BD2Decide

Big Data and models for personalized Head and Neck Cancer Decision support

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This document should be distributed as guidance to all the personnel of BD2Decide Consortium partners involved in the project execution.

Revision History

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1	10.02.2016	E. Martinelli (AOP)	ToC
1.1	30.03.2016	E. Martinelli (AOP)	Added contributions from MME
1.2	15.04.2016	E. Martinelli (AOP)	Added contributions from AOP
2	06.05.2016	E. Martinelli (AOP)	Finalized with contributions from UPM

Addressees of this document

This document is addressed to the BD2Decide Consortium. It should guide the Consortium partners throughout the project, to ensure quality, prevent and address risks and measure the achieved levels of quality for the project results.

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Abbreviations and definitions

Definitions

"Conformance": Conformance is defined as compliance of an activity, process or deliverable to the requirements, procedures and standards specified in the Quality Plan, project procedures, Technical Annex I or specification documents.

"Non-conformance": Non Conformance is defined as the partial or complete lack of compliance of the results of an activity, process or deliverable to requirements, procedures and standards as specified in the Quality Plan, project procedures, the Technical Annex I or specification documents.

Other definitions are to be found in BD2Decide Consortium Agreement and in the Grant Agreement.

Abbreviations

CA	Consortium Agreement
DoA	Description of Action, Technical Annex I to the Grant Agreement
EC	European Commission
EU	European Union
GA	Grant Agreement
GUI	Graphical User Interface
ISO	International Organization for Standardization
KPI	Key Performance Indicator
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QAP	Quality Assurance Plan (same as QP)
QAS	Quality Assurance System
QMS	Quality Management System
QP	Quality Plan (same as QAP)
SW	Software
WP	Work Package

Executive summary

BD2Decide Consortium sets quality and achievement of results as the utmost priorities for the work of all Consortium. To this aim Quality and Risk Management procedures have been agreed that address:

- Consortium quality and performance,
- Quality and punctuality of deliverables and results,
- Quality of the management,
- Performance of Consortium Parties and of Subcontractors,
- Quality of software,
- Quality of data collected for the project,
- Quality of biological samples used for genomic analysis and genomic data extraction,
- Quality of ethics factors management especially in relation to the clinical study execution.

In relation to the above quality procedures, which are detailed in this document, the Consortium has already identified potential risks and has defined the appropriate prevention and mitigation procedures, that are described in the DoA.

Task 1.2 in the project work plan clearly establishes the scope and the goals for Quality Assurance and Risk Management and indicates the relevant responsibilities, which are better detailed in this document (see section 3).

As a general rule, the provisions included in the Grant Agreement and in the project Consortium Agreement must be considered for Quality Assurance.

Some information regarding this deliverable topics have been taken from following project material:

- Grant Agreement general provisions
- Technical Annex I, DoA
- Consortium Agreement (CA).

A detailed description of the project, detailed implementation plan, information related to work packages, deliverables and internal report can be found on the DoA.

About this document

This document describes the plans and the actions that will be undertaken by the BD2Decide Consortium during the project, in order to ensure that the objectives established in the Grant Agreement are actually achieved, with the quality, timing and budget established there.

It contains:

- A summary of the application scope
- The definition of the Quality Policy applied for the project
- The definition of the quality objectives that the project Consortium is committed to achieve
- The agreed quality assurance guidelines

- The main roles (persons, organizations and bodies) that are relevant to the functioning of the quality management system
- The description of the quality levels categories to be measured
- The provisions for monitoring the progress of the project work-plan and for pursuing continuous improvement
- The description of the mechanisms to ensure the quality of project documents
- Main Quality procedures for the scientific results of the project
- The procedures for ensuring quality of procurement
- The methodologies implemented for the control of software, documentation and data
- The description of the mechanisms to ensure effective risk management, appropriate to the scale and ambition of the project

Appendixes provide the following reference material:

- Document formats
- References to important documents

1 PRINCIPLES AND OBJECTIVES

1.1 SCOPE

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 BD2Decide platform that stores and analyzes real patient's data, will allow scientists run analysis on the collected data, will be used by physicians in their clinical decision-making by means of models, data visualizations and information to help them refine the diagnosis, more accurately estimate disease prognosis and plan treatments, and allow patients to actively participate in this decision process and potentially build a more positive attitude towards their disease and life expectations.

Accuracy, reliability, privacy and security are fundamental aspects for the design and development of the BD2Decide platform and for the definition and execution of the clinical study on which this development is founded and through which the decision support tools and the overall system will be validated. Therefore the Quality Plan for BD2Decide clinical study and platform must ensure that the following expectations are met:

- 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, prognostic modeling and clinical results assessment (scientific perspective);
- the BD2Decide software platform must do what they are supposed to do in a user-friendly way, to support user needs (end-users perspective);
- the BD2Decide software platform must perform tasks correctly and be reliable (developers perspective).

From an operational and managerial point of view, the Quality Plan and Risk Assessment procedures must ensure that the objectives of BD2Decide are met with the resources available and within the timeframe of the project.

The purpose of this document is to propose the guidelines and a shared approach to ensure the quality of the BD2Decide 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 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.

[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.

1.2 THE QUALITY CONTEXT OF BD2DECIDE

BD2Decide addresses the complex framework of clinical decision support, which has extremely important effects on the healthcare delivery process, thus three 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 have been approved by the Ethical Committees of all the participating hospitals. A major concern for the project consists in the number of retrospective and prospective patients that will be recruited for the clinical study and the completeness and quality of data. The Quality Plan will establish checkpoints to verify that the involved centres comply to the agreed data and biologic specimens collection protocol and to the specific quality assurance measurements.
3. Quality of results (deliverables, software and any other expected results), that will be assessed by the Steering 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 QUALITY POLICY

The BD2Decide Consortium is committed to achieve all the clinical, scientific and technical objectives and to produce the expected impacts described in the DoA.

In this context, the Consortium intends to establish and implement an effective quality assurance system (QAS) for the fulfillment of the following results 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.

This Quality Plan has been established for the fulfilment of 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 healthcare. They must include key dimensions for healthcare such as access, safety, effectiveness, efficiency, timeliness and patient centredness.

The principles guiding the Quality Plan of BD2Decide are aimed at ensuring the utmost quality of the project results and must therefore be equally applicable by all participating organizations.

To this aim the following key concepts have been considered. The Quality Plan is:

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.

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.

To achieve these objectives, the Consortium has agreed to devote the necessary resources to put in place and operate the QAS described in this deliverable.

The BD2Decide QAS is operationally exploited into this Quality Plan and Risk Assessment, and is based on the following international 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 clinical research involving human subjects, we refer to EU Directive 2001/20/EC and to Regulation EU No 536/2014.

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 Steering Board 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 Plan 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 Plan may be reviewed by the Steering Board 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 (T1.2) and as part of Technical management (T1.3) and Ethics aspects management (T1.4).

The Quality Plan will be revised accordingly.

2.2 QUALITY OBJECTIVES

BD2Decide quality objectives are expressed in terms of its tasks and Work Packages (WP), deliverables, milestones, Key Performance Indicators (KPIs) and clinical results, Ethics requirements.

2.2.1 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.

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 Steering Board of such occurrences.

Quality of tasks and WPs will be monitored internally at two 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 the Steering Board during Consortium meetings and through the agreed periodic internal reporting (every 6 months), as established in the CA art. 7.3.2

and externally by the European Commission during periodic reviews.

Failures detected through internal quality assurance will be reported in the relevant internal periodic reports (see Appendix II) 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 (see section 3.1.11) and a shared solution/recovery plan must be issued (see section 4).

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.

2.2.2 Deliverables

BD2Decide deliverables 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. Late delivery is a non-conformity, that must be immediately addressed (see section 3.1.11).

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 (see Section 4).

Quality of deliverables will be controlled at two levels (see Section 3.1.8):

- Internally to the Consortium and prior to delivery, through a peer reviewing procedure
- By the 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 3.1.5).

2.2.3 Milestones

The milestones committed by BD2Decide 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.

2.2.4 KPI

The KPIs defined by BD2Decide 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 WP8.

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.

2.2.5 Ethics requirements

BD2Decide foresees a clinical study involving humans, biologic materials, diagnostic images with a critical privacy aspect (CT and MRI scans of the patients' head) and 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 management of the biological specimens and patients data collected during the project. For this scope the Coordinator has requested that all participating hospitals provide the

approval of BD2Decide study by their reference Ethical Committees. Copies of the approvals documents 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. An Ethics Manager has been appointed for the project.

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.

2.3 QUALITY EVALUATION 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, from two main perspectives:

- internal quality: this refers to the methods or techniques implemented in order to achieve a quality result (e.g. quality of clinical protocol for high quality clinical study, quality of software design and implementation processes, quality of documentation)
- external quality: this concerns the objective assessment of the quality of results or project outputs; e.g. measure of KPIs or quality of deliverables in terms of quality of information provided or impacts described.

To assess quality levels a scale needs to be defined, to express the degree of quality assessed by the quality evaluators, 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 ration is below 50% of target
- Acceptable: quality level is minimally sufficient, achievement level is between 50% and 65% of target
- Good: the project output/result quality satisfies the expectations and is in line with the commitments, achievement level ranges between 65% and 100% of target
- Excellent: the quality of the output/result goes beyond commitments and expectations, achievement level exceeds the committed target.

2.4 ROLES AND RESPONSIBILITIES FOR QUALITY ASSURANCE MANAGEMENT

In this section we summarize the quality management responsibilities, in conformity of what has been committed by the BD2Decide Consortium in the DoA (part B section 3.2) and in the Consortium Agreement Section 6 (Governance structure).

The Coordinator and the Steering Board, representing the Consortium members will pursue a quality assurance process to:

- execute all project activities at the highest quality level;
- adopt appropriate and effective management processes for the achievement of the defined quality standards for the management of all situations and eventual project difficulties;
- adopt and follow plans whereby planning, implementation, monitoring and review phases have been defined and/or responsibilities have been assigned;
- activate programmed control actions for a continuous monitoring of the progress of the project.

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

Role	**Type**	**Appointment**	**Responsibility**
Steering Board	Body	It consists of one representative appointed by each Partner, as well as the Project Coordinator.	It is the ultimate, strategic decision-making body of the Consortium. Responsibilities are described in section 6.3.1 of the CA.
Project Assembly	Body	It consists of the Project Manager, the Technical/ Innovation Manager, the Scientific Manager, the Exploitation Manager, the Work-package Leaders and the Ethics Manager and by Principal Investigators in participating hospitals.	It is the operational and managerial decision body of the project. Responsibilities are detailed in section 6.3.4 of the CA.
Managing Team	Body	It consists of the Project Manager, the Technical/ Innovation Manager, the Scientific Manager, the Exploitation Manager, the Work-package Leaders	It monitors the execution of the decisions taken by the Steering Board and is in charge of the day-by-day management within the project.

Role	Type	Appointment	Responsibility
Project Manager	Person	Appointed by the Coordinator.	She/he chairs the meetings of the Project Assembly and of the Steering Board. She/he maintains contacts with the Commission on behalf of the Coordinator.
Coordinator, Scientific Coordinator and Quality Manager	Person		She/he is in charge of coordinating the project and also to coordinates the Scientific activities in all Clinical Centres and the project QAS
Technical/Innovation Manager	Person	Appointed by the Coordinator.	He is in charge of the overall coordination of the project's technical work.
Exploitation Manager	Person	Appointed by the Coordinator.	She/he is in charge of the overall coordination of the project's exploitation and innovation work.
Scientific Manager	Person	Appointed by the Coordinator.	She/he is in charge of the management of the project's scientific work.
Ethical Manager	Person	Appointed by the Coordinator.	She/he chairs the Ethical Board and oversees over BD2Decide ethics aspects.
Work-package Lead beneficiary	Organization	Established in the GA.	It is responsible for the work in the respective work-package.
Work-package Leader	Person	Appointed by the respective Work-package Lead beneficiary.	She/he is in charge of the overall coordination of the respective work-package's work.
Deliverable Lead beneficiary	Organization	Established in the GA.	It is responsible for the release of the respective deliverable.

Role	Type	Appointment	Responsibility
Milestone Lead beneficiary	Organization	Established in the GA.	It is responsible for the achievement of the respective milestone.
Ethical Board	Body	It includes the PIs of each clinical study participant site in the Project, appointed by the relevant responsible Partner, plus an Ethical Manager who chairs the Board.	It manages project's ethical issues (see DoA part A, WP1, task T1.4)
External Experts Advisory Board	Body	Project Assembly	It ensures that the Project correctly pursues innovative scientific targets and maintains focus on the market. Details are provided in section 6.6 of the CA.

Table 1. BD2Decide governance and responsibilites

The following sections briefly describe the specific roles involved in QA.

2.4.1 Quality manager (Coordinator)

The Coordinator is also the project Quality Manager, responsible for the overall quality of BD2Decide work, outcomes, committed objectives, use of resources and achievement of contractual obligations. The Coordinator will be assisted in this task by the Project Coordinator Team and by the Innovation Manager, the Scientific Coordinator, the Work Package Leaders and the Ethical Advisor. tasks and responsibilities of these persons and organisms are detailed in the Technical Annex I, DoA, section 3.2.

Although BD2Decide managerial structure does not include a Quality Assurance Board, the quality procedure foresees that the Project Manager, the Technical Manager and the Innovation Manager jointly monitor and ensure the quality of technical and scientific work and results and that they are in line with the committed objectives of the project. In case of need external experts may be appointed to further assess the quality of specific deliverables or results.

2.4.2 Work-Package Leaders

For each work-package (WP), the DoA 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, who will be in charge for the coordination of the WP activities and of the relevant QA. The responsibilities of WP leaders are described in the DoA part B section 3.2.1.

In particular, the Work-package Leaders' responsibilities include the following quality aspects:

- Agree with other Partners involved in the work-package on the sharing of work and on intermediate deliveries/deadlines for project results
- Agree with other Partners involved in the work-package on the quality objectives of the work, in accordance with the policy illustrated in this document.
- Maintain strict communications with the Project Manager and the Coordinator for what concerns the advances of the WP, the onset of potential risks or non-conformities and the proposition of recovery/mitigation actions. In this activity WP Leaders shall be supported by Task Leaders and by Deliverables' Lead Beneficiaries and Milestones' Lead Beneficiaries and seek advice from other Managing Team members.
- Maintain strict contacts with other WP Leaders especially in cases of dependencies between different WPs.

2.4.3 Deliverable Lead Beneficiary

For each deliverable, the DoA 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 timeliness. 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.

2.4.4 Milestone Lead Beneficiary

A Lead beneficiary is defined in the DoA for each project milestone. This is a Consortium Partner responsible for the achievement of the milestone, in particular:

- Monitoring the work related to the respective milestone
- Periodically assess the status of the work related to the milestone and report about it to the relevant Work-package Leader and to the Project Manager.

2.4.5 Ethical Board and Ethical Manager

The Ethical Board is the project body that is in charge of addressing the ethical issues arising from the clinical study execution in the Clinical Centres, and ensuring that the appropriate ethical frameworks and procedures are in place, as illustrated in the DoA part B, section 5.

It includes the PI for each Clinical Centre in the project (as described in the DoA, Part B, Section 1.3.6) and at the subcontracting clinics (as described in the DoA, Part B, Section 4.2.1), appointed by the relevant responsible Partners, as summarized in the following table.

Clinical Centre	**Responsible Partner**
Milano	INT
Parma	AOP
Amsterdam	VUMC
Dusseldorf	UDUS
Maastricht	MAASTRO
Lisbon (INT subcontractor)	INT (GECCP)
Vienna (INT subcontractor)	INT (MUV)
UDUS subcontractors[3] (linked clinics)	UDUS

Table 2. The Ethics responsible organizations at BD2Decide Clinical Centres

The Ethical Board will be chaired by the Ethical Manager.

The responsibilities of the Ethical Board include:

- Ensure that the participating Clinical Centres have achieved ethics approval for the clinical study
- Ensuring that all ethics requirements described in the DoA and in the D7.1 are fully and timely addressed
- Promptly signal to the Coordinator any risk of not being able to address any of those requirements
- Manage the procedures related with the above and prepare relevant proposals to be submitted to the Steering Board.

A special importance has the Ethical Manager, Mrs. Kathrin Scheckenbach, MD, PhD. She is in charge of monitoring the adherence to all ethical aspects related to the clinical study execution.

[3] To be involved in case of missing patients for the prospective study

3 QUALITY ASSURANCE GUIDELINES AND PROCEDURES

Three main quality assurance streamlines have been considered in BD2Decide Quality Plan:

1. project coordination: the quality of coordination expressed by the achievement of project's committed results within the established timeframe and resources
2. clinical research perspective: the quality of the clinical study (study design, study execution, data collection, study results evaluation) and
3. technical perspective: the quality of the developed software tools throughout the whole design, development, test and users validation process.

3.1 QUALITY OF COORDINATION

The quality of coordination implies the measurement of progress and continuous improvement of the work of the Consortium. The assessment of the quality of the work for the overall project is under the responsibility of the Project Assembly, which meets usually three times a year, and by the Coordinator, through the Project Manager (PM). In fact it is the primary responsibility of the Project Manager to monitor the overall progress of the project activities and to report and justify to the Coordinator, to the Project Assembly and to the Management 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 send 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 send 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 the start of each 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 costs reports (see Annex II) and activity reports from all partners (WP Leaders are in charge of collecting such activity reports from all partners involved in their WPs). 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, DoA, part B section 3.2.2 through 3.2.5
- Consortium Agreement, Articles 6.2 (Coordination procedures), 7.1.3.1 (Monitoring of costs), 7.3.2 (Internal reporting), 7.3.3 (Payment schedule) and 11.11 (Provisions regarding default in patients enrolment).

3.1.1 Internal periodic reporting

Internal reporting is established on a six-monthly basis, in order to support the Steering Board in the supervision of the project execution 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 A):

- summary of the work performed and of objectives achieved for each WP/Task
- used resources (person hours, 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

Process for the internal periodic reporting

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

Step	Description	Input	Output
1	Within 30 days from the expiration of a project's semester, the 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 A)

Step	Description	Input	Output
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

Table 3. Quality assurance during periodic reporting

3.1.2 Periodic reporting to the EU

Official periodic reporting to the EU is required at the following months: 18, 30, 40 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 (forms C) 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 A) 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 3.1.1 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 form C for each Beneficiary:

- **personnel costs**: shall be indicated for each WP (total personnel costs by WP). For each person indicate the name, 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 DoA 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 in charge 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.

Process for the official periodic reporting to EU

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

Step	Description	Input	Output
1	Within 15 days before the expiration of a reporting period, the Manager will circulate the templates for the periodic reporting	Official periodic reporting templates. Excel sheets for costs declaration	
2	Within 20 days after the expiration of the reporting period, WP Leaders and all Beneficiaries will send to the Project Manager the reporting information described above using the provided templates		Official periodic reporting templates filled (see in Annex A) Plus excel sheets with 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 (i.e. 40 days after the expiration of the reporting period) • the concerned Beneficiaries should send the required integrations to the PM for document integration and approval • the administrative Offices of each Beneficiary upload the costs in the participants portal	Integrated periodic report forms plus requests for integration plus finalized excel sheets with costs for each Beneficiary	Integrated periodic report forms plus Forms C in the participants portal

Step	Description	Input	Output
5	Within 45 days after the expiration of the reporting period, the Project Manager • checks forms C and requires eventually revisions to Beneficiaries • makes available to the Consortium a consolidated version of the periodic (and final) report downloaded from the participants portal for 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 forms C and the official periodic (final) report	Forms C and official Periodic (Final) report	Consolidated Forms C and Periodic (Final) report
7	By day 60 after the expiration of the reporting period the Coordinator submits the Periodic Cost and Activity Report	Consolidated Forms C and Periodic (Final) report	Submitted Periodic costs and activity report

Table 4. Quality process for EU periodic reporting

3.1.3 Communications

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

- the project website: www.BD2Decide.eu (D9.1, month 4), used for dissemination and external communications purposes;
- a documents management system (see below) accessed by each Beneficiary with individual credentials
- a unique contact point for the Coordinator **BD2Dcoord@ao.pr.it** has been established by the Coordinating Institution, for all communications between the Coordinator and the Consortium and between the Coordinator and the European Commission Offices;
- mailing lists have been established by ATC to facilitate communications, which are maintained by ATC through a mailing address excel sheet published in ownclud and also at URL https://docs.google.com/spreadsheets/d/1wn7D-GERYPD6whEhsaoLOOFgp-lYj7-Pcjy_obBW5gE/edit?pref=2&pli=1#gid=523049970:
    - **all@bd2decide.eu**: all persons of the Consortium;
    - **technical@bd2decide.eu**: all persons participating to technical WPs;
    - **clinical@bd2decide.eu**: all participants to the clinical study;

  - **admin@bd2decide.eu**: legal and administrative staff representatives of Consortium beneficiaries
- 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 Steering 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 https://docs.google.com/spreadsheets/d/1wn7D-GERYPD6whEhsaoLOOFgp-lYj7-Pcjy_obBW5gE/edit?pref=2&pli=1#gid=523049970, which provides information regarding the responsible persons for each work.

The communications between Partners and the Coordinator must be sent to the following email address: **BD2Dcoord@ao.pr.it**.

The list of contacts will be maintained by the Coordinator throughout the Beneficiary ATC. 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/Steering 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 fax 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.

3.1.4 Communications with the European Commission Offices

The Coordinator is the only authorized channel for submitting all documents to the EC, and for general liaison between the partners 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.

3.1.5 Quality Assurance of project documents

The following shall be considered documents for BD2Decide.

3.1.5.1 Deliverables

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

In particular 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 DoA, Part A, Section 1.3.2), short name of the Leading Partner, short names of contributors, project logo, Filed ID, 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
- 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

3.1.5.2 Publications and dissemination materials

These include the web site (see above), 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"[4]) 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: *"BD2Decide has received funding from the European Union's Horizon2020 research and innovation porgramme (H2020-PHC30-2015) under Grant Agreement number 689715"*.

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

The Coordinator will verify the quality of each dissemination material produced and submit it for approval to the Steering Board. The Coordinator will verify that each public dissemination material complies to the above quality criteria.

The Steering 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.

Periodic internal reports

Periodic reports are collected through the document formats illustrated in Annex A. The QA procedures are described at sections 3.1.1 and 3.1.2).

Minutes of the meetings

Minutes of the meeting are collected as defined in the BD2Decide CA 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, Steering 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.

Risk registry

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

The table is managed by the Risk management procedure (see section 4).

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.

3.1.5.3 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.

3.1.5.4 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:

Document type	Role that approves the document
Deliverables	Relevant Work-package Leader
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. 8.3.1 in the CA.
Web site and Social media content	Same as previous row

Table 5. Documents approval roles

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 7).

3.1.6 Quality of the project web site

BD2Decide concerns disease management issues and offers information to professionals but also to patients. Therefore the quality of the web site is of primary relevance to the Consortium. Consequently the quality of the public web site 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 (see box). 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.

Quality Criteria for Health Related Websites

1. Transparency and Honesty

- *Transparency of provider of site - including name, physical address and electronic address of the person or organisation responsible for the site (see Article 5 and 6 Directive 2000/31/EC on Electronic Commerce).*
- *Transparency of purpose and objective of the site*
- *Target audience clearly defined (further detail on purpose, multiple audience could be defined at different levels).*
- *Transparency of all sources of funding for site (grants, sponsors, advertisers, non-profit, voluntary assistance).*

2. Authority

- *Clear statement of sources for all information provided and date of publication of source.*
- *Name and credentials of all human/institutional providers of information put up on the site, including dates at which credentials were received.*

3. Privacy and data protection

- *Privacy and data protection policy and system for the processing of personal data, including processing invisible to users, to be clearly defined in accordance with community Data Protection legislation (Directives 95/46/EC and 2002/58/EC).*

4. Updating of information

- *Clear and regular updating of the site, with date of up-date clearly displayed for each page and/or item as relevant. Regular checking of relevance of information.*

5. Accountability

- *Accountability- user feedback, and appropriate oversight responsibility (such as a named quality compliance officer for each site).*
- *Responsible partnering - all efforts should be made to ensure that partnering or linking to other websites is undertaken only with trustworthy individuals and organisations who themselves comply with relevant codes of good practice.*
- *Editorial policy - clear statement describing what procedure was used for selection of content.*

6. Accessibility

- *Accessibility- attention to guidelines on physical accessibility as well as general findability, searchability, readability, usability, etc.*

ATC is 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. ATC 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.

3.1.7 Collaborative documents management system

A shared documents management system has been established by ATC at the start of the project (URL: https://owncloud.atc.gr/owncloud/index.php/apps/files/?dir=%2FBD2Decide). 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 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:

- 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-packages: for each WP two subfolders are present:
    - working documents: contains drafts, internal documents and any other document that could be useful within the WP
    - deliverables: contains official deliverables (all released versions, delivered to the EU)
- Templates: this includes project documents standard templates

3.1.8 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 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 (owncloud).

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.

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.

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

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.

Quality aspects	Quality criteria	Quality indicators (non-conformance)	Importance[5]
Content	Completeness	Missing content / Lack of information	+++
		Redundancy	++
		Lack of details	++
	Relevance	Error in content	+++
		Missing /wrong references	++
		Insufficient documentation	++
		Ambiguity	++
	Accuracy	Non-relevant information	+
		Confusing text	++

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

Quality aspects	Quality criteria	Quality indicators (non-conformance)	Importance[5]
Document structure and appearance	Uniformity and standardization	Spelling errors Non-conformance to documents templates Usage of different fonts and types of presentations	+ + +
	Adherence to standards	Non-compliance to EU or de-facto standards	++
Timing	Punctuality	Delay	+++

Table 6. Quality indicators for documents deliverables

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 if approved, accepts the document and
    - In case of external review (by external experts), the PM sends the document to the experts, otherwise
    - delivers it (upload on participants portal)
- In case the quality of the deliverable is not satisfactory and / or it fails to conform to the quality criteria described above a «Non Conformance Report» is issued (either by the PM or by the external experts), with a list of errors and comments, and is sent back to the WP Leader and to the Editor with comments for further revision.

The process is iterative until the requested quality is reached. The process is summarized below.

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 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
3	Within 10 working days contributors shall provide the missing information plus their comments	Deliverable draft	Additional contributions

Step	Description	Input	Output
4	Within 15 days before the delivery date the Author sends the draft to the WP Leader and to the Project Manager for first assessment		Integrated draft of deliverable
5	Within 5 days the WP Leader and the Project Manager return the draft with comments to the Author	Forms C	Commented draft of deliverable
6	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
7	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

Table 7. Quality process for deliverable QA

At the end of the process the deliverable is delivered on the participants portal and uploaded on the BD2Decide owncloud documents management system. If the document is public, it will also be accessible from the public area of the BD2Decide web site.

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

External peer-review may be required for selected deliverables which may be identified during the project execution as critical. 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 external expert.

This process may take additional time and delay the submission of deliverables, therefore it will be adopted only on exceptional cases and be planned well in advance, in order to reduce the risk of delay in deliverable submission. At present we have not foreseen such external peer-review process.

3.1.9 EC project review meetings

The Project will undergo three EC project reviews, according to the following tentative schedule, established in the DoA:

- RV1, M18, Brussels, Periodic Review

- RV2, M30, Brussels, Technical Review
- RV3, M40, Brussels, 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 Project Assembly during the next Consortium meeting.

3.1.10 Project Quality reviews

Quality reviews will be performed by the Project 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:

- DoA (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 Project 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 a specific section of 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.

3.1.11 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 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

Besides the systematic QA process performed 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, 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 Assembly and/or the Steering Board for implementation.

4 QUALITY GUIDELINES FOR CLINICAL RESEARCH

The stringent compliance to good clinical practices (GCPs), rules, and regulation; adhering to declaration of Helsinki needs evaluation and oversight by the institution needs quality assurance (QA) quality control (QC) programs.

Good Clinical Practice (GCP) research guidelines as defined by ASCO have guided the quality procedures established for the BD2Decide clinical study. They are presented in the clinical protocols (D7.1) and describe the clinical study activities, processes and the management of data, clinical exams and of biological specimens.

The defined Quality Assurance (QA) programs help ensure adherence to GCP guidelines and contribute to the ability of a clinical trial site to produce first-rate data. BD2Decide quality procedures include conducting internal (self) audits, actively implementing and revising SOPs, recording protocol deviations, and initiating procedures to correct any shortcomings and prevent their recurrence.

Quality requirements

The following quality requirements have been indicated for the clinical study:

- at least 1.000 retrospective patients diagnosed HNSCC stage III or IV between 2008 and 2014 must be enrolled
- at least 450 prospective patients diagnosed HNSCC stage III or IV must be enrolled
- inclusion and exclusion criteria as indicated in the study protocols must be met
- at least 70% of the data of each CRF Item (see Annex II of D2.1) must be available for a patient to be eligible.

4.1 QUALITY PROCEDURES

Quality Assurance for BD2Decide clinical study

A) patients enrolment and data completeness

The Consortium Agreement art. 11.11 defines the criteria to assess the compliance of each participating centre towards the promised patient's enrolment ratios and data collection completeness. The Coordinator will assess the status of enrolment and the completeness of the data vs. the CRF defined in D2.1 at least 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.

B) 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 imaging data, a sample of diagnostic images and image analysis results will be exchanged at least once at the start of the project, to ensure the utmost uniformity in all participating centres.

Biomolecular testing has been centralized at INT (genomics) and VUMC (HPV) in order to minimize bias.

Biologic specimens management and RNA/DNA extraction follow standardized protocols. To evaluate operator-dependent differences, a first set of tests will be executed by the different operators in the participating centres on samples that will not be used for the study, in order to detect major internal deviations and apply the relevant corrective actions.

Transfer of biologic specimens between clinical centres will be managed by a certified courier.

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 (D7.1)
- by performing cross verifications between involved centres concerning the techniques for sample preparation and diagnostic images collection (e.g. between INT and AOP, between VUMC and MAASTRO etc.)
- by verifying (PI in each participating clinical centre) the application of the protocol by the involved laboratory personnel.

C) Quality of statistical analysis

The BD2Decide DSS and Big Data analysis require coherent and complete data to produce reliable results with significant statistics power.

To this aim the statisticians in Amsterdam have estimated the minimum number of prospective and retrospective cases to be provided (see DoA Part B section 1.3.10 "Sample size"). To ensure that multiscale prognostic factors are produced and that the maximum number of data and information is used for data analysis, the Consortium has also set a minimum threshold for the data to be provided for each patient. This threshold is applied to all categories (Items indicated in D2.1 Patient's dataset, CRF) is 80%.

However the proposed 80% is an arbitrary value, because literature does not provide any such reference value. and the distribution of the frequency of missing data for the examined patients is yet unknown, Therefore the Consortium has considered to apply a cautious approach and proposed a lower threshold (70% of data).

This lower threshold (70%) will be preferred if the following condition is verified:

$$1 - \left(\frac{1}{\frac{\#\ evaluable\ subjects\ with \geq 70\%\ data\ for\ each\ data\ Item}{\#\ of\ evaluable\ subjects\ with\ \geq\ 80\%\ data\ for\ each\ dataItem}} \right) > 20\%$$

In the optics of Big Data whose informative wealth is characterized by the high number of study subjects (rows) and by the number of collected variables for the description of patients (columns), the identification of "evaluable subject for the scope of the data analysis" is strongly related with the best balance between these two informative dimension.
Mandatory information has also been defined and agreed by the Consortium, in order to guarantee that the already studied risk/prognostic factors reported in literature and recommended in international guidelines are considered.

D) Respect of ethics

At the time of this deliverable editing, the Coordinator has already acquired the approvals by the Ethics Committees of INT, AOP, and UDUS. VUMC and MAASTRO have already achieved an extended Ethics approval for studies concerning Head and Neck Cancer Patients.

Regarding the ethical aspects concerned with electronic patients data management, the Technical Manager and the Project Manager have already established a detailed procedure in agreement with the Legal Office of the Coordinator, who has involved the Legal Responsible of the Parma University Hospital where patients are treated and patients' data are managed.

These procedures comply with the Italian and EU regulations regarding data anonymization and foresee the following:

- data anonymization: patients sensitive information is kept inside each hospital and managed by the hospital only. BD2Decide Patients Documentation System will not include any patients information which could allow identification, in particular:
  - genomic data: no full genomic profile is collected by BD2Decide, only partial genomic data are collected in anonymous modality;
  - imaging data are anonymized by the radiologists before image processing and are stored internally in each hospital, full images are not published and may not be used for patient's identity reconstruction;
- patients' data management remains under the responsibility of each participating hospital, who has received ethics approval for the BD2Decide 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.

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

4.2 SCIENTIFIC VALIDATION

The scientific validation of BD2Decide includes the assessment of clinical impacts and the overall impacts assessment as defined in WP7 and WP8. The Scientific Manager is responsible for the Quality Assurance of the Validation procedures and results. Criteria for scientific validation will be produced by month 32 by WP8 Led Beneficiary.

4.3 QUALITY ASSURANCE OF WORK PERFORMED BY THIRD PARTIES

BD2Decide foresees some activities that are subcontracted to third parties or services that are acquired from third parties. In particular critical subcontracted activities consist in the procurement of population data (subcontractor Istituto Superiore di Sanità - ISS, Italy) and the enrolment of prospective patients (subcontractors Grupo de Estudos de Cancro da Cabeça e Pescoço - GECCP, Portugal and Medical University of Vienna - MUV, Austria). Minor subcontracts may be established for specific activities (e.g. transfer of biological specimens from participating hospitals to INT for genomic tests and to VUMC for HPV tests).

For these subcontracts a strict monitoring and quality assurance is foreseen as follows (see also Consortium Agreement art. 11.11):

- the responsible partner will report to the Coordinator and to the Steering 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
- in case of non-conformity detected, corrective actions as described above (see section 3.1.11) 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 GECCP and MUV. Responsible partner INT.
    - INT shall establish a plan for patients' enrolment by subcontractors 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, 800 €/pt for retrospective cases) to the Consortium; this budget will be redirected to the clinical centre who will provide the missing cases

- a request for amendment will be immediately prepared and submitted as soon as possible to the EU.

2. Population data provision by Istituto Superiore di Sanità (ISS): responsible partner AOP.

- AOP shall verify and assess with ISS the population data that can be provided by month 4 at the latest
- AOP and ISS shall produce a plan for data provision (aggregated data and population high resolution data) by the first internal reporting period
- a plan to achieve at least initial population data for the models retuning shall be established by AOP and ISS by the first internal reporting period
- in case of (partial) default of ISS in providing the data indicated in the DoA (Part B section 4.2.1), AOP shall immediately report to the Steering Board and implement recovery actions indicated in section 4.

5 QUALITY GUIDELINES FOR TECHNICAL DEVELOPMENT

The definition of the User Interaction development cycle (end-user perspective) is characterized by the following phases:

- User Needs and Use Case Scenarios
- User Requirements and Technical Use Cases (focused on the GUI elements)
- User Interaction Flow and User Interaction Components Design (Mockups)
- Development (Functional Prototypes, Beta Versions, Full Prototypes)

Likewise, the software development cycle (developer perspective) is governed by the following phases:

- Requirements
- Software Specification
- Design
- Development
- System Design

The phases yield the documents listed in Table 8 and Table 9.

Phase	Document	Content	Responsibility
User Needs and UC Scenarios	- D2.1	Specifications of the needs and scenario as required by users	WP2 Leader
User Requirements and Technical UCs	- D2.1 (first draft) - Internal Report	Definition of the Graphic User Interface Elements and main interactions with layers and with the end Users	ATC, UPM
User Interaction Flow and User Interaction Components Design	- D2.2	User Interaction Sketches	MAASTRO, ATC, UPM
Development	Technical specifications	Full scheme of the SW component with the I/F with other modules/tools	Involved technical partners
Development	SW application	- Code of the relevant tool - CD with the relevant code	Involved technical partners
System Design	Integration with the Project Platform	- Full scheme of the platform - Description of the integration process and procedure - CD with the relevant code	Technical manager and involved technical partners

Table 8. Description of the User Interaction Development phases

Phase	Document	Content	Responsibility
User Needs and UC Scenarios	- User requirements	- Specifications of the functionalities required by users	WP Leader
User Requirements and Technical UCs	- Technical requirements (i.e. for integration purposes)	- I/F data and format (IN/OUT) - Requested standards - Other technical relevant details - Hardware and additional SW required to run the tool/module	Involved technical partners
User Interaction Flow and User Interaction Components Design	Technical specifications	- Description of the SW component - UMLS or other relevant technical diagrams - Description of SW notations with examples - Full scheme of the SW component with the I/F with other modules/tools	Involved technical partners
Development	Technical specifications	- Full scheme of the SW component with the I/F with other modules/tools - Technical design of the SW module - Description of the rationale for the selected design - References to SW specifications when applicable	Involved technical partners
Development	SW application	- Code of the relevant tool - CD with the relevant code	Involved technical partners
System Design	Integrated SW platform	- Full scheme of the platform - Description of the integration process and procedure - CD with the relevant code	Technical manager and involved technical partners

Table 9. Description of the Software control phases

The User Interaction development cycle will consist of at least 2 iterative cycles, where each phase will be evaluated with the relevant end-users and stakeholders, following a User Centred Design approach, with the aim of maximising user acceptance and consequently the impact of the system.

The software development cycle ends with the launch of the verification and validation phase.

Changes will be managed as follows:

- Changes to GUIs and software specifications requested will be managed as “change requests”.
- Change requests may entail a revision to the requirements and to other documentation; in this case a new version of these documents will be produced.

- Changes to the software requested during the field tests will be managed as "trouble reports". Trouble reports will not affect requirements but may involve a change to test procedures. A Non-conformance template is provided as Annex F of this document.

In addition to the above the following documents will be prepared for every module.

- User Guide
- Administration Guide.

Each software component must be accompanied by a report describing it.

The responsibility for these documents is of the individual implementation task manager.

The following subparagraphs provide more details about these aspects.

5.1 SOFTWARE DEVELOPMENT DOCUMENTS

The formalism is to the discretion of the responsible partners. One suggested possibility is to adopt for the project the UML (Unified Modeling Language) notation for its documentation and Use Case Tables (as those provided as chapter 6 of D2.1). UML is a language for specifying, visualizing, constructing and documenting software. The UML use will be confirmed in a technical meeting.

5.2 SOFTWARE REQUIREMENTS

Any modification to a requirement must be performed as either a new version of the requirements document or as a change request. Change requests become part of the requirements document and must clearly indicate, in the references paragraph, the version of the requirements document they modify.

Any following version of the requirements document must either incorporate the change request into the document itself or explicitly declare it obsolete.

5.3 RELEASE NOTE

The Release Note will document the release of a new version of a software module; every release of a software module must have a new major version number. Testing procedures will refer to the version number to track a module's evolution. The development cycle provides for two different kinds of releases.

A software release will be performed for the first release of a module and for the implementation of a change request. A full software release consists of:

- The compiled executables
- The User Guide
- The installation and Administration Guide

- The sources (if not in contrast with the CA rules) and related files (make file, special libraries, etc.).
- Partial software releases containing only executables are allowed for Alfa and Beta testing and for software subject to restricted distribution according to the CA.

Whenever a full software release is performed a software module a regression testing must be performed.

A patch will be issued to correct a bug or to perform minor changes to the software that do not entail the need to modify the specification documents. A patch is made up of:

- The compiled executables
- The complete sources and related files (make file, special libraries, etc.)

A release note template is provided as Annex E of this document.

5.4 TEST PLANS

Test plans describe the testing strategy of the tests and the actual test to be performed on the software modules before they are released. Test plans are under the responsibility of the Task Leader responsible for the software module. A test plan must assure coverage of all the functionality described in the functional specification. A set of checklists will be included in the test plan describing the tests to be performed.

Test plans will be defined in order to comply with the delivery dates for the individual SW modules and for the BD2Decide platform and components and in accordance to the agreed work plan approved by the E.C.

Modifications to test plans (new delivery dates, new sequence of SW release etc.) must be agreed upon by the Steering Board. Major discrepancies with respect to the official work plan must be notified to the Steering Board and – after approval – to the European Commission.

Checklists describe a set of tests to be performed, for every test the list must describe the initial status of the system, the inputs, and the expected results. The checklist must clearly reference the functionality it is meant to test. A checklist template will be provided along with the test plan and procedures at due time.

5.4.1 Software Test Methodology

Two categories of tests will be performed by technical partners:

Unit test: this test is performed by the partner in charge of the single SW component and aims at ensuring that the SW module performs the functionalities required. This test may be performed with a simulated input as foreseen by the technical specifications. The output should be consistent with the given input and the foreseen functionalities. The test should check all type of input (even wrong, non-complete or corrupted input) and output (both database recording and/or printed or displayed output) and errors.

System or integration test: this test is performed under the supervision of the technical manager and of the SW integration WP leader(s) and involves different partners, namely partners providing modules which I/F between each other. The result of this test is the assessment of a correct "SW stream" between collaborating SW modules and the correct management of input and output data, based on system specifications and design.

A software component can be released when the system test is satisfactorily completed. After release the component is available for the system test.

A set of software component composing "SW unit" performing a user functionality may be released at the end of a satisfactory system test and under the responsibility of the technical manager. This SW unit may be early released to end users for the users validation to speed-up the validation process and to early detect anomalies or misunderstandings of user requirements.

5.4.2 Test Reports

Test reports describe the results of a test session on a software module.

These reports must reference the version under test and clearly state the date of the test and the tester.

5.5 TECHNICAL VALIDATION

The following indications are provisional and will be better defined as soon as the validation process of BD2Decide starts.

The validation of the system functionalities will be performed by USERS (Pilots and External users when applicable) only after a release of integrated software modules (SW units) completing a user's functionality.

Technical partners are committed to provide all technical support to users during the Validation process. A validation plan and procedure will be set-up to maximize the outcomes of validation and to minimize communication and interaction problems between users and technical partners.

5.5.1 Validation Plans

Pilots will define Validation Plans and methodologies at least one month before the availability of the first software units to be validated. These plans will be agreed with the Technical/Innovation Manager in order to avoid interference with the ongoing technical development.

Validation Plans may be specific for individual Pilots and will be published on the project's library.

5.5.2 Reporting

Specific reporting form for problems and errors encountered and also for request for change will be agreed between Pilots and the Technical/Innovation Manager. Each form should indicate the

following information:

- SW or functionality validated
- Date
- Pilot and user
- Detailed description of the test environment
- Detailed description of the validation steps performed (eventually with screenshots, printouts of the involved databases etc.) with actual input, actual output and expected output
- Gravity of the problem and resolution requests (mandatory, recommended, nice to have, etc.)
- Urgency (extremely urgent=validation stop; urgent=as soon as possible; to be done before final release, etc.)
- Any additional clarifications which may be helpful.

Validation error reports will be collected by the Technical Manager on and evaluated in terms of urgency a weekly basis. A summary of open validation issues will be published along with comments and deadlines for bug fixing/change implementation.

The Project Manager will monitor this situation on a weekly basis and highlight potential risks with the support of the Technical Manager.

Direct interactions/communications between Pilots/users and individual technical partners should be agreed in advance and authorized by the TM and performed by exception only.

5.5.3 Quality records

The following documents shall be considered quality records:

- Changes proposed for the Quality Plan and for its procedures
- Modifications to the contract with the EC
- Test records
- Quality control reports on software
- Non-conformance statements
- Corrective / Preventive actions
- Risk Registry

All quality records pertaining shall be filed by the Coordinator.

The project Coordinator shall have all versions of the quality records and of the original documents to which the quality records apply available on file for the duration of the project.

The Coordinator should make sure that all the quality records are stored in a safe media. Quality records stored electronically are backed up onto separate disks, or by reproducing a hard copy to be stored. It is recommended that all project quality records are stored for at least 5 years following completion of the project.

6 RISK MANAGEMENT

In general, the provisions described in the DoA Part B section 3.2.5 and the roles indicated in the BD2Decide CA Art. 6.1 apply.

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

6.1 RISK MANAGEMENT PROCESS

The risk management strategy foresees a step-by-step process that started during the project proposal and continues during 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. This activity shall especially be adopted for critical tasks and WPs and will be mainly conducted by Project Coordinator, Scientific Manager, Technical Manager.

Risk monitoring

Risk monitoring is conducted by the Coordinator and by the Project Manager throughout the project execution. Potential risks identified at the start of the project, during quality reviews (see section 3.1.10) 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 C).

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.

For each foreseen or newly identified risk adequate mitigation / recovery activities will be agreed by the Project Assembly (operational risks) or by the Steering 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.

Risk identification

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 listed in the Risk Registry. The Ethics Board has the responsibility to notify any potential ethical issue to the Ethics Manager and to the Project Manager.

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.

Risk severity estimation

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 recovery

The recommended recovery actions will be implemented by the relevant partners under the supervision of the WP Leaders and of the Project Manager, who will monitor the process. The results of the implemented actions will be recorded in the Risk Registry. Should the risk not be recovered, it will be re-assessed and alternative recovery actions will be evaluated and implemented.

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

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 will assess the risk severity and impact on the project and identify possible recovery actions, jointly with the WP Leader and with the Project Team	Risk notification	Updated Risk Registry, notification to Project Assembly/Steering Board

Step	Description	Input	Output
3	The PM informs the Coordinator. Low and medium severity risks will be notified to the Project Assembly/Steering Board for discussion in the next quality review meeting	Risk Registry	
4	For high-severity risks the Coordinator calls a remote Steering Board meeting for the definition of the relevant recovery measures		Recovery measures and recovery plan

Table 10. Risk detection and management process

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.

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 at URL: https://owncloud.atc.gr/owncloud/index.php/apps/files/?dir=%2FBD2Decide%2Ftemplates

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: 689715

Project acronym: BD2Decidet

Project title: *"Big Data and models for personalized Head and Neck Cancer Decision support".*

Funding Scheme: H2020 PHC-30-2015

Date of latest version of Annex I DoA against which the assessment will be made: 2015/10/21

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

<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 (one table for Beneficiary)

LIST OF DISSEMINATION ACTIVITIES							
Type of activity [1]	Main Leader	Title	Date	Place	Type of audience	Size of audience	Countries addresed

NOTE: only presentations or demonstration events for the BD2Decide project can be listed. Poster presentations can be listed but costs are not eligible.

[1] Exhibitions, Oral presentation to a conference, Oral presentation to a wider public, Oral presentation to a scientific conference

Detailed costs tables to be completed by each Beneficiary

This detailed tables shall be completed by each Beneficiary and provided to the Project Manager for Official Periodic and Final Reports to be submitted to the EU. They are a guidance for the filling of Forms C.

Table 1 - Personnel costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

PERSONNEL AND OVERHEADS

			Number of	Hourly	Worked hours	Personnel	Person
WP	Person Name	Position	person-hours	Personnel Rate	in a month	Amount	months
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
					143,33	0,00	0,00
		TOTALS	0,00		TOTALS	0,00	0,00

Table 2 - Subcontracting costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

SUBCONTRACTING

WP	Subcontractor name	Description	Date of invoice	Amount
			Total	0,00

Table 3 - Travel costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

TRAVEL AND SUBSISTENCE

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

Table 4 - Consumables costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

CONSUMABLES

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

Table 5 - Equipment (depreciation) costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

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
WP2						60		0,00
							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%

Table 6 - Other costs table

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

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

Name of contractor: 0

Number of contractor: 0

OTHER SPECIFIC PROJECT COSTS

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

Table 0 - Summary of costs

BD2Decide PERIODIC FINANCIAL REPORT PER CONTRACTOR (EURO)

Contract No: H2020-PHC30-689715

for the period from: _____ **to:** _____ **% Funding** 100

Name of *contractor* : _____

Number of *contractor* : _____ **Cost model:** Flat rate 25%

Contact person : _____

Telephone: _____ E-mail: _____

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
Direct Costs										
1.	Personnel	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
2.	Durable equipment	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
3.	Subcontracting	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
4.	Travel and subsistence	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
5.	Consumables	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
6.	Other specific costs	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Indirect Costs										
7.	Indirect costs	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**
	Funding requested (%)	**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**

This table is automatically completed

ANNEX B. TEMPLATE FOR OFFICIAL PRESENTATIONS

H2020-689715 BD2decide

<Title>

<Title 2>

<Presenter name>
<Presenter affiliation>

<Contact details (email)>

<name of event – Location – date >

H2020-689715 BD2decide

TITLE

ANNEX C. RISK REGISTRY TABLE

	RISK IDENTIFICATION			RISK ANALISYS			RISK MANAGEMENT				MONITORING
Risk ID	Description of the problem	Risk	Involved WP	Likelihood OF THE RISK [6]	Impact on project[7]	Foreseen period/timing for impact on project	Priority[8]	Contingency Plan	Consequences of mitigation	Resp. Partners	Status and Date[9]
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	

[6] probability of the risk to materialize (100% if the risk has materialized)
[7] 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
[8] 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
[9] Status: open , in process, closed. Date refers to the status.

ANNEX D. NEW RISK COMMUNICATION

Release date	
Reported by	<name of person reporting the risk>
Work-package concerned	

Description
<Description of the detected risk>

Risk severity indicators	
Impact	<describe as precisely as possible what is the impact that the risk could have on the project outcome, should it actually materialize; classify its severity as *high*, *medium* or *low*>
Probability of occurrence	<assess the probability that the risk actually materializes; classify the probability as *high*, *medium* or *low* >

Recommended recovery actions
<provide recommendations for the solution of the risk and a proposal for actions planning, if applicable>

ANNEX E. SOFTWARE RELEASE FORM

<table>
<tr><td colspan="2">Software Release Form</td><td>  </td></tr>
<tr><td colspan="2">Module Name:
_____

Version: _____ Page ___ of ___</td><td>Ref:

WP Task Ref:</td></tr>
<tr><td colspan="2">Release Content:

_____
_____
_____
_____
_____</td><td>Media

cd ❑ diskette ❑
WEB ❑ e-mail ❑
Other _____</td></tr>
<tr><td>Released functionality or problem report ID</td><td colspan="2">Comments</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td colspan="3">Signature: (software task manager)
_____ Date_____</td></tr>
</table>

ANNEX F. SOFTWARE NON-CONFORMITY REPORT

Non Conformance Report	
Non-Conformance report Number Ref: nn	WP Task Ref:
Identification of the output/activity : _____ _____ _____ _____ _____ _____	Originator (s): _____ _____ _____ Date: _____
Description of the non-conformance: _____ _____ _____ _____ _____ _____	
Actions to be performed to solve the issue(s) (to be completed by technical partner in charge): _____ _____ _____ _____ _____	

Performance Impact Level[10]	Timescale Impact Level	Cost Impact Level
0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5

Approved by:
1._____ Date_____
2._____ Date_____
3._____ Date_____

Distribution	Signature

[10] 0=no impact; 1=minimum impact; 2=small impact; 3=average impact; 4=important impact; 5=extreme impact

ANNEX G. TECHNICAL TEST REPORT FORM

Test Report Form	
Module Name: _____ Version: _____ Check List ID:_____ Date of test: _____ Page 1 of ___ Author: _____ Signature: _____	Ref: 224483/nn WP Task Ref:
Distribution	

Test ID:	Result:	Notes:
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

ANNEX H. CHANGE REQUEST FORM

Release date	
Proposed by	<name of Partner>
Deliverable concerned or Software module	<deliverable number and title. or document id, or document title, software module etc..>
Deliverable version	<version number for which a modification is requested>

Description of the requested change(s)
<overall description of the modification requested and relevant context information>

Motivation of the request
<provide a precise justification on why the requested modification is necessary>

REFERENCES

[1] GRANT AGREEMENT NUMBER — 689715 — BD2Decide digitally sealed by the European Commission on October 21st 2015
[2] Consortium Agreement for the BD2Decide project (based on the Desca model, 2015), Version CA. Version 2016-03-03
[3] International Standard ISO 9001, Quality management systems — Requirements, Fourth edition 2008-11-15
[4] Communicating EU research and innovation guidance for project participants, version 1.0, 25 September 2014
[5] eEurope 2002: Quality Criteria for Health related Websites, Brussels, 29.11.2002 COM(2002) 667 final
[6] Assessment of the quality in statistics, Eurostat, 4-5 April 2000