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Abstract	This deliverable is presenting the exit strategy developed within CAMI in order to minimize any negative impact which might result in the end of the project because of its termination. The following actors involved in the project were considered: • Exit strategy for end-users • Exit strategy for end-user organizations • Exit strategy for solution developers • Exit strategy for universities

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1 Executive summary

Aim of the deliverable
The aim of this deliverable is to present the exit strategy developed within CAMI in order to minimize any negative impact which might result in the end of the project because of its termination.
Brief description of the sections of the document
In the context of the CAMI project, the exit strategy defines not only a good end of the project, but also the continuation of the solution after the end of the project on a commercial, but also non-commercial basis. Within the CAMI project, the consortium sought an exit strategy to minimize a potential negative impact of the project termination for the actors involved in the project: • Exit strategy for end-users • Exit strategy for end-user organizations • Exit strategy for solution developers • Exit strategy for universities
Major achievements
Different mitigation plans have been proposed for the end-users in Poland, Denmark and Romania. Data handling after the end of the project is also considered in this document.
Summary of the conclusions obtained
In Poland the plan is implementing a strong preventive approach because STOCZNIA is lacking the capability to offer end-user support after the CAMI's ending. In Denmark and Romania the users are offered with various alternatives of continuing, at least partially, the usage of the CAMI devices and services. At the same time, the end-user organizations have also foreseen strategies to reduce the financial impact at the end of the project. The university partners have sought solutions for the PhD students involved in CAMI to be able to finalize their PhD studies also after the end of the CAMI project and financing.

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4 Introduction

The end-users involved with the CAMI field trials may become dependent on the support they receive from the CAMI platform. End-users may become accustomed to the special attention and services they receive during the project and thus, the project termination may itself create problems. The aim of Task 3.3 was to design and implement a strategy that prevents any negative effects of involving end-user in the field trials.

Such a strategy must consider long-term aspects, influences and impact of the project, it must cover as many bases as possible, it has to observe and be in-line with previous work, including work done in previous projects, and it must ensure that it opens up new avenues or research and practice, including business-related. Moreover, the exit strategy intends to capitalize on the work done in the project and, intrinsically, it must synthesize or bring together, all the lessons and project's achievements.

Also, our aim was to provide adequate closure for all stakeholders, *i.e*., individual participants and the parties in the projects, such as end-users (including formal and informal caretakers), research

individuals, groups and entities, and business entities. While, this proved a difficult task, several discussions have taken place on the topic and the consortium will continue to collaborate towards finding solutions for the involved parties.

5 Mitigation plan for primary and secondary users

The trials which took place in CAMI are described in D3.4. The services developed in CAMI were tested with primary end-users (seniors) as well as with informal (family members, friends) caregivers. The pilot trials took take place in real home environments in Romania, Poland and Denmark in two stages. Towards the end of the second stage, the CAMI consortium has explicitly discussed possible situations/cases of user dependencies, for both of users and caretakers. The discussions took place in the form of consortium virtual meetings, with the participation of all parties. End-user organizations have presented the perspective of the elderly and caregivers involved in the trials while seeking answers from the technical partners regarding a possible continuation of the CAMI platform usage after the end of the project and until it becomes available on the market. A mitigation plan presented below was proposed for each country involved in the trials.

In Poland, there is no technical partner who could provide the necessary technical support in case of further use of the system by users. STOCZNIA, the only Polish partner, does not have such competences and also does not take part in the business implementation of the solution after the completion of the project. Therefore, no continuation of the CAMI usage is foreseen until it because commercially available in which case STOCZNIA will consider developing a support strategy for the CAMI users based on the experience which STOCZNIA has accumulated during the CAMI project.

However, STOCZNIA strives to identify and minimize the negative risks associated with testing of the solutions. First of all, all participants before being tested are informed about the nature of the test, with particular emphasis on the fact that the use of tested solutions is temporary. Also the testing time itself is relatively short (max. 15 days), which further reduces the potential risk of dependency.

In addition, all users are straightforwardly asked not to give up the parallel monitoring of their health (during the test) the same way they have done so far. After completing the tests, the time is devoted to thoroughly discuss the experience of using the equipment and address any questions, doubts or possible discomfort associated with completing the tests along with, if needed, discussing an alternative way to meet their needs related to health monitoring (e.g. reminders available in the Google calendar application, the possibility of buying a FitBit device or weight scales / blood pressure device with the online history of measurements on the market)

The risk of dependency is also minimized on the recruitment level. It is ensured that senior users, who take part in the tests, in accordance with the project assumptions, are not predominantly dependent on external care. Also, they are recruited in tandem with their caregivers, so they are people who have support on a daily basis, which they will not be deprived of after the testing ends.

In Denmark, a special agreement is set for the Danish test participants, that all evaluated devices and services may be kept by the participant in perpetuity (that is, the equipment need not be handed back), requiring them only to report on findings over time at their own discretion. However, the CAMI consortium can only guarantee that all online CAMI services and in-house devices will continue working for two years past deployment at the participants home of the prototypes, following the general Danish product warranties, and general ethical guidelines. Also, all consortium members are obligated to support the national consortium members with hosting and support to support the end-users.

In Romania, all CAMI users involved in the pilot studies were informed that, if they are interested in continuing using the platform until a commercial version is available, CITST will aid them in

purchasing the devices at no additional cost (zero profit for CITST). In case that they cannot cover these costs, individual strategies will be sought for each user (e.g. renting the devices from CITST, payment in installments). Users of CAMI will be asked to report on findings over time at their own discretion. The CAMI MPV services (data acquisition and processing) will be negotiated with UPB such as to find a solution for the interested pilots participants. However, due to the GDPR regulations which came into force towards the end of the CAMI project, additional data handling strategies need to be implemented which will imply additional time and costs for CITST and/or UPB. Solutions such as the possibility of obtaining and exception from the Romanian Data Protection officer have been considered. Another possible option presented to the participants was that they use the software for data processing provided by the manufacturer of the devices. For example, FitBit is providing its own app for data visualization. Also the A&D blood pressure and pulse meter can be purchased with its own interface.

Among the Romanian CAMI pilot participants, two primary users have expressed their interest to continue the use of the CAMI platform. They are husband and wife and thus living in the same household. They already own some of the CAMI MVP devices (blood pressure meter, PIR sensor). They are willing to purchase the weight scale and two FitBit activity monitoring sensors. However, they would like to use only one blood pressure monitor and one weight scale for both of them and not have to use them sequentially as during the trials. This issue will be considered in the future development of the CAMI product.

6 Privacy and data protection

An important issue which was discussed as part of the CAMI exit strategy is what will happen with the data collected during the trials. As stated also in the CAMI project proposal, the CAMI consortium partners agreed that all collected data will be discarded a year after the project is finalized. After disposal, data will not be recoverable and the risk of data disclosure will be minimized. Data protection mechanisms and procedures against such risks as loss or unauthorized access, destruction, use, modification or disclosure of data will not expire until the data will be destroyed.

The data collected during the field trials is in compliance with Directive 95/46/EC which became superseded by the General Data Protection Regulation (EU) 2016/679 (GDPR) which entered into force in towards the end of the CAMI project, *i.e.* May 2018.

To protect privacy of personal data under processing of data in CAMI, the project follows EU directive 95/46/EC legislation to regulate data in both public and private bodies, for both automatic and non-automatic data processing. Under EU law certain rights of data owner will be guarded as well as ensuring personal data protection in high standard regardless of existing conflicting data protection and challenging of globalization of new technologies with respect to businesses, public authorities and individuals transferring vast amounts of personal data across borders.

In the scope of Directive 96/46/EC, related to security and protection of personal data is any information relating to identified or identifiable natural person (“data subject”) directly or indirectly to one or more specific physical, physiological, mental m economic, cultural or social identity on the free movement of such data; (art. 2a).

The notion processing means “any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaption or alteration, retrieval, consultation, use, disclosure, by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction; (art. 2b).

The responsibility for compliance will be “the controller” meaning natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and

means of the processing of personal data; where the purposes and means of the processing are determined by national or Community laws or regulations, the controller or specific criteria for his nomination may be designated by national or Community law; (art. 2d).

'Third party' means any natural or legal person, public authority, agency or any other body other than the data subject, the controller, the processor and the persons who, under direct authority of the controller or the processor, are authorized to process the data; (art. 2f)

All personal information will be handled also after project ending by three major principles: ***Transparency, legitimate*** and ***proportionality.***

- ***Transparency*** means, the owner of data has right to be informed when his/her personal data are being processed. The controller must provide his/her name, address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair (art. 10 and 11). Thus, the data may be processed based on followed circumstances (art 7):
    - After given consent from data subject
    - By essential needs of data processing for the performance or the entering into a contract
    - Needs for processing of compliance with a legal obligation
    - Needs for processing of data to protect the vital interest of the data subject
- The data subject has the right to have access to all data processed about him/her. The data subject even has right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or is not being processed in compliance with the data protection rules; (art 12).
- Processing is also necessary for the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject. However, personal data can only be processed for specified, explicit and ***legitimate purposes*** and may not be processed further in a way incompatible with this purpose. Further processing of data for historical, statistical or scientific purpose shall not be considered as incompatible; (art. 6b).
- Personal data must be processed fairly and lawfully; (art. 6a).
- To fulfill ***proportionality principal***, personal data must be accurate and where necessary, kept up to data; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purpose for which they were collected or for which they are further processed, are erased or rectified; (art. 6c).
- Extra restriction will be applied by sensitive data processing based on specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards; (art. 8).

User's safety

To ensure users' safety also after the end of the CAMI project, the CAMI platform includes innovative tools for personalized health monitoring for individual patient by patient dashboard. Further, patient dashboard visualizes for each patient their captured health measurements beyond of state of the art medical and sensor devices. With this direction, patient dashboard ensures user safety in terms of the foreseen software as personalized guidance with an overall overview over patients' health

measurements by using of CE marked devices that are developed in EU directive rules and framework. The methodologies behind of this ICT tool is reflection of recent EU project as REACTION [1] and PICASO [2] as novel mHealth approaches.

CAMI platform embraces many components including both hardware and software that will assist self-management of chronic disease to elderly citizens so that patient's safety and risk management will be focused based on software risk management process compliant with ISO 14791 as part of EN/ICE 62304 standards for medical devices software to provide a better control and specifically risks that should be addressed in the developments life cycle. In this context, all processes, activities and tasks involved in development of components will be identified and described fully in the relevant and specified deliverable.

One another principle that is compulsory for patient safety in field trail, is the basis of appropriate plan of test with respect to ethical approved informed consent that needs to be signed (either digitally or in paper) by patients. Furthermore, Patient may revoke his/her consent if the test procedures are not in suitable for him/her.

To capture fully trust of CAMI's end users, the platform enables flexibility to its software to support several devices such as smartphone (iPhon or Android), iPad or tablet, Personal computer, in a way of the best convenient for the end-users and in such a way as to the end-users's safety by allowing usage of their own selected devices.

This flexibility will not include Robotic tools in CAMI for end users with respect to followed ISO 13482, safety standard on robot and industrial robot's standard for machine dependent (ISO 10218-1).

EU- standard regulation on personal care robots tailor specifies necessary requirements for inherently safe design, proactive measure and information for use of personal care robot the following three types of personal care robot: mobile servant robot, physical assistant robot, person carrier robot.

ISO 13482:2014 covers human robot physical contact applications as well as hazards description of each robot type. The rules include robot's movements speed, water -born, flying robot, industrial robot robots as medical devices, military or public care application robot.

The general principles for risk assessment and risk reduction will be assessed in CAMI platform by means of safeguarding or proactive measurements by medical tools with CE standards to diminish adverse system events for the patients.

ISO 14971:2007, medical devices-application of risk management to medical devices will be obtained in CAMI services to comprise tasks for:

- risk analysis +risk evaluation+ risk control
- Evaluation of overall residual risk acceptability (risk-benefit balance)
- Risk management report
- Production and post production information (Monitoring)

7 Exit strategy for end-user organizations

The end-user organizations involved in CAMI were responsible for the end-user involvement during the whole duration of the project. An exit strategy is needed such that the end of the CAMI project will not impact negatively their relationship with the end-users involved in the field trials. In this context, the two elderly wishing to continue using the CAMI platform in ***Romania*** will be offered free of charge support for 1 year with a possible continuation for a second year. Given the need to (a)

implement specific data protection privacy to obey the GDPR; or (b) to obtain an exception from the Romanian Data Protection officer; and to (c) reach agreements with the CAMI consortium partner, it is expected that the CAMI platform usage will start in the second half of 2019. Until then, CITST will offer support to the end-user for employing the native software of the devices.

In ***Denmark***, the exit strategy of ECO in keeping good relationships with its users is to offer them the possibility to keep the devices used in the trials. Financial wise, ECO has engaged in new projects to compensate for the ending of CAMI.

In ***Poland***, STOCZNIA will ensure continuation of good user relationships by ensuring that the users are aware about the limited possibilities of STOCZNIA in providing support after the end of the CAMI project. Nevertheless, the reception of the project (positive or negative) by the users involved in the field trials may potentially affect the image of STOCZNIA. This potential risk is minimalized by taking care of the relationships with all types of stakeholders, relying on transparent, partner principles. A space for honest and open feedback is provided along with comprehensive information about the project. The risks identified by the Polish partner for its own organization relates more to the financial aspects involved with the termination of CAMI. First of all, participation in this type of project (long-lasting with entirely external financing) has a noticeable effect on the stability of organizations such STOCZNIA (medium-size NGO). The ending of the project is therefore noticeable and requires proper preparation. This risk was recognized from the beginning and appropriate actions were taken to counteract both in the area of personnel management and financial liquidity. STOCZNIA has diversified sources of financing and is constantly actively acquiring new projects, which allows to ensure stability both at personal and financial level.

8 Exit strategy for solution developers

The end of the CAMI project will impact the further development and support for the CAMI platform. This should not be the case when aiming to bring the CAMI platform and associated services on the market in 2 years after the project completion. Thus, an exit strategy is needed for the CAMI solution developers. Moreover, the exit strategy has to also address the issues related to offering on-going support after end of project if the solution will be used by some of the users involved in the pilots. In the case of CITST, the following aspects were considered for the exit strategy from solution support and development point of view:

1. Is there staff available to provide support for the users who chose to continue to use CAMI's services? Is their staff available to provide constant updates?
2. Is there funding for the activities outlined at point 1? How can funding be procured?
3. What level of funding is required to enable such activities?

Identified issues to be solved for the elderly wishing the continuation of the CAMI usage are the following:

- availability of staff to offer support for CAMI services (SLA – service level agreement);
- financial resources for service and updates;
- data privacy and security;
- agreement with other CAMI consortium partners
- Production and post production information (Monitoring)

9 Exit strategy for universities

The university partners in the CAMI consortium have involved PhD students in the research carried out within the project. However, given the time span of the project, most of the students did not finalized their PhD by the end of the project. Thus, MDH and UPB have actively south additional funding. Currently, both universities have financially covered the last 1-1.5 years for the work of the students involved in CAMI through either multinational (MDH) or national grants (UPB). For example, Ashalatha Kunnappilly is currently continuing her research with funding from the CelticPlus (Dec 2018 – Nov 2021) program within a project involving, like CAMI, eHealth applications "Health5G – Future eHealth Powered by 5G".

10 Conclusions

In the context of the CAMI project, the exit strategy defines not only a good end of the project, but also the continuation of the solution after the end of the project on a commercial, but also non-commercial basis. Within the CAMI project, the consortium sought an exit strategy to minimize a potential negative impact of the project termination for the actors involved in the project:

- Exit strategy for end-users
- Exit strategy for end-user organizations
- Exit strategy for solution developers
- Exit strategy for universities

Different mitigation plans have been proposed for the end-users in Poland, Denmark and Romania. In Poland the plan is implementing a strong preventive approach because STOCZNIA is lacking the capability to offer end-user support after the CAMI's ending. In Denmark and Romania the users are offered with various alternatives of continuing, at least partially, the usage of the CAMI devices and services. At the same time, the end-user organizations have also foreseen strategies to reduce the financial impact at the end of the project. The university partners have sought solutions for the PhD students involved in CAMI to be able to finalize their PhD studies also after the end of the CAMI project and financing.

Data handling after the end of the project is also considered in this document.

11 References

[1] http://www.reaction-project.eu/news.php

[2] http://www.picaso-project.eu