# D8.2 Project Quality Assurance Handbook

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<tr>
<td>Authors</td>
<td>Christos Giachritsis (BMT) Kostas Kardaras (IP)</td>
</tr>
<tr>
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<td>Project start date, duration</td>
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EXECUTIVE SUMMARY

The objective of this document is to describe the methodology of Quality Assurance Procedure in AUGGMED project.

The methodology includes four topics which will be addressed in the following sections:

- Section 1 presents the Quality Plan for the overall project and identifies roles, responsibilities and policies. The quality control procedure apply to documents, tools and equipment and software produced during the project.
- Section 2 describes the reporting procedures both internal to the AUGGMED Consortium and between the Consortium and external organizations such as the European Commission and third parties; it will also address the preparation and submission of all contractual reports to be submitted to European Commission by Partners.
- Section 3 describes the quality control procedures to be adopted within the AUGGMED Project;
- Section 4: presents the risk management procedures, covering identification, analysis, monitoring and management of risks identified for the project.

This document will be used within the AUGGMED Project. It reflects the current state of information (organizational and procedural) and might be updated during the duration of the Project to deal with possible new needs for Quality Assurance and Project Management.

This document is based also on procedures and information already described in the following project material:

- EC contract;
- Description of Action (DOA), AUGGMED ANNEX I version 6, dated 24.03.2015

A detailed description of the project, detailed implementation plan, information related to work packages, deliverables and internal report can be found in the DOA.
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LIST OF ABBREVIATIONS AND DEFINITIONS

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<tr>
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<tr>
<td>CA</td>
<td>Consortium Agreement</td>
</tr>
<tr>
<td>DOA</td>
<td>Description of Action</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>IPR</td>
<td>Intellectual Property Rights</td>
</tr>
<tr>
<td>PC</td>
<td>Project Coordinator</td>
</tr>
<tr>
<td>PPM</td>
<td>Partner Project Manager</td>
</tr>
<tr>
<td>PR</td>
<td>Periodic Report</td>
</tr>
<tr>
<td>QP</td>
<td>Quality Plan</td>
</tr>
<tr>
<td>QAB</td>
<td>Quality Assurance Board</td>
</tr>
<tr>
<td>SB</td>
<td>Steering Board</td>
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<tr>
<td>SW</td>
<td>Software</td>
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1 AUGGMED QUALITY PLAN

This section presents the concepts under the Quality Policy of AUGGMED and the methodology and tools adopted to ensure an appropriate quality assurance contributing to the successful achievement of the project’s technical, scientific and validation objectives.

Review and Issue

The Quality Plan and procedures will be approved by the Project Management Board and authorized by the Quality Assurance Manager.

Following any amendment to the AUGGMED DOA, the Quality Plan may be revised and upgraded. The new version of the Quality Plan will be distributed through the AUGGMED file sharing tool [https://files.bmtresearch.org/](https://files.bmtresearch.org/) which is accessible only by the project partners by a secure login.

Distribution

The Quality Plan and procedures shall be distributed to:

- Steering Board members
- Consortium Partners
- The Ethical Manager
- The European Commission as an official deliverable.

1.1 Quality within the Project

AUGGMED Consortium is responsible to achieve, maintain and continually improve the quality of work and of the results of the project and of partners’ efforts, as defined in the contract. The Quality Plan (QP) draws the guidelines of such Quality Assurance process and defines the quality procedures to be followed to continuously monitor the advances of the project and the quality and effectiveness of the results achieved with respect to the available and allocated resources.

The Quality Plan is based on the following Quality Assurance principles:

- Supply methods, standards and procedures adapted to the specific project objectives, including:
  - organization of the work team(s),
  - roles and responsibilities of each participant,
  - time schedules definition and monitoring,
  - quality criteria for system development, testing, configuration, acceptance and maintenance,
  - procedures, for evaluation, acceptance and quality control,
  - plan for control action and risk assessment;
- Assist and advise the project team in its effort of producing results of highest quality;
Identify and exercise controls enabling a continuous and critical overview on the project progress regarding the contractual objective.

AUGGMED will monitor the quality of the work performed and of the results achieved with respect to the contractual obligations by applying a Quality Procedure described in this Quality Plan.

The Quality Plan includes:

- the Quality policy
- the Quality Manual addressing:
  - project quality organization, responsibilities and authority, (Sec 1.2)
  - contract review, (Sec 1.4)
  - project planning and control, (Sec 1.5)
  - procurement, (Sec 1.6, 2)
  - documents and data control, (Sec 1.7, 1.8, 1.9, 1.10)
  - test and acceptance, (Sec 1.11)
  - project reviews, (Sec 1.11.10)
  - project standards and templates, (Sec 1.9)
  - project quality procedures, (Sec 3)
  - risk management. (Sec 4)

All of this shall be fully coordinated and integrated in order to help ensure that AUGGMED meets the requirements and expectations of both the EC and the Partners.

The QP applies to all AUGGMED project activities with the exception of Partner’s financial issues.

1.2 Quality Policy

In accordance with the project targets, the Steering Board representing the Consortium Members intends to achieve quality to fully meet requirements of the European Commission and Partners in order to:

- Develop the different project phases at a high quality level
- Comply with the European Commission and Partners’ requirements
- Work with a managing system consistent with the AUGGMED Quality Plan in order to guarantee quality to both European Commission and the Partners
- Adopt plans whereby planning, implementation, check and review phases have been defined and/or responsibilities have been assigned (who’s doing what)
- Adopt appropriate management processes to cope with project difficulties
- Activate scheduled controls to meet formal project requirements as well as partners approved requirements in order to allow full monitoring of project development
Run a Consortium working in full co-operation in terms of communication and information with a view to the constant improvement of the project.

This policy shall be adopted and distributed at each partner’s level.

### 1.3 Project Quality Management

The Quality Manager is responsible for the quality procedures of AUGGMED and reports to the Project Coordinator and the Steering Board. Project Quality Management includes installing and monitoring in house quality procedures according to suitable standards, setting the success indicators in all scopes, measuring the evolution of the project according to the quality indicators and metrics, report any significant deviation to be corrected to the Steering Board, elaborate the Risk Identification and Management Plan, develop Contingency Plans, and set up a framework for other partners’ quality functions.

### 1.4 Quality System Review

Any Partner of the project may request modification of the AUGGMED Quality Plan and procedures.

Partners shall propose modifications to the Quality Manager; if the proposed change is agreed, follow the documentation change control procedure defined in the following sections. Once revisions are approved they will be distributed to the partners.

### 1.5 Contract Review

Each Partner is directly under contract with the European Commission (EC), therefore any subsequent changes to the contract, including Annex I (DOA) and II (General conditions), must be managed under formal Change Control.

Changes proposed by the EC shall be reviewed and approved by the Steering Board members. The impact of the proposed change shall be assessed and agreed by the Partners.

The Project Coordinator shall then respond to the EC Project Office with either an impact statement or the Consortium’s approval of the change. The proposed change shall only be binding when the EC and the AUGGMED Consortium have both approved and agreed this in writing.

Changes proposed by any Partner shall be documented on a detailed written document fully defining the impact of the proposed change on all Partners. This shall be reviewed and approved by the Steering Board. If approved, the Project Coordinator shall then propose the change to the EC Project Manager. The proposed change shall only be binding when the EC Project Officer has approved and agreed this in writing.

### 1.6 Quality Control

Project Planning and control addresses such issues as Estimating, Planning and Tracking of project time, costs, deliverables and reports. It also deals with the way these will be reported within the Consortium, and to the EC. These methods are implemented through 6 monthly Project
Meetings (for the Consortium) and Deliverables as well as PPR (for the EC). This shall be adhered to for the entire duration of the project.

1.7 Procurement/sub-contractors

The procurement consists of all phases and procedures by means of which goods; services and components of the AUGGMED project are purchased outside the Consortium.

No major subcontracting of management activities is allowed.

1.8 Document and data control

All deliverables (documents and software) produced during AUGGMED project will be subject to quality control by the team members responsible for its production. Software (SW) control is described in the next sections. The Quality Manager will perform the final quality validation after which the Project Manager will authorize the delivery of documents/prototypes to the European Commission Offices.

For documents the quality check will examine and assess the following aspects:

- Formal aspects:
  - Compliance to standard format (see deliverable template in ANNEX);
  - Completeness of referenced data (authors, versions, dates, references to other documents etc.);
  - Indication of reviewer’s comments (if applicable) and of the actions taken to comply with reviewers’ recommendations.
  - Content aspects:
    - Relevance with respect to the objectives of the document;
    - Completeness of the content with respect to the topics to be addressed and state-of-art information available;
    - Easiness of reading and understanding the document (structure of the content, cross-references, etc.).

- Schedule and punctuality:
  - The deliverable should be sent to the coordinator and to the Quality Manager at least ten (10) natural days before the official delivery date to the EC to enable a further peer review and approval by the assigned peer reviewers. In case of “critical” deliverables needing external peer-review, the document must be sent to the coordinator at least fifteen (15) days before the date of delivery, to enable the review by the external expert(s) and the implementation of the recommended corrections by the responsible partner(s).
1.9 Document coding

APPENDIX II lists the formal project deliverables and documentation types and the type of document, currently approved. This list will be checked and revised every year on the occasion of the re-submission of the DoW, in order to include the updated version of deliverables and delivery dates.

1.10 Document referencing and template

All AUGGMED deliverables must be in English language.

All AUGGMED documents will be edited following a common template that foresees the following sections:

- Cover page with the project identification details, name and number of the deliverable, version
- Date of issue and name(s) of the editor(s).
- Revision information
- Table of contents
- Executive Summary
- List of abbreviations
- List of figures and tables (if appropriate)
- Document core
- List of references (if applicable)
- Appendices (if applicable)

Each page (with the exception of the cover) will include:

- A header including the AUGGMED logo and the dissemination level;
- A footer including the project’s grant agreement, the deliverable number, the name of the document and the page number over the total document’s pages.

The document file name will be composed as follows:

AUGGMED_DelN.n_DelName_version.extension, where:

- DelN.n: is the number of the deliverable as listed in the Section 3.1.5 (List of Deliverables) of the DOA
- DelName: is the name of the deliverable as listed in the Section 3.1.5 (List of Deliverables) of the DOA
- version: is the version of the deliverable. For final version either “final” or blank field can be used.
- extension: is the document extension or file format (usually .doc, .docx, .pdf).
1.10.1 Version control

The issuing Partner shall be responsible for the control of the versions of its project documents and deliverables.

Deliverables can only be updated by the responsible Partner. However, requests to update the deliverable can be made to the responsible and issuing Partner by any Partner. Each new version of the deliverable shall be reviewed, approved and authorized.

A standard template for all deliverables and reports will be defined by the Project Coordinator and delivered in the file sharing repository.

Any updated deliverable shall be distributed to all partners by its publication on the web repository or using the most appropriate media (normally via e-mail). Each deliverable shall be accompanied by written notification to all partners. This notification shall be in form either of letter, or e-mail.

Information on the relevant Workpackage (WP), contractual delivery date and Editor is reported on the front page of each deliverable.

Internal deliverables, not due by contract, will too contain all the above information. They may not be subject to peer-review. They will be subject to approval by Quality Manager and by the Workpackage (WP) leader.

1.10.2 Modification and Revision Log

All the Documents and deliverables will carry information regarding the versions and the steps leading to the final edition (Revision History):

Table 1. Revision history table format

<table>
<thead>
<tr>
<th>Revision no.</th>
<th>Date of Issue</th>
<th>Author(s)</th>
<th>Brief Description of Change</th>
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1.10.3 Deliverables layout and template

The template of the standard AUGGMED deliverable is enclosed in APPENDIX I.

1.10.4 Distribution list

Documents are distributed to both Consortium members and the EC according to the distribution list identified in the document. In some confidential document containing a specific clause mentioned on the cover email each addressee shall promptly send a receipt by e-mail.
1.10.5 Documentation Change Control

Should the need to revise and issue a new copy of a deliverable ensue, the following change control procedure shall be followed:

- anyone can propose change to author;
- the author updates the document for comment/review by Approvers/Authorizers;
- the QM will check all the quality standards are followed in updating documents;
- once approved the document is formally issued, by the publication on the AUGGMED management web site and document repository, distributed with new revision number.

1.10.6 Technical documents

Technical documents should contain as much UML diagrams as required to better understand the overall technical description and process. In particular UML diagrams are recommended for main or particularly complex functionalities.

1.11 Deliverables peer review and control of non-conforming deliverables

1.11.1 Peer-review

As already described in the preceding paragraphs the quality control of deliverables is performed at different levels by contributors (partner level), by deliverable responsible (task and WP level) and finally by the Quality Manager.

The composition of this panel may change during the project, depending on the deliverable to be validated and on the expertise required for this validation.

1.11.2 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, DOA or specification documents.

1.11.3 Acceptance criteria

The EC will determine that the project is complete and has met their requirement by reference to the deliverables defined in the project program. The acceptance criteria for deliverables shall be:

- Coherence (e.g. uniform terminology and notations, standards for specifications);
- Conciseness (only concise reliable and useful information);
- Completeness (complete information within files concerning existing constitutive elements);
- Self-Evaluation (self-descriptive function giving explanations on how a deliverable is conceived);
- Traceability (root investigation through elaboration to determine origin and connections of specific information).
1.11.4 Non-conformance

By “Non-conformance” is meant 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, and the DOA or specification documents.

The detection of non-conformances in activities or components of the Project is vital for the elimination of errors that may impair the quality of the Project.

1.11.5 Non-conformance Reporting

Anyone should detect a non-conformance in an activity of the Project. Once detected a non-conformance shall promptly notify to, his Partner Project Manager (PPM) who will fill in a Non-Conformance form identifying the cause of the non-conformance and the person who is responsible for that part of the Project.

Non-conformance reports consist of four sections:

- Identification data of the output/activity
- Non-conformance description
- Guidelines for the elimination of the non-conformance
- Form distribution.

1.11.6 Detection of causes and corrective actions

The detection of causes is aimed at eliminating the causes of non-conformances (components, personnel, sub-provider, etc.).

Causes may be:

- Related to internal activities,
- Related to external activities.

1.11.6.1 Verification and Corrective Actions for Non-Conformances Related To Internal Activities

Outputs deriving from internal activities that are defined as non-conforming shall be verified and they may then be:

- Revised so as to meet the requirements stated;
- Accepted with or without intervention following the authorization of the Steering Board.

Revised outputs shall be tested again in order to assess their conformity.

1.11.6.2 Verification and Corrective Actions of external Non-Conformances

Outputs that are catered for by subcontractors / suppliers that are found to be ‘non-conform’ may be:

- Revised by the partner responsible for the subcontractors / suppliers so that they meet the Project’s requirements;
- Revised by the subcontractor so that they meet the Project’s requests.
Non-conformance outputs that undergo the first two types of corrective action shall be controlled in order to be accepted.

1.11.7 Preventive actions

All staff working for the Partners while Project activities are being developed shall be invited to make proposals to improve working processes and the management of activities and also to prevent the occurrence of situations that may impair the quality of activities.

Anyone who feels that a preventive action is needed shall promptly notify it to the Partner’s representative in the Steering Board.

If the preventive action involves more than one partner, it shall be presented and evaluated by the Project Management Board. Preventive actions shall be written in order to assess that they are applied and that they are brought into effect.

The WP leader is responsible for the development of preventive and corrective actions; he shall see that they are applied and that they are brought into effect. All of the persons who are involved in this process shall be held responsible for non-conformances, which were not removed, as well as for delays in applying and for not taking effective corrective and preventive actions.

1.12 Software control

The software development cycle encompasses the following phases:

- Requirement definition;
- Software specification;
- Software design;
- Software development
- System design and integration

<table>
<thead>
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<th>Phase</th>
<th>Document</th>
<th>Content</th>
<th>Responsibility</th>
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<tbody>
<tr>
<td>Requirements</td>
<td>User requirements</td>
<td>Specifications of the functionalities required by users</td>
<td>WP Leader</td>
</tr>
</tbody>
</table>
|                              | 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 |
| Software specifications      | Technical specifications        | Description of the SW component  
UMLS or other relevant technical diagrams | Involved technical partners |
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 software development cycle ends with the start of the verification and validation phase.

Changes will be managed as follows:

- changes to software specifications requested will be managed as “change requests”;
- change requests may entail a revision to the requirements and to other documents; 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 (see section 1.11.5).
- changes to the software requested during the field tests and involving user requirements will be managed as “change requests”. Change requests will undergo an evaluation procedure by the User representatives and the involved technical partners under the chairing of the Project Manager and of the Technical Manager. The results of the evaluation (including impacts on resources and workplan) will undergo the approval of the Steering Board before becoming effective.
1.12.1 Software Development Documents

The formalism is to the discretion of the Technical Manager. One suggested possibility is to adopt for the project the UML notation for its documentation. UML is a language for specifying, visualizing, constructing and documenting software.

The following paragraphs describe the table of contents for the various document types. These paragraphs are mandatory; the authors are free to add other relevant information to the documents.

1.12.2 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.

1.12.3 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 executable
- 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 executable
- The complete sources and related files (make file, special libraries, etc.)
- A release note template is provided as Software Release Form And Check-List Template of this document.
1.12.4 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 Technical Manager 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 AUGGMED 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 Coordinator and the WP leaders. Major discrepancies with respect to the official work plan must be notified to the QAB 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.

1.12.5 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 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.
1.12.6 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.

1.12.7 AUGGMED Validation

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 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.

1.12.8 Testbeds

Testbeds will be planned by users and are described in the dedicated deliverable(s).

1.12.9 Reporting

Specific reporting form for problems and errors encountered and also for request for change will be agreed between Pilots and the TM. 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 on a weekly basis. A summary of open validation issues will be published along with comments and deadlines for bug fixing/change implementation.

The Quality 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.
1.12.10  Control of 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 actions
- Preventive actions

All quality records pertaining to more than one Partner shall be filed by the WP leader. The WP leaders shall also present updated versions of quality records to the Project Manager.

1.12.11  Filing and Archive

Storage of quality records are at the Partners discretion. However, in case of quality records that interest more than one partner, the PPMs shall make sure that the project coordinator has all versions of the deliverable available on file for the duration of the project. The partner 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.

1.12.12  Dissemination Events scheduling and reporting

All AUGGMED Dissemination activities must be agreed with the Consortium and communicated to the SB.

Public dissemination material, scientific papers and other promotional material must be approved by the Consortium and – when applicable – by the Ethics and Safety Officer Ethical Advisory Board.

This applies to both paper and electronic dissemination material (mock-ups, demos etc.).

Dissemination activities must be reported to the Knowledge and Dissemination Manager and described in a short event report. On a quarterly basis or at any reporting periods the Dissemination activities must be reported by each partner to the Knowledge and Dissemination Manager and included into the periodic reports.

All relevant dissemination material must be published in the dissemination web site and sent to the Project Manager. The Project Manager will collect the dissemination material produced by the Consortium and send copies to the European Commission at each reporting period.
1.12.13 IPR Policy

The IPR policy is ruled by the Grant Agreement and by the Consortium Agreement, which describe the general IPR provisions. An IPR agreement will be issued by the Knowledge and Dissemination Manager and agreed by the Consortium, to address the IPR issues in further details.

1.12.14 Project reporting and monitoring

Short six-month reports (2-3 pages) will be prepared and submitted to the Commission. In addition, two Periodic Reports (PR) including a Technical Progress reports, accompanying the cost statements, will be also submitted to the Commission at M18 and M36. Any other reports will be also prepared and submitted, if required by the Contract Annex II.

All participants are requested to send, in addition to all formal work and cost reports, mentioned in the Technical Annex, a brief progress and cost report to the PC 1 month before PR is due.

The Coordinator will use the tools in the Project Management Portal, so as to perform full scheduling, budgeting control both for the purposes of the project itself, towards the Commission Services, and for the partners themselves.

The reports and graphics to be used will depict deviations from planned project targets including delays or early finishes and their implications on the overall progress will be evaluated. Then the corrective actions that are necessary for implementation will be considered and taken as appropriate.

Results and recommendations will be communicated to the Technical Manager and to the WP leaders so that corrective actions can be taken in a timely manner in order to achieve optimum performance.

The deviation monitoring related to budget and timescale will be reviewed after both six and 12 months.

2 PROCUREMENT AND SUB-CONTRACTING

This paragraph establishes general rules in case of acquisition of external SW or content. Cost sharing and IPR issues related to external SW and Know-how are addressed in the AUGGMED Consortium Agreement and in the IPR Agreement.

The procurement consists in all phases and procedures by means of which goods, services and components of AUGGMED project are purchased outside the Consortium.

Procurement shall be dealt with by Partners within each Partner’s agreed budget. In case of procurement of SW or Know-how relevant for a task or WP in which two or more partners are involved, the external procurement will be proposed by the WP leader and must be approved by all involved partners and by the SB.

The WP/task leader and the Project Manager shall be responsible for the management of selected Sub Contractors/Suppliers.
2.1 Monitoring of Subcontractors

The Contracting Partners shall clearly state requirements through Statements of Work, Requirement Specifications, Service Level Agreements or Purchase Orders as appropriate.

Commercial terms such as price, deadlines, modalities of payment, delivery, quality, confidentiality as well as contractual terms and conditions shall be clearly stated.

Systems for control (such as periodical reports, progress meetings, demonstrations, etc.) shall be agreed and established so as to monitor whether the Sub-contractors / Suppliers will meet the delivery requirements.

2.1.1 Acceptance of Services / Products Supplied

The WP/task leader and the Project Manager will ensure that acceptance criteria and process are clearly stated so that all parties can demonstrate fulfilment of the terms of subcontract or supply.

The partner shall make sure that supplies of products/services comply with the orders made, and in particular they shall monitor:

- Content of service/product
- Product/service quality features
- Price and terms of payment
- Delivery terms.

3 QUALITY CONTROL

3.1 QUALITY Procedures

Activities that impact on the quality of the Project require a procedure, describing:

- Objective of the procedure (why?)
- Identification of objects (what?)
- Description of activities (how?)
- Description of roles and responsibilities (who?)
- Time schedules (when?)
- Flow-charts

Procedures may be created and proposed by anyone operating within the Project. Procedures shall then be submitted to the QM, who will assess their compliance with the Quality Plan.

The content of the procedures shall be validated and approved by the Project Management Board. Procedures that have been approved shall then be forwarded to Quality Manager who, in his turn, shall distribute it within the Partner organizations.
3.2 Product Description

An AUGGMED “product” is any hardware, software or software component, which in the future could become an independent output to put on the market.

All products created within the AUGGMED Project shall comply with the objectives of the project described in the “Description of Action”.

3.3 Project Reviews

This section defines the scope and responsibilities for reviews that will be held on the AUGGMED project.

**EC Reviews:**

1. Scope / Purpose: to verify that the project is being duly carried out
2. Frequency: every 18 months;
3. Attendees: Project Officer, EC Reviewers (TBC), Project Management Board (TBC), Task Leaders or Workpackage Leaders (TBC).
4. Responsibilities:
   a. Project Officer: to make sure that the project is managed correctly;
   b. EC Reviewers (TBC): to make sure that the project is managed correctly;
   c. SB (TBC): to present the results achieved within the Project;
   d. Tasks Leaders or WP Leaders (TBC): to present the results achieved within the Project;
5. Recording: minutes of EC reviews;
6. Follow up: to implement reviewers’ suggestions.

3.4 Project Standards

Standards shall be proposed in the same way as described for procedures. The Project Management Board shall approve new standards, which will be notified to all Partners by the Quality Manager.

There are two types of project standards:

1. Internal Project Standard
2. Standards to be applied to Subjects who are not AUGGMED Partners

3.4.1 Internal Project Standards

Internal Project Standards are adopted by the members of the Consortium and also by Subcontractors. Here are some examples of Project standards:

1. Quality standards
   a. Deliverables shall be written in English;
b. Deliverables shall be written on the basis of standard templates;
c. All documents shall be communicated using standard communication (e-mail) and downloadable from the project’s web site private area;
d. All documents shall be available in electronic format.

2. Management standards
   a. All partners shall work in conformity with quality standards;
   b. Deliverables shall be viewed by all Partners at least 5 days before they are issued;
   c. Causes of problems shall always be identified;
   d. Corrective actions shall be communicated and taken;
   e. Non-conformity records shall be kept on file;
   f. Appropriate and timely advice shall be duly given;
   g. Improvements shall be monitored.

3. Technical standards. All technical standards are to be set together with the Technical Manager

3.4.2 Standards to be applied to Third Party Subjects

External Project Standards are standards adopted in the dissemination of the Project’s results. Here are some examples of this kind of Project Standards: that will be applied to the project in every phase:

1. Quality standards
   a. All documents produced outside the Project shall be written in English;
   b. All documents produced outside the Project shall be validated by the Quality Manager

2. Management standards
   a. Deliverables shall be viewed by all Partners 10 days before they are issued;
   b. All deliverables shall be consistent with the Project.

3. Technical standards. All deliverables shall be written using uniform terminology and annotations
4 RISK MANAGEMENT

Risk management will be managed in AUGGMED through a procedure encompassing the following steps: risk detection, risk analysis, risk assessment and risk management and monitoring. The detected risks will be reported and record maintained in a Risk Registry, which will be updated by the Project Manager and Quality Manager.

All AUGGMED partners participate to the Risk Management procedure from the identification phase to the risk mitigation and monitoring phase.

The Quality Manager is also the Risk Manager. Therefore, risks management is one of the functions of the Quality Manager. Project and Technical Managers are also part of the risk management and support the Quality Manager in all activities related to Risk Management.

Risk management tracking in AUGGMED is performed by means of the Risk Registry. This registry is the list of identified risks followed by an analysis of those risks and the definition of the strategy to be adopted by the consortium to mitigate their impact: actions and responsible partners to take charge of them. A public and updated registry of identified risks and how they are being managed is a very important tool for having a high quality project management from several points of view:

- General Project Management;
- Technical Management;
- Quality Management;

The Risk Manager (Quality Manager) is responsible for maintaining the risk registry updating and also compose a Management Board meeting when detects any important change of the risk registry that could be a potential and important risk to the project.
Initial set-up. At the beginning of AUGGMED a first risk identification has been performed to identify the main risks associated with the deployment of project activities. The risks identified in this phase have been addressed in the Technical Annex I and will be monitored and addressed throughout the project until closed. By the first quarter of AUGGMED the Risk Registry will be set-up and a template circulated to WP leaders, to check the initial risks and to update their status or add new risks if applicable.

During the project risk management is performed following a step-by-step process and will undergo a continuous monitoring.

First step: risk identification. As soon as (and anytime) a partner identifies a potential risk, this is reported to the WP leader and to the partners involved in the at-risk situation, and the risk is classified and undergoes an initial analysis. Partners must analyze the impact of risks to the work as they develop and how the risk could affect the overall project development. A priority-based mechanism is defined in order to make the comparison of risks possible in further phases of risk management. The prioritization will be done by the Management Board that is the management entity that has the wider view of the project. If the risk is potentially real, it will be included into the Risk Registry by the Technical Manager, Quality Manager, Scientific Manager or Project Manager, depending on the activities at risk. The Risk Registry will be available through the Management web site and every partner may access it. Every quarter the risks listed in the Risk Registry will be checked and their status updated if applicable.

Second Step: risk analysis. The partner that identifies and analyses a risk will make a first proposal on how to manage it, trying to establish the strategy to be followed: avoid, mitigate or accept the risk.

Third step: risk assessment. A contingency plan will be defined as well to develop the previous strategy and success with the risk management. Any strategy described in this phase will be reviewed by the Management Board in order to harmonize and prioritize all the set of contingency plans defined by the consortium. Management Board is responsible for allowing the execution of a contingency plan by a team of responsible partners. The plan will include responsibilities and an action list to be followed to solve/minimize the risk with milestones to be monitored to ensure that the problem is overcome.

Fourth step: risk management and monitoring. The last phase deals with the set-up of the corrective actions defined in the contingency plan and with the monitoring of the launched risks management strategies and with the risk registry updating procedure. When a partner reaches a milestone in the contingency procedure, it must report that milestone to the Quality Manager in order to update the Risk Registry with the status of the contingency plan related to that risk. In any case a checkpoint will be done on a quarterly basis with the distribution and update of the Risk Registry template to WP leaders who are in charge of collecting information regarding already identified or new risks.
4.1 Risk identification procedures

Biannually (every 6 months), the Quality Manager will start the procedure of collecting risks and updating the risk registry from all the partners in the consortium. Partners are requested to check the possibility of risks related to their work and their responsibilities as coordinator of works. Risks should be reported as soon as detected, independent of the quarterly assessment phase: the earliest a risk is detected the easiest will be minimizing its impact.

Risk must be reported by means of the Risk Registry template, which includes the following information:

- **Nature**: this field indicates which type of category the risk belongs to. When a risk is detected the project issue to which it refers must also be identified. Five values are possible, though more than 1 value is possible simultaneously:
  - User requirements: risks related to a bad definition of user requirements, bad interpretation of data, and/or a lack of inclusion of experts and reference entities.
  - External risks: risks related due to the reliance of the project on external inputs, data, technologies, introduction of new laws of European or national scope, equipment or components coming from contractors. Legal issues will be classified under this topic.
  - Organizational and Resources: risks related to general workflow of the project
  - Technical: risks related to technical aspects of the project such as expected inputs for a certain work package needed earlier than defined in the project schedule, or lack of definition in user requirements that informs the technical architecture, a technology chosen for development does not fit with desired functionalities.
  - Ethical risks: a special emphasis must be put in ethical risks when developing activities that imply the definition of services and the participation of end users. The Ethical Advisory Board will be deeply involved in the identification of this type of risks since are considered the most important for the final project success. These are the activities that should be analyzed in depth for ethical risks detection:
    - User requirements analysis.
    - Monitoring environment definition and deployment.
    - Pilot site definition and deployment with real end users
    - End users participation in workshops and pilots.

- **Description of the problem**: this field is used to establish the border conditions of the risk. Each partner has to explain in detail:
  - The risk origin
  - The risk issue
  - The trigger for the risk to become a reality
- **Risk**: this field is used to summarize in a short and clear sentence which is the risk that can affect the development of the project.

- **Affected workpackages**: indicate which work packages are affected by that risk and the leader of that WP

<table>
<thead>
<tr>
<th>Field in the Risk Registry</th>
<th>Possible values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>UR. User requirements</td>
</tr>
<tr>
<td></td>
<td>EX. External risks</td>
</tr>
<tr>
<td></td>
<td>ORG. Organizational and Resources</td>
</tr>
<tr>
<td></td>
<td>TR. Technical Risks</td>
</tr>
<tr>
<td></td>
<td>ETH. Ethical risks</td>
</tr>
<tr>
<td>Description of the problem</td>
<td><em>Natural language description</em></td>
</tr>
<tr>
<td>Risk</td>
<td><em>Natural language description (short and clear sentence)</em></td>
</tr>
<tr>
<td>Affected WPs</td>
<td>WPX.Y(leader), WPR.X (leader), …</td>
</tr>
</tbody>
</table>

The definition of priorities among risks is extremely important as it affects the monitoring of the contingency plan.

### 4.2 Risk analysis procedures

One of the main practical difficulties of risk management lies in assessing how real the potential risks are and what their impact might be. The Project Manager, the Quality Manager and the Project Management Board need to review carefully the team’s assessment of the likelihood of the risks occurring and their estimates of the significance of their consequences. Likelihood and impact can be accounted for using a qualitative, semi-quantitative or quantitative approach. Most often these estimates are by necessity based on semi-qualitative judgment rather than hard numbers; however AUGGMED will try to quantify risks wherever possible by using a simple scoring system to help ensure comparison of risks across the different sub-projects. The quantification of project risks will be performed considering the most likely outcome scenario for all identified risks.

This procedure encompasses the definition of values for:

- **Likelihood measurement**: this measurement describes the perception of the probability that the selected risk affects the project in an estimated amount of time (X months). This information will be used by the Quality Manager and the Project Management Board for prioritize the actions that will help to mitigate the risk. Possible values of this field are:
  - 5. CERTAIN: is affecting/will affect the project within the next X months.
- **4. PROBABLE:** not certain, but is likely to affect the project within the next months.
- **3. POSSIBLE:** could affect the project within the next X months.
- **2. UNLIKELY:** will probably not affect the project within the next X months.
- **1. VERY UNLIKELY:** virtually certain not to affect the project within the next X months.
- **0. NEVER:** will definitely not affect the project over the next X months.

**Significance/Impact Measurement:** this measurement describes the perception of the impact if the risk were realised. It is also a very powerful tool for the Management Board, the Technical Manager and to the Quality Manager to prioritize mitigation actions. Possible values of this field are:
- **5. Catastrophic/extreme effect** – the majority of targets will not be met across the project.
- **4. Major effect on project performance** – business-critical targets will be missed
- **3. Moderate effect on project performance** – local performance targets will be missed
- **2. Minor effect on project performance** – limited effect on targets
- **1. Insignificant/negligible effect**
- **0. No impact**

**Performance:** describes what can happen if the risk becomes a reality.

**Table 4. Risk registry values description**

<table>
<thead>
<tr>
<th>Field in the Risk Registry</th>
<th>Possible values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Likelihood</strong></td>
<td></td>
</tr>
<tr>
<td>5. CERTAIN</td>
<td></td>
</tr>
<tr>
<td>4. PROBABLE</td>
<td></td>
</tr>
<tr>
<td>3. POSSIBLE</td>
<td></td>
</tr>
<tr>
<td>2. UNLIKELY</td>
<td></td>
</tr>
<tr>
<td>1. VERY UNLIKELY</td>
<td></td>
</tr>
<tr>
<td>0. NEVER</td>
<td></td>
</tr>
<tr>
<td><strong>Significance/Impact</strong></td>
<td></td>
</tr>
<tr>
<td>5. Catastrophic/extreme effect</td>
<td></td>
</tr>
<tr>
<td>4. Major effect on project performance</td>
<td></td>
</tr>
<tr>
<td>3. Moderate effect on project performance</td>
<td></td>
</tr>
</tbody>
</table>
2. Minor effect on project performance
1. Insignificant/negligible effect
0. No impact

| Performance impact | Natural language description |

### 4.3 Risk management procedures

This part of the process of risk management is in charge of defining and also carrying out the procedures to avoid, mitigate or accept each one of the risks.

All partners participate to this phase but it's the Project Management Board the organism in charge of the high-level decisions in the project and of the definition of a real strategy to manage all project risks in a coherent way.

Three possible policies can be applied in order to deal with risks:

- **Avoid the risk**: some risks may be avoided with a small adjustment to the project schedule.

- **Mitigate the risk**: the majority of risk will need a mitigation action to manage them and try to minimize their impact in the project development. If this strategy is chosen, then it is necessary to define and describe a Contingency Plan for managing that risk. That implies making considerations and detailing when those actions will be executed and by which partner(s).

- **Accept the risk**: a very small number of risks will be accepted. The acceptance of a risk means that all the actions that can be applied to minimize the impact are more expensive in time and resources that accepting the consequences of that risk. Then the Project Management Board will take the decision to live with the risk, trying to control it in order to avoid it becomes unmanageable.

The effective implementation of the planned risk control strategy is essential to the entire risk management process. Risk assessment is useless without the follow-up execution of planned risk control tasks. As planning for risk control, the implementation of the risk control plans is not a responsibility of the Quality Manager but of the project management. Quality Manager is responsible only for running a high-quality risk management process.

Risk management and monitoring will therefore follow this procedure:

- First: fill in the template of the first management aspects: estimated priority of the risk, the Contingency Plan for minimize the impact and the responsible partners to execute the actions.

- Second: Risk Manager and Management Board when analyzing the Risk Registry periodically, study and correct the priority of each risk, and harmonize common actions. This means that they give the permission to start with the contingency plan to the responsible partners.
Finally, the contingency plan starts.

The above leads to the definition of the following:

- **Priority:** 1 to 10 score. “1” means the highest priority (if not executed before than any other mitigation plans the risk will become reality) and “10” the lowest (if executed after than any other mitigation strategy the risk won't became a reality). The SB defines this value.

- **Contingency plan:** defines the risk mitigation strategy (Contingency Plan), with specific tasks, which must be managed as any other project task. This includes securing the resources, assignment to individual project team members, motivating the involved project team members, overseeing and controlling the execution of the tasks and finally measuring and reporting the progress of risk mitigation. When a milestone in a risk contingency plan is achieved then it must be reported to the Quality Manager in order to update the Risk Registry with the current status of the risk. A contingency plan foresees the description of:
  - Actions;
  - Time schedule of that actions;
  - Milestones i.e. events which trigger a report to the Quality Manager to update the registry.
  - Responsible partners for those actions: i.e. identify a leader to manage the risk.
  - Estimated resources: MM.

- **Responsible partners:** summary of the previous list of responsible partners.

### Table 5. Risk registry values description

<table>
<thead>
<tr>
<th>Field in the Risk Registry</th>
<th>Possible values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority</td>
<td>0..10 (0: highest priority)</td>
</tr>
<tr>
<td>Significance/Impact</td>
<td>Actions</td>
</tr>
<tr>
<td>Schedule</td>
<td></td>
</tr>
<tr>
<td>Milestones</td>
<td></td>
</tr>
<tr>
<td>Responsible partners</td>
<td></td>
</tr>
<tr>
<td>Estimated PMs</td>
<td></td>
</tr>
<tr>
<td>Actions</td>
<td></td>
</tr>
<tr>
<td>Responsible partners</td>
<td>Partner’ s name (highlight the leader/coordinator)</td>
</tr>
</tbody>
</table>
4.4 Risk monitoring and review procedures

Review procedures are carried out by the Project Management Board and the Quality Manager supported by the Technical Manager. Every quarter, once all the contributions from all the partners have been collected, the Project Management Board meets to review, harmonize, filter and prioritize all the actions that deal with risk management.

Risk Registry and reports coming for the assessment of milestones regarding to the already working contingency plans will be read in loud-voice in order to start the reviewing process.

At the end of this meeting a new and updated Risk Registry is produced and published. The Quality Manager agrees with WP leaders the next actions related to the newly assessed risks and contingency plans follow-up.

Any time the Quality Manager receives one or more risks that are marked as high-priority (0, 1 or 2) by an asynchronous contribution of a certain partner or group of partners, a meeting (also virtual/phone meeting) of the Project Management Board should be organized in order to take a decision on how to manage the current situation. Extraordinary meeting may also be organized in particularly high-risk situations.

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The Quality Manager is in charge of updating the status of the risk after each monitoring phase, by indicating:

- **Status**: which the status of the management of the risk is. Which milestones are already achieved and reported, and the general status of the risk. Of course as a result of the risk management the priority of the risk can change: become lower or even higher. If the management is well defined and is being implemented on time the most probable is that the priority of the risk decreases. All this, should be explained at this field in natural language.

- **Date**: date when the previous description of the status has sense.
5 REFERENCES


6 Appendices

6.1 Appendix 1: Deliverable Template (download from https://files.bmtresearch.org/)
### 6.2 Appendix 2: List of deliverables

<table>
<thead>
<tr>
<th>Del. No</th>
<th>Deliverable name</th>
<th>WP.No</th>
<th>Lead participant</th>
<th>Type</th>
<th>Dissemination level</th>
<th>Delivery date</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.3.1</td>
<td>Report on ethical approvals and approvals for the collection of personal data</td>
<td>8</td>
<td>SHU</td>
<td>R</td>
<td>PU</td>
<td>M1</td>
</tr>
<tr>
<td>8.3.2</td>
<td>Project Ethics Handbook</td>
<td>8</td>
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### 6.3 Appendix 3: Deliverable review list

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