# Deliverable 1.2

## List of all risks and defines

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| **Project Number** | AAL 2017 – AAL -035 |
| **Project Name** | Ella4Life |
| **Duration** | June 1st 2018 – May 31st 2021 (36 Months) |
| **Coordinator** | Virtask |
| **Document ID** | D 1.2 |
| **Release Number /Date** | V3.0 June 2021 |
| **Checked and released by** | Patty-Lou Middel |
| **Document Type** | Report, Final |
| **Original Due Date** | V 1.0/1st July 2018 |
| **Dissemination Level** | Public |
| **Main Editor** | Ellen Steenmeijer (VIR) |
| **Contributing Partners** | VIR, HSL |
| **Reviewed by** | HSL |

| Version | Date | Changes | Name | Organisation |
|---------|------|---------|------|--------------|
| 1.0 | 2018-07-01 | Initial Creation | Dennis Kleinbussink | Virtask |
| | 2018-09-28 | Review | Alexey Andrushevich | HSL |
| 2.0 | 2019-09-25 | Review | Ellen Steenmeijer | Virtask |

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**Abstract**

This document will shortly go in to the management structure and set of procedures that ensures the management of the project is of high quality. In our Consortium Agreement we've described in detail how we assure the quality management within Ella4Life.

We will address risks that we might encounter. And if we encounter a risk, how we will respond to that. We'll pay special attention in that respect to Ethical Aspects and Data protection.

**Content:**

# 1 Quality Management

The whole management structure and set of procedures around it are directed towards assuring the achievement of the high-quality requirements settled for the project by its participants. In our Consortium Agreement we've described in detail how we assure the quality management within Ella4Life.

The quality assurance system applied in the Ella4Life project is to be reviewed considering:

- Formal internal review procedure by different consortium partners that will guarantee the quality of all documents.
- A Quality and Risk Management Plan to ensure the quality of all the project results.
- A highly adequate staff allocation for the tasks set in the project.
- Efficient collaboration tools, a combination between modern technologies, traditional media and personal contact.
- Regular online and face-to-face meetings.
- Peer evaluation of deliverables to monitor quality and progress of work

## 2 Risk management

Pilot project risks have the potential to affect project goals and pilot goals.

The project partners have defined risk as any event which is likely to adversely affect the ability of the project to achieve the defined objectives. Pre-defined procedures will be taken into account in order to minimise the possible occurrence of adverse events in the construction and deployment of the project.

The following risks and resolution strategies **for the project as a whole** have been identified. They are listed in the table below: (Probability (Prob) and Severity (Sev): 1...low, 2...medium, 3...high).

| Nr | Risk | Description | Prob | Sev | Resolution Strategy |
|---|---|---|---|---|---|
| 1 | Inadequate WP leading | A WP leader is not able to coordinate the tasks of the WPs. | 2 | 2 | Substitution of the WP leader by an adequate representative among other partners. |
| 2 | Lack of communication | Lack of communication between project partners. | 3 | 3 | The project coordinator will establish a proper communication process including regular meetings and progress reporting. With emphasises on managing expectations and listening. |
| 3 | Incomplete tasks | A task cannot be finished because of a lack of knowledge, time or resources. | 1 | 2 | The WP Leader or project coordinator allocates the tasks according to detailed and sincere skill profiles of the project partners. If tasks cannot be finished, the project partner has to report as soon as possible. |
| 4 | Delays | Participants are not able to meet the deadlines. | 3 | 3 | The WP leaders and Task leaders are responsible for engaging additional staff to manage the work load. To be flexible in the sense or to be creative in how to address things |

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| | | | | | in a different way to make up for 'lost time'. |
| 5 | Problems with national regulations and standards | Inconsistencies or changes in national regulations or standards can affect the project in any phase. | 1 | 3 | Regular monitoring of the relevant national regulations and relevant standards. The Covid-Pandemic required serious adjustments to the schedule and testing. |
| 6 | Changes of profitability aspects during Business Model development | Occurrences of new aspects and changes through time must be incorporated. | 3 | 2 | We constantly must monitor costs and pricing and what our competitors do in the market. Be very aware of our USP's and the CBR's and use that information to make the right decisions for the development of the system. |
| 7 | Data protection and data security impact | Data protection or security leaks could lead to an immediate removal of the system | 1 | 3 | Data protection and data security guidelines defined by GDPR will ensure that the risk of malicious misuse of the system by third parties is minimised |
| 8 | Overrun the Budget | The costs are higher than the budget. | 2 | 2 | Monthly monitoring of the development of the costs. We will stay budget neutral, since more hours have to be spent in phase 2 for the end users and business/marketing, but in phase 1 there was an underspending. |
| 9 | Too large project scope | The scope of the project is too large. | 2 | 3 | The project scope will be reviewed and adapted accordingly. |

## The following risks for testing with end-users have been identified:

| | Risk | Level | Impact | Contingency Plan |
|---|---|---|---|---|
| End-users enrolment | Drop-outs and the failure to attend the study. | Medium | Medium | A reserve list of potential users that meet the inclusion criteria will be constructed in each site. |
| Acceptance | The new technological solution does not match to the user's expectations in terms of comfort. | Low | Medium | The previous knowledge and experience of the partners will be used during the pilot evaluations to avoid any problem in respect to the end users. Moreover, during the pilot the participant will be specifically asked about the systems and any feedback provided will be delivered to the technical team for implementation. |
| Functionality | The system is unable to collect data. | Low | High | During the functional trials, the functionality of the system will be validated long before the system is used with potential users, this to ensure that the system is stable in terms of data collection, data processing and data analysis and presentation. |
| Feasibility | The participants are unable to use the system alone and unable to | Medium | Medium | The participants will require assistance in the beginning and detailed explanation to be able to operate the system alone. Personnel will explain the operation to the subjects; Participants will |

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| | operate the system. | | | also receive a written manual. |
| Usability | The participation of the users is low as participants do not regard the system to be useful for them. | Low | Medium | The validation sites have experience in conducting this kind of activities and they have direct links with end-users and stakeholders.

Devoted dissemination campaigns and publicity will be carried out before the start of the validation phase, to ensure a wide participation. Moreover, experts in gerontology, psychology and geriatrics will be involved to motivate the participants and avoid drop-outs. |
| | The participants do not think they will require such a system and therefore do not intend to use it. | low | medium | The system will be designed based on user needs as are expressed in the literature and based on the user requirements. Therefore we do not expect such a scenario. In the case it will occur, the teams will explain the usefulness of the system to the participants and show the many ways it can help in improving daily life. |

*Because of their importance we will elaborate on Ethical Aspects and Data Protection.*

## 2.1 Ethical Aspects

Ethical Issues strategy acts as points of reference for the implementation of all Ella4Life project activities and is shared by all partners and members of staff participating. Ella4Life addresses and closely monitors the following ethical issues identified:

a) **Anonymity:** End-users will provide private data on their daily routine, state health and so forth. As regards data protection information about the participants in the focus groups and interviews will be treated with respect to anonymity and without any kind of violation of personal data of participants. In any case, relevant national and EU legislative frameworks will be respected, with GDPR as a common framework of reference for participating countries, as well as the right to respect for private and family life and the protection of personal data (Article 8 ECHR, Articles 7 and 8 of the EU Charter).

b) **Addressing gender equality** at the level of senior participants in the research. The Ella4Life Consortium will give particular emphasis on how gender gaps should be handled.

c) **Addressing vulnerability and frailty** at the level of senior participants in the research. The independence of those affected decreases gradually, partly due to age and partly due to care.

In the often very complex nursing situations (medical-nursing, financial, psychological, social or institutional), the needs and rights of people in need of care must be at the centre of care, so that they take place appropriately, meaning in the interests of those in need of care. It is therefore essential that the care is based on the principles of human dignity, in order to meet the special attention and care needs. This was specifically the case during the COVID-pandemic, when strict rules and regulations were implemented to guard health and safety of all citizens. The consortium therefore agreed to respect and protect human dignity, including informational self-determination in line with the principles and case law of the European Convention of Human Rights and the EU Charter of Fundamental Rights. Also, the directives issued for ICT developments by the UN International Action Plan on Ageing will be followed strictly.

**Staff contact with seniors:** Given that the project activities involve directly participation of elderly, only persons already working or being authorized to carry on the research tasks will participate in the related activities. Staff of partners' organisations to be involved in these activities must be trained on elderly' rights and the data protection policy of their organisation. Appropriate reporting mechanisms and sources of support for any ethical issues encountered will be put in place Ella4Life Consortium. All participants will be asked for their informed consent to participate, based on an appropriate, detailed explanation of the process and use of information.

d) **Technical assistance systems will align to the human rights and the European Social Charter:**

- to enable elderly people who are in need of care to be part of society for as long as possible by enabling them to participate. They must be provided with information about services and facilities and about their use;

- to support elderly people in need of care, "to choose their way of life freely and to lead an independent life in their usual environment as long as they wish to do so" through appropriate housing adjustments and health care.

e) **Distributive justice and fairness in the access to the provided services** should be considered throughout pilot implementations and commercial launch. Providing a personal assistant to help older adults can only work if the aims and wills of the people concerned are taken into account carefully. The provided solution should be prepared to support people but not to incapacitate them.

## 2.2 Data protection

With the introduction of new technical assistance systems for the care sector, aspects of data protection and all its dimensions must be taken into account. Data protection, data security and the right to informational self-determination are central aspects that have to be considered together with the corresponding legal situation - in the most up-to-date version.
In the course of product development the following five principles must be observed:

1. **Data economy/data avoidance**: Only as much data may be collected as is absolutely necessary for the process (do not create data collections).
2. **Data storage:** Data storage must be limited in terms of fact and time and may only be performed as long as required to provide the service.
3. **Data transparency**: It must be clear at all times which data are collected by whom and what happens to them.
4. **Data sovereignty**: The user should have as much control over his own data as possible. If data storage is required, this should be done to the user as far as possible. Third parties may only get access to the data in exceptional cases.
5. **Data security**: Secure data communication and transmission of the data must be ensured.

Storage and processing of this data is not prohibited, but the applicable legal regulations must be observed. How can privacy issues be solved with this in mind and what should be considered in a special way?

- Define who may collect and use which data in the process: It must be specified - as contractually agreed as possible - which of the persons involved in the process may collect which data and in what form.

- Determining responsibilities and contact persons: It is essential to determine who is the main person responsible for collecting the data and who is the contact person for the customer. It should only be a process-responsible, in the sense of "One face to the customer", for the customer central contact person.
- Data protection risks may only be limited to the user: Even by storing the data on the terminal of the user, the data-gathering person cannot release himself completely from his (legal) obligations.
- Informed consent: Many of the critical data collections and uses (eg profiling and tracing) are possible if the user is informed in detail and in an understandable form. In particular, the presentation of usage information on the Internet offers many creative ways to present it understandably.
- Cloud services: Due to the difficult data protection situation, only cloud service providers from the EU should be used.
- Consent for required data: Consent to the use of data only applies to the data required in the process. Further data may not be collected - even if the consent of the user exists.
- Switch off the systems: It must be possible at any time to switch off the system or completely and permanently delete the collected data.
- Variability and scalability of the system: The services should be designed in such a way that it is possible to use a less personalized service with a low data input and then to step by step into a very individualized system by entering a lot of personal data. The user should be free to choose at any time how much data he enters or releases.

In addition, some peculiarities should be considered. On the one hand, it is important to precisely determine the distribution of roles and the visibility of the data collected and to take appropriate technical precautions. In addition, it is important to consider persons with "legal care" (formerly: guardianship), for example, in advanced dementia, separately. Here, the consent that their data is collected, further processed and possibly evaluated, regulated in advance by a power of attorney or be obtained from the legal guardian. This is also why we decided to not work with google: we develop our own systems, so we can guarantee the maximum of data security.

Ella4life will direct special attention to identify critical privacy and confidentiality requirements of data with respect to information flow security. The measurement, processing and storage of personal data are subject to the European Data Protection Directive and the respective national implementations thereof. These regulations will be taken into consideration in the project and its pilot implementations by any of the partner organisations. Additionally, the data protection directive for electronic communications 2002/58/EC and Article 8 of the European Convention on Human Rights have to be considered.

All partners work with end-users as well as with their informal caregivers according to high ethical standards. User participation targeted those groups of older adults that are legally capacitated and capable of giving informed consent.

In order to ensure a common level of data protection, the project coordinator set up a data protection agreement, incorporating the points raised above. Each partner signed such an agreement within the first three months of the project. Supervision over compliance was entrusted to the project board.
Every activity undertaken with the users will be fully compliant to the international and European and national privacy and data protection law. Therefore, previous to users participation, the relevant national ethics committee or/and relevant competent authorities got contacted and informed.

The following aspects were taken into special account in the data protection agreement:
Information provided to the end-users and their relatives include in language understandable to the participant or the representative:
- A description of the project and its aims.
- A specification of all partners and involved end-user groups.
- The system capabilities, the selection criteria, the evaluation procedure and the expected duration of the subject's participation.
- A description of any benefits to the subject or to others, which may reasonably be expected from the project, such as independent and more comfortable living.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. In fact, personal data and information of the persons that will participate in the validation process will be encoded in order to preserve anonymity.
- An explanation of whom to contact for answers to pertinent questions about their rights and privacy issues.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty.
- Informed consent will then be obtained from the participants and any payments, inducements or other benefits, if any and in accordance with national approved normative practice, to be given to the persons concerned, will be specified.

Integrity, Health, Safety and Accessibility of the person: safety protocols and procedures will be defined and used during user participation with the aim of preserving users' security.
Finally, privacy and dignity of the users will always be preserved as all the partners of the consortium will conform to the relevant EU legislation such as the Directive 95/46/EC9, Directive 2006/24/EC10, Directive 2002/58/EC11 and The Charter of Fundamental Rights of the EU12.

Since Medicine Men is a certified ISO27001 company, ISO/IEC 27001 requires that management:

- Systematically examine the organization's information security risks, taking account of the threats, vulnerabilities, and impacts;
- Design and implement a coherent and comprehensive suite of information security controls and/or other forms of risk treatment (such as risk avoidance or risk transfer) to address those risks that are deemed unacceptable; and
- Adopt an overarching management process to ensure that the information security controls continue to meet the organization's information security needs on an ongoing basis.