PRECISE4Q

PREDICTIVE MODELLING IN STROKE

DELIVERABLE

Project Acronym: **Precise4Q**

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Project Title: **Personalised Medicine by Predictive Modelling in Stroke for better Quality of Life**

D7.1 – Project Management Plan and Quality Assurance Process Guidelines

Revision: 1.0

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CI	Classified, information as referred to in Commission Decision 2001/844/EC	

Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

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0.1	04.07.2018	MvT	Empirica	Outline and first draft
0.2	23.07.2017	DF, MvT	CUB, Empirica	Implementing comments from internal revision
1.0	27.07.2018	RT	EMP	Final version

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Abstract (for dissemination)	This deliverable D7.1 describes the PRECISE4Q project management structure and procedures related to quality assurance. The main objective of the quality system will be to ensure that all project outputs will be produced and delivered in a way which assures that all project objectives are met and with satisfactory quality.
Keywords	Management structure, quality assurance, conflict resolution, reporting, advisory board, deliverable peer review

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Glossary

Abbreviation	Description
AB	Advisory Board
AD	Administrative Coordinator
CO	Confidential
CUB	Charité Universitätsmedizin Berlin
DEM	Demonstrator
DFKI	Deutsches Forschungszentrum für Künstliche Intelligenz GmbH
DIT	Instituid Teicneolaiochta Bhaile Atha Cliath
DMP	Data Management Plan
DoA	Description of Action
DoW	Description of Work
EC	European Commission
EMP	Empirica
ETH	Eidgenössische Technische Hochschule Zuerich
FP7	Framework Programme 7
FR	Financial Report
GDPR	General Data Protection Regulation
GUT	Fundacio Institut Guttmann
H2020	Horizon2020
ICT	Information and Communication Technology
LIU	LINKOPINGS UNIVERSITET
LPEC	Legal, Privacy and Ethical Committee
MUG	Medizinische Universitaet Graz
ORDP	Open Research Data Pilot
PC	Project Coordinator
PCC	Project Coordination Committee
PEC	Project Executive Committee
PMA	Administrative Project Manager
PMO	Project Management Office
PPR	Periodic Progress Reports
PU	Public
QA	Quality Assurance
R	Report

RIA	Research Innovation Action
RP	Reporting Period
RTD	Research and Technical Development
SPC	Scientific Project Coordinator
TL	Task Lead
UTARTU	University of Tartu
WP	Work Package
WPL	Work Package Lead
WT	Workplan-Table

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Executive Summary

This deliverable describes the PRECISE4Q management structure and procedures related to Quality Assurance (QA). It includes a description of processes and mechanisms to ensure high quality and effective monitoring of the project activities, in particular the deliverables as defined in the Description of Work (DoW, chapter 1.3.2 WT2: List of Deliverables). The main objective of the quality system will be to ensure that all project outputs will be produced and delivered in time and in a way which assures that the project objectives are met. In addition, the role of the advisory board and a preliminary list of board members is presented; the reporting to the European Commission and conflict resolution procedures are described.

1 Management Structure and procedures

PRECISE4Q has been designed by a group of leading organisations in the area, to provide a focal point for integrating and expanding knowledge and experience. This experience includes successful scientific and administrative management of FP7 and H2020 projects. The scientific coordination of the project will be with Charité (CUB), the administrative and financial management with empirica (EMP). In line with the requirements and aspirations of a H2020 RIA, management is organised in a robust, not too complex manner, maintaining a balance between supporting an open, creative, productive RTD atmosphere and keeping close (also bureaucratic) control of project progress and economic resource usage. The following components constitute the PRECISE4Q management structure:

The **Project Coordinator (PC) is** responsible for overall management, communication, and coordination of the entire research project and acts as official interface to the EC. Support will be provided by a PCC secretariat, whose members have extensive experience in FP and H2020 project administration.

The **Project Coordination Committee** (PCC) has full responsibility and decision-making power for the project including any significant changes in the work plan. Given the size of the consortium and the established strong collaboration links, the PCC (respectively a subset of its members, i.e. the Project Coordinator (PC), the administrative Project Manager (PMA), and all WP Leaders (WPL)), will also take over the function of a Project Executive Committee (PEC) with responsibilities for core technical and operational management decisions. Compliance with ethical standards, data protection regulation, as well as the quality of the results is given special attention.

The **Scientific Project Coordinator** (SPC) is responsible for overseeing all RTD related work within the project. He has overall responsibility for meeting the scientific and technical goals of the project.

Project management office (PMO): The project management office provides the needed infrastructure and organisational support for all management activities across the project, including ICT-facilitated planning and control tools supporting the various tasks identified. Key contractual (legal) and financial matters will be handled by the contractual and financial administration office of empirica (PMO); specific templates for collecting input to the required EU documents/ Manage the Community financial contribution regarding its allocation between partners and activities will be provided.

The **administrative project manager (PMA)** will head the PMO and will be responsible for day-to-day running of the project. Activities include to ensure smooth coordination of all management tasks, including financial ones, through appropriate project management; to ensure the timely preparation and drafting of reporting documents to be delivered to the EC; to maintain a project communication infrastructure (website, document repository, GoTo-Meeting facilities); to organise PCC and project management meetings, and provide services for RTD focused meetings; to perform administrative tasks in the preparation, executing/ post-processing of EC technical reviews; to handle any legal issues which may arise and maintain the consortium agreement; to provide feedback to the partners on administrative issues - timesheets, progress reports, financial statements, eligibility of costs.

Integrated into the project management office processes will be a dedicated Administrative Manager, a Financial Manager, and a Quality Assurance Manager.

The administrative manager coordinates work performed by the RTD work packages (WPs) by calling meetings, drafting agendas and controlling action points, calling for and co-chairing meetings of the PCC, monitors the compliance of partners with their RTD obligations under the grant agreement by assessing their efforts performed, the accomplishment of tasks, and the achievement of milestones. The AD supervises and controls the implementation of RTD-related recommendations of the EC and technical reviews. Furthermore, the PC – in close cooperation with the respective WP leaders - identifies, assesses, and mitigates RTD-related risks. The project management office will support the PC.

The **Work Package Leaders (WPL)** are responsible for performing the actual project work, monitoring and managing the activities within the respective WP, and matching the expected project results with the strategic and research directions of the project. They also ensure the highest quality of the deliverables assigned to them/assisted by the Task Leaders (TL) that have been defined in the WP and task description section. Each TL will directly report to the related WPL and assist him/her in the coordination of task's activities.

The **Legal, Privacy and Ethical Committee (LPEC),** which will be responsible for all the contractual obligations related to ethical issues deriving from the usage of personalised modelling, or the possible use of clinical data in the project. Issues like data protection and anonymity will be under thorough consideration, considering also current changes resulting from the GDPR that took effect in May 2018. Also, any legal issues arising in the context of executing planned project work will be appropriately dealt with by the LPEC, PMO and/or, as the need may be, via approaching experts available at partner organisations or from EC or other external offices.

The **Quality Manager**, who is directly accountable to the PCC, is responsible for the implementation of the quality assurance procedures, as described in the present document, and the verification of the project results. The main responsibilities are: monitoring of the implementation of quality procedures along the project duration; internal review of project deliverables; and informing the Project Coordinator on general progress and if actions are required. The Quality Manager can take part in PCC meetings on demand, and works in close cooperation with Advisory Board experts (see chapter 4).

In order to enhance effective communication and management between consortium members an online shared workspace will be provided. The Project Coordinator will provide the workspace with access being restricted to the consortium members only to avoid broadcasting of the sensitive data and interim results. Solutions currently considered for this include Dropbox, box, ownCloud or Nextcloud.

Furthermore, in order to achieve efficient project management, technical and general meetings between the consortium partners will be organised on a regular basis. To reduce management and travel costs, the plenary meetings of PRECISE4Q will be scheduled on a regular six-monthly basis, i.e., only two meetings per year for the main executive bodies of the project. The schedules will be fixed in advance to allow maximum preparation time. These periodic project meetings will be organised to compare progress against the project plan, distribute information pertinent to the project, discuss technical aspects of the project, decide on corrective actions in case of delays, and monitor and control the project resources. The PC will take a comprehensive set of minutes at all meetings with clearly stated action points, time-plan and responsible persons and partners.

Technical meetings and telephone/video conferences will be held involving all relevant partners. For this purpose, online meetings via the GoToMeeting platform will be scheduled to take place once a month for the PCC and on demand for the various work packages and tasks and throughout the project lifetime.

2 Quality Assurance

The project is structured around a set of deliverables which are a central focus of quality assurance and control within the project. The Quality Manager, accountable directly to the PCC and closely working with the Project Coordinator and the Advisory Board, is responsible for the adherence to the following quality assurance procedures.

Deliverable production to specification and schedule is the responsibility of the WP Leader of the work package concerned. The objective of deliverable quality assurance is to subject key deliverables to an internal peer-review to obtain feedback from partners within the project consortium (i.e. selected participants not involved in the deliverable concerned) and, where appropriate, from an external expert who is member of the Advisory Board (AB). The work on this activity started with planning and defining a schedule and responsible partners for "internal revision" and these have been assigned for the key project deliverables (see chapter 3).

In a second step, a template for Quality Assurance was generated (see Annex 1), which serves as an assessment template for the reviewers of the key deliverables. This Quality Verification Sheet includes information about the intended objectives and results of the key deliverable in each case. This means general information about work package and task leaders, the reviewer(s) of the report and the deliverable date as well as the objectives and the contents which the deliverable has to ensure. The internal peer-reviewers are asked to fill in the document and to assess the delivered paper in comparison to the respective task descriptions and based on their expertise in the field.

The activity is executed through a peer review and deliverable approval process as follows (Figure 1).

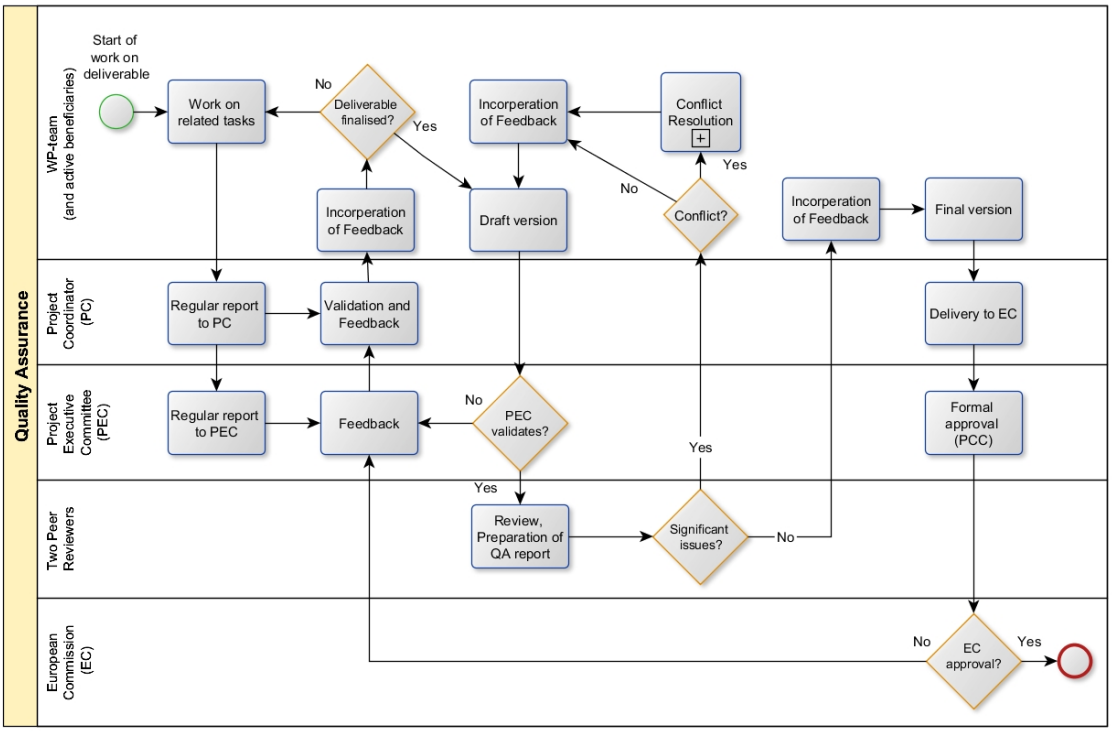

Figure 1: Quality Assurance Process

At least one project partner will be appointed by the Quality Manager (in coordination with the PCC) to review key deliverables. The relevant project partner(s) provide experts to support the peer review process; peer reviewers are drawn from personnel who have not been involved in the related work task. Where appropriate, advisory board members may be provided with key deliverables together with instructions about the feedback expected.

On receipt of the deliverable, at the latest 2 weeks prior to its due date, the peer reviewers review and check the deliverable for overall quality of contents, presentation, comprehensibility etc. and

particularly also its adherence to the requirements stipulated in the DoA for the respective work task. This serves to compare the achievements documented in the deliverable with the deliverable specification, the context of the deliverable in the Work Package concerned, and with the purpose of the deliverable in terms of the impact on project work dependent on the delivered result. IF deemed necessary by the PCC, the internal peer reviewers can prepare a short report for the deliverable lead, using the Quality Verification Sheet (see Annex 1). This sheet is distributed to authors and all other partners.

The WP Leader responsible for the deliverable responds to the review reports, usually through modification and resubmission in the case of major discrepancies or significant issues. Any changes made are documented in a suitable format, e.g. the track changes and commenting features in MS Word. The Quality Manager is responsible for making sure that all comments are addressed in a thorough manner.

In case of fundamental disagreement between the reviewer(s) and the deliverable author(s), the Quality Manager will inform the Project Coordinator and attempt to mediate. If regarded as prudent, he/she may ask for a further opinion from another expert.

If no objections are raised by participants to the response by the contractor responsible, the modified deliverable is submitted to the Commission by the Coordinator. The formal approval of the deliverable by the Consortium is documented at the next PCC meeting following delivery.

3 Deliverables

Led by the PMA and supported by the quality manager, deliverable scheduling as well as quality assurance mechanisms will be implemented. Deliverable production according to DoA specification and schedule is a core responsibility of each WP Leader. However, key deliverables defined in the DoA are subject to internal peer-review and acceptance by defined internal reviewers.

The table below lists all deliverables over the project lifetime. It shows the allocation of peer review responsibilities for key deliverables to partners for all deliverables and when the deliverable is due.

No.	Name	Lead short name	Key deliverable. Internal revision by:	Type	Dissemination level	Delivery
D1.1	SoA for stroke risk factors, prognosis and outcomes	GUT		R	PU	Jul 31, 2018
D1.2	Categorized and ranked clinical challenges and needs	GUT		R	PU	Jul 31, 2018
D1.3	Use cases and their inputs/outputs specifications	GUT		R	PU	Oct 31, 2018
D1.4	Set of functional requirements and architecture	CUB		R	PU	Feb 29, 2020
D1.5	Empirical study on attitudes towards personalized medicine	ETH		R	PU	Dec 31, 2019
D1.6	Ethical framework and oversight mechanisms for big data health research	ETH		R	PU	Apr 30, 2022
D1.7	Ethics of personalised medicine and data-driven modelling	ETH		R	PU	Apr 30, 2021
D1.8	Release of the deliberative dashboard	ETH		DEM	PU	Apr 30, 2020
D2.1	Overview of data sources and a plan to access available data sources	CUB		R	PU	Oct 31, 2018
D2.2	Implementation of accessing and bridging functionalities	CUB		R	PU	Apr 30, 2019
D2.3	**Decision of build of the data warehouse**	**CUB**	**Key deliverable. Revision by: MUG, DIT, DFKI**	**R**	**PU**	**Oct 31, 2018**
D2.4	Functional harmonization of Users, Roles and Access	CUB		R	PU	Apr 30, 2019

D2.5	Licensed and running data warehouse	CUB		DEM	CO	Apr 30, 2019
D2.6	Written concept which is approved by the regulation authorities	CUB		R	PU	Apr 30, 2019
D2.7	Reliable interfaces implemented as service connectors	CUB		DEM	CO	Oct 31, 2019
D2.8	**Pilot for clinical decision support system**	**CUB**	**Key deliverable. Revision by: GUT, AOK, LIU, UTARTU**	**DEM**	**CO**	**Apr 30, 2021**
D2.9	Data Management Plan (DMP)	CUB		R	CO	Oct 31, 2018
D3.1	First prototype of dictionary + ontology	MUG		DEM	CO	Jan 31, 2019
D3.2	**First release of dictionary + ontology**	**MUG**	**Key deliverable. Revision by: DFKI, DIT**	**DEM**	**CO**	**Oct 31, 2019**
D3.3	Intermediate version of dictionary + ontology	MUG		DEM	CO	Apr 30, 2021
D3.4	Final dictionary + ontology	MUG		DEM	CO	Jan 31, 2022
D3.5	First version of text analyser	MUG		DEM	CO	Apr 30, 2019
D3.6	Second version of text analyser	MUG		DEM	CO	Apr 30, 2020
D3.7	First version of text-to-onto mapping	MUG		DEM	CO	Apr 30, 2021
D3.8	Final version of text-to-onto mapping	MUG		DEM	CO	Jan 31, 2022
D3.9	Quality report	MUG		R	CO	Jan 31, 2022
D3.10	Paper on Best practices for data sharing in in-silico modeling	MUG		R	PU	Apr 30, 2022
D4.1	**White paper on stroke risk, health and resilience factors**	**CUB**	**Key deliverable. Revision by: GUT, AOK, LIU**	**R**	**PU**	**Feb 28, 2019**

D4.2	QoL targets for the models created in created in T4.5, T4.6, T4.7, T4.8	DIT		R	PU	Feb 28, 2019
D4.3	**Data Schema Designs for Each Model**	**DIT**	**Key deliverable. Revision by: CUB, DFKI, GUT, ETH**	**R**	**PU**	**Sep 30, 2019**
D4.4	White paper on hybrid model fusion strategies	DIT		R	PU	Feb 28, 2019
D4.5	**Personalised stroke prevention model**	**DIT**	**Key deliverable. Revision by: ALL PARTNERS**	**DEM**	**CO**	**Oct 31, 2021**
D4.6	Personalised hybrid model predicting short term stroke outcome	DIT		DEM	CO	Aug 31, 2021
D4.7	Personalised Hybrid Model Predicting Post-treatment Quality of Life	DIT		DEM	CO	**Oct 31, 2021**
D4.8	**Personalised rehabilitation model**	**DIT**	**Key deliverable. Revision by: ALL PARTNERS**	**DEM**	**CO**	**Oct 31, 2021**
D4.9	Model Predicting Long-Term Reintegration and Well-Being	DIT		DEM	CO	**Oct 31, 2021**
D4.10	Integrated digital stroke patient platform for the life-cycle	CUB		DEM	CO	**Oct 31, 2021**
D5.1	Electronic patient recorded outcome framework (ePRO)	CUB		R	PU	Apr 30, 2019
D5.2	Study design for stroke treatment	CUB		R	PU	Apr 30, 2019
D5.3	**Stroke treatment study performed**	**CUB**	**Key deliverable. Revision by: GUT, AOK, LIU, ETH**	**R**	**PU**	**Apr 30, 2021**
D5.4	Study design rehabilitation/reintegration	GUT		R	PU	Apr 30, 2019
D5.5	**Stroke rehabilitation/reintegration study performed**	**GUT**	**Key deliverable. Revision by:**	**R**	**PU**	**Apr 30, 2021**

			GUT, AOK, LIU, ETH			
D6.1	Socio-economic model of long-term care dependency	DIT		R	CO	Apr 30, 2022
D6.2	Innovation management plan and exploitation report	EMP		R	CO	Apr 30, 2021
D6.3	Deployment scenarios and cost-benefit-analysis	EMP		R	PU	Apr 30, 2021
D6.4	Report on Industry Forum and Liaison	EMP		R	CO	Apr 30, 2022
D6.5	**Final business plan**	**EMP**	**Key deliverable. Revision by: ALL PARTNERS**	**R**	**CO**	**Apr 30, 2022**
D7.1	Project management plan and quality assurance process guidelines	EMP		R	PU	Jul 31, 2018
D7.2	Periodic activity reports and annual dissemination report	EMP		R	CO	Apr 30, 2022
D7.3	Corporate identity, branding policy, and project website	EMP		R	PU	Jul 31, 2018
D7.4	Communication and publication strategy	EMP		R	PU	Oct 31, 2018
D7.5	**Launch of European Modelling Platform for Open Stroke Research**	**CUB**	**ALL PARTNERS**	**ORDP: Open Research Data Pilot**	**PU**	**Oct 31, 2021**
D8.1	HCT – Requirement No. 1	CUB		Ethics	CO	April 30, 2019

4 Advisory board

A scientific Advisory Board (AB) to act as independent external source of review and quality assurance will be initiated during the first six months of the project and maintained throughout the project lifetime. By critically accompanying the project's progress the AB will provide valuable guidance from the perspective of major stakeholder groups or be involved in the internal revision of key deliverables.

Potential advisory board members, with whom the coordinator has already established contacts and who will be invited to join the board are listed below (subject to confirmation). Additional advisory board members may be contacted for selected fields of expertise.

Name	Organization; location	Key field of expertise
Prof. Toby Richards	UCL	Scientific Advisor
Christoph Lengauer	Boston	Business Development Advisor
Prof. Johner	Germany	Certification and Regulation Advisor
Prof. Kristian Hildebrand	Germany	Machine Learning Advisor

The AB may be invited to meet physically with specific consortium partners or with the whole consortium to provide input and expertise. This can be during workshops, conferences, project meetings or internal bilateral meetings. In addition to taking part in physical meetings, AB members may be invited for online meetings when needed to get external expertise. Throughout the project duration, the AB will be regularly informed by the project team about progress made, and can in particular be asked to provide written feedback about the following key deliverables:

No.	Name	Lead short name	Key deliverable. Internal revision by:	Type	Dissemination level	Delivery
D2.3	Decision of build of the data warehouse	CUB	Key deliverable. Revision by: MUG, DIT, DFKI	R	PU	Oct 31, 2018
D2.8	Pilot for clinical decision support system	CUB	Key deliverable. Revision by: GUT, AOK, LIU, UTARTU	DEM	CO	Apr 30, 2021
D3.2	First release of dictionary + ontology	MUG	Key deliverable. Revision by: DFKI, DIT	DEM	CO	Oct 31, 2019
D4.1	White paper on stroke risk, health and resilience factors	CUB	Key deliverable. Revision by: GUT, AOK, LIU	R	PU	Feb 28, 2019
D4.3	Data Schema Designs for	DIT	Key	R	PU	Sep 30,

	Each Model		deliverable. Revision by: CUB, DFKI, GUT, ETH			2019
D4.5	Personalised stroke prevention model	DIT	Key deliverable. Revision by: ALL PARTNERS	DEM	CO	Oct 31, 2021
D4.8	Personalised rehabilitation model	DIT	Key deliverable. Revision by: ALL PARTNERS	DEM	CO	Oct 31, 2021
D5.3	Stroke treatment study performed	CUB	Key deliverable. Revision by: GUT, AOK, LIU, ETH	R	PU	Apr 30, 2021
D5.5	Stroke rehabilitation/reintegration study performed	GUT	Key deliverable. Revision by: GUT, AOK, LIU, ETH	R	PU	Apr 30, 2021
D6.5	Final business plan	EMP	Key deliverable. Revision by: ALL PARTNERS	R	Cp	Apr 30, 2022
D7.5	Launch of European Modelling Platform for Open Stroke Research	CUB	ALL PARTNERS	ORDP: Open Research Data Pilot	PU	Oct 31, 2021

5 Reporting

The Periodic Progress Reports (PPR) that have been presented in the DoA description of WP7 aim to report the undertaken activities during the past period by each partner and to compare results with the established Description of Work. The PC will oversee collecting contributions from all partners and reporting to the Commission. A Financial Report (FR) will be delivered at the end of each official reporting period. Reporting Period 1 (RP1) is from PM1-PM18; RP2 is from PM19-PM36 and RP3 is from PM37-PM48.

Each financial report will contain a cost statement prepared by each participant, and a financial summary sheet prepared by the co-ordinator (that will bring together the incurred costs of the consortium and the requested community contribution, broken down by participant and type of activity). Finally, there are various other deliverable reports that will be prepared during the lifespan of the project, categorised according to their confidentiality. These deliverables will be forwarded to the EC in electronic form (in PDF) or/and in hard-copy if requested. These deliverables can contain project assessment, WP reports for reviews, minutes from Consortium Meetings and Project Meetings, expenditure profiles and technical project meetings reports.

6 Conflict Resolution Procedure

The Project Coordination Committee is the highest decision making body of the project. Each partner will have equal votes. Project Executive Committee is a central tool in operational management of the project. It combines the scientific, clinical and technical views of the project and gives guidance to the Work Package Leaders. WPLs manage their work according to a 6-month or annual work plan. In case of a problem that cannot be resolved on the WP level or with a WP leader and the PC or PMA together, WPLs may bring the concern to the attention of the Project Coordination Committee. The detailed decision making procedures are defined in the Consortium Agreement, which is due to be signed by all partners at the writing of this deliverable. The aim of these procedures is to minimise the risk of problems occurring during the implementation of the project and to find amicable resolutions to possible conflicts.

7 Annex 1: Quality Verification Sheet

Quality Verification Sheet

WP: WPx

WP Leader: xxx

Deliverable: Dx.y

Reviewer:

Affiliation:

Date:

Summary of contents, structure and work responsibilities (to be filled by deliverable lead):

Objectives, task and timing of the deliverable (to be filled by deliverable lead):

Assessment of the deliverable by peer reviewer

Verification of DoA objectives (comparison of outcome of deliverable with the project plan):

Comments/observations on the quality of the overall approach (for the purposes it is intended for):

Suggestions for modification / improvement (bearing in mind the timing, resource and other features of the research context):

Any other observations (e.g. minor corrections that need attention):