Acronym:	Cordon Gris
Name:	Making sense of data to promote effortless healthy eating habits and autonomy for older people
Call:	AAL Call 2015
Contract nr:	AAL-2015-1-016
Start date:	02 May 2016
Duration:	24 months

D2.1 Ethical Roadmap

Nature[1]: P
Dissemination level[2]: PU
Due date: Month 3
Date of delivery: Month 3
Partners involved (leader in bold): **UNIEKBO**, FhP, SCML, SONAE, RNS, CC,
Authors: Ciska van Harten (UNIEKBO), Ayla Schwarz (FhP)

[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario
[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Partner list

Nr.	Partner name	Short name	Org. type	Country
1	Fraunhofer AICOS *(coordinator)*	FhP	R&D	Portugal
2	Santa Casa da Misericórdia de Lisboa	SCML	End-user	Portugal
3	SONAE (Modelo.com – Vendas por correspondência, S.A.)	SONAE	IND	Portugal
4	Red Ninja Studios	RNS	SME	United Kingdom
5	Can Cook	CC	SME, End-user	United Kingdom
6	Unie KBO	UNIEKBO	End-user	Netherlands

Revision history

Rev.	Date	Partner	Description	Name
1	15.06.2016	Unie KBO FhP	First version deliverable for revision and discussion partners	Ciska van Harten Ayla Schwarz
2	04.07.2016	FhP	Revised and filled in details about national legislation and relevant data protection office in the UK	Ana Correia de Barros

3	12.07.2016	**Approved by FhP**	

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1. Introduction

This ethical road map is a strategic plan containing the basic principles and agreements that all project partners need to comply with during the Cordon Gris project with regard to ethical aspects in research, concerning elderly people.

During the project this ethical road map needs to be the foundation on which many other documents are based. This explicitly applies to documents relating to research carried out with the help of elderly people.

The collection and processing of data plays an important role in the project. Therefore, attention is given to the recently adopted EU legislation on data protection, the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679).

The main goal of the Cordon Gris project is to fight malnutrition by allowing people to have a balanced and healthy diet while helping them to save money and avoid food waste.

2. End user participation in the project

The end-user participation within Cordon Gris can be found in three parts of the project and requires different levels of ethical consideration:

1. Investigation phase - In the first phase, senior citizens will play an active role to get a clear picture of the users' wishes and needs and thus the design of the Cordon Gris system. A user requirement survey will be conducted with individuals from each end-user project partner. Through this survey the needs, requirements, design and market opportunity for Cordon Gris are assessed. This survey can be filled out on the internet, via e-mail or on paper. In parallel with the survey, focus groups/ workshops will be conducted in Portugal, the UK and in the Netherlands.

2. Development phase - From the beginning of the development phase, users with different profiles will also be involved in co-design. The development of the system and in particular of the user interfaces will follow an iterative and human-centred process. This means that they will be designed together with end users through a repetitive cycle where the user interfaces are analysed, designed, tested and validated.

3. Trial phase - In the third phase, the system will be used in real-life settings. Elderly people of the three countries will be asked to use it in their own home. This will allow to perform adjustments and corrections to the system and to assess users' interest in, and acceptance of the system.

In the project plan different target groups are described: users living alone, couples, users who are supported by institutions regarding meals, users who go out of the house to eat with others, users who cook (by themselves or with cooking robots), users who do not cook and users who have trouble saving money. In Work package 2 (WP2) the target groups will be more precisely formulated resulting in different scenarios/use cases, which will define the trial-environment in the three different countries.

In order to avoid risks and extreme cases during research, in the chapter about risks some inclusion and exclusion criteria are formulated.

Overview end-user involvement in Cordon Gris

Activities	**Nr. users Portugal**	**Nr. users UK**	**Nr. users Netherlands**
Life habits, independence and nutritional assessment (*qualitative & quantitative research*)	60	40	40
Service definition (*focus groups*)	10	10	10
User interface design and testing (*workshops & usability testing*)	20	20	10
Field trials (*daily use for 3 months*)	60	40	10

3. Legislation and General Ethical Principles of Cordon Gris

The members of the Consortium declare that the project will comply with the current legislation and regulations of the countries in which the research will be conducted. Moreover, the project will comply with all relevant EU legislation, especially the legislation described below:

3.1. The European Charter of Fundamental Rights

'The Charter of Fundamental Rights of the EU' brings together in a single document the fundamental rights protected in the EU. The Charter contains rights and freedoms under six titles: dignity, freedoms, equality, solidarity, citizens' rights and justice' (EU, 2013). The Charter became legally binding in 2009 when it was signed together with the Treaty of Lisbon. Meaning that all European legislation needs to conform to the principles of the Charter, including research policy. Several principles of the Charter are relevant in the context of research policy and are depicted below.

European Union, 2009:

Article 3 – Right to the integrity of the person (dignity)

'Everyone has the right to respect for his of her physical and mental integrity'.

'In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law'.

Article 7 – Respect for private and family life (freedoms)

'Everyone has the right to respect for his or her private and family life, home and communications'.

Article 8 – Protection of personal data (freedoms)

'Everyone has the right to the protection of personal data concerning him or her'.

'Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.'

'Compliance with these rules shall be subject to control by an independent authority'.

Article 25 – The rights of the elderly (equality)

'The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.'

Article 38 – Consumer protection (solidarity)

'Union policies shall ensure a high level of consumer protection'.

3.2. Declaration of Helsinki

The Declaration of Helsinki was developed by the World Medical Association (WMA) to lay out ethical principles for medical research involving human subjects. It is seen as the cornerstone of human research ethics in the world. Even though this is not a legally binding document through international law, most legislation of different levels have based their ethical principles on this Declaration and should therefore be highly respected. Relevant articles include (WMA, 2008):

Article 6: 'In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests'.

Article 11: 'It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects'.

Article 14: 'The design and performance of each research study involving human subjects must be clearly described in a research protocol'.

Article 15: 'The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins'.

Article 21: 'Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects'.

Article 23: 'Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity'.

3.3. Convention on Human Rights and Biomedicine of the Council of Europe

This Convention was set up by the Council of Europe and signed in 1997, an additional protocol was signed in 1998 on the prohibition of cloning human beings. This convention is also amended in the EU Lisbon Treaty in 2009. Relevant articles include (Council of Europe, 1997):

Article 1: 'Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental rights with regard to the application of biology and medicine'.

Article 2: 'The interest and welfare of the human being shall prevail over the sole interest of society or science'.

Article 5: 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

3.4. Relevant EU Directives and other EU legislation

Directive 95/46/EC: Describes the protection and freedoms of persons with regard to the processing of personal data. Several aspects on personal data are highlighted: quality, legitimacy of processing, processing of special categories, information given to the data subject, right of access, right to object of processing, confidentiality, notification of processing to supervisory authority.

Directive 2002/58/EC: Concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). Especially focused on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Nothing in the Cordon Gris may conflict the opinions of the European Group of Advisors on 'the Ethical Implications of Biotechnology and concerning respect of human person' (1991-1997) and the opinions of the European group on 'Ethics in Science and New technologies' (as from 1998).

3.5. New EU regulation on data protection

According to the Charter of Fundamental Rights of the European Union, natural persons have the fundamental right to the protection of personal data concerning him or her.

The European Commission adopted new legislation on this subject. Currently the old legislation still applies. But within the project we will adhere to the new legislation already.

The Council adopted the Regulation and the Directive on 8 April 2016. The Regulation and the Directive were adopted by the European Parliament on 14 April 2016. The Regulation (EU) 2016/679 (General Data Protection Regulation), repealing Directive 95/46/EC will enter into force on 24 May 2016 and shall apply from 25 May 2018. The Directive (EU) 2016/680 (Data Protection Directive) will enter into force on 5 May 2016 and shall apply from 6 May 2018.

The Eurobarometer survey on protection and personal data, conducted among 28000 EU citizens in March 2015 reveals concern among EU citizens. For example, a majority agrees that “providing personal information is an increasing part of modern life” (71%), “that their explicit approval should be required in all cases before their data is collected and processed” (69%), or “that they would want to be informed should their data ever be lost or stolen”.

Further, eight out of ten EU citizens feel that they do not have complete control of their personal data. However, GDPR applies adapted regulations, which build and maintain trust. The overall change concerns the same data protection rights across EU. This means for businesses that the single, pan-European law for data protection build consistency between 28 countries. Moreover, one-stop shop involves one single supervisory authority (Data Protection Authority, DPA), which will promote clarity and make it cheaper for companies to do business in the EU. Same rules apply when goods and services are offered on the EU market. By means of a risk-based approach, rules will be tailored to risks and therefore avoid one-size-fits-all obligation. Rules incentivise businesses to innovate, by means of data protection by design, meaning to build data protection safeguards into products and services from the earliest stage of development. Techniques as anonymisation, pseudonymisation and encryption are promoted to protect personal data (important in terms of big data) and thereby enable big data innovation. Transparency is core to the adapted version on data protection, stating that organization should publish transparent and easily accessible data protection policies. "Simple icons on a website could explain how, by whom and under whose responsibility personal data will be processed" (European Commission, 2016).

All in all, red tape will be reduced, meaning that no more notifications (fees for processing data) need to be provided to supervisory authorities. Small- and medium-sized businesses are for example also able to charge a fee for providing access to data (every penny counts). Data protection officers do not need to be appointed by the large majority of small- and medium-sized businesses. Only when the core activities involve “regular and systematic monitoring of data subjects on a large scale” a data protection officer needs to be appointed. Only very risky data processing activities will need to carry out data protection impact assessments. Thereby, a privacy-friendly environment will be created.

In terms of controlling personal data and in order to build and maintain trust in online environment, the adopted Regulation states that easier access to personal data is ensured. Also, EU citizens have the right to data portability, which means that data can be transferred between services by the user. Thereby, trust is strengthened and fair competition created: especially small- and medium-sized businesses can compete giants within the single market. The right to be forgotten means that if requested, data must be deleted. Moreover, users have the right to know when data has been hacked. Thus, by means of

clear affirmative actions, meaning that users give their consent for processing personal data. In case of data breaches, the data protection authority of each Member State as well as the user need to be informed as soon as possible – where feasible within 72 hours.

All in all, the adapted Regulation ensures:

- Enhancing transparency
- Fostering consumers' trust
- Boosting competition through new right of data portability
- Creation of a level playing field for all companies active in the single market

3.6. Relevant National Regulations

As mentioned in chapter 2 within Cordon Gris, focus groups and pilot trials will be carried out by some or all project partners. Therefore, Cordon Gris does not only take account of the EU regulations, which is relevant to healthcare research with human subjects, but will also consider the following national legislation.

The Netherlands:

- Wet Bescherming Persoonsgegevens (WBP) / Personal Data Protection Act (6 July, 2000)
- Wet medisch-wetenschappelijk onderzoek met mensen (WMO) / Law on medical research with human subjects (26 February, 1998)

United Kingdom:

- Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents)

Portugal:

- Lei da Protecção de Dados Pessoais (Lei n.º 67/98, October 1998)

As national regulations might adapt within the following years, due to GDPR, the Cordon Gris Consortium declares to stay up-to-date with adaptations of relevant national regulations in each country.

3.7. General Ethical Principles Cordon Gris

Based on the above mentioned legislation, Cordon Gris will uphold the following six general ethical principles:

1. Respect for the integrity and dignity of persons (protecting them from being used for any other purpose than stipulated).
2. Follow the "do no harm" principle. Any potential risks must be clearly communicated to the elderly person involved.
3. Acknowledge the rights of individuals to privacy, personal data protection and the freedom of movement.
4. Honour the requirement of informed consent and continuous dialogue with the paticipant.
5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).

6. Treat societal concerns seriously – listen to the public/older person and engage with them in a constructive dialogue, transparently, honestly and with integrity.

4. Recruitment of the Participants

Each organisation (Unie KBO, FhP, Can Cook and Santa Casa de Misericórdia de Lisboa) will use their own contacts and recruitment methods. The recruitment method will have to comply with the methods and targets of the investigation.

Potential participants will be informed about what they can expect during the research. This information will be handed out to the participants in written form by means of an information sheet. Potential participants will be notified in their own language and in a comprehensible way, about the research targets and methods.

The researchers will make future participants aware that their participation is completely voluntary, that they have the right to refuse to participate, and that they can terminate their participation without the need to motivate their decision. The researchers will inform participants on a number of important factors that may influence their decision to participate (like risks, inconveniences, potential adverse consequences or restrictions to confidentiality) and they will elaborate on any other aspect on which the future participant may have a question. The researchers will inform participants on the feedback report method and the nature of the research results that will be reported or published. The participant will get ample opportunity to read through the information, to ask the researcher any questions and to consider their potential participation.

The Cordon Gris project will not approach people who are unable to give their informed consent. In case such a situation would accidentally occur, the approach will be terminated immediately.

In order to recruit participants, no unsuitably high financial compensations nor any other rewards may be used. It is nonetheless allowed to give participants a small and suitable present. The costs for expenditure related to participation will be paid by the organization conducting the research.

Should the research to take place with participants who have specific problems, for instance with specific diet requirements or health issues, the researchers would first have to address these issues before recruiting these individuals for the research. This will be done by using an appropriate and short standardized questionnaire in the field trials phase. In case of any doubt the researchers need to consult experts on the issue (like a medical physician or a dietitian) specialized in the field concerned.

5. Data Protection and Privacy

The project Cordon Gris will comply with Regulation (EU) 2016/679 (General Data Protection Regulation), updated in 27 April 2016 and applying in May 25, 2018. According to Regulation (EU) 2016/679, same data protection rights across the European Union applies in the European-wide project Cordon Gris. Data protection and privacy are fundamental rights, which need to be respected. Privacy covers the right to manage one's personal information, while being free from secret surveillance. Data protection entails the integrity and control of one's data with regard to the purposes of data processing.

As the Cordon Gris project involves partners from different countries in the European Union, personal data need to be processed across borders inside the European Union. Due to the adapted Regulation (EU) 2016/679, protection safeguards will be implemented from the earliest design stage of the project and will be observed during the course of the Cordon Gris project. Therefore, each entity will store their own data in order to prevent cross-border processing. Also, personal data will be anonymised/pseudonymised/encrypted in order to protectively process big data. Core to the data protection and privacy regulations in the Cordon Gris project is transparency, meaning that data protection policies will be published. On top of that, in order to apply with the adapted Regulation (EU) 2016/679 and to build trust between the services provided by the Cordon Gris project and its end-users, data accessibility will be applied. This means that users will get access to their personal data, if requested. Further, users can ask for their personal data for data portability use, enabling them to easily transfer their data to other services. If requested, personal data will be deleted once and for all. Particularly in terms of data protection, the data protection authority of each Member State as well as the user will be as soon as possible – where feasible within 72 hours, informed in case one's personal data have been hacked.

A main rule for businesses, either employing 250 employees or whose core activities involve processing data on a large scale, is that they are obliged to designate a data protection officer, either as a full-time employee or as an ad-hoc consultant. This designated data protection officer will be responsible for all tasks, relating to data protection and will act as the contact point for the supervisory authority. However, in the Cordon Gris project no data protection officer needs to be announced, as neither data of special categories nor data on a large scale will be processed (Article 37, n.º 1 b), c)). Because of the nature of the data, data protection impact assessments will not be conducted. However, the Cordon Gris Consortium will stay informed about any changes and will adapt accordingly. In addition, only data will be processed after informing research participants and obtaining a signed informed consent.

Since three countries, Portugal, the UK and the Netherlands, are involved in the project, each partner will ensure compliance with its data processing activities and will be monitored by the supervisory authority of its country (Article 51).

In particular, citizens can access their own data. As a result, the personal data of all citizens will have equivalent protection across the European Union.

5.1. Processing of Personal Data

Personal data refer to any information which is relating to an identified or identifiable natural person. Cordon Gris Consortium will apply to the regulation, set out previously. In terms of privacy, personal data is treated in a confidential way. Especially as Cordon Gris Consortium is dealing with data about a person's health, data will be treated respectfully.

Personal data: any piece of data regarding an identified or identifiable natural person, for example date of birth, gender, address.

- Cordon Gris Consortium will handle personal data confidentially and will abide by all applicable legislation.
- The privacy of all participants is respected by giving control over the processing of personal data. Personal data that may lead to the identification of a participant will be disconnected from the research data.
- Personal data gathered for Cordon Gris will only be used for its assigned goals defined in advance, or for objectives that are consistent with these defined goals.
- Members of the Cordon Gris Consortium will not hand over any personal data to any third party, without the participant´s prior written and clearly stated consent. Even so, passing personal data to any third party is only allowed if this would serve the Cordon Gris research.
- If a database with directly identifiable personal data will be constructed within Cordon Gris, the researcher must provide its registration according to national rules.
- The researchers will take all suitable precautionary technical and organisational measures to prevent any loss of data or illegitimate access or processing.

6. Informed Consent

Reinforced by Regulation (EU) 2016/679, informed consent should be communicated in clear and plain language. Informed consent involves a voluntary agreement with an action proposed by another. This proposal should include the nature, significance, implications and risks of the trial and should be either handed written or in exceptional cases orally. Also, it should include its right to withdraw from the trial at any time and a contact point to obtain further information. For the collection and use of personal data, informed consent should be asked for and include a simple explanation of who is collecting their personal data and why, how to obtain a copy of the data and details of who will have access to the data.

In case of the Cordon Gris project, the Cordon Gris Consortium has to ensure that participants are capable to make rational and voluntary decisions of participating. Participants, who are assessed as incapable of making rational and voluntary decisions will be excluded of the Cordon Gris project's trials. As the Cordon Gris project will treat health data - which must be treated as sensitive data, this will be communicated explicitly. For example, it includes the statement that personal data will not be processed for other purposes by third parties (e.g. health insurances or banking companies).

In the end, the informed consent document covers:

1. Purpose of the project
2. Research procedures and purpose
3. Duration
4. Benefits for participants, society and economy
5. Potential risks
6. Alternatives to participation
7. Incentives for participation
8. How data will processed and by whom
9. Participation rights: Refuse or withdraw of participation
10. Data protection and privacy
11. Research results and publishing
12. Recording, pictures and videos
13. Emergency care, compensation for injury or damage

7. Applying Ethical Principles to the Cordon Gris project

In this chapter a description is provided about how the ethical principles mentioned before are applied across the different research parts within Cordon Gris.

7.1. User Requirements phase

Goal: By conducting a survey and a workshop amongst the end-users at the starting phase of the project, we will be able to define the user requirements for our product, specifically with regards to: needs, habits, requirements, design, market opportunity and interest for such a product.

7.1.1. Survey

The user requirement survey can be filled in anonymously. Except when participants decide they would be interested in either continuing to participate and/or would like to receive updates on the project, in which case they will be asked to leave their contact details. However, these contact details will directly be separated from their survey results and will be shuffled. Even though it would be useful to have the survey results linked to the participants who will also take part in further research, most information will be asked again in more detail in a later stage. Therefore, to optimise the anonymity level at this stage we believe it is more effective to separate this information.

Additionally, the contact details collected will only be held by the project partner that received them. Since the further research with these potential participant will also be conducted at their organisation, there is no reason to transfer this data across borders. All the data a part from the contact details will be collected by Red Ninja Studios and will be further analysed and written up in a report. The survey can be conducted online (website), via e-mail (word document) or on paper. This will ensure that everyone can fill in the survey without any trouble or barrier. In order to collect information online, SurveyMonkey (surveymonkey.com), an online survey development cloud-based software will be used. Surveys are administered by the survey creator (Cordon Gris, through its registered account). The registered user (Cordon Gris) will be the sole owner of all data. SurveyMonkey respects the privacy of its users and collected data as stated on its data protection policy. SurveyMonkey does not sell them to anyone and does not use the survey responses for purposes unrelated to its services, except in a limited set of circumstances (e.g. if they are compelled by a subpoena). SurveyMonkey safeguards respondents' email addresses too. To make it easier to invite people to take surveys via email, Cordon Gris will be able to upload a list of email addresses, in which case SurveyMonkey acts as a mere custodian of that data. SurveyMonkey does not sell these email addresses and will use them only as directed by Cordon Gris and in accordance with this policy. The same goes for any email addresses collected through the surveys. SurveyMonkey takes its users' security and privacy concerns seriously. SSL (Secure Sockets Layer) is a protocol developed for transmitting private documents or information via the Internet. SSL creates a secure connection between a client and a server, encrypting sensitive information being transmitted through the web page. SSL encryption is automatically turned on for all surveys. If the URL of the survey that the user receives begins with https://, the responses are sent over a secure, SSL encrypted connection.

In this part we will provide participants with project information to guarantee that they will understand the content of the project, the purpose of the survey and any potential risks or benefits this method might cause.

7.1.2. Workshop

We hold these workshops in order to get general end-user perspectives, therefore we merely need the insights not linked to a name. The note-taker will write up general notes and will never link these notes to a specific person. Furthermore, the researchers will maintain an objective view of every participant and will ensure a pleasurable experience for all end-users. Every workshop participant (end-user) should feel respected and valued for the input they provide.

In this section we will provide participants with an informed consent form to guarantee they understand the content of the project, purpose of the workshop and any potential risks or benefits this method might cause.

The participants will be informed about the results of the survey and will receive the report of the workshops. We will ask the participants if they want to be involved in phase 2 and if they would like to receive the newsletter of the project.

7.2. Development phase

Goal: The goal of involving users in this phase is to have a continuous end-user perspective every step of the project, to ensure the product fulfils all the needs of the target group. Leading to an optimised product that is expected to need fewer adjustments during the prototype testing from the end-user perspective.

In this phase we will use methods like interviews, workshops, focus groups and product tests via usability testing (from low- to high-fidelity prototypes). With regard to the privacy in the recruitment phase, the conditions set out in chapters 4 and 5 apply. When possible, the participants from phase 1 are asked to join this phase. In this phase we will work also with an informed consent form that needs to be signed by the participants. If necessary, the informed consent will be adjusted for each subsection of this phase. From this phase and onwards, the participants can be more actively involved in the project (if they wish to) and they can be informed more frequently about the project's progress.

7.3. Pilot Trials of the System

Goal: To test the prototype developed in practice with end-users in real life with older people in their natural environment(s) in order to adjust features, to improve user friendliness, effectiveness and the system's benefits for end-users' health status.

There will be a rich pilot application with the use of the system in three different scenarios, one per country. Scenarios include: 1) interaction of individual users with food retailer; 2) interaction of institutions supporting users with food retailer; and 3) interaction with service provider. Together, the pilot phase will involve 110 participants from the 3 countries. In particular, the following scenarios will be covered: serviced apartments, nursing homes, day-care centres, home support and independent living seniors in the community (here two different use cases, one where seniors cook by themselves and another where they use a food processor for assistance). The demonstrator will also include a control group against which the results of Cordon Gris can be compared. (Project plan Cordon Gris).

The system will be deployed in each country and all users will benefit from its basic functionalities, getting meal plan suggestions that take into account personal characteristics, personal preferences, health background, affordability or season. Every trial participant will be able to obtain nutritional support from the system and will be able to use external devices beyond the main user interfaces, in

order to feed Cordon Gris with additional information. When integrated with a retailer in a given country, the system will be able to personalise the recommendations even further taking into account budget restrictions and the products' price and will be able to generate shopping lists.

After recruitment, people's complete mental and physical health status is measured to asses the before and after use of the product. Furthermore, this baseline health status will be of influence to the level and type of advice the Cordon Gris application will provide. Moreover, the participants will be provided with a basic training at the start on how to use the system. In addition, a technical help desk will be set up during these pilot trials to provide technical support wherever necessary.

Participants will be thoroughly informed, both written and verbally in a special information session for the recruited participants. After this session they will have enough time to consider the project and make their decision for participation. When participants agree to participate they will have to sign the informed consent form to ensure they have understood the anticipated risks and benefits that are attached to this research. Furthermore, the legal liabilities are clearly outlined, in particular for privacy and data protection.

8. Possible Risks

If there would be any risks for elderly people participating in the Cordon Gris programme, we suspect they could occur in either research part 2 or part 3. In this chapter we will describe the possible risks for these two research parts. Obviously, these possible risks will be explained verbally and written (informed consent form) to the participants before the start of the research.

In order to prevent risks for elderly people, who are participating in the Cordon Gris project beforehand, the following actions will eliminate risks:

- The ethical roadmap identifies possible risks and take appropriate measures before entering the field, before including participants and before starting the project's main activities (outlined in the following).
- After the completion of work package 2 (WP2) the end-users of the Cordon Gris project will be defined in detail.
- A regular update on the progress of the project, regarding ethics will confirm or redefine the target end-users and project's activities. This update will be performed once every six months.
- After the field trial phase a detailed description of target end-users will help to eventually eliminate emerging or still existing risks of the project.

By this means, the project eliminates all possible existing and emerging risks and thereby ensures optimal market implementation.

8.1. Development phase

Possible risks for this research part can be: mental stress for lack of knowledge in the mobile device technology. Mental stress or frustrations due to the mobile technology can occur, especially when end-users face difficulty with familiarising themselves with the technology. It is important for researchers to be aware of this fact and ensure people on an individual basis if they face difficulty, this is normal and would happen to individuals from any age group. Furthermore, these people will receive extra training where necessary, leading to a development in mobile technology skills. Consequently, these participants will be able to contribute much more during the development process, since they will be able to provide in detail feedback on the developed technology. In the end, these participants will perceive themselves and are experts of their age group.

8.2. Pilot Trials of the System

We would expect a higher exposure to risks in this research part, since the application will be tested and end-users will, if they so wish, follow certain nutritional recommendations that are advised by the system. The main prevention for these possible risks will be the complete mental and physical health assessment we will conduct at the start of the pilot trials. Such an assessment will identify the type of nutrition that fit best to the individual's lifestyle. During this assessment we will ask the participants about their conditions such as chronic diseases, CHD and mental illnesses, such as dementia or Alzheimer's disease. All these circumstances will be taken into account before starting the pilot trial. Thereby, the possible risk that remains is kept as low as possible.

In order to provide individuals with appropriate and personalised recommendations, possible risks concerning food intake need to be taken into account. By means of creating a profile, individuals can for

example indicate food allergies or food aversions. Thereby, food products containing those particular ingredients will be excluded in food and meal recommendations. Further, and most importantly users will only receive recommendations they can follow if they want to. This means that based on a user's profile, algorithm will figure out the most appropriate healthy and/or cost-effective products. Concerning the definition of a medical device (as defined by Council Directive 93/42/EEC and Directive 2007/47/EC), the Cordon Gris Consortium concluded that the product will not fall under the definition of a medical device. Our decision was inter alia based on the decision diagram "Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices" (p. 9). Since the line between medical devices and health are blurring, it is important to follow the definition of the manufacturer, as it is stated that "It is the obligation of the manufacturer to identify the boundaries and the interfaces of the different modules" (p. 18 of the guidelines). The product of Cordon Gris is intended to provide lifestyle services, in the form of recommendations, an individual can voluntarily decide to act upon. It will not include any form of prescription, whereby a doctor, dietitian or nutritionist would need to be included. This might be considered as not covered by the rules applicable to the Directive 93/42 EEC on medical devices, although they can indeed improve health and contribute to the prevention of diseases, yet, indirectly and not intended as main goal. Cordon Gris will provide food/meal recommendations, tailored to an individual's health status. One risk which need to be managed beforehand is the health profile of the target end-user. In order to avoid extreme cases and provide appropriate food recommendations the following primary end-users will be included/excluded:

Inclusion criteria:

- Seniors, aged 55 and older
- Seniors who are interested in receiving support and recommendation to create a healthy/cost-effective meal plan

Exclusion criteria:

- Seniors with severe health condition (including chronic diseases, as diabetes)
- Seniors who are not willing to have a meal plan set-up of six moments (breakfast, snack, lunch, snack, dinner, snack)
- Seniors who follow a prescribed or individually-chosen diet

In order to further eliminate the risks for secondary end-users (e.g. family members, friends, neighbours) the following activities will be undertaken:

- Ask questions to for example relatives who want to share a meal in order to prevent extreme cases (80+; particular diseases as diabetes, high blood pressure; following a particular diet (individual or prescribed)
- Inform primary end-user about possible risks of applying individual meal plan to relatives

Another risk involves the danger of users becoming dependent on using the system during the trials and for example improved their quality of life, independence, autonomy and personal finances. Further, a sudden or uncontrolled end of the trials might lead to inconvenience for senior participants or even a setback to their former eating habits. Therefore, it will be ensured that users of the trials can make use of Cordon Gris (and related services) after the project has ended.

Because the one of the features being tested is the ability of the system to produce high-quality recommendations, the Cordon Gris Consortium will apply the following when meals are not appropriate planned:

- Translate recommendation back to nutrition guideline and see whether faults emerge.
- Have recommendations checked by dieticians from United Kingdom, the Netherlands and Portugal

As during the trial only a prototype will be used, dietitians will be included in the phase for further support, for example, in case the system is not working as intended. This will be regularly checked, by means of controlling participants.

The remaining possible risks for the Cordon Gris application can be for example:

- Data breach
- Risks for *secondary end-user* during the trial phase (e.g. family members, friends, neighbours)
    - However, the following activities can be undertaken to eliminate risks:
        - Ask questions to for example relatives who want to share a meal in order to prevent extreme cases (80+; particular diseases as diabetes, high blood pressure; following a particular diet (individual or prescribed)
        - Inform primary end-user about possible risks of applying individual meal plan to relative

All the possible risks will be described in the informed consent form and will be discussed with the potential participants in a face-to-face session. After this session people will have enough time to consider their participation and to sign their informed consent form (or not). Moreover, we would like to stress participants can stop the trial at any time they feel like and Cordon Gris will follow-up on these participants in order to ensure no negative health effects will occur due to the Cordon Gris application.

9. Possible Benefits

In this chapter the possible benefits on an individual and societal level will be described.

9.1. Development phase

The benefit of participating in the survey and workshop is to have the opportunity to be part in further research of Cordon Gris that could participants' health status. The survey could lead to an increase in awareness of people's health status, eating habits and knowledge of technologies. The participants have the possibility to stay informed and thus remain involved in an innovative project. Already from an early stage of the project, Cordon Gris thereby actively promotes e-inclusion of all citizens, focusing on including older people, who are often excluded due to a lack of media competences. The project offers the chance for older people to become part of a fast innovating society.

For the development phase, potential benefits could be that participants thus learn more about new technologies and how to use them in practice. End-users could use their new gained skills by decreasing loneliness and having easier contact with their family and friends (social networks and other applications). Obviously, another possible benefit is that they will be able to use the Cordon Gris system once it launched on the market.

For the pilot trials we can expect significant benefits in people's health status and eating habits. The sole purpose of the Cordon Gris system is to improve the health status and eating habits. Therefore, the main possible benefits are an improved health status, empowerment to live independently and in charge of their own decisions, and awareness of their health status as well as of their eating habits. Additional side benefits could be for example, familiarity with mobile technologies.

Moreover, other benefits are a decrease in loneliness, due to higher knowledge in mobile technology and its application, such as social networking. It is easier for elderly people to stay in touch with their family members and for example participate in more e-health treatments. Furthermore, elderly people are in charge of managing their personal finances and thereby can save money.

9.2. Society

One possible benefit for society in general is that the Cordon Gris system promotes healthy ageing. In this case prevention is the keyword. The healthier and more aware people are while getting older, the fewer expenses they will have in terms of healthcare, living and social benefits. Additionally, when people are healthier while ageing they have the ability to independently live at home for a longer time, which is beneficial for society.

In general, it is important for society to compromise existing knowledge, regarding food and nutrition and communicate it in such a way that people can easily adapt the knowledge and are in charge of translating it in new and adapted behaviours: personalised food and meal recommendations.

In terms of the ripple effects of managing personal finances, elderly people are more likely to participate in the mainstream financial industry. Thereby, citizens are encouraged to manage and save money, and thereby be able to fully participate in society. Also, it promotes a healthy economy.

Cordon Gris therefore will promote:

a. Active citizenship
b. Social learning

c. Stimulation of the economy and
d. Contribution to the environment (for example reduces loss and food waste)

10. Reports

The dissemination and publication of the results obtained are two of the primary aims of scientific researchers. Publishing research results also involves a conflict between the privacy interests of individual participants and the need for free exchange between scientific experts. There are a number of good practice codes and regulations that guide the researcher in handling this conflict. For example, on issues previously discussed such as privacy, data protection and anonymity. The Helsinki Declaration in its latest version (World Medical Association – Declaration of Helsinki) states the following (WMA, 2008):

'Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.'

All partners in Cordon Gris will adhere to the Declaration of Helsinki. For statistical analysis, only data that are anonymous are used and results will only be published as summary statistics in order to prevent re-identification of individual participants. In the Cordon Gris project, reports will be situated with in the AAL programme framework.

11. Evaluation

Research ethics requires an independent evaluation of the research activities and its possible consequences. It is a matter of awareness and looking beyond the research objectives, to consequences for everyone involved and the possible impact. This aspect will be considered in the final evaluation of the Cordon Gris project.

Important institutes in the Netherlands on this issue:

Centrale Commissie Mensgebonden Onderzoek (central committee for people research)

Postbus 16302, 2500 BH Den Haag

+31 (0)70 340 6700

Parnassusplein 5

2511 VX Den Haag

www.ccmo.nl

Autoriteit Persoonsgegevens (Board for Personal Data Protection)

Postbus 93374, 2509 AJ Den Haag

For questions regarding personal data: +31 (0)900-2001-201

Prinsa Clauslaan 60

2595 AJ Den Haag

www.autoriteitpersoonsgegevens.nl

Important institution in the UK:

Information Commissioner's Office (ICO)

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Tel: 0303 123 1113 (local rate)

https://ico.org.uk/

Important institution in Portugal:

Comissão National de Protecção de Dados (National Commission for Data Protection)

Rua de São Bento n.° 148, 3°

1200-821 Lisboa

+351 21 39 28 400

https://www.cnpd.pt/

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