Acronym:	COTIDIANA
Name:	Mobile Patient-centred System to Improve Drug Trials and Care of Older-adults with Rheumatic Diseases
Call:	AAL Call 2020
Contract nr:	AAL-2020-7-146-CP
Start date:	01 April 2021
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D1.5 Project quality and risk plan

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Partners involved (leader in bold): **AICOS**, Definition12, Raffeiner, MUW, Pryv, UNL-NMS-CHRC
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[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	Associação Fraunhofer Portugal Research	AICOS	Research	Portugal
2	Definition 12 AG	Definition12	SME	Switzerland
3	Mag. Andreas Raffeiner	Raffeiner	SME	Austria
4	Medizinische Universität Wien	MUW	University	Austria
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6	Universidade NOVA de Lisboa	UNL-NMS-CHRC	User	Portugal

Revision history

Rev.	Date	Partner	Description	Name
1	04.05.2021	FhP	First draft	Joana Silva
2	13.05.2021	FhP	Added risk plan	Joana Silva

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Glossary

AAL: Active Assisted Living Association
AAL JP: Active Assisted Living Joint Programme
CMU: Central Management Unit of the AAL Joint Programme
Consortium budget: Refers to the allocation of all the resources for the activities of the consortium within the project. When referred to, it means the sum of all the individual budgets and grant agreements in the consortium.
DoW: Description of Work. It is made on the basis of Part B of the proposal, consisting of the technical description at the time of proposal submission.
NCP: National Contact Point for the AAL JP
WP: Work Package

List of figures

List of tables

Table of contents

1. Introduction

1.1. Important preliminary note

This document summarizes the most important aspects related with project quality management and risk plan. COTIDIANA partners will use this document to follow the procedures that will not only help them for work execution, but also guarantee quality. Nevertheless, the document does not replace the CODITIANA Consortium Agreement that all partners signed.

1.2. Scope of the document

The deliverable describes the quality plan for the COTIDIANA project. It is meant to be a tool available to each partner that, together with the *Project management plan*, is able to assist partners during the course of the project. According to instructions from the AAL Joint Programme (AAL JP), this document may be updated when needed during the course of the project.

In case of conflict between this document and the Consortium Agreement, the latter will take precedence.

2. Reports

COTIDIANA will produce different types of reports, prepared at different times, and for different purposes. The following sub-sections describe these reports, their periodicity and existing templates.

2.1. Official reports and templates

The consortium will create annual progress and financial reports about each calendar year of the project. These reports will be delivered up to 2 months after the end of the respective calendar year:

- Annual progress and financial report 2021 (M11)
- Annual progress and financial report 2022 (M23)

The template for this report is provided by AAL JP to the consortium.

2.2. National reports

Some national funding agencies require partners to produce reports about project execution at different points. These reports are responsibility of each individual partner and refer to the documents asked by each NCP in accordance with the respective National Grant Agreement. Partners will refer to the NCP to know about deadlines and templates to use in these reports.

2.3. Mid-term review

The mid-term review is mandatory for all the projects in the AAL JP. The review serves three main purposes: 1) to evaluate performance and the status of the project against the plan, 2) to provide an opportunity for project partners and AAL JP representatives to share experiences from further programme development, and 3) to provide an opportunity for the consortium to get feedback and fresh perspectives about the project along with new possibilities.
The mid-term reviews shall be scheduled for shortly after the end of the mid-term in the project. They shall be organised between the project coordinator, the CMU and the 'lead NCP'.
In specific cases, a final project review may also take place.
The reviews are non-public events. Two independent expert reviewers will eventually be contracted to assist in the review process. The review meetings are physical and typically last 4 hours. It is desirable for the project to be represented as broadly as possible, with a minimum of 1 (one) representative of each partner profile (R&D, Industry, End-user).
Below is the tentative schedule for the project reviews.

Tentative schedule of project reviews			
Review no.	Tentative timing, i.e. after month X = end of a reporting period	Planned venue of review	Comments, if any
1	After project month: 14	To be decided	Mandatory
2	Not later than project month: 28	To be decided	If required by the AAL JP CMU

There is a template for the mid-term review report, which made available by the Coordinator to all partners in due time.

2.3.1. Documents to submit prior to the review meeting

At least two weeks prior to the review meeting, the following documents should be submitted by the project:

- Updated agenda of the meeting
- Questionnaire about timing, consortium, etc.
- A publishable 1-2 page summary in a format that may eventually be used for the AAL yearly brochure. Permission to publish the summary or extracts from it should be made available.
- Other relevant material in electronic format, e.g. DoW, annual reports, deliverables, brochures, links to videos, etc.

One week ahead of the review meeting, an attendee list of consortium participants should also be available.

2.3.2. Materials to deliver during the review meeting

The project should deliver presentations on:

- Project structure, resources and management issues
- Project content issues—IT and technology perspectives, end-user perspectives, service- and business perspectives—that would enable the reviewer to do an assessment as required on the review form.

A printed copy of the presentation should be provided to the review team.

2.4. Closure phase

Within two months (60 calendar days) after the end of the project a Final Report will be submitted electronically to the CMU and the NCP of the coordinator, i.e. 'lead NCP'. The template for this report will be made available by the Coordinator to all partners in due time.

2.5. Report preparation and submission procedures

For each report, with the exception of National reports (see section 2.2) the project coordinator will send requests and/or reminders to the project partners, namely to WP leaders. Each partner will be asked to be responsible for and prepare their own reports (e.g. financial, effort, impact, activities). The coordinator will compile all the reports from the partners and submit the final version to the CMU.

3. Document handling procedures

The documents shared by the consortium shall have a common repository.
In order to ease the work flow and promote high quality, this section defines procedures for different stages of documentation preparation and acceptance.

3.1. File naming

The file naming standard will be the following:

Dx.x_DELIVERABLE_TITLE.FFF

Where:

- **Dx.x** refers to Deliverable number
- **DELIVERABLE_TITLE** refers to the title of the Deliverable
- **FFF** refers to the file format (doc, docx, pdf…)

3.2. Document edition

The responsible partner for each Deliverable is already defined in the DoW. For the remaining documents, the edition responsibility is as follows:

- Minutes of the GA meeting: Responsibility of the Project Coordinator.
- Minutes of working meetings (remote or in person): Responsibility of the partner organizing the meeting.

3.3. Document acceptance

3.3.1. Minutes

Minutes must be generally available within 15 (fifteen) days after the meeting. After the first release, partners involved will be allowed to revise, propose modifications or submit comments within the timeframe of 1 (one) week. Once having a final version, the document will be accepted as definitive by the hosting partner. A visual representation of the procedure is show on Figure 1.

Figure 1 Minutes acceptance procedure

3.3.2. Deliverables

The complete timing for the generation of a deliverable or report can go up to 2 months, during which it should follow the steps described below and in Figure 2.

- **Preparation and submission of the index** by the Deliverable responsible and sent to all. The index should identify partners assigned to and responsible for each section.
- **Reception of contributions and compilation.** The partners send their contributions to the Deliverable responsible, who will then compile all the contributions. This should be done up until 1 (one) month after the index was sent.
- **Last draft and first version.** Within 2 weeks after receiving all the contributions, the responsible partner for the Deliverable should make a first version available to the Project Coordinator and, when applicable, to the Technical Committee for review.
- **Edition of first version.** The Project Coordinator and, if applicable, the Technical Leader, will review and edit the version before circulation amongst all the partners. This must be done within 1 (one) week of reception.
- **Edition of final version and submission to the CMU.** One week after circulation among all partners, the Project Coordinator (and Technical Leader when applicable) will edit the final version with eventual comments received by the partners. The Project Coordinator will then submit the Deliverable to the CMU. The whole process will take a maximum of 10 days.
- If public, the Deliverable shall be made available in PDF format on the project website by the Project Coordinator.

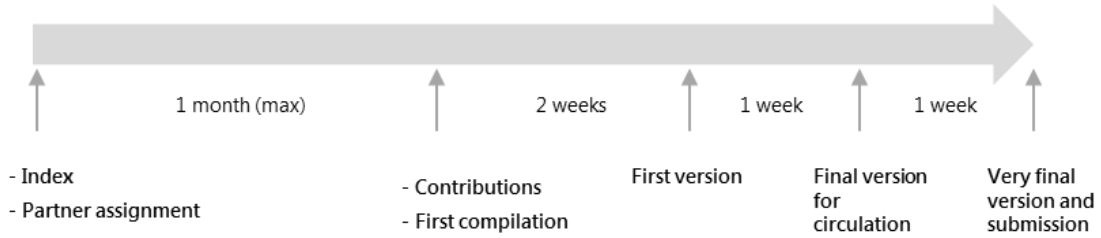

Figure 2 Deliverable preparation and acceptance procedure

4. Risk assessment plan

Through the preventive measures such as plans for shared documentation, and meetings every two weeks to enable Agile development, partners in COTIDIANA expect

to detect and act upon signs of risk at very early stages. As a starting point, the consortium has anticipated a number of technology-, management-, standardisation-, cost- and market-risks and has detailed ways in which they can be prevented and mitigated.

Table 1. Anticipation of possible risks and respective remedial actions

Possible risk	Impact	Prob.	Remedial Actions
Technical or scientific risks			
Reduced contact with users due to COVID-19	Lack of user involvement in user research, design or testing	High	**Prevent**: T2.1-T2.3, T3.1, and T4.1 will not be affected as they have been planned to occur in person or remotely. We would meet participants using remote tools, e.g., Zoom, or send them packages with equipment for data collections. **Abate**: Trials visits can be reduced to two: beginning and end of trial; with remaining data collection through the app.
Inadequate fit between the technology and field site or user conditions	Trial delays or need to ajust the technology	Low	**Prevent**: WP4 will define the configuration and adaptations for each site. A forecast of the environment characteristics, materials and equipment needed for the optimal performance of the trial for each location will be considered. **Abate**: If users' smartphones have unsupported old versions of Android, partners have a fall-back mechanism of providing smartphones to some participants. Field trial start can be delayed until validation trials.
Unusable data due to usability issues	Poor evidence and missed opportunity to assess technology acceptance	Low	**Prevent**: The system will be co-designed with stakeholders to be as user friendly as possible. Usability tests will remove potential issues prior to the pilots and training will ensure its use during the trial period. **Abate**: Use insights from the feasibility trial will improve usability and use passive sensing data collected anyway.
High drop-out rate during fieldtrials	Lack of robust evidence to demonstrate readiness to market	Med.	**Prevent:** WP4 planned multiple trials, one focused on testing and improving the solution, and two focused on validation, which increases the chances for collecting evidence. Moreover, trial sites will recruit 20% more participants to deal with potential drop-outs. **Abate**: Recruit more users and extend validation trials.
Difficulties recruiting enough users for field trials	Insufficient number of users for relevant evidence	Med.	**Prevent**: Preliminary analysis by each partner in the project about how many users they may bring to the project at each stage. Risk is reduced as MUW and UNL-NMS-CHRC have very large patient cohorts. **Abate**: The consortium will engage with Pharma to plan the drug trial validation aligned with drug trials from Pharma to achieve the highest impact.
Management risks			
Delays in project activities	Discrepancies between the plan and reality.	Low	**Prevent**: Internal periodical meetings and progress reports will let the coordinator know the state of the project and act. **Abate**: Identify possible deviations and correct any possible deviations according to Project quality and risk plan.

Work division issues	Discrepancies between partners or about the assigned work	Low	**Prevent**: Work assignment and related questions will be decided in internal meetings. Responsibility per deliverable is assigned in the DoW. **Abate**: Discrepancies between partners will be discussed in internal meetings and the final decision belongs to coordinator.
Partner withdrawal	Incomplete consortium	Low	**Prevent:** All partners' points of view and needs will be considered in project decisions. **Abate**: Partner will be replaced by one with similar skills, or its roles assumed from an existing partner in the consortium.
Commercialisation risks			
Changing regulations of certification	Difficulties to certify COTIDIANA	Med.	**Prevent/Abate**: Regulators, standardization organisations, and other relevant bodies will be consulted by RAFFEINER and Definition12, who will inform the consortium properly.
Poor fit to market due to differences between countries	Difficulties launching in multiple countries	Low	**Prevent**: Market entry will be performed in Austria, Germany, and Switzerland, markets our business partners know well. Other countries will follow with possible price adjustments, to be discussed during the project. **Abate**: Adjust business planning during the project and seek further funding for continuation while COTIDIANA is still ongoing.
No proper market key aspects evaluation	Lack of good positioning in the market	Med.	**Prevent/Abate**: WP5 will analyse competitors and market to strategically adjust positioning of the system. As the solution builds on partners' business services, market potential seems good, so this risk will be minimal.
Operational costs higher than expected	Wrong estimations	Low	**Prevent**: Estimate operational expenses each time the technology setup is changed and (re-)iterate business plan accordingly. **Abate**: Seek specialised counselling in the market as soon as estimates give signs of being wrong.