REal-time data monitoring for **S**hared, **A**daptive, **M**ulti-domain and **P**ersonalised prediction and decision making for **L**ong-term Pulmonary care **E**cosystems

D1.1: Quality, risk, and IPR management plan

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Abstract

This document describes the organisation and procedures of quality control, risk management and Intellectual Property Rights (IPR) management that are necessary to ensure a high-quality delivery of the project.

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Symbols, definitions, abbreviations, and acronyms

AI	Artificial Intelligence
APM	Administrative project manager
CA	Consortium Agreement
CC	Clinical coordinator
CCC	Complex chronic conditions
COPD	Chronic Obstructive Pulmonary Disease
D	Deliverable
DMP	Data management plan
DOI	Digital object identifier
DPO	Data protection officer
EAB	External Advisory Board
EC	European Commission
EU	European Union
GA	Grant Agreement
GeA	General Assembly
H2020	Horizon 2020
IC	Innovation Committee
IM	Innovation manager
IP	Intellectual Property
IPR	Intellectual Property Rights
ISBN	International standard book number
M	Month
MS	Microsoft
OA	Open Access
PC	Project coordinator
PEC	Privacy and Ethics Committee
PMO	Project Management Office
PMT	Project Management Team
ROAR	Registry of Open Access Repositories
RPN	Risk priority number
RWD	Real-world data
TSC	Technical-scientific coordinator
UT	University of Twente
WP	Work package
WPL	Work package leader

1. Introduction

This document describes all procedures and organisational bodies necessary for delivering the RE-SAMPLE project with the highest quality without overburdening the collaborators on the project. The deliverable relates to Task 1.2 “Quality control and risk management” and Task 1.6 “Innovation management and IPR management” of Work Package (WP) 1 “Project management”. The deliverable is divided into three parts:

- quality management;
- risk management;
- Intellectual Property Rights (IPR) management.

Importantly, IPR management will be further addressed in WP1 Deliverable 1.3 “Innovation management guidelines” and in WP8 “Dissemination, exploitation, and policy making”.

Parts of the procedures described below have been adopted from the Best Practice document developed by the Project Management Office (PMO) at the University of Twente (UT) [1]. By using the Best Practice document, the PMO can continuously sustain the highest quality of all measures and matters pertaining to project management.

All information related to quality management processes has been communicated to the entire consortium during the Kick-off meeting on 10-11 March 2021. For convenience, a two-page summary of this deliverable for all consortium members is available in the project’s shared workspace. It can be used by the members as a quick reference guide to the quality procedures, which should facilitate a more effective implementation of this plan.

2. Objectives

The objectives of this deliverable are:

1. to describe the management processes necessary to ensure a high-quality output and the overall success of the project, and
2. to create a reference document for project participants that they can rely upon in the matters of quality assurance, risk, and IPR management.

3. Quality management

This section describes all quality assurance and control measures in the RE-SAMPLE project. The Project Coordinator (PC) will ensure the quality of the project and its administration in accordance with the provisions of the Grant Agreement (GA) and the Consortium Agreement (CA). The PC will be responsible for setting up governing bodies and an internal communication framework for an efficient and effective functioning of the project. The latter entails, among other things, organising face-to-face and online meetings and providing access to an online communication and conferencing platform, as well as to a shared workspace. The PC will be ultimately responsible for the development, internal review, and submission of the deliverables and periodic reports. This section also lays down the procedures for disseminating project results and refers to standardised forms and templates used in project quality management.

3.1 Project governance

Quality assurance and control are secured by the management structure of the project (see **Figure *1***). Decision-making bodies feature the General Assembly and the Project Management Team. The external Advisory Board and the two committees (Privacy and Ethics Committee and Innovation Committee) strengthen the project's overall quality. Work package leaders are responsible for the communication within respective work packages (WP) and for their performance. All the roles in the governance bodies are appointed by Month 3 of the project run. The different bodies and their scope are described below.

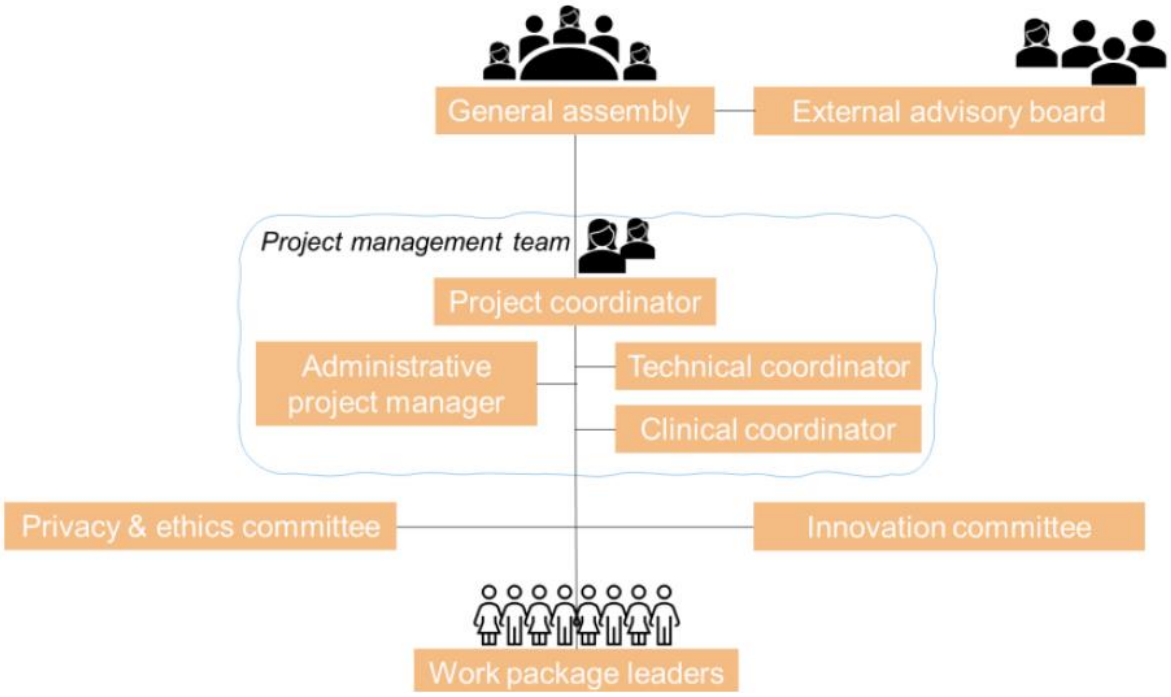

Figure 1: RE-SAMPLE management structure

The Coordinator is the legal entity acting as the intermediary between the project Beneficiaries and the Funding Authority. The Coordinator, in addition to its responsibilities as Beneficiary, performs the tasks specifically assigned to it in the Grant Agreement (GA) and the Consortium Agreement (CA).

The Project Coordinator (PC) is an employee of the Coordinator responsible for the overall project implementation in compliance with the GA and the CA. The PC acts as a single point of contact for the European Commission (EC). The PC executes the day-to-day management of RE-SAMPLE, monitors

the progress of the activities, and resolves possible conflicts. The PC is furthermore supported by the Administrative Project Manager, the Clinical Coordinator, the Technical Coordinator, the Innovation Manager, the Data Protection Officer, and the Project's Ethical Supervisor.

The Project Management Team (PMT) consist of the leaders of the PC, the Administrative Project Manager, the Clinical Coordinator, and the Technical Coordinator. The PMT is chaired by the PC. The PMT is responsible for the day-to-day management of the project and for the coordination between WPs. The PMT will meet on the weekly basis.

The Administrative Project Manager (APM) supports the PC and the partners of the consortium. The APM is appointed by the UT and is an employee of the UT's professional Project Management Office. The APM is mainly involved in administration, contractual arrangements, planning and control, financial issues, and cost reporting. For example, setting up meetings and taking minutes, assisting with working out the CA, maintaining contact with WP leaders to supervise the progress of the project, and helping to make sure that periodic reports are delivered to the EC on time and with top quality.

The Clinical Coordinator (CC) is responsible for monitoring the progress of scientific development in the medical domain and clinical developments carried out in the project. The CC oversees the activities in the clinical domain, i.e. the cohort studies and clinical studies and assessment, as well as the correct set up of the procedures and protocols needed for the execution of these, and coordinates the overall cooperation between pilot sites and external clinical organisations. The CC works closely with RE-SAMPLE's Ethical Supervisor and with the Data Protection Officer (DPO). The CC is assisted by the clinical WP leaders who have the expertise in the medical and ethical domains. The CC oversees the correct set up of the procedures and protocols needed for the execution of clinical studies within the project, early detection of risks, and adoption of contingency plans if needed.

The Technical-Scientific Coordinator (TSC) is responsible for all the technical development and integration activities to build the RE-SAMPLE platform with virtual companionship programme. In addition, the TSC ensures that state-of-the-art scientific and technological methods are deployed in the project. The TSC is supported by the technical WP leaders who have the expertise in the AI and privacy-security research domain and the specific technological innovations. The TSC oversees the time plan of the development within the technical WPs, detects risk and takes action if needed, and detects opportunities for innovation potential in close contact with the Innovation Committee.

The Innovation Committee (IC) is chaired by the Innovation Manager (IM). The IC is responsible for the continuous monitoring of innovation potential that arises from the project's tasks and possibly leads to protectable Intellectual Property (IP). The Innovation Committee will consist of all WP leaders and the exploitation representatives from all consortium partners. Each member is responsible for communicating innovation potential and exploitation within his or her own organisation and within the WP meetings. All members report to the IM about developments on innovation and exploitation within the Project as well as observed market trends and visions. The IM is responsible for evaluation and control of the innovations within RE-SAMPLE and reports back to the Project Coordinator.

The Privacy and Ethics Committee (PEC) is chaired by the project's Data Protection Officer (DPO). It ensures that the project complies with all privacy regulatory obligations and with the national and EU ethics regulations throughout the project time span, and that diversity is carefully considered. The PEC will address any ethical issues that could arise. The PEC consists of the DPO as well as the Project's Ethical Supervisor, and the representatives from the pilot sites. The DPO closely collaborates with the DPO's of the consortium partners and reports back to the Project Coordinator.

The Work Package Leaders (WPLs) coordinate the work of respective WPs and report to the PC. RE-SAMPLE has nine (9) WPs each managed by a WPL, with the exception of WP9, which for coordination and management purposes falls under the responsibilities of WP1. WPLs handle the day-to-day management of the WPs. They coordinate all activities necessary for the advancement of their WP and ensure effective communication and follow-up on WP meetings. Each WPL will:

- develop a management structure that is tailored for the tasks to be undertaken;
- report at each consortium update meeting, at least, on achievements, difficulties encountered, self-evaluation of progress and forecasting;
- make sure that there is a close cooperation between the WPs so that the project activities are integrated, installed and fully evaluated;
- submit the WP deliverables to the PC on time.

Changes that have effect outside the WP (e.g., delayed milestones/deliverables) must be communicated timely to the PC.

The General Assembly (GeA) represents the highest decision-making body of the project. It will be assembled once every year. The GeA can also have in-between meetings as and when required. For instance, to resolve a conflict between consortium partners, to add or remove a consortium partner, or to make pressing financial decisions. The GeA meetings are initiated by the PC.

The External Advisory Board (EAB) safeguards the quality of the project from an external perspective and helps the project to keep its focus on societal and economic impact. The EAB consists of international members that represent complementary knowledge fields of chronic disease, patients' representation, AI and user interactions, industry and data management and security. The EAB will provide valuable external input and advice on these scientific fields of interest, and will furthermore strengthen the involvement of patients and stakeholders in the project. The EAB provides advice to RE-SAMPLE on essential (design) decisions through individual commentary, group discussions with the other board members online and/or at a yearly physical meeting with the consortium. The following four members have been approached and expressed their interest to participate and signed a letter of intent.

- Tanja Effing, PhD (female) epidemiologist, a highly-acknowledged expert in chronic respiratory diseases and self-management. She works as a medical researcher at Flinders University, Adelaide, in collaboration with Europe. She focuses her research on moving the field of self-management in chronic respiratory diseases forward. She has been the initiator of an international expert group around Chronic Obstructive Pulmonary Disease (COPD) self-management, organised several respiratory self-management post-graduate courses, and has been part of several national and international expert panels.
- Prof. Simone Fischer-Hübner (female), a world-leading researcher in the area of privacy-enhancing technologies. She has been successful in pursuing cross-disciplinary research to bridge the gap between technical and legal aspects of privacy. She is a recipient of several prestigious awards from both the scientific community and industry. She also is a leading privacy advocate in the society at large. Her outreach includes serving on the Swedish Civil Contingencies Agency (MSB) IT Security Advisory Board and vice-chairing the Institute of Electrical and Electronics Engineers (IEEE) Sweden Computer/Software Engineering Chapter, as well as serving as expert for ENISA (European Union Agency for Cybersecurity) and Scientific Advisory Committee of Science Europe.
- Hans Bloo, MSc PT (male), a rehabilitation and sport physical therapist at Paramedisch Instituut Rembrandt. Board member of the Dutch Foundation for Physical Therapy in Health Sports, advisor for the Royal Dutch Foundation of Physical Therapy. Developer of the multidisciplinary guidelines for COPD care in the Netherlands.
- Dr. Pippa Powell (female), Director of European Lung Foundation, the European representative of patients in Europe. She will be advising on how to involve patients in the treatment of COPD and multi-morbid complex chronic conditions (CCCs), advising on specific needs and differences as well as state-of the art developments, and showing the European patient perspective.

More members can be invited to the EAB during the project in order to request advice in the corresponding field of expertise. Furthermore, during half-yearly (online) EAB meetings, different stakeholders represented in patient panels and expert working groups will be asked to provide their

advice on essential aspects in the project (e.g., design, real-world data (RWD) collection, privacy and ethics requirements, use of technology, communication, dissemination of project results beyond the consortium), as well as provide suggestions on improvements and solutions to identified issues.

3.2 Internal communication

3.2.1 Meetings

Structured and frequent communication processes ensure a timely and grounded decision making, a smooth collaboration between WPs, and an early identification of risks. Accordingly, the following meetings have been planned:

- General Assembly meetings: at least once a year
- Whole Consortium update meetings: bi-weekly
- Project Management Team meetings: once every two weeks between Project Coordinator and Administrative project Manager, and once every two weeks between Project Coordinator, Administrative project Manager, Clinical Coordinator and Technical Coordinator.
- Innovation Committee meetings: bi-monthly
- Privacy and Ethics Committee meetings: bi-annually
- Advisory Board meetings: twice a year, as well as on special request of the PC if necessary
- Work Package meetings: at the discretion of the WPLs, but at least once a month

3.2.2 Communication platform

Due to privacy concerns, Microsoft Teams (MS Teams) hosted at the UT's premise will be the sole file sharing platform in the project. The MS Teams platform will enable the RE-SAMPLE team to communicate through videoconferencing and the chat, and to share files and cooperate on deliverables – all in a single dedicated environment. Other tools, such as Zoom, cannot be used due to privacy risks. If a consortium member is invited to a Zoom meeting by an external party and it is not possible to use an alternative, the UT recommends following a few safe use guidelines[1]:

- Open an incognito or privacy window for the Zoom meeting and set the cookie settings in the browser to minimum/necessary;
- Do not share a screen with Zoom;
- Do not share files via Zoom;
- Do not download files that are shared;
- Do not record Zoom meetings;
- Ask the Zoom meeting host to set a password and only share it with those who are invited to participate;
- Ask the host not to enable the "Attendee Attention Tracking" feature;
- Set audio and video to "mute" by default; do not enable it until you participate in the meeting.

3.3 Deliverables

All deliverables should be written in the same template and have to undergo an internal quality assurance process. All deliverables are to be submitted and reviewed in Microsoft Word format with the help of Track Changes function and a respective review template (see Annex A – Deliverable Review Template). The following description of procedures (Sections 2.3-2.8) has been adopted and adapted from the Best Practice document [1] developed by the UT's Project Management Office (PMO).

[1] Source: https://www.utwente.nl/en/cyber-safety/privacy/Privacy-and-tools.

3.3.1 Collaboration on deliverables

All documents will be available in a shared MS Teams folder, where all participants have access to and can work on the latest version. Before the deliverable review process starts (see 3.3.3), documents should be named according to the versioning rules, and a new version will be initiated after the review has been performed.

Privacy sensitive data will not be shared on public platforms, nor downloaded to individuals' computers, but will be kept in the MS Teams environment at all times. Shared documents, such as deliverables, should always contain anonymised information unless informed consent has been received upfront from the data subjects.

Aside from journal and conference papers all documents should be in a Microsoft Office Format (e.g. Word, Excel, PowerPoint, etc.).

3.3.2 Version control

While in draft, all documents titles will follow the same format:

<Project Name> <Number> <Title> <Version> <Participant>.

Example: RE-SAMPLE D1.1 Quality, risk and IPR management plan v0.1 SK.

When finalized the document will change format to:

<Project Name> <Number><Title><Version>Final.

Example: RE-SAMPLE D1.1 Quality, risk and IPR management plan v1.0 Final.

All documents will start with version 0.1 and will increment to 0.2 only on the authority of the author. All other participants who edit the deliverable will increment the version to the next available number behind the version number, e.g.: v0.1.1 Deliverables submitted to the European Commission (EC) for the first time will have version v1.0.

In short, Version is numbered (X.Y.Z) where X can be edited by the coordinator, Y by the author, and Z by anyone contributing.

3.3.3 Reviews

All documents should be reviewed by two internal reviewers before submission. The official internal reviewers are appointed by the Project Management Team, and have not been directly involved with the writing of the deliverable. The reviewer of the deliverable will use the Review Template as explained in Section 3.3.4. The deliverable review procedure is outlined below (see **Figure *2***).

- T-10wd: ten working days before the deadline – the main responsible author sends a complete draft document to the appointed reviewers (with CC to the Administrative Project Manager). This could also consist of a definitive draft version in MS Teams.
- T-5wd: five working days before the deadline – the reviewers send their comments and feedback to the deliverable's main author (with CC to the Administrative Project Manager).
- T-2wd: two working days before the deadline – the author sends the corrected draft to the Reviewers, the Administrative Project Manager, and the Project Coordinator.
- Last days: In the last two days, the Project Coordinator and the Administrative Project Manager will check and approve the deliverable, if necessary cross-check it again with the responsible author and the reviewers, and submit the document to the EC portal.

In this procedure, we consider working days as all Mondays, Tuesdays, Wednesdays, Thursdays, and Fridays without any exception for holidays. Planning during holidays will be avoided if possible.

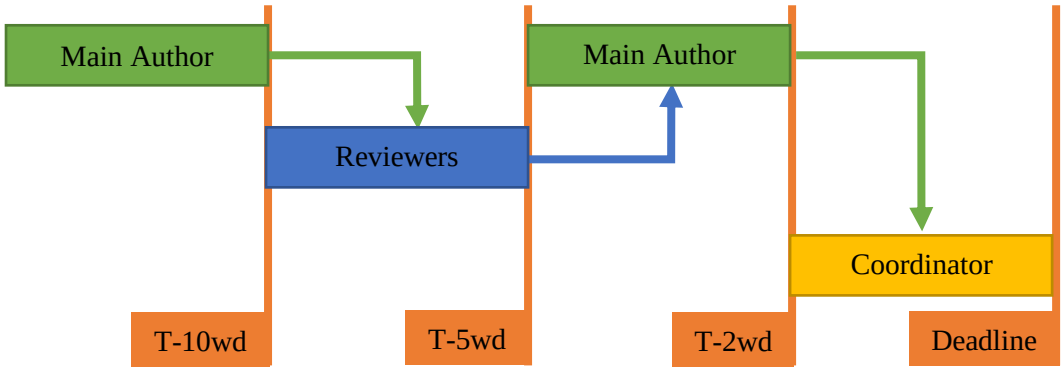

Figure 2: Deliverable review and submission procedure

3.3.4 Review Template

A dedicated review template (see Annex A – Deliverable Review Template) will be provided to all reviewers to ensure the quality of the review process and thereby the quality of the deliverable.

A deliverable reviewer is required to fill in the checklist as well as supply their comments, changes and suggestions using Track Changes in the Word Document as provided on the MS Teams environment. The review files will be stored in the same folder as the original document.

3.4 Templates

Templates are a necessary item for all projects, to ensure uniformity, ease of use, quality, and structure. The following templates and standardised dissemination items will be accessible to all RE-SAMPLE partners:

- Deliverable report
- PowerPoint presentation
- Poster template
- Newsletter
- Dissemination factsheets

The project manager will provide the partners at the end of a period with the following templates and instructions:

- Financial Statements
- Progress reports

Furthermore, the project coordinator will use standardised templates for:

- Meeting agenda's and minutes
- Management reports
- Change requests
- Deliverable reviews

All templates will comply with EU regulations.

3.5 Dissemination

A detailed dissemination and exploitation plan will be delivered later in the project (D8.1, M6). Therefore, this section discusses the procedures that ensure that the communication and dissemination of project results is up to a certain standard from the outset. The section first clarifies the differences between dissemination, communication, and exploitation, then it focuses on the dissemination process,

and then lays down the regulations concerning the proper implementation of the requirements from the EC, including the obligation to use the dissemination disclaimer and to publish Open Access.

3.5.1 Communication, dissemination, exploitation

We distinguish between three types of dissemination actions: communication of the action, dissemination of the results and exploitation of the results.

Communication of the action aims at promoting the action and the results to the general public, media, and stakeholders. This will happen all through the project by means of the strategy devised in the Dissemination and exploitation plan. The goal of the communication actions are to engage with stakeholders, create awareness about the project, promote cooperation, results, and the successes of public funding.

Dissemination of the results aims at disseminating the results to anyone who can learn from the results or may be able to take up the results. This will be done through Open Access as much as possible, i.e. through scientific journal publications, conferences, and inclusion in EC databases. Dissemination will be done as soon as the first results are generated until after the end of the project. The aim is to maximise the results' impact and assist other researchers in their continuous scientific journey.

Exploitation of the results aims at making concrete use of the results for commercial, societal, and political purposes. This can be done by industries as well as policy makers, civil society, or other interested parties. Exploitation is usually done towards the final stages of the project.

The dissemination procedure process is governed by the following principles:

- In general, all partners are encouraged to maximise the impact of the project through communication, dissemination, and exploitation.
- In case of *dissemination and exploitation of results*, an official procedure is in place that allows consortium partners to review the dissemination action and possibly object to its publication (see 3.5.23.5.2).
- In case of *communication*, consortium partners are free to disseminate information that relates to their own organisation or the project in general, where no reasonable objections can be made by other partners.
- All communication, dissemination, and exploitation actions should be reported to the project management and should be noted in the Dissemination and Communication Excel spreadsheet provided on MS Teams.

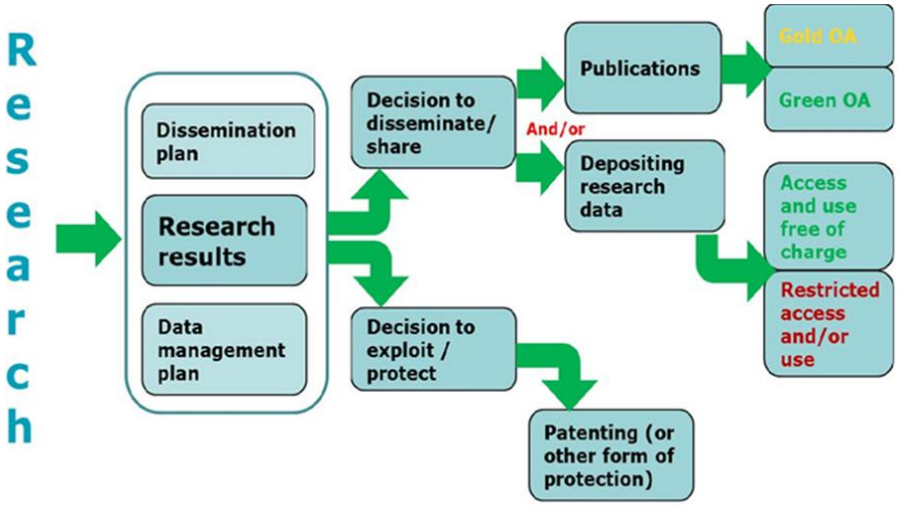

Figure 3: How to disseminate results

3.5.2 Dissemination process

All consortium members will be invited to mention any opportunity or intent of communication, dissemination, or exploitation actions during the bi-weekly whole consortium update meetings. A short reminder will also be added to the meeting agendas, it will contain the contact information of the dissemination partner in the consortium.

An important part of dissemination is the validation process especially regarding conference participation where abstracts and papers are to be sent long before the event itself. To specify, external communication needs to be approved by all Consortium partners before publication. This way, the communication can be checked for unpublished project results or for describing activities of a partner that did not author the communication. This is to ensure no preliminary results will be made public, nor IP will be infringed. Furthermore, it will ensure that the communication and dissemination activities are of sufficient quality.

The dissemination process is governed by the procedure of Article 29.1 of the GA and Article 8.4.2 of the CA. The disseminating partner will send the item to be reviewed at least fourteen (14) calendar days before the submission date to the consortium partners. All partners will than have ten (10) working days to review and object. Objections should be made in writing to the coordinator and the disseminating partner with concrete proposals for changes. If a partner stays silent, it is assumed they have no objections to dissemination. If objections have been raised, the partner will send the final version of the action to all partners for a final approval. Again, if a partner stay silent, it is assumed they approve of dissemination.

As stated in Article 8.4.2.2 of the CA, an objection is justified if

(a) the protection of the objecting Party's Results or Background would be adversely affected;
(b) the objecting Party's legitimate interests in relation to the Results or Background would be significantly harmed.

As stated in Article 8.4.2.3 of the CA, the objecting partner shall not unreasonably continue the opposition if appropriate measures are taken. The objecting partner can request a delay of not more than ninety (90) calendar days from the time it raises such an objection. After that the dissemination is permitted.

3.5.3 Disclaimer

External communication should comply with the EU regulations on disclaimers and use of logo. Therefore, the following sentence and the EU logo should be added to communication and dissemination items where relevant.

> This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965315.

The logo of the European Union should be used, not the logo of the European Commission:

Figure 4: Correct use of the disclaimer logo

3.5.4 Open Access

All publications should be published through Open Access (OA) publishing. It is possible to choose between the two main open access publishing modes:

A. *Gold OA* in either full or hybrid OA journals. Partners can choose for *gratis* or for *libre* OA (gratis access is free of charge, but it is not permitted to distribute or re-use the item further, and libre access is free of charge and free for some further distribution and reuse) and
B. *Green OA* through self-archiving journal articles in OA repositories.

Consortium members will be encouraged to publish in journals contained/registered in the Registry of Open Access Repositories (ROAR). In case the results should be kept confidential for a longer period, this can be requested by the WP leader and will be discussed in the PMT meeting. Clear reasons should be given why the publication will be kept confidential for a longer period, and it should be specified how much longer the confidentiality should be put in place, but no longer than ninety (90) days as stated in the CA. All papers fall under the dissemination procedure as mentioned in Section 3.5.2. Furthermore, the authors must provide the disseminating partner and the coordinator with the following information per paper when it is possible or available:

- DOI (Digital Object Identifier)
- Type of publication
- Repository Link
- Link to publication
- Title
- Authors
- Title of the Journal/Proceedings/Books series/Book (for book chapters)
- Number, date or frequency of the Journal/Proceedings/Book
- Relevant Pages
- ISBN (International Standard Book Number)
- Publisher
- Place of publication
- Year of publication
- Availability in Open Access (Gold, green, none)
    - If Gold, the costs should be stated.
- Peer reviewed publication (yes/no)
- Joint public/private publication (yes/no)

The Project Coordinator will keep an overview of all papers submitted and published.

3.6 Change Management

In case a partner wants to make significant changes to the proposed work (changing the lead partner in a task, postponing the deadline of a deliverable, and so on), they can submit a change control request. A template will be made available for this on MS Teams. Once the request is handed in, a change control board, preferably the PMT, but in cases of substantial changes the GeA, will decide on the proposed change. In case of substantial changes, the change should be discussed with the Project Officer (PO), and an amendment on the Description of Action should be submitted to the EC. Smaller changes will be addressed within the PMT meetings.

3.7 Data Management

A data management plan (DMP) will be developed by M6. It will be a living document describing the data management life cycle for the data to be collected, processed, and/or generated according to the

template provided by the EC (in the H2020 Online manual[2]). The plan will be coordinated by RE-SAMPLE's DPO. All project management data will be stored on the MS Teams site, or at a secure server at the UT's premise if some restrictions are in place.

3.8 People management

During the kick-off meeting RE-SAMPLE participants discussed a communal set of values that are shared within the entire consortium. Having these shared values hopefully enables us to manage expectations as well as boundaries, set up effective and cherished communication and create an overall pleasant environment to work in. Our shared values can be summarised as follows:

- Open and transparent communication including
    - Honesty
    - Communicating problems
    - Communicating also when we don't know something yet
    - Being reachable
- Respect
- Being supportive and encouraging
- Multi(or inter)disciplinarity
- Creating added value for patients through
    - Strengths-based approach
    - Human-centered approach
    - Respect for patients' rights
    - Positive healthcare
    - Inclusiveness

As Project Management we truly care about the safety and wellbeing of our project partners and participants. And we clearly want to state that this is not about risk management, this is not about quality control. This is not about the project, this is about people. In these times, with all the stress of the COVID-19 pandemic, it is extra important that we all look out for one another. We will therefore regularly check in with the partners and avoid unnecessary movements as much as possible. We will also try to create a little bit of flexibility in deadlines if possible, because we don't want these additional stressors to be the tipping point for people's mental health. We want to be a project where people feel safe and welcome, a compassionate place, just so they will continue to be able to function as human beings in times like these.

[2] H2020 templates: Data management plan v1.0 – 13.10.2016. Source: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm.

4 Risk management

The following description of risk management procedures has been adopted and adapted from the Best Practice document [1] developed by the UT's Project Management Office (PMO).

Risk management is the systematic process of identifying, analysing, and responding to project risks. It includes maximising the probability and consequences of positive events and minimising the probability and consequences of events adverse to project objectives.

Risk management consists of:

- Risk management planning
- Risk assessment
- Risk identification
- Risk analysis
- Risk response planning
- Risk monitoring and control

4.1 Risk management planning

The Project Coordinator is responsible for the risk management plan. The risk management plan consists of a risk inventory and risk contingency plans for bigger risks. The inventory will be available at the start of the project and it will be updated after every PMT/whole consortium update meeting, or in case of unexpected consequences, immediately. The risk contingency plans will be reviewed annually or in case of emergency, immediately. The risk management plan will be discussed in every progress report. No contingency budget is available. In case of risk occurring with a big impact it might be necessary to redistribute the budget, in order to be able to mitigate the consequences. These decisions will be proposed by the PMT and will be taken by the GeA.

4.2 Risk assessment

Risk assessment consists of the identification of the possible risks and the analysis of the impact of the potential risk. The PMT is responsible for the continuing identification of risks throughout the project and how to deal with the risks and its consequences.

A risk inventory will be kept in the project management folder at all times. This inventory will be discussed at every PMT meeting. The risk inventory will contain:

- The risk
- The likelihood of happening
- The impact when happening
- The Risk Priority Number (RPN)
- The person/partner responsible
- First mitigation measures
- Specified contingency plans for Risk with a RPN higher than 14.

4.3 Risk identification

Risk identification is the identification of possible obstacles that could endanger the correct implementation of the project. This has to be performed throughout the life-cycle of the project. It is important that awareness is created on risk identification. If risks are not identified in a timely manner, mitigation measures might not be sufficient or will be taken too late.

In order to create awareness in the project, risk identification strategies have been identified:

- Every PMT meeting the members will discuss the existing and possible new risks.
- Furthermore, every annual GeA meeting will have a brainstorm session where all participants can contribute to identifying risks and response strategies.

- All participants can bring up risks to the WP leader and/or the PC. This risk will then be discussed in the next PMT meeting.

Categories for potential risks are:

- Technical
- Financial
- Schedule
- Staffing
- Contractual
- Data management
- Ethics

4.4 Risk analysis

All risks will be analysed both on impact and likelihood. For each risk the responsible WP leader will identify:

1) The likelihood of the risk occurring (P)
    - 1 very unlikely
    - 2 unlikely
    - 3 not likely but not unlikely
    - 4 likely
    - 5 very likely
2) the impact the risk might have (I)
    - 1 very low
    - 2 low
    - 3 not low, not high
    - 4 high
    - 5 very high

When combined (P*I), a risk priority number (RPN) can be calculated and classified as low, medium or high priority (see the Section below). The initial RPN analysis was carried out and introduced during the Kick off meeting of the RE-SAMPLE project. This analysis shall be regularly updated and presented at biannual consortium meetings.

4.5 Risk response planning

There are four ways to deal with risks:

- Avoid: try to avoid the risk from happening all together;
- Mitigate: take action so the risk will do as little damage as possible;
- Transfer: externalise the risk at some cost;
- Accept: if none of these measures are feasible, accepting the risk remains the only option.

For all risks with a RPN higher than 14, a risk response plan will be written. A risk response plan describes in detail if the risk will be avoided, mitigated, transferred or accepted, and what measures will be taken to carry out the action. The person responsible will be identified, depending on the risk, this should be either a WP leader, the PC or a member of the GeA. Furthermore, in case of the risk occurring, a process will be described how to handle the risk and its impact, and a communication strategy will be put into place, so all participants will know how to act.

For all risks with a RPN between 7 and 14, it will be described in the risk inventory if the risk will be avoided, mitigated, transferred or accepted, with enough detail to be able to react promptly in case of happening. Furthermore, a partner responsible will be identified, depending on the risk, a WP leader or the coordinator.

For all risks with a RPN lower than 7, a responsible partner will be identified, preferably a WP leader, who will be in charge of proposing a strategy in case the risk occurs.

A special category will be taken into account, which is the very low likelihood but extremely high impact. This might be the case where certain actions might threaten the existence of companies inside the Consortium, for example. These risks will be identified beforehand and a risk owner will be identified, this will be someone from the GeA. Mitigation measures will be described. When the risks occur out of the blue, a risk task force will be put into place in order to mitigate the consequences.

Concerning mitigation measures, risk avoidance, risk sharing, risk reduction and risk transfer will be taken into account when considering options.

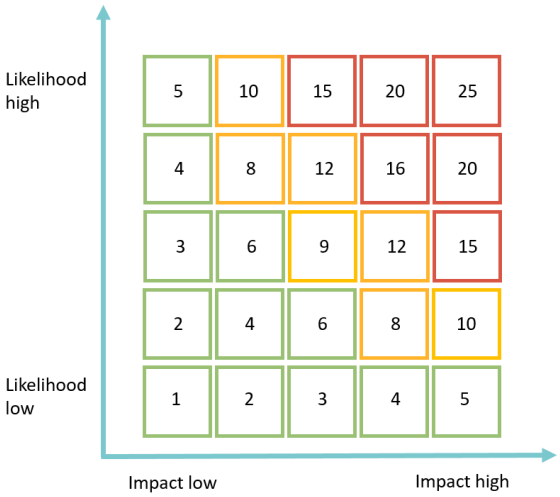

Figure 5: Risk priority matrix

4.6 Risk monitoring and control

Identified risks and new risks will actively be monitored by the WP leaders and reported regularly to the PMT. Each PMT meeting the Risk inventory will be discussed and updated.

Risk control will be executed by means of the risk response plans and ownership of all risks. In case risks are foreseen to have great impact on schedule, costs, technology, or society, the PO will be informed about the risks and the countermeasures.

4.7 RE-SAMPLE risk inventory

The following table lists the project risks, their probabilities, as well as proposed response strategies. This table is based on the RPN analysis presented by WP leaders at the Kick off meeting of the RE-SAMPLE project, which included the risks identified in the GA. It is a living inventory that shall be updated at biannual consortium meetings.

Table 1: RE-SAMPLE risk inventory

Risk	Likelihood	Impact	RPN	Response	Strategy	Responsible
Delay in user requirement and co-design activities due to COVID-19 meeting restrictions	4	2	8	Avoid	Seek early cooperation with partners to initiate recruitment and involvement early on, plan for online co-design activities	RRD

Low response rate to recruitment for co-design activities	3	3	9	Avoid	Early setup of panels consisting of patients and healthcare professionals in the Netherlands, Italy, and Estonia	RRD MST GEM TUK
Not being able to identify validated features or markers to COPD and CCCs disease progression from the state-of-the-art literature search	1	3	3	Mitigate Transfer	Approach leaders in the field to ask for assistance in finding the latest relevant literature	RRD
Not being able to obtain data from additional databases and data sources to enrich our existing datasets	2	2	4	Transfer	Due to our extensive research network we can approach key research leaders, involved in large additional databases and data sources	RRD
Insufficient data or data quality or synergy for creating the predictive models	3	3	9	Mitigate Transfer	- Static data: seek collaboration with other databases and cohorts; - Real-world data (RWD): seek collaborations within pilot partner's ecosystem	ATOS MST UT
Prediction model with high accuracy is not possible as a result of 1) insufficient, inappropriate data, or 2) the wrong definition of the model training algorithms	2	3	6	Avoid Mitigate	For 1) - Start with full set of variables (exploration) to identify key variables - Early start of prospective data collection - Annotate retrospective data For 2) Evaluate multiple model training algorithms to find best models	DFKI
High runtime of secure multiparty computation based privacy-preserving machine learning	3	2	6	Avoid	Proposed approach allows trading off levels of data privacy, runtime, and prediction performance	UT UPRC
Time of development takes too long, limiting sufficient time for evaluation in daily care	3	2	6	Mitigate	Switch to a series of minimum viable prototype for the correct execution of the evaluation in the initial phases, while the developments continue to be carried out in parallel	iSPRINT
Lack of operability between the models, data, technologies developed and health systems	2	2	4	Mitigate	In case the operability of data is too complex, prioritise elements which are critical to interoperate. If prioritisation is not possible, assign more efforts to this task	ATOS
Delay in RWD gathering	3	4	12	Avoid	Early establishment of the Data Management Plan among all partners	UPRC
Delay in defining purposes of processing	3	4	12	Avoid Mitigate	Dedicated workshop during the first five (5) months for the General Data Protection Regulation (GDPR) issues by DPO	UPRC
Delay in requirements elicitation activities due	4	2	8	Mitigate	In the last year the partners responsible for user involvement	iSPRINT

to COVID-19 related restrictions (dependency)					have learned strategies for online activities	
Low interest from primary or secondary end-users in (one of the) virtual companionship programme components	1	4	4	Avoid	Close engagement with end-users from the early stages of the project	iSPRINT
Difficulties in end-user engagement activities (Task 5.5) due to COVID-19 related restrictions	4	2	8	Avoid	In the last year RRD has learned multiple strategies for online co-design and evaluation activities with end-users	RRD
Delay in the recruitment of patients for RWD cohort and virtual companionship programme due to COVID-19 related limitations for face-to-face contact	4	3	12	Avoid Mitigate	MST has in the past set up a cohort study of 800 patients with COPD, so the experience is present. MST has performed various prospective studies in COPD with hundreds of patients over the past two decades. MST has a very experienced research office to assist in patient recruitment	MST
Too little involvement of users in specifications and evaluations, resulting in low usability or acceptance	1	3	3	Transfer Mitigate	Seek collaboration within the pilot partner's ecosystems e.g. other hospitals, primary care practices, patient organizations, health insurance platforms to involve patients, request through the European Lung Foundation. As in case of Covid-19 or alike, create alternative means for user involvement online	RRD MST GEM TUK
Ethical or privacy/security issues hinder the RWD gathering and/or evaluations of the virtual companionship programme as part of daily life	2	4	8	Avoid	Establish a process for privacy-preserving GDPR compliant data management in the early stages of the project	UPRC
Analyses of the evaluations do not match expectations	2	3	6	Mitigate	Identify possible weak points in technology, service model design, and/or methodology in the earliest phases of their development	UT RRD
Public acceptance (recruitment-related; building trust)	3	4	12	Avoid Mitigate	Inform patients and public in respect to the purpose of processing of their health data and the measures taken for protecting their privacy	RRD MST GEM TUK
Competing platforms and initiatives (market-related)	2	4	8	Mitigate	Underline RE-SAMPLE unique features; collaborate with other projects	HOPE
Different views on exploitation or exploitation plan that is not actionable (exploitation-related)	2	3	6	Avoid	Aim for a strong business model with early buy-in from partners	iSPRINT

No uptake of the gained evidence by policymakers or healthcare authorities	3	3	9	Avoid	Early stakeholder involvement. This in an effort to raise awareness and learn about actors' interests early on, as well as to adapt strategies if need be. A strong business plan will also play key role to address financial feasibility questions	HOPE

5. IPR management

IPR management issues (conditions detailed in the Grant Agreement, Article 23 and following) will be dealt with by maintaining and updating an IPR list and regulating IPR shares of the various contributors to the RE-SAMPLE platform, detailing ownership of results and joint/individual exploitation intentions. More detailed innovation management guidelines (D1.3, M6) and a dissemination and exploitation plan (D8.1, M6) will be delivered later in the project.

5.1 IPR in the Consortium Agreement

A legal framework for IPR within RE-SAMPLE will be established in the Consortium Agreement (mainly in Section 9) that is currently under development. The CA will deal with ownership of results and access rights, including:

- Protection of individual partners pre-existing know-how
- Protection of IPR gained in the project
- A contingency plan that ensures the access to foreground if a partner (with project-critical IPR) leaves the consortium
- Settlement of Disputes
- Specific provisions for access rights to software

All software development activities to be undertaken within the RE-SAMPLE project are carried out by consortium partners. The actual source code produced will be a joint effort of the technological providers who have participated in their development and will be protected under a joint or set of individual IPR scheme. However, this copyright protection should not violate the terms and conditions of the license of the background systems, sub-systems and components adopted, customised and integrated in the RE-SAMPLE system (see **Table *2***).

5.2 Background technologies and know-how

The table below lists all background technologies and know-how that the consortium partners have used for the implementation of the RE-SAMPLE project, with particular emphasis on the Intellectual Property Rights (IPR) associated.

Table 2: IPR ownership of background technologies and know-how used in RE-SAMPLE

Background technology / know-how	Owner	TRL (if applicable)
Health Data Hub	ATOS	
Terminology Service	ATOS	
Patient Data from the GEM Datawarehouse	GEM	
HEALTHENTIA, an eClinical platform that is used for capturing and processing of RWD	iSPRINT	
HEALTHENTIA Composite Biomarker	iSPRINT	
Existing data from previous studies	MST	
Know-how with regard to self-management of patients with COPD and comorbidities	MST	
Know-how with regard to action plans for multi morbid exacerbations	MST	
Existing data from previous studies	TUK	
Know-how in conducting postal surveys and recruiting COPD patients to the prospective cohort studies based on inclusion and exclusion criteria	TUK	
Retrospective data on diagnosis, investigations, interventions, consultations, and hospitalisations of COPD patients	TUK	

5.3 Foreground technologies and know-how

The table below will serve to provide information regarding the envisaged IPR ownership of the RE-SAMPLE outcome(s) is provided. However, the presented information should be considered preliminary, since it is to be updated and finalised towards the end of the project. Indications regarding IPRs ownership will be provided based on the development of the relevant outcome(s) by specific partners.

Table 3: IPR ownership of foreground technologies and know-how

Foreground technology / know-how		Owner	Co-owner	Expected TRL	Delivery date
RE-SAMPLE Integrated platform					
Front -end layer	Web Application				
	Web Platform				

Moreover, the next table serves to provide an overview of the rights for using the foreground and possibly a specific software license for future use at the end of the project lifecycle.

Table 4: IPR ownership of foreground technologies and know-how for future use

Foreground technology / know-how		Owner	Co-owner	Background needed to use this foreground	Rights to use the foreground (licence)
RE-SAMPLE Integrated platform					
Front -end layer	Web Application				
	Web Platform				

5.4 Tracking dependencies with internal and external software artefacts

Managing the background and foreground IP of RE-SAMPLE, like in any project that involves software development, can be challenging considering the software dependencies with internal and external components (software artefacts, libraries, etc). For this reason, the project will maintain a table that shows components' dependencies, with details about licensing (see Table 5). This is a very critical step to avoid backwards incompatibility aspects between licenses, as it should not be taken for granted that a system consisting of several (open-source) licenses can be licensed under any license. This table will also support the selection of licenses, in line with the exploitation plans of individual partners and the whole consortium.

Table 5: IPR components' dependencies table

#	Component full name	Artefact latest version	Owner WP	Inception year	Background (if any)	Partners involved in the foreground	External to RE-SAMPLE dependencies and their licenses	RE-SAMPLE dependencies	Comments

5.5 Exploitation Plan

RE-SAMPLE exploitation plan intends to ensure the sustainability of project outcomes after the project lifetime. To achieve that goal, the exploitation strategy planned by the RE-SAMPLE consortium relies on increasing the project impact, market uptake and facilitating the adoption of the RE-SAMPLE solution by the stakeholders.

The RE-SAMPLE exploitation strategy is initially presented in D8.1 (M6) and will be evolved during the project to adjust it to the project's achievements and partners exploitation interests. The strategy is focused on helping partners to develop an exploitation route for their outcomes created within the project, as well as achieving a successful joint exploitation agreement to further exploit or commercialise the RE-SAMPLE outcomes.

Joint Exploitation Plan

The final goal for the RE-SAMPLE exploitation strategy is to bring the project solution as a whole to the market. During the project, several planned exploitation activities aim at defining a feasible scenario for the joint exploitation:

- Market analysis to know the context of the RE-SAMPLE project and its competitors. The market knowledge will help the consortium to better know the position of project outcomes in the market, strengths and weaknesses, commercial opportunities, etc.
- Internal workshops among partners to plenary discuss the possible business models for RE-SAMPLE solution.
- External workshop with stakeholders to define the adoption roadmap of the results.
- Development of a Business plan to assess the feasibility of the RE-SAMPLE solution and pave the way for the commercialization.

At this phase of the project, the RE-SAMPLE consortium has identified two possible scenarios for the joint exploitation and commercialisation of the project outcomes:

Scenario 1: All consortium partners

In this scenario, all technical partners – who are responsible for one or more components/subsystems/know-how (as detailed in **Table *3***) – will license their IPRs to the Venture (to be established) through bilateral commercial agreements and provide their technical support for such components/sub-systems, as necessary.

Scenario 2: One consortium partner will take the responsibility to commercialise the platform in the European market

In this second scenario, all technical partners – who are responsible for one or more components/subsystems/know-how (as detailed in **Table *3***) – will license their IPRs through bilateral commercial agreements and provide their technical support for such components/sub-systems, as necessary. The responsible partner will then sell a commercial solution (on the cloud or on-premises), consisting of the RE-SAMPLE platform and different combinations of services (according to the customer needs), and provide technical support to potential customers who will pay monthly fees. Technical partners could also sell specific licenses for their IPRs to other entities.

The commercialisation scenarios wil be discussed during the wokshops, general assemblies, etc. The Innovation Committee will be in charge of monitoring and checking the possible exploitation agreements among partners. All the legal and IPR aspects related to the exploitation of any RE-SAMPLE result will be monitored by the IPR Manager.

References

[1] van Loon, J. (2021). Quality, risk and IPR management plan: Best practices. Enschede: the University of Twente.

Annex A – Deliverable Review Template

REal-time data monitoring for **S**hared, **A**daptive, **M**ulti-domain and **P**ersonalised prediction and decision making for **L**ong-term Pulmonary care **E**cosystems

Review Template

Deliverable title:	
Version:	
Review Date:	
Reviewer:	

Introduction

All reviewers who are assigned to review a deliverable should fill out this review template. This template contains a general impression section, where the general impression and general improvements can be addressed. Furthermore, a checklist is provided in order the ensure the quality of the deliverable.

In case of specific remarks that take more explanation, please use the Further Comments box. Provide details on which section of the documents you are commenting on in the form of headers, page numbers etc. Put in suggestions for improvements.

All remarks and suggestions on spelling, grammar and other textual changes should be addressed in the Word Document of the deliverable with Track Changes. When submitting your edited deliverable, please pay attention to the file name (versioning) before returning the document.

For example, John Doe is the author of v0.8.0 of the deliverable, submitted for review:

D1.1 Quality, risk and IPR management plan v0.8.0 JD

The reviewer, Jane Smith, should after the review change the document name to:

D1.1 Quality, risk and IPR management plan v0.8.1 JS

General Impression
General impression of the deliverable:

General Improvements

Checklist

Section	Item	Y	N	Comments/Changes
Basics	The title page includes all required information from the Deliverable Template.	☐	☐	
	There is a table of contents, table of figures and table of tables reflecting correct page numbers and section names.	☐	☐	
	The document contains a "Symbols, abbreviations and acronyms" section, which is complete and accurate.	☐	☐	
	The document contains an "Introduction" section (§1), explaining clearly the scope and context of the deliverable.	☐	☐	
	The document contains an "Objective" section (§2), explaining clearly the purpose and structure of the deliverable.	☐	☐	
Content	Deviations from the description of work are sufficiently explained.	☐	☐	
	The outlook to future works follows from the research as described in the deliverable.	☐	☐	
	All figures and tables contain information that are described in the corresponding text.	☐	☐	
	All figures and tables are labelled accurately and consistently (numbering and clear captions).	☐	☐	
	Content clearly describes the problem	☐	☐	
	Content clearly describes methods/analyses	☐	☐	
	Content clearly describes solution/design	☐	☐	
Copy Review	Abbreviations, product names and terminology are used consistently (e.g., proper nouns capitalized).	☐	☐	
	Acronyms are spelled out completely in the first instance.	☐	☐	
	All hyperlinks and references have been tested and work.	☐	☐	
	Spelling and grammar check are complete.	☐	☐	
	Bibliography has a uniform format	☐	☐	
Style	Footer contains the correct deliverable name and page numbers.	☐	☐	
	All Headings, Body Text, Tables and Captions are styled in accordance with the Deliverable Template.	☐	☐	

Further comments