Confidence

D2.4 - Report on the Ethical Issues

Project Deliverable

Project Number	AAL-201-4-024
Project Name	Confidence
Duration	June 2012 – May 2015 (36 Months)
Coordinator	Salzburg Research Forschungsgesellschaft

Document ID	D 2.4
Release Number /Date	V01 / February 9th, 2014
Checked and released by	Luiza Spiru -AAIF
Document Type	Project Deliverable
Original Due Date	1st version
Dissemination Level	Public
Main Editor	Ileana Turcu – AAIF
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Short Description

This document belongs to the WP2–REQUIREMENTS AND COMMUNITYBUILDING and describes the relevant ethical and legal issues related to the close cooperation with the end-users during the project running.

The Confidence project is Co-funded by the European AAL Joint Programme

Confidence

Revisions

Rev.	Date	Author	Description
0.1	09.02.2014	Ileana Turcu	First Version
0.2	14.07.2014	I. Turcu, A. Sterea	Second version
0.3	06.08.2014	Cornelia Schneider	Reformatting and table of contents
0.4	07.08.2014	Cornelia Schneider	Revision and input
0.5	08.08.2014	Manfred Feichtenschlager	Revision and input
0.6	26.01.2015	Ileana Turcu	Revision and input
0.7	26.01.2015	Thomas Meyer	Revision and input
0.8	02.02.2015	Ileana Turcu	Revision and input
1	11.02.2015	Viktoria Willner	Review

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1. Executive Summary

The document gives an overview on ethical and legal issues taken into account in Confidence when working with end-users. It contains background, up to date information about the ethical provisions adopted by the Ambient Assisted Living Joint Programme, as well as by the providers of AAL applications for seniors care, in the US and especially in Europe. The section 3.1 refers to the ethical aspects regarding advanced technology for old or frail people in Europe, while 3.2, 3.3 and 3.4 give an overview of the specific ethical and legal frameworks in the three pilot countries: Austria, Romania and Switzerland. The ethical aspects related to people with dementia are described in section 4. Section 5 describes the ethical concerns particular to the three Confidence pilots: Austria (Section 5.3), Romania (Section 5.4) and Switzerland (Section 5.5), and the solutions adopted to fulfil them (end-users recruitment, involvement and participation in field trials; transparency in using data; the exit rights; the principles and guidelines to solve the ethical dilemmas in this field). Several considerations about consumer protection, product safety and the exit strategy are also pointed out.

Glossary of terms

AmI	Ambient Intelligence - electronic environments that are sensitive and responsive to the presence of people
Geo-fence	A geo-fence is a virtual perimeter for a real-world geographic area.
PEU	primary end-user
SEU	secondary end-user
Assistant	in the Confidence project, a person skilled in Confidence app use, which supports PEUs and SEUs during the preparation and execution of field trials
Mentor	responsible person at the end user organisation who coordinates the preparation and execution of a field trial

2. Background

Concerns on Ambient Assisted Living

Smart assistive technology can provide golden answers to the challenges of population aging. AAL applications can help old people to preserve or improve their physical mobility and mental agility, and to accomplish their activities of daily living. It can also improve their health monitoring, maintain them active and socially inserted, and can increase old people's safety indoors as well as outdoors. The UN International Plan of Action on Ageing (Madrid 2002) states the development of supportive environments and Assistive Technology (AT) as its 3rd Priority Direction - Ensuring Enabling and Supportive Environments. (1) Among the United Nations Principles for Older Persons, those of Independence ("older persons should be able to live in environments that are safe and adaptable to personal preferences and changing capacities"), Care ("older persons should have access to social and legal services to enhance their autonomy, protection and care"), and Dignity ("older persons should be treated fairly regardless of age, gender, racial or ethnic background, disability or other status …") are closely touching Ambient Intelligence and AAL developments. Based on the basic

pillars of the WHO concept on Active Ageing (2), the specific needs of older people should be classified into six groups: physical and mental health, safety, independence, mobility and general social interaction, participation and intimacy. It is expected that due to better information, in the near future the patients will be more proactive in seeking AAL applications able to support their needs from each of these categories and improve their quality of life.

Classic geriatric health providers and AAL applications

It was documented that the care provided by an interdisciplinary team results in better clinical outcomes and higher satisfaction of the patient [3]. In exploring such new, “shared care” models of health care delivery the involvement of AAL applications may add real value to the long-term care giving. The requirements for demand - complex services is estimated to grow in the coming years, so that “the use of smart home technology to support independent living is hereby inevitable” [4]. However, their implementation can be difficult because of their costs that might be too big for the health insurance companies. Another possible barrier should be the reluctance of old people to more or less sophisticated smart devices. Among the studies that investigated the compliance of old users with various disabilities to video-based smart home care solutions, that of Ziefle M and Holzinger A (2011) points out that users’ acceptance, needs and wants must be seriously considered in the design of new smart assistive technologies (5). Other authors consider that due to the more and more frequent exposure to computer applications the old people of tomorrow will be more open and increasingly competent in using smart technological innovations. However, not all elderlies will be able to take advantage of these technological advances. The "digital divide" will persist, due to a significant variability of their educational background and experience with smart technology [6].

US geriatric health care and smart assistive technology

Seventy millions of Americans over the age of 65 are estimated by 2030, a population shift that will exert unprecedented pressure on healthcare providers. Important legislation has been recently introduced in the Congress to attract and retain trained healthcare professionals and direct care workers and to promote career advancement opportunities. On these issues Active Assisted Living (AAL) technologies are thought to provide some significant relief. The American Association of Homes and services for the Ageing (AAHSA) and especially The Leading Age Center for Aging Services Technologies (CAST) are among the most active promoters of the development, evaluation and adoption of emerging health, safety, connectedness and caregivers’ electronic documentation technologies in the USA. The growing interest in the concept of “smart houses” an development of eHealth, eMobility, eCommunication and other high-technology solutions is paralleled by the equal, sustained development of basic assistive technology devices, that continues to be widely used with positive impact on everyday activities, independence promotion, health-care costs and hospitalization, at relatively low cost (6). The Americans with Disabilities Act of 1990 prohibits disability-based discrimination in the provision of goods and services by public and private stakeholders and promotes standardization as an essential element (7).

European geriatric care and smart assistive technology

In the more industrialized European countries life expectancies are higher, families are smaller, and the “young” are sometimes middle-aged. The majority of the elderly are living alone. (8). Older people in need of full time care are estimated at 5% for the age group 65-69 years, 10% for the 70-79 age group, and 30% for the group aged 80 and over (9). The care of chronic and disabled patients involves lifelong treatment under expert supervision. Home

Care has been considered as a fundamental component of long term care, capable of reducing expenses, institutionalization and risk of death. Ambient Intelligence (AmI) is envisaged as a major component of home care, but AmI platforms as constituent parts may be provided by different manufacturers and need to be made compatible with each other. Standardization may reduce the cost of AmI systems. ISO (International Standardization Organization) and International Electrotechnical Commission (IEC) have together produced the ISO/IEC Guide 71:2001: Guidelines for standards developers to address the needs of older persons and persons with disabilities. The ISO/IEC Joint Technical Committee One (JTC1) issued ISO/IEC JTC 1/SC 35; User Interfaces and ISO/IEC JTC1 SC36; Information Technology for Learning, Education, and Training (10).
By the highly innovative solutions that it may provide, AAL technology meets "the new paradigm on ageing" promoted by the most recent European programmatic document – the Strategic Plan of the European Innovation Partnership on Active and Healthy Aging – EIP-AHA 2011. (11) This new paradigm includes among other the development of personalized, dynamic and sustainable care services. According to the third pillar of the Strategic Plan – the Active Ageing and Independent Living – the "deployment of innovative approaches and solutions, including those enabled by social innovation and by ICT can facilitate change of current practices and better deliver the desired results. Social innovations and new ways of organizing society around independent living for older people can be strengthened by wider use of innovative ICT solutions." The document also points out that "for being interoperable, scalable and ensure 'buy-in' of the end users, the technical solutions for active independent living still need to overcome a number of barriers, such as limited standardization, complex procurement procedures and limited involvement of users in the innovation process."(11) At the same time, the use of ICT raises challenging ethical issues.

3. Ethical aspects regarding advanced technology for old or frail people

The Annex 3 of Guidelines for ethical considerations in the projects cofounded by the Ambient Assisted Living Joint Programme (AAL-JP) specifies that the ethical issues pursue two distinct categories:

- issues related to the implementation of the project, and
- issues related to the solutions adopted in the project. (16)

Both must apply the national and international ethical rules specific for end-users and to society in general, from the concept phase to test installations and eventually launching in the market. It is pointed out that the nature of AAL projects raises a broad range of ethical concerns, most of them related to the technology involved that is often unfamiliar to the end-users and being sufficiently complex to not allow a full transparency for end-users and other stakeholders (privacy, control of personal data, confidentiality, autonomy and dignity). The solutions developed must be trusted, accessible and accepted by all user groups involved in the project, and must address the relationships and social networks of the involved and eventually future end-users. Ethical rules in AAL projects concern end-users recruitment and, their participation in the project development process, the informed consent as a standard procedure, the protocol of their participation in prototypes testing and validation, and the precise information on how the end users can withdraw from the project at any time and the possible compensations provided to them for participating (expenses or fees paid, etc.), the possibility to contact a person in their own country for ethical issues and related questions. The exit rights for individual end-users (withdrawal from the project at any time, without giving a reason and without incurring costs or penalties) must be clearly specified and carefully managed because termination of the project may create problems in the terms of

losing a help they got accustomed with. Other important issues that require ethical awareness are information and data management, the storage and transmission of personally identifiable information, the application of the national rules of the involved partners, the statement or permission by national and partner institution ethical committees, and the macro level distributive ethics (justice, equality of access, choice etc.). Of a great importance and help in the ethical management is the permanent communication with the National Contact Point.

3.1 Ethical aspects regarding advanced technology for old or frail people in Europe

In the Internet Encyclopaedia of Philosophy the field of ethics includes concepts of right and wrong behaviour systematization, defending and recommendation (12). In the field of AAL, ethics supposes what the specific stakeholders 'should' do as the right thing for primary and the other categories of users.

Quoting the definition of Ethics advanced by G. Hermerén as being the "result of our pursuit to systematically reflect on, analyse, and question the norms and values that guide human action", I. Borges (13) points out that "there is a very fine line between technology that promotes independence and technology that threatens individual freedom". The actual development of assistive technology must carefully consider the moral and ethical issues related to its use, especially the key ethical principles able to avoid the compromise of the basic human rights: end-user autonomy and consent, safety and independence, balance between avoiding harm and respecting decisions, privacy protection, dignity, integrity and preferences, treating the individuals fairly and equally. The most important approach lies in the concept of "human centred design approach" (13), meaning that end users must be involved in the technological research process and design. Other operant issues are the creation of user's feel of ownership, acceptance (human-machine compliance), choice, and freedom to "opt out" at his/her own convenience, as well as the creation of legal frameworks able to guarantee the involvement of fragile or mentally disabled people. Another critical non-discriminative item is the equal economical accessibility of old or frail people at need and the need of developing specific socioeconomic studies, promoted including from governmental level.
In accordance with the "ICT for elderly people, Final report from the consensus conference of The Norwegian Board of Technology (2000)", "the introduction of information technology may reinforce existing problems and dilemmas, at the same time as it may involve improvements for each individual in need of nursing. Clarification of the ethical aspects is therefore vital". Also, the Report points out that "for decision-makers in state and local authorities the saving of economic means by introducing ICT in welfare services maybe an important motivation. This is understandable and not necessarily unethical. However, when the introduction of information technology reduces the quality of welfare services, the matter is different. Technology is not a substitute of care and human contact" (14). Rather, these technologies are to be regarded as a necessary complement.

S. Rogerson proposes three ethical perspectives in smart assistive technologies development: the Utilitarian perspective, the Aristotelian, and the Kantian one. (15) The utilitarian principles include utility ("ethically good" means provided benefit, "ethically bad"

means harming), equality (treating everyone equally), and overall utilitarian strategy (the most benefit and the least harm).Essential “utilitarian” questions may be:

- How can be support and opportunity equality achieved?
- Should equality for all be the product start-up default?
- How can affordability be achieved?
- What are the obligations regarding affordability of ICT applications and whose obligations are they? (15)

Inside the Aristotelian ethical perspective (raising citizens who regularly adopt courage, integrity, reliability, responsibility, prudence, temperance, justness, persistence etc.), Rogers formulates several key questions:

- “How are self-determination and risk taking by the elderly incompatible with current e-inclusion thinking?
- In order to promote self-determination, how all citizens are involved in the development of e-services that promote social inclusion?
- Is it acceptable that assistive technologies that exceed human abilities are developed and in particular for those people with disabilities?
- Is it defensible that those people who, for whatever reason, have no or limited access to on-line services are disadvantaged?
- To what extent are on-line government services perceived as untrustworthy by disaffected groups?
- What is the balance between sustaining individual privacy and promoting e-inclusion?
- What is the balance between sustaining individual privacy and promoting e-inclusion?(15).

Finally, there are several important questions issued by S. Rogers inside the Kantian ethical perspective (worth in him/her and “in charge of their own lives and actions”):

- “How can government on-line services be implemented in a way that respects the EU as a heterogeneous population in terms of culture, economic prosperity and age?
- How can public access points to on-line government be de-stigmatised?
- How can the design of human interfaces for smart environments ensure people with sensorial, physical or cognitive restrictions are treated with worth and dignity?
- In order to promote ICT acceptance and effectiveness, how can respect for cultural diversity be realised in generalised ICT products and services?
- In order to treat people with dignity, how can e-inclusion initiatives cater for changing requirements and preferences as people get older?
- Regarding e-inclusions what is special about informed consent for people with disabilities?
- What is important about an individual’s autonomy and dignity when planning e-inclusion initiatives?”

A comprehensive review of the ethical issues related to research and practice of smart assistive technology for frail and disabled elderly in Europe is provided by the CARE Project in its Report on Ethical Considerations of the Design and Implementation of CARE (17). The Report investigates the technology related ethical aspects, EU legislation background regarding ethical issues, overviews the European organizations acting in the field of ethics and provides ethical guidelines for research and deployment phases related to the CARE

project. The ethical framework has to deal with rules to be applied in order to act right: consequentialism (the action that is likely to provide more benefits is the right one), Kantian ethics, autonomy, beneficence (non-maleficence), justice, distributive ethics, affordability, age-friendly design and the ethical approach of intergenerational solidarity.

CARE project Report also signals the importance of the opinion of The European Group on Ethics in Science and New Technologies' on Ethical Issues of Healthcare in the Information Society (1999, Opinion 13) and its content: "the pervasiveness of a technology that many people do not understand; the lack of transparency that may be brought to the work of healthcare professionals and its effects on the doctor/patient relationship; the difficulty in respecting privacy and confidentiality when third parties may have a strong interest in getting access to electronically recorded and stored personal health data; the difficulty in ensuring the security of shared personal health data; the lack of adequate infrastructure in certain regions and the absence of computer literacy in certain sections of the population, which may reinforce existing inequalities". Contextual dimensions such as culture, TIC literacy degree, adaptability to certain types and components of technology are equally connected to the important ethical principle of beneficence (non-maleficence). In the CARE Project, the elaborated user needs and requirements interview and questionnaire for end-users, caretakers and other stakeholders were reviewed and approved by The Budapest University of Technology and by the Economics Behavioural and Biomedical Institutional Review Board. (17)

European and international laws, rules and regulations

Various European and international laws, rules and regulations on human rights are able to provide important guides for smart assistive technology development.

Human rights (civil, political, cultural, economic, the right to liberty and free expression, equality before the law), are the obligatory background of frail and disabled people care and their assistance by means of smart technology. The Universal Declaration of Human Rights adopted by the general Assembly of the United Nations in 1948 and The European Union Charter of Fundamental Rights, adopted in 2000, are fundamental guiding marks in this respect. Their provisions related to the right of elderly to dignity, independence, privacy, non-discrimination (insertion in the social and cultural life, access to medical preventive, treatment, and recovery care) personal (data) protection, are especially tangent to the development of smart assistive technology (17, 18, 19).

The European Convention on Human Rights and Biomedicine (20) also contains provisions important for the research and practical aspects of AAL applications development such as primacy of the human being (of its interest and welfare that must prevail over the sole interest of society or science) (Article 2), equitable access to health care of appropriate quality and the concern for specific measure to be taken (Article 3), and the issue of professional standards (Article 4). Chapter III of the Convention refers to the private life right and right to information.

The EU Directive on Clinical Trials (2001) requires Member States to elaborate a system of ethical provisions and the implementation of good clinical practice in the conduct of research (clinical trials) that involves human subjects (21). The Directive does not apply to non-interventional trials (clinical development program of new pharmaceutics) (22), but in the Article 1 states that "good clinical practice is a set of internationally recognized ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects

are protected, and that the results of the clinical trials are credible. The principles of good clinical practice and detailed guidelines in line with those principles shall be adopted and, if necessary, revised to take account of technical and scientific progress in accordance with the procedure referred to in Article 21 (2)."

Several European documents are addressing the issue of the protection of individuals and the handling of their personal data, an issue closely related to the research and implementation in the field of smart assistive technologies for seniors. The Directive of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Directive 95/46/EC) (23) regulates the above issues within the EU as component of EU privacy and human rights law. On 25.01.2012, the European Commission launched the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (24). The European Data Protection Supervisor (EDPS), an independent supervisory authority, has the mission to stand over the keeping of privacy and data protection by the European institutions when they handle and process personal data and develop new policies, in accordance with the REGULATION (EC) No 45/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (25).

In the context of actual ICT progress ethical and legal regulations are seriously challenging. "Rapid technological developments have brought new challenges for the protection of personal data" whose "sharing and collecting has increased dramatically. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities." (24) Compulsory rules are elaborated in accordance with the main principles related to transparency, the right of the person to be informed that a category of its personal data are under processing and the purpose of processing, to be informed about the recipients of the data. The rules also state the person's right to access all his data under processing, the right to demand for the rectification, blocking or deletion of incomplete, inaccurate data related to her/him. The building of trust in the online environment is the key element or, in absence, a serious barrier for smart assistive applications. The mandatory ethical and legal criteria of data processing include person's consent about his/her data processing. The provisions concern the purpose of data processing and the obligations of data processors: e.g. the data have to be processed in the interest of their owner, for accomplishing a task of public interest or for the fulfilment of a contract etc. (23). The data must be processed in an adequate and not extensive way, and will not be further processed beyond the initially specified, explicit and legitimate purposes. The modality of data keeping must permit the identification of their owner only on the period necessary to accomplish the purpose for which they are collected. For longer periods, justified by statistical or scientific reasons, additional safeguarding means must be brought. A special attention must be paid to the sensitive personal data of racial, political, philosophical religious or other order.

Equal opportunity, no discrimination and universal accessibility of people with disabilities are overviewed by Szajbely K et al. in 2007 (26). Among the measures authored by Article 13 of Treaty of Amsterdam there are several dealing with the non-discrimination by religion, age, disability, sexual orientation etc., and equal access to goods and services.

The Decision No. 771/2006/ of the European Parliament and of the Council (2006) established the European Year of Equal Opportunities for All 2007, “towards a just society”. (27)

The European Network of Equality Bodies (EQUINET) has the mission of supporting the uniform implementation of EU anti-discrimination law and protection for victims of discrimination.

3.2 Ethical aspects regarding advanced technology for old or frail people in Austria

In the following, the Austrian approach for the development and testing of Confidence regarding ethical aspects is presented.

If applicable, in Austria following directives and laws have to be considered:

- Medizinproduktegesetz– MPG
- Datenschutzgesetz 2000 - DSG 2000
- Declaration of Helsinki

Additionally, the Austrian ethics check list (50) has to be considered.

In Austria the first step regarding ethical and legal aspects in the development of assistive technologies is the clarification whether the technology will be marketed as medical device or not. This is the case if the device will be used for therapeutic or diagnostic purposes. In Austria the “Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH“ short AGES is the contact point for this clarification process. No matter whether AGES has classified the AAL solution as medical device or not the appropriate ethics commission has to be contacted in order to explain whether they declare themselves responsible for the project or not. For this purpose an application for assessment of the project (available at http://www.ethikkommissionen.at/) and the informed consent has to be brought in. The informed consent should at least include the following elements:

- Full name of the project
- Purpose of the project/trial
- Trial procedure
- Benefit of participation
- Possible risks
- Impact on daily life and obligations
- Premature termination of the trial
- Data processing
- Costs and compensation
- Contact person for further questions
- Consent

In parallel, the application has to be registered at the “Datenverarbeitungsregister” were you receive a “Datenverarbeitungsnummer – DVR” for the project.

3.3 Ethical aspects regarding advanced technology for old or frail people in Romania

Bioethics has become a discipline of applied ethics since the early 70s, when medical practices were beginning to inquire a morality approach. Soon a method able to provide solutions for the moral problems became imperative, as well as some methods by which the moral choices of medical staff can be evaluated. C. Maximilian, one of the pioneers of the modern bioethics in Romania, gave it a definition that was as concise as memorable: bioethics is a meeting point of all those who seek the human destiny under science's pressure.
The first bioethics committee of Romania was founded in 1990 and is a national ethics committee of the Ministry of Health. In 2005, in the context of accession to the European Union, the requirement of an ethics committee in each public institution such as hospitals, schools or universities appeared.
Taking into account the 4 principles of bioethics:

- to do what is best for the health and welfare of people,
- not to hurt, that is to avoid or prevent consecutive diseases or insufficiently scientifically sustained or clinically tested therapies;
- respecting the patient's autonomy, cultivation of the personal free will, protection of the patients with restricted individual autonomy, and finally,
- promote the legal principle related to the more balanced distribution of benefits and disadvantages,

in practice we face many problems related to disease type and stage of memory (easy / moderate / severe) in which the patient can be classified.
Given the complexity of the problems of bioethics especially raised by memory impairments, principles and guidelines to help resolve the ethical dilemmas in this field have been developed, considering at the same time that each patient represents a particular situation and the decisions related to him/her should be individual.

The existence of appropriate structures for developing and monitoring ethics standards in the medico-social assistance of cognitively impaired people is equally important. The National Committee on bioethics of the Ministry of Health of Romania was founded in 1990 and a Committee on Bioethics near the Academy of Medical Sciences of Romania was subsequently founded (33). The first local ethics committee was created only in 1999, through the Emergency Ordinance 152/1999 on medicinal products for human use. (L no. 336 M.Of. published in no. 418 dated: 06/17/2002, OU and no. 152 M.Of. published in no. 508 dated: 10/20/99).]

The Ministry of Health and the National Agency of Medicines have developed "rules of good practice in the clinical studies", provided in accordance with the recommendations of the Management Committee of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH).

It is important for the medico-social act for the patients with memory disorders, but not only, that the following of the ethical aspects and developing principles, standards and profile guidelines must take into account the identification of ethical issues specific to this field, the frequency of their occurrence, and how they are reflected in practice (34).

The medical practice based on ethics involves knowing how the specific of the medical discipline, the requirements for the medical staff and social assistance influence on its ethical attitude, on the establishment of structures entitled to judge the deviations and developing effective corrective measures.

A topic lesser discussed is that of the old legal principle "audiatur et altera pars", namely, what should be the ethical attitude of the patient, especially if the patient is more or less

cognitively impaired, which would be his/her expectations and options and which would be their socio-cultural and historical basis?

An important aspect is that of cooperation with other professionals, especially in the legal field and that of cooperation with the government's decision organisms and representatives of civil society in order to develop and promote standards of ethics and professional deontology strongly rooted in reality and disseminated through mass media and education, including through mass education.

The two lows below were adopted by the Romanian Parliament as implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data:

- Law no. 677/2001 of 21st of November 2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data (published in the Official Journal of Romania, Part I No. 790 (35).
- Law no. 102/2005 regarding the setting up, organisation and functioning of the National Supervisory Authority for Personal Data Processing (36).

The National Supervisory Authority for Personal Data Processing has its headquarters in Bucharest and is set up as a public authority, autonomous and independent in relation with any other public authority, natural or legal person, with legal personality, exercising its attributions according to the present law, as well as to the special laws regulating the activity of personal data processing and the free movement of the data. It aims at protecting the fundamental human rights and liberties of the natural persons, in particular the right to private and family life, with regard to personal data processing and free movement of these data. The National Supervisory Authority's powers and duties are set up by Law no. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data (36).
The legislation related to old people protection and care in Romania also includes the Law Nr. 17/06.03.2000 – Social care of old people (Legea nr 17/06.03.2000 – Asistentasociala a persoanelorvarstnice (37), and the Ordinance 246/27.03.2006 – Approval of minimal specific quality standards for old people (Aprobareastadardelor de calitateminimespecificepersoanelorvarstnice.
The activity of the Romanian Authority for Disabled Persons is legally based on the Law Nr. 448 /2006 – the promotion and protection of the rights of disabled persons (38).

3.4 Ethical aspects regarding advanced technology for old or frail people in Switzerland

In the following, the Swiss approach for the development and testing of the Confidence-device regarding ethical aspects is presented.
In Switzerland, the following laws and directives have to be taken in account if personal (medical) data are recorded during field tests:

Art. 13 der Bundesverfassung

(that says that "everyone has the right that his private and family-life, his home, his mail and his telecommunication have to be respected. Everyone is entitled to protection against misuse of his personal data.)

Bundesgesetz über den Datenschutz (Stand 1. Jan. 2014, esp. Art 3c, 2)
Verordnung zum Bundesgesetz über den Datenschutz

Regarding field tests with probands the „Bundesgesetz über die Forschung am Menschen“ (Humanforschungsgesetz, HFG)has to be considered.

In Switzerland the „Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter“ in Bern is responsible for all questions of data security. It has to be clarified if especially sensitive (medical) data of identifiable testing persons (probands) will be sent to third persons. If this is the case, the kantonal or the eidgenössische Ethikkommission has to be informed or must be asked for its statement. In Switzerland, the second field tests shall be held in different Kantonen, i.e. Thurgau, Luzern and (perhaps) Solothurn. The president of the kantonal ethic commission in the Kanton Thurgau, Dr. Rainer Andermatten, has been contacted and expressed the opinion that this commission must not consent in the tests. Employees of the „Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter“ guessed that the commissions should be informed nevertheless.
Every proband in Switzerland has to sign a letter of informed consent. The wording of this letter has been arranged with the then president of the kantonal ethic commission in the Kanton Luzern, Prof. Dr. Gregor Schubiger, before the Swiss partners of Confidence started with the first field tests. A new phrase will beaded according to the advise of an employee of the “Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter“ (Mr. Siedler): “Es können besonders schützenswerte Daten weitergegeben warden an das iHomeLab der Hochschule Luzern.” Thus probands have the possibility to reflect on whom they entrust their data before they take part.

4. Ethical aspects related to people with dementia

The psychological impact, the social and legal implications of stigma to the patient, may result in the isolation of the patient and the partial injury to his interests, contrary to the bioethics principles. The recommendations related to diagnostic disclosure include patient and his/her family’ information and patient’s option whether he/she wants to know the results of the medical tests and their significance, or not. The bioethical dilemmas are different depending on the social, cultural and religious origin of the patient (for example, there are societies where a sick man cannot be cared by a woman, or societies where the help from outside the family is not accepted, or societies that don’t allow certain types of therapy). Even if the informed consent and other ethical issues do not raise special challenges in people with MCI, the practical application of ethical related principles (e.g. obtaining informed consent, use of assistive technology etc.) and the impact on individuals in terms of respect for personhood, autonomy and dignity, are under debate.

Given the complexity of the problems of bioethics raised by the cognitive impairments, principles and guidelines for solving the ethical dilemmas were developed, considering at the same time that each patient represents a particular situation and the decisions related to him/her should be individual. The existence of appropriate structures for developing and monitoring ethical standards in the medico-social assistance of the cognitive diseases is equally important.

Alzheimer Europe and its member organisations are committed to promoting the autonomy and self-determination of people with dementia. “The disclosure of the diagnosis to people with dementia is of paramount importance for people with dementia to take an active part in decisions affecting their lives” (39).

Alzheimer associations provide a range of services. A survey of Alzheimer Europe proved that in 24 from 26 involved countries the Alzheimer associations provided support groups for people with dementia and their carers. Training programmes for carers were performed in 23 countries, helplines were present in 23 countries, day care in 14 countries and home care in 11 countries (40).

Alzheimer Europe emphasized its position and guidelines on the ethical use of assistive technology by people with dementia. The association also proposed an ethical framework for decision making (41). Various ethical principles can be found in national laws and several European and international conventions (the European Convention on Human Rights and the European Convention on Human Rights and Biomedicine, the United National Universal Declaration of Human Rights). The relevant principles of using assistive technologies are non-discrimination, self-determination, privacy and dignity, beneficence and autonomy, data protection. The Convention on Human Rights and Biomedicine details the issue of consent in the case of people lacking capacity.

Bio- and ambient sensors may be of great help by allowing carers to rest or sleep or accomplish other activities, at the same time ensuring patient's safety and facilitating assistance to a larger number of people in residential care facilities for example.

Movement sensors can remotely signal that the person remained unusually immobile for a long time, e.g. because of a fall, or may allow the control which could in some cases be an indication of a fall or problem. However, movement detectors may abuse person's privacy, but this depends on the type of used equipment: temporarily used "just checking" devices may gain on the matter.

In home video surveillance (CCTV) may be considered as privacy invasive and against person's dignity, and a form of restraint in the vision of The Royal College of Nursing and the Mental Welfare Commission for Scotland (41). It is necessary to carefully choose who should have access to video recordings and the most convenient form of recordings storage. Another important issue is the use of video-assistive technology on a personal basis. Less intrusive use of this technology may provide important protection with respect to falls for example. Patient's consent is mandatory. Electronic video equipment may be useful for identifying intruders and for abuse prevention and reduction. The possibility of switching off the camera may substantially amend the aggression of privacy.

Tracking and tagging devices suppose the wearing of a special device combined with a device which alerts the carer may improve the safe mobility of cognitively impaired people and minimize their dependence. "Geo-fencing" allows the adaptation of tracking technology to the particular cognitive state of the individual. The problem is complex and still under debate. Tracking technology balances between safety/security and autonomy and liberty. The positive view on tracking is equally present, not only for the caregivers but even for patients (45).

Another problem related to the use of smart assistive technologies meets the notion of stigmatization, frequently present in people with disturbed cognitive functioning. The use of such smart application may raise the feeling of shame. Even having an electronic device on one's person can generate stigma. The ethical framework for making decisions related to the use of smart assistive technology is actually one of the main concerns of Alzheimer Europe organization.

5. Ethical aspects in the Confidence project

This section describes the ethical aspects required by Confidence project implementation, established in accordance with the specific national and international rules, recommendations and procedures. Finally, the Confidence Pilots Ethical Manual, elaborated as the specific practical guide to be used by the three project's pilots for managing ethical approach during the fulfilment of their tasks, is attached as Annex 1.

5.1 Short description of the trials conducted in the Confidence project

The Confidence consortium comprises three end-user organizations (pilots) in three countries (Austria, Switzerland and Romania), which are responsible for testing the Confidence system. In chronological order, the following activities define the main phases of Confidence prototype evaluation during the project running:

- Local kick-off meeting in each of the three pilots, with representatives of the project's target group (dementia patients and caregivers), as well as various stakeholders dealing with the long-term care of old people with special needs, for discussing project's aims, its envisaged impact, the role of voluntary end-users and stakeholders to be involved and the relevant ethical issues.
- Target group and investigators recruitment (SEUs-PEUs pairs, assistants), based on the previously established inclusion-exclusion criteria and the recruitment protocol
- Acceptance Tests (1st Acceptance Test, 2nd Acceptance Test), accomplished with SEUs-PEUs pairs and assistants based on a unique testing protocol throughout the three pilots, for collecting their feedback about usability and usefulness of the Confidence services in their mock-up version. The obtained results are used for improving the prototype design to its next, fully functional version.
- The First Field Trial – for testing the first fully functional version of the prototype with the end-users in real settings (at home), based on a unique testing protocol throughout the three pilots, for collecting their feedback about usability and usefulness of the Confidence services in their first design version.
- The Second (Beta) Field Trial – for testing the second fully functional version of the prototype with the end-users in real settings (at their home), based on a unique testing protocol throughout the three pilots, for collecting their feedback about usability, usefulness and effectiveness of the Confidence services in their final design version.

The 1st Acceptance Test, which took place in Switzerland and Austria, was accomplished with 10 primary and 10 secondary end-users. The 2nd Acceptance Test included 18 primary and 14 secondary end-users, as well. The tests took place in Switzerland, Austria and Romania.

The first field trial was accomplished with 20-25 PEUs and 10 SEUs in each test region from urban and respective rural areas (Switzerland, Romania urban, Romania rural, Austria urban and Austria rural),, which used the Confidence services at their home for about 40 days, under the supervision of 10 assistants and their mentor. The obtained results about interfaces and services' usability and usefulness of the Confidence "Assistant" and "Webportal" components were collected, analysed and reported, and provided valuable information for prototype improvement toward its final version.

The second trial will evaluate the final version of Confidence prototype ("Assistant" and "Webportal"), also in real settings (end-users' home), for at least 42 consecutive days.[48] The main results of this beta trial will be the validation of the prototype developed during the project running, and the collection of some information related to its exploitation (preferences for the various services provided, interest of buying them, affordability etc.).
Either be the testing phase the testing protocol includes several key steps of working with the end-users: presentation of project's progress, actual testing goals and end-users roles, protocol running and how to use its working documents (questionnaires, diary etc.). At the beginning of each testing session, the end-users have to sign an Informed Consent form.

5.2 The informed consent and self-determination in the Confidence project

In order to unify criteria in living lab test the minimum features to take into account in the creation of consent forms are listed below:

- The information on must be written as simple as possible in order to be widely understandable.
- In some cases, the research might involve users with serious disabilities. In this case assent from guardian or tutor is mandatory.
- There should be at least two signed copies, one for the main researcher and other for the user.
- An explanation of the research accounting the institutions involved, purpose, procedures must be included explicitly.
- The opportunity to withdraw from the study without any consequence has to appear on the consent. This is crucial for user organizations where there is any kind of membership since it must be clear for users that the withdrawal from the project does not affect their membership or service given by the organization.
- The consent form must contain the affirmation that he/she is allowed to ask any question involving the project.
- A section on confidentiality of data and availability is only for investigative purpose. Reference to the national or European law on the subject should be made. This states that the research meets the legal requirements concerning data protection.
- This data can be rectified at any moment by the user.
- The name of the researcher and his/her contact must be written on the form as an ultimate responsible person for inquiries.
- Each specific Consent form applied at each of the different site locations complies with the above mentioned requirements so that a common approach is generated across the sites. A copy of each of the consent forms provided together with a transcription in English at the end of this document.

5.3 Ethical issues within the Austrian Pilot

5.3.1 Personal data protection

Data collection and processing is carried out according to the Austrian data protection law (DSG 2000). During the field trial period following data are collected:

- Name
- Address

- Phone number,
- Movement data (GPS, accelerometer data)

At the end of the field trial name, address and phone number will be anonym. Movement data recorded during the trial will exclusively been used for research purposes. According to Austrian law, it is possible to revoke the consent for data processing at any time.

5.3.2 Security of networks and services, confidentiality of communication

Confidence data are hosted at the RAIKA Rechenzentrum in Klagenfurt. Details on data security, network and service security can be found in the Confidence deliverable D 3.3 – Security Concept.

5.3.3 Management of possible user's complaints and withdrawal request

User complaints and withdrawal requests are managed by the Austrian end user partner Hilfswerk by the Confidence assistants and the Confidence mentor. In Austria each user has the right to quit the trial at any time without stating reasons. In the informed consent it was clarified that the rejection of participation or early withdrawal has no adverse consequences for the continued support by the Hilfswerk Salzburg.

5.3.4 Ethical control instruments in Austria

Confidence has been submitted to the ethics commission in Salzburg which declared that they are not responsible due to the fact that Confidence is no medical device. Nevertheless they gave valuable feedback for the formulation of the informed consent and the trial execution. The Austrian Confidence team stays in contact with the ethics commission and the "Patientenanwaltschaft" represented by Mag. Thomas Russegger.

5.4 Ethical issues within the Romanian Pilot

The field trials with voluntary end-users in Romania will take into account the aforementioned national legislation and local regulations. In every project that supposes the involvement of human subjects, the facility of AAIF - **The Centre for the Diagnosis and Treatment of Memory Impairment Diseases and Medical Rehabilitation,** which hosts the Confidence Romanian Pilot, performs the recruitment of old voluntary end-users based on previously established inclusion-exclusion criteria. Within the Romanian Pilot the end users will remain as much as possible the same along the entire duration of the project. If a new end-user recruiting becomes necessary for replacing someone who withdrew his/her participation, then the entire procedure of end-users recruitment, including Consent Form and the other ethical matters is performed. The contact details of the principal investigator and president of the AAIF's Ethics Commission – Prof. Luiza Spiru MD, PhD, able to solve the possibly issued ethical matters, are provided to each voluntary end-user. Each investigator is trained about the legal and ethical rules to be pursued during the work sessions with the end-users. All the ethical aspects related to the activity of the Romanian Confidence Pilot are supervised by the National Ethics Commission, which works under the aegis of the Romanian College of Doctors.

5.4.1 Personal data protection in Romania

"Publicly available electronic communications services over the Internet open new possibilities for users but also new risks for their personal data and privacy. In the case of public communications networks, specific legal, regulatory and technical provisions should be made in order to protect fundamental rights and freedoms of natural persons and legitimate interests of legal persons, in particular with regard to the increasing capacity for automated storage and processing of data relating to subscribers and users", specifies the Directive 2002/58/EC (44).
In accordance with this Directive the Confidence smart application to be created will take the most appropriate technical and organizational measures for safeguarding the security of its services, if necessary in conjunction with a provider of a public communications network.

In Romania, all the organizations involved in research are under the jurisdiction of National Authority for the Supervision of Personal Data Processing (Annex 1), and the legal framework is represented by:

- Law no. 226/2009 on the organization and functioning of the official statistics in Romania
- Law no. 677/2001 on the protection of persons regarding the processing of personal data and on the free movement of such data
- Law no. 682/2001 on the ratification of the Convention for the Protection Individuals related to Automatic Processing of personal data, adopted in Strasbourg on 28.01.1981, as amended subsequent
- Confidentiality rules of statistical data- National Statistics Institute.[42]

5.4.2 Security of networks and services, confidentiality of communication in Romania

The project will take appropriate measures to safeguard the security of their services in conjunction with the network provider. Specific risks may especially occur for electronic communications services over an open network such as the Internet or analogue mobile telephony. Informing users of any risks of a breach of network security is mandatory. It is particularly important for users of such services to be fully and free of charge informed by their service provider about the existing security risks which lie outside the scope of possible remedies by the service provider, except for any nominal cost that subscriber may face while getting the information (e.g. by downloading an electronic mail message). Especially the Article 17 of Directive 95/46/EC rely on this issue. Informing users on particular security risks does not exempt service provider from the obligation to take immediate measures to remedy at its own costs.
Measures in the project will be adopted dealing with:
prohibiting listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic data by persons other than users, without the consent of the users concerned, except when legally authorized to do so in accordance with Article 15(1) of the Directive 95/46/EC.
not preventing technical storage which necessary for the conveyance of a communication without prejudice for the principle of confidentiality

Processing of traffic and location data

In the project the systems for the providing electronic communications and services will be designed to limit the amount of necessary personal data to a strict minimum. The Paragraph

14 of Directive 95/46/EC specify that location data may refer to the latitude, longitude and altitude of the user's terminal equipment, to the direction of travel, to the level of accuracy of the location information, to the identification of the network cell in which the terminal equipment is located at a certain point in time and to the time the location information was recorded. The Paragraph 35 points out that “in digital mobile networks, location data giving the geographic position of the terminal equipment of the mobile user are processed to enable the transmission of communications. Such data are traffic data covered by Article 6 of this Directive. However, in addition, digital mobile networks may have the capacity to process location data which are more precise than is necessary for the transmission of communications and which are used for the provision of value added services such as services providing individualised traffic information and guidance.” The paragraph specifies that, “processing of such data for value added services should only be allowed where users have given their consent. Even then, they should have a simple means to temporarily deny the processing of location data”. Such data may only be stored to the extent that is necessary for the provision of the service, after which traffic data should be erased. For instance, for a voice telephony call the transmission will be completed as soon as either of the users terminates the connection.
Where the provision of a value added service requires that traffic or location data are forwarded from an electronic communications service provider to a provider of value added services, the subscribers or users to whom the data are related should also be fully informed of this forwarding before giving their consent for the processing of the data. (paragraph 32)

5.4.3 Management of possible user’s complaints and withdrawal request

As specified including in the Informed Consent procedure, the end-user volunteer is entirely free to withdraw the study at any time, at its convenience and with no penalty. However, he is informed that the explanation of withdraw is important for the investigators and the study, so is up to the end-user volunteer to provide it at his/her convenience.
The possible complaints of the end user will be addressed to the principal investigator of AAIF – Prof. Luiza Spiru, which has the task to solve them and specify these situations in the study report.
The researchers involved in the preparation of evaluation trials and end-user feedback collection and analysis within each pilot site have the obligation to comply with the ethical and legal framework detailed in this D2.4 document, even after the cessation of the activity in the respective organization.[42]

5.4.4 Ethical control instruments in Romania

Ethical issues will be managed according to the ethical statements in the DoW and CA. In each country the trial executing organisations are responsible for further management of country-specific ethical issues.

The Pilot’s ethical team

In Romania the AAIF ethical committee will supervise all the activities with the end-users during the field trials, i.e. the accomplishment of the ethical requirements comprised in the Pilot’s Ethical Manual. The team will also manage the possible “exit related ethical issues” from part of the voluntary users already acquainted with the prototype during its testing and

validation. The Ethical Committee of Ana Aslan International Foundation is coordinated by Prof. Luiza Spiru MD, PhD. The National Ethical Commission of the Romanian College of Doctors, coordinated by Prof. Valentin Astarastoae, MD, PhD, will supervise the activity of AAIF ethical committee.
Related to the management of personal data processing, the AAIF has the supervision of the National Authority for the Supervision of Personal Data Processing.

5.5 Ethical issues within the Swiss Pilot

5.5.1 Personal data protection in Switzerland

Data collection and processing is carried out according to the Swiss data protection law (Bundesgesetz über den Datenschutz (Stand 1. Jan. 2014, esp. Art 3c, 2)). During the field trial period following data are collected:

- Name
- Address
- Age
- Phone number
- Movement data (GPS, accelerometer data)

At the end of the field trial name, address and phone number will be anonymized. Movement data recorded in Switzerland (see above) during the trial will exclusively been used for research purposes.

5.5.2 Security of networks and services, confidentiality of communication

Confidence data are hosted at the RAIKA Rechenzentrum in Klagenfurt. Details on data security, network and service security can be found in the Confidence deliverable D 3.3 – Security Concept.

5.5.3 Management of possible users' complaints and withdrawal request

User complaints and withdrawal requests were managed by the responsible person from terzStiftung, who administered the Confidence test. In Switzerland, each user had the right to quit the trial at any time without stating reasons. In the informed consent it was clarified that the rejection of participation or early withdrawal has no adverse consequences.

5.5.4 Ethical control instruments in Switzerland

The president of the ethic commission in the Kanton Thurgau, Dr. Rainer Andermatten, has been contacted and expressed the opinion that this commission must not consent in the tests. Nearly all probands were instructed and live in the Kanton of Thurgau. The Confidence-device is not seen as a medical instrument in Switzerland. In addition, there has been contact to the office of the responsible person for data security in entire Switzerland,

the „Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter“ (see above, chapter 3.4). From there, we received feedback how to formulate the „informed consent“.

6. Consumer protection and product safety (Electro Magnetic Compatibility issues)

The electromagnetic compatibility issues in the Confidence project do not exceed those, otherwise still under debate, related to the effects of prolonged use of mobile phones. Mobile phone functioning does not interfere with cardiac pacemaker devices.

7. The Exit strategy

A special attention will be paid to the exit strategy.

According to the DoW (page 8), it is planned that the participating professional care organisations (Hilfswerk Salzburg, TerzStiftung, Ana Aslan International Foundation) will offer CONFIDENCE as an operational services beyond the life time of the project. However, if these organisations decide that they cannot maintain the service over a longer time period, it may be possible for end users (persons with the dementia, their family carers and trusted volunteers) to still use the community portal to provide assistance in a self-organised manner as long as the community portal will be hosted by RAIKA. Yet, we need to keep in mind that CONFIDENCE is a research project, which means that there is always a certain risk involved, that the idea fails (due to various reasons; see contingency planning 2.6). Therefore, at the beginning of the project we informed the participants who volunteer to test and validate the service that, after the project ends, it may be possible that they face some discomfort because of service discontinuation.

A special set of measures will be applied in order to manage the possible discomfort experienced by the end-user when s/he must give up the devices s/he already learned to use and the useful services provided by the Confidence app. This set of measures will include:

Clear information about the role, of the end-user, i.e. the expectations for him as voluntary contributor to the accomplishment of Confidence project goals, phases and activities. During the project running, this task was accomplished in the introductory presentation of each field trial with the end-users, but it will be especially envisaged in this 2nd trial phase when the end user will work during three weeks at their own homes with the fully functional services provided by the prototype.

During initial training session after the installation of the app at the older person’s home s/he will be informed about the measures that project’s team adopted for minimizing the possible discomfort experienced by him when giving up the equipment and stopping to receive the smart services:

The possibility to withdraw his/her participation at any time during the trial phase with any repercussion,

The possibility to solve any unwanted situation or complaint by calling or e-mailing the principal investigator of the pilot site, whose contact details will be entrusted to him/her during the initial training session after the installation of the app.

A closing seminar will be arranged at the end of the project at each pilot site, with the end-users involved in the project and their relatives, in which they will gain recognition of participant to the multidisciplinary and multinational Confidence project, able to be further involved as experienced voluntary end-user in a new projects envisaging the creation of smart applications for seniors.

8. Conclusions

Confidence project deals with a vanguard research area in dementia care – to develop that segment of care which lies on advanced technology apps, complementary to the so called "human assistance" provided by the medical and social professionals, and able to significantly reduce the costs of care.

While developing the Confidence platform in a permanent, close connection with a group of voluntary end users for a true user-centred design, the researchers gave a sustained attention to both national (i.e. pilot country's) and international ethical and legal issues in force (Chapter 3 of this document).

A special concern was that of implementing the ethical aspects related to the solutions adopted in the project in accordance with the requirements and recommendations comprised by Annex 3 of "Guidelines for ethical considerations in the projects cofounded by the Ambient Assisted Living Joint Programme":

- in each trial the researchers watched the issues related to the unfamiliarity of the involved end users with the advanced technology solutions used by the Confidence app., and managed them especially through training the investigators on how to conduct the trial for helping the end-users to cope with this issue, but without directly intervening in the accomplishment of a task by the end-user;
- to mention the end-users that the objective is to test the platform, not them and their capability, was found to be important for their proactive participation;
- the trustiness, accessibility and acceptance by the end-users of the solutions adopted by the Confidence platform have been also carefully watched during each of the trials.

The ethical and legal provisions related to voluntary end-users recruitment and involvement were also carefully considered, with maximum concern for the PEUs medical condition – dementia in its mild-to-moderate phase.
Regarding those PEUs, the compliance with the national and international ethical and legal provisions detailed in the Section 4 (Ethical aspects related to people with dementia) of this document, was also strictly pursued.
In this respect, the content of the main ethical instrument – the Informed Consent form – was carefully drafted and agreed inside the consortium, as well as discussed with each PEU previously to his signature. There was any case in which a PEU's relative or a carer had to sign the Informed Consent form, because the mild-to-moderate stage of dementia doesn't involve mental changes able to impede the person to sign a document in full awareness.

Moreover, PEU's recruitment was realized in accordance with the inclusion/exclusion criteria (especially based on suitable scorings on cognitive assessment scales relevant for project's aims) established at the beginning of the project.
Also, the investigators directly acting in the trials were professionals currently working with dementia people and able to manage their stigma and self- confidence.

The researchers equally focused on the management of the end-users' cooperation withdraw, which generally was from objective personal reasons and not related to the platform or its testing protocols. The leaving end-users were replaced with other people of the same condition, involved according to the same recruitment protocol.

During the project's development, there were any complaints addressed by the voluntary cooperating EUs to the person designated in this respect by each of the three pilots' ethical committees.

The exit strategy aspects were managed according to the items and measures detailed in the Section 7 of this document. There were no exit strategy issues manifested by the voluntary end-users which cooperated during the project running.

The focus on ethical and legal aspects related to the close working with the end-users in the Confidence project also included their privacy, control of personal data, confidentiality, autonomy and dignity. Personal data management and the storage and transmission of personally identifiable information, were managed in accordance with the specific national laws connected to the European ones, and under the supervision of the pilot's local and national ethical control instruments. The main measure taken in this respect were the anonymization of sensitive personal data (including those of medical order), but also of the opinions and suggestions provided by the EUs as their feedback during the trials. These measures were mentioned and explained to the end-users in the Informed Consent form and are detailed in the sections 5.3, 5.4 and 5.5 of this document.

The electromagnetic compatibility issues in the Confidence project do not exceed those, otherwise still under debate, related to the effects of prolonged use of mobile phones. Mobile phone functioning does not interfere with cardiac pacemaker devices.

Related to the ethical control instruments, they were defined at the level of each end-users organization which hosted one of the three pilot sites (Austria, Romania and Switzerland) and were represented by their ethical committees, as well as by the national ethical and personal data protection authorities, as detailed in the sections 5.3, 5.4 and 5.5.

During the Confidence project running, no critical situations of ethical order were faced.

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