table 37 CTC component system tests results.

Test ID	Test case	Steps	Description	Prerequisites	Status	Execution date	Expected result	Result
CTC_ST-1	CTCs report management.	**N = 11**	**A CTC counting system's user manages a patient's reports. In this management the user adds, modifies and deletes reports from the system.**	-	Passed		-	-
		1	The user logs in successfully to the CTCs application.	The user has been registered in the system.	Passed	13/01/2023	The user is successfully logged in and is shown the application's main screen, where a text input box with the heading "Patient ID" appears together with a search button with a magnifying glass icon.	The user is successfully logged in and can correctly see the following screen with the text input box and the search button.

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		2	The user can type the patient ID in the text entry box and submit it by clicking on the search button.	The user has been successfully logged in to the CTCs application.	Passed	13/01/2023	The information is sent and the application is kept waiting for a response from the server.	The application is kept waiting for a response from the server.
		3	The user can see the patient's CTC reports, with different fields and sorted by issued date.	The user was able to type the patient ID in the text box and press the search button. The patient ID typed by the user has been previously registered in the system.	Passed	13/01/2023	The list screen is updated showing the user a list of the patient's CTC reports, sorted by issued date and including the information related to the fields: Issued, CLASS 1, CLASS 2, CLASS 3, TOTAL and Cancer type. Next to these fields, two buttons are displayed: edit (notebook and pencil icon) and delete (a bin icon) report. A general button to add (+ icon) a new report is also displayed.	The list screen is updated and the user can see a list of the patient's CTC reports, sorted by date of issue and including the information relating to the above fields. You can also see the edit and delete report buttons. The button to add a new report is also displayed.

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		4	The user can click on the create button to access the screen for creating a new report.	The user was able to access the report listing screen where the create button is also located.	Passed	13/01/2023	The application shows the user the screen for creating a CTC report, with the different fields to be filled in: class 1, class 2, class 3, cancer type, issued date and report brief description. Two different buttons for attaching images and PDF reports are also displayed. "Save" and "Cancel" buttons are displayed at the bottom of the screen.	The application shows the user the screen for creating a CTC report with the different fields to be filled in and also the two buttons for attaching images and PDF reports. "Save" and "Cancel" buttons are displayed too.
		5	The user can fill in all the fields that appear on the screen and press the "save" button to create a new report.	The user accesses the screen for creating a CTC report.	Passed	19/01/2023	The user can correctly fill in the different fields and attach images and PDFs within the form to create a CTCs report. Upon submission, the user is shown a message that the report was created correctly.	The user is able to fill in the text fields, attach files from the system and select the cancer type and the issued date. The confirmation message is shown when clicking on "save".

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		6	The user can see the newly created report in the report list.	The user created a new CTCs report.	Passed	19/01/2023	The user sees in the list screen the new report created together with the previous reports. The correct values are shown in the summary fields and the report appears at the top of the list.	The new created report with the correct values is displayed at the top of the reports list.
		7	The user can click on the edit button next to a report's information to access the modification screen of an existing report.	The user was able to access the report listing screen where the edit buttons are also located.	Passed	19/01/2023	The screen for editing a report is displayed to the user. This screen shows all the fields that were covered during its creation along with the defined values.	The edit report button takes the user to the edit screen. The current values of each field are displayed correctly.
		8	The user can edit the fields displayed on the modification screen and press the "Save" button to send the new values.	The user accesses the screen for modifying a CTC report.	Passed	19/01/2023	The user can successfully modify the different fields and delete or attach new images and PDFs within the form to edit a CTCs report. Upon submission, the user is shown a message indicating that the report has been successfully modified.	The user is able to modify the values of an existing report. For example, change the value of a text field, delete an attached image or change the issued date. When saving the changes, a confirmation message is displayed to the

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								user.
		9	The user can see the newly modified report in the report list.	The user has modified a CTCs report.	Passed	19/01/2023	The user sees the modified report on the list screen. The correct values are displayed in the summary fields and the report appears at the top of the list.	The user can see the changes made to the summary fields in the report list.
		10	The user can click on the delete button next to a report's information to delete an existing report.	The user was able to access the report listing screen where the delete buttons are also located.	Passed	19/01/2023	The user is shown a report deletion confirmation message with two buttons: "yes" and "no".	When clicking on the delete report button, the user is shown a confirmation message with two buttons: one to confirm (yes) and one to cancel (no).
		11	The user can click on the "yes" button to delete a report.	The user has clicked on the delete report button and a report deletion confirmation message with two buttons: "yes" and "no" has been displayed.	Passed	19/01/2023	The report to be deleted disappears from the list of patient reports.	When the user clicks on the yes button, the deletion of the resource is confirmed and the resource disappears from the patient's resource list.

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CTC_ST-2	Automatic counting of CTCs in fluorescence microscope images.	**N = 11**	**A CTC counting system's user uses the system's automatic counting to analyse a microscope image.**	-	Passed	25/01/2023	-	-
		1	The user can click on the drop-down menu button, and within this, on the automatic CTCs prediction option to access the corresponding screen.	The user has successfully logged into the application and accessed the main screen.	Passed	25/01/2023	The user is shown the microscope's image upload screen where a button appears to attach a new image.	The user accesses the automatic CTC prediction screen where he/she is allowed to upload an image.
		2	The user can click on the "upload a new image" button.	The user has been able to access the microscope's image upload screen.	Passed	25/01/2023	A pop-up window with a "select files" button appears to select the image to be processed by the system.	The user can see a pop-up window with a button to select files.
		3	The user can click on the "select files" button which appears on the pop-up window to upload microscope's images.	A pop-up window with a "select files" button has been shown to the user on the microscope's image upload screen.	Passed	25/01/2023	A new pop-up window appears on the screen, allowing the user to select an image on the file system.	The user is shown a pop-up window with access to his/her own file system.

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		4	The user can select an image from the file system to be uploaded to the CTCs automatic counting system.	A pop-up window to select an image from the user's file system has appeared on the microscope's image upload screen.	Passed	25/01/2023	The uploaded image's name appears on the screen. Next to it, a "delete" button (a bin icon) is also shown to the user.	The user is shown the name of the selected file system image along with a button to delete it.
		5	The user can delete the uploaded image by clicking on the "delete" button.	The user has been able to upload a microscope's image from the file system to the CTC web application.	Passed	25/01/2023	The uploaded image's name disappears from the screen.	A delete confirmation message is displayed and upon confirmation, the name of the uploaded image is deleted.
		6	The user can upload two or more images in the microscope's image upload screen.	The user has clicked on the specific buttons to upload an image and the pop-up window to select an image from the user's file system has appeared on the microscope's image upload screen.	Passed	25/01/2023	The name of the uploaded images is displayed on the screen. Next to them, the corresponding "delete" buttons (a bin icon) are also shown to the user.	The user can see the name of the uploaded images on the screen along with a button to delete each of them.

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		7	The user can click on the "upload images" button to send the selected ones to the CTC automatic counting service.	The user has been able to upload one or more microscope's image from the file system to the CTC web application.	Passed	25/01/2023	The selected images are sent to the CTC automatic counting service and it returns a prediction ID which is displayed on the screen. This ID is also sent to the user by email next to the number of CTCs the algorithm has predicted.	The user receives a prediction identifier that he can see both on the application screen and in his own email. The email also indicates the number of detected CTCs.
		8	The user can click on the drop-down menu button, and within this, on the prediction retrievement button to access the corresponding screen.	The user has successfully logged into the application.	Passed	25/01/2023	The user is shown the retrievement prediction screen where a text input field appears together with a "retrieve prediction" and a "cancel" button.	The user receives a prediction identifier that he can see both on the application screen and in his own email. The email also indicates the number of detected CTCs.
		9	The user can type the prediction ID in the text input box and submit it by clicking on	The user has been able to access the retrievement prediction screen.	Passed	25/01/2023	The prediction retrievement screen is updated showing the user a list of the	The user can see the results of the prediction system. The CTCs detected

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			the "retrieve prediction" button.	The user has received from the CTCs prediction service an prediction ID when sending one or images to process.			predicted CTCs for each of the uploaded images. Each of the predicted CTCs are shown broken down into the different components that make them up. Each predicted CTC is also displayed twice along with two sliders for managing brightness and applying a colour intensity filter.	in each of the images sent are shown decomposed in the layers that form it together with slider bars to modify brightness and colour intensity (in each layer).
		10	The user can manage the brightness and the colour intensity using the sliders.	The prediction retrievement screen has shown the user a list of the predicted CTCs for a specific prediction ID. They are shown broken down into the different components that make them up along with two sliders for managing brightness and applying a colour intensity filter.	Passed	25/01/2023	The brightness and colour intensity of the different components of the CTCs change depending on the position of the sliders.	The slider bars allow you to correctly modify both the brightness and the colour intensity of each layer.

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		11	The user can delete a predicted CTC from the user interface by clicking on the "delete" button next to each of the predictions.	The prediction retrievement screen has shown the user a list of the predicted CTCs for a specific prediction ID.	Passed	25/01/2023	The deleted prediction disappears from the user interface.	The CTC deleted by the user is no longer visible on the screen.

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6. Security, legal and ethics privacy-protecting mechanisms

Introduction

The aim of this contribution is to provide an analysis of PERSIST technology and detect the main challenges that the latter must overcome to be compliant with the GDPR. This contribution will employ in its methodology relevant doctrines, reports, and several guidelines provided by the European Data Protection Board (EDPB). Finally, this document will provide insights on data protection for subsequent steps of PERSIST technology. It must be underlined that this activity is focused strictly on PERSIST technology, therefore, does not take into consideration data protection questions related to the pilots. An analysis and evaluation of the latter is provided in D7.3.

Overview

When it was brought into force, on 25 May 2018, the GDPR instituted a vast framework for privacy and data protection. This regulation has been "an essential step to strengthen individuals' fundamental rights in the digital age and facilitate business by clarifying rules for companies and public bodies in the digital single market" (E. Commission, 2022). Most notably in this regard, the GDPR has set provisions on the lawfulness of data treatment; security of data processing; and the entitlement of certain data rights to the data subjects. On the other hand, this wide-ranging regulation introduced several legal obligations for developers, organisations and tech companies. Understandably, this new piece of legislation produced a deep impact in the tech field and in the app market (J. e. al., 2022).

The change of pace was deeply felt also in the sub-group of healthcare apps, given the nature of the latter, as for the GDPR, "data concerning health" is inherently sensitive. Therefore, it is classified as a "[s]pecial category of data" (Art. 9, GDPR) and subjected to extra-care. The rationale behind this legal choice is that with this specific variety of data there are always risks to the privacy and fundamental rights of individuals (T. Mulder, 2019).

Given this challenge, it is particularly appropriate to conduct an assessment of the compliance of PERSIST technology with the GDPR. The following sections will analyse the ICT architecture of the latter through the lens of privacy, data protection and security of processing. As already mentioned, this process will employ in its methodology the relevant best practices and frameworks. This includes a thorough analysis of the GDPR text and of several documents released by the EDPB. The final outcome of this activity addresses five specific challenges that have been spotted in PERSIST technology and will provide tailored insights.

GDPR challenges

This contribution will address the main challenges regarding privacy and data protection for PERSIST technology. At last, it will include an analysis of the security of processing in accordance with Art. 32 of the GDPR. Notably, the final outcome should be kept in mind

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for the creation of the final and tailored privacy policy to insert inside PERSIST technology and to be compliant with the GDPR.

But first, a premise: the Art. 13 of the GDPR enshrines a list of information that must be given compulsorily to the data subject. This is a general requirement, necessary for data processing and usually is fulfilled through the provision of a privacy policy. Accordingly, the information to be provided are:

1. Identity and the contact details of the controller or of the latter's representative;
2. The contact details of the data protection officer, if present;
3. The purposes and the legal basis for the processing of personal data;
4. Explain the "legitimate interest" pursued by the controller or by a third party, where the legal basis of the processing is Article 6(1f);
5. The recipients of the personal data, if any;
6. Whether the controller intends to transfer personal data to a third country or international organisation;
7. The data retention period for which the personal data will be stored. If that is not possible, the criteria used to determine that period;
8. The communication that the data subject is entitled to certain rights vis-à-vis the controller. Namely, the right to access, rectify, erase own personal data, or to restrict the processing concerning the data subject or to object to it as well as to data portability;
9. Where the processing is based on "consent" or "explicit consent", the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing previous to the withdrawal;
10. The right to lodge a complaint with a supervisory authority;
11. Whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;
12. The existence of automated decision-making, including profiling. In addition, the logic employed, the significance and the impact of such processing for the data subject.

While these are the general requirements, the following paragraphs will inquire about specific facets that concern PERSIST technology:

- ➔ Legal basis;
- ➔ Automated decision-making and profiling;

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- Data subject rights;
- Security of processing;
- Data Protection Impact Assessment (DPIA).

The GDPR addresses all these aspects and they have specific repercussions for the compliance of PERSIST technology with the former. Therefore, they are worthy of this in-depth and tailored analysis.

Lawfulness of data processing

The legal basis for processing personal data are enumerated in Art. 6 of the GDPR. Accordingly, there are 6 choices available:

- Consent;
- Performance of a contract;
- Legal obligation;
- Vital interest of the data subject or another individual;
- Task of public interest;
- Legitimate interest of the data controller.

However, it must be highlighted that in the case of PERSIST technology the choice between all these legal basis is more restricted as it processes “health data”. Indeed, according to Art. 9(1) of the GDPR, this kind of data is part of a “special category " in which processing is in general prohibited. The typical exception to this rule is when the data subject gives his/her “explicit consent” (Art. 9(2)). Therefore, a suitable legal basis for the processing of health data is “consent”, with additional and specific safeguards stemming from being “explicit”.

On a side note, “explicit consent” is not the only exception through which can be avoided the general prohibition to process “special category” data contained in Article 9(1) of the GDPR. Still, since the present contribution takes into consideration a scenario beyond the research context, but PERSIST technology itself, “explicit consent” is the most appropriate legal basis for the treatment of the health data of the patients. Furthermore, it is the most ethical choice as it entrusts the patients with the control of their relevant personal data, empowering them with their own decisions. Notably, this was the route employed also in the pilots, as it will be depicted in a few paragraphs.

Consent alone is defined in Art. 4(11) of the GDPR as:

> ***“any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”.***

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In other words, consent connects the will of the data subject to the purpose of data processing. In addition, Art. 7 of the GDPR enumerates other requirements necessary for a legally valid consent. Accordingly, the request for consent must be presented to the data subject:

> ***"In a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language".***

How consent must be obtained in practice is not addressed in the GDPR: in this regard, the only requirement is that it must be demonstrable. For this reason, the consent can surely be obtained through digital means. For instance, "an 'I-agree-button' combined with a privacy policy, is one of the most common mechanisms" for an app to be in compliance with the GDPR. (T. Mulder, 2019).

However, as aforementioned, the processing of health data warrants for additional safeguards. Namely, obtaining consent from the subject is not sufficient, as it must also be "explicit". The precise meaning of the latter term is not deepened in the GDPR, but, according to the EDPB, a consent is deemed "explicit" when the data subject "gives an express statement of consent" (E. D. P. Board, 2020). In other words, an "explicit" consent cannot be inferred, but must be clearly expressed. Accordingly, an obvious instance of "explicit consent" would be "to expressly confirm consent in a written statement". The following table will sum up the mentioned requirements for "consent" and "explicit consent", according to the GDPR.

The consent:	***Is any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action***	***Art. 4(11)***

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The consent:	*Must be demonstrable*	*Art. 7(1)*
The consent:	*Shall be presented in a manner which is clearly distinguishable from the other matters*	*Art. 7(2)*
The consent:	*Is intelligible and easily accessible form, using clear and plain language*	*Art. 7(2)*
The explicit consent:	*Is not to be subsumed, but must be clearly expressed*	*Art. 9(2a)*

"Explicit consent" can be obtained in a digital setting. Therefore, it can be adapted to the needs of PERSIST technology. The EDPB stated that it is acceptable to fill in an electronic form, send an email, use an electronic signature or even upload a scanned document with the signature of the data subject using an electronic signature. Notably, the latter solution was the one employed in the pilots of PERSIST. For the sake of clarity, the next paragraph will offer a practical example of the difference between "consent" and "explicit consent" (E. D. P. Board, 2020).

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Example: A data controller may also obtain explicit consent from a visitor to its website by offering an explicit consent screen that contains Yes and No check boxes, provided that the text clearly indicates the consent, for instance "I, hereby, consent to the processing of my data", and not for instance, "It is clear to me that my data will be processed".

Given the discipline just described, it is necessary to take into consideration all these requirements and formalities necessary to obtain the "explicit consent" in the PERSIST technology. It could be possible to confirm the solution employed in the pilots – to upload a scanned document with the signature of the data subject – or to choose another route if deemed more practical. It must be highlighted that the Partners in the F2F meeting in Maribor have almost unanimously agreed that should be developed a more practical method to obtain the "explicit consent" in the future.

Profiling and automated decision-making

Another challenge to overcome concerns profiling and automated decision-making, both explicitly carefully addressed in the GDPR. The reasons behind this wariness lie in the potential impact that these kinds of activities can have on fundamental rights and society. In this regard, the Art. 29 WP stresses that the massive availability of personal data on the Internet and the development of the Internet of Things (IoT) has enabled the possibility "to find correlations and create links" between "aspects of an individual's personality or behaviour, interests and habits to be determined, analysed and predicted". Similar activities, whether left unchecked, may be concerning as they "can perpetuate existing stereotypes", fostering discrimination, "social segregation" and "lock a person into a specific category and restrict them to their suggested preferences" (A. 2. D. P. W. Party, 2018).

The GDPR deals with automated decision-making in Article 22. Here, it is stated that an individual has the right "to not be subject to a decision based solely on automated processing" which has an impact on him/her. This is regardless of whether the decision-making is based on profiling or not. However, it must be noted that this provision does not apply to PERSIST technology, as it only provides assistance to the decision-making process, leaving the final word to clinicians.

Given the presence of the human-in-the-loop, it is safe to assume that PERSIST technology does not support fully automated decision-making. Therefore, what remains to assess is if it executes profiling. For this purpose, it is necessary to take into account the technical architecture of PERSIST and the definition of profiling provided in Art. 4(4) of the GDPR. Which accordingly states:

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> **"Profiling means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movement".**

This broad definition is integrated by the Art. 29 WP. Accordingly, profiling is composed of three elements:

- ➔ it has to be an automated form of processing;
- ➔ it has to be carried out on personal data;
- ➔ the objective of the profiling must be to evaluate personal aspects about a natural person. **(A. 2. D. P. W. Party, 2018)**

Indeed, PERSIST architecture (see D2.5) supports profiling activities. First, it enshrines a Clinical Decision Support System (CDSS), which enshrines an inference engine which performs reasoning function (D5.1). Secondly, the latter activity is enabled through the stream of data provided by the Open Health Connect (OHC), which ensures "all of interfaces to be connected to and make decisions across disparate data sources in real time. [Providing also] the framework and set of tools for the integration, ingestion, storage, indexing and surfacing of patient information" (D4.1). Lastly, a MultiModal Sensing Network (MMSN), "an edge component which acts as a data collector and aggregator as well as an interface between patient and clinician/system" (D2.5).

These components aim to deliver, jointly in the PERSIST system, "an open and interoperable ecosystem to improve the care of cancer survivors". According to this reconstruction, the PERSIST technology does execute profiling from a legal perspective, as it processes personal data through automated means for the sake of predicting the health aspects of the patients. Therefore, it is consistent with the definitions of profiling provided above.

Nonetheless, it must be highlighted that the GDPR does not prohibit profiling tout court, but only states the need for extra-care and to uphold fairness and transparency in the processing. This includes the possibility of triggering the necessity of a DPIA, as explained in the section 2.5 of this document. This is deepened by the Recital 60 of the GDPR, which affirms that data subjects should be informed of the existence of profiling; its consequences; if it is compulsory for the purpose of the treatment; and the related reasons. To sum up, PERSIST technology does not execute automated decision-making, but it does perform profiling. The presence of the latter activity should be made clear in its entirety for the data subject.

Data subject rights

The legal privacy frameworks of the new generation are commonly featured by a thorough focus on the s.c. dynamic protection. This terminology means that the data subject is

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enabled to keep control of its personal data, even after the latter has been released into the digital space. For this purpose, the GDPR grants the data subject a range of rights. Specularly, the controller is obliged to enable and facilitate their effective exercise. More in general, the controller is accountable for the respect of all principles relating to the processing of personal data. This includes the effective enforceability of data subject rights. Which, according to the GDPR, they are:

- The rights to access
- The right to rectification
- The right to erasure
- The right to restriction of processing
- The right to data portability
- The right to withdraw your consent
- The right to lodge a complaint

The PERSIST technology supports a Consent Manager (for more information, D4.1) which enables the sharing of data without losing control. This feature allows patients to set their preferences for data sharing. It records 'Opt-In' and 'Out-out' preferences by organisation and purpose. This system employs fine-grained management of the consent, which allows the sharing and filtering of data through consent permissions (see also, AI Ready section of the present document, p.18).

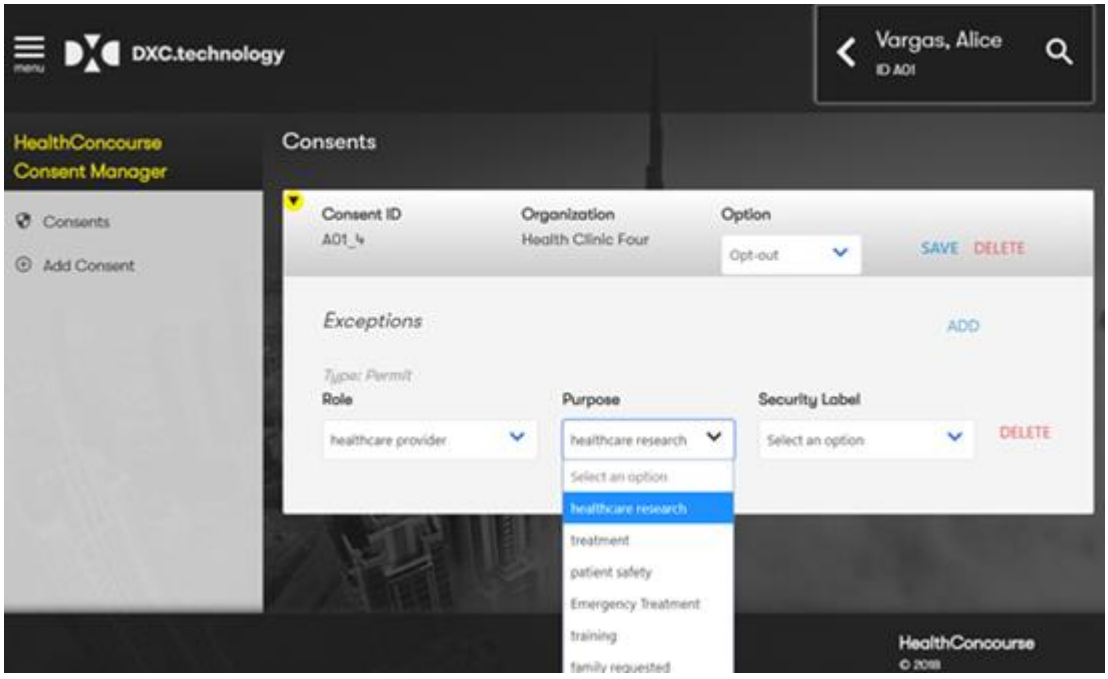

Figure 9 Adding a consent statement to the patient record by clinician or research team.

In conclusion, the Consent Manager is a welcomed effort of privacy-by-design. It facilitates the compliance of the controller with the GDPR, giving the data subject direct control of her/his personal data (Recital 59, GDPR). Nonetheless, this channel does not replace the

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more general obligation for the controller to provide his/her contact details to the data subject, as this remains the main way for the latter to exercise data subject rights. All these aspects should be taken into consideration in the final draft of the privacy policy, as the determination of the controller in charge of the data processing, or one of his representatives, and the relevant contact details must always be clear.

Security of processing

While the world is entering the digital age, cyberspace is already permeating our society, enabling and/or facilitating different aspects of life. For this reason, it is growing the awareness that is essential to protect our digital assets and structures. In general, the discipline which is in charge of this task is cybersecurity and can be defined as the "practice of protecting systems, networks, and programs from digital attacks" (CISCO, 2022).

Cybersecurity has become even more relevant in recent years, as there is a steady and outstanding surge of cybercrime. According to CyberVentures the estimation of only ransomware attacks for 2020 was 20 billion $, while for 2031 it is the striking amount of 265 billion $ (CISCO, 2022). This trend has not spared even the healthcare sector: according to a survey, 34% of the hospitals interviewed were hit by ransomware in 2021 and 41% were not, but were expecting to be hit as well in the future (D. Braue, 2022). For this reason, the development of PERSIST technology, including software components and a big data platform, triggers the necessity analysis through the lens of cybersecurity.

The focus of this section will be on the security of processing: a specific facet of cybersecurity linked with data protection and enshrined in Article 32 of the GDPR. This mechanism is grounded on a risk-based approach. Namely, it assembles an obligation to implement "appropriate technical and organisational measures to ensure a level of security appropriate to the risk". It may be premature to deliver a full assessment in this regard, as this process in the end should also consider the aspects related to security, protocols, network and storage of the eventual customers.

Nonetheless, the process can already be kickstarted through the thorough enumeration of all the measures which PERSIST technology employs to protect its own stream and storage of data. Must be highlighted that Article 32 of the GDPR mentions explicit measures like "the pseudonymisation and encryption of personal data". But also, more in general, it encompasses the "ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services". A list of the technical measures enacted to guarantee the security of processing is provided in the D7.3: Security Management Report.

Data Protection Impact Assessment

Another requirement for PERSIST technology may be the execution of a DPIA: an assessment of the impact of the data process on the fundamental rights of the data subject. The discipline of this mechanism is enshrined in Article 35 of the GDPR, which states that it is mandatory when the data process "is likely to result in a high risk to the rights and freedoms of natural persons". For this reason it is of the utmost importance to identify the risks for the data subjects and assess their degree.

This outcome can be obtained by analysing jointly the Art. 35 of the GDPR with the Guidelines on Data Protection Impact Assessment (DPIA), released by the Art. 29 WP (R. Pifer, 2022). In the former it is stated that a DPIA is required when the data process encompasses:

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1. Evaluation or scoring, including profiling and predicting, especially from “aspects concerning the data subject's performance at work, economic situation, health, personal preferences or interests, reliability or behavior, location or movements;
2. Automated-decision making with legal or similar significant effect, ex Art. 22;
3. Systematic monitoring: processing used to observe, monitor or control data subjects, including data collected through networks or “a systematic monitoring of a publicly accessible area” (Article 35(3)(c))15 .
4. Sensitive data or data of a highly personal nature: this includes special categories of personal data as defined in Article 9 (for example information about individuals’ political opinions), as well as personal data relating to criminal convictions or offences as defined in Article 10.
5. Data processed on a large scale;
6. Matching or combining datasets, for example originating from two or more data processing operations performed for different purposes and/or by different data controllers in a way that would exceed the reasonable expectations of the data subject;d
7. Data concerning vulnerable data subjects, like children, elderly or patients;
8. The use of new technological or organisational solutions, like combining use of fingerprint and face recognition for improved physical access control, etc.
9. When the processing in itself “prevents data subjects from exercising a right or using a service or a contract”, like it may happen in a fully automated decision-making;

On average, the presence of two or more of these criterias triggers the obligatoriness of a DPIA, but this is not always the case. A “hospital processing its patients’ genetic and health data” encompasses criteria 4, 5 and 7: as such it elicits the execution of a DPIA (A. 2. D. P. W. Party, 2017). Differently, the processing of “personal data from patients or clients by an individual physician” encompass criterias 4 and 5, but do not require a DPIA (Recital 91, GDPR).

According to the Art. 29 WP, in case of doubt it is recommended to execute a DPIA. But it must also be highlighted that not every application of PERSIST technology would need one: Art. 35 of the GDPR affirms that “a single assessment may address a set of similar processing operations that present similar high risks”. In other words, in similar contexts executing one DPIA for all is a valid choice. This outcome should be taken into consideration by the Consortium.

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7. Conclusions

1. PERSIST architecture has got a high degree of complexity, which has required the validation at different stages and levels - unit, integration and functional - of each of the components that make it up.
2. The use of a common framework and the creation and iterative review of the validation plan, including test cases and test execution results has enable the validation of the functionality of each component and the successful integration of all of them into a working system with three user interfaces that can provide meaningful results to cancer survivors, oncologists and liquid biopsy laboratory technicians.
3. PERSIST's architecture ensures the scalability of the proposed care model. The design of the DC4H platform, the deployment of PERSIST services in the cloud, and the use of the HL7 FHIR standard will smooth the process of incorporating new data sources, new users and increased loading without compromising the availability, performance and usefulness of the PERSIST care model.
4. PERSIST technology needs the "explicit consent" of the data subject for operating in compliance with the GDPR. This has already been taken into consideration in the pilots. Therefore, the matter is only to confirm the solution employed during the pilots or to take another choice.
5. PERSIST technology does not support in its protocols a fully automated decision-making. Therefore, the discipline of Article 22 of the GDPR does not apply in the case at hand. Instead, it is executed profiling. This should be kept in mind in the future steps of development of PERSIST technology. Profiling requires transparency and a few additions to the privacy policy.
6. The Consent Manager embedded in PERSIST technology should be praised, as a good example of privacy-by-design. Nonetheless, it should be remembered that the controller must establish an effective link with the data subject to enable the latter to exercise his/her data rights.
7. Article 32 of the GDPR calls for a cybersecurity assessment of the measures employed to mitigate the risks of data processing. This can hardly be finalised at this stage. Nonetheless, the task can already be kickstarted by providing a thorough enumeration of the cybersecurity protocols employed by PERSIST technology and at which stage of the data processing they are placed.
8. According to the GDPR, the DPIA is an activity that can be mandatory or not. In the case of PERSIST technology it depends for the most part on the scale of the processing and on the identity of the data controller.

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8. References

- W. E. Howden, "Functional Program Testing," in IEEE Transactions on Software Engineering, vol. SE-6, no. 2, pp. 162-169, March 1980, doi: 10.1109/TSE.1980.230467.
- M. A. Jamil, M. Arif, N. S. A. Abubakar and A. Ahmad, "Software Testing Techniques: A Literature Review," 2016 6th International Conference on Information and Communication Technology for The Muslim World (ICT4M), Jakarta, Indonesia, 2016, pp. 177-182, doi: 10.1109/ICT4M.2016.045.
- Angelina Samaroo, Geoff Thompson, and Brian Hambling. 2015. Software Testing: An ISTQB-BCS Certified Tester Foundation Guide 3rd ed (3rd. ed.). BCS, Swindon, GBR.
- Miller, R., & Collins, C. T. (2001). Acceptance testing. Proc. XPUniverse, 238.
- QALovers, “Introducción al Testing: Pruebas no funcionales” (2021). [Online]. Available: https://www.qalovers.com/2019/01/pruebas-no-funcionales.html
- E. Commission, «Data Protection in the EU,» [Online]. Available: https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en. [Consultato il giorno 10 October 2022].
- J. e. al., «GDPR and the lost generetion of innovative apps,» NBER Working Paper Series, 2022.
- T. Mulder, «Health Apps, Privacy Policies and the GDPR,» European Journal of Law and Technology, vol. 10, n. 1, 2019.
- E. D. P. Board, «Guidelines 05/2020 on consent under Regulation 2016/679,» 4 May 2020. [Online]. Available: https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf. [Consultato il giorno 10 October 2022].
- A. 2. D. P. W. Party, «Guidelines on Automated individual decision-making and Profiling,» 6 February 2018. [Online]. Available: https://ec.europa.eu/newsroom/article29/redirection/document/49826. [Consultato il giorno 10 October 2022].
- CISCO, «What is Cybersecurity?,» [Online]. Available: https://www.cisco.com/c/en_uk/products/security/what-is-cybersecurity.html. [Consultato il giorno 13 October 2022].
- D. Braue, «CyberVentures,» 2 June 2022. [Online]. Available: https://cybersecurityventures.com/global-ransomware-damage-costs-predicted-to-reach-250-billion-usd-by-2031/. [Consultato il giorno 10 October 2022].
- R. Pifer, «CyberSecurityDive,» 30 June 2021. [Online]. Available: https://www.cybersecuritydive.com/news/healthcare-cybersecurity-ransomware-sophos/602632/. [Consultato il giorno 10 October 2022].
- A. 2. D. P. W. Party, «Guidelines on Data Protection Impact Assessment,» 4 April 2017. [Online]. Available: https://ec.europa.eu/newsroom/just/document.cfm?doc_id=47711. [Consultato il giorno 11 October 2022].
- Project Management Institute, A Guide to the Project Management Body of Knowledge (PMBOK Guide) 6th ed., Project Management Institute, 2017.

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