DELIVERABLE REPORT

Grant Agreement number: 688303

Project acronym: LUCA

Project title: Laser and Ultrasound Co-Analyzer for thyroid nodules

Funding Scheme: H2020-ICT-28-2015

Deliverable reported: D1.2 Project management and quality assurance plan

Due date: 30.04.2016

Name, title and organisation of partner: Katharina Krischak, EIBIR Gemeinnützige GmbH zur Förderung der Erforschung der biomedizinischen Bildgebung (EIBIR)

Project website address: www.luca-project.eu

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1) Objectives

The objectives of Deliverable 1.2: Project management and quality assurance plan are (1) to provide a concise overview of project management procedures for partners participating in the project and (2) to document policies and procedures for assuring project quality through the identification and appropriate handling of risks.

The project management and quality assurance plan is applicable to all project partners. Groups identified within the plan include: the Consortium General Assembly, Steering Committee, Work Package Leaders as well as the Project Coordinator and the Project Office.

The deliverable is divided into two sections: The first section presents the LUCA project management procedures, the second addresses risk management through quality assurance.

Part A - Project Management

Clearly defined project management procedures and responsibilities are vital to ensure high quality project output and the timely delivery of work. Part B of this deliverable describes the overall LUCA project management procedures and shall serve as manual and guideline for all consortium partners.

2) General Project Information

a. Consortium

Participant No	Participant organisation name	Country
1 (Coord.)	Fundacio Institut de Ciencies Fotoniques **(ICFO)**	Spain
2	Politecnico di Milano **(POLIMI)**	Italy
3	Consorci Institut d'Investigacions Biomediques August Pi I Sunyer/Hospital Clinic **(IDIBAPS)**	Spain
4	HemoPhotonics **(HEMO)**	Spain
5 (SME)	VERMON SA **(VERMON)**	France
6 (SME)	ECM Echo Control Medical **(ECM)**	France
7	University of Birmingham **(UoB)**	United Kingdom
8	EIBIR Gemeinnuetzige Gmbh zur Foerderung der Erforschung der Biomedizinischen Bildgebung **(EIBIR)**	Austria

Table 1: The LUCA Consortium

b. Management Structure

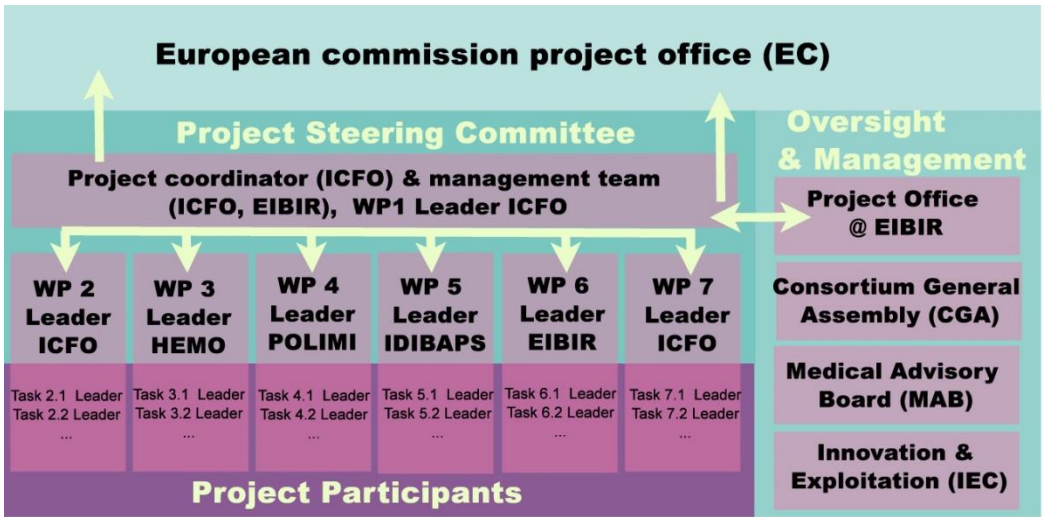

Figure 1: The LUCA Management Structure

c. Project Decision Making

Consortium General Assembly (CGA)

The Consortium General Assembly is the overall decision-making body and consists of representatives from all partners. The CGA is chaired by the Project Coordinator Prof. Turgut Durduran (ICFO). The CGA will provide a forum for discussion and will decide on major modifications of the work plan, budget distribution, possible addition of and calls for new partners as well as unresolved management issues. Furthermore, the CGA will also decide on requests for amendments to the European Commission. The CGA approved the management structure (as laid down in the Consortium Agreement) and all decision-making procedures and responsibilities. The CGA will meet at least once a year back to back with scientific and technical consortium meetings to ensure transparent project evolution and governance. If deemed necessary extraordinary meetings (preferably electronic meetings) can be arranged.

Steering Committee (SC)

The Steering Committee (SC) is the executive operational body and comprises the Project Coordinator, the Project Manager and all Work Package Leaders. The SC is the interface between work packages and the SC and will be responsible for monitoring the technical progress of the project, quality assurance, and the ad hoc coordination of scientific and technological activities. Procedures for managing future exploitation of results will be discussed and assessed. The SC will also perform a general assessment of the technical, scientific, and commercial results produced according to the project objectives and to the metrics identified. For this, the expertise from the Medical Advisory Board (MAB), internal metrics and indicators will be compared to market insights and recent technological developments. Furthermore, the SC will assess the feedback from the EC on the annual periodic reports and take it into account to adjust the project work and plan for the next period. The SC will meet at least twice a year either face-to-face (at least once a year) or by telephone/video conference. These meetings will serve as preparation for the EC review and the obligatory technical reporting and aim to report on the project progress and to redefine (if necessary) the Description of Action, for the remaining part of the contract.

d. Medical Advisory Board

The Medical Advisory Board (MAB) will provide the project partners with an external perspective from both the medical and the device-engineering point of view. The MAB is made up of external experts who advise the consortium on the performance and progress of the project well as the appropriate resolution of potential conflicts and deviations. It will provide input on the interface of the technological developments, research and medical aspects carried out and guidance on the conclusions reached. Its responsibilities also include giving advice on how to improve project results and their impact on the industry sector and suggesting additional avenues of application, exploitation and dissemination. The members of the Medical Advisory Board are Dr Manuel Puig-Domingo and Dr Paolo Ravazzani. Both have reconfirmed their agreement to serve on the board and have been involved from the project start. They will be invited to join the next meeting of the CGA in September 2016 to provide the consortium with their expert advice.

Dr Manuel Puig-Domingo is president Spanish Society of Endocrinology and Nutrition (Sociedad Española de Endocrinología y Nutrición –SEEN-): He is a well-known endocrinologist in national and international community. He is the director of Institut d'Investigació Germans Trias I Pujol (IGTP), head of the Endocrinology department in Hospital Germans Trias i Pujol and director of the Rossend Carrasco and Formiguera Foundation. Formerly, he was the medical director of the Maresme Health Consortium, Director of Research at the Hospital of Mataró and vice-president of Catalan and Spanish Endocrinology and Nutrition societies. He is Professor of Medicine at U. Autonoma Barcelona.

Dr Paolo Ravazzani is currently a member of the Technical Committees (CT62) on electrical devices for medical use of the Comitato Elettronico Italiano CEI. CEI is responsible for standardization in the electrotechnical, electronics and telecommunication engineering fields. In details, Paolo Ravazzani is a member of the three sub-committees related to common aspects of electric devices for medical use (62A), devices for biomedical imaging (62B) and electromedical devices (62C). Moreover he is member of the Working Group 15 of the CENELEC Technical Committee 106X, on EMF assessment with respect to active implantable medical devices in electric, magnetic and electromagnetic fields.

e. Innovation and Exploitation Committee

The Innovation and Exploitation Committee (IEC) is a subcommittee of the SC and the body responsible for the monitoring of the strategic and commercial gains as well as the overall impact of the project. The IEC is responsible for the management of the new knowledge generated within the project by continuous identification, monitoring and qualification of tangible and intangible results that may have an impact in future exploitation strategies and may need to be kept confidential and/or protected via patents and licenses to ensure legal protection of the intellectual property and/or disseminated or transferred to third parties.

The IEC is composed of the three industrial LUCA partners HEMO, VERMON and ECM together with the ICFO knowledge and technology transfer unit (ICFO-KTT) and IDIBAPS.

f. Meetings

The following meetings have been planned and budgeted for:

1. Consortium General Assembly will meet at least once a year over 4 years
2. Steering Committee will meet at least every three months either face-to-face or via electronic means
3. Medical Advisory Board meetings will be briefed about the project progress and, if deemed appropriate, will join the meetings of the Consortium General Assembly.
4. The Innovation and Exploitation Committee will meet at least every six months either face-to-face or via electronic means

Additional meetings for specific issues, tasks or WPs will be organised if required. Whenever possible, meetings will be held via electronic means.

g. Deliverables and Milestones

i. General Aspects

- Most Deliverables are written reports.
- Deliverables that are of a nature other than written reports, such as “demonstrators” or “others” should also be accompanied by a short report, so that the EC has a record of their existence. They include supporting material, such as: photos of the prototype, descriptive guidelines, etc.
- If a Deliverable has been cancelled or regrouped with another one, then this needs to be indicated in the activity report and in the Deliverables list.
- If a new Deliverable is proposed, this needs to be indicated in the activity report and in the Deliverables list.

ii. Layout

- A Deliverable template has been provided by the Project Coordinator and is available for download on Teamwork.
- For final submission to the European Commission, Deliverables will be converted into PDF-Format.

iii. Delivery

Deliverables have to be drafted and/or finalised according to the Deliverables’ time schedule listed in the DoA.

- 14 days prior to submission Deliverables should be uploaded as a text document (.doc, .txt) **not** PDF to the deliverables repository of the LUCA Teamwork platform for review and final preparation by the Project Coordinator:
- Final approval of deliverables will be the responsibility of the Project Coordinator
- After successful review, the Project Coordinator will submit the deliverable to the European Commission.

iv. Changes

- Within one reporting period the shifting of Deliverables is possible, but a brief explanation of such deviations must be provided (e.g. necessary meeting took place at a later date, new developments, etc.).
- The shifting of Deliverables beyond reporting periods is not recommended; in case this becomes necessary, a detailed explanation and work plan as to how the Deliverable will be fulfilled in the near future has to be provided.

v. Publication

- Deliverables will be presented and published to all consortium partners, the European Commission and (depending on its nature) the public.

vi. Milestones

- Milestones should be briefly explained in the Periodic Report, including results.
- Usually a milestone is used as a project checkpoint to validate how a project is progressing and revalidate the work.
- A milestone is the end of a stage that marks the completion of a work package or phase. There is no direct task associated with it (although preparing a milestone can involve significant work).

vii. Overview of Deliverables and Milestones

Reporting Period 1 (February 2016 - July 2017)

	2016											2017						
	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July
	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18
WP1			D1.1, D1.2, D1.8, MS1						D1.3									
WP2			MS1														D2.1, D2.2, D2.3, D2.4, D2.5, D2.6	MS2
WP3			D3.1, MS1															MS2
WP4			MS1			D4.1						D4.2, D4.4					D4.3, D4.5	
WP5			D5.1, MS1															
WP6	D6.10		D6.1, D6.2, D6.3, MS1			D6.4						D6.5						
WP 7			MS1						D7.7						D7.1		D7.4, D7.5	

Reporting Period 2 (August 2017 – January 2019)

	2017					2018												2019
	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan
	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36
WP1		D1.4				D8.1, D8.2, D8.3						D1.5						
WP2						D2.7			MS3									D2.8
WP3						D3.2			MS3	D3.3		D3.4						D3.5, MS4
WP4						D4.6. D4.8, D4.9			D4.7, MS3									MS4
WP5									MS3			D5.3						D5.2, D5.4, MS4
WP6						D6.6, D6.11												D6.7
WP 7						D7.3												D7.8, D7.9, D7.10, D7.12

Reporting Period 3 (February 2019 - January 2020)

	2019											2020
	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan
	M37	M38	M39	M40	M41	M42	M43	M44	M45	M46	M47	M48
WP1		D1.6										D1.7, MS5
WP2												D2.9, MS5
WP3				D3.6								D3.7, D3.8, MS5
WP4												D4.10, MS5
WP5									D5.5, D5.6, D5.7, D5.8			D5.9, MS5
WP6											D6.9	D6.8, D6.12, MS5
WP 7												D7.2, D7.6, D7.11, D7.13, MS5

h. Guidelines for Internal Communication

i. Communication Strategy

The project communication strategy aims at keeping the partners regularly informed about the project status, work planning and all other issues that are important in order to obtain appropriate transparency and to increase the synergy of cooperation. The figure below illustrates the LUCA communication scheme.

Figure 2: LUCA Communication Scheme

WP leaders will be responsible for the WP internal communication and maintain the communication with the entire Steering Committee.

The Steering Committee will be the key address of the internal communication between work packages. Relevant information related to any issues will be communicated to the SC, who will be responsible for distributing this information to all partners involved.

All partners will actively and timely inform the Project Office on changes of their contact details, contact persons or changes in any other information needed for executing the project. The Project Office will update the data on regular basis and will make this information available for all partners.

ii. Communication Methods

The following methods will be used for monitoring and reporting the progress of the project:

- face-to-face coordination and decision-making meetings
- WP team meetings on request
- telephone conferences

Via the Teamwork platform all project-related documents, templates and guidelines and a directory of all consortium partners and their contact information, as well as other useful information to facilitate project management and communication and the sharing of information will be available.

Every project member will be able to read and up-/download documents.

Further communication means are any standard telecommunication equipment, such as email, phone and Internet.

Four mailing lists were created and populated for communication:

1. LUCA-tech: For the technical partners including students, postdoctoral fellows, engineers and others. This list serves to discuss technical matters in a timely manner.
2. LUCA-wpleaders: This list includes the WP leaders and it is utilized for discussion between WP leaders.
3. LUCA-everyone: This is the list of everyone involved in the project and is used for general announcements.

4. LUCA-admin: This includes the admin personnel from all partners.

The aim of this proactive communication on many different levels is to create a supportive, collaborative culture giving rise to fewer mistakes, less redundancy, quicker problem solving, better decision making, reduced research and development costs.

iii. Communication Channels and Ethics

All project partners are encouraged to communicate with each other in order to plan the next steps of the project, to discuss project results, etc., and to conform to the following proactive communication ethics:

- In the case of any unclear reporting issues (e.g. have not received, where can I find, until when, don't know how to fill in, etc.) partners are asked to contact the Project Coordinator and Project Office for advice.
- Please meet the deadlines, especially during the official reporting. Please fill in the forms as early as possible.
- Any important issues need to be communicated directly and/or cc'd to the Project Manager.
- Inform the Project Manager immediately about any changes regarding contact details or additional persons involved (e.g. assistants, secretaries, etc.); official amendment requests to the EC have to be carried out by the Project Coordinator.

3) Project Reporting

a. Official Reporting Procedure to European Commission

Reporting to the European Commission is a contractual obligation for all project partners. By signing the contract, all partners agreed to meet this obligation. Because all financial reporting can be completed electronically partners should confirm with their LEARs that the right to sign electronically in the electronic system of the European Commission been appropriately assigned rights to ensure there are no delays in the payment process.

i. Reporting Periods

Progress and fulfilment of tasks according to the Description of Action will be evaluated by the European Commission (EC) over three reporting periods:

- Period 1 (M18 – 31.07.17)
- Period 2 (M36 – 31.01.19)
- Period 3 (M48 – 31.01.20)

There will be three periodic reports (D1.4, D1.6, and D1.7) and two interim reports (D1.3 and D1.5). The interim reports are brief status reports and include a technical and management progress report with a section on risk management and contingency plan.

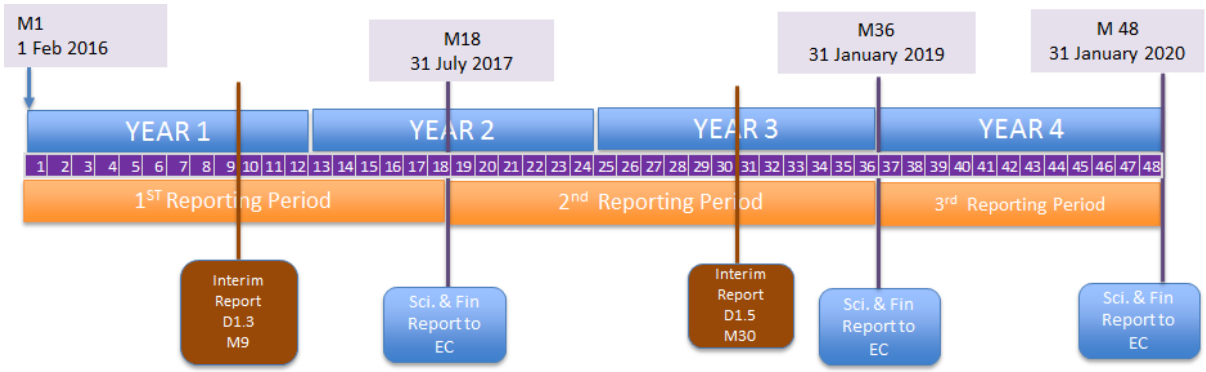

Figure 3: LUCA Reporting Periods

ii. Periodic Reports

Every Periodic Report needs to be submitted within 60 days after the end of each reporting period. Core contents of these reports are:

- **Periodic Technical Report**
  - Overview of progress of the work
  - Summary for publication
  - Plan for the exploitation and dissemination of results
  - Questionnaire

Templates for the periodic report and detailed instructions for the reporting will be provided by the Project Coordinator well in advance.

- **Periodic Financial Report**
  - Use of the resources and
  - Financial Statement (individual & summary)

iii. Final Report

The Final Report must be submitted within 60 days after the end of the project. Details and deadlines for communication and delivery of all templates, deliverables, etc. will be sent to the partners at an early stage.

Core contents of these reports are:

- **Final Technical Report**
  - Overview of results and their exploitation & dissemination
  - Summary for publication
  - Conclusions and socioeconomic impact
- **Final Financial Report**
  - Summary Financial Statement
  - Certificate on Financial Statement (if needed):
    When the actual EU contribution to a partner reaches € 325 000 one Certificate of Financial Statements will be required at the end of the project. This form can be completed electronically.

b. Reporting Notes and Hints

i. Periodic Report

Describing real added value of the work performed is important to show that the aims per WP have been achieved.

ii. Direct costs:

Direct costs are eligible costs which can be attributed directly to the project and are identified by the partner as such, in accordance with its accounting principles and usual internal rules.

iii. Personnel costs & Time sheets

As there is no distinction between cost models, any partner may include in its personnel costs "permanent employees" who have permanent working contracts or "temporary employees" who have temporary working contracts with the project partner.

Each person working in the project has to fill in a separate **Time sheet**. It is necessary to have one time sheet per month.

The time sheets have to be signed by the person carrying out the work and the supervisor/project leader in your institute (generally, this is the main responsible contact person of the project partner).

You can use your own (electronic) timesheets or templates you have in your institute or you may use the template provided on Teamwork.

In any case, it is important that each timesheet includes the following necessary information:

- Full name of the partner organisation
- Full name of the individual working in the project
- Title of the project
- Project account number should be indicated.
- Time period concerned (for instance on daily, weekly, monthly basis) according to the partner's normal practice.
- Number of hours claimed for the project. All hours claimed must be able to be verified in a reliable manner
- Full name and signature of the working person and the supervisor (person in charge of the project)

Note that all your administrative/general work must also be added to your work package(s) in your time sheet (e.g. kick-off, any other meetings, phone conferences, reporting, etc.).

IMPORTANT NOTES:

If you are engaged in more than one EU project, you have to keep a time sheet where working hours for all EU PROJECTS and NON-EU ACTIVITIES are listed. The European Commission and the external auditor will certainly demand an exact record of these hours worked per project.

It is important to assign the working hours to a specific WP as the personnel costs and the person months are billed by WP.

iv. Travel and subsistence allowances

Actual travel and related subsistence costs related to the project may be considered as direct eligible costs. They have to be adequately recorded.

For specific questions on reporting please also see the Annotated Grant Agreement.

c. Dissemination List

This section should describe the dissemination measures, including any scientific publications relating to foreground. Its content will be made available in the public domain thus demonstrating the added-value and positive impact of the project on the European Community.

For **workshops, press releases, presentations etc.**, the **EU emblem and Photonics21 logo** must be displayed prominently together with the text "Photonics Public Private Partnership".

On all publications the EU emblem and the following text must be displayed:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 688303.

The link **www.photonics21.org** also has to be included. When communicating on Twitter or other social media about project activities, **#Photonics** shall be included together with **@Photonics21** and **@PhotonicsEU**.

4) Data Management

In the course of the project various data sets will be generated and collected. These include but are not limited to design drawings (subsystems and LUCA system), (opto-)electronics board and component designs and specifications, research laboratory data (test results of components), sub-systems and the LUCA system, research application data, evaluation data, standards conformity data, exploratory data. The data management of the LUCA project will rely on the data management policies of the partner institutions generating the data. A Data Management Plan (D.1.8) has been developed, which presents details on the procedures of creating 'primary data' (data not available from any other sources) and of their management. This public deliverable will be made available on the LUCA website.

Part B - Quality Assurance Plan

The goal of the quality assurance plan is (1) to provide for successful implementation of tasks, milestones, deliverables and the overall project objectives, and (2) to produce deliverables with high scientific quality. Taken together, risk management and quality assurance are interdependencies necessary to guarantee successful project results.

Defining risks and establishing policies and procedures to address risks are therefore necessary to proactively respond to any challenges that could negatively impact the overall quality of the project or jeopardize the completion of individual tasks, work packages, deliverables, or the outcome of the entire project.

Risks are defined as potential variations which would have a negative impact on the project, be it a decrease in quality, increase in cost, delay in completion or even a failure of the project.

Therefore the proposed Quality Assurance Plan aims at:

- Creating a set of clearly defined quality procedures to cover all key project processes for both project management and research activities.
- Ensuring an effective workflow and progress through identification and management of risks that could impede the successful execution the project.
- Providing procedures for maintaining transparent documentation of quality management activities and results.
- Establishing regular review of individual processes and the quality system itself to evaluate effectiveness and facilitate continual improvement.

5) Quality Assurance

All partners have responsibility towards the quality assurance for LUCA until obligations of the project are fulfilled; the specific responsibility of each partner is described below:

a. General

- Partners should make any quality assurance issues known to their work package leaders (WPL). If the issues cannot be solved within the work package, WPLs will bring it to the Steering Committee, which will develop a mitigation strategy and, if necessary, propose it for decision by the Steering Committee.
- Quality assurance issues will be discussed within the regularly held Steering Committee meetings and telephone conferences.
- Approval from the Work Package Leaders will be sought before scientific news on work packages is distributed.

b. Deliverables

i. Preparation of Deliverables

- Regular communication between the Project Coordinator, Project Office and consortium partners to discuss the quality of the current status of project-related developments.
- A template for Deliverables has provided to partners and is available on the internal communication tool (Teamwork platform).

- If deemed necessary by the Project Coordinator, the Consortium General Assembly and Medical Advisory Board may be asked to provide feedback on Deliverables.
- Deliverables will be made available to all partners via the Teamwork platform.

ii. Review of Deliverables

- Deliverables will undergo review by the Project Coordinator prior to submission to the European Commission.
- The reports will be sent to the Project Coordinator, who will, if required, provide feedback to the authors of the Deliverable.
- Final approval of the Deliverable from the Project Coordinator will be required before submission.

iii. Update of Deliverables

- Possible updates to Deliverables during the project life time will be discussed by the co-operating partners within a work package task to incorporate improvements and new findings.
- Regular communication of such improvements to the entire consortium will be done via the Teamwork platform, news messages, meetings and teleconferences.

6) Risk Management

a. Roles and Responsibilities

Responsibility for risk management is carried by many contributors within the project and each contributor must be aware of risk warning signs throughout the project's lifetime. The Consortium General Assembly, the Steering Committee, Work Package Leaders, the Project Coordinator and the Project Office are the main contributors to quality assurance. Representative roles and responsibilities within the project are defined as follows:

i. Quality Assurance and Risk Management by Work Package 1

Quality and risk management will be performed under the auspices of the Project Coordinator, in collaboration with the Project Office, who will be responsible for the following tasks:

- Allocating the required resources and time to execute the quality assurance plan within the scope of the project budget and schedule
- Developing, distributing and implementing the quality assurance plan
- Monitoring the project continually to identify any new or changing risks
- Developing and updating a risk register with the support of the Steering Committee and incorporating it into the work plan
- Contributing to risk mitigation and contingency planning
- Coordinating with the risk owners to monitor risks and implement risk response strategies
- Managing quality control procedures on deliverables
- Continually monitoring of the effectiveness of the risk management strategies
- Reporting regularly to the Consortium General Assembly; and
- Making the final decision on risk actions, in co-ordination with the WP Leaders.

ii. Consortium General Assembly

In close cooperation with the LUCA consortium, the Consortium General Assembly supports the Quality Assurance and Risk Management as follows:

- Approving and endorsing the risk register and quality assurance plan
- Supporting development and revision to the quality plan and the risk register; and
- Maintaining a list of risk and response strategies.

iii. Steering Committee

Steering Committee responsibilities include:

- Developing and/or updating the risk response strategy
- Monitoring the assigned risks and informing the Project Coordinator of any threats or opportunities to the project
- Assessing the probability that a risk will occur and specifying the criteria used to assess the probability; and
- Assessing the impact of risks on project cost, time, scope, and quality objectives, and specifying the criteria used to assess the impact.

iv. Work Package Leaders

Work Package (WP) Leaders are responsible for the following tasks within their work package(s):

- Identifying and describing any risk
- Helping to identify the risk owners and assisting in developing the risk response strategies
- Performing the risk response steps assigned
- Reporting on the progress of the risk response to the Project Coordinator; and
- Assisting the Project Coordinator in activities associated with risk monitoring and control.

7) Risk Processing

Risk identification, analysis, planning, and monitoring and control are the steps involved in processing risk. As part of risk processing a risk register will be established and will be used as a tool to document to record all possible and realised risks to the project and any subsequent measures or actions required. The risk register will be placed on the Teamwork platform and will be continually updated. The discussion of the risk register will be a fixed agenda item for every Steering Committee Meeting taking place at least twice a year.

8) Risk Identification

Risk identification will be performed within work packages. WP leaders will report the risks and suggestions for the risk priority to the Steering Committee, which will agree on the final risk priority as well as on the respective response strategy. WP leaders will report the developed strategy to all WP partners and implement it.

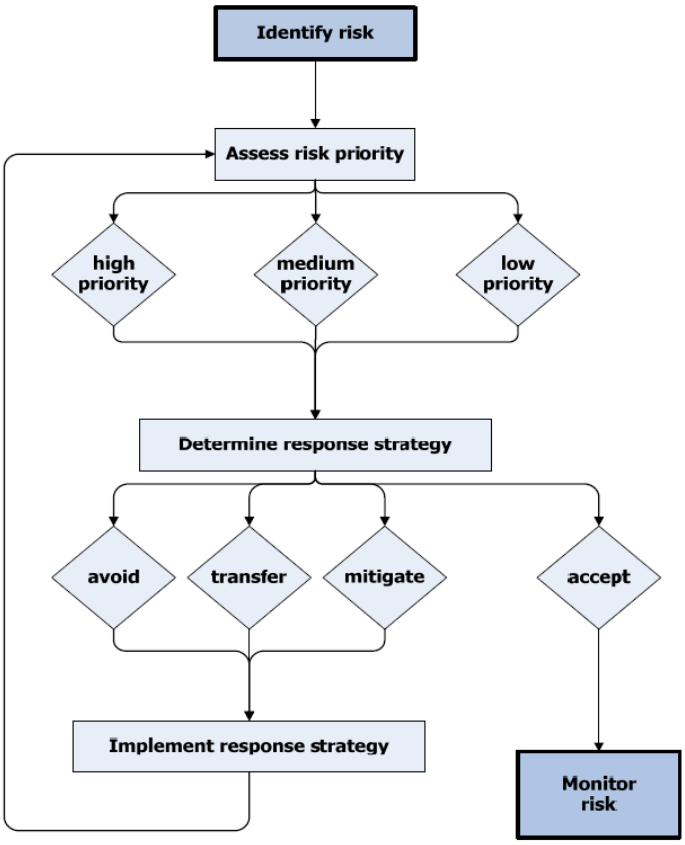

Figure 4: LUCA Risk Management Process

a. Sources

Risk identification is done throughout the life-cycle of the project, with an emphasis on identifying risks as early as possible so effective response planning and subsequent monitoring can take place. The following are tools and techniques for risk identification:

- Analysis of high-level deliverables
- Analysis of WP schedules and scopes
- Analysis of project assumptions
- Project consortium input (interviews, brainstorming, etc.)
- Review performance and status reports

b. Documentation

Identified risks will be documented and entered into a risk register with the following details:

- Risk ID
- Short descriptive title of risk
- WP or task number
- Entry date
- Risk identified by (name or group)
- Risk category (see Annex part B)
- Mitigation measures

9) Risk Analysis

a. Background

After a risk or group of risks has been identified and documented, it is important to assess the probability that the risk will occur and the impact of the risk, if it occurs.

Quality Assurance and Risk Management is an iterative process — following proactive response to a risk, the remaining risk should be reassessed to determine if further response is needed.

Risk impact analysis can be qualitative or quantitative. Qualitative analysis should occur prior to conducting quantitative analysis. Not every risk needs to go through quantitative analysis.

b. Qualitative Analysis

Analysis should be performed by gathering data on the:

- Probability of the risk occurring (see Annex part B)
- Qualitative impact on the project (see Annex part B)
- Value assigned to the risk (see Annex part B)
- The quality of the risk data being utilised

c. Documentation

The results of risk analysis will be documented and entered into a risk register with the following details:

- Risk priority
- Date of analysis

10) Response Planning

a. Background

During risk response planning, strategies and plans are developed to minimise the effects of the risk to a point where it can be controlled and managed. During response planning, higher priority risks should receive more attention than lower priority risks. Every risk that poses a threat should be assigned to a responsible party (owner) during response planning.

b. Risk Management Strategies

There are several methods of risk response. In all cases (except for *iv. Accept*) following implementation of the strategy the risk should be reassessed to determine if any threat to LUCA remains.

i. Avoid

Risk avoidance involves changing aspects of the overall project plan to eliminate the threat, isolating project objectives from the risk's impact, or relaxing the objectives that are threatened (e.g. extending the schedule or reducing the scope). Risks that are identified early in the project can be

avoided by clarifying requirements, obtaining more information, improving communications, or obtaining expertise.

ii. Transfer

Risk transference involves shifting the negative impact of a threat to a third party. Risk transference does not eliminate a threat; it simply makes another party responsible for managing it.

iii. Mitigation

Risk mitigation involves reducing the probability and/or the impact of a risk to an acceptable level. Taking early and proactive action against a risk is often more effective than attempting to repair the damage a realised risk has caused. Contingency planning is an example of risk mitigation.

iv. Accept

Acceptance is often taken as a risk strategy since it is very difficult to plan responses for every identified risk. Risk acceptance should normally only be utilised for low-priority risks. Risk acceptance can be passive, where no action is taken at all, or active. The most common active approach to risk acceptance is to develop a cost and/or schedule revision to accommodate known (or unknown) threats. Utilising a risk acceptance approach determines that the risk should be monitored rather than reassessed.

c. Documentation

The results of response planning will be documented and entered into a risk register with the following details:

- Proposed action/risk management strategy to be implemented
- Individual/group responsible for implementing the response planning
- Date of implementation

11) Risk Monitoring and Control

a. Timing and Communication

The Quality Assurance and Risk Management process will occur in conjunction with the Steering Committee meetings/conference calls. Following this interval, reporting will flow from the Steering Committee to the Consortium General Assembly.

Each Work Package Leader is responsible for the Risk Management and Quality Assurance within their Work Package. Each project partner is highly encouraged to communicate and discuss any (possible) risks and response planning with their Work Package Leader.

It is vital that open communication continues and all project partners are encouraged to be attentive to and report on quality and risk issues throughout the project's lifetime.

b. Documentation

The results of monitoring and control will be documented and entered into a risk register with the following details:

- Date of risk reassessment
- Evaluation of the action taken
- Further action required
- Date of resolution of risk

12) Annex - Part B: LUCA Risk Register

a. Risk Categories

The following diagram shows predefined risk categories. Risk categories should be used when thinking about and identifying new risks.

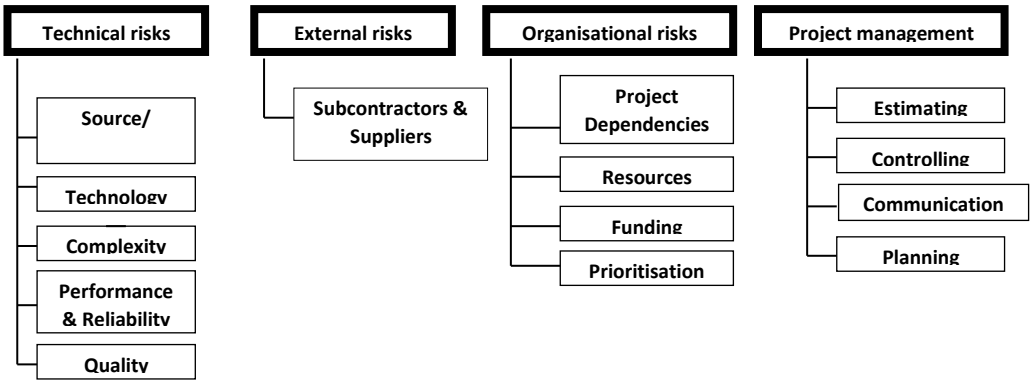

Figure 5: Risk Categories

b. Risk Probability Definitions

The following chart shows risk probability definitions. During risk analysis/risk identification the potential likelihood that a given risk will occur is assessed, and an appropriate risk probability is assigned.

Probability Category	Description	Score
High	Risk event expected to occur	7-9
Medium	Risk event may or may not occur	4-6
Low	Risk event less likely than not to occur	1-3

Table 2: Risk Probability Definitions

c. Risk Impact Definitions

The following chart shows risk impact definitions across each of the potentially impacted project areas (cost, schedule and performance). During risk analysis the potential impact of each risk is analysed, and an appropriate impact level is assigned by selected a score from one 1 to 9 while entering the risk into the LUCA Risk Register. The area(s) of impact is then selected and added to the risk entry.

Risk Impact	Low Score: 1-3	Medium Score: 4-5	High Score:5-6
Cost	< 10% cost impact	10-20% cost impact	> 40% cost impact
Schedule	< 5% schedule impact	5-10% schedule impact	> 20% schedule impact
Performance	Minor areas impacted	Major areas impacted	Impact unacceptable to EC

Table 3: Risk Impact Definitions

d. Risk Scoring and Thresholds

In order to ensure that the impact and likelihood of individual risks occurring can be tracked and identified quickly and efficiently, all risks entered into the Teamwork Risk register are scored in terms of probability and impact. The scores entered for each of these two factors (from 1 to 9 in order of severity) are then automatically combined to generate an overall risk score. This risk score then serves as clear indicator of which risks require immediate action. The risk score matrix provides vital threshold score ranges which allow the consortium to identify and prioritise risks.

Risk Level	Score Range	Action required
Low	1-20	No immediate action required
Medium	21-40	Action may be required soon and Work Package Leader responsible should be prepared
High	41-60	Action required immediately and Work Package Leader responsible should inform Project Manager of mitigation action taken
Extreme	61-81	Risk may jeopardise project: urgent and immediate action must be taken

Table 4: Risk Scoring and Thresholds

e. LUCA Risk Register: Probability and Impact Matrix and associated contingency plans

All risks contained in the LUCA project's Description of Action have been entered into the Risk Register on the Teamwork project management platform (see figures below) which is accessible to all partners. The consortium has been instructed that the Risk Register is a living document which should be updated continuously throughout the project lifetime.

Project Risk Report: LUCA

	Risk Source		Probability			Impact			Result	Impact Areas			Mitigation / Response Plan	Status
			Low	Medium	High	Low	Medium	High		Cost	Schedule	Performance		
1	LUCA fails to distinguish malignant and benign nodules	Katharina K.		5				8	40		X	X	Seek the reasons. If it is due to signal-to-noise ratio or other problems, we will attempt to address it at the hardware level. If it is an inherent problem due to specificity of the optical parameters, we will seek to add additional parameters, computer aided diagnosis methods and/or attempt a larger study to improve the discriminatory power	Open
2	LUCA (DCS,TRS, Ultrasound , software & algorithms) fails to obtain a contrast, i.e. cannot detect, from nodules even with US guidance	Katharina K.		5			5		25		X	X	Seek the reasons. If it is due to signal-to-noise ratio or other problems, we will attempt to address it at the hardware level. If it is due to inherent lack of contrast, we will (1) look for alternative signatures, (2) add more measurement locations using US guidance to improve spatial resolution by overlapping measurements, and (3) use computer aided diagnosis methods to derive composite indices	Open
3	DCS laser has unstable coherence and/or suffers from heavy mode hopping	Katharina K.	2					8	16		X	X	Re-design the laser driver circuitry including temperature control and, if unsuccessful, there are many alternative providers to try	Open
4	DCS auto-correlator has systematic deviations or worse noise performance than more expensive option	Katharina K.	2					8	16		X	X	Re-implement the FPGA firmware and test on a software solution	Open
5	Integration of optical and US sub-systems leads to cross-talk and other problems between the two	Katharina K.	2					8	16	X	X	X	A bulkier, more expensive solution can be designed that isolates the two better	Open
6	The final device is not economically viable for the scope expected and the market targeted	Katharina K.	2					8	16			X	Since the fabrication costs will be defined early in the project, alternative procedures or a change of scope to address different markets where viability is guaranteed will be sought	Open

Figure 6: The LUCA Risk Register (1)

7	Lack of accuracy and alignment between US and Optical	Katharina K.	2				5		10		X	X	Review of the probe design and optimization of the geometry and characteristics of US/OPT devices	Open
8	Use of TRS data as prior knowledge in DCS	Katharina K.	2				5		10		X	X	Use of standard models as prior knowledge	Open
9	Use of US image as prior knowledge in DCSTRS	Katharina K.	2				5		10		X	X	Use of TRS guided information of regional (depth related) information	Open
10	Lack of accuracy of transferred image coordinates from US system to Optical system	Katharina K.	2				5		10		X	X	Software development according to IS0 62304 requirements and extensive software final validation	Open
11	Poor signal-to-noise ratio of the detector for TRS	Katharina K.	2				5		10		X	X	Change the supplier of silicon photomultipliers (SiPM); or use smaller SiPM with lower noise if the amplitude dynamic is too low	Open
12	Poor linearity in the timeto- digital converter used for the TRS technique	Katharina K.	2				5		10		X	X	Re-design the layout of the converter in order to improve the signal integrity and the linearity	Open
13	Alternative DCS detector is unavailable	Katharina K.		5		2			10	X	X	X	Use the standard solution compromising on cost	Open
14	Integration of subcomponents introduces loss of quality	Katharina K.	2				5		10		X	X	Implement original setup, investigate alternative designs	Open
15	Cannot meet subject recruitment goals on time	Katharina K.	2				5		10		X	X	Develop new strategies; possibly expand to other collaborating centers in the SEEN network to increase the subject pool	Open
16	LUCA fails to pass the ex vivo validation	Katharina K.	1					8	8		X	X	In this unlikely event, we will look for the root of the problems and introduce solutions. For example, the depth insensitivity can be overcome by additional source-detector pairs	Open
17	LUCA fails ethical approvals	Katharina K.	1					8	8		X	X	The specific reasons will have to be studied and addressed. Given the previous approvals and our long term experience, this is highly unlikely. Previous problems had risen from poorly written protocols, missing documentation and the need for additional documentation from different authorities. These can be taken care of with minor delays	Open

Figure 7: The LUCA Risk Register (2)

18	Exploitation by one partner requires IP from other parties	Katharina K.		4		2			8		x	x	IEC will monitor potential applications and the required agreement among the partners. Proper IP management procedure will be in place to deal with these issues	Open
19	A blocking patent affects exploitation	Katharina K.	1				4		4			x	Does not directly affect the project progress. It affects the final exploitation goals. If necessary, license agreements may be sought	Open
20	Either too high power consumption or too big size of the prototype resulting from the integration of TRS, DCS and US	Katharina K.	1			1			1			x	Re-design the boards and the housing of the various opto-electronic components. The prototype would be anyhow assembled and tested, while the re-design will run in parallel	Open

Figure 8: The LUCA Risk Register (3)

13) Conclusions

This document presented the project management and quality assurance plan tailored to the LUCA project. Project coordination and project supporting procedures as well as quality assurance, data management, and risk management processes key for the successful implementation of the project have been established and put in place to ensure the obligations of the project are fulfilled.