SAFECARE

Integrated cyber-physical security for health services

Deliverable Name

Deliverable 2.4

Lead Author: EOS

Contributors: All Partners

Deliverable classification: (PU)

Version Control Sheet

Title	*D2.4 Initial Quality Plan*
Prepared By	*Klaudia Tani*
Approved By	
Version Number	*V0.3*
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Revision History:

Version	Date	Summary of Changes	Initials	Changes Marked
V0.1	09/10/2018	1st draft	KT	KT
V0.2	24/10/2018	Internal review	JF	JF
V0.3	26/10/2018	Revision after review	KT	KT

Contents

LIST OF FIGURES

LIST OF TABLES

List of Acronyms	
AB	Advisory Board
EAB	Ethics Advisory Board
D&C	Dissemination and Communication
DoA	Description of Action
GA	Grant Agreement
KPIs	Key Performance Indicators
QM	Quality Manager
SAB	Security Advisory Board
WP	Work package

Figure 1 - List of Acronyms

The SAFECARE Project

Over the last decade, the European Union has faced numerous threats that quickly increased in their magnitude, changing the lives, the habits and the fears of hundreds of millions of citizens. The sources of these threats have been heterogeneous, as well as weapons to impact the population. As Europeans, we know now that we must increase our awareness against these attacks that can strike the places we rely upon the most and destabilize our institutions remotely. Today, the lines between physical and cyber worlds are increasingly blurred. Nearly everything is connected to the Internet and if not, physical intrusion might rub out the barriers.

Threats cannot be analyzed solely as physical or cyber, and therefore it is critical to develop an integrated approach in order to fight against such combination of threats. Health services are at the same time among the most critical infrastructures and the most vulnerable ones. They are widely relying on information systems to optimize organization and costs, whereas ethics and privacy constraints severely restrict security controls and thus increase vulnerability.

The aim of this project is to provide solutions that will improve physical and cyber security in a seamless and cost-effective way. It will promote new technologies and novel approaches to enhance threat prevention, threat detection, incident response and mitigation of impacts. The project will also participate in increasing the compliance between security tools and European regulations about ethics and privacy for health services. Finally, project pilots will take place in the hospitals of Marseille, Turin and Amsterdam, involving security and health practitioners, in order to simulate attack scenarios in near-real conditions. These pilot sites will serve as reference examples to disseminate the results and find customers across Europe.

Introduction

This Deliverable focuses on presenting the rules and guidelines to assure quality of the SAFECARE deliverables as well as material produced by the project to external stakeholders. Specifically, in the first section the Consortium presents "Quality Management" as a concept and how it will be implemented. Additionally, the targets which need to be reached by the authors of the documents and material are out.

The second section presents the responsibilities per partner type. Since SAFECARE is comprised of 21 partners with different roles within the project, all parties are involved in the quality assurance process but in different ways. What it is also explained in this process is how the Security officer, Security Advisory Board (SAB) and Ethics Advisory Board (EAB) are also involved in the process.

Thereafter, the following section is divided into two linked processes, the deliverables and the dissemination material quality management process. Here the Consortium presents in detail the process which will be followed for the whole life cycle of the project to assure maximum quality. The last part of this deliverable presents the Key Performance Indicators (KPIs) with which the quality of the outputs will be measured with.

Deliverable 2.4

Within this deliverable, the consortium draws specific guidelines to be followed through the life span of the project in terms of procedures to achieve maximum quality of the project outputs. This first iteration of this document will be based on experience in past projects which have achieved the appropriate objectives. Furthermore, the Consortium will also present the templates to be used consistently internally but also for external dissemination and communication purposes.

The most important aspect of this document is the drafting of the initial Key Performance Indicators (KPIs). These indicators have a scale starting from satisfactory to non-satisfactory and do not only include requirements for the authors of documents, but also question for the internal reviewing process of SAFECARE.

This document receives, amongst others, inputs from:

- The SAFECARE Grant Agreement (GA)
- EU Grants: H2020 AGA — Annotated Model Grant Agreement – ARTICLE 19 – Submission of Deliverables
- Deliverables related to Data Protection and Privacy.

Quality Management

Quality Management principles are considered vital for the production and validation of project outcomes and dissemination material. Project Quality Management includes all the activities and intermediate monitoring undertaken by the responsible parties to reach high quality project objectives. To achieve appropriate quality, SAFECARE has introduced certain standards which will be measured against the quality KPI's.

Quality Targets

The metrics used for the quality identification of SAFECARE material and outputs will range on a qualitative "yes" or "no", the former presenting the acceptability of the KPI and the later the need for improvement. If no, then the author is required to make changes.. More details on the QM process will be thoroughly mention in Sections:

Key roles and responsibilities. This process thus aims to achieve:
- o   High quality outputs as the Consortium assumed in detail in the DoA;
- o   Create a homogeneous approach internal which will embrace consistency through the project;
- o   Showcase SAFECARE to external stakeholders in a consolidated manner and with common messages.
- o   Assure delivery of project output in a timely manner.

Key roles and responsibilities

For the purposes of this process in this section we are presenting the role of each consortium partner in addition to the roles of the Advisory Boards (AB). It is crucial that Consortium partners understand their role in his process and embrace the responsibility from the beginning of SAFECARE. Mitigation risks are also presented in the Section *Quality Risks and Mitigation Actions*.

Type of partner	Role	Reports to
Project coordinator: APHM	Final receiver of Deliverables: The project coordinator receives all relevant material from the Quality Manager (QM) for final submission. The Coordinator makes the final adjustments, if necessary, to the text and material produced by partners.	European Commission
Quality Manager (QM): EOS	Intermediary receiver of Deliverables: The QM creates the delivery process with the contribution of all partners. The QM assures the implementation of this process and report to the Coordinators should delays in delivery occur. Additionally, the QM is the only partner that will review all RESTREIN UE deliverables before submitting.	Project Coordinator and Management Board
Project Security Officer (PSO)	The party submits all RESTREINT UE deliverables to the EC: The PSO will inspect all the deliverables that are security sensitive and give inputs to the Consortium if further amendments or additions to the text are needed. Also, any presentations to the public that are based on content shall be inspected by	Independent to the Consortium

	the PSO for sensitivity and classified information.	
Security Advisory Board (SAB)	Provides suggestions to the Consortium regarding deliverables related to security: The SAB provides input related to classified material as well as security issues being / have been raised during the project.	Independent
Ethics Advisory Board (EAB)	Provides suggestions to the Consortium regarding deliverables related to ethics: The EAB provides input related to deliverables including ethical components and issues being raised during the project.	Independent
WP leaders	The leaders of the SAFECARE 8 WPs are responsible for: - Consistency within their WP; - Definition of a 6 months work plan to align outputs of their WPs with others; - Regular updates and transparency within the WP; - Ensure timely delivery of results; - Communicate delays and re-adapt the work plan; - Participate in WP leader meetings and provide regular updates.	Project Coordinator
Task leaders	The SAFECARE Task Leaders are responsible for:	WP leaders Project Coordinator

	- The successful implementation of theirs Tasks; - Coordination and communication amongst contributing partners; - Successful delivery of Task objectives; - Provide regular updates to WP leaders.	11
Deliverable leader	The SAFECARE Deliverable leaders are responsible for: - Successful and timely delivery of their reports; - Coordination of deliverable contributors and assignment of contributions; - Create a 6 month timeline for timely submission; - Delivering the document for review to the internal reviewers and the QM; - Assign further contributions, if necessary, after the internal reviewers report; - Inform the Coordinator and QM for possible delays; - Inform the Coordinator and QM about underperforming partners.	Task leader WP leader Project Coordinator Quality Manager

Table 1 – Partner Responsibilities

Quality Management for Deliverables

In this section the process from the drafting to the delivery of written outputs and other material will be described in detail. The roles described in the Key Roles and Responsibilities Section are interlinked and their responsibilities are explained further.
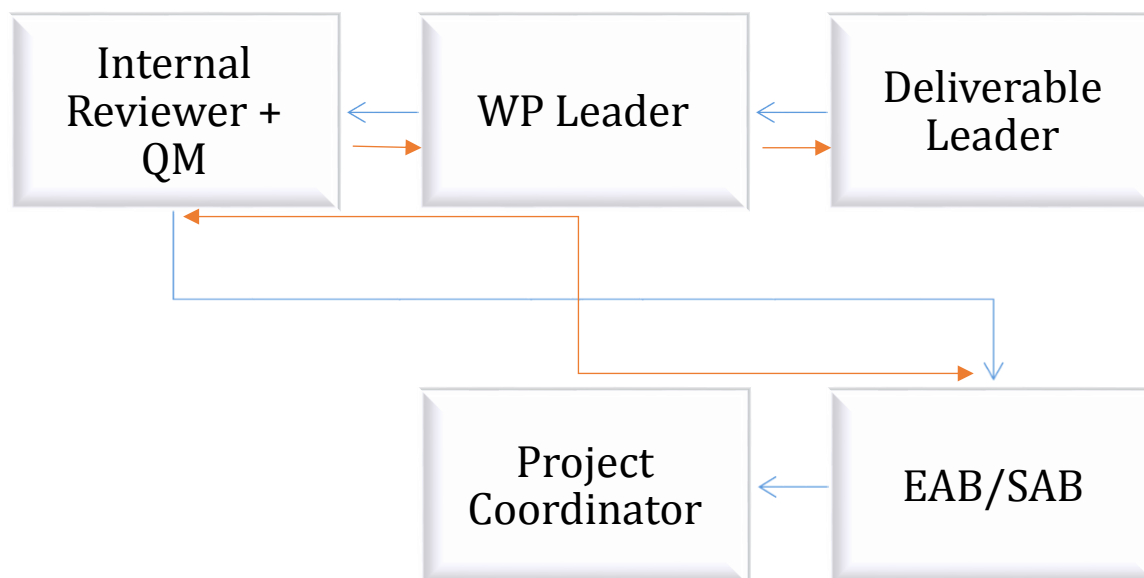

Figure 2 – Quality Management Process

The process commences with the **Deliverable leader**, who - as mentioned - has the responsibility to assign contributors, create a timeline for on time submission and communicate any difficulties faced during the writings process to the Project Coordinator and QM. The Deliverable leader, whether an individual or an organization, has a delivery date specified in the Description of Action (DoA) which must be met. That deadline is the starting point for planning the actions to achieve the deliverable objectives that must happen in conjunction with the **WP leader** to avoid miscommunication and duplication within the WP.

The Deliverable leader has to send the outline of the deliverable to the **Internal Reviewers and the QM**, 25 days before submission. 10 days before the official submission of the deliverable the Deliverable lead must send a full draft to the Internal Reviewers and the QM. In the case that the deliverable contains ethics or security issues, the deliverable has to be sent to the Internal Reviewers and the QM, 30 days and 14 days before submission respectively.

The Internal Reviewers and the QM have 7 and 5 days respectively to provide the authors with a Deliverable Review Sheet (DRS), which is provided by the QM. A copy of this template is located in Annex 2 –Deliverable Review Report. Depending on the comments/feedback received the author has 3 days to implement the changes and submit a final version to the **QM and Project Coordinator** for final checks.

Quality management for External Material and Dissemination

Due to the sensitive nature of SAFECARE, the Consortium has decided to implement a standard approach to Dissemination and Communication material, including key messages. These will be thoroughly explained in D8.1 Dissemination and Communication Strategy (D&C). The D&C lead and the QM are from the same organisation, EOS, which will monitor the compliance to the quality standards set in this document, but also in WP8.

According to the DoA, partners will not only organize certain events that will assure SAFECARE exploitation, but also attend different scientific, technical and policy activities. For this purpose SAFECARE needs to obtain a common, reliable and exploitable brand. To achieve such a brand representation, material which are produced for this type of activities will have to follow certain criteria.

Except from the templates which have been produced by the QM in terms of Deliverables and Presentations, the WP8 lead will create flyers, roll-ups and eventually the website to compliment these activities. Further to that, the impact of these activities will be measured by the WP8 lead and depending on that the partner will receive further material, if deemed necessary. The reasons for concentrating the production of such material is consistency.

Additionally, all workshop invitations and data protection and management of participant information will be managed by WP8 always with the guidance of KUL, the partner responsible for such activities. This will allow the consortium to follow a standard process for activities involving external stakeholders in terms of messaging, but also handling of personal information. The data management aspects are expected to be integrated in the second version of this deliverable.

The SAFECARE lexicon

To achieve a consolidated vision throughout the consortium and establish a brand, it is crucial for the project to create a lexicon of common language and definitions used in the area of healthcare. Partners will be called upon to propose common definitions used in their stakeholder groups and after consulting with the Management Team, SAFECARE will present a list with the 2nd iteration of this deliverable. A few key definitions will include: critical assets, critical infrastructure, criminality and crisis management among others.

Key Performance Indicators (KPIs)

The KPIs within SAFECARE are separated between two categories a) Format Review and b) Content Review. The format review contains the editing, phrasing and structure of the document as well as its adaptation to the template. The Content Review is the content style of the document, writing stale, coherence, methodology and factual components.

Format review – What should exist in the document	Yes Completely Agree	Agree	Partially Agree	No Disagree	N/A	Comments
Deliverable number and title on the front page and on the header.						
Grant Agreement number						
Lead Beneficiary (and the people involved) and Contributing Beneficiaries (and people involved)?						
Dissemination level						
Release history table						
Table of contents						
List of tables						
List of figures						
List of acronyms						
Executive Summary						
Introduction						
Conclusion						
Appropriate font (Cambria, 11pt)						
Paragraph space (1.15 between the lines)						

Table 2 - Key Performance Indicators

Content review	Yes Completely Agree	Agree	Partially Agree	No Disagree	N/A	Comments
Is the content presented clear and consistent?						
Is the Executive Summary self-contained and includes the main ideas of the document?						
Does the introduction make clear what is the purpose, structure and presents some main results?						
Is the conclusion different form the executive summary and the introduction?						
Is the Conclusion presenting key results?						
Does the content of the document match the description in the DoA?						
Is the document complete?						
Is there any superfluous or unnecessary content in this document?						
Are all references in the document included in the						

references section?					
Is the document clearly understood and well written?					

Table 3 - Content Key Performance Indicators

Quality Risks and Mitigation Actions

In this section the Consortium has identified several "common" issues, that could impact quality management, associated either with the quality of deliverables or with the lack of consistency regarding dissemination and communication of project results to external stakeholders. Thus, below the issues are listed and mitigation actions are outlined.

1. Underperforming partners

Issue:
In many occasions in EU funded projects, it has been observed that some partners may not perform as indicated in the DoA. That will result to delays for submission of the specific documents and internal conflicts. SAFECARE is a consortium of 21 partners with multiple nationalities, expertise and cultures, thus, differences in operational capacity between the partners are expected.

Mitigations:
- It is expected that the processes are explained as clearly as possible, partners are encouraged to ask questions or mention issues with those specific processes from the beginning of the project, and for its efficient continuation.
- WP Leaders are encouraged to inform the Coordinator once such behavior is beginning to affect project outcomes. The Project Coordinator together with the Management Board will make an informed decision about the specific partner and inform their upper management if such behavior continues.

2. Deliverable submission delays

Issue:
Every deliverable mentioned within the DoA has a specific deadline. The QM has established a timeline for timely submission which partners are encouraged to follow. If this is not the case deliverables will start being delayed globally due to the fact that SAFECARE's deliverables, in most cases, are cascading deliverables. Most deliverables are based on the previous one.

Mitigations:
- The Task or Deliverable leaders are responsible to contact the Project Coordinator and Quality Manager when these issues occur. Once the two parties have been informed, they will contact the relevant partners to understand what the situation is in detail. Actions will be taken thereafter in the Management Board.
- Meanwhile the QM will identify other partners that could potentially replace the initial contribution. If the QM anticipates a delay in submission, the Project Coordinator will be informed and he will be in a position to contact the PO.

3. Lack of quality in deliverables

Issue:
Low quality deliverables in content and in writing are reasons for rejection of the deliverable by the PO, but also discourages the brand name SAFECARE is trying to establish. The quality of the deliverable whether in content or in writing is the responsibility of the Deliverable Leader.

Mitigations:
- It has been specified during the kick-off meeting that the QM and Internal Reviewers will not be a revision mechanism for any deliverable, editing the content is the responsibility of the partner leading the drafting of such report.
- The suggestions and feedback of the QM and the Internal Reviewers is not compulsory, but it is advisable. The Internal Reviewers or the QM should not change the meaning of the text they are reviewing, but only make comments and small adjustments.
- Every partner responsible for a deliverable is obliged to an internal editing of the text before sending the document to the QM and the Internal Reviewers.

4. WP Objectives are not met holistically

Issue:
Due to the cascading component in SAFECARE, in the case that one WP cannot complete or partially-achieve its objectives that causes an issue throughout the project. Delays will occur, and low-quality results will be produced.

Mitigations:
- In this case the WP leader has to inform the Management Board. Under these circumstances the Management Board will discuss amendments and actions to consider in order to achieve the WP objectives.

5. Objectives and intended results per task and their benefit for the overall project are not clear

Issue:
In the proposal, objectives were mentioned, whether technical or societal, these objectives were a planning of how the Consortium sees the topic it was applying for. Implementation of such actions can bring up some challenges not anticipated in the proposal phase. One re-occurring issue is the interlinkages between WPs and Tasks. Non-communication or isolated Tasks can lead to coordination issues, but also delays in submission of deliverables and milestones.

Mitigations:
- Mailing lists have been established for all WPs for their internal coordination. That induces transparency and accountability as well as good internal communication to avoid unclear Tasks.
- An internal newsletter with the highlights of the projects will be circulated internally every 4 months in order to interlink and inform all WPs.

Conclusion

SAFECARE partners have taken several measures to assure the efficient delivery of their outputs in the quality that it is required. The Consortium will follow all these guidelines for the whole duration of the project and will report directly to the Project Coordinator and QM for additional issues or amendments are necessary. The guidelines mentioned here will be measured against the KPI's after the first six months in order to assess what will work and what not in terms of process.

During the second iteration of this deliverable, the Consortium will present a common lexicon to be used by all partners in order to align the language used in deliverables and dissemination material. Alongside updated KPI's the second version will be the definitive rulebook to be followed. Deliverables and material up to that point will be processed by the Internal Reviewers and the QM as stated in the text above.

Annex 1 – Internal Reviewers list M01 – M06

Deliverable No	Deliverable name	Reviewer 1	Reviewer 2	Due Date	Type
D1.1	Templates of the informed consent	Klaudia Tani (EOS)	-	30 September, 2018	CO
D1.4	Collecting and/or processing of personal data must nominate a Data Protection Officer	Klaudia Tani (EOS)	-	30 September, 2018	CO
D2.4	Initial Quality Plan	AIRBUS	UG	31 October, 2018	PU
D3.1	Critical Assets in health Infrastructure	SPF	APHM	30 November, 2018	RESTREINT EU
D8.1	Dissemination and Communication Strategy	KEMEA	SGSP	30 November, 2018	PU
D2.6	1st report on cumulative expenditure	EOS		31 December, 2018	CO

Annex 2 –Deliverable Review Report

SAFECARE project | D1.X – Deliverable title | Month XXX (MXX) | DATE

Deliverable Review Report

Title	Deliverable Review Sheet
Prepared By	
Approved By	
Date	
Version Number	
Dissemination level	
Related WPs	
Reviewer Name	

Revision History:

Version	Date	Summary of Changes	Initials	Changes Marked
V0.1				
XX				
XX				

Deliverable Name

Deliverable X.X

Deliverable classification: (PU, CO, CI)

SAFECARE project | D1.X – Deliverable title | Month XXX (MXX) | DATE

Format review – What should exist in the document	Yes	No	NA	Comments
Deliverable number and title on the front page and on the header.				
Grant Agreement number				
Lead Beneficiary (and the people involved) and Contributing Beneficiaries (and people involved)?				
Dissemination level				
Release history table				
Table of contents				
List of tables				
List of figures				
List of acronyms				
Executive Summary				
Introduction				
Conclusion				
Appropriate font (Cambria, 11pt)				
Paragraph space (1.15 between the lines)				

SAFECARE project | D1.X – Deliverable title | Month XXX (MXX) | DATE

Content review	Yes	No	NA	Comments
Is the content presented clear and consistent?				
Is the Executive Summary self-contained and includes the main ideas of the document?				
Does the introduction make clear what is the purpose, structure and presents some main results?				
Is the conclusion different form the executive summary and the introduction?				
Is the Conclusion presenting key results?				
Does the content of the document match the description in the DoA?				
Is the document complete?				
Is there any superfluous or unnecessary content in this document?				
Are all references in the document included in the references section?				
Is the document clearly understood and well written?				

SAFECARE project | D1.X – Deliverable title | Month XXX (MXX) | DATE

The appointed reviewer(s) consider(s) DXXX.YY – Title of the reviewed document as:

	Accepted, no changes required.
	Accepted, changes required.
	Not accepted, it must be reviewed after changes are implemented.

Additional Comments:

Annex 3 – References

EU Grants: H2020 AGA — Annotated Model Grant Agreement – ARTICLE 19 – Submission of Deliverables

Project Management Institute. A Guide to the Project Management Body of Knowledge (PMBOK Guide) – Fifth Edition