Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases

D5.3 Quality Assurance Plan

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Document Information

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28.3.2022	1.0	PMS, MvG	Final consolidation of comment and changes	First consolidated version of deliverable

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Abbreviations

CA	Consortium Agreement
TUNI	Tampere University
POLIMI	Politecnico di Milano
CCM	Centro Cardiologico Monzino
PUL	Protestant University of Applied Sciences Ludwigsburg

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1. Quality Objectives

The quality objectives of the project are:

- to obtain the research results described in the PerCard project proposal document at the agreed time, within the agreed cost budget;
- to guarantee a close continuous cooperation between all participants within the project;
- to maintain the staff members' professional competence and to utilise their capabilities; and
- to maintain a system to disseminate research results and provide cooperation with parties within as well as outside the consortium.

The Quality Assurance Plan defines and documents the required procedures, responsibilities, quality criteria and quality assurance measures to reach the Quality Objectives. The plan is evaluated and assessed by the PerCard Management Board, composed by one PI (Principal Investigator) from each partner.

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2. Operating Practice of the Project

2.1. Governance and Operational Procedures (Art. 8 of CA)

The General structure of governance and General operational procedures for the Management Board are governed by Article 8 of the Consortium Agreement.

2.2. Planning and Reporting

The project comprises a number of well-defined work packages, and activities therein are the basis of management and monitoring of the work. Each work package is allocated to a Work package Manager who is in charge of the co-ordination of all the activities of the work package. The Work package Manager reports to the Project Coordinator.

Work package	Work package Manager
WP1: Clinical Research and Validation.	Claudio Tondo (CCM)
WP2: New information discovery using AI and ML.	Luca Mainardi (POLIMI)
WP3: Personalised CVD Decision Support in Clinical Practice.	Antti Vehkaoja (TUNI)
WP4: Ethical, Legal and Societal Aspects (ELSA).	Kirsten Brukamp (PUL)
WP5: PerCard management.	Mark van Gils (TUNI)

The activities in the work packages are subdivided into tasks. Technical and coordination meetings, when needed, are organised by the Work package Manager. He/she is responsible for the deliverables of his work package. Each Work package Manager provides at least quarterly updates indicating the progress for their work package. This can be done through meetings with Project Coordinator or in another free format, e.g., by copying the minutes of work package meetings and sending them to the Project Coordinator. The reports will form the basis for annual reporting to ERA PerMed.

2.3. Deliverable Handling

Quality assurance for deliverables is implemented by review procedures for approval of all deliverables to ERA PerMed. If deemed necessary, one or two reviewers can be appointed by the Management Board to review a certain deliverable. Reviewers can be chosen from PerCard consortium members or by seeking specific external review (appropriate confidentiality ensured) for competence areas not covered by partner organisations. The Work package Manager of the work package to which the deliverable belongs will propose suitable reviewers to the Management Board. The proposal will be deemed accepted if no objections have been received within 7 days after making the proposal. Reviewers will evaluate the deliverable's contents, provide feedback to authors and eventually report their findings to the Management Board. The Management Board will subsequently decide on acceptance. In case of approval, the deliverable will be signed by the Project Coordinator and made available to ERA PerMed, in case changes need to be made, the partners responsible for the deliverable will be informed at shortest possible notice about the actions to undertake.

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If separate reviewers are appointed by the Management Board, the schedule for the above steps is as follows:

Time (in days, t = planned delivery date)	Action
t – 30	WP leader identifies deliverable owner
t – 30	Management Board assigns one or two reviewers (as proposed by WP leader)
t – 21	Complete deliverable to reviewers
t – 14	Reviewers comments to Management Board and deliverable owner
t – 5	Revised deliverable completed
t – 3	Reviewers confirm acceptance
t	Acceptance by Management Board

If NO reviewers are appointed the schedule is:

Time (in days, t = planned delivery date)	Action
t – 30	WP leader identifies deliverable owner
t – 14	Complete and final draft to Management Board
t – 8	Comments from Management Board to deliverable owner
t – 3	Revised, final version to Management Board
t	Acceptance by Management Board

The planned delivery date refers to the dates in the project plan, but it may be adapted due to time schedule changes as needed and agreed with funding organizations.

3. Documents

During the project, documents of various nature will be produced, i.e. documents directly relating to work being done (reports), publication in scientific journals, and documents pertaining to the management and financial administration of the project.

Dissemination activities including but not restricted to publications and presentations shall be governed by CA Article 13 Publication of the results.

Other documents may be produced during the project by nature of the results of research and/or requirements related to project management. Responsible persons, reviewers and recipients will be determined according to the nature of the document.

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4. Standards

4.1. Documents

Wherever possible, documents should adhere to the layout and contents style that remains the same throughout the project. Document templates (in MS-Word and MS-Powerpoint format) that can be used are made available on the PerCard internal project site (link).

4.2. Document Version Management

In the creation of documents the following version numbering is maintained:

Version numbers consist of two fields, denoting the major version, and the minor version. For example, "Version 1.1" indicates major version 1 of the document, minor version 1. Major version number 0 is used for (draft) documents prior to submission to the Commission. Formally, each new version supersedes all earlier versions. The naming convention for filenames includes the version at the end of the filename (e.g., "PerCard D1.2 V1.1.doc").

The differences between major, minor, and update versions are as follows:

Major Version: A major version represents significant additions to the document, including but not limited to major additions to the contents. A major version is published on as wide as possible forum (within the restrictions set by the Consortium Agreement), e.g., as deliverable to ERA PerMed. A major version consolidates all errata and corrigenda to data. The publication of a major version supersedes any prior documentation for major and minor versions.

Minor Version: A minor version may include small or large additions to the contents or other significant normative changes. A minor version is typically distributed only within the Consortium. A minor version incorporates selected errata as appropriate.

During the writing process, so-called *Update Versions* of documents may exist, e.g., when receiving comments and contributions from different co-authors. Such versions should contain the major and minor version numbers as well as an initials or acronym of originating source (e.g. 'PerCard D1.2 V0.2_TUNI.doc' contains TUNI's comments/additional contributions to the second draft version). An update version is distributed within the working group (authors, editors, reviewers) that works on the document.

The version history is reflected by a table at the start of each document, identifying version number, date, authors, reviewers and summary of the document's status.

4.3. Software

Software will be developed especially for the purposes of WP2: New information discovery using AI and ML, and WP3: Personalised CVD Decision Support in clinical practice. Additionally, software routines may be developed for data curation, harmonisation and handling in WP1 and statistical analysis in WP4. No specific requirements with respect to formal software development methods are being imposed upon the different partners participating in the development of software. Nevertheless, the adoption of

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TRIPOD guidelines (https://www.tripod-statement.org/) are encouraged to be followed in the AI and ML prediction models development.

5. Communication Mechanisms

Since cooperation is crucial to the success of the project, communication mechanisms are implemented that make the communication within the project as straightforward as possible. Although every partner has one contact person, in principle, communication within the project is as 'horizontal' as possible - anyone should be able to communicate with anyone else at all times.

The main daily communication takes place via e-mail, phone and Internet-based communication tools from Microsoft Teams and the project collaboration internal site (link). Mailing lists ('reflectors') containing e-mail addresses of all partners' employees related to the parts of the project work are established. Mailing lists exists for:

The entire consortium: percard@list.tuni.fi

WP1 members: percard-wp1@list.tuni.fi

WP2 members: percard-wp2@list.tuni.fi

WP3 members: percard-wp3@list.tuni.fi

WP4 members: percard-wp4@list.tuni.fi

WP5 members: percard-wp5@list.tuni.fi

For example, by sending a message to the e-mail address percard-wp2@list.tuni.fi, all members subscribed to this list will receive this message. The Project Coordinator maintains this list and keeps it up to date. Additional lists can be created whenever needed.

A central storage point for all project related information is established is the PerCard Microsoft Teams space group to be found at link. This contains meeting reports, publications, document templates, task lists, discussion forums, contact information, a calendar and to-do list and any other additions brought in by project members, this site uses can only be accessed via adding members by the Project Coordinator.

The project's public website can be found at PerCard project: Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases | Tampere universities (tuni.fi). This website contains general information about the project, public documents, contact information and relevant links. Maintenance of this page is in the hands of the Project Coordinator.

Although communication via Internet and telephone can be used for much of the co-operation, person-to-person meetings remain a crucial part in the project, whether they are at 'management level' or at 'work' level and are encouraged. Depending on the nature of the meeting, such a meeting can be organized by either the Project Coordinator, the Work Package Manager or organized by any partner

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'locally'. In any case, minutes of the meeting should be made available to the Project Coordinator within 10 working days after the meeting.

6. Publications Guidelines

1. All participants are encouraged to promote the PerCard project by proposing and preparing research papers to be submitted to international scientific journals and conferences.
2. These papers will be disseminated, following Article 13 "Publication of the result" of the Consortium Agreement.
3. In publications whose contents have been developed with support from ERA PerMed, the following needs to be added: ***"****This project was supported by* ***[name of funding organization, or an acknowledgment as requested by national funding organization]****, under the frame of ERA PerMed."*

7. Ethical Considerations

Ethical Considerations are governed by Article 14 "Personal Data" of the Consortium Agreement. Any prospective clinical data from which individual patients may be identified will be the property of the Principle Clinical Investigator (Claudio Tondo) at the associated clinical institution (CCM), and may not be distributed outside that institution without proper anonymization process. The Principal Clinical Investigators may seek for authorisation to access data of identifiable clinical subjects for other members of the Consortium, if it is needed to support the data analysis or signal processing activities.

In addition, other datasets used in the project are owned by their legal owners and handled according to the practices of the data owners.

A detailed specification of ethical and security aspects considered in the project can be found in D5.1 PerCard data management plan.

8. Changes and modifications in the Project Quality Plan as the projects proceeds

During the project course, the nature of the results of research and/or requirements related to project management may require changes to the Project Quality Plan. Suggestions for such changes need to be addressed to the Project Coordinator who will present it for discussion to the members of the Management Board.

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