AAL Call 2020

Deliverable 1.3

Data Management Plan

Work Package 1: Project Management and Coordination

Smart Intervention for Senior Isolation: SI4SI Project

Project reference: aal-2020-7-108-CP

Start date: 01/04/2021

Project duration: 24 months

Funded under programme(s): Aal Programme

Application areas addressed: Active Living and Assisted Living

Type of Project: Collaborative project

Disclaimer

The SI4SI consortium consists of the following Partners.

Table 1 - Consortium Partners List

No	Name	Short name	Country
1	DS Tech Srl	DST	ITA
2	GIOMI CARE Srl	GIOMI	ITA
3	Canary Technology Innovations	CTI	RO
4	University of Medicine and Pharmacy “Carol Davila” Bucharest	UMFCD	RO
5	Caretronic	CRT	SI

Document Information

Table 2 – Document information

Project short name and Project reference	SI4SI (aal-2020-7-108-CP)
Work package	WP1
Deliverable number	D1.3
Deliverable title	Data Management Plan
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Involved beneficiaries	DSTech Srl
Type[1]	**R**
Dissemination level[2]	**CO**
Contractual date of delivery	30/09/2021
Last update	31/01/2022

[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.
[2] **PU:** Public; **CO:** Confidential, only for members of the consortium.

Document History

Table 3 – Document History

Version	Date	Status	Authors, Reviewers	Description
v 0.1	16/11/2021	Draft	Laura Laurenzi (GIOMI), Laura Valery (GIOMI)	Table of contents and peer review
v 0.2	21/12/2021	Draft	Laura Laurenzi (GIOMI), Laura Valery (GIOMI)	Finalization of the content and peer review
V 0.3	22/12/2021	Draft	Dr. Emilia Reda (GIOMI)	Additional content review from the Scientific coordinator
V1.0	31/01/2022	Final	Andrea Valerio Chentrens (DST)	Final review

Acronyms and Abbreviations

Table 4 – Acronyms and Abbreviations

Acronym/Abbreviation	Description
AAL	Ambient assistance living
DPA	Data Protection Agreement
GDPR	REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
MD	Medical Devices
RTD	Research technology development
ENISA	European Union Agency for Cybersecurity

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Executive Summary

The following document aims at providing all the necessary information to the partnership in terms of management, repository and disclosure of personal data, either inside and outside the partnership. The Data Management Plan has been designed in compliance with the General Data Protection Regulation no. 2016/679 (GDPR) that represents the European data protection law whose fundamental principles are Responsibility and Transparency.

Due to the European Regulation, the EU moves to a vision of data control which allow data free movement while, at the same time, strengthening person interested rights, who must be able to know if his/her data *is used and how it is used* to protect him/her and the whole community from the risks deriving from data processing.

The Data Management Plan will ensure that all data collected by the SI4SI project partners during the project implementation, through the website and tests, will strictly comply with GDPR and with the Italian, Romanian and Slovenian domestic laws.

The document is divided in several headers that are taking into account the following aspects on data management:

- the general framework of the data management in the healthcare sector at European and national level
- the approach used by the SI4SI partnership regarding data protection and data anonymization, in compliance with the GDPR and the national legislation
- templates that will be used by the partnership regarding informed consent and pseudonymization of personal data

The following outcomes produced by the SI4SI project could be used as a future reference for other projects focused on data management and IoT implementation for Smart Living Environment and sustainable solutions for professionals working with the elderly.

1 INTRODUCTION

The following data management plan, developed by the Italian partner GIOMI CARE s.r.l and shared and validated by the SI4SI project partners, aims at identifying, defining and adapting the testing phase and the IT architecture developed by the technical partners to main requirements regarding privacy-related issues, data protection and privacy.

This task will continuously monitor the impacts of SI4SI on the requirements identified in architecture of the new system solution as the ICT solutions that will be integrated, tested and evaluated. The task will ensure that the outcomes of the impact assessment are implemented by all partners, in compliance with the European and domestic legal framework regarding data protection and privacy management.

2 DATA SUMMARY

The Data Management Plan has been designed in compliance with the General Data Protection Regulation no. 2016/679 (GDPR) and the partnership's national laws regarding data and privacy protection. Consequently, the Data Management Plan will ensure that all data collected by the SI4SI project partners during the project implementation, through the website and tests, will strictly comply with GDPR and with the Italian, Romanian and Slovenian domestic laws.

The data:

- will be collected and treated only on the basis of specific rules that authorize their automated processing;
- will be treated for specific legitimate purposes;
- will not be used for other purposes that could be conflicting with the original intents and purposes;
- will not be used after the end of the Project.

Through consent, the data holder will authorize the data processing. Consent will therefore be linked to a specific project's activities purpose. If the treatment is based on consent, the data holder will provide the information and guarantee the data portability.

The consent will be informed: the data holder will be able to know which data are processed, with the methods and purposes and the rights that are attributed to him/her by law. Furthermore, the data holder will be properly informed of the consequences of his/her consent (for example, it must be indicated that in the absence of consent he/she will not be able to access specific website sections). The communication will be made through the appropriate information, which will become a condition of treatment legitimacy.

2.1 Types of data managed throughout the project's lifetime and in the pilot phase of the SI4SI project

The data used in the SI4SI project comes in the form of personal data that will be collected during the pilot programme and the communication activities within the partnership and the dissemination activities carried out externally from the partnership, using varied spatial extents (meaning that the geographical positions taken into consideration are more than the ones inside and outside the countries included in the partnerships) and means of verification (through recordings, videos and pictures).

The Consortium has identified the following target groups who will especially benefit from data that will be disclosed to a wider public in the SI4SI project:

Table 5 – Target groups that will benefit from data protection strategies

Target groups for data management outside the pilot	Target groups for data management inside the pilot
Industry representatives	Head of the research team in charge of the pilot activities
Medical researchers and academics	
Grant consultants	
Policy makers at national and European level	

It is also essential to underline that all the sensitive data managed from the pilots has to be authorized by the tester/owner of that sensitive information through the formal consent and signature of the document available in Annex I named *Informed consent template*. Regarding the divulging and sharing of personal data of the testers (either the focus and control group), their information will be pseudonymized, meaning that their data won't be divulged by sharing their names and personal details through codes that are associated with their identity. The code of identification will be known by the person in charge of the pilot test only, and it won't be disclosed to anyone, neither the caregivers and nurses involved in the personal care of the testers in question. The data randomization will be carried out by the partners in charge of the development of the testing phase of the SI4SI solution.

2.2 National specifications for data management

Although in the healthcare sector, at both national and European level, the management of personal data does not have any specific regulations, each country involved in the project has its own judicial and legal path that has to be followed when it comes to the management of confidential patients' data. In the next sections are presented the current laws and legal paths that have to be undertaken in the SI4SI project countries where pilotes will be arranged.

2.2.1 Italy

Italy has different privacy-related laws that are regulating the flow of the personal data of its citizens. Specifically, the documents in question analyzed in this circumstance are:

- Personal Data protection Code (Decree Law n.196 30th June 2018), also known as *privacy code* in Italian[3]
- Code of ethics for the personal data for scientific purposes[4]. The document will provide additional information on data management, especially when it comes to managing sensible data for scientific purposes
- Decree's Law of 10th August 2018[5]. The Decree was enforced in 2018 and it's an integration on what is stated in the GDPR adopted by the European Union

These documents are extremely relevant in the Italian system for the data management, however the most relevant legal direction to be taken into consideration is the General Data Protection Regulation[6] (GDPR) and here it is specified how personal data should be lawfully processed (including how it's collected, used, protected or integrated at European level). Given the high importance attributed by Italy to the GDPR, the great majority of the data protection management and control-related activities are regulated by this directive and, according to the civil law Italian system, all the other legal acts and proceedings that were or wouldn't be entirely covered in the GDPR are established to compensate the lack of information available from the UE Directive. The SI4SI project does not include the additional

[3] https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg

[4] DELIBERA 19 dicembre 2018 Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica. (Delibera n. 515/2018), https://www.gazzettaufficiale.it/eli/id/2019/01/14/19A00181/sg

[5] https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg

[6] https://eur-lex.europa.eu/eli/reg/2016/679/oj

legal proceeding that could differ from the rules established in the GDPR and further specified in the *code of ethics for the personal data for scientific purposes*[7].

2.2.2 Romania

The relevant data protection legal norms applicable in Romania are:

- European Regulation no. 679 of 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, which repealed Directive 95/46/EC (GDPR", which took effect and became directly applicable in Romania on May 25, 2018
- Guidelines issued by the National Authority for the Supervision of Personal Data Processing (the "DPA") on September 21, 2017 with regard to the implementation of the GDPR
- Various Guidelines issued by the Article 29 Data Protection Working Party on data processing at work (June 8, 2017)[8], on automated individual decision-making and profiling for the purpose of the GDPR (October 3, 2017), on personal data breach (October 3, 2017), on consent (November 28, 2017), on transparency, on data protection impact assessment (DPIA) of April 4, 2017

The applicability of the legal proceedings and activities associated with the management of personal data is done by the National Supervisory Authority for the Processing of Personal Data[9], an autonomous central public authority with general competence in the field of personal data protection. In addition to this, it's also important to highlight that all the data processing form third parties outside the European Union it's possible only if the these requirements are met:

- the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards;
- the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of pre-contractual measures taken at the data subject's request;
- the transfer is necessary for the conclusion or performance of a contract concluded, in the interest of the data subject, between the controller and another natural or legal person.

The transfer of personal data outside the country is no longer the object of a Notification to the Data Protection Agreement (DPA).

Any additional activity carried out by the National Supervisory Authority for the Processing of Personal Data is in full compliance with the GDPR requirements.

[7] DELIBERA 19 dicembre 2018 Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica. (Delibera n. 515/2018), https://www.gazzettaufficiale.it/eli/id/2019/01/14/19A00181/sg

[8] https://www.buzescu.com/romanian-data-protection-laws/

[9] https://www.dataprotection.ro/index.jsp?lang=en&page=home

3 THE FAIR PRINCIPLE: MAKING DATA FINDABLE, ACCESSIBLE, INTEROPERABLE AND RE-USABLE

The FAIR Data Principles are a set of guiding principles in order to make data findable, accessible, interoperable and reusable (Wilkinson et al., 2016). These principles provide guidance for scientific data management and stewardship and are relevant to all stakeholders in the current digital ecosystem. They directly address data producers and data publishers to promote maximum use of research data. Research libraries can use the FAIR Data Principles as a framework for fostering and extending research data services.

The Privacy Policy and standards used in the SI4SI project for the protection of personal data are based on the following principles:

- **Responsibility.** The processing of personal data is managed over time by specific functions with specific responsibility, identified within the SI4SI management structure.
- **Transparency**. Personal data is collected and processed according to the principles expressed in this Privacy Policy, in compliance with the current legal provisions. For the aforementioned, the interested party is provided, in compliance with the provisions of the law, a summary and complete information on the purposes and methods of processing, on the mandatory or optional nature of providing data, on the consequences of failure to provide data, on the subjects or on the categories of subjects to whom the personal data can be communicated and the scope of communication of the same, on the rights foreseen by the rule (access, integration, updating, correction, cancellation, opposition to the treatment), on the identity and the headquarters of the owner and the controller. The interested party is then called to express his/her consent after having been informed, in a free and specific manner (for further details please consult Annex I); this consent will be documented for the cases provided for by the law (sensitive or health data).
- **Relevance of The Collection.** Personal data is processed in a lawful and correct manner, and is recorded for specific, explicit and legitimate purposes. They are relevant and not excessive for the purposes of the processing. Finally, they are kept for the time necessary for the purposes of collection.
- **Purpose of Use.** The purposes of the processing of personal data are disclosed to interested parties at the time of collection. Any new processing of data, if unrelated or in addition to the declared purposes, is activated only after new information to the interested party and any new request for consent, when required by law. In any case, personal data are not disclosed to third parties and / or disseminated without the prior consent of the interested party.
- **Verification.** Personal data is updated over time. They are also organized and stored so that the interested party is given the opportunity to know, if he/she wishes, what data has been collected and recorded, as well as to check its quality and request any correction, integration, cancellation for violation of the law or opposition to the processing and to exercise all other rights, pursuant to and within the limits of the legislation in force, at the addresses indicated in the information that has been given.

- **Security**. Personal data is protected by technical, IT, organizational, logistic, and procedural security measures, against the risks of destruction and / or loss, even accidental, as well as unauthorized access or unauthorized processing. These measures are updated periodically based on technical progress, the nature of the data and the specific characteristics of the processing; they are also constantly checked and verified over time.
- **Data communication scope.** The personal data provided may be disclosed to third parties to fulfil legal obligations, or to comply with orders from public authorities or to assert or defend a right in court.

3.1 Data management guidelines

In full compliance with Art. 5.1 of Regulation (EU) 2016/679, any processing of personal data will take place in compliance with the principles of the GDPR:

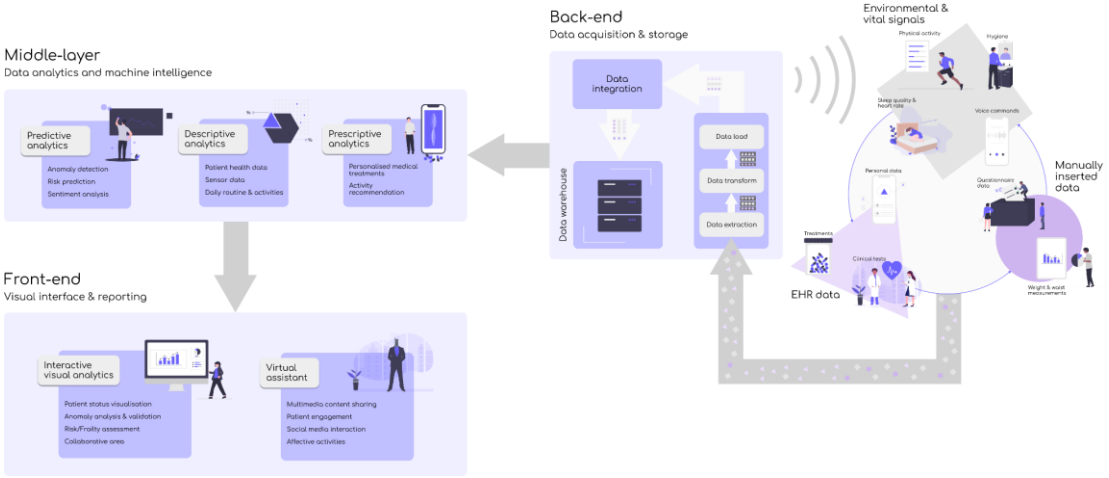
- Processed lawfully, fairly and in a transparent manner in relation to the data holder (*lawfulness, fairness and transparency*);
- Collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (*purpose limitation*);
- Adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (*data minimisation*);
- Accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (*accuracy*);
- Kept in a form which permits identification of data holders for no longer than its necessary purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data holder (*storage limitation*);
- Processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures (*integrity and confidentiality*)

3.2 Data Storage

Data collected through the smart bend and the sleep tracker (indirectly) will be sent to the back-end. Once collected, they are sent to a Database managed by Caretronic.
The back-end saves the data on a Database, accessible via query.
These data are exposed through end-points to make them usable by the machine learning anomaly detection module.

3.3 Data processing

Figure 1 - Data processing workflow.



The following processing modules are foreseen:

- Back end layer: this is the sensing devices acquisition module. This module will cover the sensor deployment and the communication between different devices. Sensing devices are set of non-invasive sensing devices (IoT sensors, wearables, sleep sensor, localization sensor) to track Functional activities and Social Activities, detecting Emotional Patterns and Behaviours that can be associated to Social Isolation and Social Exclusion. Seniors' analysis will be performed on two main axes: a) Indoor daily activity analysis b) emotional status by using biosensing devices such as wearable devices measuring heartbeat rate, body temperature, body posture, or blood pressure. In order to test the platform, the back-end will run scripts in order to create dummy data of artificial yet plausible anomalies for every patient, based on their normal daily routine.
- Middle Layer: this is the data analytics and machine intelligence layer. Three types of analytics will be provided:
    a. DESCRIPTIVE ANALYTICS: this module continuously analyses information related to patients' historical data, patient profile and interactions via sensing interfaces, clinical tests, treatments, etc.. Statistics on these data will be derived, both on single patients and patient cohorts.
    b. PREDICTIVE ANALYTICS: Predictive analytics is based on innovative machine learning methods suitable for the type of considered data (sequential learners, autoencoders, etc). Specifically, the following predictive features will be provided:
        - **Abnormal Behaviour Detection** (ABD): This module will focus on analysing sensing information to identify abnormal behaviours. Exploiting intelligent capabilities of an indoors activity recognition methodology, employing ambient and depth sensors, environmental sensors and mobile based sensors, this core subsystem will provide

the system with the capability of assessing occasional or drift deviations from the expected daily conduct of the person,

- **Multimodal Fusion Subsystem** that receives information from the ABD subsystem and provides combined, higher level information regarding the behaviour of patients, based on ABD from sensor data and their emotional status. It works by utilising deep Learning techniques.
- **Risk prediction**: based on patient's trajectories as acquired from sensor and wearable,, this module will provide early estimates of pathological risks (especially related to patient's mental status, such as depression and Alzheimer)

c. PRESCRIPTIVE ANALYTICS:

- **Personalized medical treatments**: based on patients' data from sensing devices, clustering techniques can be adopted for patient stratification, helping doctors in defining most effective treatments. The focus is the customisation of services and their functionalities.
- **Activity recommendation**: based on the system-provided assessment of patients' health conditions, anomalous or drifting behaviours and mental status, and caregiver's best practises, this module will provide recommendations for affecting activities, social interactions, and other engaging activities to reduce frailty and social isolation .

- Front-end layer : this is the **visual data processing** and reporting component. It includes a **Virtual Assistant** that proposes a series of engaging activities (e.g. listening to music) to sustain the patient's well-being. It also includes an **Visual Analytics Interface** for the caregivers that reports daily activities, patient statistics, and detected anomalies. The caregiver can inspect each patient's usual behaviour and select four sub-types of anomalies (duration, frequency, start time and order) of monitored actions. The caregiver can also insert photo albums that will be notified to the user who can easily use them with a very simple experience.

4 DATA SECURITY

4.1 Data access

The access to the data will be granted to the personnel involved in the project only and the individual that will take part in the pilot test will sign an informed consent (Annex I). The consent will be informed: the data holder will be able to know which data are processed, with the methods and purposes and the rights that are attributed to him/her by law. Furthermore, the data holder will be properly informed of the consequences of his/her consent (for example, it must be indicated that in the absence of consent he/she will not be able to participate in the pilot activities anymore and/or access specific website sections). In order to be fully compliant with Art. 6.1 of the Regulation 2016/679, the data holder has to give the consent to the processing of his or her personal data for one or more specific purposes. The formal acceptance of the terms and conditions will be possible through the signature done by the data holder. The signature of the informed consent will become a condition of treatment legitimacy.

In addition to the data holder, the data will be also available for the following categories:

- SI4SI scientific consortium members in charge of data storage
- DPOs (Data Protection Officers) detected and nominated by each project partner
- Unit Members organizing the project inside the AAL Association

No personal data is transmitted to parties outside the recipients and the legal framework mentioned. The European Commission will not share personal data with third parties for direct marketing purposes.

4.2 Repository and data preservation

To preserve the data, security systems are adopted at every level of the system.

Most of it is done on the back-end: The database keeps the data, the passwords are saved encrypted, there will be no plaintext passwords. All communication of data exchange from front-end and back-end takes place in HTTPS / REST.

Data will not be openly accessible, the data will be usable only after authentication, with the exchange of a session token.

Furthermore the participant's data will be anonymised, thus the participant will not be identifiable, the data will be related to the code allocated to the participant.

The correlation between the code and the name and related contact data will be available in different documents, not stored in the same place as the study data.

5 ETHICAL ASPECTS

The SI4SI project is fully compliant with the General Data Protection Regulation (GDPR) regulations laid out in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC and respects regulations on intellectual property rights (IPR)[10].

Sensitive data is data that is either private or confidential and includes personal user data. The proper management of sensitive data is imperative to maintain the individual privacy and remain in compliance with both EU and international regulations. In order to ensure sensitive data is properly managed, data that is considered sensitive should first be identified. Any response data captured via these stakeholder and expert interviews are considered sensitive data and will be treated responsibly and securely.

Thus, for the SI4SI project, the main ethical and privacy issues with sensitive data arise from ensuring the data remains private and that proper consent is obtained before the data is shared or published in any way. Sensitive data will be stored in Caretronic Backend. Measures to protect the privacy of individuals providing sensitive data will be taken in any instance where sensitive data will be collected and published. During the pilot phase of the SI4SI workflow, sensible and response data will be pseudonymized so that it cannot be directly attributed to the responder (for example, as formerly mentioned, by identifying a numeric code to an individual). In addition, data will be reported in aggregated forms to further prevent any firm or individual from being identified through their responses.

Further insights will be provided in Annex I, that will provide details of the initial data collection as well as of the informed consent procedure.

[10] https://europa.eu/youreurope/business/running-business/intellectual-property/rights/index_en.htm

6 PERSONNEL EFFORT AND ALLOCATION OF RESOURCES

6.1 Project costs associated to the data management plan

The SI4SI project will take advantage of the internal software and services provided by CRT that will be used to make the data of the project open to the project partners involved in the pilot testing by following a FAIR procedure.

DS Tech DPO will be used as the data identifier for the project, while Caretronic DPO will be used as the data repository. The costs associated with the data management activity are included in the project costs associated with WP1 and the cost definition follows the principle of *best value for money*.

6.2 Person of contact for the data management-related issues

Tasks involving data management are present in all stages of the project. GIOMI will lead the first substantive data management tasks that begin in WP1 by creating the first draft of the Data Management Plan. On the other hand, DS Tech will conduct the peer review by the end of M10.

In case the data holder wants to check how personal data are stored, modify, correct or wants to delete them, or if he/she has questions about the information processed in the context of the project, or about his/her rights, the data holder can contact the Lead Partner DS Tech at the following email address: si4si@dstech.it.

REFERENCES

3.Italian National legislation in terms of privacy of sensitive data
https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg

4. DELIBERA 19 dicembre 2018 Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica. (Delibera n. 515/2018),
https://www.gazzettaufficiale.it/eli/id/2019/01/14/19A00181/sg

5. Italian Decree Law on GDPR an its integrations in the National legal space
https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg

6. Full GDPR text, available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

7. Romanian Data Protection Laws https://www.buzescu.com/romanian-data-protection-laws/

8. Romanian National Supervisory Authority For Personal Data Processing
https://www.buzescu.com/romanian-data-protection-laws/

9.IPR Rights in the European Framework https://europa.eu/youreurope/business/running-business/intellectual-property/rights/index_en.htm

AAL Call 2020

Annex I
Informed Consent Template

Work Package 1: Project Management and Coordination

Smart Intervention for Senior Isolation: SI4SI Project

Project reference: aal-2020-7-108-CP

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5	Caretronic	CRT	SI

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Involved beneficiaries	DSTech s.r.l
Type[1]	R
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Last update	31/01/2022

[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.
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Document History

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v 0.1	16/11/2021	Draft	Laura Laurenzi (GIOMI)	General definition of the contents that will be delivered in Annex I
v 1.0	31/01/2022	Final	Andrea Valerio Chentrens (DST)	Final version

Annex I

INFORMED CONSENT TEMPLATE

Project Partner: XXX

Piloting development facility: XXX

INFORMATION FOR THE USERS

The following information will be for the user and his/her participation to the innovation project named "**SI4SI-Smart Intervention for Senior Isolation**" and aimed at implementing home automation solutions in controlled facilities, monitoring daily living activities.

Identification code for the user:

Facility	ID user	Registration number of the device

FACTSHEET FOR THE USER

Dear Sir/Madam,
You are hereby asked to participate in the above-mentioned research project and this document is intended to inform you about the aims and methods used in the research. In this regard, you will find the following information

- about the research conducted by XXX (please insert the name of the partner involved in the testing);
- about the domotic devices used for the collection of data useful for research purposes;
- about the various procedures that will be implemented during the research and the duration of your participation;
- on the treatment of data collection and data management;

Please read this document carefully before making any decision about your possible participation in the research; you will have plenty of time to decide whether or not to participate and, if you wish, you can discuss the issues with your relatives and your doctor. In addition, you will be free to ask questions to the staff involved in the project, asking for clarification and repetition of questions for which you have not received a clear and/or complete answer. If you need further clarification, please do not hesitate to ask any of the doctors or caregivers involved in the research or any of the facility's staff. If, after reading and understanding all of the information provided, you decide to take part in this research, you will be asked to personally sign and date the Informed Consent Form and Privacy Policy attached to this document. You should keep this factsheet throughout the whole duration of the research.

PROJECT'S AIMS AND OBJECTIVES

The SI4SI research project involves the following International partners:

- the company GIOMI CARE S.r.l. as the subject proposing the experimentation at XXX (IT),
- DSTech, leading company of the Research Project, which will treat the data in an anonymized way (IT);
- Sapienza - University of Rome, Department of Informatic Engineering, as the Research Body, which will also treat the data in an anonymized manner (IT);
- Canary Technology Innovations – CTI, technological partner involved in the research project (RO)
- University of Medicine and Pharmacy "Carol Davila" Bucharest as the subject proposing the experimentation at XXX (RO)
- Caretronik, technological partner involved in the research project (SI)

The purpose of this research is to identify, prevent, and eliminate social isolation of the elderly by stimulating active aging. The SI4SI project's objectives are:

- identify the social isolation of the elderly through a less invasive and innovative Smart Living Environment, detecting both Physical, Social and effective behaviors
- intervene promptly through AI Based Advisor
- improve the levels of home care by Professional Caregivers
- foster emotional relationships between family members and the elderly
- promote the social involvement of the elderly

DESCRIPTION OF THE RESEARCH STUDY

SI4SI is an Active & Independent Living solution that, through a network of non-invasive IoT devices, enables indoor recognition of behaviors symptomatic of elderly's social isolation and activates home care protocols and services, through a dashboard for professional Caregivers and family members thus supporting Integrated Care synergies. Simultaneously, an AI Advisor interacts vocally with the elderly, through a Domotic Assistant, improving their state of mind, creating empowerment and encouraging virtuous behaviors for mental and physical well-being.

Making use of already tested technologies the equipment has very simple and fast functionalities. The instruments used are:

- smartwatch for the detection of vital parameters useful for research purposes;
- tablet for the detection of the vocal parameter;
- environmental sensors, called "Beacons", installed in common areas and in the rooms of the users.

The listed instrumentation will be used to monitor activities of the user's daily living (sleep, hygiene care, movements in the door) and his/her location in the structure.

RISKS RELATED TO THE PARTICIPATION OF THE STUDY

After a careful analysis of the technology used and the way in which it is used, it is possible to say that there are no detectable risks to the health of the user who will decide to undergo the research.

WHAT YOUR PARTICIPATION IN THE STUDY ENTAILS

The research will last for approximately 7 months and it will be carried out in the facility of (please insert the name of the facility involved and its legal and operating address). During these 7 months, the testers will have the opportunity to participate in living-lab testing activities and home trials, according to the patients' needs and necessities. If you agree to participate in the research, you will be asked to sign the informed consent form which is an integral part of this document.

You will then undergo an initial checkup (day 0) to verify that your condition meets the criteria required by the research. By signing the informed consent form, you authorize the project partner to proceed with the trial.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study, without penalty, and your doctors will continue to provide you all the necessary care that you need.

RESEARCH INTERRUPTION

Similarly, the trial may be interrupted if the doctor finds that there are elements that prevent it from continuing.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it, at the end of the study, you may be notified of the results of the study in general and of your results in particular. The results of this study may be published in a medical journal with appropriate anonymization to prevent any form of recognition.

STUDY FEES

You will not incur any expenses for your participation in this study, either for the visits made during the study nor for the equipment used.

CONFIDENTIALITY

The partnership will act in accordance with the responsibilities provided by the rules of good clinical practice (Legislative Decree 211/2003), in compliance with the current rules on privacy (Privacy Regulation 2016/679, more commonly known as GDPR - General Data Protection Regulation). The European legislation establishes new rules for organizations that hold and process data of individuals residing in the European community, regardless of their location.

Your personal and clinical data, particularly health data, will be processed exclusively for the purpose of conducting research. For this reason, the data indicated will be collected at (please insert the place where the study will be carried out and/or the partner that will carry out the pilot)

NATURE OF DATA

The study research personnel will identify you by a code. All data about you collected during the study, with the exception of your name, will be transmitted to the trial team, recorded, processed and stored together with your code, date of birth and gender. Only the doctors and authorized staff personnel in charge of the study will be able to link this code to your name.

The data, processed by electronic tools, will be disseminated only in strictly anonymous form, in order to ensure the confidentiality of your identity.

RIGHTS EXERCISE

You may exercise the rights provided for by the Personal Data Protection Code and subsequent additions (e.g. access your personal data, integrate them, update them, oppose their processing for legitimate reasons, etc.) by contacting (please insert the name of the project partner in charge of the testing).

You may interrupt the participation in the study at any time and without providing any justification: in this case the data related to you will be destroyed. Furthermore, no further data concerning you will be collected, without prejudice to the use of any data already collected and used to determine, without altering them, the results of the research.

COMPENSATION IN CASE OF DAMAGE

If a medical problem arises as a result of the research, you are assured of receiving the most appropriate treatment at no additional charge.

If additional information about SI4SI becomes available during your participation that may affect your willingness to continue participating in the study, you will be notified immediately. If, as a result of this information, you decide to continue in the study, you will be asked to personally sign and date a new informed consent form.

CONTACT PERSON

For further information or communication during the study's activities, or in case of emergency, please contact the following staff who will be available at all times:

Name	Address	Contact Number

The SI4SI study has been prepared in compliance with Good Clinical Practice Guidelines, European Union regulations, and the ethical principles set forth in the Declaration of Helsinki and subsequent revisions.

You may report any questions regarding research activities involving your participation in the study to the Management of the project partner (please insert the name of the project partner in charge of the testing).

INFORMED CONSENT

on

The **SI4SI-Smart Intervention for Senior Isolation** project**,** aimed at implementing home automation solutions in controlled facilities, monitoring daily living activities.

Identification code for the user:

Facility	ID user	Registration number of the device

Date and Place…….
I undersigned ……..…….. born in…….
the ……, living ……..
Declare that:

- I accept the proposal to participate in research aimed at implementing home automation solutions within controlled facilities for the monitoring of activities of daily living and health.
- I have been adequately informed about the purpose of the study and its methods, in particular:
- I have read the patient information integral to this document that confirms what was verbally explained to me regarding the study and the study home automation devices;
- I am aware of how the device will be applied and how clinical data will be collected;
- I am aware of the benefits that may occur to me from the use of the home automation equipment used in the research;
- I am aware, however, that at any time I can suspend the trial and demand to be treated ordinarily, without any obligation on my part to justify the decision, unless the same does not result from the appearance of disorders or adverse effects, in which case I undertake to communicate promptly to the doctor in charge of the study nature and extent.
- I declare that my consent is the expression of a free decision, not influenced by promises of money or other benefits, nor by obligations of gratitude or friendship and/or kinship towards the doctor in charge of the study.
- I accept as of now that subjects authorized by the International partnership may have access to my clinical data (and only for the purpose of treatment of my identity), in accordance with privacy laws in force.
- I authorize the use and disclosure in anonymous form for scientific and administrative purposes only and always in compliance with the code on the protection of personal data and subsequent authorizations, the results of the trial, including clinical data concerning me (Legislative Decree 30 June 2003, n.196, and Resolution of the Guarantor of 24/07/08 No. 52. Deontological rules for treatments for statistical purposes or scientific research carried out within the National Statistical System published pursuant to art. 20, paragraph 4, of Legislative Decree 10 August 2018, n. 101 - December 19, 2018).

- I authorize the usage of my photos by the partnership only for purposes related to the SI4SI project and the AAL Programme.

Date_____/_____/20_____ Signature_____

I undersigned Dr. _____ I declare that the patient has voluntarily signed the free participation in the study. I also declare:

• To have informed the user about the purpose, procedures and possible risks and benefits related to the study;

• To have given the patient all the time necessary to make his decision and the possibility to ask for clarification in relation to the study;

• Not to have unduly forced or influenced the user to obtain his consent.

Data: ____ /____ /20____ **Doctor's signature**_____

Signature of the referring caregiver (if the patient is unable to read the caregiver must be present during the discussion of the informed consent and sign below)

I undersigned_____

testify that this document has been read and explained to the patient and that he has given his oral consent to participate in the study and has signed the consent form.

By signing this sheet, I certify that the written information, an integral part of this consent, has been carefully explained to the patient and understood by him and that the consent has been freely given.

Date: ____ /____ /20____ *caregiver*'s signature_____

INFORMATION ON THE PROCESSING OF PERSONAL DATA
(in compliance with Article 13 of Regulation 2016/679 / EU and Legislative Decree 196/2003)
This Information on the processing of Personal Data describes your rights and offers explanations about the ways in which your personal and health-related information will be used, communicated and protected. This type of information is defined as "Personal Data" and is subject to the protection of European (EU) and Italian legislation on data protection (Legislative Decree 196/2003 and EU Regulation 679/16 / EU). GIOMI CARE S.r.l., the Chief doctor and the staff involved in the conduct of the study are required to comply with this legislation as well as with the legislation and regulations on observational studies.

In order for you to participate in this study, it is necessary that you give your permission for the collection, use and disclosure of your personal data. If you do not agree, you will not be allowed to participate in the Study.

A. OWNER OF THE PROCESSING OF PERSONAL DATA

Data Controller: GIOMI CARE S.r.l.
Email: dpo.giomicare@giomirsa.com
An updated list of the Authorized to the Treatment and of the internal and external subjects who take part in the data processing operations, is available from the Data Controller and you can obtain a copy by contacting the Responsible Doctor who provided you with this document.

In compliance with European regulation 2016/679, you may address your requests relating to the exercise of your rights to the Data Controller.

B. PURPOSE OF THE PROCESSING OF PERSONAL DATA AND SPECIAL CATEGORIES OF PERSONAL DATA

Your Personal Data, as described above, will be processed only where necessary to achieve the objective / objectives of the Study that has been described to you. An example of the use of your Personal Data for the purposes of this Study could be to deepen the knowledge of your health conditions and related treatments.
The processing of your Personal Data is also required by the legislation on the conduct of observational studies. The Data Controller may or may not use your Encoded Data to fulfill legal obligations.

C. NATURE OF THE PROVISION OF PERSONAL DATA

The legal basis for the processing of your Personal Data is represented by consent. You can refuse to give your consent to the collection, use and communication of your Personal Data to other subjects, as explained in this document. If you refuse, you will not be able to participate in the study.
Primarily collected data will be given
1. from devices and sensors to measure the state of health and monitor physical and social activities;
2. from processing to extract the evaluation of emotional behaviors;
3. from the analysis of the collected data to create behavioral models and produce predictive analyzes and AI recommendations for end users.
SI4SI will design and implement distributed data storage with a federated approach so as not to transmit data outside the GIOMI servers, or in any case so that sensitive data does not leave the local office without being made anonymous. The responsible person in charge of the data storage and the staff of GIOMI CARE Srl, before the transfer of Personal Data, will delete any information that allows you to be directly identified (for example your name, address and contact details), indicating a generic code that no one else is in able to connect to your identity.

In order to help answer the questions envisaged by the study, certain Personal Data concerning you may be collected from your existing medical documentation, in order to be able to understand your medical history. Furthermore, during the study, both the information that you will report (by answering questions) and the data relating to the routine assessments carried out will be collected.

Below are some examples of Personal Data that may be collected:
• Lifestyle information
• Information deriving from the use of the installed technology
• The results of laboratory tests and analyzes that fall within the standard of care (blood tests)
• Information relating to your medical history, your health conditions, medical treatments and procedures together with the relative dates of execution.

D. PROCESSING METHODS AND DATA STORAGE TIMES

The methods of data collection and processing are computerized / automated. The methods of collection and treatment are carried out by means of operations or series of computerized and automated operations, with the aid of electronic tools, and aimed at the collection, registration, organization, storage, consultation, processing, to the modification, selection, extraction, comparison, usage, interconnection, blocking, communication, dissemination, cancellation and destruction of data.
The Data Controller, the Responsible Doctor and his staff will keep your Personal Data (including Encoded Data) in a safe place with limited access. They are required, by law, to safeguard the confidentiality of your Personal Data, and to use and communicate them only as described in this document. Access to Personal Data will be allowed only to the competent Regulatory Authorities and Certifying Bodies, in order to verify that the data of the Study are recorded accurately and that the Study is conducted appropriately.

GIOMI CARE srl may keep the Personal Data received for as long as it is carrying out the research object of this Study or for a longer period if so required by the European Union or Italian/Romanian legislation or regulations governing the research activities, but in any case not exceeding 10 years**.**

E. CATEGORIES OF ADDRESSEES OF PERSONAL DATA AND SCOPE OF DISCLOSURE OF THE DATA

Your data may be disclosed for the sole purpose of carrying out our health services, to service providers, to associated companies or to other entities, to Authorities or companies that have established a contractual or institutional relationship with our company, among which, there are service companies of various kinds, including IT services, digitalization services, medical and healthcare services, including freelancers in the medical field. These subjects are usually appointed as data controllers and therefore will be under our supervision and control; your personal data may only be known by authorized personnel for data processing (e.g. administrative staff, system administrators, etc) within the limits of what is necessary for the performance of health services. Finally, your data may be disclosed to health control bodies, public administration bodies, public security authorities, judicial authorities and insurance bodies and other subjects, bodies or authorities acting in their capacity as independent data controllers, to whom it is mandatory to communicate Personal Data by virtue of legal provisions or orders of the authorities. The personal data of our users are in no way disclosed. We also inform you that patient data are not transferred outside the European Union and the European Economic Area, except for any technical maintenance interventions and on an occasional basis aimed at solving a malfunction of medical devices by external suppliers who in any case guarantee compliance of the requirements and obligations provided for by the new EU Regulation 2016/679.

The results of this study may be published in reports related to the study or in presentations and scientific publications. Such reports, presentations and publications will not include any information that can identify you or that could be used to trace your identity.

F. RIGHTS OF THE INTERESTED PARTY AND WITHDRAWAL OF CONSENT

You are granted specific rights, such as: confirmation of the existence or not of personal data concerning you with the data controller, even if not yet registered, their communication in an intelligible form; the right to obtain information on the origin of personal data and the purposes and methods of electronic processing; the identification details of the owner, the rectification or, when interested, the integration of the data; the cancellation of the data; the interested party has the right to object, in whole or in part, for legitimate reasons, to the processing of personal data concerning him/her, even if pertinent to the purpose of the collection and to the processing of personal data concerning him/her.

In particular, you will have the right to view and obtain a copy of your documentation relating to the clinical study, and you have the right to request a correction if you believe that your Personal Data is not accurate or complete. It is important that you are aware of the fact that since it only retains the Encoded Data, the tecnica partners or other subjects different from GIOMI CARE S.r.l. may not be able to fully follow up on your request. For requests relating to the Encoded Data stored by the aforementioned subjects, you must contact the Doctor of the Facility who participates in this research and who in turn will forward your request. If technical partners are unable to satisfy your request, a valuable anD legal reason will be given.

In addition to the rights listed above as an interested party, within the limits of the provisions of the new Regulation, you may also exercise the rights to limit the processing, to oppose the same and to portability exclusively for the personal data you have provided to the data controller, in accordance to art. 20 of the Aforementioned Regulation. We also inform you that on the basis of the Privacy Code and the new Regulation you can propose to protect your rights before the Guarantor for the protection of personal data (so-called complaint provided for by art.77 of the aforementioned Regulation) or propose an appeal to the competent court.

Finally, we inform you that you can exercise the right to withdraw your consent to the processing of data. If you request that the collection and communication of your Personal Data by us be interrupted, you will not be able to continue to continue with the Study. This decision will not result in any penalty or loss of any of the benefits to which you are otherwise entitled. Your decision to withdraw yours has no effect on the legitimacy of the data processing carried out in accordance with the consent you gave prior to the consent refusal.

CONSENT AND AUTHORIZATION TO TREATMENT

OF THE USER'S PERSONAL DATA

(compliant to Article 7 of EU Regulation 2016/679 / EU)

- I have read and understood the content of this Information on the Processing of Personal Data.
- I was given the opportunity to ask questions and all my questions were answered satisfactorily.
- I am fully aware of the fact that consent to the processing of my Personal Data, although optional, is essential for me to participate in this Study.
- I consent to the processing of personal data in the manner and within the limits set out in the attached information.

An original signed copy of this consent form will be delivered to me or to my legal representative / Support Administrator / Caregiver Referent. Pursuant to the provisions of EU Regulation 2016/679 / EU and Legislative Decree 196/2003, I authorize the access, use and transfer of my Personal Data as described in this form

Name and surname of the user: _____

Date and user's signature

____/____/____ _____

Name and surname of the legal representative

_____

Date and legal representative's signature

____/____/____ _____

*Name and surname of the *Caregiver* referee:

_____

Date and signature of the *Caregiver* referee

____/____/____ _____

** The intervention of the caregiver is required if the subject is unable to read the consent form (for example, if the subject is visually impaired, illiterate or does not speak the language used to draw up the consent). The caregiver must be present during the entire consent interview. The signature done by the caregiver confirms that the information contained in this document has been illustrated to the user and that the user appears to have understood it and given his / her consent.*