Big Data supporting Public Health policies

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Project Quality and Assessment Plan

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Executive Summary

This deliverable sets out the quality practices for the project, and the goal is to provide assurance that the quality requirements are planned appropriately. It defines the Assurance Teams: the Quality Assurance Team (QAT), who is responsible for the administration of the Quality Assurance Plan and the Technical Assurance Team (TAT) which assures the proper quality of the work conducted both at the business and implementation levels. Then, the Deliverable Peer Review process is presented. Also, the list of the partners who are responsible for reviewing each Project Deliverable are presented.

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1

Introduction

The Quality Assurance Plan is the document setting out the quality practices for the project, and is to provide assurance that the quality requirements are planned appropriately. Once accepted by the Consortium, it becomes part of the documents. The Quality Assurance Plan should be adjusted, where applicable, to include co-ordinating instructions. This Quality Assurance Plan will be used by:

- The Partners of the Consortium (Beneficiaries BEF), responsible for preparing and amending deliverables
- Internal Quality Experts of Consortium Partners responsible for reviewing completed quality plans
- Any responsible of a Consortium Partner for approving work to be done by third parties, in order to complete deliverables

Quality Assurance planning is an integral part of management planning. It has been prepared in an early stage of the project, in order to demonstrate and provide the Consortium with the assurance that:

- The Grant Agreement requirements and conditions have been reviewed
- An effective quality planning has taken place
- The quality system is appropriate

The Quality Assurance Plan specifies the activities to be implemented, including their sequence, in order to ensure that the project and its deliverables conform to specific requirements. Those responsible for ensuring that the required activities are carried out, and the resources, which are crucial for their successful completion, are identified within the subsequent chapters of this document. In that respect, the Quality Assurance Plan includes explanation, necessary to show how quality requirements for activities are met.

2

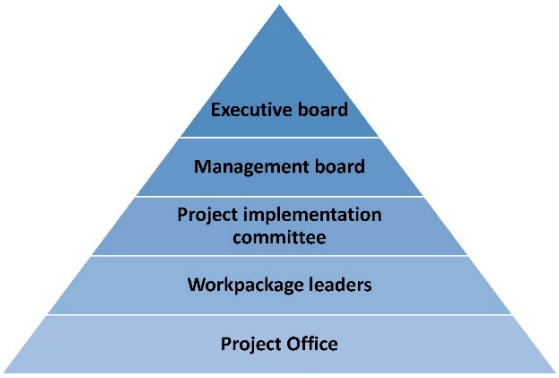
Definition of Management Structure & Assurance Teams

2.1 Definition of Management Structure

The management of the IASIS project is structured in such a way that it will allow the project to address issues swiftly and effectively, taking into account the nature of this project and the target outcome.

A a multi-tier management approach (see Figure 2.1) will be followed in order to facilitate the participants needs and ensure proper and efficient management. At the top of the hierarchy, the Executive Board (EB) maintains ultimate authority in the project. The Management Board (MB) is the core organisational and decision-making body reporting back to the Executive Board for key-decisions that affect the scope and the success of the project. The Project Implementation Committee (PIC) coordinates both the innovation and the technical work plan in close collaboration with the Work package Leaders, towards aligning developments with real advances for the market needs, and supervised by the Management Board for proper coordination between the different WPs. Finally, the Project Office provides all the administrative support required by the above roles to seamlessly perform their responsibilities. Table 2.1 presents the members of the IASIS EB, MB and PIC.

Figure 2.1: Project Management Hierarchy



Further, the **Executive Board (EB)**, orchestrated by the Project Coordinator, is composed of high-

ranking officials of each participant (one person per participant). **The Management Board (MB)**, chaired by the Project Coordinator, is the core organisational and decision-making body on business level, providing technical and innovation directions and management. The **MB** will report and be accountable to the **EB**. The **MB** consists of: the Project Coordinator, the Technical & Quality Assurance Director, the Innovation Manager, the Finance and Administration Manager and the WP leader of each WP. The **MB** will meet at least twice per year. In practical terms, the **MB** represents the Consortium in all related affairs. The responsibilities of the **MB** include, but are not limited to:

1. supervising the overall project plan and work progress,
2. monitoring the use of resources and budget,
3. producing and maintaining the overall risk management and contingency plan,
4. controlling the allocation of work and address changes in the work allocated to partners depending of change of circumstances, and
5. resolving and arbitrating conflicts if and when these arise.

The **Project Implementation Committee (PIC)**, chaired by the Technical Director, is comprised by one technical leader by each participant and reports to the MB. It has the following responsibilities:

1. Leadership and coordination of technical activities;
2. Responsibility for technical set-up and customisation of the pilots;
3. Definition of the architecture and constant monitoring that the development and technical work adhere to the architecture;
4. Technology and market watch, ensuring that technical work remains at state of the art level;
5. Any technological developments that could render work within the project obsolete or redundant;
6. The PIC will meet on a regular basis or whenever an issue within the project occurred.

The Project Coordinator (PC), is designated by the coordinating participant (NCSR) and has the authority to run the project on a day-to-day basis on behalf of the both the **EB** and the **MB** committees, within the constraints set by these decision making bodies. The responsibilities of the PC are to:

1. Maintain all project monitoring plans for effort, budget, tasks and issues. These are provided from each WP leader and the PC maintains a consolidated version of the plans;
2. Coordinate the project office and financial management activities;
3. Inform the MB for any deviations from the agreed guidelines of budget and effort that exceed the agreed thresholds defined by the EB;
4. Provide both the MB and the EB with information required to assist the decision making process; Furthermore, the Project Coordinator is the primary and sole contact point between the Consortium and the European Commission. As such, PC is responsible to:
5. Ensure the communication between the Consortium and Commission;
6. Receive and distribute the EC contribution;

7. Ensure prompt delivery of all hardware, software and data identified as deliverable items in the Contract as soon as received from the WP Leaders or requested by the European Commission for reviews and audits, including the results of the financial audits prepared by independent auditors

NAME	ORGANIZATION	EB	MB role	PIC
George Paliouras	NCSR "D"	✓	Project Coordinator	
Anastasia Krithara	NCSR "D"		Project & Technical Coordinator & Quality Assurance Manager	✓
Vassiliki Rentoumi	NCSR "D"		WP4 Leader	
Grigorios Tzortzis	NCSR "D"			✓
Anastasios Nentidis	NCSR "D"			✓
Christiana Armeniakou	NCSR "D"		Finance & Administrator manager & WP10 Leader	
Anna Triantafillou	ATC	✓		
Nikos Dimakopoulos	ATC		WP6 Leader	
Panagiotis Kokkinakis	ATC			✓
Ernestina Menasalvas Ruiz	UPM	✓	WP2 Leader	
Consuelo Gonzalo	UPM		✓	
Alejandro Rodríguez González	UPM			✓
Alison Evans	ARUK		WP9 Leader	✓
Matt Norton	ARUK	✓		
Roderic Guigo	CRG	✓		
Gian Tartaglia	CRG		WP3 Leader	
Gian Tartaglia / Jordi Rambla de Argila	CRG			✓
Dr. Sőren Auer	UBONN	✓		
Maria Esther Vidal	UBONN		WP5 Leader	✓
Mariano Provencio	HUMPH	✓		
Maria Torrente	HUMPH		WP8 Leader	
Jesús Rey	HUMPH			✓
Robert Lawrence	SGUL	✓		
Peter Garrard	SGUL		WP7 Leader	
Eleftherios Samaras	SGUL			✓
María Fernández	SLCG	✓	✓	✓
Louiqa Raschid	USMF	✓	✓	✓

Table 2.1: EB, MB & PIC Members

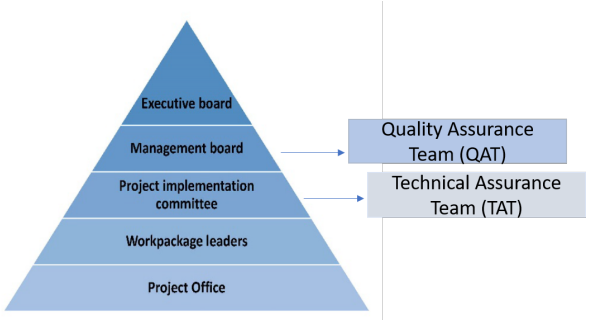
2.2 Assurance Teams

Moreover for assuring the proper quality of the work conducted during the project, a **Quality Assurance Team (QAT)** and a **Technical Assurance Team (TAT)** have been created. The QAT team comprises the same team members as the MB. Moreover, the TAT team comprises the same team members as the Project Implementation Committee (PIC) (see Figure 2.2).

The TAT assures the proper quality of the work conducted during the project both at the business and implementation levels. The Quality Assurance Team (QAT) is defined with responsibility for the administration of the Quality Assurance Plan, and has the authority to identify problems during internal audits, and to initiate actions, resulting in effective problem solutions.

In particular the QAT predicts that problems should be raised within the project meetings, unless an urgent problem, which is realized as a significant constraint to project progress work, comes up and

Figure 2.2: Project Management Hierarchy & Assurance Teams



should be handled via email exchange. The minutes of a project meeting should describe the exact problem and record the agreed solution, as well as the time bound action to be taken to solve it. Once a problem has been identified, there is a requirement to provide sufficient evidence that the problem has been cured. All involved in providing the Consortium with services are to be qualified in the area they are to work within, inspect or verify.

The QAT performs and verifies all work affecting the project quality. This is documented in the manual and is meant to encompass the following aspects:

1. Initiate action to prevent the occurrence of any non-conformity,
2. Identify and record any relevant problem,
3. Initiate, recommend and/or provide solutions through the reporting system,
4. Verify the implementation of solutions,
5. Monitor and control further processing, delivery or installation of any preferred solution to ensure that any reported non-conformance has been corrected.

The QAT should also ensure that the Quality Assurance Plan is available to all concerned and that its requirements are met.

The QAT will ensure the quality of the envisaged project results. Thus, it will be responsible, for:

- Developing a detailed quality strategy and criteria for each deliverable.
- Assuring the conformity of all deliverables with the initial criteria defined for them and guaranteeing that the deliverables are in accordance with the technical proposal.
- Consulting the Work Package Leaders, on the expected technical characteristics of the deliverables.

In that respect, the QAT members will undertake the following main tasks:

- Make an overview of the technical reports produced.
- Check the quality control of all deliverables submitted.
- Provide the WP Leaders with guidance (upon request) on the expected characteristics and contents of the relevant Deliverables.

As a result of the above mentioned responsibilities, the QAT members are to ensure that:

- All the outputs are consistent with the requirements as per the Grant Agreement.
- All the project reports / documents do have the highest quality, regarding their overview and context.

In order to meet the objectives, the QAT consists of one representative per partner and will be chaired by the representative of NCSR "D" (Anastasia Krithara). Further Table 2.2 presents the IASIS QAT and TAT Assurance Teams.

NAME	**ORGANIZATION**	QAT(MB)	TAT(PIC)
George Paliouras	NCSR "D"	✓	
Vassiliki Rentoumi	NCSR "D"	✓	
Anastasia Krithara	NCSR "D"	✓	✓
Grigorios Tzortzis	NCSR "D"		✓
Anastasios Nentidis	NCSR "D"		✓
Christiana Armeniakou	NCSR "D"	✓	
Panagiotis Kokkinakis	ATC		✓
Nikos Dimakopoulos	ATC	✓	
Ernestina Menasalvas Ruiz	UPM	✓	
Consuelo Gonzalo	UPM	✓	
Alejandro Rodríguez González	UPM		✓
Alison Evans	ARUK	✓	✓
Gian Tartaglia	CRG	✓	
Gian Tartaglia/ Jordi Rambla de Argila	CRG		✓
Maria Esther Vidal	UBONN	✓	✓
Maria Torrente	HUMPH	✓	
Jesús Rey	HUMPH		✓
Peter Garrard	SGUL	✓	
Eleftherios Samaras	SGUL		✓
María Fernández	SLCG	✓	✓
Louiqa Raschid	USMF	✓	✓

Table 2.2: QAT & TAT teams

Moreover, the Quality Assurance & Technical Assuracnce Teams will be responsible for the monitoring and control of the KPIs. Table 2.3 summarizes the IASIS' expected outcomes and the corresponding KPIs towards which the project results will be evaluated.

Table 2.3: Overview of KPIs

Outcome	KPI
Mapping comprehensive big data in a reachable and manageable way by applying principles for sharing and reusability, creating a network of knowledge by linking heterogeneous data sources for public health strategy	Large and shared data repository for lung cancer and dementia with data of at least 25,000 patients, from at least 5 different, heterogeneous sources
Emerging data driven analytics and advanced simulation methods to study causal mechanisms and improve forecasts of spatial and temporal development of ill-health and disease;	Decisions about the diagnosis, treatment and prognosis of the disease (measured in the validation activities) will increase by 10% over conventional ways and/or if only one source of data was available.
Develop innovative approaches to improve current risk stratification methodologies;	patient's risk status (measured in the validation activities) will improve by 10% over conventional risk stratification methodologies
Turning large amounts of data into actionable information to authorities for planning public health activities and implementation of an approach "health in all policies";	At least 5 more centres or health authorities will have committed to join and use the **IASIS** decision support platform to support multidisciplinary team decisions processes, by the end of the project.
Placing prevention strategies on evidence base, evaluation of the efficiency and effectiveness of implemented strategies, feedback of results into the development of methods	At least 100 users (i.e. clinicians and health policy makers) from at least 5 research centres validate the system performance and accuracy; and at least 50 external from the project users validate the project results.
Analysing the efficiency of patient pathway management both at primary care level (prevention and early detection) and en route encompassing;	At least 100 users (clinicians or public health policy makers) access the **IASIS** Web services four times per month in average. Additionally, the impact on early detection is achieved, if the number of detections of diseases in earlier stages can be increased in at least 10% over conventional ways; this will be measured in the validation activities.
Aligning big data and advanced simulation methods in order to provide high-leverage policy analysis for public health officials, across a range of epidemiology challenges;	If decisions about the definition of public health policies (measured in the validation activities) can be increased in at least 10% over conventional ways.
Cross-border and networking coordination and technology integration facilitates interoperability among the components of Big Data value chain.	A minimum of 10 dissimilar clinical and genomic data sets from at least two different countries are fully integrated with open pharmacogenomics data sources into the **IASIS** knowledge base. Moreover, the impact on interoperability resolution will be achieved, if the **IASIS** platform receives at least 400 requests per month to execute the Web services deployed by the different layers of the **IASIS** architecture.

3

Peer Review

3.1 Deliverable Peer Review process

The QAT will comment, whenever a technical report is released among the partners, and provide the WP leaders with guidance, based on their experience and relevance to the objectives of the respective WP.

As far as the Project Deliverables are concerned, two (2) examiners / evaluators are considered per each deliverable:

1. The first examiner / evaluator is a representative from the Consortium Members, who will act as an internal inspector and will be the most relevant (technically wise) one with the deliverable under consideration / examination. This member will be selected by the QAT representatives.
2. The second examiner / evaluator is the QAT representative of the partner the first examiner belongs to.

The process for the peer reviewing of a deliverable is as follows: The deliverable under consideration / examination will be forwarded, through the Work Package Leader, to all the members of the QAT. The deliverable must be in its pre-final draft version, from the authors' perspective, and must be available for review at least 15 days before its contractual delivery time as per the Grant Agreement. The first examiner as selected by the respective QAT member will study and revise the deliverable, within five (5) working days, and each of them prepares a draft "Peer review Report" (see chapter 5), which is collected by the QAT of the respective partner. The latter upon receiving the above report and consulting his/her "Peer Review Report", compiles a list with all the approved deviations that have to be repaired. Furthermore, he/she compiles a "Corrective Actions List", along with the person responsible for carrying this action and the required date to be done, always up to two (2) working days. The above list is, also, forwarded to the corresponding Work Package Leader(s), for their information. All the proposed corrections should be incorporated immediately within the specific deliverable, so as the final draft will be ready on time.

In Table 3.1, the list of the partners who are responsible for reviewing each Project Deliverable is presented.

Table 3.1: The list of partners responsible for reviewing each project deliverable

LEADER	DELIVERABLES	Reviewer	Submission for Quality Assurance
UPM	D2.1Harvesting services for clinical data v1.0	UBONN	9/1/2018
	D2.2Harvesting services for clinical data v2.0	UBONN	12/10/2019
	D2.3Clinical notes & image analysis v1.0	UBONN	9/1/2018
	D2.4 Clinical notes & image analysis v2.0	UBONN	12/10/2019
	D2.5 EHR semantic indexing v1.0	SGUL	9/1/2018
	D2.6 EHR semantic indexing v2.0	SGUL	12/10/2019
	D2.7 Predictive modelling v1.0	UBONN	9/1/2018
	D2.8 Predictive modelling v2.0	UBONN	12/10/2019
CRG	D3.1 Harvesting services for genomic data v1.0	NCSR-D	9/1/2018
	D3.2 Harvesting services for genomic data v2.0	NCSR-D	12/10/2019
	D3.3 Genomic semantic indexing v1.0	HUMPH	9/1/2018
	D3.4 Genomic semantic indexing v2.0	HUMPH	12/10/2019
	D3.5 Genomic data analysis v1.0	UBONN	9/1/2018
	D3.6 Genomic data analysis v2.0	UBONN	12/10/2019
NCSR - D	D4.1 Harvesting services for open data v1.0	UPM	9/1/2018
	D4.2 Harvesting services for open data v2.0	UPM	12/10/2019
	D4.3 Open data semantic indexing v1.0	SLCG	9/1/2018
	D4.4 Open data semantic indexing v2.0	SLCG	12/10/2019
	D4.5 Open data analysis v1.0	ATC	9/1/2018
	D4.6 Open data analysis v2.0	ATC	12/10/2019
UBONN	D5.1 Interoperability analysis of biomedical data	ATC	3/9/2018
	D5.2 IASIS Conceptual Schema and Integration Rules v1.0	ATC	9/1/2018
	D5.3 IASIS Conceptual Schema and Integration Rules v2.0	ATC	12/10/2019
	D5.4 Data Management Plan	UPM	9/1/2018
	D5.5 IASIS Access Control and Provenance Model v1.0	UPM	9/1/2018
	D5.6: IASIS Access Control and Provenance Model v2.0	UPM	12/10/2019
	D5.7: Data Management Services	UPM	12/10/2019
	D5.8: High-Level Analysis Services v1.0	CRG	9/1/2018
	D5.9: High-Level Analysis Services v2.0	CRG	12/10/2019
ATC	D6.1: Definition of System Architecture	NCSR-D	10/10/2017
	D6.2: Initial Platform Prototype	NCSR-D	9/1/2018
	D6.3: Final Platform Prototype	NCSR-D	2/7/2020
SGUL	D7.1: Report on user requirements for the dementia use case v1.0	SLCG	3/9/2018
	D7.2: Report on user requirements for the dementia use case v2.0	SLCG	3/8/2019
	D7.3: Dementia pilot plan	HUMPH	3/9/2018
	D7.4: Report on dementia data sources	HUMPH	9/9/2017
	D7.5: User evaluation of dementia pilot v1.0	SLCG	3/8/2019
	D7.6: User evaluation of dementia pilot v2.0	SLCG	2/7/2020
SERMAS	D8.1 : Report on user requirements for the lung cancer use case v1.0	ARUK	3/9/2018
	D8.2 : Report on user requirements for the lung cancer use case v2.0	ARUK	3/8/2019
	D8.3 : lung cancer pilot plan	SGUL	3/9/2018
	D8.4 : Report on lung cancer data sources	SGUL	9/9/2017
	D8.5 : User evaluation of lung cancer pilot v1.0	ARUK	3/8/2019
	D8.6 : User evaluation of lung cancer pilot v2.0	ARUK	2/7/2020
ARUK	D9.1 Project Website	-	6/9/2017
	D9.2 Communication Plan	SLCG	9/9/2017
	D9.3 Dissemination & Communication Report V1.0	SLCG	9/1/2018
	D9.4 Dissemination & Communication Report V2.0	SLCG	2/7/2020
	D9.5 Training Activities Report	ATC	9/10/2019
ATC	D9.6 Market & Exploitation Plan	HUMPH	3/8/2019
	D9.7 Exploitation Plan	HUMPH	2/7/2020
SGUL	D10.1: Dementia data management plan v1.0	HUMPH	9/9/2017
	D10.2: Dementia data management plan v2.0	HUMPH	3/8/2019
	D10.3: Privacy- and Trust-Aware Strategies for the dementia use case v1.0	SLCG	3/9/2018
	D10.4: Privacy- and Trust-Aware Strategies for the dementia use case v2.0	SLCG	3/8/2019
	D10.5: lung cancer data management plan v1.0	ARUK	9/9/2017
	D10.6: lung cancer data management plan v2.0	ARUK	3/8/2019
	D10.7: Privacy- and Trust-Aware Strategies for the lung cancer use case v1.0	SGUL	3/9/2018
	D10.8: Privacy- and Trust-Aware Strategies for the lung cancer use case v2.0	SGUL	3/8/2019
	D10.9: Ethics committee report v1.0	ATC	9/1/2018
	D10.10: Ethics committee report v2.0	ATC	2/7/2020

* Submission for Quality Assurance predicts that each deliverable should be submitted for internal review three weeks prior to the official submission to the PO as this is predicted in IASIS DoW. Further, 10 days before the official delivery date the deliverables should be sent back to the project office (Christiana Armeniakou) at NCSR Demokritos.

3.2 Control of non-Conforming Deliverables

This section provides the procedures to be followed, when a Deliverable is not conforming to fundamental requirements. As it has, already, been stated in the previous section, the Deliverables peer reviewing is undertaken by the QAT members.

The responsible QAT members, after having studied the specific Deliverable under consideration, must evaluate it with respect to a set of key points and must conclude whether the Deliverable should be accepted or not. These key points can be distinguished into two categories and the assessment for the acceptance or rejection of the Deliverable is based on both groups.

The first category has to do with general comments and includes the following key points:

- Layout of the Deliverable
- Deliverable contents thoroughness
- Innovation level
- Correspondence to project and programme objectives
- Particular remarks in format, spelling, etc.

Apart from the above mentioned general key points, a set of specific comments are to be inspected for the specific Deliverable and are summarized in the following:

- Relevance
- Response to user needs
- Methodological framework soundness
- Quality of achievements
- Quality of presentation of achievements

The relevant comments produced by the QAT members will be included in a Deliverable Peer Review Report (see chapter 5).

All reviewers will send their Peer Review Reports within 5 working days from Deliverable draft receipt to the responsible Beneficiary for revising the Deliverable and to the Project Coordinator. The responsible Beneficiary will also forward the peer review report to the QAT. In order to achieve the synthesis, the QAT is delegated the authority to disregard some comments of the reviewers, for example in the case of conflicting comments coming from different reviewers.

The final rating of the Deliverable draft will be marked as:

- acceptable in the current state.
- acceptable with minor revisions.
- acceptable with major revisions (new quality assurance review required after revision).

The relevant Beneficiary has to respond by email, providing justification on whether corrections indicated by the peer reviewers can be accepted or not.

4

Conclusions

This document presented the processes for providing assurance, that the quality requirements are planned appropriately. This document, once accepted by the consortium, must be followed by all project Beneficiaries and members during the whole project life time.

Bibliography

5

Annex: Peer Review Report

In this annex, the report of the peer review form is presented:

IASIS: Integration and analysis of heterogeneous big data for precision medicine and suggested treatments for different types of patients

http://project-iasis.eu/

H2020-727658
Project Quality and Assessment Plan Review

Deliverable No:
Deliverable Title:

Distribution: Restricted

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1. Objectives
Assess the satisfaction of the objectives of the document, as set IASIS DoW:

(a) High

(b) Fair

(c) Poor

Comments:

---

2. Technical Completeness
Regarding the technical completeness, this document is justified as:

(a) Excellent

(b) Good

(c) Poor

Comments:

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3. Innovation
Regarding the innovation of the work presented, this documents innovative aspects are

(a) High

(b) Moderate

(c) Poor

Comments:

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4. Presentation
Regarding the presentation of the work in this document, this is justified as:

(a) Excellent

(b) Good

(c) Poor

Comments:

---

5. QA confidence
Assess your confidence in reviewing this document:

(a) High

(b) Moderate

(c) Poor

Comments:

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6. Final recommendation
This document is:

(a) acceptable in the current state.

(b) acceptable with minor revisions.

(c) acceptable with major revisions (new quality assurance review required after revision).

Comments:

Comments to the coordinator *(not to be sent to the authors):*

6

Appendix: IASIS Deliverable Structure

6.1 Executive Summary

6.2 Introduction

6.3 i.e. Problem Definition

6.4 i.e. Problem Solution

6.5 Conclusions