MedGUIDE

ICT Integrated System for Coordinated Polypharmacy Management in Elders with Dementia

D5.1 Project quality control plan

Project acronym:	MedGUIDE
AAL JP project number:	AAL 2016-052
Deliverable Id :	D 5.1
Deliverable Name :	Project quality control plan
Status :	Final
Dissemination Level :	Public
Due date of deliverable :	M3
Actual submission date :	April 30, 2017
Author(s):	Lisa Seravalle, Martijn Vastenburg
Lead partner for this deliverable :	ConnectedCare Services b.v.
Contributing partners :	

Project partially funded by AAL Joint programme and "ZonMW" (NL), "The Research Council of Norway" (NO), "Federal Department of Economic Affairs, Education and Research/ State Secretariat for Education, Research and Innovation (SERI)" (CH), "Unitatea Executiva pentru Finantarea Invatamantului Superior, a Cercetarii, Dezvoltarii si Inovarii (UEFISCDI)" (RO) and "Research Promotion Foundation" (CY) under the Grant Agreement number AAL-2016-052.

VERSION HISTORY

Version	Authors	Date	Description
0.1	Lisa Seravalle, Martijn Vastenburg (CCARE)	23-04-2017	First full draft, distributed to all partners for input
0.2	Martijn Vastenburg (CCARE)	28-04-2017	Final draft, ready for review
0.3	Ionut Anghel, Tudor Cioara (TUC), Ritta Hellman (KARDE)	28-04-2017	TUC&KARDE reviewed version
1.0	Lisa Seravalle, Martijn Vastenburg (CCARE)	30-04-2017	Final version

TABLE OF CONTENTS

1 Executive summary 4
2 Project management structure 5
2.1 General structure 5
2.2 Roles and responsibilities of each ones 5
3 Continuous monitoring and improvement of project processes 8
3.1 Resolution of problems and conflicts 8
4 Risk Contingency Plan 9
5 Quality assurance plan 11
5.1 Definition of minimal quality standards for deliverables 11
5.2 Quality assurance process 11
6 Peer review process and communication 12
6.1 Peer review process 12
6.2 Tools, methods and techniques to communicate 12
Annex 1: Overview of deliverables 13

1 Executive summary

The project quality control plan document presents an overview of the project management structure, describing the roles and responsibilities of the consortium bodies – all in accordance with the Consortium Agreement. The document also establishes the foundations for the quality assurance process by describing the procedures for continuous improvement of project processes, risk contingency and peer review of project deliverables. To ensure the quality of project deliverables, the document provides a baseline for the quality expectations.

Annex 1 presents the list of deliverables, including the partner responsible for each deliverable, the list of reviewers for each deliverable, and the planned delivery date.

Acronyms used in this deliverable	
CCARE	ConnectedCare Services B.V
HU-UAS	Stichting Hogeschool Utrecht / Utrecht University of Applied Siences
IVM	Stichting Instituut voor Verantwoord Medicijngebruik
MAT	AgeCare (Cyprus) LTD – Materia Group
KARDE	Karde AS
VIGS	Vigisense SA
TUC	Technical University of Cluj-Napoca

2 Project management structure

2.1 General structure

The MedGUIDE project management structure is shown in figure 1 below.

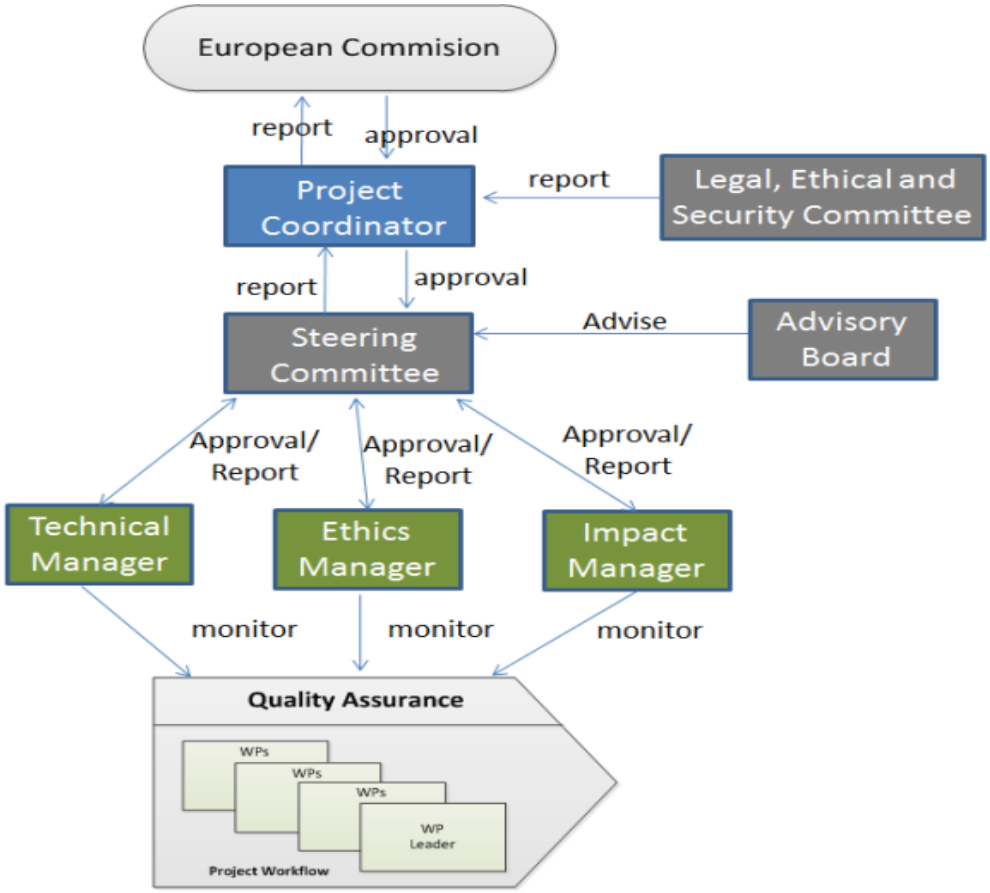

Figure 1: MedGuide project management structure (including bodies).

2.2 Roles and responsibilities of each ones

The **Coordinator**, dr. Martijn Vastenburg from CCARE, is the intermediary between the partners and the AAL2 JP CMU, and is responsible for:

- Overall legal, contractual, ethical, financial and administrative management of the consortium.
- Monitoring compliance by the partners with their obligations and the implementation of corrective decisions.
- Collecting, reviewing to verify consistency and submitting reports and other deliverables (including financial statements and related certifications) to the AAL2 JP CMU.
- Administering the community financial contribution and fulfilling the financial tasks described in Article 7.3 -General conditions of EU Grant contracts-.
- Providing, upon request, the partners with official copies or originals of documents which are in the sole possession of the coordinator when such copies or originals are necessary for the Parties to present claims.
- Preparing, updating and managing the consortium agreement between the partners.

The **Scientific and Technical Manager**, dr. Tudor Cioara from TUC, is responsible for ensuring that the conduction of the work will follow the plan. Main tasks are:

- Coordination of the overall scientific and technical operational activities of the project.
- Ensuring the high scientific and technical quality of reports and deliverables submitted to the AAL2 JP CMU.
- Consortium level coordination of knowledge management and innovation-related activities.
- Reporting and monitoring of the progress of work packages covering scientific and technical issues to the Steering Committee and the Coordinator.
- Ensure the translation of scientific, technical, practical requirements into technical solutions.

The **Impact Manager,** dr. Martijn Vastenburg from CCARE, leads the general dissemination and exploitation actions of MedGUIDE, in order to maximize the exploitation potentials for project results. Specific tasks are:

- Meet regularly with representative of each partner to define, coordinate and update a collaborative exploitation and dissemination plan. Identification of conferences, magazines and journals for dissemination.
- Coordination of dissemination activities like a brochure or the project web site.
- IPR definition and data maintenance and harmonization of the projects' policies.
- Evaluation and coordination of the effort required to develop marketable products.
- Release of a business plan covering one or more preferred models concerning the partnership in the exploitation, the organization, the royalties, the market estimates and risks.
- Market analysis, key stakeholders and commercialization channels identification for successful market outcomes of project results. Planning of exploitation strategies and joint initiatives.

The **Ethics Manager,** pof. dr. Helianthe Kort from HU-UAS, monitors project ethics and is responsible for:

- Defining the project's daily ethical guidelines (code of conduct) to be followed by all researchers and practitioners participating in the project.
- Supervising the process of applying for ethical approvals from national ethics boards and committees, according to each participating country's research ethical regime, appropriate and necessary for the project's topic.
- Supervising the process of making all necessary self-declarations and the like, in each participating country vis-a-vis national rules and regulations for data security arrangements and that of handling person(-al)/sensitive data, and privacy.

The **Steering Committee** (SC) is composed of one representative for each project partner. Chaired by the Coordinator, the SC addresses all strategic issues and is responsible for decision making. The SC has periodic meetings to review the project progress, achievement of deliverables and milestones, review resource planning and results and resolution of any issues. The Scientific and Technical Manager, Impact Manager and Ethics Manager are part of the SC. The SC is responsible for:

- Checking / ensuring that the progress of the work meets the project functional requirements.
- Supporting the Coordinator in preparing meetings with the AAL2 JP CMU and in preparing related data and deliverables.
- Monitoring the effective and efficient implementation of the project.

- Collecting information at least every 6 months on the progress of the project and examining it to assess the compliance with the consortium plan and, if necessary, proposing modifications.
- Preparing the content and timing of press releases and joint publications by the consortium or proposed by the EU Commission in respect of the procedures of the EC-GA Article II 30.3.

The **Advisory Board** (AB) is a board with a direct link to the MedGUIDE management team and is recruited from accessibility research platforms and initiatives, as well as from dementia elders associations and representatives. The advisory board is consulted at each critical step within the project, in technical aspects and in issues where commercial exploitation and standardization of the project results are addressed. The committee will remain actively involved during the life of the project, as a key holder between the project and end-users. It is planned to have industry partners from the targeted application domains (potential early adopters) to promote exploitation and commercialization.

A **Legal, Ethical and Security Committee** is formed, chaired by a designated project Ethics Manager, who will work with the project Steering Committee to ensure that all necessary local ethical approvals are obtained. One of the aims of this committee will be to ensure that researchers' interactions with end-users are ethical and that best practices ethical management has been applied.

3 Continuous monitoring and improvement of project processes

The technical, ethics and impact managers will monitor the MedGUIDE procedures and outcomes on a regular basis along with the WP leaders, taking any action (if needed) on the moment. When issues scale up or a joint effort must be done by the consortium, the steering committee is the body where the contingency actions will be decided.

Informal skype meetings regarding ongoing activities in the work plan have been also arranged, about every 6 weeks in order to keep all consortium partners up-to-date with ongoing project activities, and to make sure all partners are involved in the day-to-day collaborative project work.

A physical **plenary meeting** will take place twice a year, where all the work done will be presented, and future plans will be discussed. In particular, the plenary meeting will be used to track the status, progress and quality of all the processes, and to discuss and align the direction of upcoming activities.

Minutes will be made of all steering committee meetings and plenary meetings. The minutes will summarize the information discussed, and will highlight the decisions taken to improve the quality of the project, along with an specific list of actions points, responsible and deadlines. The Coordinator will circulate the minutes of steering committee meetings and plenary meetings to the consortium to be approved by all partners and will monitor the completion of all suggested action points.

3.1 Resolution of problems and conflicts

The consortium recognises that the resolution of problems and conflicts must be handled systematically. Identification of any conflicts which arise in the project is the responsibility of all project participants. Any signs of disagreement between project participants should be notified to the WP Leader. If the WP leader is unable to resolve the conflict the Scientific, Technical and Impact Managers (as appropriate) are notified, to instigate the conflict resolution procedure, escalating to higher levels only if necessary (see Figure below). In particular:

(1) The notified manager should separately contact all parties involved either in person or by telephone, to identify the different viewpoints. It is important not to use email: that medium very often leads to a rapid escalation of disagreements. Based on a clarification of viewpoints, the notified manager should try to propose a solution. If a solution is achieved, it should be recorded in a short report; if not, no documents should be produced, and the problem should be escalated.

(2) If step 1 fails, the matter should be taken up by the project management board (steering committee). At this level, all work should be in writing. If necessary, partner representatives will be required to vote on the issue. The steering committee will take the final conflict resolution decision which will be communicated to the involved parties.

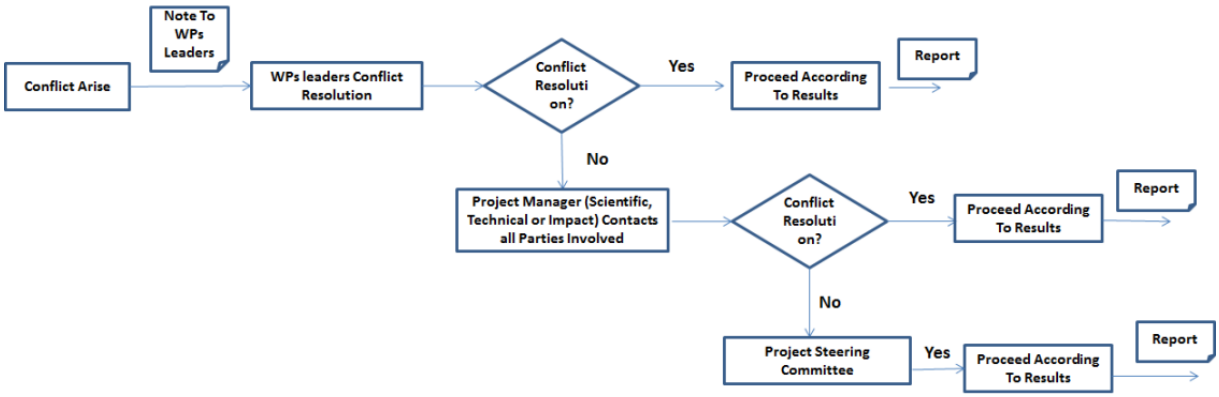

Figure 2: MedGuide Conflict resolution workflow.

4 Risk Contingency Plan

Risk management in the MedGUIDE project will be enacted through an iterative cycle of: (i) Identifying risks, (ii) Analysing risks, (iii) Managing risks and (iv) Monitoring risks. The consortium has approached the risk management by carefully defining WP structures and tasks to clearly indicate responsibilities and identify the potential risks. Milestones and deliverables were set up carefully to monitor, identify and analyse risks, including those which may arise during the project lifetime. Additionally, the risk management process will be continuously monitored and supported by this project quality control document throughout the whole project; updates to the risk table below will be included in periodic progress reports whenever relevant. Preliminary risk analysis was performed and the following potential risks were detected:

Risk	WPs	Contingency Plan/ Mitigation actions
Technological and implementation risks		
MedGUIDE services are not available or interfacing problems are detected	WPs 1-3	Define interfaces, check consistency and low coupling of system architecture in WP1. Adopt independent services testing methods and integration guidelines in WP3. Verification of interfaces. Teleconferences and face to face meetings.
Understanding phase does not provide results in desired quality level or completeness.	WPs 1,4	High-level engagement of end users. Employment of user centric design methodology. All categories of user will be continuous involved. KARDE, IVM and MAT will increase the opportunities for user feedback, informal validation and evaluation cycles in next development phases.
Poly-pharmacy management techniques not effective	WP 2	Involving partners providing dementia and polypharmacy knowledge in innovation development. Organize regular meetings with technical partners to track progress against milestones, and to assure successful knowledge transfer.
MedGUIDE monitoring infrastructure doesn't provide expected data	WPs 2,3	Focus on off-the-shelf sensors and wearable devices. Where sensors are to be installed as part of the project a timeline for their activation and delivery of data should be established.
Shortage of resources and/or change of personnel	WP 5	Make binding agreements on the availability on resources. Keep close contact with all partners. Early communication of budget and personnel problems. If necessary, redefine goals and responsibilities.
Lack of communication among the partners	WP5	Keep close contact with all partners by organizing regular teleconferences, virtual meetings, plenary and technical meetings at different partners' sites.
Incompatibility with platforms that are likely to be used by end users.	WPs 1-5	The software modules are designed to be used on multiple platforms. To avoid incompatibility, manual code optimization is minimized; compiler capabilities are used instead. Testing of required 3rd party libraries for compatibility / support before selection for project.
The prototype does not match end-user requirements and business models	WPs 2-4	Involve end-users and domain experts in the definition of requirements and exploitation plans. Early feedback from piloting evaluation. Revision of project requirements with end-users. Revision of suitable business models with community and end-users.
Poor engagement of end-users in pilots	WP 3	Secure a high number of end-users since the proposal phase. Conduct pilots in seven different sites. Engage end-user (elders, doctors, etc.) through specific enablement, empowerment and education actions carried out continuously.

Field trials deployment and success indicators assessment problems	WP 3	Engage 3 end-user partner organization in the project. In extreme case in which some integration issues are identified close to the end of the project, either a shift of emphasis or reduced functionality may be considered. All ICT components will be initially tested in-lab environments and then in 2 trials in end-user homes.
Dissemination not effective	WP 4	Dedicate enough resources to dissemination. Dissemination planning. Monitor and evaluate the dissemination results.
Commercialization and market uptake risks		
New legislative barriers reduce MedGUIDE viability	WP 4	Caregivers' representatives and user related partners will provide a continuous link to legislative bodies to be informed at an early stage about any barriers.
MedGUIDE fails to produce targeted improvements in quality of life of elders with dementia	WPs 1-5	The exploitation and business plans show significant opportunity for cost savings and also the consortium has the right expertise and experience to deliver this. Employ a user centric design approach. System will be pilot in home environment of elders to obtain relevant feedback on usability, effectiveness and scalability.
MedGUIDE system do not achieve the requestedmaturity for market uptake	WPs 1-5	Develop the system reference implementations on the basis of lower level technologies. The consortium will seek for new standardization by contacting other potential market or partners and/or industrial developers.
MedGUIDE pricing strategy doesn't correlate with brand and technology position	WP 4	Initial business plan and price estimation was conducted. Estimated costs of MedGUIDE will be continuously revised. Conduct cost benefit analysis for MedGUIDE features. Define MedGUIDE suites with less functionality and lower price. Use penetration pricing for attracting customers and gaining market share.
Lack of standards, privacy and security concerns	WPs 2,3	MedGUIDE will use standards in the area of cloud computing and also plans to be a contributor to standards. Greater involvement of partners with connection with standard committee/bodies. Build around ethics policies defined in section 3.4.
New products and technologies may emerge making MedGUIDE outdated	WPs 1-4	Continuous evaluation of dementia care and polypharmacy products and technologies available on the market. Action to incorporate new emerged technology in the MedGUIDE product. Change/adaptation of specification the address new technologies.

5 Quality assurance plan

The purpose of this Quality Assurance Plan (QAP) is to control the quality of all deliverables (documents and software) that must be submitted to the AAL CMU. The plan describes the expectations which have to be met in order to ensure the quality of the deliverables.

The Scientific and Technical Manager is responsible for the quality control process. All participants in MedGUIDE project are committing to perform the work to a high standard.

The QAP is intended to be used by the authors of the deliverable, by the appointed reviewers and by the Scientific and Technical Manager. For each deliverable, a responsible partner has been assigned (see Annex 1). This partner will make sure the ready-for-review version of the document is presented to the internal reviewers in time. The list of internal reviewers is also shown in Annex 1. The internal review will be performed by project Coordinator and two competent partners for each deliverable.

5.1 Definition of minimal quality standards for deliverables

The MedGUIDE deliverables should meet the qualities specified below:

(1) Each deliverable should meet professional standards.
(2) Each deliverable should meet the expectations as set out in the CA.
(3) Each deliverable should be handed over at the time specified in Annex 1.

5.2 Quality assurance process

The quality assurance process for deliverables consists of quality checks at two levels:

(1) Internal reviewing of each deliverable by the Coordinator and two appointed partners.
(2) Internal monitoring of the review process during plenary meetings.

The Scientific and Technical Manager can propose improvements to the process at any time during the project.

6 Peer review process and communication

6.1 Peer review process

To ensure the quality of deliverables, as described in chapter 5, a **peer review process** has been established. Two partners not involved as key contributors to the deliverables have been appointed as reviewers, taking into account the number of reviews per partner and timing (to avoid overloading partner). The list of reviewers per deliverable can be found in Annex 1.

For written deliverables the following procedure has been stablished:

- **14 days** before due date: lead contributing partner sends final draft to Coordinator and appointed review partners
- **7 days** before due date: feedback from Coordinator internal reviewers provided to the lead contributing partner
- **2 days** before due date**:** feedback from reviewers and Coordinator has been incorportated; the document is sent by lead contributing partner to reviewers and Coordinator for approval
- **Submission to CMU in time by the Coordinator**

Partners shall use the deliverable template as provided by the Coordinator for deliverables and presentations. Templates and all draft and final versions of the documents will be shared with the consortium using the project cloud drive.

6.2 Tools, methods and techniques to communicate

Document properties are shown on the title page and/or the header/footer of the document. Properties shall be updated to reflect the document status during document creation.

The first page of the document includes Logos of MedGUIDE project, AAL JP project number, project acronym, project full title, document name and other document properties:

- Project acronym
- Project number
- Deliverable Id
- Deliverable Name
- Status
- Dissemination Level
- Due date of the deliverable
- Actual submission date
- Organization name of lead partner responsible for this deliverable
- Author(s)
- Contributing partners

Annex 1: Overview of deliverables

ID	Title	Responsible partner	Type	Diss level	Due month	Reviewer 1	Reviewer 2
D1.1	1st version of end-user requirements and specification	**HU-UAS**	**R**	**PU**	**4**	**MAT**	**CCARE**
D1.2	1st version of MedGUIDE system architecture, user interfaces and services design	**KARDE & CCARE**	**R**	**PU**	**10**	**HU-UAS**	**VIGS**
D1.3	Final version of MedGUIDE system architecture, user interface and services design – improved based on first trials results	**KARDE**	**R**	**PU**	**14**	**IVM**	**TUC**
D2.1	Social network-based monitoring and information sharing service – 1st release	**CCARE**	**R/P**	**CO**	**12**	**KARDE**	**IVM**
D2.2	Activity and Polypharmacy Monitoring Service – 1st release	**KARDE**	**R/P**	**CO**	**12**	**CCARE**	**HU-UAS**
D2.3	Big Data Assessment Service – 1st release	**VIGS**	**R/P**	**CO**	**12**	**MAT**	**KARDE**
D2.4	Dementia Care and Polypharmacy Management Service – 1st release	**TUC**	**R/P**	**CO**	**12**	**VIGS**	**HU-UAS**
D2.5	Polypharmacy management knowledge base	**TUC**	**R/P**	**CO**	**12**	**IVM**	**CCARE**
D2.6	Social network-based monitoring and information sharing service – 2st release	**CCARE**	**R/P**	**CO**	**22**	**MAT**	**VIGS**
D2.7	Activity and Polypharmacy Monitoring Service – 2nd release	**CCARE**	**R/P**	**CO**	**22**	**TUC**	**HU-UAS**
D2.8	Big Data Assessment Service – 2nd release	**VIGS**	**R/P**	**CO**	**22**	**MAT**	**CCARE**
D2.9	Dementia Care and Polypharmacy Management Service – 2nd release	**TUC**	**R/P**	**CO**	**22**	**HU-UAS**	**KARDE**
D2.10	Refined polypharmacy management knowledge base	**TUC**	**R/P**	**CO**	**22**	**CCARE**	**HU-UAS**
D2.11	Social network-based monitoring and information sharing service	**CCARE**	**R/P**	**CO**	**28**	**VIGS**	**MAT**
D2.12	Activity and Polypharmacy Monitoring Service – final release	**CCARE**	**R/P**	**CO**	**28**	**TUC**	**HU-UAS**
D2.13	Big Data Assessment Service – final release	**VIGS**	**R/P**	**CO**	**28**	**MAT**	**CCARE**
D2.14	Dementia Care and Polypharmacy Management Service – final release	**TUC**	**R/P**	**CO**	**28**	**CCARE**	**MAT**
D2.15	Final polypharmacy management knowledge base	**TUC**	**R/P**	**CO**	**28**	**KARDE**	**MAT**
D3.1	MedGUIDE Wizard of Oz 1st evaluation in controlled environment	**KARDE**	**DEM**	**PU**	**12**	**IVM**	**CCARE**
D3.2	MedGUIDE system prototype – 1st release	**VIGS**	**P**	**CO**	**16**	**TUC**	**KARDE**
D3.3	MedGUIDE system prototype evaluation in controlled environment	**IVM**	**DEM**	**CO**	**18**	**MAT**	**HU-UAS**
D3.4	Field Trial evaluation feedback report – 1st release	**HU-UAS**	**R/DEM**	**CO**	**20**	**KARDE**	**CCARE**
D3.5	MedGUIDE system prototype – 2nd release	**VIGS**	**P**	**CO**	**22**	**TUC**	**CCARE**
D3.6	Evaluation feedback report – 2nd release	**MAT**	**R/DEM**	**CO**	**26**	**HU-UAS**	**IVM**
D3.7	Final release of the MedGUIDE system prototype and evaluation report	**MAT**	**R/P**	**CO**	**30**	**CCARE**	**KARDE**
D4.1	MedGUIDE website	**CCARE**	**OTHER**	**PU**	**3**	**VIGS**	**IVM**
D4.2	Dissemination plan	**TUC**	**R**	**PU**	**12**	**HU-UAS**	**KARDE**
D4.3	Intermediate business plan/model	**CCARE**	**R**	**CO**	**15**	**VIGS**	**IVM**
D4.4	Exploitation plan	**KARDE**	**R**	**CO**	**15**	**VIGS**	**TUC**
D4.5	Final business plan/model	**CCARE**	**R**	**CO**	**30**	**KARDE**	**VIGS**
D5.0	Code of Conduct	**HU-UAS**	**R**	**CO**	**6**	**CCARE**	**IVM**
D5.1	Project Quality Control Plan	**CCARE**	**R**	**CO**	**3**	**TUC**	**KARDE**
D5.2	First Year Report	**CCARE**	**R**	**CO**	**12**	**KARDE**	**TUC**
D5.3	Mid-term review questionnaire	**CCARE**	**R**	**CO**	**15**	**KARDE**	**VIGS**
D5.4	Second Year Report	**CCARE**	**R**	**CO**	**24**	**HU-UAS**	**MAT**
D5.5	Final Report	**CCARE**	**R**	**CO**	**30**	**VIGS**	**TUC**