Acronym: ExerGetic **Project Title:** ExerG: An innovative digital solution to individually improve physical and cognitive functions using an exergame (video game-based) training in an ecologically valid and safe setting for the geriatric population **Call:** AAL Call 2020 **Contract nr:** aal-2020-7-48-CP **Start date:** 01 May 2021 **Duration:** 30 months

D1.3 Project Quality Plan

Nature¹: P Dissemination level²: PU Due date: June '21 Date of delivery: June '21 Partners involved (Coordinator in bold): **Sphery,** RHF, ZHdK, VASCage, RZM, HCIGG Author(s): Yanick Riederer (Sphery)

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)

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Revision history

Rev.	Date	Partner	Description	Name		
1	19.05.2021	Sphery	Create the document	Yanick Riederer		
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7	29.06.2021	Approved by Sphery				

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Glossary

AAL: Ambient Assisted Living Association

CMU: Central Management Unit of the AAL

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.

GCP: Good Clinical Practice

NFA: National Contact Point for the AAL

WP: Work Package

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1. Introduction

The objective of this document is to define a set of common operative procedures and rules in order to facilitate the collaborative work between the Consortium partners. Note that this document should not replace the AAL Grant Agreements. This document intends to clarify those concepts not specifically addressed in the DoW and/or agreed upon during the meetings.

1.1 Scope of the document

The deliverable describes the quality plan for the ExerGetic 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. This document may be updated when needed during the course of the project.

The document is important because it defines and establishes the main procedures to be followed by the Consortium. All the activities done in the framework of ExerGetic, documents delivered and written reports must be created according to accepted Quality Standards. This document intends to be a help tool, in addition to the procedures described in the DoW and the signed Grant Agreements.

Areas and issues not explicitly covered by this document are left to the discretion of the partners' project leaders. In case of conflict between this document and the contractual conditions written in the Grant Agreements, the latter will take precedence. In case of conflict between this document and the Consortium Agreement, the latter will take precedence.

2. Reports

There are different types of reports which are prepared at different times and for different purposes. The following subsections describe these reports, their periodicity and existing templates.

2.1 Periodic progress and annual central reports

A progress report shall be completed every six months and will be part of the Steering Committee meeting.

Annual central reports shall be completed after the end of the respective 12-month period:

- D1.5 Annual central progress report I (Feb '22)
- D1.5 Annual central progress report II (Feb '23)

At the end of the thirty months, this should be achieved by the central final report (D1.7). The templates for these reports are made available by the Coordinator to all partners in due time. More details on this report are described in D1.2.

2.2 Interim reports

This report is to be used to assess project progress, risks and allow forecasts. It will compile information from the project's first half. It will contain: progress of the work, financial interim statement, and project assessment. This document corresponds to:

• D1.6 Interim management report (M15)

2.3 National reports

This is a report of the sole responsibility of each individual partner and refers to the documents asked by each NFA in accordance with the respective National Grant Agreement.

2.4 Mid-term review

The mid-term reviews are mandatory for all the AAL projects. 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 representatives to share experiences for 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 (month 15). They shall be organised between the Project Coordinator, the CMU and the 'lead NFA'. The Project Coordinator will be reminded two months before the mid-term review by the CMU.

The reviews are non-public events. Two external reviewers will be invited to assess the status of the project and provide recommendations for the next phase. The review meeting

will be physical (if possible) and typically lasts 4 hours. It is desirable for the project to be represented as broadly as possible, with a minimum of one representative for each project partner.

Below is the tentative schedule for the 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: 15	To be decided	Mandatory
2	Not later than project month: 30	To be decided	If required by the AAL CMU

Table 1. Tentative schedule of project reviews.

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

2.4.1 Documents to submit prior to the review meeting

The Project Coordinator will provide at least two weeks before the review meeting:

- An agenda for the meeting
- A questionnaire on timing, finance, consortia, etc.
- Provide all other relevant materials in electronic form (e.g. updated DoW, Financial Plan, CA, annual reports, deliverables, brochures, links to videos, etc.)
- Replies to the online satisfaction survey (at least 1 reply per partner)

2.4.2 Materials to deliver during the review meeting

The project partners should present:

- Project structure, management and finance issues
- Project content
 - End-users' involvement process
 - Business model(s) and plans
 - Technology development/integration
 - Dissemination and exploitation activities
 - Project management update

All the information (templates etc.) regarding the mid-term review will be made available by the Project Coordinator to all project partners.

2.4.3 Report following the review meeting

The review report signed by the independent experts is sent to the Project Coordinator two to three weeks after the meeting. The Project Coordinator is requested to respond to the set of recommendations included in the report within three weeks.

2.5 Closure phase

Two external reviewers (same as for the mid-term review) will be invited to assess the status of the project and provide recommendations for the after-project phase. The reviewers will prepare a set of questions. The project consortium will be asked to replay during a two-hours teleconference call between the reviewers and the coordinator. All deliverables will be assessed. Additional materials can be provided (videos, app, access to website etc.). Furthermore, the project consortium must provide the final project report. The Project Coordinator will be reminded two months before the mid-term review by the CMU.

2.5.1 Report

Publishable Project Results Summary (1 page):

- resulting production/service
- needs/problems the product/service responds to
- targeted groups of users and payers
- technological innovation of the product/service
- social innovation of the product/service
- expected time to market

Confidential Part

- Deliverables submitted & milestones achieved during the project
- Scientific/technical project results
- Business models & indicators
- End-users' indicators
- Other indicators
- Financial information

The report will be submitted electronically within two months (60 calendar days) after the end of the project to the CMU and the lead NFA. The template for this report made available by the Coordinator to all partners in due time.

2.6 Report preparation and submission procedures

For each report, with the exception of National reports (see section 2.3) 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 Project Coordinator will compile all the reports from the partners and submit the final versions to the CMU. Apart from the reports listed above, each NFA may require specific scientific and/or financial reports.

3. Document handling procedure

It is essential that high quality standards for documentation and a well-defined procedure for correct handling are established. In order to ease the work flow and promote high quality, this section defines procedures for different stages of documentation preparation and acceptance.

The documents shared by the consortium shall have a common repository. As it is explained later in 3.4, a Google Drive space is used as a repository for shared documents and important material. The access is conveniently protected by secure access as the Consortium has access to the project folder. The partner responsible for the maintenance of this shared space is Sphery.

Appropriate templates to be used for the different types of reports, deliveries, documents and presentations are available from the repository and their use is compulsory for the entire ExerGetic activities.

3.1 File naming rules

Documentation and reports are important outcomes of ExerGetic project activity. The management and the quality of the generated documents are very important. In this section, it is defined the naming policy and rules to be observed by the partners for a correct identification and repository management. The naming of the deliverables will be as it is described in the following:

Dx.x_TTT(_Vy_AA).FFF

Where:

- **x** identifies the deliverable number to which the document is related (in this case Dx.x refers to the code in the list on DoW)
- **TTT** identifies the title of the document
- (_Vy_AA) identifies the version number of the document and the initial letters of its author. This part is optional and <u>not</u> mandatory.
- **FFF** refers to the file format (doc, pdf...)

The naming of the further documents (if appropriate) will be as it is described in the following:

WPx_TTT(_Vy_AA).FFF

Where:

- **x** identifies the WP number to which the document is related
- **TTT** identifies the title of the document
- (_Vy_AA) identifies the version number of the document and the initial letters of its author. This part is optional and <u>not</u> mandatory.
- **FFF** refers to the file format (doc, pdf...)

3.2 Document edition responsibility

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 consortium meeting: Responsibility of the Project Coordinator with the assistance from the WP leader.
- Minutes of working meetings (remote or in person): Responsibility of the partner organizing the meeting.
- Any other kind of document edition responsibility will be discussed and agreed by the concerned partners if not specified yet. By default, the responsibility will be suggested by the Coordinator.

3.3 Document acceptance procedure

This section establishes the complete documentation acceptance procedure: timing, responsibilities, steps to follow, etc.

3.3.1 Minutes acceptance procedure

Minutes must be generally available within three working days after the meeting. The responsibility for the Minutes edition is established above in 3.2. After the first release, partners involved will be allowed to revise, propose modifications or submit comments within the timeframe of 3 working days. Once the phase for modifications and inputs is completed, the document will be accepted as definitive by the hosting partner. A flowchart of the procedure is shown in **Figure 1**.

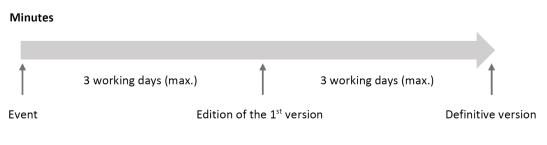


Figure 1 Minutes acceptance procedure.

3.3.2 Deliverable acceptance procedure

The responsible partners for the Deliverables edition are specified in the table of the DoW. The premises for a Deliverable document edition are:

- Deadline must be strictly adhered to.
- The responsible for the edition must organize the correct process.
- In case of problems, the situation must be reported to the responsible person as soon as possible.

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 contents** (By the deliverable responsible and sent to all) This must include the content details and the sections with assigned responsibilities to the concerned partners. Contributing partners are mainly identified in the DoW document and additional contributions could be asked for or suggested by the edition responsible.
- **Reception and compilation of contributions** (All sent to the Deliverable responsible). This must be done within a period of 1 month after the content generation. All contributing partners must be aware of this part and act proactively.
- **First version** (Deliverable responsible sends to predefined reviewers). Within one week after receiving all the contributions, the responsible partner for the Deliverable should make a first version available to the reviewers (normally one to two reviewers). Between all partners, reviewers will be previously assigned for reviewing the deliverable.
- Edition of the first version (Reviewers send it back to the Deliverable responsible and then to the Project Coordinator). When the review of the first version is finished, reviewers should send their feedback and corrections back to the Deliverable responsible. This must be done within one to two weeks (depending on the document size) of reception. The Deliverable responsible must perform the suggested adjustments if necessary. Then, the Deliverable responsible will share the reviewed version with all the partners. The partners will have one week to comment on the document.
- Edition of the final version and delivery to AAL (Coordinator sends the final version to AAL). After one week, the Project Coordinator would receive minor comments and finalise the document. The final version will be submitted on time to AAL. This combined process will take a maximum of 10 days.

Deliverables							
Î	1 month (max)	Î	2 weeks	Ť	1 week	1 we	ek
- Index - Partner assignment	t	- Contributions - First compilation		First version	Final	version for ation	Very final version and submission

Figure 2 Deliverables preparation and acceptance procedure.

3.3.3 Liability disclaimer

The editor shall insert the following liability disclaimer in all the Deliverables:

DISCLAIMER

The work associated with this report has been carried out in accordance with the highest technical standards and the ExerGetic partners have endeavoured to achieve the degree of accuracy and reliability appropriate to the work in question. However, since the partners have no control over the use to which the information contained within the report is to be put by any other party, any other such party shall be deemed to have satisfied itself as to the suitability and reliability of the information to any particular use, purpose or application.

Under no circumstances will any of the partners, their servants, employees or agents accept any liability whatsoever arising out of any error or inaccuracy contained in this report (or any further consolidation, summary, publication or dissemination of the information contained within this report) and/or the connected work and disclaim all liability for any loss, damage, expenses, claims or infringement of third party rights.

3.4 Document repository

A Google Drive repository has been set up to store all files and provide access to all ExerGetic members. Every member that has access to the repository is authorised to make changes within the files. Older versions of the files can be restored if needed and changes can be tracked. All the information related to the Project is stored in this space. **Figure 3** shows the structure of the "Working space" part. A specific folder has been created for each Work Package, where all the evolution of a document will be stored when the partners apply the naming and acceptance procedure described in previous sections.

Für mich freigegeben > AAL ExerGetic Project 👻 🚉						i
Name	\uparrow	Eigentümer	Zuletzt geändert	Dateigröße		
	Project	Alexandra Schättin	04.05.2021 Alexandra Schättin	_		
	Work package 1 (Coordination)	Alexandra Schättin	01.06.2021 Alexandra Schättin	_		
	Work package 2 (Concept, Focus groups, Implementation)	Alexandra Schättin	01.06.2021 Alexandra Schättin	-		
	Work package 3 (Usability)	Alexandra Schättin	01.06.2021 Alexandra Schättin	-		
	Work package 4 (Pilot RCT)	Alexandra Schättin	01.06.2021 Alexandra Schättin	-		
	Work package 5 (Dissemination)	Alexandra Schättin	01.06.2021 Alexandra Schättin	-		

Figure 3 Repository's folder structure.

4. Communication

In order to facilitate the internal communication between the partners, the Coordinator has organized a private Slack and Trello workspace to be used by all the specified users of the participant Organizations.

4.1 Slack

Within the Slack workspace, several communication channels were created to group the exchange platform according to different topics.

The following channels were already created (further channels will follow when needed):

- #general: This channel will work as the main communication line for general matters about ExerGetic. This list includes all the persons involved in the project.
- #consortiummeeting: A channel for project administration purposes. This channel includes all the persons that are part of the steering committee.
- #dissemination: Within this channel, the information about dissemination is collected.
- #deliverables: In this channel, links for the deliverables and reminders are sent for the review of all group members.

Main constraints for the use of the Slack workspace are:

- Only the persons indicated by each partner are allowed to use the list.
- Management corresponds to Sphery. For the updates of the users list, the partners must contact Sphery.
- Partners are asked to send a minimum number of files attached to the messages. They are encouraged to widely use the shared repository for file sending and management.
- Messages should be clear and should indicate, whenever possible, the WP to which they are related to.

4.2 Trello

On the Trello workspace, all WP's, its Deliverables and Tasks are listed in order to get a proper overview of the work that has to be done. ExerGetic members can be tagged on the specific Task or Deliverable they are working on and deadlines can be created.

5. Ethics

5.1 General ethical principles of ExerGetic

For the purpose of ensuring the quality of ethics, the ExerGetic project will uphold the following five 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: clearly communicating any potential risks to the 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 dialog with the persons constructively and transparently.
- 5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).

Apart from this, all members of the Consortium declare that the ExerGetic project will comply with the current legislation and regulations of the countries in which the research is to be carried out. Moreover, the project will comply with the *Declaration of Helsinki* (latest version October 2013).

5.2 Informed consent

Declared one of the most important principles in research ethics in many international conventions and guidelines, informed consent is meant to guarantee voluntary participation in research and is probably the most important procedure regarding integrity and privacy issues.

Informed consent consists of three important components: adequate information, voluntariness and competence. This implies that, prior to consenting the participation, participants should be clearly informed about research goals and procedures, potential risks and the possibility to refuse participation or withdraw from research at any time and without consequences. It's important that participants are competent to understand the information and should be fully aware of the consequences of their consent. Therefore, people incapable of making their own choices will not be approached for the ExerGetic project.

Participants will be asked for their informed consent by signing the informed consent document on the basis of the provided information. Numerous anthropological studies have pointed out that participants rarely recall what they agreed to when just signing an informed consent form. That's why a more interactive approach would be desirable and could address this issue (e.g. elaborating the written information and the informed consent document verbally).

In each phase of the ExerGetic project the respective information and informed consent needs to be adapted to the research goal.

5.3 Internal ethical review board

All the ethical issues should be supervised by an internal ethical review board. The supervision by an internal ethics committee should help to ensure the project's full adherence to the important ethical aspects. The internal ethical board has the following members:

- Sphery Alexandra Schättin & Yanick Riederer
- RHF Frank Behrendt
- ZHdK Anna Martin-Niedecken & Sonja Boeckler
- HCIGG Lennart Nacke & Katja Rogers
- VASCage Tina Henneken
- RZM Barbara Seebacher

All issues with an ethical content should receive first the approval of the ethical review board of ExerGetic. The internal ethics committee is especially responsible for:

- Evaluation and approval of inclusion and exclusion criteria
- Supervision of the recruitment process of participants
- Support of developing the informed consent document
- Evaluation and approval of rules for privacy and data protection
- Evaluation of potential risks and analysis of safety issues
- Approval of all documents containing ethical issues (especially reports)
- Supervision and support of the approval by the national ethical committees especially defining the timeframe for writing and submitting to the relevant authorities at the national level