Deliverable 11.3 – POPD – H – EPQ - Requirement No. 3

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Table of Contents

TABLE OF CONTENTS ....................................................................................................................... 3
INDEX OF TABLES .............................................................................................................................. 4
GLOSSARY ........................................................................................................................................ 5
EXECUTIVE SUMMARY ...................................................................................................................... 6
1 INTRODUCTION ............................................................................................................................. 7
2 AIM ............................................................................................................................................... 8
3 HEALTH AND SAFETY PROCEDURES ......................................................................................... 9
4 DATA COLLECTION ......................................................................................................................... 11
  4.1 PROCEDURES THAT WILL BE IMPLEMENTED FOR DATA COLLECTION ..................................... 11
  4.2 STORAGE ................................................................................................................................ 11
  4.3 PROTECTION .............................................................................................................................. 12
  4.4 RETENTION ............................................................................................................................... 12
  4.5 DESTRUCTION ........................................................................................................................... 12
5 NATIONAL AND EU LEGISLATION CONSIDERED AND FOLLOWED ............................................. 13
  5.1 EU REGULATIONS ...................................................................................................................... 14
    5.1.1 Human dignity and integrity of user ..................................................................................... 14
    5.1.2 Privacy ............................................................................................................................... 15
    5.1.3 Bioethics and medical trials ............................................................................................... 18
    5.1.4 New technologies ................................................................................................................ 20
  5.2 INTERNATIONAL LEVEL ............................................................................................................ 21
6 CONCLUSION ................................................................................................................................ 22
7 ANNEXES ..................................................................................................................................... 23

ANNEX 1. ADAS&ME DATA COLLECTION CHECK LIST ....................................................................... 23
Index of Tables

TABLE 1 HEALTH AND SAFETY PRECAUTIONS........................................................................................................... 9
TABLE 2: LAWS AND DIRECTIVES TO BE CONSIDERED (AS A MINIMUM) BY ADAS&ME ETHICS BOARD.......... 13
Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADAS</td>
<td>Advanced Driver Assistance Systems</td>
</tr>
<tr>
<td>ADAS&amp;ME</td>
<td>Adaptive ADAS to support incapacitated drivers Mitigate Effectively risks through tailor made HMI under automation</td>
</tr>
<tr>
<td>CE</td>
<td>Conformity European</td>
</tr>
<tr>
<td>CTR</td>
<td>Clinical Trials Regulation</td>
</tr>
<tr>
<td>EB</td>
<td>Ethics Board</td>
</tr>
<tr>
<td>EEG</td>
<td>Electroencephalogram</td>
</tr>
<tr>
<td>EOG</td>
<td>Electrooculography</td>
</tr>
<tr>
<td>GPS</td>
<td>Global Positioning System</td>
</tr>
<tr>
<td>GSR</td>
<td>Galvanic Skin Response</td>
</tr>
<tr>
<td>GTPR</td>
<td>General Data Protection Directive</td>
</tr>
<tr>
<td>HR</td>
<td>Heart Rate</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>QM</td>
<td>Quality Manager</td>
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<td>RR</td>
<td>Respiration Rate</td>
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<tr>
<td>UNCRC</td>
<td>United Nations Convention of the Rights of the Child</td>
</tr>
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<td>UNESCO</td>
<td>United Nations Organization for Education, Science and Culture</td>
</tr>
<tr>
<td>WMA</td>
<td>World Medical Association</td>
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Executive Summary

In addition to the Ethics Manual Deliverable (D10.3) under WP10 “Management”, three additional Deliverables related to ethical requirements were requested by the EC, under WP11 “Ethics requirements”. This document corresponds to the requirement of D11.3 “POPD – H – EPQ - Requirement No. 3”.

The deliverable describes how to ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. Detailed information is provided, describing the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.
1 Introduction

ADAS&ME objective is to develop adaptive ADAS, able to decide when and how the vehicle needs to take over or recover control in relation to driver’s/ rider’s state, taking into account the current situational and environmental context. ADAS&ME includes 7 Use Cases, each one representing either a specific safety system where automation, in combination with driver/rider monitoring, is expected to have a high safety impact or, on a higher level, a vehicle category where several automated systems interact with the user, depending on task and driver/rider state. They cover different types of vehicles and environments, but also different levels of automation, targeting different user groups like drivers of truck, e-cars, cars, riders and bus drivers. ADAS&ME is a user oriented project where the participation of humans is essential for a successful outcome. A sound and correct ethical treatment of participants is therefore of great importance for ADAS&ME. In ADAS&ME data collections for algorithm development, HMI iterative tests and evaluations of final systems with human participants involved are taking place in five countries (Sweden, Germany, Spain, Italy and Greece).

This will be done in compliance with the ethics requirements at international and national level. In ADAS&ME D10.3 Ethics Manual the procedures and responsibilities will be clearly defined.

In addition, the EC has added three additional deliverables relevant to ethical requirements, to make sure that ADAS&ME fulfils all relevant ethical requirements:

- D11.1 H - Requirement No.1
- D11.2 POD - Requirement No. 2
- **D11.3 POPD - H EPQ - Requirement No. 3**

This deliverable is focused on the Requirement No. 3.
2 Aim

The aim of this deliverable is defined by the EC as:

“The applicant must ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.”
3 Health and safety procedures

Pilot teams at each site should ensure that the national and institute health and safety procedures and policies are followed related to work environment and research conduction. The following general health and safety precautions and guidelines (see Table 1) are based on the requirements set by NHTSA for self-driving vehicles (www.nhtsa.gov/staticfiles/rulemaking/pdf/Automated_Vehicles_Policy.pdf). Those are the most mature and extended guidelines from our point of view and even though they are not European they are to some degree applicable in EU. We also take into account the EU guidelines, however they are still highly influenced by the United Nations 1968 Vienna Convention on Road Traffic (http://www.politico.eu/article/us-and-eu-battle-for-first-place-in-self-driving-car-sprint/).

Table 1 Health and Safety Precautions.

<table>
<thead>
<tr>
<th>Precaution</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure that the participant will know how to drive the vehicle and fulfils the prerequisites of the study.</td>
<td>This is important for two reasons: a) the drivers have the experience to drive the certain vehicle and, thus, we may gather meaningful data, and b) familiarisation will ensure the participant will be and feel safe. The person should know the basic operation and limits of the introduced technologies and knows how to resume control (in the use cases this is relevant).</td>
</tr>
<tr>
<td>Ensure on-road testing minimizes the risk for other road users and not only for the pilot participant;</td>
<td>This is important in order to increase safety.</td>
</tr>
<tr>
<td>Limit testing to traffic, environmental and road type conditions that are familiar to the user (or at least suitable to their capabilities)</td>
<td>This is important to increase safety and comfort whenever is feasible and makes sense;</td>
</tr>
<tr>
<td>Ensure any transitions are made without any time lapses, incidents, problems and are safe and simple to execute;</td>
<td>This is important in order to increase safety.</td>
</tr>
<tr>
<td>Ensure any malfunctions or problems are easily identified and the driver is directly informed without any hazard or stress (physical or psychological) occurrence.</td>
<td>This is important in order to increase safety.</td>
</tr>
<tr>
<td>Ensure no existing commercial safety systems or features are affected either by installation or combination of systems; detailed technical verification is required at any step of the procedure and especially before any testing session with participants;</td>
<td>This is important in order to increase safety.</td>
</tr>
<tr>
<td>Ensures a driving instructor is always present (when is relevant and necessary).</td>
<td>This is important in order to increase safety.</td>
</tr>
</tbody>
</table>
Appropriate health and safety procedures will conform to relevant local/national guidelines/legislation, and they will be followed for staff involved in this project. It is the responsibility of the principal investigator to make sure this is informed.

To make sure this is the case the following is defined:

▪ Ensure physical, mental and psychological wellbeing in all phases of interaction with the participant;

▪ Make a breath analysis to guarantee sober test leader (the driver that will go with the participant in the car during the test) and check for a valid driving licences. This is done by the principal investigator.

▪ All participants should at arrival do a breath analysis to guarantee a sober driver and check should be done for a valid driving licences.

▪ If driving is on real road, select testing and driving areas that have low traffic and minimal accident risk; depending on nature and context of addressed use cases;

▪ Make sure that test leaders working night time are well prepared in terms of sleep the day before.

▪ Offer free transportation to and from test taking place night time or with sleep deprived drivers.

▪ The test leader is encouraged to terminate trials which they deem to be unsafe. Test leaders are provided with predefined criteria to identify high risk situations. Criteria for terminating trials include:

  ✓ If the participant does not act according to general road rules. For example speeding even though he / she is told not to once.

  ✓ If the participant is asking for the trial to be terminated.

  ✓ If the participant seems to be too sleepy/ inattentive or stressed so he/she is not a safe driver.

  ✓ If the weather conditions is not safe for example snow / ice / lot of rain on road surface.

  ✓ If the test vehicle is not behaving in a safe way.

  ✓ If the test equipment is not working perfectly.
4 Data collection

Procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation will comply with national and EU legislation, see also D10.3 ethics manual for details.

4.1 Procedures that will be implemented for data collection

Data collection will be completed within tasks WP7.2, supporting WP4.2 and WP4.3, and in WP7.3 for a final evaluation of the integrated system.

In ADAS&ME we have identified which data protection rules to apply (see also Ethics Manual - D10.3) and established a checklist (see Annex 1) to go through before starting any test or evaluation involving humans, taking to account the following:

- What kind of data will be processed?
- What is the purpose of the processing?
- Will the data exceed the purpose of the study?
- Are there procedures ensuring that data is processed only for the originally identified purposes?
- Who is the owner of the data?
- Is data connected to other information?
- Will data be commercially exploited?
- What is the duration of the storage of the data?
- Where will the data be stored and according to which national legislation?
- Who will access the data? Are they secured?
- Will the user be recorded?
- Which biometrics will be implemented?
- Who will supervise the data protection?

4.2 Storage

Data gathered will be of different types depending on the aim of each study. The following data list is the data collection that will be gathered in a project study:

- Vehicle data (speed, lateral position, steering, braking)
- Environmental data (GPS)
- Physiological data (HR, RR, GSR, EEG, EOG)
- Video data (Eye gaze, mouth position)
- Subjective Scoring (subjective reporting’s of sleepiness, stress, negative emotions)
- Objective Scoring (face expression)
- Questionnaires (background information about sleepiness, stress and health issues in general)

Personal data on participants will be used in strictly confidential terms and will be published only as integrated statistics (anonymously) and under no circumstances as individual data set.
All test data will be anonymized. Only one person per site will have access to the relational reference for linking test participants’ anonymized code and their personal identity. One month after the tests end, this reference will be deleted, thus safeguarding full anonymity. No other identifier will be kept. Nevertheless, stored data will by no means relate to a person’s beliefs or political or sexual preferences. The participants will be informed about this at the start of the trial.

The storage itself will be done on local servers at each partner doing tests. Advanced security protocols for data protection will be used to mitigate any malicious actions. Data can be shared by sites, but through secure servers.

4.3 Protection

Only anonymised data will be processed and, therefore, no personal data will be collected in relation to specific user. The name will not be connected to other characteristics (age, sex, nationality and health condition). Participants will be recorded only if they provide informed consent (See D10.3). All this information falls under the European legislation for the lawful processing of personal data. Special attention is also given to national legislation. These provisions have to be respected even if the users have given their consent for the processing of their personal data. Especially regarding sensitive data, about physical or mental health, sexual orientation and ethnic origin, more restrictions apply.

To avoid risks related to the processing of personal data such as identity theft, discriminatory profiling or continuous surveillance, the principle of proportionality has to be respected. Anonymization or pseudonymising is a way to prevent violations of privacy and data protection rules. Processing has to be limited to what is truly necessary and less intrusive means for realising the same end have to be considered.

4.4 Retention

Data can be used only for the initial purpose for which they were collected. If part of data will be used later this must be agreed upon beforehand with the test persons and included in the informed consent.

4.5 Destruction

One month after the tests end, the reference linking the person’s identity and the data will be deleted, thus safeguarding full anonymity. No other identifier will be kept. Nevertheless, stored data will by no means relate to a person’s beliefs or political or sexual preferences.

Raw Data will be saved at the partner responsible for the test/evaluation, however without anonymized. The data itself will not be destructed.
5 National and EU legislation considered and followed

The legislation, regulation and ethical codes named below will be considered; they are defined, and it is described how they are met in terms of processes, timing and responsibilities. ADAS&ME Ethics (and Quality Control) Board will oversee the ethical concerns involved in the project. They will consider the relevant laws and directives on ethical issues and personal data protection in the field, see Table 2.

Table 2: Laws and directives to be considered (as a minimum) by ADAS&ME Ethics Board.

<table>
<thead>
<tr>
<th>Ethical &amp; Social risk</th>
<th>Ethical field</th>
<th>Law/directive</th>
</tr>
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| Human dignity and integrity of user | Human Rights      | • European Convention for the Protection of Human Rights and Fundamental Freedoms  
• Charter of Fundamental Rights of the European Union |
| Privacy              | Data protection    | • Convention 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe)  
• Directive 95/46/EC of the European parliament and 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  
• Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC  
• Directive 2011/24/EU on the application of patients' rights in cross-border healthcare |
| Bioethics and clinical trials | Medical research  | • Directive 2001/20/EC of the European Parliament and of the council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the Clinical Trials Directive)  
• Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine |
ADAS&ME (688900)
D11.3 – POPD – H – Requirement No. 3

<table>
<thead>
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<th>Ethical &amp; Social risk</th>
<th>Ethical field</th>
<th>Law/directive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC</td>
</tr>
</tbody>
</table>

The ethical guidelines and regulations reported in the following sections are applicable for the project progress, and not for the use of the final product of ADAS&ME. Ethics can be defined as “a system of principles governing morality and acceptable conduct” 1 or “the study of fundamental principles that defines values and determines moral duty and obligation” 2. However, in this context, a wider and more specific definition is required. Specifically, the rights that are protected need to be identified, as well as the reasons for which these are protected.

### 5.1 EU regulations

The ethical guidelines, provided in the following sections, are written in accordance with the following EU legislation and guidelines:

#### 5.1.1 Human dignity and integrity of user

- **European Convention for the Protection of Human Rights and Fundamental Freedoms**

The Convention for the Protection of Human Rights and Fundamental Freedoms, better known as the European Convention on Human Rights, was opened for signature in Rome on 4 November 1950 and came into force 3 September 1953. It was the first instrument to give effect to certain of the rights stated in the Universal Declaration of Human Rights and make them binding.

The Convention sets several fundamental rights and freedoms (right to lift, prohibition of torture, prohibition of slavery and forced labour, right to liberty and security, right to a fair trial, no punishment without law, right to respect for private and family life, freedom of thought,

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conscience and religion, freedom of expression, freedom of assembly and association, right to marry, right to an effective remedy, prohibition of discrimination).

Parties undertake to secure these rights and freedoms to everyone within their jurisdiction. The Convention also establishes an international enforcement machinery. To ensure the observance of the engagements undertaken by the Parties, the European Court of Human Rights in Strasbourg has been set up. It deals with individual and inter-State petitions.

- **Charter of Fundamental Rights of the European Union**

  The rights of every individual within the EU were established at different times, in different ways and in different forms. For this reason, the EU decided to clarify things and to include them all in a single document which has been updated in the light of changes in society, social progress and scientific and technological developments.

  The Charter entrenches:
  - all the rights found in the case law of the Court of Justice of the EU;
  - the rights and freedoms enshrined in the European Convention on Human Rights;
  - other rights and principles resulting from the common constitutional traditions of EU countries and other international instruments.

  The Charter sets out a series of individual rights and freedoms. The Charter is a very modern codification and includes 'third generation' fundamental rights, such as:
  - data protection;
  - guarantees on bioethics; and
  - transparent administration.

  The Charter is consistent with the European Convention on Human Rights adopted in the framework of the Council of Europe: when the Charter contains rights that stem from this Convention, their meaning and scope are the same.

5.1.2 **Privacy**

- **Convention 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe)**

  This Convention is the first binding international instrument which protects the individual against abuses which may accompany the collection and processing of personal data and which seeks to regulate at the same time the trans frontier flow of personal data.

  In addition to providing guarantees in relation to the collection and processing of personal data, it outlaws the processing of "sensitive" data on a person's race, politics, health, religion, sexual life, criminal record, etc., in the absence of proper legal safeguards. The Convention also enshrines the individual's right to know that information is stored on him or her and, if necessary, to have it corrected.

sector and Regulation (EU) NO 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the EU Cookie Directive)

The EU Cookie Directive is amended privacy legislation designed to increase consumer protection. The EU Cookie Directive requires websites to obtain informed consent from visitors before they store information on a computer or any web connected device. This is storage is mostly done by cookies, which can then be used for tracking visitors to a site.

The previous privacy legislation required websites to give users information on how they could remove or opt-out of cookies, which was commonly placed in privacy policies that went mostly unread. With the EU Cookie Directive the user of a site will now be required to opt-in when using a website containing cookies. So the website has to block cookies, until visitors have given their informed consent to their use.


This Directive is concerning the processing of personal data and the protection of privacy in the electronic communications sector. The Directive sets out rules to ensure security in the processing of personal data, the notification of personal data breaches, and confidentiality of communications. It also bans unsolicited communications where the user has not given their consent.

- **Directive 95/46/EC (the Data Protection Directive)**

EU Data Protection Directive is a directive adopted by the European Union designed to protect the privacy and protection of all personal data collected for or about citizens of the EU, especially as it relates to processing, using, or exchanging such data. Directive 95/46/EC encompasses all key elements from article 8 of the European Convention on Human Rights, which states its intention to respect the rights of privacy in personal and family life, as well as in the home and in personal correspondence. The Directive is based on the 1980 OECD "Recommendations of the Council Concerning guidelines Governing the Protection of Privacy and Trans-Border Flows of Personal Data."

These recommendations are founded on seven principles, since enshrined in EU Directive 94/46/EC:

- Notice: data subjects whose data is being collected should be given notice of such collection.
- Purpose: data collected should be used only for stated purpose(s) and for no other purposes.
- Consent: personal data should not be disclosed or shared with third parties without consent from its subject(s).
- Security: once collected, personal data should be kept safe and secure from potential abuse, theft, or loss.
- Disclosure: data subjects whose personal data is being collected should be informed as to the party or parties collecting such data.
• Access: data subjects should be allowed to access their data and make corrections to any inaccuracies.
• Accountability: data subjects should be able to hold personal data collectors accountable for adhering to all seven of these principles.

In the context of the Directive, personal data means "any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity" (Article 2a). Data is considered personal when it enables anyone to link information to a specific person, even if the person or entity holding that data cannot make that link. Examples of such data include address, bank statements, credit card numbers, and so forth. Processing is also broadly defined and involves any manual or automatic operation on personal data, including its collection, recording, organization, storage, modification, retrieval, use, transmission, dissemination or publication, and even blocking, erasure or destruction (paraphrased from Article 2b).


The Data Retention Directive was a Directive issued by the European Union and related to telecommunications data retention. According to the directive, member states will have to store citizens’ telecommunications data for a minimum of 6 months and at most 24 months. Under the directive the police and security agencies will be able to request access to details such as IP address and time of use of every email, phone call and text message sent or received. A permission to access the information will be granted only by a court. On 8 April 2014, the Court of Justice of the European Union declared the Directive invalid in response to a case brought by Digital Rights Ireland against the Irish authorities and others.


The General Data Protection Directive is a regulation by which the European Parliament, the Council and the European Commission intend to strengthen and unify data protection for individuals within the European Union (EU). It also addresses export of personal data outside the EU. The primary objectives of the GDPR are to give citizens back the control of their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU. When the GDPR takes effect it will replace the data protection directive (Directive 95/46/EC) from 1995. Perhaps confusingly for some, there is a new directive as well as a new regulation; it will apply to police procedures, which will continue to vary from one Member State to the other.

The proposed new EU data protection regime extends the scope of the EU data protection law to all foreign companies processing data of EU residents. It provides for a harmonization of the data protection regulations throughout the EU, thereby making it easier for non-European companies to comply with these regulations; however, this comes at the cost of a strict data protection compliance regime with severe penalties of up to 4% of worldwide turnover." The Parliament's version contains increased fines up to 5%. After trilogue negotiations between the
European Parliament, the European Commission and the Council of Ministers, there is general consensus on the wording of the GDPR and also the financial penalties for non-compliance.

The regulation was adopted on 27 April 2016. It enters into application 25 May 2018 after a two-year transition period and, unlike a directive, it does not require any enabling legislation to be passed by national governments.

- **Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare**

  The Directive 2011/24/EU sets out the conditions under which a patient may travel to another EU country to receive safe and high quality medical care and have to cost reimbursed by their own health insurance scheme. The directive also encourages cooperation between national healthcare systems.

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5.1.3 **Bioethics and medical trials**


  The Clinical Trials Directive is a European Union directive that aimed at facilitating the internal market in medicinal products within the European Union, while at the same time maintaining an appropriate level of protection for public health. It seeks to simplify and harmonize the administrative provisions governing clinical trials in the European Community, by establishing a clear, transparent procedure. The Clinical Trials Directive is a European Union directive that aimed at facilitating the internal market in medicinal products within the European Union, while at the same time maintaining an appropriate level of protection for public health. It seeks to simplify and harmonize the administrative provisions governing clinical trials in the European Community, by establishing a clear, transparent procedure.


  All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the new Clinical Trials Regulation (CTR) EU No 536/2014 will become applicable, which will be no earlier than 28 May 2016. For further information please see the information on the Clinical trials Directive and the transition period.

  The new Clinical Trials legislation, which was adopted on 16 April 2014 and entered into force on 16 June 2014, has taken the legal form of a Regulation. This will ensure that the rules for conducting clinical trials are identical throughout the EU. This is vital to ensure that Member States, in authorising and supervising the conduct of a clinical trial, base themselves on identical rules.

  The Clinical Trials Regulation aims to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, for all EU Member States.

  **Transition period**

  Until the Clinical Trials Regulation EU No 536/2014 will become applicable, all clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive.
Trials Directive. This Directive will be repealed on the day of entry into application of the Clinical Trial Regulation. It will however still apply three years from that day to:

- Clinical trials applications submitted before the entry into application (no earlier than 28 May 2016);
- Clinical trials applications submitted within one year after the entry into application if the sponsor opted for old system.

- **Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine**

The Convention is the first legally-binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. The Convention's starting point is that the interests of human beings must come before the interests of science or society. It lays down a series of principles and prohibitions concerning bioethics, medical research, consent, rights to private life and information, organ transplantation, public debate etc.

It bans all forms of discrimination based on the grounds of a person's genetic make-up and allows the carrying out of predictive genetic tests only for medical purposes. The treaty allows genetic engineering only for preventive, diagnostic or therapeutic reasons and only where it does not aim to change the genetic make-up of a person's descendants. It prohibits the use of techniques of medically assisted procreation to help choose the sex of a child, except where it would avoid a serious hereditary condition.

The Convention sets out rules related to medical research by including detailed and precise conditions, especially for people who cannot give their consent. It prohibits the creation of human embryos for research purposes and requires an adequate protection of embryos where countries allow in-vitro research.

The Convention states the principle according to which a person has to give the necessary consent for treatment expressly, in advance, except in emergencies, and that such consent may be freely withdrawn at any time. The treatment of persons unable to give their consent, such as children and people with mental illnesses, may be carried out only if it could produce real and direct benefit to his or her health.

The Convention stipulates that all patients have a right to be informed about their health, including the results of predictive genetic tests. The Convention recognises also the patient's right not to know. The Convention prohibits the removal of organs and other tissues which cannot be regenerated from people not able to give consent. The only exception is, under certain conditions, for regenerative tissue (especially bone marrow) between siblings.


The Directive 2001/83/EC brings together all the existing provisions in force on the sale, production, labelling, classification, distribution and advertising of medicinal products for human use in the EU. Some of the key points are that all medicines offered for sale in the EU must have prior authorisation from either a national authority or the European Medicines Agency, and to receive authorisation, manufacturers must provide a range of detailed therapeutic information about the product, including any possible side-effects.
5.1.4 New technologies


This Regulation lays down clear rules on the organisation and operation of accreditation, within the European Union (EU), of conformity assessment bodies responsible for performing evaluation tasks to ensure conformity with the applicable requirements. It is important to guarantee a high level of market surveillance in order to satisfy the requirements of protection of public interest such as health and safety in general, health and safety in workplace, protection of consumers, the environment and security. Accreditation is the final public control step within the conformity evaluation system and attests to the technical competence of the conformity evaluation bodies. It also contains rules on CE marking.

These rules reinforce the existing system, without weakening existing instruments such as the General Product Safety Directive, which has on the whole been successful.


The General Product Safety Directive requires firms to ensure that items on sale are safe and to take corrective action when that is found not to be the case. It introduces an EU rapid alert system for dangerous non-food products. This enables national authorities to share information promptly on any measurements taken to withdraw such products from sale. Some of the key points are that products placed on the EU market must be safe, and the products must bear information enabling them to be traced, such as the manufacturer’s identity and a product reference.


The decision sets out common principles and procedures which EU legislation must follow when harmonising conditions for marketing products in the EU and the European Economic Area. It also includes reference requirements to be incorporated whenever product legislation is revised. As such, it is a template for future product harmonisation legislation. Some of the key points are that the decision provides clear definitions for relevant terms, such as ‘manufacturer’, ‘placing on the market’, ‘recall’ or ‘withdrawal’ of products, it also show clear divisions of responsibility are set for manufacturers, importers and distributors along the product chain.

- Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

The objective of this Regulation is to improve the free movement of goods in the Community. It establishes rules and procedures which should be followed by the authorities of Member States when they take or intend to take a decision which could hinder the free movement of a
product lawfully marketed in another Member State and not covered by harmonised rules at Community level. It applies from 13 May 2009.

5.2 International level

In addition to the aforementioned EU regulations, the following international conventions and declarations have been also taken into consideration:

- **Universal Declaration of Human Rights**
  The Universal Declaration of Human Rights is a milestone document in the history of human rights. Drafted by representatives with different legal and cultural backgrounds from all regions of the world, the Declaration was proclaimed by the United Nations General Assembly in Paris on 10 December 1948. The declaration consists of 30 articles that states that all men are born free and equal, we all have the right to life, and to live in freedom and safety. We are all equal before the law, and our human rights are protected by law.

- **World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects**
  The World Medical Association (WMA), an international organization of physicians, was formally established on September 17, 1947, pursuant to the resolutions of the First General Assembly of WMA held in Paris, France. In 2007, the WMA had a membership of 84 national medical associations and represents some 9 million physicians. The goal of the World Medical Association is to serve humanity by endeavoring to achieve the highest international standards in medical education, science, ethics, and health care for all peoples of the world.

- **Universal Declaration on Bioethics and Human Rights (UNESCO)**
  Since the 1970s, the field of bioethics has grown considerably. While it is true that bioethics today includes medical ethics issues, its originality lies in the fact that it goes much further than the various professional codes of ethics concerned. It entails reflection on societal changes and even on global balances brought about by scientific and technological developments. To the already difficult question posed by life sciences – How far can we go? – other queries must be added concerning the relationship between ethics, science and freedom.

- **The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, signed in Oviedo on 4 April 1997, (the Oviedo Convention)**
  This Convention is the only international legally binding instrument on the protection of human rights in the biomedical field. It draws on the principles established by the European Convention on Human Rights, in the field of biology and medicine. It is a framework Convention aiming at protecting dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

- **UN Convention on the Rights of the Child, 2002**
  The United Nations Convention of the Rights of the Child is a legally-binding international agreement setting out the civil, political, economic, social and cultural rights of every child, regardless of their race, religion or abilities. Since it was adopted by the United Nations in November 1989, 194 countries have signed up to the UNCRC, with only two countries in the
world still to ratify. All countries that sign up to the UNCRC are bound by international law to ensure it is implemented. This is monitored by the Committee on the Rights of the Child. Under the terms of the convention, governments are required to meet children’s basic needs and help them reach their full potential. Central to this is the acknowledgment that every child has basic fundamental rights. These include the right to life, survival and development; protection from violence, abuse or neglect; an education that enables children to fulfil their potential; be raised by, or have a relationship with, their parents and to express their opinions and be listened to.

- **Universal Declaration on the human genome and human rights adopted by UNESCO**

The Declaration is a document that was issued by UNESCO in 1997 and is perhaps best known for its statement against human cloning and abuse of human genome against human dignity.

### 6 Conclusion

The aim of this Deliverable was to clearly describe how to ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. Detailed information is provided, describing the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.
7 ANNEXES

Annex 1. ADAS&ME data collection check list

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>What kind of data will be processed?</td>
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<tr>
<td>What is the purpose of the processing?</td>
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<tr>
<td>Will the data exceed the purpose of the study?</td>
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<tr>
<td>Are there procedures ensuring that data is processed</td>
<td></td>
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<tr>
<td>only for the originally identified purposes?</td>
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<tr>
<td>Who is the owner of the data?</td>
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<tr>
<td>Is data connected to other information?</td>
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<tr>
<td>Will data be commercially exploited?</td>
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<tr>
<td>What is the duration of the storage of the data?</td>
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<tr>
<td>Where will the data be stored and according to which</td>
<td></td>
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<tr>
<td>national legislation?</td>
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<tr>
<td>Who will access the data? Are they secured?</td>
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<tr>
<td>Will the user be recorded?</td>
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<tr>
<td>Which biometrics will be implemented?</td>
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<tr>
<td>Who will supervise the data protection?</td>
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