BD4QoL
BIG DATA FOR QUALITY OF LIFE

BD4QoL

Big Data Models and Intelligent tools for Quality of life monitoring and participatory empowerment of head and neck cancer survivors

D10.1 Quality manual

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3.0	15.05.2020	E. Martinelli UMIL	Integrated comments by CSS

Addressees of this document

All Consortium partners and linked third parties, the European Commission.

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Abbreviations and definitions

Definitions

Quality: the total set of characteristics of a product or service that affect its ability to satisfy a customer's stated or implied needs.

Quality system/Quality Assurance System (QS/QAS): the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality assurance (QA): the systematic and independent examination of all research-related activities and documents. These audits determine whether the evaluated activities were appropriately conducted and that the data were generated, recorded, analyzed, and accurately reported according to WPs and tasks described in the grant agreement, the clinical study protocol, standard operating procedures (SOPs), and good clinical practices (GCPs).

Quality control (QC): periodic operational checks within each functional department to verify that the activities set in the Annex I to the Grant Agreement are duly and timely performed and that clinical data are generated, collected, handled, analyzed, and reported according to protocol, SOPs, and GCPs.

CA	Consortium Agreement
DoA	Description of Action – Annex I to the Grant Agreement
EC	European Commission
EU	European Union
GA	Grant Agreement
GCP	Good Clinical Practice
HNSCC	Head and Neck Squamous Cells Carcinoma
KPI	Key Performance Indicator
PoC	Point of Care
SoC	Standard of Care
QA	Quality Assurance
QP	Quality Plan
QC	Quality Control
SOP	Standard Operating Procedure (for actions performed in the clinical study)
WP	Work Package

Abstract

This Quality Manual describes the procedures established to fulfil the above goals based on a quality-driven framework within which the project will be conducted and implemented. The quality framework incorporates two main dimensions: healthcare quality and technical quality as support to the care delivery objectives of the clinical study. They must include key dimensions for healthcare such as access, safety, effectiveness, efficiency, timeliness and patient centredness.

This document complements the quality provisions foreseen in the Technical Annex I DoA and in the Consortium Agreement for what concerns project responsibilities, coordination and decision-making. It has the objective to:

- provide methods, standards and procedures related to:
  - development, verification and maintenance of quality criteria;
  - acceptance and quality control;
  - risk assessment and monitoring;
  - control and recovery actions;
- advise and assist the project working team(s) in the achievement of high-quality results;
- plan, organize and perform controls aimed at a permanent and critical assessment of the progress of project activities vis-à-vis the expected results and the project goals.

1 PRINCIPLES AND OBJECTIVES

1.1 Introduction

Quality assurance and risk prevention are crucial in the context of healthcare management and, consistently, impact on the development of Information Technology tools. This is particularly true for the BD4QoL platform that involves the collection of patients' health data (sensitive data) also by means of mobile apps. In this sense quality should also consider ethical and legal aspects associated to patients' privacy, freedom and fundamental rights and to data security. Additionally the collected data will generate interventions by Point of Care (PoC) physicians (e.g. phone calls to ascertain patient's health status, messages to provide patients with some advice how to handle non-critical conditions such as doing some physical activity), thus quality of collected data and of the algorithms developed to analyze these data and to produce alerts/feedbacks to patients and physicians and to activate interactive and proactive actions for the establishment and possible improvement of health status and quality of life of patients is fundamental. Most importantly, risks linked to the execution of the clinical study and of the technology development need rapid detection, accurate assessment of impacts, timely intervention and precise documentation.

Consequently, BD4QoL must adopt a suitable quality procedures, detailed in this document (Quality Manual), aimed at ensuring that the clinical study, the developed tools and the BD4QoL Platform meet the following requirements:

- the clinical study complies to all ethical and legal aspects for what concerns privacy, security, patients' safety and safeguard of patients' health (clinical perspective);
- the clinical study must collect sufficient data with the needed quality and completeness to ensure scientific accuracy of data analysis, patients' QoL assessment and clinical results assessment (scientific perspective);
- the BD4QoL data collection apps must be secure (in terms of cybersecurity, data protection), allow data analysis in privacy-preserving way, user friendly, compliant with patients' rights and supportive to users needs (patients and caregivers);
- the BD4QoL software platform must perform tasks correctly (developers perspective) and be reliable in particular for what concerns algorithms that generate alerts to patients and physicians (ethics and users perspective).

From an operational and managerial point of view, the Quality Manual sets the procedures for quality assurance and risks management that the objectives of BD4QoL are achieved with the resources available and within the timeframe of the project.

1.2 Scope

The purpose of this document is to propose the guidelines and a shared approach to ensure the quality of the BD4QoL clinical study and software platform, in accordance with users' needs, technical architecture and scientific rigour.

Our approach is adapted from different sources (e.g. ISO) and considers the ethical requirements set

in the Section 5 of the DoA and the specific quality requirements for healthcare organizations[2], and it involves end users, scientists and software developers throughout the whole design, development/execution and validation process.

The overall Quality Assurance Strategy and guidelines of BD4QoL are addressed in Chapter 3.

1.3 The quality context of BD4QoL

BD4QoL involves monitoring the quality of life of head and neck cancer survivors and informs survivors and physicians on possible health status deterioration and on actions to be taken to prevent, mitigate and address such changes, thus four levels of Quality Assurance interventions need to be considered:

1. Quality of the involved actors/Consortium: this has been assessed during the preparation of the project and will be continuously monitored by the Coordinator throughout the project execution.
2. Quality of the clinical study: the study endpoints, the quality criteria for patients enrolment, data collection and data analysis have been extensively described in the clinical protocol and must be approved by the Ethical Committees of all the participating hospitals. A major concern for the project consists in the number of cancer survivors that will be recruited for the clinical study and will accept to use the developed monitoring and QoL reporting tools, and the completeness and quality of data. The Quality Plan will establish checkpoints to verify that the involved centres verify patients' compliance to the data collection protocol and to the specific quality assurance measurements and will foresee appropriate mitigation actions.
3. Quality of the devices and tools used to collect and analyse the data: the selected devices for unobtrusive data collection (e.g. physical activity, sleep, etc. as described in the clinical study protocol) shall be verified for quality in terms of accuracy of data collection. In this respect we will endeavour to use commercial devices and sensors that have been already assessed and reported in previous studies, so that their measurements accuracy level can be taken into consideration in the developed algorithms. The Plan will establish a specific checkpoint in WP3 to assess this quality indicator.
4. Quality of results (deliverables, software and any other expected results), that will be assessed by the Project Board and by the Coordinator as part of the Quality Assurance and Coordination activities as defined in the Technical Annex I DoA, part B section 3.2 and in the Consortium Agreement Section 6, and for what concerns the clinical and scientific aspects in the frame of WP7 and WP8. If necessary external independent experts (the Advisory Board) will be appointed to further verify the quality of results (see Consortium Agreement Art. 6.6).

[2] see for example: U.S. Department of Health and Human Services "Developing & Implementing a QI Plan" and The Collaborative for Excellence in Healthcare Quality "A guide to developing and assessing a quality plan for healthcare organizations.

2 QUALITY POLICY

The BD4QoL Consortium is committed to achieve all the contractually defined clinical, scientific and technical objectives and to produce the expected impacts described in the DoA.

An effective quality assurance system (QAS) is therefore established for the fulfillment of the following obligations described in the DoA:

- Achieve all project milestones within the relevant due date
- Produce all project deliverables, in conformance to the delivery date, resources and budget and quality levels established in the DoA
- Accomplish all Ethics requirements committed in the clinical study protocol and, in general, related to the implementation of the project, according to EU regulations
- Achieve the promised quantitative KPIs, concerning the most relevant aspects of the project performance and results
- Monitor and control major risks that can potentially affect the achievement of the project objectives, both already identified in the DoA and new risks upcoming during the execution of the project activities.

The principles guiding the Quality Assurance Policy of BD4QoL are aimed at ensuring the utmost quality of the project results and must therefore be equally applicable by all participating organizations. The project's quality manual therefore implements procedures that are:

1. aligned with the strategic objectives of the project and of the participating organizations,
2. described in terms that are clear and easily understandable and interpreted,
3. designed to have measurable objectives,
4. evaluated on a yearly basis,
5. feasible based on available resources and on the foreseen timeframe.

2.1 Quality policies approvals and revisions

The Quality policies described in this deliverable have been approved by the project Consortium and authorized by the General Assembly at the date of issue, indicated in the cover page of the document.

Project procedures will be prepared by the responsible partner (WP leader/Task Leader) and will be reviewed for internal quality assurance by the Project Manager (PM).

Any Consortium partner may request the upgrade or the modification of the Quality Manual and procedures as necessary at any time during the project execution, in the aim to increase the level of quality and to facilitate the quality assurance work. Modifications shall be agreed and approved by the Management Board and then distributed to all Consortium members.

The Quality Manual may be reviewed by the Project Board and submitted for approval to the General Assembly during Consortium meetings to take into consideration:

- the adequacy of project partners staff for the tasks and activities foreseen and/or undertaken or the usage of resources,

- the results from project reviews and from internal audits,
- deficiencies or problems concerning any project deliverable,
- the preventive and/or corrective action requests from all the above,
- problems with subcontracting,
- the eventual risks and the related corrective/mitigation actions.
- need for new quality procedures,
- users' dissatisfaction,

Records of such meeting decisions will be kept by the Coordinator and actions decided will be followed as part of the quality assurance and risk management task (T10.3) and as part of Technical management (T10.2) and Ethics aspects management (T10.4).

3 BD4QOL ORGANIZATIONAL STRUCTURE

Chapter 3.2 of the Annex I to the Grant Agreement and Articles 6.1 through 6.3.3.5 of the BD4QoL Consortium Agreement set the project responsibilities. For what specifically concerns quality management and assurance, a Quality Manager has been appointed (prof. G. Fico, UPM), who will be responsible for the overall quality of the project, risks management and QA, as well as to monitor the achievements of each WP and task, assisted by Work Package Leaders (WPLs).

The project organizational structure is presented in the figure below.

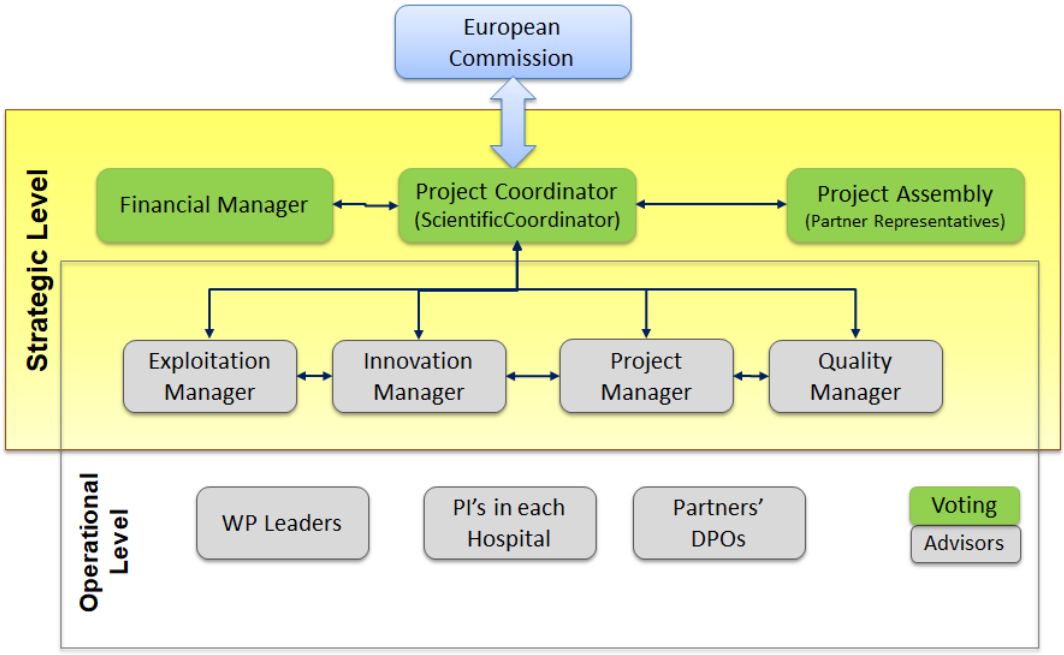

Figure 3-1. Organizational and Management structure of BD4QoL

The following table summarizes the project governance structure and the main responsibilities connected with the project Quality Assurance.

Table 3.1 – BD4QoL responsibilities

Role	Type	Members	Responsibility
General Assembly (GA)	Body	Consists of one Representative of each Party including the Coordinator PI and, when requested, by the Financial Manager.	To deliberate, negotiate and decide on (see CA Art. 6.3.1.2) content, finances and intellectual property rights, evolution of the Consortium, risks, disputes, partners' under- or non-compliance.
Project Board	Body	Consists of the Project Coordinator PI, the Innovation Manager, the Project Manager, the Quality Manager and the Exploitation Manager.	To orient and monitor the project works for the effective and efficient implementation of the project, in accordance to the decisions of the General Assembly (see CA Art. 6.3.2.3).

Role	Type	Members	Responsibility
Coordinator	Organization	Established in the Grant Agreement	To ensure that the Project is executed and the results are achieved in compliance with the Grant Agreement (see CA Art. 6.3.3). It is the primary responsible partner against the European Commission.
Project Manager	Person	Appointed by the Coordinator	To manage the project on a day-by-day basis, chair meetings, ensure communications within the consortium, review deliverables, monitor risk mitigation actions.
Technical/Innovation Manager (Prof. G. Fico UPM)	Person	Appointed by the Project Assembly.	In charge of the overall coordination of the project's technical work, assisted by a technical management team at UPM.
Quality Manager (Prof. G. Fico UPM)	Person	Established in the Annex I to the Grant Agreement and confirmed by the Project Assembly	To ensure the overall quality of the project, risks management and QA, and to monitor the achievements of each WP and task, assisted by Work Package Leaders (WPLs).
Scientific Coordinator (Prof. L. Licitra UMIL)	Person	Established in the Annex I to the Grant Agreement and confirmed by the Project Assembly	To coordinate the execution of the clinical study execution, the quality of the clinical research and of the scientific results.
Exploitation Manager	Person	Appointed by the Coordinator.	To coordinate the external communications, and the project's exploitation and innovation work.
Work Package Leader (WPL)	Person	Appointed by the respective WP lead beneficiary	To coordinate the work of partners participating to WP execution, monitor their work and take decisions concerning the execution of WP tasks. To review all deliverables foreseen for the WP
Task Leader	Person	Appointed by the respective task lead beneficiary	To execute the expected works of the task, to monitor the activities of collaborators (including other beneficiaries) and to report to the WP Leader.

Role	Type	Members	Responsibility
Deliverable lead beneficiary	Organization	Established in the Grant Agreement	To timely release the expected deliverables

3.1.1 Quality Manager

Given the high relevance of technical works in BD4QoL, the Technical Manager of the Project is also the Quality Manager, responsible for the overall quality of the project's work, outcomes and committed objectives. To do that, Prof. Fico is supported by a management team (composed by Laura Lopez, from UPM as Operational Technical Manager, Aitor Almeida from UDEU as Innovation Manager and Franco Mercalli from MULTIMED as Exploitation Manager) that is providing support to all the technical activities and decisions.

Decisions will be categorized as high, medium or low priority, assigning to each level a response time:

Table 3.2 – Categories of quality assurance decisions

Priority	Time frame	Examples of decisions by criticism
High	1 day	Technical action that should be made due to issues with the clinical data collection.
Medium	1 week	Technical action of a needed solution with a close deadline
Low	1 month	Other situation, such as technical decisions of the activities to be conducted in the next months

The technical management, given the project scope is focused on the technological developments of the project. To this aim, biweekly conference calls with all the technical partners (i.e. leaders of WP2, WP3, WP4, WP5 and WP6 and WP8 and IECISA) will be carried out. Minutes of the meetings will be taken in real-time using online reporting tools (i.e. Etherpad[3])

The technical manager also monitors – jointly with the Coordinator – the correct use of resources and the achievement of contractual obligations.

The Coordinator will be assisted in this task by the Project Board and the Work Package Leaders. Tasks and responsibilities of these persons and organisms are detailed in the Technical Annex I, DoA, section 3.2.

3.1.2 Work-Package Leaders

For each work-package (WP), the Annex I to the Grant Agreement establishes a Lead beneficiary, i.e. a Consortium Partner responsible for the work in the respective work-package. The WP Lead Beneficiary appoints a WP Leader (person), who will be in charge for the coordination of the WP

[3] https://etherpad.wikimedia.org/

activities and of the relevant QA. The responsibilities of WP leaders are described in the Annex I to the Grant Agreement part B section 3.2.1.

Work Package Leaders appointed for BD4QoL are listed in the table below.

Table 3.3 – BD4QoL Work Package Leaders

WP #	Wp Title	Lead Beneficiary	WP leader
1	Ethics	UMIL	Prof. Lisa Licitra
2	Personal data sources monitoring for HRQoL	UDEU	Mr. Aitor Almeida
3	Data collection platform for HRQoL	DOT	Mrs. Elisabeth Filippidou
4	Point of care support	UPM	Mrs. Laura Lopez-Perez
5	Patient empowerment platform	IBMI	Mr. Faisal Ghaffar
6	Multidimensional QoL prediction models	UiO	Prof. Arnoldo Frigessi
7	Clinical Study	UMIL (INT)	Dr. Carlo Resteghini
8	Impacts assessment	MME	Mr. Franco Mercalli
9	Exploitation, dissemination and communications	RL (ARIA)	Mrs. Francesca Sapio
10	Coordination	UMIL	Prof. Lisa Licitra

3.1.3 Deliverable Lead Beneficiary

For each deliverable, the Annex I to the Grant Agreement establishes a Lead beneficiary, i.e. a Consortium Partner responsible for coordinating the deliverable preparation work. The representative of the Beneficiary in charge of a deliverable is responsible for its quality and must deliver it to the WP leader on time for review, before the official delivery date. In particular they are responsible for:

- Proposing and agreeing with other contributors the structure of the deliverable (e.g. ToC for deliverables of type Report, architecture for deliverables of type Demonstrator, etc.) and the relevant individual contributions required
- Monitoring the production of contributions from involved Partners
- Ensuring the editing of the draft and final versions of the deliverable
- Promptly signal to the relevant Work-package Leader any potential risk for the deliverable, such as the possibility of delayed release or insufficient quality.

4 QUALITY OBJECTIVES

4.1 Quality of data and of data collection devices

In BD4QoL the majority of data are collected by means of mobile apps. The quality of the devices used to collect the data is fundamental to avoid issuing unnecessary alerts and to ensure correct data analysis and data interpretation.

In this context, the devices that will be used to collect data from participants will rely on slip technology, i.e. self-correction of activity recognition when possible. In addition, when data collected seem to be out of normal range of values or certain high level activities seem to be out of the participants expected life behaviour, our approach is to consider these events as "triggers" that will generate conversations between the chatbot and the participant. These conversations will be derived valuable information about whether the data collected are correct or not, and accordingly decide whether this should be kept or discarded.

In this direction, the quality strategy involves choosing the "right" smart devices that can meet the intervention goals towards the participants. These involve capturing a large number of data on a 24/7 basis about one's social, physical, sleeping and nutrition behavior in a non-obstructive way that promotes engagement with the project and reduces drop-out. The project will analyse available market devices and choose the ones that meet these intervention goals in a way that promotes data openness, durability and sustainability of devices, as well as collaboration with device providers. A set of acceptance criteria will be set to balance the need between quantity of data versus quality and will be tested in order to recommend the appropriate smart devices for the participants.

4.2 Tasks and Work Packages

Tasks and Work Packages (WP) are detailed in the DoA part A section 1.3.3, along with the responsible partners and the execution timing and deadlines. Tasks and WPs must be completed according to the committed timing and to the allocated resources, as described in the DoA, and in respect to the relevant ethical aspects.

Delays and exceeding the allocated resources (personnel and/or budget) shall be considered deviations and non-conformity vs. the plan and shall be addressed immediately and mitigation or recovery actions shall be put in place. Task/WP leaders are responsible to immediately inform the Coordinator and the Project Board of such occurrences. The Risk Management procedures detailed in the following address these cases.

Quality of tasks and WPs will be monitored internally at three levels:

- by the WP leader, through periodic assessment of the progress of the WP (at least on a monthly basis and even more often in case of near delivery deadlines)
- by the Coordinator and/or the Project Manager and the Project Board through periodic management and coordination conference calls (every two weeks or at least on a monthly basis in consideration of the difficulties of physicians to attend due SARS-COV2 outbreak).
- by the General Assembly during Consortium meetings and through the agreed periodic internal reporting (every 6 months), as established in the Annex I to the Grant Agreement,

section 3.2.3: "The PM will verify costs and resources spent over a 6-monthly basis (internal reporting) and will produce the requested periodic reporting to the EU as defined by the Grant Agreement. The Coordinator will report any major deviations from the Project objectives or the work plan to the EU Project Officer and will agree the necessary actions."

and externally by the European Commission during periodic reviews.

Failures detected through internal quality assurance will be reported in the relevant internal periodic reports along with the agreed corrective actions and the results of such corrective actions. Quality problems that affect other tasks or WPs shall be evaluated jointly with the affected WP/Tasks leaders, relevant risks shall be assessed and addressed and a shared solution/recovery plan must be issued (see section 9). Major or unresolved failures shall be also reported in official periodic reports submitted to the EU.

An insufficient quality rating at a project review is a serious non-conformity that should be immediately addressed through adequate corrective and preventive actions, in compliance with the recommendations received as part of the independent reviewers' report. Actions implemented will be described in the periodic report to be submitted to the European Commission Offices and – if required – in specific documents to be provided as required.

4.3 Deliverables

The official deliverables due by BD4QoL Consortium are listed in the table WT2 reported in the DoA, Part A, Section 1.3.2 and are better described in the relevant Work Package Descriptions in DoA part A, section 1.3.3. They constitute the results of tasks/WPs.

Deliverables must be released to the European Commission by uploading them to the EU Participant Portal, within the due date indicated in the DoA and in the portal. Late delivery is a non-conformity, that must be immediately addressed (see section 5.2.3)

Deliverables must be completed within the resources allocated to the work-package to which they belong. Exceeding the allocated resources is a relevant risk that should be carefully monitored throughout the project execution.

Quality of deliverables will be controlled at two levels:

- Internally to the Consortium and prior to delivery, through an internal reviewing procedure.
- By the European Commission after delivery, through contractual project reviews.

Same as WP/Tasks, insufficient quality evaluation of a deliverable received after a project review is a major risk that shall be addressed as recommended by the evaluators in the shortest time (see section 9).

4.4 Milestones

The milestones committed by BD4QoL Consortium are described in the table reported in the DoA, Part A, Section 1.3.4. Similar to WPs and Deliverables, milestones are assigned to a lead beneficiary and have a committed delivery date. The DoA also provides indications on how to measure the degree of achievement for the milestone, which constitutes the measure of quality for the milestone.

Failure in achieving a project milestone is a major risk, that should be carefully monitored along the project duration and constitutes a non-conformity that should be addressed through adequate actions.

4.5 Key Performance Indicators (KPI) measurement

The KPIs defined by BD4QoL Consortium (see DoA part B, section 2.1) provide quantitative quality objectives that relate to the impacts foreseen from the project. Each KPI indicates the indicator to be measured, measurement criteria and a quantitative threshold for quality achievement. They are mostly related to the scientific/clinical impacts to be assessed in WP7 and technical works relevant to WP4 through WP6.

Missing a KPI objective should be carefully monitored along the project duration and should be immediately addressed through adequate corrective and preventive actions. The Coordinator, the Project Manager and the Scientific Manager are in charge of monitoring the achievement of KPIs.

4.5.1 Quality levels

The level of quality required is important to establish the acceptability of project outputs as defined in the previous paragraphs. To assess the quality level the quality responsible persons at all levels shall be assigned a list of metrics that will be used for quality evaluation, similar to what is usually applied by the European Commission during project reviews. This scale indicates the level of achievement of the expected result as follows:

- Unacceptable: quality level is unsatisfactory, achievement ratio is below 60% of target
- Acceptable: quality level is sufficient, achievement level is between 60% and 70% of target
- Good: the project output/result quality satisfies the expectations and is in line with the commitments, achievement level ranges between 70% and 100% of target
- Excellent: the quality of the output/result goes beyond commitments and expectations, achievement level exceeds the committed target.

4.6 Ethical considerations regarding quality assurance

BD4QoL foresees a clinical study involving humans and data collected by means of mobile apps, with a critical privacy aspect relevant to patients' sensitive data. Thus ethical aspects have been addressed in depth both in the DoA part B section 5 and in the clinical protocol D7.1.

Regarding Ethical aspects, the Coordinator is responsible to ensure that all participating hospitals fulfill the National and European regulations regarding safety, security, privacy and all aspects concerning the deployment of the mobile applications and patients' data collected during the project. For this scope the Coordinator has requested that all participating hospitals provide the approval of the BD4QoL study by their reference Ethical Committees. Copies of the ethical approval documents as well as the signed informed consent from each study participant are maintained by the Coordinator.

Ethical Committees established in each clinical centre have approved the clinical study protocols (for prospective study and for retrospective study) and the relevant ethics framework and quality assurance guidelines have been set as part of the protocol. Data Controller, supported by Data Protection Officers (DPO) in each participating hospital and partner organizations involved in data

processing will be in charge of ensuring that patients' data protection regulations are accomplished. They will refer to the Data Controller of their organizations and to the Coordinator. Applied procedures to ensure study subjects' rights and data protection are detailed in chapter 5 of the Annex I to the Grant Agreement.

Failure to satisfy an ethics requirement is an extremely serious non-conformity that can stop the clinical study execution and consequently invalidate or jeopardize the project execution and results. Therefore, it should be immediately addressed through adequate corrective and preventive actions and should also be monitored as part of risk management.

5 QUALITY OF COORDINATION

The quality of coordination implies the measurement of progress and excellence of the work of the Consortium. The assessment of the quality of the work for the overall project is under the responsibility of the General Assembly, which meets usually three times a year, and by the Coordinator, through the Project Manager (PM) with the assistance of the Quality Manager. In fact it is the primary responsibility of the Quality Manager and of the Project Manager to monitor the overall progress of the project activities and to report and justify to the Coordinator, to the General Assembly and to the Project Board such progress, any deviations and any modifications to either the work results or the schedule of activities. The Coordinator has therefore established a specific project monitoring procedure, to be executed by the PM:

- at the start of each month the PM sends an email to all involved WP leaders and partners representatives reminding of deadlines occurring in the next three months (tasks activities, deliverables and milestones) and asking for a workplan within two weeks;
- at the start of the delivery month for any project deliverable or milestone, the PM issues a reminder to the interested WP leaders and task leaders, asking to receive a draft of the document to be approved at least one week before the official delivery date;
- in case of any delays, the PM contacts the WP and/or the task leaders directly by phone or by any other videoconferencing method, in order to assess the status of work, any problems and to agree on the actions to be performed;
- in any case at least once a month the PM performs a phone or videoconference survey on all open tasks, to assess the progress of work, to verify that all involved partners are informed and working and to check with the WP Leader possible risks;
- every 6 (six) months the Project Manager collects report on activities performed for each WP-Task and related resources devoted (see Annex I) from all partners. WP Leaders are in charge of collecting such activity reports from all partners involved in their WPs, and to provide the summary to the PM. This will assess the progress of the project and the usage of resources and allow a correct planning for the next 6 months ahead. The 6 months periodic reports will be used internally to the Consortium and eventually presented and discussed during Consortium Meetings. They will also be used to verify the compliance of partners and of Third Parties.

Details of agreed quality assurance related actions are included in the following reference documents:

- Technical Annex I, part B section 3.2.2 through 3.2.5
- Consortium Agreement, Articles 6.2 (General operational procedures for all Consortium Bodies), 6.3 (Specific operational procedures for the Consortium Bodies), 7 (Financial provisions).

5.1 Internal periodic reporting

Internal reporting is established on a six-monthly basis, in order to support the Project Board in the monitoring of the project execution, resources used and status of activities.

Content of the internal periodic reporting

The following data items will be provided by each beneficiary, with reference to the reporting period (see template in Annex I):

- summary of the work performed and of objectives achieved for each WP/Task
- used resources (person months, other costs)
- description of activities performed by subcontractors / third parties
- brief description of the work and deliverables planned by for the next reporting period
- dissemination activities performed, meetings attended

In addition, WP Lead Beneficiaries should provide a summary for the WP:

- summary of the work performed and of the objectives achieved
- brief illustration of the work planned for the next reporting period
- list and of major deviations from plan, risks and/or other elements affecting or likely to affect the project execution, applied corrective actions and results of such actions.

The quality procedure for periodic reporting is detailed in Annex G.

5.2 Periodic reporting to the EU

Official periodic reporting to the EU is required at the following months: 18, 36, 48,60 as stated in the Grant Agreement. The official reporting templates shall be submitted by the Coordinator on behalf of the Consortium within 60 days after the end of the reporting period. The report comprises the periodic report, according to the predefined format provided in the EU participants portal and the costs declaration forms submitted by each Beneficiary to the Coordinator through the EU participants portal.

Content of the periodic reporting to EU

The templates used for internal periodic reporting (see Annex I) will also be used to guide Beneficiaries in providing the necessary information for the editing of the official periodic Activity (and Final) reports and to allow a verification of the correct costs declarations prior to the official submission.

Each Beneficiary and WP Leaders are required to complete the reporting templates as specified at 5.1 above. Costs declared shall be coherent with the activities performed in the period by the Beneficiary. Additionally, the following information shall be indicated as justification of costs in the Costs Report for each Beneficiary:

- **personnel costs**: shall be indicated for each WP (total personnel costs by WP). For each person indicate the position in the organization, the person months devoted to the project in the reporting period.
- **subcontracts**: shall be indicated for each WP and subcontractor. The description of the subcontract and the sustained cost must be in line with the budget indicated in the Technical Annex I to the Grant Agreement part B section 4.2.

- **other costs**: shall be indicated for each WP and cost type (travel, consumables, etc.). Detailed description shall be indicated for each cost (e.g. name of provider, description of the purchase or of the cost, location and motivation of travels, etc.).

The Coordinator is responsible of verifying the coherency of costs vs. the declared and performed activities in the reporting period and may ask revisions (reject costs) to the Beneficiaries.

The process for periodic report to the EU is detailed in Annex G.

5.2.1 Project review meetings by the European Commission

The Project will undergo three EC project reviews, according to the following tentative schedule, established in the Technical Annex I to the Grant Agreement:

- RV1, M18, Luxembourg, Periodic Review #1
- RV2, M36, Luxembourg, Periodic Review #2
- RV3, M48, Luxembourg, Periodic Review #3
- RV4, M60, Luxembourg, Final Review (Technical & Scientific). This Review might be performed at a Pilot site upon agreement with the EC.

The format and specific content of these reviews will be established by the EC in agreement with the Coordinator.

The corresponding review reports that the EC will forward to the Consortium will be an input to the project QAS.

They will be analyzed by the Coordinator and by the Project Manager and possible identified non-conformities (e.g. rejected project deliverables) will be addressed in the Quality reviews to be taken by the General Assembly during the next Consortium meeting.

5.2.2 Project Quality reviews

Quality reviews will be performed by the General Assembly during each Consortium meeting to ensure continuous monitoring of quality throughout the project. The Coordinator chairs such reviews. Quality reviews will consider the following inputs:

- Technical Annex I to the Grant Agreement (tasks, deliverables, KPIs, timings, costs)
- Non-conformities / risks detected during the period since last Quality review
- Reports from EC project reviews
- Official communications from the EC concerning project execution or additional requirements
- Additional contingency information, relevant to the project, including from sources external to the Consortium, when relevant.

The Coordinator and the Project Manager will assess and present to the General Assembly the status of the project and the quality achieved vs. the quality objectives and targets. All Beneficiaries will be requested to provide relevant additional technical, scientific and/or managerial information to identify non-conformities, risks and to agree on corrective measures.

The results of the Quality reviews will be recorded into the relevant meeting minutes and will include the following elements (when relevant) to be used for actions:

- Updated tables of milestones
- Revised KPIs and/or clinical impacts to be measured
- Updated Ethics requirements
- Updated Risks
- List of non-conformities (e.g. deliverables to be revised).

For each item a responsible Beneficiary will be appointed and corrective actions will be agreed and described.

5.2.3 Management of non-conformities

Non-conformities shall me monitored throughout the project execution by all participants. Examples of non-conformities are:

- Lack of enrolled patients vis-à-vis the planned number
- Delay in the collection of data required for the project execution
- Delay in the submission of a deliverable
- Deliverables of insufficient quality
- Missing a milestone
- Missing a KPI or a committed scientific/clinical impact
- Failure to satisfy an ethics requirement
- Overspending on a work-package
- Insufficient dissemination activities.

Besides the systematic QA process performed by the Quality Manager, by the Project Manager and by the Coordinator on periodic reports and during Quality reviews, each member of the project team is encouraged to notify to the relevant WP Leader and to the Project Manager any non-conformity as soon as she/he detects it.

Addressing non conformity

The WP Leader and the Project Manager or the Quality Manager, within 7 days upon either a non-conformity detection or the reception of a non-conformity notification from another team member, must analyze the non-conformity, assess its seriousness, prepare a proposal for a corrective action, and submit the proposal to the Coordinator for further follow up and removal of the non-conformity.

Preventive and corrective actions

Each member of the project team is encouraged to suggest to the Project Manager any preventive actions that may contribute to improve the capability of the project to achieve its stated quality objectives and to suggest corrective actions that may increase the success in risk recovery.

Proposals for preventive or remedial actions may be advanced through email messages addressed to the Project Manager and to the Coordinator. The Project Manager will assess the applicability of the suggested actions and decides which ones shall be proposed to the Project Board for initial action and, in case the non conformity is not solved, to the General Assembly. The GA will take further

decisions regarding remedial actions that will be communicated to the Steering Board for implementation.

5.3 Quality assurance of work performed by third parties

BD4QoL foresees some activities that are subcontracted to third parties or services that are acquired from third parties as detailed in the Technical Annex I to the Grant Agreement section 4.2.3. In particular critical subcontracted activities consist in the enrolment of prospective patients (subcontractor Spedali Civili di Brescia) and s subcontract of ARIA for the integration of BD4QoL with Lombardy Region health data (DaaS system).

For these subcontracts a strict monitoring and quality assurance is foreseen as follows:

- the responsible partner will report to the Coordinator and to the Project Board on a quarterly basis concerning the status of the subcontracts
- the Coordinator and the Scientific Manager / Technical Manager, as applicable depending on the subcontract, will verify with the responsible partner that the subcontractor is correctly performing the activities with the requested quality levels within the established deadlines
- in case of non-conformity detected, corrective actions as described above (see section 5.2.3) will be implemented.

Partners subcontracting part of their work will perform it within their own budget and will remain fully responsible for the performance of the subcontractor.

The Coordinator will periodically assess the work of subcontractors as part of the activities of the reference Beneficiary, in the frame of the internal periodic reporting (every 6 months).

5.4 Communications

The Coordinator endeavoured to establish a fast, reliable and easily accessible communications infrastructure comprising:

- the project website: used for dissemination and external communications purposes;
- a documents management system (see below) accessed by each Beneficiary with individual credentials: URL: http://188.210.218.152:8880/nextcloud;
- mailing lists have been established by the Coordinator to facilitate communications, which are maintained by UMIL through a mailing address excel sheet published in the shared project area: http://188.210.218.152:8880/nextcloud/index.php/f/4285
- video-conferencing based on Skype™, and phone conferencing facility e.g. free of charge Zoom services (https://zoom.us/) to be used for remote meetings and urgent decisions of the Project Board or of the Assembly;
- a mechanism (based on periodic reporting) to monitor the usage of resources and the advancement of the project activities (see below).

All internal communications must be sent to the official emails of project participants, as indicated in the tables available at URL: http://188.210.218.152:8880/nextcloud/index.php/apps/files/?dir=/Documents/Mailing%20lists&fileid=4116.

The list of contacts will be maintained by the Coordinator throughout the Beneficiary IECI. It is a precise responsibility of each Beneficiary to promptly inform the Coordinator of any modifications to the mailing-list and to the contact details of the involved personnel.

Internal correspondence for the usual communications and transmission of documents (minutes of meetings, decisions of the Project Assembly/Project Board etc.) will usually be managed by emails. In case of restricted or confidential communications (but this is encouraged for all email communications), the following sentence should be added:

"This communication, which may contain confidential and/or legally privileged information, is intended solely for the use of the intended addressees. All information or advice contained in this communication is subject to the terms and conditions provided by the agreement governing each particular client engagement. If you have received this communication in error, please notify us immediately by responding to this email; then please delete it from your system. Any use, disclosure, copying or distribution of the contents of this communication by a not-intended recipient or in violation of the purposes of this communication is strictly prohibited and may be unlawful. The transmission technology used to send this mail can grant neither the sender identity nor the data integrity."

All **official correspondence** must be held in English language, will be sent by email or letter.

Copies of all official correspondence will be retained in the originator and recipient files.

All official and internal correspondence must be identified by:

- The Grant Number, the project acronym and the project name (for internal correspondence the project acronym is sufficient)
- The originating organization
- The author
- The date
- References to previous/related documents, letters, emails or other communications
- A unique sender reference ID
- Distribution list and addressees of the communication
- Confidentiality level.

E-mails must be acknowledged whenever requested; in such cases an explicit request will be included in the communication stating "PLEASE ACKNOWLEDGE RECEIPT". In this case the recipient(s) is(are) requested to send an explicit acknowledgment (not automatic), within three (3) working days. In case the recipient is absent an automatic message should be sent informing the sender.

5.5 Communications with the European Commission Offices

The Coordinator is the only authorized channel for submitting all documents to the European Commission (EC), and for general liaison between the Consortium and the EC. All general communications and all documentation for the European Commission must be through the Coordinator. Whenever possible the communications should be performed through the devoted functionality in the participant portal.

Exceptions are commercially sensitive communications that concern individual partner's IPRs or confidential business plans or patents: these might be directly addressed by the concerned Beneficiary to the relevant EU Offices (e.g. IPR helpdesk). This is only acceptable for communications that are commercially sensitive and confidential.

5.6 Collaborative documents management system

A shared documents management system has been established by IECISA at the start of the project (URL: http://188.210.218.152:8880/nextcloud). The repository is accessed by all Consortium members though personal access credentials. The Coordinator grants Partners the appropriate access rights, based on the roles and responsibility of a given Partner. Access to the repository must be asked to the Coordinator.

The Coordinator through the Project Manager is in charge of monitoring the quality of the documents' repository.

Organization of the repository

The repository is organized in folders, with self-explaining names, to group the different document categories managed by the project, under the root folder "Documents" at URL: http://188.210.218.152:8880/nextcloud/index.php/apps/files/?dir=/Documents&fileid=3662:

- Administration: this contains in subfolders all the administrative and official documents
- Meetings: this includes a subfolder for each meeting in which all documents related to the meeting are collected (agenda, minutes, signature sheets, presentations, etc.)
- Work-package documents: for each WP two subfolders are present:
    - working documents: contains drafts, internal documents and any other document that could be useful within the WP
    - officisl deliverables: contains official deliverables (all released versions, delivered to the EU)
- Templates: this includes project documents standard templates
- Mailing lists: include the updated mailing lists of project bodies and beneficiaries contact persons.

6 QUALITY ASSURANCE OF PROJECT DOCUMENTS

The following shall be considered documents for BD4QoL.

6.1 Deliverables

Deliverables should have the format of this document, to be taken as e template. They should:

- Have a cover page with the following data: ID, version number, contractual delivery date, actual delivery date, status, dissemination level (as established in Technical Annex I to the Grant Agreement, Part A, Section 1.3.2), short name of the Leading Partner, short names of contributors, project logo, Reference project documents
- Include a history of changes, which, for each version of the document, lists: the version number, the version issuing date, the author(s) of the version, a description and motivation of the modifications made in comparison with the previous version.
- Include a list of addresses for the document
- Include a table with definition and abbreviations
- Include an executive summary or abstract
- Include a header on every page with the Project Acronym and the Grant Agreement number
- Include a footer on every page with the title of the deliverable and the page number, followed by the total number of pages

6.1.1 Quality of deliverables

The internal quality check of deliverables is a mandatory step that will be performed at three levels:

- The deliverable Lead Beneficiary
- The relevant WP leader
- The Project Manager
- The Coordinator

The objective is to provide deliverable authors with comments and suggestions on the deliverable, that can help in improving quality. The quality check is initially applied to a sufficiently completed draft of the deliverable, that allows significant assessment of its content.

Comments and suggestions of the internal quality check are shared among deliverable contributors using email and the collaborative document management system.

The Coordinator has the last word for the approval of a deliverable and its submission to the EU.

Quality requirements for deliverables

- **Content.**

The responsibility for the content of each deliverable is always with the author(s). The following quality requirements must be met regarding all information included in reports and deliverables.

Relevance. Only information relevant for the scope of the deliverable must be provided. Accessory information or data may be provided in Annexes.

Completeness. Information provided in the deliverable must be reliable and must correspond to reality. All background information must be supported by references; foreground must be supplied in

clear statements and supported by evidence as much as possible (supporting data, measurements, comparisons etc.). Clarity is fundamental in order to avoid misinterpretation.

Accuracy. Content of deliverables must be focussed on the scope of the deliverable and present the key facts and issues. The content must include all the necessary information to enable verifications by readers and to be well understood by the specific target addressees.

- **Document structure and appearance.**

Uniformity and standardization. Deliverables shall conform to unique standards characteristics for the project, such as uniform structure, documents organization and appearance. To this aim specific templates are foreseen for the different types of deliverables, which must be used by all staff involved in BD2Decide.

Adherence to standards. In specific cases such as publications for journals/books, videos or other forms of documentation, international or de-facto standards must be adopted.

- **Timing**

Punctuality. Deliverables and information in general must be provided to the relevant addressees and especially to the European Commission in relation to the particular phase of the project's development and according to the project work plan. Punctuality in official delivery of documents and project results is mandatory.

Although the editor(s) are responsible for the above quality criteria of their deliverables, the WP Leaders and the Project Manager are in charge of further assessment of such quality.

The quality criteria indicated above are measured by the key indicators, summarized in the following table. They relate to the defects or points that require amendments in the documents and are categorized as non-conformities.

Table 6.1. Quality indicators for documents deliverables

Quality aspects	Quality criteria	Quality indicators (non-conformance)	Importance[4]
Content	Completeness	Missing content / Lack of information Redundancy Lack of details	Very High High High
	Relevance	Error in content Missing /wrong references Insufficient documentation Ambiguity	Very High High High High
	Accuracy	Non-relevant information Confusing text	Medium High
Document structure and appearance	Uniformity and standardization	Spelling errors Non-conformance to documents templates	Medium Medium

[4] +++: very important; ++: important; +: to be corrected but not very important

		Usage of different fonts and types of presentations	Medium
	Adherence to standards	Non-compliance to EU or de-facto standards	High
Timing	Punctuality	Delay	Very High

Process for the quality assurance of deliverables

- The WP leader verifies the document and then releases it to the Project Manager;
- The PM revises the document and
    - in case of medium/high non conformance indicators, rejects the document and sends it back to the author and Deliverable Responsible and in CC to the WP Leader with comments regarding the required revisions;
    - if approved, accepts the document and delivers it (upload on participants portal).

The process is iterative until the requested quality is reached. The process is detailed in Annex G.

Internal peer-review will be required for all deliverables, including a first revision of the Table of Content, and a final revision of the "final" deliverable. In such cases:

- The expert revises the document, send comments and recommendations to the Project Manager
- The PM forwards the peer-review to the relevant WP leader and verifies that the recommendations are considered and applied, then sends back for final approval the document to the internal reviewer.

6.2 Periodic internal reports

Periodic reports are collected through the document formats illustrated in Annex A. The QA procedures are described at sections 5.1 and 5.2).

6.3 Minutes of the meetings

Minutes of the meeting are collected as defined in the BD4QoL Consortium Agreement section 6.2.5. The minutes of meetings have the same format of project deliverables and shall include these mandatory items:

- Type of meeting (Consortium, Technical, Project Board, WP meeting, etc.)
- Date and venue of meeting, meeting duration
- List of participants
- Scanned signatures of participants
- Results of the meeting
- List of actions, deadlines and responsibilities agreed.

6.4 Risk registry

Risks are collected and monitored though a Risk Registry table (Annex F).

The table is managed by the Risk management procedure (see Section 9).

6.5 Other documents

Partners can produce other documents, beyond those listed above, as they see fit for the activities at hand. These "working documents" have a free format, however they should use a similar header and footer as indicated for deliverables, in order to identify the project, the scope of the document and the dissemination level. Versioning management is also recommended when applicable.

6.6 Version control

Each project document should have a version number, in the format *v*x.y, and have a edition date in the document footer. Deliverable should also have a history of changes, that track changes from one version to the next.

6.7 Documents approval and change management

Each version of a document is subjected to the approval by a responsible project role, as illustrated in the following table.

Table 6.2 Documents approval roles

Document type	Approval Responsible Body/Role
Deliverables	Relevant Work-package Leader Project Manager
Periodic internal reports	Project Manager
Periodic costs reports	Beneficiary FSIGN
Periodic and final reports to the EU	Coordinator's LSIGN
Minutes of meetings	Meeting chair person
Documents delivered to the EC other than deliverables	Project Manager
Technical / scientific working documents	The Partner that issued the document
Documents to be delivered externally to the Consortium or EC services (e.g. brochures, web site, papers to be published at conferences or on journals, etc.)	All Partners, as per provisions in art. 29.1 in the GA and art. 8.4 in the CA and Coordinator
Web site and Social media content	Same as previous row

Documents that have to be delivered to the EC should be additionally approved by the Project Manager, before the forwarding takes place.

Changes to the documents can only be implemented through the issuing of a new version, with an appropriately updated history of changes. Any Partner may propose a document change, as described in the documents' quality assurance procedure (see *Table **0.3***).

6.8 Publications and dissemination materials

These include the web site (see below), pages in social media, and all public materials (brochures, videos, newsletters, presentations, papers and publications, etc.). They should be produced to:

- Orient toward the needs of the audience, using appropriate language and information levels.
- Include various dissemination methods: written text including illustrations, graphs and figures; electronic and web-based tools, and oral presentations at community meetings and scientific conferences.

The dissemination materials must therefore conform to the following quality principles:

- Responsive: i.e. adapted to each target audiences.
- Concise: i.e. short and to the point; be sure that information is easy to find.
- Interesting: sort through all findings, and present just those that are new and/or compelling.
- Highlight key points: use bulleted lists, with one finding or conclusion per bullet.
- Logical: make sure the points progress in a logical order.
- Useful: have clear conclusions and recommendations; if readers know what to do with the information, they will be more likely to apply it.
- Complete: must include all information necessary for a full understanding of the dissemination message and content.
- Attractive: have an attractive graphic design; attractive materials are more likely to be read. If possible, documents should be printed in colour.
- Accredited: include sources of data and information and contact details for clarifications requests.

The following quality requirements for language and design aimed at easy reading are also recommended:

- Use simple language
- Use uniform heading formats
- Use a clear and readable font
- Avoid overfilled pages; limit the amount of text, graphics, and bullet points to the essentials.
- Always include page numbers.

All publications and dissemination materials shall comply to the quality requirements established by the European Commission for H2020 projects (see: "Communicating EU research and innovation guidance for project participants"[5]) and to the quality requirements defined by the GA Art. 29 and Art. 38.

All public dissemination material shall bear the EU flag and include a disclaimer stating the EU contribution as follows: *"BD4QoL has received funding from the European Union's Horizon2020 research and innovation programme (H2020-DTH01-2019) under Grant Agreement number 875192"*.

The Coordinator and the Exploitation Manager will verify the quality of each dissemination material produced and submit it for approval to the Project Board. The Coordinator and the Exploitation

[5] http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-guide-comm_en.pdf

Manager will verify that each public dissemination material complies to the above quality criteria.

The Project Board will also ensure that no secret or confidential information belonging to any of project participants is disclosed.

An official template for project presentations has been defined (see Annex B). Other templates will be defined for standard public communications (e.g. newsletters, press releases), that will be published on the appropriate directory of the project's documents repository.

6.8.1 Scientific papers

Scientific papers will be redacted according to the publisher's guidelines. The Main Author will be in charge of the quality of the paper. The writing of the paper must be approved by the Scientific Coordinator and by all involved PIs and must be authorized by the General Assembly. Quality of the paper will be assessed by the Scientific Coordinator. Publications or disclosures using the data or results generated by the project must include at least one (1) co-author of the data providing partner and at least one (1) co-author of the data receiving/data processing partner.

Management of publications is ruled by Consortium Agreement provisions ex art. 8.4.2.1.

6.8.2 Project web site

BD4QoL concerns quality of life monitoring after cancer treatment and offers information to professionals but also to patients and to the general public. Therefore, the quality of the web site is of primary relevance to the Consortium and will be measured and assessed based on the following criteria, compliant with the EC guidelines and according to the quality criteria defined by the EC for health-related web sites (Ref. https://www.ncbi.nlm.nih.gov/pubmed/12554546). The following quality criteria will be followed:

- Transparency of purpose of the site,
- Transparency of authorship/ownership of information,
- Transparency about financing and sponsorship,
- Clear separation of advertising and editorial,
- Transparency about use of personal information gathered by the site,
- Keeping information up-to-date.

These criteria should be applied in addition to relevant Community law.

RL and ARIA are responsible to maintain the web site, of its integrity, backup and recovery, accessibility from any client device (including mobile devices) and for the majority of browsers. ARIA will also produce the automatic quality indicators necessary for quality assessment (e.g. automatic measurements of accesses to the website, in anonymous way).

The Scientific Coordinator is responsible for the quality of the Scientific information disclosed to the public. The Coordinator will ensure that appropriate disclaimers are included in the website, to correctly inform the public regarding the quality of information provided, the sources and the usage of such information.

All partners are responsible to provide high-quality contributions, including links to public domain documents of interest for the specific clinical and technical domains addressed by the project.

The Coordinator is responsible to monitor and periodically assess the quality of the web site.

7 QUALITY ASSURANCE IN THE CLINICAL STUDY

As related to clinical trials, QA includes all those planned and systemic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice and the applicable regulatory requirements. In consideration of the SARS-COV2 outbreak, specific quality procedures need to be adopted to ensure the quality of the clinical study conducted within BD4QoL, and to consider and distinguish COV-19 impacts on cancer survivors QoL. As no data concerning these specific aspects are available at date, we will consider any published/available new information on these aspects while developing BD4QoL platform and models for HRQoL monitoring.

7.1 General quality framework for BD4QoL clinical study

The Scientific Coordinator is responsible for the study execution, quality of conduction and results. To this aim a Quality Control procedure is established.

The following provisions are to be adopted at all participating hospitals.

1. The study protocols must be agreed by all PI of the involved hospitals and by the relevant Research Ethics Committees
2. The study protocols must be implemented, under the supervision of the study local PI, immediately after the approval by relevant Research Ethics Committees
3. The local Data Controllers, supported by their DPOs are responsible to ensure personal data privacy throughout the study
4. The local PI is responsible to appoint a Quality Control Team (QCT) that includes:
    a. The study research personnel (study nurse(s), involved physicians)
    b. One IT support person either from hospital IT or external consultant specifically devoted to provide assistance on the developed apps to both patients and internal study team
    c. The data manager, appointed by the local PI, who is responsible of data collection and of data quality check.

In particular, for what concerns the conduction of the BD4QoL clinical study, it is critical that study PIs develop a Quality Control (QC) plan for each key operational stage of the study that defines standards against which QC will be conducted, including:

- sampling plan to be used (if applicable)
- data source to be used for QC at each operational stage
- metrics to be documented
- acceptable quality levels
- appropriate methods to report and distribute results.

To achieve these objectives, the Consortium has agreed to devote the necessary resources to put in place and operate the QAS especially addressing risks management, exploited into this Quality Manual, and that is based on the following standards:

- ISO/IEC 25000, ISO/IEC 25040, ISO/IEC 25041, ISO/IEC 25042 and ISO/IEC 25043
- for software evaluation we refer to ISO/IEC 14598-3 and 14598-4
- for mobile devices and sensors quality assurance we refer to the quality standards required for CE marking (Medical Device Regulation (EU) 2017/745)
- for clinical research involving human subjects, we refer to EU Directive 2001/20/EC and to Regulation EU No 536/2014
- for the mHealth software apps we will refer to the works of the CEN/TC 251 'Health informatics' work group [6] and, in particular for UK, to the specification PAS 277 issued by BSI. We will also take into consideration the European Medical Device Directive 93/42/EEC (MDD) in consideration of the fact that the apps developed within the project are intended for a "medical purpose" i.e. "to be used for human beings for the purposes of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease".

7.2 QA for BD4QoL clinical research

Definition of study eCRF and data to be collected

The study's eCRF and the data to be collected by the mobile apps will be compared to the objectives set forth in the protocol to ensure that the eCRF and the apps are designed to collect all necessary data. Guidelines for the control of eCRF and collected data completion are established and quality criteria set (see below).

During the data management process, the accuracy of the initial data entry is verified by the data manager. In case of data collected by means of the developed mobile apps, data quality is part of the technical quality assurance procedure that establishes verifications regarding the automatic collection through the mobile devices. The reality of the data is checked with a preprogrammed logic check program (based on rules defined by the local PIs) and a subsequent manual review. The database entries are then quality checked versus the eCRFs.

Selection of study research personnel.

The responsible PI at each participating hospital will establish an internal research groups in compliance to the following criteria:

- experience in conducting clinical trials activities
- experience in the data collection and data management
- personal involvement

Monitoring of study execution

The following conditions must be met and verified by the study PI or by a delegated responsible person, under the responsibility of the study Pi:

- subject informed (signed informed consent form)

[6] Ref. http://www.ehealth-standards.eu/quality-reliability-for-health-and-wellness-apps/

- subject's eligibility (inclusion/exclusion)
- protocol compliance
- adverse events (AEs) and incidental findings (if any)
- interventions applied as of SoC and relevant reports

Compliance with regulations

- 21 CFR 11, 50, 54, 56, 312
- EU Clinical Trial Directives 2001/20/EC and 2005/28/EC
- ICH/GCP Consolidation Guidelines (ICH-EG).

QA activities (auditing)

The study activities will be internally audited for QA by the local PIs and centrally by the Scientific Coordinator, following an audit procedure that specifies what internal processes of the study will be audited from initial study design, site and data management, and the final Study Report. The audit will also consider the EU Clinical Trial Directives. The audit procedure includes:

- review of the approved protocol and amendments
- review of compliance with SOPs and regulatory requirements
- SOPs (both general and study-specific), any specialized training associated with the study
- annotated CRFs and/or annotated data structure of collected data
- documented evidence that QC was appropriately conducted.

Quality of the clinical study execution

All PI's and investigators in the participating centres have been already introduced to the protocols and to the quality procedures to be adopted.

The SOPs of the clinical study as defined in the clinical protocol will be reassessed every 4 months in order to verify compliance. For what concerns QoL questionnaires for PROMs/PREMs collection:

- the EORTC standard forms will be adopted for the prospective study ad described in the study design and protocol
- the available QoL questionnaires from retrospective cohorts from previous studies will be harmonized to match the EORTC standard forms by the involved clinical PIs under the supervision of prof. Singer (Partner University of Mainz) who is the leader of the EORTC QoL work group.

Site management metrics

Internal audits of the site selection and management processes ensure that qualified investigators are selected, that they have adequate facilities and adequately trained staff, and that the study was conducted in compliance with the protocol and all appropriate regulations. The following metrics will be evaluated:

- percentage of evaluable subjects (no protocol violations)
- percentage of properly executed informed consent forms
- number/ percentage of missing data entries par study subject and on average for the study.

Computer Systems Validation

Computer systems validation examines all aspects of the data handling computer systems (hardware and software) to ensure the accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. This procedure is described in section 8 of this deliverable.

Data management QA

Data entry and the database QC process are other critical areas of the data management process. The audits review the documented evidence that shows the data accuracy and integrity were verified and checked manually, independently, and programmatically to ensure the data were logical. The percentage of database errors will be monitored both manually and using a rule-based software, and immediate correction must be applied.

Study site performance QA

The Scientific Coordinator must report to the General Assembly on the study conducts in all participating hospitals, relevant to protocol and regulatory compliance, to ensure that the safety and welfare of study subjects are addressed, and to confirm that problems reported by study monitors have been resolved. QA's criteria for site performance evaluation include:

- patient enrollment ratio
- study staff turnover.

Adequate documentation of case histories (source documents) shall be maintained at participating hospitals and produced to the Coordinator as requested, such as: medical records, progress notes, interventions applied and informed consents. Audits examine whether all the actions defined in the study protocol have been executed at the due times.

QA site audits evaluate the timeliness of entering data into a CRF, and examine the accuracy of the data by comparing them to their respective source documents mentioned above.

Patients' enrolment and data completion

The Technical Annex I to the Grant Agreement defines the overall enrolment ratio for the prospective study (400 HNSCC survivors). The following enrolment criteria, agreed by each enrolment hospital, will apply:

- INT: 50 pts/year for a total 100 pts
- INT subcontractor: 40 pts/year for a total 80 pts
- CSS: 60 pts/year for a total 120 pts
- UoB linked third party: 50 pts/year for a total 100 pts.

These numbers consider a dropout ratio of 20% patients.

Regarding data completion, we consider the medical data and the PROMs/PREMs collected at the timepoints specified in the clinical study protocol. We consider adequate collection of at least 70% of requested data for each patient and each timepoint. The data to be collected are indicated in the Annex I to the Grant Agreement (Ref. Table 3- Technical Annex I part B) reported below.

Table 7.1. Data collected in BD4QoL study

Procedure/evaluation/type of collected data	***At last FU***	***At study start***	***Continuous (24 months from start)***	***At study month 6, 18***	***At study month 12***	***At study month 24***
Informed consent		All				
Baseline evaluation (clinical, QoL)	Retrosp	Prosp			Prosp	Prosp
Demographics	Retrosp	Prosp				
Cancer family history	Retrosp	Prosp				
Cancer therapy history (°)	Retrosp	Prosp				
Demographic info (age, gender etc.)	Retrosp	Prosp		Prosp	Prosp	Prosp
Medication and medical events review (*)	Retrosp	Prosp		Prosp	Prosp	Prosp
HPV and pathology, staging, tumor site	Retrosp	Prosp				
Genomics (when available)	Retrosp					
Physical/emotional/social monitoring apps			Exp. arm			
QoL data (evaluation)	Retrosp	All	Exp arm	Prosp	Prosp	Prosp
QoL questionnaires (§)	Retrosp	All		Prosp	All	All

(°) Type of treatment, dosage, timing
(*) If available (e.g. from external (regional) patients' electronic folders of from electronic records available in hospitals)
(§) For retrospective study the QoL is detected at least at three timepoints: end of treatment, month 6, month 12 (pls at 3 years for UoB)

The Coordinator will assess the status of enrolment and the completeness of the data vs. the CRF defined in the study protocol on a quarterly basis.

Preventive actions have been established to provide backup / recovery solutions in case of partial default of a clinical partner in the enrolment of patients or in the provision of the required data.

Quality of the adopted investigation techniques and equipment is assessed a priori by the relevant responsible PI and by the Scientific Manager and the Scientific Coordinator as follows:

- by indicating the detail procedures to be applied in the clinical protocol
- by performing cross verifications between involved centres concerning the collection of medical data and of QoL questionnaires
- by verifying (PI in each participating clinical centre) the application of the protocol by the involved study research staff.

Statistical plan

The models and Big Data analysis to be developed in BD4QoL (WP6) require coherent and complete data to produce reliable results with significant statistics power. To this aim the statisticians at UiO and UMIL have estimated the minimum number of prospective and retrospective cases to be

provided.A statistical plan has been performed by UMIL and UiO and is part of the study protocols (D7.1).

7.3 Respect of ethics

Regarding the ethical aspects concerned with electronic patients' data management and in particular regarding data collection by means of mobile apps, the Technical Manager and the Project Manager have already established a detailed procedure in agreement with the EU regulations regarding data management, which are detailed in section 5 (ref. section 5.1.8 and section 5.3 Items 4.6, 4.8, 4.13 and 4.15) of the Technical Annex I to the Grant Agreement.

These procedures comply with the Italian and EU regulations regarding data protection and secure management throughout the project execution, data pseudo-anonymization procedures and data minimization, as briefly summarized as follows:

- data pseudo-anonymization: patients' sensitive information is kept inside each hospital and managed by the hospital only. BD4QoL eCRF will not include any patients information which could allow identification, in particular:
  - medical data will be encoded before any data transfer
  - personal data collected from the mobile apps will remain on the mobile device of the study subject and will be locally analyzed for the production of aggregated behaviour modifications over specified time periods, which will not involve any personal profiling of the detailed activities performed by the study subject but also identifiy and report changes in behaviour patterns;
  - study subjects' rights to discontinue data collection will be under the control of the study subject who can decide to stop or discontinue the use at anytime or to withdraw from the study and have data erased;
- patients' data management remains under the responsibility of each participating hospital, who has received ethics approval for the BD4QoL clinical study, and patient's consent to data treatment and to the participation to study execution through the informed consent form signed at the time of the enrolment or at the time where data and/or biologic specimens are collected;
- each participating hospital has appointed a DPO in charge of the monitoring of correct application of GDPR and/or of any additional National regulations (e.g. for Norway);
- beneficiary IECISA will securely manage data in its secure cloud environment as defined in Technical Annex I to the Grant Agreement section 5.3, Item 4.6).

The Coordinator has already verified with the representative of each participating hospital that these procedures are in place.

The consortium has also identified the legal basis for data processing based on signed informed consent, based on patients' signed informed consent and on specific derogations as allowed by GDPR or national laws (e.g. for UK, see below). The data collected in the Project are ***"necessary"*** in that without them the clinical study would not be possible.

In case the informed consent for secondary use of previously collected data cannot be acquired by study subjects from previous/ongoing studies - specific derogations will be evoked, upon individual risk assessment at each participating data provider institution:

"Disproportionate effort": the GDPR foresees *"exemption to patients' right to be informed about the use made of their data (Article 14 para 4b), when providing the information is a "disproportionate effort"*.

"Public interest". The "public interest" basis is foreseen in article 9.2(g), which states: "*processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject*." This includes healthcare research and healthcare provision which is the scope of BD4QoL.

In particular for what concerns the DPA in force in UK, lawful basis for the use of health-related data (sensitive data) in clinical research allow derogations (exemptions) based on the following:

- Processing for health and social case purposes, e.g., for purposes of assessment of the working capacity of an employee, medical diagnosis, provision of health care, or treatment, or social care, etc.7
- Processing for public health purposes8 where done by or under the supervision of a health/social work professional, or someone who owes a duty of confidentiality under law6 and it is necessary for reasons of public interest in the area of public health.
- Processing for journalistic, academic, artistic, and literary purposes9 where the:
  a) processing is done with a view to publication of journalistic, academic, artistic or literary material;
  b) the controller reasonably believes that publication would be in the public interest; and
  c) the controller reasonably believes that application of the publication would be incompatible with the aforementioned purpose.

More details will be provided in deliverable D2.4.

7.4 Quality assurance of work performed by third parties relevant to the clinical study

BD4QoL foresees some study subjects enrolment for data provision that are subcontracted to third parties. In particular critical subcontracted activities consist in the enrolment of prospective patients (subcontractor of INT: Spedali Civili di Brescia)

For these subcontracts a strict monitoring and quality assurance is foreseen as follows:

- the responsible partner will report to the Coordinator and to the Project Board on a quarterly basis concerning the status of the subcontracts
- the Coordinator and the Scientific Manager will verify with the responsible partner that the subcontractor is correctly performing the activities with the requested quality levels within the established deadlines

[7] Schedule 1, Part 1, paragraph 2 DPA.
[8] Schedule 1, Part 1, paragraph 3 DPA
[9] Schedule 2, Part 5, paragraph 26 DPA.

- in case of non-conformity detected, corrective actions as described above (see section 5.2.3) will be implemented.

Partners subcontracting part of their work will perform it within their own budget and will remain fully responsible for the performance of the subcontractor.

The Coordinator will periodically assess the work of subcontractors as part of the activities of the reference Beneficiary, in the frame of the internal periodic reporting (every 6 months at the latest).

Specific cases of subcontracts affecting the clinical study execution.

1. Patients' enrolment by Spedali Civili di Brescia. Responsible partner INT.

- INT shall establish a plan for patients' enrolment by subcontractor as soon as the clinical protocol is approved by INT Ethics Committee and report this plan to the Coordinator by the first internal reporting period at the latest
- the Coordinator will request at least on a quarterly basis the status of activities (patients' enrolment and data availability) of the subcontractors
- INT shall provide this information without delay to the Coordinator
- in case of insufficient number of enrolled cases of insufficient amount of data (missed the promised eligible patients amount), INT shall immediately notify the Coordinator and the recovery actions identified in section 4 must be immediately started
- in case INT cannot take over the obligations of the defaulting subcontractor, INT will make available the relevant budget quota to cover the procurement of the missing patients (500 €/pt for prospective cases) to the Consortium; this budget will be redirected to the clinical centre who will provide the missing cases
- in case the budget allocated by INT for the prospective patients' enrolment and study data collection is not sufficient, INT shall immediately notify the Coordinator and a remedial action shall be foreseen to address patient's cohort numerosity and the relevant resources applied. If needed a request for amendment will be immediately prepared and submitted as soon as possible to the EU.

8 TECHNICAL QUALITY ASSESSMENT

The software development cycle is governed by the following phases: Requirements, SW and system specification and design, Development and evaluation, and System overall evaluation. To ensure the quality of the resulting products, the development of each component will be part of a User-Interaction framework. This framework encompasses different activities, such as identification of user needs and use case scenarios or user requirements and technological use cases. User interaction flow and user interaction components (mock-ups) will also be needed before the final development (functional prototypes, beta versions, final prototypes) and evaluation.

In this section, details about the technical quality assessment is detailed.

8.1 Overall technical quality control

This process is going to be further elaborated and specified in during the project, as specified in *Table **8.1**. Description of the technical quality control***Errore. L'origine riferimento non è stata trovata.**. Expected content, also related to the User-Interaction framework results are specified, together with the related partners.

Table 8.1. Description of the technical quality control

Phase	Deliverables	Content	Responsibility
Requirements	WP2 deliverables, D3.1 (v1), D3.6 (v1), D4.1, D5.1, D8.1	User needs and requirements for each BD4QoL technology: data model, data collection, infrastructure, PoC and patient empowerment system.	UDEU, DOT, IECI, UPM, IBMI
SW and system specification and design	Intermediate internal versions of: D3.1, D3.2, D3.3, D3.4, D3.5, D4.2, D4.3, D5.2, D5.3, D5.4	Technical requirements and specifications for each BD4QoL element, also including the design principles. First mockups. Integration between all BD4QoL components. Templates for the evaluation strategy should be included in these deliverables.	UDEU, DOT, UPM, IBMI
Development and evaluation	D3.1 (v2), D3.2, D3.3, D3.4, D3.5, D3.6 (v2), D4.2, D4.3, D5.2, D5.3, D5.4. And intermediate internal versions of D8.2, D8.3	Development of the different components of the BD4QoL system and the integration among them. Evaluation of each component.	UDEU, DOT, UPM, IBMI

Phase	Deliverables	Content	Responsibility
System overall evaluation	D8.2, D8.3	Evaluation of the entire BD4QoL system carried out during the pilot execution.	UPM, MME

The software development cycle ends with the evaluation phase. However, if during the system overall evaluation, any change will be requested by users, it will be managed as follows:

- Changes will be requested as “change requests”.
- Any change carried out will be reflected in a new version of the deliverable affected.
- If issues need to be reported, those will not affect the deliverable content but will be notified as ‘Issue report’.

These reports will be done following the template included in the **Errore. L'origine riferimento non è stata trovata.**.

Deliverables of final solutions must include a user guide.

Different versions of BD4QoL software elements will be documented in the Release Notes. They should be appended in the last version of the deliverables. Testing procedures will refer to the version number. A template of Release note is included in **Errore. L'origine riferimento non è stata trovata.**. The final release will consist of:

- Compiled executables, sources and related files
- User guide (when possible embedded in the tool itself)
- Installation and administration guide

8.1.1 Evaluation plans

A complete strategy of the BD4QoL evaluation will be defined in T8.1. This strategy must ensure that the tools are functional before they are released. Any test planned must assure coverage of all the functionalities described in the specification deliverables. These deliverables must include the procedure and specific templates to report the results of the tests conducted. Templates are proposed in Annex E. Evaluation report template and any modification to those must be approved with the Quality Manager.

Final deliverables of the BD4QoL solutions should report the quality assessment conducted under two categories:

- **Unit tests**. These tests will be performed by the responsible partner of each single components and aims to ensure that the tool satisfies the functionalities declared in the requirements deliverables. The Technical Manager will review the results before submitting those in the final deliverables.
- **Integration tests**. These tests will be performed by the responsible partner of each single components, under the supervision of the Technical Manager. These tests aim to assess the

correct software stream between the different parts of the BD4QoL system and the right management of input/output data, based on system specifications and design.

Software components will be released once the tests achieve satisfactory results.

User experience assessment will be included in the D8.2, and the strategy to follow will be included in D8.1. **Validation plan and methodologies must be agreed with the Technical and Innovation Manager and the Scientific Coordinator**, to ensure the alignment with the pilot execution. Validation plans can be personalized for individual pilots, if needed, and must be defined and agreed **at least one month before the pilot execution**.

Validation error reports will be collected and evaluated by the Technical Manager and should report the following:

- Tool and functionality validated
- Date of validation
- Pilot and user
- A detailed description of the test environment
- A detailed description of the validation steps performed (together with screenshots whenever is possible) with actual input and output and expected output
- The gravity of the problem and resolution request (mandatory, recommended, nice to have, etc.)
- Urgency (extremely urgent, meaning that validation should stop; urgent, meaning that need to be solved as soon as possible; to be done before final release)
- Any additional information which may be useful

During the validation phase, a summary of validation issues will be published with comments and deadlines for bug fixing implementation.

Direct interactions between pilot users and individual technical partners should be agreed in advance and authorised by the Technical Manager.

8.1.2 Overall ethics and security issues

BD4QoL will ensure that all developments have been subjected to appropriate ethical regulation and that all staff will have the proper training supported by confidential documents.

BD4QoL aims to improve the QoL of HNC patients through person-centred monitoring and follow-up management. Therefore, BD4QoL requires not only an eCRF for data collection but also a smartphone (and possible comfortable sensors) for non-clinical data collection and patient monitoring. HNC patients' data will be visualised through the PoC tool managed by clinicians at each hospital. Personal data of participants will be protected to defend their privacy by highly advanced security mechanisms.

The BD4QoL technical quality assessment aims to ensure the system to be secure, scalable and interoperable complying with EU policies. In the following sections, specific quality procedures will be indicated, taking into account the nature of each BD4QoL system component. More information about the ethical aspects will be reported in D10.3.

8.2 Quality framework for BD4QoL infrastructure

This section will detail the quality procedures of the BD4QoL infrastructure components.

8.2.1 Anonymisation procedure for the retrospective study

Retrospective data will be anonymised to eliminate any identifiable data, before sharing this to the BD4QoL cloud. This procedure will be conducted at hospital infrastructures, with secure methods ensuring that no data included in the dataset derive insights on a discrete individual, even by the party that is responsible for the anonymisation. To ensure patients privacy, anonymisation should place the processing and storage of personal data outside the scope of the GDPR.

8.2.2 Pseudo-anonymization procedure for the prospective study

Data from prospective studies will be pseudo-anonymised and de-identified using privacy-compliant procedures. The matching of patient personal data and BD4QoL study ID will be stored in the hospital the patient belongs. Each hospital will manage patient personal data in compliance to GDPR. Contact details will be only facilitated for internal BD4QoL communications between study participants and PoC. Patients data will be only accessible by the PoC authorised personnel.

Data that can contribute to one's identification, like personal e-mail, or name, surname, telephone number, etc will be stored at online databases at the premises of the hospital.

Specifically:

- The digital security of these "remote" databases (allocated and administered by the hospitals) will be established by setting appropriate encryption algorithms.
- Remote secure access to these databases will be enabled, in order to comply with general guidelines for "social distancing" in order to deal with the social consequences of the COVID19 epidemiology, allowing only clinicians with special permissions to monitor and review participants' data at a personalised (re-identified) level (i.e. from "home").
- The fact that these remote databases will be at hospital premises provides an additional level of physical security to the sensitive data collected and stored.

Maintenance of all patient (re)-identification data on data servers managed by the hospitals that are involved in the pilot studies, rather than within BD4QoL data infrastructure, will ensure a higher level of security policy.

8.2.3 Secure cloud environment

BD4QoL cloud will be implemented using the interoperable TIER IV (Uptime Institute) capabilities of the Murcia Data Processing Center, the IECI cloud datacenter which provides the highest levels of security in an existing location in the European Union and under the national scheme of Spanish security. This centre has obtained the following certifications that will ensure compliance with regulations along relevant dimensions such as data security and personal data protection:

- UNE-ISO/IEC 27001 Information Security Management Systems (ISMS)
- ISO22301 certification (Business Continuity Management System)
- LEED Platinum (energy) granted by the Green Building Council of the United States in its CPD of Murcia

- CEEDA (Certified Energy Efficiency Data Center Awards) in progress.

Standard AES[10] for data encryption will be fully applied to prevent identification disclosure. The secure data access layers established as part of data exchange in BD4QoL Cloud will guarantee GDPR compliance.

The security of the system provides as an additional layer, transverse to the system, which exposes the relevant operations only and exclusively after an access layer that will give way to a Unified Portal. The proposed model, by incorporating the algorithm into an "As a Service" model, allows the use of defined and published algorithms, which favours the creation of a community that, eventually, can bring new knowledge to the platform.

Further details on quality assurance considered in the secure cloud and from the pseudo-anonymised procedure will be included in D2.2/D3.6.

8.2.4 Data integration and terminology standards

Data integration techniques with external datasets (Foursquare, Open Street Maps, physical activity levels measured by accelerometer,etc.) will demonstrate the viability, scalability and reliability of our sound privacy-preserving framework. To ensure system interoperability and scalability, data fusion techniques will be implemented in T3.3, always guaranteeing the maintenance of quality standards and data enrichment.

Further details of quality assurance in terms of data integration will be included in D3.3.

8.3 Quality framework for BD4QoL technologies and services

This section details the security policies of each tool implemented in BD4QoL and of the exchange communication channels.

8.3.1 Data management in the BD4QoL patient app

Data collected through mobile apps will be managed according to GDPR and relevant guidelines and will comply with the General Data Protection Regulation (EU 2016/679).

BD4QoL mobile app will manage pseudo-anonymous data. In the exceptional case that patients' smartphone gets lost or stolen, the user account will be disabled (app functionalities will be disabled) and no data will be sent to the server.

Security will be implemented by granting anonymity and data encryption. Algorithms such as TripleDES, Twofish or Blowfish will be used to support the encryption policy. Data will be sent to the BD4QoL cloud using HTTPS connection with trusted certificate and an authentication mechanism in the Web Service functionality. The communication between the Cloud and the Smartphone is logged with technical details, such as:

- IP of the remote host (Smartphone)
- IMEI of the phone
- Operating system and software version

[10] https://csrc.nist.gov/csrc/media/publications/fips/197/final/documents/fips-197.pdf

- User account (BD4QoL ID)
- Requested functionality (get/post data)

Security communication will also be established between the patient empowerment platform. Coaching system will be integrated within the mobile app, and details of this system are described in 8.3.2. Communications with the PoC system will be through the BD4QoL, so no additional communications need to be established.

WP3 leader will be in charge to monitor the Smartphone activity, and the Smartphone account could be deactivated remotely to disconnect the Smartphone from the BD4QoL cloud if needed.

Further details on the data quality collection will be included in the D3.1.

8.3.2 Patient empowerment platform

This platform is built on top of IBM Watson APIs, that counts with API Connect's security built on IBM DataPower Gateway, including single, singed and encrypted gateway. These APIs are microservices-based architecture that can scale its components to improves user experience while maintaining performance. The flexibility of these APIs allows connecting to the rest of BD4QoL components.

Additional details on how data quality will be ensured in the patient empowerment platform will be added in the D5.2/D5.4.

8.3.3 Point of Care management system

PoC management system will access to patients' data through the BD4QoL cloud, by following the privacy and ethics policies build in the server. Similar to the mobile app, HTTPS connection with trusted certificate and an authentication mechanism in the Web Service functionality will be employed to access the data.

The implementation of this system will consider the new regulations on medical devices (Medical Device Regulation (EU) 2017/745) to ensure patient safety and allow the secure usage of this system in the public health environment.

Further details on the quality standards and certified procedures will be included in the D4.3.

8.3.4 Prediction models

As regards model building, data quality assurance procedures will be defined in T7.4. Models developed in WP6 will analyze these data quality checks, and the data processing conducted will be transparently and reported in D7.4. For benchmark models implementation with retrospective data, ethical approvals are under definition to allow the data processing at UiO. In contrast, for the Advanced models with retrospective and prospective data, the data will be directly accessed and processed through the BD4QoL Cloud, through secure and private APIs following the policies mentioned in sections 8.2.1 and 8.2.3.

Final decisions and implementation of data quality rules will be reported in the D7.4.

9 RISK MANAGEMENT

In general, the provisions described in the DoA Part B section 3.2.5 and the roles indicated in the BD4QoL CA Art. 6.1 apply.

A specific task of the project coordination (T10.3) is devoted to QA and risk management, under the responsibility of the Coordinator. The Quality Manager (QM), Dr. G. Fico, UPM, will be responsible for the overall quality of the Project, risks management and Data Quality assurance, as well as monitor the work of each WP, assisted by the WP leaders. He will report to the Project Manager and to the Project Board. Risk management strategies proposed by Project Board Members will be submitted to the General assembly for discussion and final decisions.

Risk management includes procedures for risk identification, evaluation and assessment, recovery planning, risk monitoring and mitigation, control and solution.

9.1 Risk management process

The Project Manager will monitor risks in collaboration with WP leaders for timely detection of risks. Risks reports will be internally managed on a quarterly basis and checked at Project Milestones. The Risk registry in the EU participants portal will be updated. Risk monitoring and management will be supported by monthly verifications and assessment reports, focused on identifying the impact of every identified risk in relation to three main variables: cost, schedule and performance. The project manager and WP leaders are the key actors of this process.

The risk management strategy is a step-by-step process, in which risks are identified, analyzed, prevented (if possible), managed and monitored throughout the Project lifetime.

Risk prevention

This activity is part of all project tasks and is based on in-depth assessment of each task and on the appropriate allocation of responsibilities, skills and resources. It is aimed at analysing in advance potential risks before they occur in critical areas (WPs, Tasks) of the workplan and implement the relevant preventive actions. This review process, conducted prior to the submission of the present proposal, will continue throughout the project lifetime, in the aim to establish preventative actions, re-assess project's priorities vs. expected results, address difficulties and prepare in advance corrective actions and contingency plans. Potential risks identified at the start of the project, during quality reviews (see section 5.2.2) and those proposed by Consortium participants during the execution of tasks/WPs or deriving from the under-performance of third parties will be monitored by means of a Risk Registry (Annex III).

This activity shall especially be adopted for critical tasks and WPs and will be mainly conducted by Project Coordinator, Scientific Coordinator, Technical Manager and Quality Manager.

Risk detection

This activity is part of the day-by-day monitoring of tasks and WPs and is aimed at early identification of risks and at the application of preventative measures. Unforeseen risks will be immediately addressed. Risks are notified in writing through normal communications (emails). In case the risk affects more than one WP, WP/Task leaders should be also notified in CC.

Risks will be linked to specific parts of the project, as for instance tasks, deliverables or milestones, in order to make it easier to monitor them. This will allow prioritizing risks that have major impacts that need to be addressed and solved, risks which shall be managed as from usual practice, and minor risks which shall be monitored without taking specific actions. Depending on the type and level of the risk, adequate corrective or mitigation actions will be defined and implemented. Experience of Consortium partners will support risk estimation.
Several critical implementation risks that must be monitored have been identified before the start of the proposal, and are specified in the DoA, Part A, Section 1.3.5. The Risk Registry will be updated anytime a risk occurrence is identified or a new risk is detected. In particular these issues shall be constantly monitored:

- underperformance of partners or of third parties
- non complete achievement of milestones, KPIs or committed scientific/clinical impacts
- unforeseen ethical issues
- missing project deadlines
- overspending or incorrect use of the project budget.

Risk estimation and assessment
Each risk will be evaluated and assigned a severity score based on the potential impact on the project results and/or on the interests of the Consortium. project in terms of duration, quality, costs, meeting users' requirements or the overall exploitation of results. This activity is carried out at all levels and by any partner and is aimed to early detect potential risks in the execution (or non execution) of some tasks. WP Leaders are the main actors of this activity. Identified risks shall be promptly reported to the PM and to the Quality Manager and listed in the Risk Registry.

Each risk will be evaluated and assigned a severity score based on the potential impact on the project results and/or on the interests of the Consortium. Depending on the type and level of the risk, adequate corrective or mitigation actions will be defined and listed in the Risk Registry. The PM performs these activities supported by WP Leaders.

Depending on the risk severity and response strategies, the following risk solving approaches will be applied.

- High severity risks will be addressed if possible in advance (risk monitoring) and specific contingency planning proposed and implemented. The plans must indicate the involved partners, their roles and the expected actions, as well as measurement criteria.
- Low and medium severity risks will be managed as soon as they are detected and the relevant corrective measures defined at implemented at that moment.

Risk management

For each foreseen or newly identified risk adequate mitigation / recovery activities will be agreed by the General Assembly (operational risks) or by the Project Board (critical risks for the achievement of the project strategic goals) and responsible persons will be appointed. The outcomes of the proposed actions will also be recorded in the Risk Registry and also reported in periodic reports.

The process for the management of new risks is described in the following table.

Table 9.1. Risk detection and management process

Step	Description	Input	Output
1	The participant identifying the risk shall notify the relevant WP Leader and the PM		Notification of risk
2	Within 5 working days after the risk notification the PM and the QM will assess the risk severity and impact on the project and identify possible recovery actions, jointly with the WP Leader and with the Project Board	Risk notification	Updated Risk Registry, notification to the Project Board for risks assessment and mitigation proposal
3	The PM informs the Coordinator. The Project Board proposes mitigation activities. Low and medium severity risks will be notified to the Project Assembly for discussion in the next quality review meeting	Risk Registry	Notification to General Assembly for risk management decisions
4	For high-severity risks the Coordinator calls a remote Project Assembly meeting for the definition of the relevant recovery measures	Risk registry	Recovery measures and recovery plan
5	In case of need the Coordinator will inform the EU Project Officer and agree on further actions as defined in the Consortium Agreement or in the Grant Agreement	Risk Registry	Notification to the EU and official measures undertaken

ANNEX A. TEMPLATES FOR INTERNAL PERIODIC ACTIVITY AND RESOURCES USAGE REPORTS

Template for internal activity report which must be provided every 4 months includes information:

- cover page
- table of contents
- publishable executive summary (length: one page or the number of pages foreseen by the standard template for official periodic reports)
- detailed activity report for each WP and task and for each beneficiary
- summary of dissemination activities
- summary of meetings
- summary of costs
- detailed costs by Beneficiary (only for official periodic reports).

The template of the periodic activity follows the structure of the standard reports required by the European Commission at official reporting periods.
The tables for costs collection are meant to facilitate the uploading of costs to the Forms C in the participants portal.

The templates are available to the Consortium in the shared documents repository.

For sake of simplicity we report in the following the WP/Task related information required to project Beneficiaries that will be used by the Project Manager to edit the periodic report.

Cover page

PROJECT PERIODIC REPORT

Grant Agreement number: 875192

Project acronym: BD4QoL

Project title: *"Big Data Models and Intelligent tools for Quality of Life monitoring and participatory empowerment of head and neck cancer survivors ".*

Funding Scheme: H2020 DTH01-2019

Date of latest version of Annex I DoA against which the assessment will be made:

Reporting Period no.:

Period covered: from to

Beneficiary:

Editor:

Date:

Version:

Objectives for the period

This section (two pages maximum) is completed by the Project Manager and describes:

- the foreseen objectives and goals, deliverables, milestones, KPIs and intermediate results
- the actual achievements
- any problems encountered and the applied solutions

Detailed activity report by each Beneficiary

This section is repeated for each WP.

This section shall be completed by each project Beneficiary. It comprises a general WP assessment edited by the WP Leader grey box and a set of tables reporting the activities performed by the Beneficiary in the reporting period green boxes.

WP summary (To be completed by the WP Leader).

Summary of objectives for the WP in the period

<Short description or bullet list>

Achieved results.

<Short description or bullet list>

Problems encountered/Risks

<describe any problems>

Actions taken

<describe how the problems were addressed>

The following tables shall be completed by each Beneficiary for each WP.

Beneficiary n.	<Beneficiary Name - Short name>
Work Package	<WP number>
Tasks	**Activities performed and results achieved**
<Task n.>	• list of activities performed in the six months (for example: managed internal contracts or production of 6 month report) •
<Task n.>	• list of activities performed in the six months (for example: managed internal contracts or production of 6 month report) •
<Task n.>	• list of activities performed in the six months (for example: managed internal contracts or production of 6 month report) •
<Task n.>	• list of activities performed in the six months (for example: managed internal contracts or production of 6 month report) •
<Task n.>	• list of activities performed in the six months (for example: managed internal contracts or production of 6 month report) •

WP meetings attended

Date and Location	**Description**	**Scope of Meeting and attendees**	**Main results**

Use of resources

<Indicate if the resources used are in line with forecast. If not please explain.>

Person-months (Y: p-m used in **this** reporting period / Z: **total** planned p-m)	Y / Z	**Sustained costs (%)** (Y: costs incurred in **this** reporting period / Z: **total** planned costs)	Y / Z (in %)

List of dissemination activities

List of scientific publications issued in the Period

Type	Authors and title	Date	Journal, proceedings, book, etc.	Partner
Article in journal				
Publication in Conference proceedings/Workshop				

List of communication activities conducted in the Period

Type	Description	Place and date	Estimated audience	Partner
Exhibition				
Website				
Organization of a conference				
Participation to an Event other than a Conference or a Workshop				
Press release				
Organization of a workshop				
Training				
Other				
Exhibition				
Participation to a Workshop				

Costs report templates (to be provided at each contractual periodic reporting period)

BD4QoL
BIG DATA FOR QUALITY OF LIFE

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)
Contract No: H2020-DTH01-875192

for the period from:		**to:**	
Name of *contractor* :	**UMIL**	**% Funding**	100
Number of *contractor* :	**1**	**Cost model:**	Flat rate 25%
Contact person :		E-mail:	
Telephone:			

DO NOT FILL THE FOLLOWING LINES. THEY ARE AUTOMATICALLY CALCULATED FROM THE REST WORKSHEETS.

Sum per cost category			Costs for the period (Euro) WP1	Costs for the period (Euro) WP2	Costs for the period (Euro) WP3	Costs for the period (Euro) WP4	Costs for the period (Euro) WP5	Costs for the period (Euro) WP6	Costs for the period (Euro) WP7	Costs for the period (Euro) WP8	Costs for the period (Euro) WP9	Costs for the period (Euro) WP10	Costs for the period (Euro) Project
Direct Costs													
	a.	Personnel costs	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	b.	Personnel declared as unit costs (average cost)	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	c.	Durable equipment	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	d.	Subcontracting	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	e.	Travel and subsistence	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	f.	Consumables	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	g.	Other specific costs	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
	h.	Costs of internally invoiced goods and services	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
Indirect Costs													
	i.	Indirect costs	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**
		Total costs	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**
		Funding requested (%)	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	**100,00**	
		Funding	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**		**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-DTH01-875192

for the period from:	00/01/1900	to:	00/01/1900
Name of contractor:	UMIL		
Number of contractor:	1		

DURABLE EQUIPMENT

WP	Description	Procurement (Purchase / Lease)	Cost/ Value (C)	Date of invoice	Months charged to this report (A)	Depreciation (months) (B)	% Allocation to Project (D)	Amount to be charged
							Total	**0,00**

Martinelli Elena:
Depreciation is applied
• The Formula: (A/B) * C * D, where
A is the period of months during which the durable equipments is used for the project after invoicing, in the reporting period;
B is the normal depreciation period;
C is the actual cost of the durable equipment
D is the percentage of usage of the durable equipment for the project

EXAMPLE
Iron Bars: (20/36) * 1000 * 60%

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-DTH01-875192

for the period from: 00/01/1900 to: 00/01/1900

Name of contractor: UMIL

Number of contractor: 1

PERSONNEL AND OVERHEADS

WP	Position	Number of person-hours	Hourly Personnel Rate	Worked hours in a month	Personnel Amount	Person months
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
					0,00	
	TOTALS	**0,00**		**TOTALS**	**0,00**	**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-DTH01-875192

for the period from: 00/01/1900 to 00/01/1900

Name of contractor: UMIL

Number of contractor: 1

PERSONNEL COSTS DECLARED AS UNIT COSTS (AVERAGE)

WP	Position	Number of person-hours	Hourly Personnel Rate	Personnel Amount	Person months
				0,00	
				0,00	
				0,00	
				0,00	
				0,00	
				0,00	
				0,00	
				0,00	
	TOTALS	**0,00**		**0,00**	**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-DTH01-875192

for the period from: 00/01/1900 to: 00/01/1900

Name of contractor: UMIL

Number of contractor: 1

SUBCONTRACTING

WP	Description	Date of invoice	Amount
		Total	**0,00**

PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

: **No: H2020-DTH01-875192**

eriod from: 00/01/1900 to: 00/01/1900

contractor: UMIL

of contractor: 1

TRAVEL AND SUBSISTENCE

Name of participant	Destination (City / Country)	Date of travel	Purpose of travel	Amount
			Total	**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)
Contract No: H2020-DTH01-875192
for the period from: 00/01/1900 to: 00/01/1900
Name of contractor: UMIL
Number of contractor: 1

CONSUMABLES

WP	Provider name	Description	Date of invoice	Amount
			Total	**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)
Contract No: H2020-DTH01-875192
for the period from: 00/01/1900 to: 00/01/1900
Name of contractor: UMIL
Number of contractor: 1

OTHER SPECIFIC PROJECT COSTS

WP	DESCRIPTION	Date of invoice	Amount
		Total	**0,00**

BD4QoL PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-DTH01-875192

for the period from: 00/01/1900 to: 00/01/1900

Name of contractor: UMIL

Number of contractor: 1

OTHER INTERNALLY INVOICED COSTS

WP	Description	Date of invoice	Amount
		Total	**0,00**

ANNEX B – BD4QOL TEMPLATE FOR PRESENTATIONS

H2020-875192 BD4QoL

<Title>

<Title 2>

<Presenter name>
<Presenter affiliation>

<Contact details (email)>

<name of event – Location – date >

TITLE

<name of event – Location – date >

ANNEX C. CHANGE LOG TEMPLATE

Change log – BD4QoL

Check log ID:

ID	Functionality ID	Initial state	Action	Expected result

ANNEX D. RELEASE NOTE TEMPLATE

Release note – BD4QoL	
Module name: Version:	**WP task ref:**
Release content:	

Released functionality IF or check log ID	Comments

Software task manager:

Date:

ANNEX E. EVALUATION REPORT TEMPLATE

Evaluation report form – BD4QoL

Module name: WP task ref:

Version:

Check list ID:

Description:

Test ID	Result	Notes

Tester:

Date:

ANNEX F. BD4QOL RISK REGISTRY TEMPLATE

	RISK IDENTIFICATION			RISK ANALISYS			RISK MANAGEMENT				MONITORING
Risk ID	Description of the problem	Risk	Involved WP	Likelihood OF THE RISK [11]	Impact on project[12]	Foreseen period/timing for impact on project	Priority[13]	Contingency Plan	Consequences of mitigation	Resp. Partners	Status and Date[14]
1		Describes the risks for the project in terms of: - timing (delays) - results (affects results) - management - other…				Describe when and for which activities the risk has impact on the project		Describe the contingency plan identify to minimise/solve the risk. Possible to indicate a reference to a document describing the contingency plan.	Describe the consequences of the mitigation on the project's workplan or outcomes	Partners responsible for the contingency actions implementation	

[11] probability of the risk to materialize (100% if the risk has materialized)
[12] 0= no impact; 1=low impact, no major problems; 2=medium impact, corrective actions recommended; 3=high impact, corrective actions mandatory; 4=show stopper: need immediate action
[13] 0= very low; 1= low but necessary before impact time; 2=medium, to be addressed asap; 3=high, urgent; 4=very high, needs immediate reaction
[14] Status: open , in process, closed. Date refers to the status.

ANNEX G. DELIVERABLES PROCEDURES

Process for the internal periodic reporting

The following table summarizes the steps needed for the internal reporting.

Table 0.1 Quality assurance during periodic reporting

Step	Description	Input	Output
1	Within 30 days from the expiration of a project's semester, the Project Manager will circulate the templates for the periodic reporting	Periodic reporting templates	
2	Within 15 days from the expiration of a project's semester, WP Leaders and all Beneficiaries will send to the Project Manager the reporting information described above using the provided templates		Periodic reporting templates filled (see in Annex I)
3	Within 5 working days from receipt of the contributions from Beneficiaries, the Project Manager checks quality of contributions and sends requests for integration to the concerned beneficiaries	Completed reporting forms	Individual reporting forms plus requests for integration
4	Within 5 working days the concerned Beneficiaries should send the required integrations to the PM for document integration and approval	Individual reporting forms plus requests for integration	Integrated periodic report forms
5	The Project Coordinator makes available to the Consortium a consolidated version, in order to support Steering Board decision making at the end of the semester.		Consolidated version of internal project reporting to be presented to the Project Assembly

Process for the official periodic reporting to EU

The following steps are performed to ensure the quality of official periodic reporting to the EU:

Table 0.2. Quality process for EU periodic reporting

Step	Description	Input	Output
1	Within 15 days before the expiration of a reporting period, the PM will circulate the templates for the periodic reporting. The EM will circulate a template for the collection of publications materials	Official periodic reporting templates. Excel sheets for costs declaration	
2	Within 20 days after the expiration of the reporting period, all Beneficiaries will send to the Project Manager the reporting information described above using the provided templates		Official periodic reporting and detailed costs
3	Within 10 working days from receipt of the contributions from Beneficiaries, the Project Manager checks quality of contributions and sends requests for integration to the concerned beneficiaries	Completed reporting forms	Individual reporting forms plus requests for integration
4	Within 10 working days the Beneficiaries should provide integration to the periodic report and upload costs in the EU portal.	Integrated periodic report forms, final costs for each Beneficiary	Integrated periodic report forms plus Forms C in the participants portal
5	Within 45 days after the expiration of the reporting period, the Project Manager checks costs, asks for revisions and produces the periodic report for partners approval.	Forms C	Requests for revisions Forms C and official Periodic (Final) report
6	Within 55 days after the expiration of the reporting period the Beneficiaries consolidate their costs, the relevant part of the gender table, the SME impacts table in the EU portal, and the official periodic (final) report	Forms C and official Periodic (Final) report SME impacts, Gender table	Consolidated Costs reports and Periodic (Final) report all sections available in the EU participants portal
7	By day 60 after the expiration of the reporting period the Coordinator	Consolidated Forms C and Periodic (Final) report	Submitted Periodic costs and activity report

Step	Description	Input	Output
	submits the Periodic Cost and Activity Report		

Process for QA of project deliverables

Table 0.3. Quality process for deliverable QA

Step	Description	Input	Output
1	At least 2 months before the delivery date, the deliverable Lead Beneficiary circulates a proposal for the deliverable to the Consortium		Deliverable TOC and guidelines for contributions
2	Within 5 working days, assigned-peer reviewers will provide their comments		Comments to the TOC
3	Within 30 working days before the official delivery date, the Author appointed by the deliverable Lead Beneficiary circulates a draft to contributions and asks for revisions/complementary information	Deliverable contributions by co-authors	Deliverable draft
4	Within 10 working days contributors shall provide the missing information plus their comments	Deliverable draft	Additional contributions
5	Within 15 days before the delivery date the Author sends the draft to the peer reviewers for first assessment		Integrated draft of deliverable
6	Within 5 days the peer reviewers return the draft with comments to the Author	Forms C	Commented draft of deliverable
7	Within 5 days before the delivery date the Author sends a final revision to contributors, to the WP Leader and to the PM for approval		Final deliverable for approval
8	The PM collects final feedbacks from WP Leader, integrates the comments and finalizes the document. The Coordinator checks and approves the document	Final deliverable to be checked	Finalized deliverable for submission

At the end of the process the deliverable is delivered on the participants portal and uploaded on the BD4QoL documents sharing repository and to the participant portal documents management system. If the document is public, it will also be accessible from the public area of the BD4QoL web site.

This procedure applies to all deliverables which can be presented in electronic format, including videos and animations.

Assignments of the peer-reviewers by deliverable

Table 0.4. Peer Reviewers of the Project Deliverables

Del No.	Deliverable name	Lead partner	Reviewer 1	Reviewer 2
D1.1	POPD – Requirement No. 8	UoB		
D1.2	H - Requirement No. 2	UMIL		
D2.1	Ontology of personal data for HRQoL v1	UDEU	IECI	UiO
D2.2	Ontology of personal data for HRQoL v2	UDEU	IECI	UiO
D2.3	Repository conceptual design	IECI	DOT	UiO
D2.4	PREM/PROM specs and design	UMIL	MME	UPM
D2.5	Privacy protection and ethics management specifications	RL	MME	UPM
D3.1	Mobile data collection modules	DOT	MME	UDEU
D3.2	ETL tools for external dataset import	DOT	MME	UPM
D3.3	Data integration and fusion modules	UDEU	MME	UiO
D3.4	Hybrid Activity Recognition System	UDEU	IBMI	DOT
D3.5	BD4QoL mobile app	DOT	MME	IBMI
D3.6	BD4QoL data Management infrastructure V1	IECI	MME	IBMI
D3.7	BD4QoL data Management infrastructure v2	IECI	MME	IBMI
D4.1	Workflow design and data interpretation and visualization design	CSS	UMM	SEPI
D4.2	BD4QoL WfMS	UPM	UMM	DOT
D4.3	Implementation and deployment of the data interpretation and visualization suite	UPM	DOT	IBMI
D4.4	Guidelines for the integration of PoC services into regional EHRs	RL	MME	CSS
D5.1	BD4QoL counseling strategy	UMIL	UPM	UMM
D5.2	Coaching tools	IBMI	MME	UPM
D5.3	Personal data reporting engine	DOT	MME	UPM
D5.4	Coaching chatbot	IBMI	MME	UPM
D6.1	Benchmark risk stratification models	UiO	UPM	UMIL
D6.2	Advanced early detection models	UDEU	MME	UMIL

D7.1	Study operational protocol	INT	UMIL	UoB
D7.2	The integrated occupational data repository	SEPI	UMIL	UDEU
D7.3	Intermediate Study report	INT	CSS	UMM
D7.4	Data quality check rules	UPM	MME	UDEU
D7.5	Pilot experience in a Regional setting	RL	INT	UMIL
D7.6	Final Study report	INT	UMIL	UoB
D8.1	HTA data collection plan	MME	IECI	UMIL
D8.2	User validation	UPM	UDEU	DOT
D8.3	Cost-effectiveness analysis	MME	IECI	UMIL
D9.1	Dissemination and Communication Plan v 1	RL	MME	UPM
D9.2	Dissemination and Cmmunication Plan - v 2	RL	MME	UPM
D9.3	Dissemination and Communication Plan - Final release	RL	MME	UPM
D9.4	Project Website and communication materials - V1	RL	IECI	MME
D9.5	Website and Communication materials v2	RL	MME	UPM
D9.6	Market study	IECI	MME	DOT
D9.7	Business Planning	IBMI	MME	DOT
D10.1	Quality Manual	UMIL	All	All
D10.2	Data Management Plan	RL	UMIL	UPM
D10.3	Ethical Framework	RL	UMIL	INT
D10.4	Innovation management plan	UPM	UMIL	UiO
D10.5	Ethics implementation report	RL	UMIL	INT
D10.6	Data Protection Impacts Assessment	UMIL	IECI	UPM