Ethical Manual

Ethical Manual

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Abbreviations

Abbrev.	Description
AAL	Ambient Assisted Living
PC	Personal Computer

Executive Summary

The Deliverable D2.1 is documenting the work on done in the task T2.1. Specifically the work done regarding the Ethical and Legal Issues, Informed Consent and data protection as well as the whole process and documents concerning the Ethical committee approval. Especially the Ethical committee approval was necessary in this project as patients are involved in the project. Furthermore the Ethical committee approval was necessary before involving any patients and therefore of a high priority. The document reflects all considerations in this process and provides the complete Ethical committee approval documents in the ANNEX.

1 About this Document

MEMENTO provides a solution to help people with dementia to live with a decline of memory. The project follows the International Organization for Standardization's (ISO) portfolio (ISO 9241 and 13407 in particular) and it is based on a centered design process where primary users (subjects with dementia) and secondary users (caregivers) will be regularly involved.
It is very important to ensure the protection of participants concerning security and privacy, as well as to ensure ethically correct procedures concerning written consent and rules of protection of personal data.

1.1 Role of the Deliverable

The Ethical Manual concerns ethical and professional conduct principles of the Memento project in order to protect participants concerning security and privacy.

1.2 Relationship to other Memento Deliverables

Table 1: Relationship to other Memento Deliverables

Deliverable	**Relation**
D2.2 – End-User Requirements	The Process of end user requirements analysis could only be started with an approved ethical committee. Furthermore it is necessary that the involvement of patients in all stages of the project follow the guidelines of this document.
D3.1 / D3.2 – Specification of hardware design and interfaces	The design of the hardware should consider the requirements and the specifications from the ethical committee protocols. Especially safety regulations need to be considered and to be taken care of also in the hardware development process.
D4.2 / D4.4 – Hardware Prototype	The hardware development needs to apply the ethical protocol specification in all stages when testing with the end users.
D5.2 / D5.4 – Software Prototype	The software development needs to apply the ethical protocol specification in all stages when testing with the end users

1.3 Structure of this Document

The document is structured as follows. Chapter 2 will introduce general ethical protocols finished in the project. The protocols which are considered as relevant for such a kind of project are introduced. Chapter 3 is describing the topic of data management and data security. It explains how this critical topics are addressed in the different trial countries. The ANNEX of the document contains all the complete ethical regulation protocols which have been submitted in Austria as well as in Italy. These documents have already been approved and the ethical committee has been successfully passed in Austria as well as in Vienna. The process in Spain is still open and therefore not presented in this document.

2 Importance and Relevance of the Ethical and Professional Conduct Principles

2.1 Ethical and Deontological Principles in General

Research involving human subjects should be carried out only by, or strictly supervised by, suitably qualified and experienced investigators and in accordance with a protocol that clearly states:

- the aim of the research
- the nature and degree of any known risks to the subjects
- the sources from which it is proposed to recruit subjects
- the means proposed for ensuring that subjects' consent will be adequately informed and voluntary

The protocol should be appraised by one or more suitably constituted review bodies, independent of the investigators. Since scientific review and ethical review cannot be clearly separated, ethical review committees consider both the scientific and the ethical aspects of proposed research.

In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed to be at liberty to abstain from participation in the study and to be free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
Informed consent is consent given by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.
Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

2.2 Ethical and Deontological Principles in Particular

The Medical University of Vienna (MUW), the University of Perugia (UNIPG) and the Bidaideak - Sociedad Vasca de Minusválidos (Bidaideak) consulted the local ethical committee in order to receive the approval to the study.
An Informed Consent was developed and translated into German, Italian and Spanish. All local ethical committees received the documents on the MEMENTO project together with the Informed Consent.
If the local ethical committee required more information or had specific questions, each center supplied the requested information. The process has been closed and successfully passed in Austria and Italy.

All the necessary legal and ethical authorizations will be provided (if not yet available and needed) to the CMU in due course, before starting the phase of the project concerned by the authorizations themselves. No trial will be performed without checking if approval by the ethical committee and data protection authorities of the respective countries is needed and if so these approvals are obtained. The pilot/field trials are for testing and validation purposes and will respect the following aspects:

- Subjects/patients will be informed volunteers;
- A formal informative consent will be prepared and signed by the subjects/patients;
- The re-examination of data is independent from the presence of the patient/subject;
- Data will be password protected to ensure privacy.

Because of the decentralized consortium building in the MEMENTO project it can be necessary that personal data will travel across borders inside the EU. As a result, data concerning the citizens of one member state are sometimes processed at other partners. Therefore, as personal data are collected and exchanged more frequently, regulations on data transfers become necessary and will be implemented and observed in the project. It is stated explicitly that data will be transferred from one partner to another within the consortium only after it was made anonymous. To the degree pilot/field trials are conducted, this will be done in accordance with the highest ethical standards from Europe and the countries where these tests are to be conducted. To ensure that the information is easy to understand, all written information that is given to subjects has to be proved by experts on “Easy to Read” guidelines. All collaboration with end-users will be based on an “Informed Consent Form” prepared before the project start.

Participants will get information in a way that is easy to understand. There has to be consent for all activities of each single participant to take part in the project. A cancellation of the participation is possible at any point and any time without giving a reason. There will be written information about the usage of all collected data.

3 The Data Collection, Monitoring, Storage and Security

3.1 Legal Considerations

The Data Protection Directive (officially Directive 95/46/EC on the protection of individuals with regard to the processing of personal data (PII (US)) and on the free movement of such data) is a European Union directive adopted in 1995 which regulates the processing of personal data within the European Union. It is an important component of EU privacy and human rights law.

On 25 January 2012, the European Commission (EC) announced it would attempt to unify data protection law across a unified European Union via proposed legislation called the "General Data Protection Regulation."

The General Data Protection Regulation (GDPR) will come into effect in the spring of 2018, replacing the Data Protection Directive 95/46/EC and imposing new obligations on organizations that process the personal data of European Union residents.

The GDPR forbids a controller from processing “special categories of data” – sensitive data revealing racial or ethnic origin, religious or political beliefs, as well as genetic, biometric, and health data – except in certain enumerated circumstances, such as where the data subject provides “explicit consent” or where the data that was “manifestly made public by the data subject” (Article 9(2)(a); Article 9(2)(e)).

Moreover, in addition to allowing researchers to process sensitive data where the data subject explicitly consents or makes her data public, the GDPR also permits a controller to process sensitive data for research purposes. In particular, Article 9(2)(j) allows a researcher to process sensitive data where “processing is necessary for [research] purposes in accordance with Article 89(1) based on Union or Member State law which

shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject." Thus, as clarified in Recital 52, research serves as a basis for processing sensitive data only "when provided by Union or Member State law and subject to suitable safeguards."

With a particular focus on public health research, this is treated as a subset of scientific research under the GDPR (see Recital 159), and, therefore, the same exemptions and requirements apply. However, the GDPR also contains several provisions applicable exclusively to public health research.

Recital 54 defines public health according to Regulation (EC) No. 1338/2008 as "all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality." Given this broad definition, the activities of social media and other online platforms may qualify as public health research.

In such a context, GDPR encourages the member states to enact greater protections for the processing of sensitive data for health-related purposes. Recital 53 states that, although the Regulation is intended to create "harmonized conditions for the processing of special categories of personal data concerning health, […] Union or member state law should provide for specific and suitable measures so as to protect the fundamental rights and the personal data of natural persons." This is particularly the case where the controller processes genetic, biometric, or health data.

Although the GDPR creates heightened obligations for entities that process personal data, it also creates new exemptions for research as part of its mandate to facilitate a Digital Single Market across the EU. Specifically, the GDPR exempts research from the principles of storage limitation and purpose limitation so as to allow researchers to further process personal data beyond the purposes for which they were first collected. Research may furnish a legitimate basis for processing without a data subject's consent. The Regulation also allows researchers to process sensitive data and, in limited circumstances, to transfer personal data to third countries that do not

provide an adequate level of protection. To benefit from these exemptions, researchers must implement appropriate safeguards, in keeping with recognized ethical standards, that lower the risks of research for the rights of individuals.

3.1.1 General Considerations

The collection, storage and sharing of information needs to comply with the established privacy legislation, confidentiality policies and de-identification processes. In particular, some principles must be respected:

1. *Ethics, privacy and security.* Information should be gathered ethically and ethical standards should be applied for the use of all data and information. Clear details on how information will be used must be provided to users during the consent process. Data holders must respect the rights of individuals to access their personal information.
2. *Fitness to purpose.* Data and information collected should be of a quality necessary to inform planning, decision-making and evaluation. Only data and information which is necessary and useful must be collected
3. *Efficiency and effectiveness*. The collection and storage of data and information should be time and cost efficient and planned and coordinated within the life cycle of a project. Where possible, data should be standardised, with consistent and common definitions to facilitate information sharing. Duplication and gaps in data collection and storage will be identified and addressed.
4. *Transparency and interpretability.* Data will be collected and stored with appropriate metadata to accurately define and describe it.

In order to comply with ethical aspects and general regulations, some best practices are identified in relation to the collection and storage of data as part of the research project.

I. Confidentiality and Anonymity

Confidentiality of personal data collected during any research project is essential and investigators should ensure that they only collect data which is necessary for the study. According to this consideration, all personal information will be encoded or anonymised as far as possible and consistent with the needs of the study. Participants/users should be assigned a reference number or code

as early as possible and data should be stored against this number/code rather than against the names of participants.

II. Storage of Primary (or Raw) Data

Clear rights and levels of access to the data should be specified at the outset of any research project and it is recommend to encrypt primary data. Data should be stored safely with appropriate backup and contingency plans in the event of loss, damage or unauthorised access to the data. As a consequence, data must be encrypted before storage. Wherever possible a complete duplicate set of the original data should be retained.

a. Data Archiving
   If any partner involved in the project intends to add any collected data to a data archive in compliance with funder policies, participants will be informed of this at the study's outset. Participants should be made aware of how the data will be anonymised, used and stored. Participants should also be made aware of the length of time the collected data will be stored, how they can withdraw their data and the timescales for this.

b. Interview Notes/Questionnaire Responses/Transcribed Interviews
   Wherever possible, interview notes/questionnaire responses/transcribed interviews should be stored in their original form or as scanned copies

c. Images/Audio & Video Recordings
   Images/Audio & Video Recordings should be retained in their original form. This is particularly important where they are subsequently enhanced

III. Recording Methods of Data Collection

Clear and accurate records of all procedures followed (including approvals granted and interim results) should be maintained during the research project. This is necessary to demonstrate that proper research practice has been followed, but also in case questions are subsequently raised about either the conduct of the investigator(s) or the results obtained.

IV. Withdrawal of data

All participants will be given the opportunity to request that their data be destroyed/withdrawn from the research project. In all cases, investigators should aim to comply with such a request

V. Obtaining Consent from Participants

Before agreeing to take part in the research study, participants must be provided with full information on:

- Who will own the data created in the course of the research.
- The format in which the data will be stored.
- Who will have access to the data.
- The length of time for which data will be stored.
- What the data will be used for.
- Who will own the final results of the research.
- Whether and where the data will be archived

Consent will be obtained from all participants and, wherever possible, copies of consent forms should be kept with the raw data, normally for the same period of time. Anonymized data should be stored separately from the coding details or codebook.

With particular attention to the MEMENTO project, all data from interviews, questionnaires and other methods that are gathered during the testing phase of the MEMENTO system will be saved in a big data storage. As a consequence of the identified best practices, all data will be analyzed anonymously. Only partners of the consortium have access to the anonymous data and will only use them for further development in this project. Personal data can be deleted during the study on explicit request of users.

According to data saved in MEMENTO infrastructure, a series of measures of security will be introduced to comply with current regulation.
In particular, the system administrator will be responsible for the maintenance of the server. She or he will also be responsible for managing users in the system. In addition, access to all data centers and server rooms used to host hardware and software on which personal data is stored will be restricted only to those staff members that have clearance to work there.

Passwords used to access PCs, applications, databases, etc. should be of sufficient strength to deter password cracking or guessing attacks. A password should include numbers, symbols, upper and lowercase letters.
Paper records and files containing personal data should be handled in such a way as to restrict access only to those persons with business reasons to access them.

In relation to the processing of personal data, a process of control and verification of the security of the information system is constantly underway through the use of specific tools at system level, database management and application level.

The whole infrastructure will be hosted on high-availability servers that offer a good resilience to situations of normal technical failures and with redundant disks make it possible to restore data availability in case of failure.

A series of organizational measure will be adopted to protect data and avoid the implementation of processing of personal data for purposes other than those authorized and permitted.

Measures introduced to protect network architectures, applications and databases (logical data protection criteria) include:

- measures to protect against unauthorized access to confidential information (User-id, password, screensaver with password);
- measures to protect against possible damage to information (antivirus);
- measures to protect against any loss of data availability (complete daily backup file server, mail server, application server etc.);
- the measures necessary to register the access log of system administrators.

According to publications, investigators should ensure that the published results of their research are anonymised, and that no information is published that would allow individuals to be identified. Research results can be published outside of the European Economic Area, on the internet or by other means, but if the results contain any personal data, the specific consent of the data subject must, wherever possible, be obtained.

3.1.2 Detailed analysis of legal and judicial Austrian framework

The study was submitted to the Ethics Committee of the Medical University of Vienna in accordance with the Austrian Medical Products Act.

In addition to completing a detailed online application form, the ethical committee required the following documents:

- Covering letter of the study promoter

- Comprehensive study protocol, including cognitive and quality of life parameters, inclusion criteria, information note for the protection of personal data and list of participating centers
- Investigator's declaration on conflict of interest
- Informed consent for the participants / Informed consent forms
- Authorization by the investigator including the professional curriculum
- Additional declaration by the promoter in the case of "no profit" studies
- Insurance documentation,
- Clinical diary and questionnaires

Ass. Prof. Priv. Doz. Dr. Elisabeth Stögmann acts as Austrian coordinator and investigator responsible for the Medical University of Vienna of the study "MEMENTO - A persuasive system supporting Memory and Moments of people with Early and Middle internships of dementia" funded by European Commission in the framework of the Active and Assistive Living (AAL) program and the Österreichische Forschungsförderungsgesellschaft (FFG).

The document reported that the study is codified as a proposal aal-call-2016-069 presented in 2016 at AAL and that is registered under number MI-29326.

The study protocol describes the general objective of the study, the centers involved and their function in the project. The MEMENTO team, consisting of interdisciplinary experts from different fields, was introduced:
Researchers in the medical field (the Medical Universiy of Vienna, the University Hospital in Perugia and the Bidaideak care facility in Spain) as well as in technology research (AIT Austrian Institute of Technology GmbH) and design experts (BKM Design Studio) work together to create a solution that is easy to use and meets the needs of the target audience. Further industrial and technical partners (VirtualWare, WeTouch, Integris Data Analytics & Cognitive Solutions of Rome and Citard Services) in the consortium are also focused on getting the developed solution to market.

The official EU wide project start was indicated to be May 2017, at the MUV June 2017. The duration of the project is given as 30 months.

Furthermore, the structured project schedule with work packages with direct involvement of the MUV was defined. This includes the number and the

planned involvement of patients, such as a description of intended interviews, workshops and system testing.

Some tools (tests, scales, questionnaires and calligraphy analysis) were annexed:

- Mini Mental State Examination (MMSE: Folstein, Folstein, & McHugh, 1975) - Screening test for the assessment of cognitive functions widely used in dementia research.
- Addenbrooke's Cognitive Examination Revised (ACE-R: Pigliautile et al., 2012) - Screening test of cognitive functioning that contains MMSE;
- Clinical Dementia Rating Scale (CDR: Hughes et al., 1982) - is a scale for the overall clinical classification of dementia severity
- Trail Making A and B (TMT A and B: Amodio et al., 2002) - is a test that assesses attention and executive functions
- World Health Organization Disability Assessment Schedule 2 (WHODAS 2.0) - It is a tool set up by the World Health Organization to evaluate self-perceived functioning independently of a medical diagnosis. It can be given to both the patient and a family member.
- SF-36 Health Survey (SF 36) - measure of quality of life;
- Activity of Daily Living and Instrumental Activities of Daily Living (ADL and IADL: Lawton and Brody 1969) - tools for the evaluation of functioning in the basic and instrumental activities of daily life, specific for patients with dementia and administrable to a family member.
- Questionnaires for patients, family members and medical staff.

Furthermore, in- and exclusion criteria were defined. The document states, that only consenting patients with mild dementia or a prior stage of dementia such as mild cognitive impairment are included in the study.

To ensure the privacy of the participants, only anonymized data will be passed on.
The personal data (raw data prior to anonymisation) is accessible only to the user himself and to selected developers who are subject to a non-disclosure agreement. In addition, personal media (photo, audio and video recordings) are evaluated as automated as possible. In order to ensure that only certain persons have access, a user management system is used in which roles or rights can be assigned. All data stored on the cloud, with the exception of the calendar, will not be shared with relatives. Also, the calendar is only shared with user-selected relatives who are involved in the Informed Consent. The data is stored up to a maximum of 6 months after the end of the project. The data is encrypted only from and to the cloud. A state of the art secure protocol is used (for example, TLS 1.2) Furthermore, the data is stored on the cloud service encrypted. Again, a state of the art secure algorithm (e.g., AES 256) is used.

The study will take place in full compliance with current Austrian legislation.

Regarding the Austrian Medical Products Act , the document states that the MEMENTO system in all its components and manifestations will be developed in the course of the project and that the planned clinical trial of the Memento system is not considered to be a medical device approval test, but is intended to provide further information as part of the development in terms of applicability, clinical utility and usability. The prototypes developed in the Memento project are developed, tested and labelled in accordance with MDD 93/42 / EEC Medical Device Directive 2007/47 / EC and meet the essential requirements. Harmonized standards will be applied where appropriate. The development is based on a certified quality management system according to ISO 13485: 2012.

3.1.3 Detailed analysis of legal and judicial Italian framework

For the Italian partners, the study was submitted to the “Comitato Etico delle Aziende Sanitarie dell’Umbria” (CEAS Umbria – Ethical Committee) as “Interventional studies other than pharmacological studies or medical devices”.

The Ethical Committee required the following documents:

- Transmission letter of the study promoter / CRO prepared according to an Annex model (Annex I1),
- Additional declaration by the promoter in the case of "no profit" studies (Annex I2),
- Possible delegation CRO,
- Request for authorization by the investigator including the professional curriculum (Annex I3),
- Investigator's declaration on conflict of interest (Annex I4),
- Synopsis of the study in Italian (Annex I5),
- Informed consent for the participants / Informed consent forms (Annex I6),
- Study protocol identified and drafted, according to relevance, according to D. M. 15/07/97 (Annex I 7)
- Information note for the protection of personal data (Annex I8),
- Insurance documentation (Annex I9),

- Data Collection, Clinical Diary, Patient Questionnaires, Cognitive Tests and Scales,
- List of participating centers,

All the paper material was accompanied by a copy in electronic format.

All documents must contain data and version number in force, in addition to the identification data of the study according to Ministerial Decree 21/12/2007 - All 2 - 6.1.2).

In the letter of transmission of the study, for the Italian part it was specified that Prof. Patrizia Mecocci is the Italian Coordinator and Investigator responsible for the center of Perugia of the study titled "MEMENTO - A persuasive system supporting Memory and Moments of people with Early and Middle internships of dementia" funded by European Commission in the framework of the Active and Assistive Living (AAL) program and the Ministero Istruzione Università e Ricerca (MIUR).

The document reported that the study is codified as a proposal aal-call-2016-069 presented in 2016 at AAL and that is registered under number MI-29326.

The partners and the aim of the study was described. In particular, it was stressed that MEMENTO is a European study involving collaboration between experts in the clinical field (Section of Gerontology and Geriatrics of the University of Perugia, the Medical University of Vienna, and the Bidaideak treatment center in Spain) and technological research (Integris Data Analytics & Cognitive Solutions of Rome and the Austrian Technological Institute) to provide market solutions with a high level of usability and designed on the needs of the patient suffering from dementia.
The document specified that the start (1/10/2017) and the end (October 2019) dates of the study and that each clinical center receives 15-20 patients to have a total number of 45-60 subjects.
It was declared that no instrumental or laboratory tests are scheduled while clinical tests and usability tests are planned.
Some tools (tests, scales, questionnaires and calligraphy analysis) were annexed:

- Mini Mental State Examination (MMSE: Folstein, Folstein, & McHugh, 1975) - Screening test for the assessment of cognitive functions widely used in dementia research.
- Addenbrooke's Cognitive Examination Revised (ACE-R: Pigliautile et al., 2012) - Screening test of cognitive functioning that contains MMSE;

- Clinical Dementia Rating Scale (CDR: Hughes et al., 1982) - is a scale for the overall clinical classification of dementia severity
- Trail Making A and B (TMT A and B: Amodio et al., 2002) - is a test that assesses attention and executive functions
- World Health Organization Disability Assessment Schedule 2 (WHODAS 2.0) - It is a tool set up by the World Health Organization to evaluate self-perceived functioning independently of a medical diagnosis. It can be given to both the patient and a family member.
- SF-36 Health Survey (SF 36) - measure of quality of life;
- Activity of Daily Living and Instrumental Activities of Daily Living (ADL and IADL: Lawton and Brody 1969) - tools for the evaluation of functioning in the basic and instrumental activities of daily life, specific for patients with dementia and administrable to a family member.
- Questionnaires for patients, family members and medical staff.

At the same time, it was declared that other tools (interviews concerning the use of the device) will be defined during the first year of experimentation. The analysis of the calligraphy of the participants is also scheduled.
The document states that:

- there are no substations with respect to that indicated in the attachment number;
- no serious and unexpected adverse events are expected in the patients enrolled but any information on any adverse effects will be reported in writing;
- the processing, communication and transfer of personal data of all study participants will take place in accordance with the provisions of the Organic Law 15/1999 concerning the protection of personal data in force in Italy;
- to identify the data collected during the study, a numerical code will be used and in accordance with the applicable legislation, you may exercise the right to access, rectify, cancel and oppose the processing of your personal data by contacting the doctor in charge of the study;
- the results of the study will be disseminated within the scientific community through congresses and / or publications. In this context, information will never be provided to identify the subjects;
- The study will take place in full compliance with current Italian legislation.
- Declaration to operate in compliance with the GCP, the Helsinki Declaration and all the current legislation in this area;
- Declaration of notification of serious and unexpected adverse events and annual and final study reports;
- Declaration of ownership / publication of data prepared according to the principles set out in the chapter "General Aspects - Property and publication of data".

3.2 Exit Strategy

Study participants are aware that the project will end after a specific time period and gave their consent. As potential support after the study, participants of MEMENTO project will be offered to stay in close contact with the respective outpatient memory clinics and be informed on project main results. Additionally, they will be offered to participate in other, following studies.

4 Conclusion

An Ethical appropriate project process is very important for a project working on a solution for patients. The project has taken care of this by passing a ethical committee before the first contact with any patient. This ensured a process inside the project itself where all documents have been carefully prepared, the process has been thought through and the aim of the patient involvement has been well considered.
As a second point and of course connected to the ethical committee approval is the handling and the privacy of data. It is very important that the project is following the new data regulations (GDPR). Also this point is carefully addressed by the project. AIT has even a data protection officer in place who carefully checks the process and all required documents.

Please find enclosed in the ANNEX the ethical protocol and corresponding votes from the countries Austria and Italy.
Spain has not passed yet the ethical committee.

Ethical Declaration Austria

The Ethics Committee of the Medical University of Vienna is established in accordance with the relevant provisions of the Declaration of Helsinki, the EU-GCP Note for Guidance, the “Arzneimittelgesetz” (Austrian Pharmaceuticals Act), the “Medizinproduktegesetz” (Austrian Medical Products Act), the Wiener “Krankenanstaltengesetz” (Viennese Hospitals Act), the “Kranken- und Kuranstaltengesetz” (Austrian Hospitals Act) and the “Universitätsgesetz” (Universities Act). The approved protocol for this study is provided as supplement (Protokoll_Memento_2017_10_02.pdf and 2017-11-02 MUV-Ethics_final.pdf).

Ethical Declaration Italy

The “Comitato Etico delle Aziende Sanitarie dell’Umbria” (CEAS Umbria – Ethical Committee)” is established in accordance with the relevant provisions of the Declaration of Helsinki, the “Linee Guida per la Buona Pratica Clinica”, the legislative decree 200/07, and the current legislation in clinical trial (Annex 1 - D.M. 15/07/1997; D. Lgs. 200/2007; D. Lgs. 211/2003; D.M. 21/12/2007; Legge n. 189 del 08/11/2012). The approved protocol for this study is provided as supplement (Italy Ethical Declaration.pdf).

List of Tables

Partners

Supporting Organizations