DELIVERABLE

D7.5 – Data Management Plan - DMP - first release

Project Acronym: UNCAP

Grant Agreement number: 643555

Project Title: Ubiquitous iNteroperable Care for Ageing People

Revision: v.1.0

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Project co-funded by the the Horizon 2020 Framework Programme of the European Union		
Dissemination Level		
P	Public	**x**
C	Confidential, only for members of the consortium and the Commission Services	

1. Revision history and statement of originality

1.1. Revision history

Rev	Date	Author	Organization	Description
v0.0	10-06-2015	Claudio Eccher	FBK	First draft (ToC)
V0.1	15-06-2015	Claudio Eccher	FBK	Added section InterRAI
V0.2	17-06-2015	Leonardo Plotegher	TRILOGIS	Added part of UNCAP section
V0.3	19-06-2015	Leonardo Plotegher	TRILOGIS	Added missing pieces to UNCAP section
V0.4	22-06-2015	Claudio Eccher	FBK	Minor changes
V0.5	25-06-2015	Claudio Eccher and Leonardo Plotegher	FBK+TRILOGIS	Added Informed consent section and other missing parts
V0.6	29-06-2015	Giuseppe Conti	TRILOGIS	Revision
V1.0	30-06-2015	Giuliana Ucelli	TRILOGIS	Quality check

1.2. Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

2. List of references

Number	Full Reference
1	*D1.2 Regulatory constraints*
2	*D1.3 System architecture*
3	*D1.5 Assessment module based on InterRAI scales*
4	*www.interrai.org*
5	*www.ascotlc.it*
6	*http://www.openstreetmap.org/copyright/*
7	*http://wiki.openstreetmap.org/wiki/OpenRouteService*

3. Table of Acronyms

Acronym	Description
AL	*Assisted Living*
CAP	*Clinical Assessment Protocol*
CHA	*Community Health Assessment*
GIS	*Geographical Information System*
HC	*Home Care*
ICW	*Internet Central Website*
LTCF	*Long Term Care facilities*
POI	*Point of Interest*

4. Executive Abstract

This document reports on how the data will be handled during the UNAP project. The goal is to consider the many aspects of data management, metadata generation, data preservation, and analysis, in order that data is well managed in the present, and prepared for preservation in the future.

The present document is the first release of the DMP, and is divided in three main sections. Future releases are planned on a 12-month basis.

Section 8 is devoted to the presentation of the informed consent for data treatment that has to be signed by all the patients enrolled in the studies. The complete informed consent is reported in the Annex. The same section describes the website created to effectively manage the informed consent, and the procedure for subscribing and using the informed consent site.

Section 9 deals with the management of the data acquired with and produced by the Alt@nte/InterRAI™ system, used by the pilot sites in the first phase of the clinical investigation to collect baseline data for the initial assessment of patient in order to refine the inclusion and exclusion criteria, and to evaluate the intervention with UNCAP during the clinical investigation. Since Alt@nte/InterRAI™ is a commercial software specifically created as a clinical tool for managing patient data with the kind of impairments object of the UNCAP project, this chapter does not go into the details of Alt@nte/InterRAI, which instead can be found within Deliverable 1.5 and Alt@nte/InterRAI™ specifications and user manuals.

Section 10 presents the minimum set of data that will be managed by the UNCAP system. These will be extended/refined in the successive releases of the DMP with further set of data identified by the pilot sites in the course of the pilot preparation and system deployment phase.

Moreover, the detailed policies of management of data in the UNCAP system will be object of the next DMP releases.

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8. Informed consent

Among the various activities that have been carried out for defining the deployment plan of UNCAP at the various pilot sites, specific administrative procedures have been studied and addressed. These include from legal requirements to the preparation and collection of signed acceptance forms from users and the later storing of their personal data.

In fact, in order to be enrolled in the study, the patients have to sign an informed consent for data treatment. The informed consent is a printed document that the patient must carefully read and sign when enrolled in the study. UNCAP will provide to the pilots a template for the informed consent for data treatment (see Annex: Informed consent).

The first phase of the study uses the Alt@nte system ("pre-UNCAP assessment") while the second phase will be the clinical trial to evaluate UNCAP.

To optimize collection and management of the informed consents, Trilogis has created and operates a Intenent Central Web site (ICW), which allows collecting and archiving in a central repository the personal data of the patients along with the signed consents. The doctor responsible for enrolling the patient and distributing and managing the informed consent in the pilot organization (pilot site responsible from now on) can access the site if he/she possesses the authentication credentials (Login and password).

In the following, the description of the procedure for obtaining the credentials is provided, and for managing the enrolment of the patients as well as the collection of the signed consents:

- The person responsible for enrolling the patient at each pilot site must request an account on ICW to Trilogis (a person has been appointed for the task as detailed within the form in Annex), specifying his/her personal data and the reference pilot site. Trilogis will create the ICW user and communicate the access credential to the requester by phone or email.
- With the access credentials, the pilot site responsible connects to the ICW login page at the address: http://5.249.148.19:8080/consent/. The user can log in the ICW by accessing the login page (Figure 1), inserting the login and password and clicking "*Login*".
- Upon the successful login, the user is redirected to the page where he/she can download and print the informed consent and access the patient enrolment page (Figure 2).
- The user downloads and prints the informed consent by clicking the button "*Download informed consent template*" and hands it over to the patient. The patient must carefully read the document, provide his/her data and sign the last page. The printed version of the signed document must be managed according to the internal archiving procedures for the informed consents in operation in the pilot site.
- The person in charge for managing the enrolment must fill in and sign the last page and scan the last two pages of the signed document to produce a pdf or jpg electronic version.

- By clicking on the lower button in Figure 2("*Add patient*"), the person in charge for managing the enrolment, accesses the patient enrolment page (Figure 3), in which he/she can add a patient (by providing the required data) and upload the signed consent. The user must provide the personal data of the patient and (if needed or applicable) the personal data of the legal representative (Figure 3), if the patient is not capable to provide the consent.
- The person in charge for managing the enrolment has to upload the scan of the informed consent. At the bottom of the page, the button "*Choose file*" opens a dialog window to choose the scan(s) of the signed consent and upload it to the consent management system. If the scan of the two last pages (step 6) produces two separate files (e.g., two jpeg images), the user must upload both of them or, alternatively, a unique zip file containing the two files.
- Once the user has chosen the file(s) to upload, he/she must click the "*Upload*" button that uploads the scanned document to the system, closes the page, and ends the procedure.

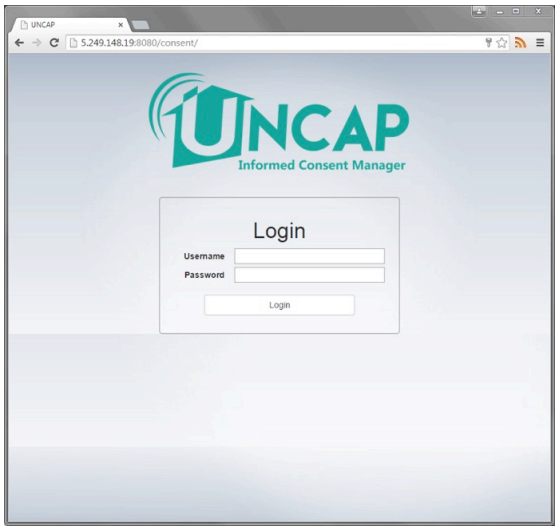

Figure 1. Login page to the informed consent system

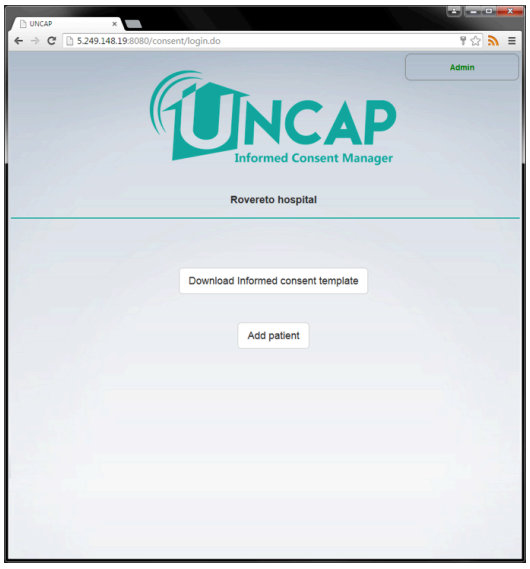

Figure 2. Page to download the informed consent document (upper button) or to add a patient to the informed consent archive (lower button)

Figure 3. Page to enroll the patient in the study and upload the informed consent document

The data collected are stored in a database (PostgreSQL) that is backed up every 24 hours. Access to the database is granted to those registered, but the functionalities are limited: the user can create new entries but cannot remove an entry once it is uploaded (minor edits are permitted in case of misspelled entries).

Details on the structure of the database is reported in the following figures.

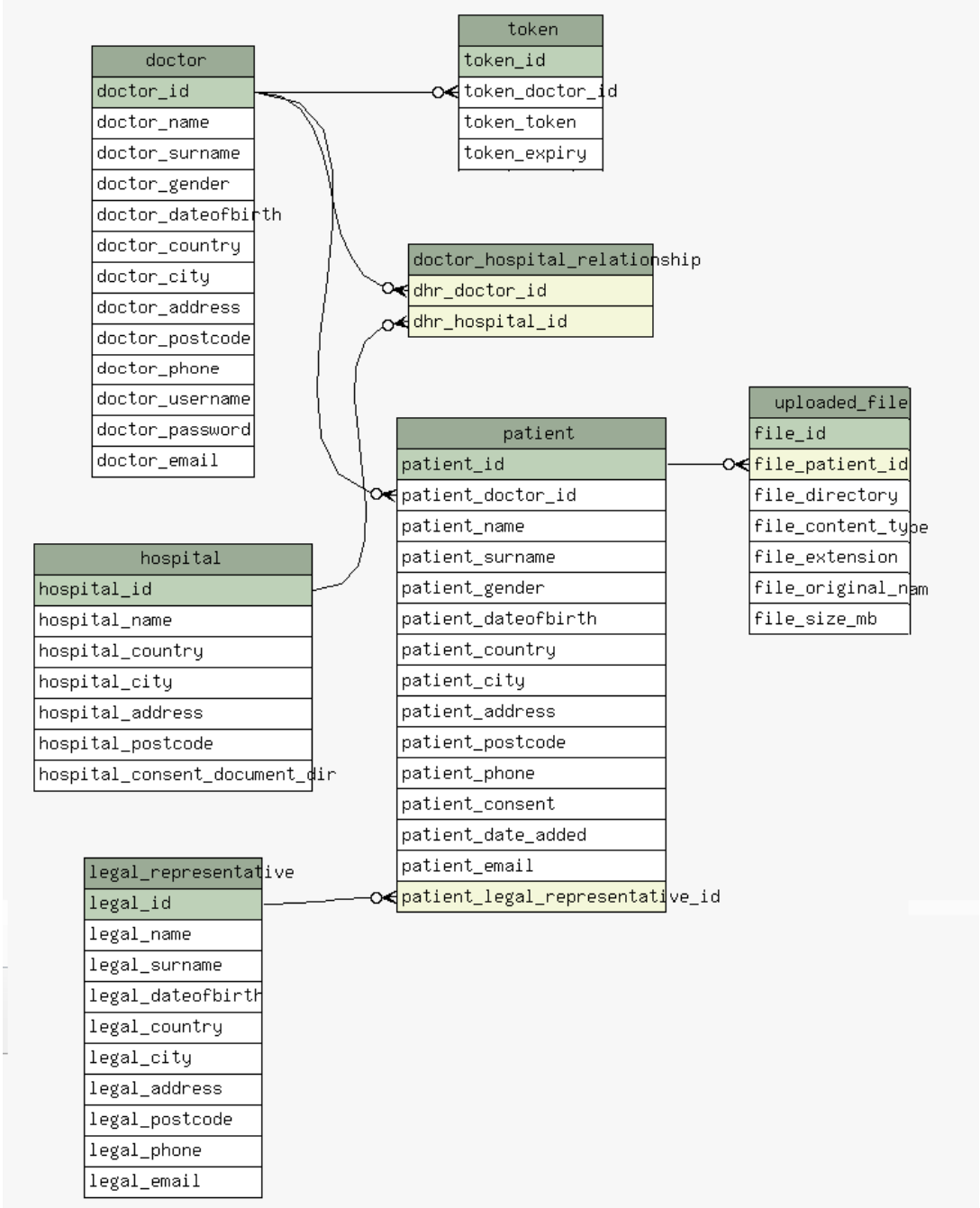

Figure 4. structure of the database for the informed consent

Table	Column	Type
doctor	doctor_address	text
doctor	doctor_city	text
doctor	doctor_country	text
doctor	doctor_dateofbirth	date
doctor	doctor_email	varchar
doctor	doctor_gender	gender
doctor	doctor_id	bigserial
doctor	doctor_name	varchar
doctor	doctor_password	varchar
doctor	doctor_phone	text
doctor	doctor_postcode	text
doctor	doctor_surname	varchar
doctor	doctor_username	varchar
doctor_hospital_relationship	dhr_doctor_id	int8
doctor_hospital_relationship	dhr_hospital_id	int8
hospital	hospital_address	text
hospital	hospital_city	text
hospital	hospital_consent_document_dir	varchar
hospital	hospital_country	text
hospital	hospital_id	bigserial
hospital	hospital_name	varchar
hospital	hospital_postcode	text
legal_representative	legal_address	text
legal_representative	legal_city	text
legal_representative	legal_country	text
legal_representative	legal_dateofbirth	date
legal_representative	legal_email	varchar
legal_representative	legal_id	bigserial
legal_representative	legal_name	varchar
legal_representative	legal_phone	text
legal_representative	legal_postcode	text
legal_representative	legal_surname	varchar
patient	patient_address	text
patient	patient_city	text
patient	patient_consent	bool
patient	patient_country	text
patient	patient_date_added	timestamp
patient	patient_dateofbirth	date
patient	patient_doctor_id	bigserial
patient	patient_email	varchar
patient	patient_gender	gender
patient	patient_id	bigserial
patient	patient_legal_representative_id	int8
patient	patient_name	varchar
patient	patient_phone	text
patient	patient_postcode	text
patient	patient_surname	varchar
token	token_doctor_id	bigserial
token	token_expiry	timestamp
token	token_id	bigserial
token	token_token	text
uploaded_file	file_content_type	varchar
uploaded_file	file_directory	text
uploaded_file	file_extension	varchar
uploaded_file	file_id	bigserial
uploaded_file	file_original_name	varchar
uploaded_file	file_patient_id	int8
uploaded_file	file_size_mb	float4

Figure 5. Structure of the database for the informed consent (continued)

9. Data managed by InterRAI™

9.1. Description

The InterRAI™ suite is a set of standardised comprehensive assessment tools based on evidence-informed clinical practices, and was designed by an international network of researchers to collect and interpret high-quality data about the characteristics and needs of the people accessing the health and social services settings (see D1.5 – Assessment module based on InterRAI™ scales).

Common language also empowers families, advocates, and payers to track the progress of program participants across settings. Even if separated, all instruments work together to form an integrated health information system, since they all refer to the same clinical concept in the same way.

What of interest in relation to the Data Management Plan are the InterRAI™ scales, which define the set of data collected through the system, and the data deriving from the status and outcome measures performed by InterRAI™.

The scales and outcome measures have been internationally validated through clinical trials, studies of clinical acceptability, and longitudinal studies of care outcomes in real-life settings. In the following the brief description of the scales, details can be found in D1.5.

9.1.1. Home Care (HC)

The InterRAI™ Home Care assessment system (HC) allows assessing the health status of persons with chronic needs for care (e.g., fragile elderly or persons with disabilities), as well as those with post-acute care needs (e.g., after hospitalization or in a hospital-at-home situation).

It is composed by 17 sections of data grouped by the type of information: Identification Information, Intake and Initial History, Cognition, Communication and Vision, Mood, Psychosocial Well Being, Functional Status, Continence, Disease Diagnoses, Health Conditions, Nutritional Status, Medications, Treatment Procedures, Social Support, Environmental Assessment, Discharge, and Assessment Information.

9.1.2. Long Term Care facilities (LTCF)

The InterRAI™ Long-Term Care Facilities Assessment System (LTCF) is very similar to the HC, but it is specific for people both receiving short-term post-acute care in skilled nursing facilities and living in chronic care and nursing home institutional settings.

It enables for a comprehensive and standardized evaluation of the needs, strengths, and preferences of the patients.

9.1.3. Community Health Assessment (CHA)

The InterRAI™ Community Health Assessment (CHA) instrument constitutes a robust modular assessment system, which can be used in a range of settings from independent residences through assisted living.

Its supplement, InterRAI™ Assisted Living Supplement (CHA-AL), evaluates the needs, strengths, and preferences of persons served by various types of residential

care facilities, identifying functional, medical, and social issues that either limit the quality of life or functional status of the person or that are likely to become limiting for the person, if unaddressed.

9.1.4. The outcome of the clinical assessments

All the *items* present in each assessment (HC, LTCF, CHA, AL) are combined through complex algorithms, developed by InterRAI™, and contribute to highlight the presence and severity of certain problems in certain areas. All the problem areas constitute the InterRAI™ outcome, namely the "Clinical Assessment Protocol" (CAP).

These areas, if activated (triggered), serve as an indicator for the operator of the health aspects of the patient where it is necessary to assess interventions. The triggered problem areas basically report open or potential problems in the health status of the patient, which should therefore be addressed by the operator in the care service plan.

Alt@nte is able to generate a Word/PDF documents containing the outcomes witch can be saved and managed directly by the system or downloaded by the user.

9.2. Data acquisition at pilot sites

The above parameters are acquired through the Alt@nte system, which is a self-standing database-based software licensed for the use of the InterRAI™ tools for multidimensional assessment.

As regards the data management, the Alt@nte system implements:

- Collection and storage of patient data and history of all tests and measurements taken by the specific healthcare services.
- Re-processing of data collected or any data by identifying profiles, classes and statistics.
- Macro-analyses of data collected using customizable research criteria.
- Production of Microsoft Word documents, such as sample letters, summaries, certifications, etc., and management of the documents produced.
- Extraction of data, directly or by exporting into Microsoft Excel, for automatic processing and re-classification of data and graphics.
- Transfer of all information concerning the care recipient from one service to another through direct access to the database or through the Internet.

In the first phase, the Alt@nte system will be used by the pilot sites in the current scenario (i.e., before introducing the UNCAP solutions) to collect baseline data from month 6 to month 18 of the project. Each pilot will acquire the data using the InterRAI™ scale, most suitable for the specific needs and conditions of the patients followed in that clinical setting (see the following table for details on the scales used by each pilot).

Table 1: scales used by each pilot

Pilot	InterRAI scale
Pergine	HC
Tarzo	LTCF
Baia Sprie	LTCF
Höhenkirchner	LTCF
Athens	HC
Thessaloniki	CHA + CHA-AL
Maribor	HC
Simleu Silvaniei	HC
Skopje	LTCF

9.3. Information about data and data format

Substantially, the InterRAI™ scales above are composed by structured parameters that can be of the following data types:

- Fixed length strings (e.g., social security number, ZIP code),
- Dates (e.g., birth date, assessment date),
- Boolean values (e.g., if the patient has fallen in the last month),
- Predefined lists of allowed values (strings), between which to choose one or more options (e.g., Race),
- Integers (e.g., how many times the patient has fallen during the last month),
- Predefined lists of integers to score performances, improvement or decline of the status (e.g., hearing: 0 adequate, ..., 4 no hearing),
- Free text, i.e. variable length strings (Person's expressed goal of care).

or combination of them: e.g. PAIN SYMPTOMS in the HC scale.

For further details see Annex section in "D1.5 - Assessment module based on InterRAI™ scales" where is reported the full list of data used by each scale.

9.4. Management of data at short and long term

9.4.1. Data storage

As explained above, Alt@nte/InterRAI is a commercial software currently used by a number of healthcare organisation in the clinical routine to provide care and

assistance to patients with specific needs. Consequently, the conceptual/physical model of the system database has been specifically designed to accommodate and manage the types of data detailed above. Moreover, the manufacturer guarantees that the system is compliant with the requirements posed by national and European directives regarding the protection of personal and sensitive data managed by electronic tools.

For the same reason, the algorithms to process the acquired parameter scales to assess the patient capabilities and needs are not of public domain. On the other hand, the manufacturer guarantees that they, and the corresponding results, have been internationally validated by several clinical studies (see for example[1, 2]).

For more details, refer to the documentation of the Alt@nte/InterRAI™ system.

9.4.2. Data Hosting

The Alt@nte/InterRAI™ suite is hosted on the servers of the data centre of the Asco Tlc S.p.A (http://www.ascotlc.it), a company, specialized in providing housing/hosting services for critical data management. Consequently, the compliance of the application and data hosting service with the requirements of privacy, security and data integrity prescribed by the European directives and the Italian Data Protection Code 196/03 is guaranteed by the company. In particular:

- Last generation 64 bit servers, monitored at application and hardware level;
- Backup/Disaster Recovery system;
- Virtualized and dedicated Hosting;
- Service Availability Level 99.99 %;
- Incremental Daily backup.

9.5. Policies for access, sharing, and re-use

Alt@nte/InterRAI™ is a tool already in use in two pilot sites. In any case, it is a clinical tools used only by the healthcare personnel of the healthcare facility. No direct access to the system is or will be allowed to external users or to healthcare professionals inside the hospital/nursing home not authorised by the data controller to be in charge of data processing.

In the first study phase (6th - 18th month), the Alt@nte/InterRAI™ data will be acquired by the care team of the pilot site to determine the detailed inclusion/exclusion criteria to enrol the patients in the final clinical study to evaluate the UNCAP suite.

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[1] Kim H, Jung YI, Sung M, Lee JY, Yoon JY, Yoon JL. Reliability of the interRAI™ Long Term Care Facilities (LTCF) and interRAI Home Care (HC). Geriatr Gerontol Int. 2015 Feb;15(2):220-8. doi: 10.1111/ggi.12330. Epub 2014 Aug 27.

[2] Travers C, Byrne GJ, Pachana NA, Klein K, Gray L. Validation of the interRAI Cognitive Performance Scale against independent clinical diagnosis and the Mini-Mental State Examination in older hospitalized patients. J Nutr Health Aging. 2013;17(5):435-9. doi: 10.1007/s12603-012-0439-8.

In the second phase of the project (18th - 32th month), the InterRAI™ assessment tool will be used to assess the status of the patients assisted by using UNCAP at the beginning and at the end of the clinical study. The outcome will be used o compare the intervention group with the patients in the non-intervention branch, who will continue to receive the usual treatment in place at the care facility.

The Alt@nte/InterRAI™ data could be also aggregate with and compared to the data from other structures.

In any case, the patient data will be extracted and processed by the Alt@nte hosting provider (ASCO) in an aggregate and anonymous form on request of the investigator. The anonymised data will have an identification code in order that only the care personnel authorized by the care facility responsible (data controller) can, in the case of problems, reconnect the data to the original identity of the subject.

No transfer of non-anonymised sensitive data will be allowed between the pilot sites.

10. UNCAP Data

This section describes the data that will be managed directly by UNCAP. The section is subdivided into different groups to cover all the different types of information collected. Since the development and integration phase is not yet started at the time of the delivery of this document, the following paragraphs should be considered as a general introduction that will be refined during the course of the project and will be reported in the following releases of the Data Management Plan (second release at M18 and third release at M30).

10.1. Personal Data/registry

The UNCAP system collects and stores information about the personal data of the patients enrolled in the study and that are using UNCAP.

The minimum required dataset that will be collected is as follows:

- Name,
- Surname,
- Date of birth,
- Address,
- UserID: unique identifier of the user, shared between all applications connected to UNCAP,
- Password: password of the user's account, stored as a token,
- Authorization profiles: list of the roles and services accessible by the user,
- Others to be defined during the implementation phase (WP2).

The creation of a new user is managed using roles:

- Administrator: has full access to the system and can create new users with any role.
- Clinical staff: clinicians will be able to add a new patient to UNCAP.
- Patient: is the end user of the system and has access only to his own data. A patient cannot subscribe himself/herself autonomously to UNCAP but the subscription should be managed by a clinician or an administrator.

This list should be considered as the minimum required set but can be expanded or modified during the course of the project.

10.2. Health-related data

A number of health-related data will be collected during the project course, specifically during the piloting phase from M19 to M30. Data is collected from external devices that will be integrated during the implementation phase. Right now the devices that are planned to be integrated are:

- Pulse oxymeter: it is a non-invasive device used for monitoring blood saturation and heart rate. O_2 saturation is expressed as a percentage with a measurable range going from about 70% to 99%. Heart rate (pulse) represents the number

of times the heart beats per minute, with ranges typically going from 30 to 250 bpm.

- Blood pressure monitor: the output of the device is a value, expressed in mmHg (millimetres of mercury), representing the pressure exerted by circulating blood upon the walls of blood vessels. It is composed of two values that should always be reported together: the maximum pressure (systolic) and minimum pressure (diastolic).
- Glucometer: used to determine the concentration of sugar in blood. It is commonly represented in terms of millimoles per liter (mmol/L) or milligrams per decilitre (mg/dL).
- Scale: Wi-Fi/Bluetooth scales are now commercially available. Those devices report a number of measures related to the person health status such as:
    - Body weight: a value representing the mass of a person expressed in kilograms (or pounds).
    - Body fat percentage: it is the total mass of fat divided by the total body mass. It is expressed in percentage.
    - Total body water: expressed as a percentage represents the quantity of water contained in the body.
    - Body mass index: it is defined as the body mass divided by the square of the body height and is consequentially expressed as kg/m^2.
    - Bone density: is the amount of mineral matter per square centimetre in bones.
- Heart rate monitor: monitors the pulse. From the point of view of the data collected this does not differ from a pulse oxymeter.

Depending on the sensor used and on the value measured, UNCAP will store measurements in two different formats: as single entries or as time series. As an example a glucose measure will be stored as a single entry while heart rate may be stored as a time series since it is a representation of a measured value collected repeatedly during a period of time.

Each entry in the database, in addition to the measured value, will report the user ID to which is associated the measurement, the device ID associated to the sensor used and a timestamp representing the time in which the measure was collected.

10.3. GIS data

During the project course, a lot of information will be collected in the GIS (geographic information system) domain. What we address as GIS is basically every data needed to describe something that has some geographic features. In our case that data is composed of:

- Maps: those can be both outdoor and indoor maps.
- Outdoor maps will be used mainly as background layers in the client frontends. The maps are acquired from open data repositories available online such as OpenStreetMap [6]. Maps will not be stored but will be requested directly from the client application when needed (caching on the client device may be enabled).

- Indoor maps are used to represent the pilots spaces involved in the project. For each pilot a request for a detailed map of the structure will be done. If needed, the collected maps will then be converted in a digital format and orthorectified to correctly represent the structure in world coordinates. The maps will be uploaded on the UNCAP Cloud and will be accessible from the exposed services of UNCAP both as raster images and as vector graphics.
- Routing graphs: routing graphs are lists of nodes (points) and connections (lines) used to represent paths between places. UNCAP will use online available repositories (from the OpenRouteService [7]) and will integrate indoor graphs needed for indoor routing inside the pilots. Indoor graphs are manually created starting from the pilot maps described before.
- Points of Interest: online available repositories will be integrated to show the nearest POI such as hospitals and stations. We will also let each user store the position of their own personally preferred places (i.e. friend's house, rehabilitation centre, …) that will be stored in UNCAP and will be accessible only to who created them.
- Localization data: localization is one of the most important aspects in the project. The information on the position of specific users may be collected and stored in the system, both outdoor and indoor (for the pilots that plan to install an indoor location base service). Knowing the position of a user is a key aspect in case of emergency. Positions will be stored as geometries in UNCAP:
    - Points: used to store the position as a single entry (i.e. when the user calls for help).
    - Multipoint: to collect paths with multiple positions (i.e. to store a running session).

  With respect to localization data is mandatory to notify the data treatment to the Data Protection Authority. For further details see "D1.2 Regulatory constraints".

10.4. Videos

During the project course some pilots may choose to integrate the video cameras solution developed by Trilogis. It is an application for indoor localization and fall detection that is based on the use of video cameras (specifically it uses Microsoft Kinect). The application is able to automatically detect people by processing video streams through computer vision algorithms. Each video camera is directly connected to a PC that is in charge of the processing and forwards to UNCAP the position of people in the room and alarms when specific rules are triggered (i.e. someone has fallen).

It has to be highlighted that the stream is NOT forwarded to anyone/anything and that every frame, once processed, is **dropped and deleted**: the video is not stored, nor are images. The video stream, in real time, can be retrieved only by accessing the PC directly connected to the video camera and it is restricted to system administrators for configuration purposes.

11. Annex: Informed consent

CONSENT TO PARTICIPATE IN THE TECHNOLOGICAL STUDY PROJECT UNCAP APPLIED TO THE ASSISTANCE FOR THE IMPROVEMENT OF CARE AND ASSISTANCE SERVICES

Consent to participate in the technological study project UNCAP applied to the assistance for the improvement of care and assistant services.

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The safety of our guests is our main priority!

That is the main reason for which our nursing home has decided to participate in an international project called UNCAP (UBIQUITOUS Interoperable CARE FOR AGEING PEOPLE.

The purpose of this project is to study new technologies and new ways of working that allow us to be able to offer an always better service.

When you feel fragile, you need constant care, whether you are in a nursing facility or at home.

Knowing that you can count on someone even when you are alone is a goal that all patients would achieve. Many patients are forced to change health facilities several times, while they could be treated at home with modern technologies.

Long hospitalizations can lead to a functional decline, since patients feel lonely and sad in a strange environment.

Being able to move during the stay in the facility or to know that even at home there is the possibility to be constantly followed by the structure and by doctors allows patients to re-achieve more quickly their skills and independence and live diseases in a more serene way.

In order to do so, we must study the patients and identify the level of risk that they are facing and theirs degree of autonomy.

Only in this way, we can find the right personal and individualized solution to be made available to each and every patient.

In order to do so, we intend to study and develop technologies that allow us to assist you more quickly in times of difficulty or emergency, but that leave you free to live in absolute confidentiality when needed. For this reason, we plan to study and design technologies to follow your movements and to intervene when you are in danger.

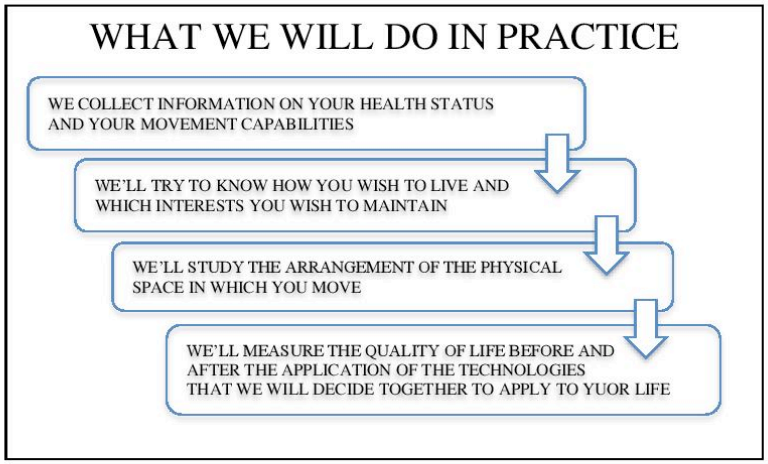
Some of these technologies allow us to locate patients in every moment of their life within the structure and / or at their doorstep. This allows us to be able to identify and see if and when they are in danger or distress.

Consent to participate in the technological study project UNCAP applied to the assistance for the improvement of care and assistant services.

We want to ensure that our nurses and doctors can follow you at all times, not only in your rooms but wherever you are, and to intervene when necessary.

Some of these tools are already available, such as cameras, sensors and telemedicine tools and must be implemented according to the rules that this draft study will show us. Others, however, have to be invented, designed and built specifically so as to achieve this goal.

We ask you to be part of this change. For your health and that of the people in need around the world.



The goal of our data collection is to measure fragility

The study will identify patients who need further in-depth evaluation and specialized services, but does not need necessarily support services.

The information that we need to collect is the following:

- Basic data (name, birth data, ethnicity, address, phone number, names of people in the family that the patient wants to keep close)
- Where do the patients live, if their house or structure have architectural barriers and which are the dangers that we have to keep in mind for their safety
- The medical history and the severity of their condition
- The degree of autonomy to perform daily living activities such as bathing, cooking, walking with or without help
- Hospitalizations;
- The social history and the places the patients love to attend;
- People who are caring and that can intervene in case of need as children, the neighbours, caregivers, etc.
- The history and the circumstances of his/her previous falls.

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In particular, the project to which we ask you to participate has these basic goals:

a) To study and develop IT tools, technology, video surveillance, remote monitoring of vital signs that can allow a greater freedom of movement inside and outside the structure, thus guaranteeing the possibility of intervention in emergency situations.
b) To allow the staff to be able to control from a distance in order to intervene in a more quick and accurate way. The projects that we intend to implement are based on location through cameras and other computer equipment.
The technology applied to these devices activates alarm signals in particular conditions to draw the attention of doctors and nurses.
c) To study tools that allow medical staff and nurses to come to the rescue when the patient is at home and/or outside the structure.
d) To develop tools that can be adapted to patient's house. The practical application will be made only with his/her specific consent.
e) To publish the study data, in anonymous and aggregate form, and to make them available to designers and health facilities around the world.

All this will take place with full transparency and with the obligation to respect it in all circumstances by the organizations participating in the project.
Your Participation is completely voluntary.
Before deciding whether to participate, you must read the following information and seek clarification from the physician who will follow you.

Risks and discomforts

The study does not need to add any type of active substance, drug and / or supplement to your care.
It requires no invasive clinical procedure than the one necessary for your treatment path.
The study does not imply more clinical risks than those already in your usual course of treatment.
You will be free in your movements but, only in the case of implementation of all or part of the systems, the structure will be able to identify the place, your vital parameters and your geographical position. This will be done by collecting additional and specific consent.

You are free to not participate in the study. Anyhow, in this case, you will receive all standard therapies planned for your condition, without any penalty, and the doctors and nurses will continue to follow you with due care welfare.

Data processing

In order to proceed to the study we need to know exactly the health care needs of our guests, so it is necessary that you authorize us to process your personal data and those relating to your medical condition for these specific study activities.
Part of the information concerning them and useful to the compilation of your medical record is already in possession of the structure: for example name, address, medical history, diseases and medicines that you take.

Other information will be requested through an interview that will concern you and the people who are close to you. You will be free to answer or not the questions. If you do not answer, we will not able to collect quality data and, consequently, the study may not be accurate. In this case, at the discretion of the structure, you will be excluded from subsequent testing phases.

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The data used in the project will be collected in a particular medical record, since we have to activate a route allowing you to know if, and how, your conditions have been improved, and that will allow us to extract, in an anonymous and statistical information useful for the development of the technologies described above.

We will evaluate the data related to your health condition and the degree of autonomy before and after the implementation of the technologies.

We will ask you, then, to evaluate your emotions and your likings with the changes that we will implement.

Who will use data

A. **The** _____ with your collaboration and that of the doctors that treats you, will be responsible for the processing of your personal data.
Only the staff of the nursing home will have access to medical records. The data useful to the project will be provided to the Provider (TRILOGIS SRL), who coordinates the project only in an aggregate and anonymous way. The data will then be combined with other data from other healthcare facilities so that they can be compared, by combining experiences and the best care activities.
Storing of images and electronic tracks will remain in the structure. Access can only be granted to personnel in charge and only in order to protect your health, safety and to allow an immediate intervention. The images and electronic tracks will be preserved for 48 hours and then destroyed.
The controller designated by the nursing home is _____.

B. **Trilogis SRL** based in Rovereto (TN), henceforth called PROVIDER, is the company coordinating the study. It will have access only to the aggregated data. Should it be necessary to access your data, it will do so only through a doctor, so that your personal and health-related data will always be reserved.
Initially, the identified technologies will be implemented in the nursing home so that you can measure their actual advantage.
In a second phase, the project will also include the implementation of these technologies at the address of those patients who retain sufficient autonomy to live independently but that require assistance even from a distance.
These technologies consist of telemedicine equipment, devices measuring vital signs, sensors and cameras able to operationalize the implementation of the care process and enhance your security.
The presence of instruments of control within the facility will ensure in any case the confidentiality of all clinical and biological activities.
Only the nursing and medical staff can view any acquired image for care purposes. The Provider will retain the recording systems and the recordings themselves on systems located in Italy and / or within the nursing home/hospital and, in any case, for a time not exceeding 48 hours.
The Provider and who working for it can access the data only for maintenance purposes or in the case that clinical and / or safety needs require the access on the orders of the nursing home/hospital or the patient.

C. **SOCIAL-IT** is a company specialized in the development of software for the provision of health care assistance. Its role is of system administration and responsible for data security.

In particular, it will made available to the nursing home a medical record called "Atl@nte" whose purpose is to re-order, compare, and extract anonymous data and information collected through your participation.

From the medical records, statistical models and comparison of care pathways will be developed.
The same company may use companies specialized in data retention that will operate with duty of confidentiality and the prohibition of direct access data.
Data will be stored on computer platforms able to ensure maximum confidentiality and security of data.
The storage location of the data is in Italy and / or in another European country that provides a similar or higher degree of security protection.
No transfer of data will be made outside the European community.

D. **DOCTORS OF THE STRUCTURE.** Only doctors and the nursing staff will have direct access to your medical records. The personal and health data will be extracted in an anonymous and aggregate way and can be further aggregated with those from nursing homes that participate in the European industrial and healthcare research project.

E. In the project, other persons responsible will intervene, such as technicians, doctors, statisticians, engineers specifically appointed responsible of the treatment by one of the parties and kept to the absolute requirement of confidentiality and secrecy.

Your rights

The keeping of medical records is a requirement of the structure and that does not change if you adhere to the project or not.
You are free to withdraw at any time without prejudice for your future care or the right to assistance.
You will continue to use the services already ensured and will keep the relationship with your doctor.

In providing the care/assistance service, the Nursing Home will operate with competence and professional diligence and respecting confidentiality and ensuring protection of sensitive data and confidential information concerning the patient or his/her family.

The Clinic is committed to providing accurate and timely information on the mode of operation of the organization and on the professionals to whom to turn for your different needs.

Clinical data will be stored by the nursing home for a time commensurate with the objective to reach statistical and scientific results and for two years after the closure of the project.

Aggregated data will be stored by the provider for as long as necessary in view of the future enlargement of the trial, but no later than five years from the end of the project.

Each person participating in the trial within his/her competence is aware of the responsibilities required by the standards of good clinical practice in compliance with the European directive DIRECTIVE 95/46 / EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 October 1995 and by national laws for the processing of personal data.

Your personal and sensitive data will be processed through papers and electronic formats by the partners involved in the project, and will be accessible to the staff in order to dispense you care services.

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All stakeholders and staff are obliged to respect the confidentiality of information learned in the course of the activities that will be made.

The data will be held on information systems of your doctor and of the nursing home, and only to the extent necessary. They will be made accessible to providers and managers of technical services, such as service centres, Scientific Committees, managers of the server (the latter only for needs of archiving management), and to other companies that will be identified by the provider for purposes solely related to the success of the project.

Moreover, data can also be used in an aggregate and anonymous way for the aim of research, study and development of techniques of care.
In this case, the data can also be used in studies and researches at the national and international level.

The Provider will have access to sensitive personal data for purposes of monitoring and control only through a doctor specially appointed.

Your medical record is also used to follow your healthcare path. The data included therein cannot be deleted but can be blacked out in one or more part if you deem it necessary.

You may instead withdraw the authorization to the processing of data for the purposes of the research project at any time.

The technical systems used will conform to the indications of the best technological knowledge and to the laws for their conservation and protection.

The data processed using electronic tools will be disclosed only in an anonymous form, such as through scientific papers, statistics and scientific meetings.

All technological systems will be kept within the European community with the application of the best conservation techniques given through instruments guaranteed under every technical, legislative and security point of view.
All those who participate in the project are required to comply with the confidentiality and professional secrecy.

You, as subject of the treatment, have the following rights:

1. You have the right to obtain confirmation as to whether or not personal data concerning you exist, regardless of their being already recorded, and communication of such data in intelligible form.
2. You have the right to be informed:
   a) of the source of the personal data;
   b) of the purposes and methods of the processing;
   c) of the logic applied to the processing, if the latter is carried out with the help of electronic means;

d) of the identification data concerning data controller, data processors and the representative designated according to the instructions of the project and in compliance with the regulations in the State of the nursing home;
e) of the entities or categories of entity to whom or which the personal data may be communicated and who or which may get to know said data in their capacity as designated representative(s) in the State's territory, data processor(s) or person(s) in charge of the processing.

3. You have the right to obtain:
   a) updating, rectification or, where interested therein, integration of the data;
   b) erasure, anonymization or blocking of data that have been processed unlawfully, including data whose retention is unnecessary for the purposes for which they have been collected or subsequently processed;
   c) certification to the effect that the operations as per letters a) and b) have been notified, as also related to their contents, to the entities to whom or which the data were communicated or disseminated, unless this requirement proves impossible or involves a manifestly disproportionate effort compared with the right that is to be protected.
4. You have the right to object, in whole or in part,
   a) on legitimate grounds, to the processing of personal data concerning him/her, even though they are relevant to the purpose of the collection;
   b) to the processing of personal data concerning him/her, where it is carried out for the purpose of sending advertising materials or direct selling or else for the performance of market or commercial communication surveys.

The nursing home is in charge for the treatment of your clinical data and is the only entitled to access the data in an intelligible form.

Trilogis srl is responsible for processing the aggregated data provided from the extraction from medical records and interviews.
Trilogis srl has designated as responsible of the treatment Mr. Leonardo Plotegher to whom you may direct any requests for exercising the rights referred to in the previous paragraph, as responsible for the replay.
Social-it is responsible of treatment for the purposes of conservation and extraction of the data and management of the platform on which the data will reside. The role is technical and for this purpose the appointed system administrator of system is Mr. Maurizio Gianordoli.

To exercise your rights or for any other information you can address to _____.

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DECLARATION OF CONSENT

I the undersigned

LAST NAME	
NAME	
DATE OF BIRTH	
FISCAL CODE	
Other data	
TELEPHONE NUMBER / Email	
Legal representative in the case of patients who are unable to give consent	

DECLARE

1. I understand to participate in an experimental management of chronic patients as illustrated in the agreement signed with the nursing home;

2. I understand that I can withdraw at any time from the project without incurring in any obstacle and without jeopardizing the continuity of my care;

3. I have been informed by the nursing home on the rights to privacy of personal data within the meaning of the European directive and that I understand that these data will be used exclusively for the management of activities related to the project.

I have read (or someone has read to me) the information provided in the previous pages. I was given the opportunity to ask questions and received satisfactory answers. I was also given a copy of this form.

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In addition,

□ __ I CONSENT TO PARTICIPATE IN THE PROJECT AND AGREE TO THE PROCESSING OF MY DATA REFERRED TO THE EXTENT OF WHAT WRITTEN ABOVE

_____
Name of the subject

_____
Name of legal representative (if appropriate)

_____ _____ _____
Signature of the person or legal representative Date

SIGNATURE OF THE DOCTOR THAT PROVIDES THE INFORMATION

I have explained the study to / to Mr / Ms ……
and / or to his/her legal representative and I answered all his/her questions. I think he/she understood the information provided and contained in this document and has given his/her voluntarily consent to the participation and to the processing of personal data within the limits indicated above.

_____
Name of the investigator

_____ _____
Signature of the Investigator Date (must be the same as the signature of the subject)