D1.1 - Project Management and Quality Guidelines

Version 1.4

Document Information

Contract Number	101046475
Project Website	https://qustom-project.eu
Contractual Deadline	30/03/2024
Dissemination Level	PU - Public
Nature	R - Report
Author	Gabriela Espinosa (BSC)
Contributors	
Reviewers	Susana Castel (FrontWave), Ana Rodríguez (VHIR)

European Innovation Council

Funded by the European Union

UK Research and Innovation

The QUSTom project has received funding from the European Union's Horizon Europe research and innovation programme under the Grant Agreement Nº 101046475, and for the UK partner from the United Kingdom Research and Innovation ("UKRI") under the UK Government's Horizon Europe Guarantee with UKRI Reference No. 10038375.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Innovation Council. Neither the European Union nor the granting authority can be held responsible for them.

Change Log

Version	Description of Change
V1.0	Initial draft for internal review
V1.1	Reviewed by Mireia Cos
V1.2	Reviewed by Josep de la Puente
V1.3	Reviewed by Susana Castel
V1.4	Review Meeting suggestions implemented and additional formal review

Table of contents

1. Executive Summary

The purpose of the Management Plan and Quality Guidelines deliverable is to provide an overview of the internal management procedures for the QUSTom project, and to ensure both efficient project execution and high-quality project results. It will also serve as a support reference manual for project partners as it describes, in a comprehensible way, the governance structure, the reference project legal documents, the project management procedures and tools, and the reporting procedure. It also includes roles and responsibilities and the internal monitoring process for project progress.

Planning the management procedures contributes to the Management objectives of the project and will indirectly influence its technical implementation by ensuring an efficient working environment.

This living document may be updated during the project lifetime (as a parallel document used for internal monitoring). This deliverable is necessary to achieve all project objectives and milestones successfully.

2. Project Coordination and Management

QUSTom comprises five partners from three EU Member States and one Associated Partner from the UK. This section describes the Consortium's governance bodies' organisation and the planned meetings and interactions for optimising the project implementation.

2.1 Governance Structure

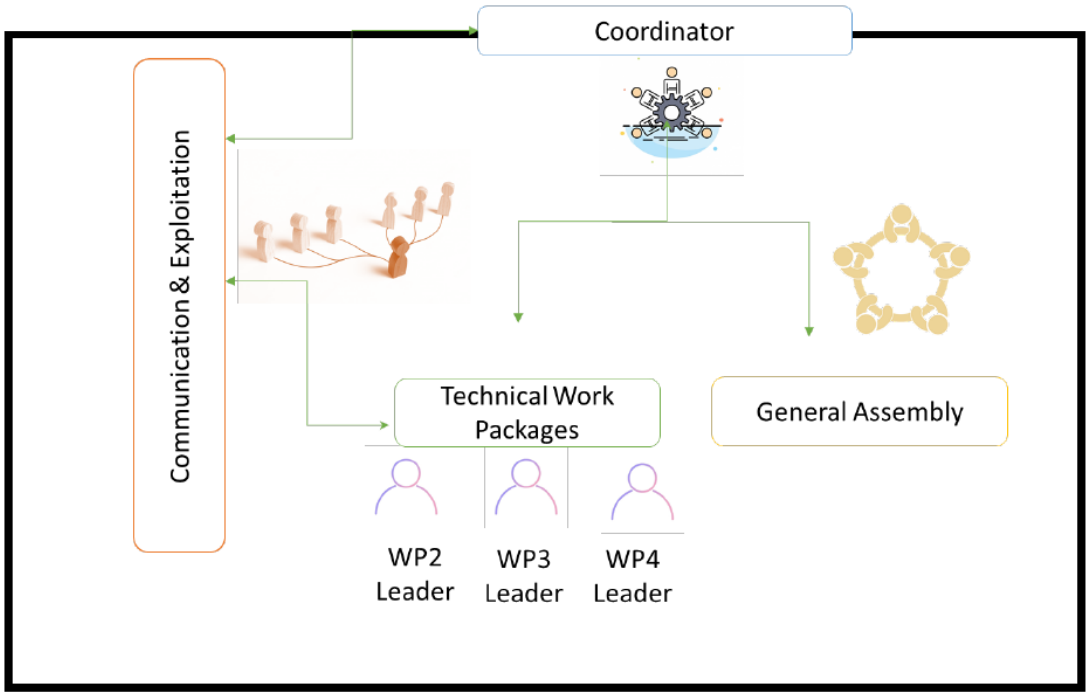

Figure 1. *QUSTom Management Structure*

2.1.1 Project Coordination

The Barcelona Supercomputing Center will serve as the Coordinator of the QUSTom project. This role will be shared between the General Manager (GM) and the Project Manager (PM) under the leadership of the Principal Investigator (PI).

The Principal Investigator (PI), Josep de la Puente, will drive the project's overall strategic agenda and ensure that the project's scientific and technical objectives are met on time and within budget. The PI will be responsible for regularly reporting to all partners' General Assembly (GA).

Josep de la Puente will be the General Manager (GM), who chairs the General Assembly and performs the day-by-day management of the project by coordinating and supervising the Work Package leaders (WPLs) activity. Moreover, the GM organises technical presentations of project progress to external parties and ensures the appropriate involvement and visibility of the project members. The GM will also identify and track possible problems and propose suitable corrective actions (e.g. resource reallocation, task force creation).

The Project Manager (PM), Josep Casellas, will act as the official key contact between the Commission and the Beneficiaries and will be responsible for the day-to-day administration of the project, including, but not limited to: organising meetings, taking and distributing minutes, and the general legal, financial and administrative management and Periodic Reports and Financial Statements. The PM will help to ensure the timely delivery of project objectives and deliverables by continuously monitoring the project's progress against the plan. The PM will also be responsible for quality assurance. The PM will report to the GM.

2.1.2 Management Board (MB)

The Work Package Leaders (WPLs) are responsible for the scientific and technical work of their respective Work Packages, see Figure 2. These tasks include planning and controlling all activities within the Work Package, preparing deliverables and collecting the contributions from other partners participating in the respective Work Packages for internal and external reports. They will meet regularly via teleconference or face-to-face as a part of the Management Board (MB) and arrange for additional technical meetings when necessary. They are expected to raise critical issues in the Technical Board and to support General Manager in coordinating cross-work package relationships within the appropriate activity area. They must actively participate in the regular project-related meetings as well as prepare technical and status presentations as required. Each WPL is appointed by the organisation responsible for the respective WP. The WPLs may nominate separate task leaders when necessary. The WPLs report to General Manager.

The QUSTom teams and work package leaders are:

- WP1 Josep Casellas (BSC)
- WP2 Natalia Gutierrez (FrontWave) / Susana Castel (FrontWave)
- WP3 Nicole Ruiter (KIT)
- WP4 Ana Rodríguez (VHIR)
- WP5 Maria Paz Baghetti (BSC) / Joan Farnós (BSC)

Figure 2. *Description of WPs and their relation to TRL increase.*

Three technical work packages are related to the scientific exploration of the imaging algorithms (WP2, TRL 2), technical development of hardware and software (WP3, TRL 3) and clinical validation (WP4, TRL 4) within 24 months. On top of that, a management work package (WP1) will oversee the proper functioning of the project, and an exploitation/communication work package (WP5) will take care of outreach, dissemination and aspects related to IP management.

2.1.3 Partners

The project has five partners and one associated partner from different countries with the responsibility to:

- Execute and deliver the agreed work defined in the DoA.
- Proactively report any problem or unforeseen deviation to WPLs and PM.
- Coordinate the project contributions carried out by their staff.
    - Report technical and financial work on time.
    - Notify the Consortium of changes in the contact data of the partner.

2.1.4 General Assembly

The General Assembly (GA) is the formal decision-making body with the highest authority level in the project. It is also responsible for resource allocation, the review/approval of the Periodic Reports and Deliverables, the preparation of project reviews, and the coordination of exploitation plans. The Principal Investigator chairs it and consists of one representative from each partner. The GA is formally responsible for successful project completion. The General Assembly makes decisions by consensus when possible. In the case that it cannot be obtained, the GA puts decisions to a vote that is decided by a simple

majority. In the event of a tie vote, the PI casts the deciding vote. The PM will act as GA secretary and support the PI in leading the activity of the GA. The GA meets monthly with the Project Supervisory Board (PSB), bringing together GA members, Technical Committee, and all Managers and accepts any project participants in an informative role.

Participant nr.	Participant organisation name	Part. short name
1	Josep de la Puente	BSC
2	Susana Castel	FrontWave
3	Nicole Ruiter	KIT
4	Martina Murovec	ARCTUR
5	Ana Rodríguez	VHIR
6	Oscar Calderón	IMPERIAL

Table 1 – *QUSTom General Assembly*

2.1.5 Dissemination Manager

The QUSTom Dissemination Manager (DM), María Paz Baghetti, from BSC, ensures the project results are disseminated according to the Dissemination Plan (D5.1). In addition, the DM provides templates for project deliverables and presentations, guidelines for project visual identity and publications, and recommendations for increasing the visibility of the action.

2.1.6 Innovation Manager

Joan Farnós (PIM) will fulfil a key role in coordinating the various exploitation activities. With the contribution of the whole Consortium, the PIM will be responsible for developing a rolling Exploitation Plan and setting up the exploitation strategies.

- **Identification of exploitable project outcomes**, including interim and final results to conclude on potential commercial services, business ideas and exploitation pathways.
- **Intellectual Property Rights (IPR)** protection of the individual codes and toolkits developed in QUSTom. In order to ensure a smooth execution of the project, the project partners will define the details concerning the Access Rights for Exploitation to Background and Results in the Consortium Agreement (CA).

- **Analysis of the exploitation context and business opportunities** to determine the actual market situation for the application covered in the project.
- **Assessment of the competitive environment** of the project: technology readiness, integration, standardisation and regulation, policy framework at the targeted markets, and future trends at the social, business and policy levels.
- **Dissemination activities** related to the exploitation of the results, such as publications in international conferences and journals, and presentation of results in trade fairs, workshops and related events or press releases in technical media

2.1.7 Regulatory Manager

Cristina Durán (RM) will fulfil a key role in coordinating regulatory activities. The function of a Regulatory Manager is to combine knowledge of scientific, regulatory and business issues to enable products that are developed, manufactured or distributed to meet required legislation.

Core responsibilities for this function include:

- **Evaluate regulatory risks** of processes and procedures.
- **Provide regulatory input** to product lifecycle planning.
- **Monitor regulatory outcomes** of initial product concepts.
- **Identify emerging issues**.
- **Anticipate regulatory obstacles** and emerging issues throughout the product lifecycle and develop solutions.

2.1.8 Equality Manager

The QUSTom Equality Manager (EM), Maria Paz Baghetti, from BSC, coordinates the Gender Equality Committee. The responsibilities include the following tasks and activities:

- **Collect, analyse and disseminate** relevant, objective and reliable statistical information on gender issues within the Consortium.
- **Contribute** to the implementation of QUSTom surveys and survey data analysis.
- **Support** the improvement of existing gender-sensitive data/indicators and promote further disaggregation of data according to gender and other social characteristics (e.g. age, ethnicity, education).

- **Produce** comparative statistical data and gender analysis addressing stakeholders' needs for communication purposes.
- **Initiate and organise** meetings to support the QUSTom gender Equality work.

2.2 Meetings

The First Project Meeting. The kick-off meeting was celebrated at BSC's premises in Barcelona on 4-5 April 2022 with the objective of establishing the basis of the project and first tasks. The presentations from all the partners and the minutes of the meetings are available in the internal repository.

GA Meetings. The GA meetings will hold monthly conference calls (Zoom) to evaluate progress, assess risks, and take any decision needed to meet the project goals timely. The GA Meetings will be organised by the GM together with the PM. The GM and PM will prepare the meeting agenda, chair the meeting, and provide the meeting minutes at the end of the event.

PSB Meetings. The PSB gathers the GA members, Technical Committee and Managers. The meeting is held monthly on the same day and format as the GA meetings. The members of the PSB and their roles are shown in the following table:

Who	Role
Josep de la Puente	PI, GM and GA
Josep Casellas	WP1
María Paz Baghetti	Dissemination and Equality Manager
Joan Farnós	WP5 and Exploitation Manager
Susana Castel	GA
Cristina Durán	Regulatory Manager
Natalia Durán	WP2
Nicole Ruiter	WP3 and GA
Martina Murovec	WP3 and GA
Ana Rodríguez	WP4 and GA
Oscar Calderón	GA

Table 2 – *PSB members.*

WP Meetings. Each WPL might organise biweekly or monthly online meetings to monitor and coordinate the activities inside their respective WP. Moreover, bilateral WP Meetings will be organised whenever necessary to address the dependency between the various QUSTom WPs.

The WPLs will prepare the meeting agendas, chair the meetings, and provide the meeting minutes at the end of the event.

The minutes from all QUSTom meetings will be made available to the Consortium through the B2DROP repository (described later).

To help with the time planning of the various administrative and technical gatherings, all WPLs have access to a shared QUSTom calendar of meetings and events.

2.3 Conflict of interest

Goodwill to avoid any conflict of interest and to act in good faith is essential for the success of the QUSTom project. When Beneficiaries identify conflicts of interest that cannot be resolved through bilateral communication, they should immediately bring the issues to the attention of the PI. The PI will present the issue to the General Assembly for discussion and hold a vote if required. According to the Consortium Agreement, the General Assembly shall strive to make decisions by consensus. If consensus cannot be achieved, a majority of two-thirds shall take decisions on proposals. If it is impossible to obtain a majority of two-thirds, after 30 minutes, a second ballot shall take place, and a simple majority of the cast votes shall take the decision. In case of a tie, the PI will have a casting vote.

2.4 Emergency procedures

Any event that may jeopardise the project's overall completion should be reported immediately to the PI. The PI will resolve the issue as soon as possible by calling an emergency General Assembly Meeting to determine the next steps.

3. Project Coordination and Management

3.1 Grant Agreement

The Grant Agreement is the main legal document underpinning the project's execution. It is a contract between the project participants and the European Commission. The Grant Agreement mainly provides information on the grant (parties, duration, start date, budget, maximum funding, etc.), obligations of the beneficiaries towards the funding agency (such as reporting requirements), as well as the intellectual property framework and other legal conditions. The QUSTom Grant Agreement is dated on the 1st of April 2022 and has number 101046475.

Beyond its core terms and conditions, mostly standard text, the Grant Agreement also includes the following annexes, which form an integral part of the contract:

- Annex I. Description of the action (DoA)
- Annex II. Estimated budget for the action
- Annex Ill. Accession form for beneficiaries
- Annex IV. Model for the financial statement
- Annex V. Specific Rules

The most extensive and important Annex to the Grant Agreement is the Description of Action (DoA), which comprises the technical description of the work to be undertaken in the project (work packages, tasks, deliverables, milestones), the description and roles of the different partners, allocated efforts in person-months, and budget details.

3.2 Consortium Agreement

The Consortium Agreement (CA) is set among the project participants and aims to provide a legal framework for their collaboration within the boundaries of the Grant Agreement. The CA includes governance, intellectual property, dissemination, and liability provisions, among others. The funding agency is not a party to the CA.

3.3 Changes to the Grant Agreement

The Grant Agreement can and must be changed when an important project parameter changes: partnership, duration, budget, etc. Implementing such changes must follow a specific "Grant Agreement Amendment" procedure. Most changes that trigger Grant Agreement Amendments relate to updates in the DoA

(e.g., changes in tasks and deliverables, changes in efforts allocated to partners, changes in partner's teams, budget transfers across participants, etc.). Changes tend to be grouped and implemented simultaneously in an amendment whenever possible.

Grant Agreement amendments are submitted to the Funding Agency through the Funding and Tenders Portal by the Coordinator on behalf of the Consortium. This implies that the Consortium must be informed and agree on the proposed changes before the amendment is requested. The PM will be responsible for preparing and following up on the Grant Agreement amendments during the project. Participants should contact the PM and GM for any modification they consider necessary. The PM should contact the Project Officer to inform him/her about the proposed changes before launching the amendment officially through the Portal.

4. Internal communication

Establishing internal communication channels is essential in order to ensure proper project implementation. The QUSTom Consortium will use electronic mail as the main tool of communication and will document all meetings by means of agendas and minutes, which will be made available through the official project repository (B2DROP).

4.1 Mailing lists

The following mailing lists have been created to facilitate internal communication:

gustom@bsc.es: All QUSTom contacts

gustom_core@bsc.es: PIs

gustom_mngt@bsc.es: Financial and Managerial issues contacts

gustom_ipr@bsc.es: Legal issues contacts

gustom_WP2@bsc.es: WP2 participants

gustom_WP3@bsc.es: WP3 participants

gustom_WP4@bsc.es: WP4 participants

gustom_WP5@bsc.es: WP5 participants

gustom_GEC@bsc.es; Gender Equality Committee

gustom_support_IP@bsc.es: Exploitation contacts

The PM manages the mailing lists and is responsible for granting access to any new QUSTom team member.

4.2 B2DROP repository

A project repository (hosted by BSC and accessed by all project participants) has been created to keep track of project results and other documents useful for project implementation (such as the Consortium Agreement and QUSTom Grant Agreement). An overview of the B2DROP repository structure is illustrated in Figure 3.

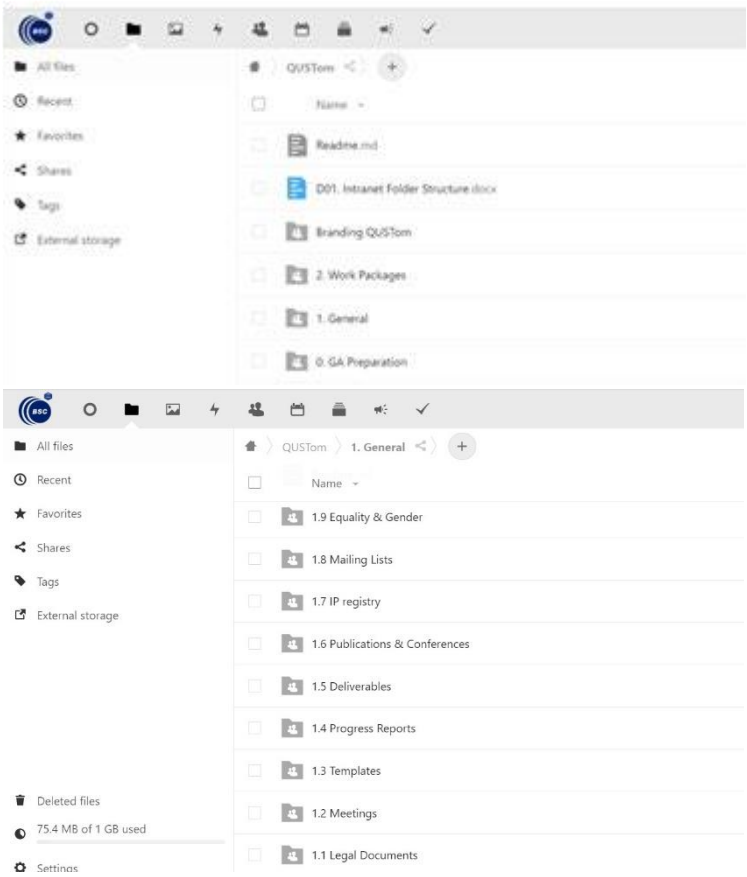

Figure 3. *QUSTom B2DROP repository structure.*

5. Project management procedures and tools

5.1 Financial management

To continuously monitor the QUSTom project's financial status, the partners must provide information about the project expenses every eight months. The PM will provide an internal monitoring template, where they must indicate the person months incurred across the WPs they are involved in and other costs together with their justification. This exercise allows the project coordination team to detect any potential deviation and take corrective actions when necessary.

5.2 Deliverable quality criteria and review procedure

Project deliverables are the outcome of the project implementation across the various WPs. As a general rule, the creation of deliverables is the responsibility of the corresponding WPLs, who must gather contributions from WP participants as appropriate. Prior to submission on the Funding and Tenders Portal, deliverables are examined for quality and undergo an internal review process, as detailed in subsections 5.2.1 and 5.2.2, respectively.

The QUSTom deliverable template, including a general deliverable structure, was shared with all partners and is available on the B2DROP repository.

5.2.1 Deliverable Quality criteria

The deliverable review procedure uses the following quality criteria as reference:

- **Completeness.** The document must address all aspects related to the purpose for which the information is produced. Information redundancy must be avoided, as it may obscure the clarity of the deliverable. Information should be provided to the depth needed for the purpose of the document.
- **Accuracy.** The information provided in the deliverable must be evidence-based. This means relevant and up-to-date references should support all factual information in the deliverables.
- **Relevance**. The information provided in the deliverable should focus on project key issues and be written in a way that takes into consideration its target audience.
- **Adherence to a uniform appearance.** All deliverables must be prepared following a uniform appearance and structure, as they originate from the same initiative (project). Therefore, the official QUSTom template must be used for all deliverables.

5.2.2 Review procedure

The Deliverable Review Procedure ensures that the document has been reviewed against the quality criteria described above. The 21 Deliverables planned for QUSTom have been distributed for review among the four partners. This does not exclude other partners not appointed as reviewers, who can provide comments on the different deliverables if they wish to do so. The list of deliverables and their corresponding authors and assigned reviewers were discussed and agreed upon among the partners and are available on the B2DROP repository.

The following table summarises the internal deliverable review process established to ensure their timely submission.

Timeframe	Review steps
5 weeks before the deadline	The PM reminds the author of the upcoming deliverable/s and informs about the appointed reviewer indicating when the draft should be ready for review.
3 weeks before the deadline	The author sends the draft deliverable to the appointed reviewer for comments.
2 weeks before the deadline	The appointed reviewer returns their comments to the author (Track changes document).
5 days before the deadline	The author sends the consolidated deliverable back to the reviewer.
2 days before the deadline	The reviewer confirms that the deliverable is accepted, and the author sends the final version to the PM.
Submission deadline	The PM reviews the format and deliverable label before uploading the document to the Funding and Tenders Portal.

Table 3 – *Deliverable Review procedure.*

All the reviewers must provide constructive suggestions for improvement in writing to the Deliverable Owner. Upon receiving the suggestions for improvement, the Project Manager works with the Deliverable Owner to determine the schedule to complete the Deliverable.

5.2.3 EC Reports

There are two official reporting periods (M1-M12 and M13-M24) with two deliverables associated:

- D1.5 Midterm technical & Scientific review meeting document
- D1.6 Final Technical & Scientific review meeting document

5.2.4 Reporting Calendar

All the reporting periods (internal and EC) are summarised below:

- M1-M8: First Internal QR
- M1-M12: Mid-term Report
- M13-M20: Second Internal QR
- M1-M24: EC Final Report

5.3 Milestones management

At the end of each phase in the project, a milestone is set up to perform key technical reviews and make strategic decisions to guarantee that the project's progress is aligned with project objectives. Table 4 presents the QUSTom milestones, while the means of verification for each of them can be found in the DOA.

Milestone number	Milestone name	Related WPs	Due date (month)	Means of verification
MS1	Consortium Agreement	1	0	Signature by all partners
MS2	Project website live	5	3	Live and announced
MS3	Gender and equality committee	1	3	Guidelines communicated at the Consortium level
MS4	3D-USCT-III device assembled	3	6	Specifications and initial calibration shared
MS5	3D-USCT-III prototype installed in the hospital	4	9	VHIR acknowledges installation
MS6	Authorisation to conduct a study at the hospital	4	9	Favourable decision by the hospital ethics committee

MS7	Scientific suitability of UQ-FWI assessed	2	12	Report shared and UQ-images clinical feasibility study full scope agreed upon by VHIR -> TRL3 achieved
MS8	Live repository	5	12	Live and announced
MS9	Project workshop	5	18	Recording of presentations
MS10	Final version of UBIware	3	18	Version with documentation uploaded and deployed.
MS11	Clinical feasibility study finished	4	21	Results shared internally with all partners (D4.2) -> TRL4 achieved
MS12	White paper	5	24	Published at project website

Table 4 – *Milestones.*

WP number	Work package title	Lead participant	Start month	End month
1	Project Management	Barcelona Supercomputing Center	1	24
2	Image and Uncertainty Generation	Imperial College London	1	24
3	Technology Enablement	Karlsruher Institute für Technologie	1	24
4	Clinical Validation	Vall d'Hebron Institut de Recerca	1	24
5	Exploitation, Communication and Dissemination	Barcelona Supercomputing Center	1	24

Table 5 – *List of Work packages.*

Task number	Tasks	Lead participant	Start month	End month
1.1	Administrative and Financial Management	BSC	1	24
1.2	Technical Coordination	BSC	1	24
1.3	Internal communication, Quality and Risk management	BSC	1	24
1.4	Gender and equality committee management	BSC	1	24
2.1	FWI with uncertainty quantification	FrontWave	1	12
2.2	Multiparameter extension	FrontWave	7	18
2.3	Extension of uncertainty quantification to other modalities	FrontWave	13	24
3.1	Assembly of 3D- USCT-III device	KIT	1	6
3.2	Preparation of device in validation study	KIT	7	9
3.3	Setup of 3D-USCT-III device and adaptation to full-waveform inversion	FrontWave	1	9
3.4	Development and optimisation of 3D HPC inversion software	ARCTUR	1	21

3.5	Co-design of current and 3D-USCT-IV device	KIT	10	24
4.1	Regulatory management	FrontWave	1	18
4.2	Ethics management	VHIR	1	9
4.3	Adaptation of novel imaging to clinical image analysis environment	FrontWave	7	9
4.4	Installation, preliminary calibration and diagnosis suitability	VHIR	10	12
4.5	Clinical validation	VHIR	13	21
4.6	Clinical trial preparation	VHIR	22	24
5.1	Dissemination and communication activities	BSC	1	24
5.2	IP registry and exploitation	BSC	7	24
5.3	Open repository	BSC	7	21

Table 6 – *Task distribution.*

5.4 Risk management

The level of complexity in the QUSTom project, which includes the design of a prototype in a short period of time, needs continuous collaboration throughout the project to deal with risk assessment, planning, and implementation of responses

and/or contingency measures. This role is taken in the QUSTom project by BSC, assisted and supported by the PMT in the framework of WP1. The Risk Management Plan will be completed in full detail with the Development of this Work Package, particularly under the execution of Task 1.3 and the production of Deliverable D1.1.

Task 1.3: Internal communication, Quality and Risk management will ensure Project Implementation Risks (non-technology related risks). BSC will develop a risk management strategy, including risk identification, qualification/ quantification, and risk response planning, and will be updated throughout the project. This will ensure proper cooperation, the development of grant agreement revisions (as needed), the accuracy and timeliness of financial and administrative processes, decision-making issues, communication concerns, IP leakage, etc.

5.4.1 Risk management procedure

Risk management aims to identify and manage those things that, should they occur, would prevent an organisation from achieving its objectives. It accomplishes this by calculating both the risk's impact, how severe the risk's consequence will be if it occurs, and the probability that the event will occur.

The risk management process described in Task 1.1 consists of activities that allow risk to be assessed, communicated and addressed appropriately throughout the project. The process will be repeated in the project's various work packages and phases. WP2 and WP3 look into technology-related risks with respect to the QUSTom idea, including reliability, environmental, health and safety aspects to be taken into account in the design.

The risk procedure aims to support better decision-making by understanding risks, their causes, likelihood, impact, timing and the choice of responses.

The Risk Management Process (Figure 4) includes five sequential steps: Planning, Identification, Analysis, Evaluation and Treatment. Two additional transversal activities include the Monitoring and Review of the RMP.

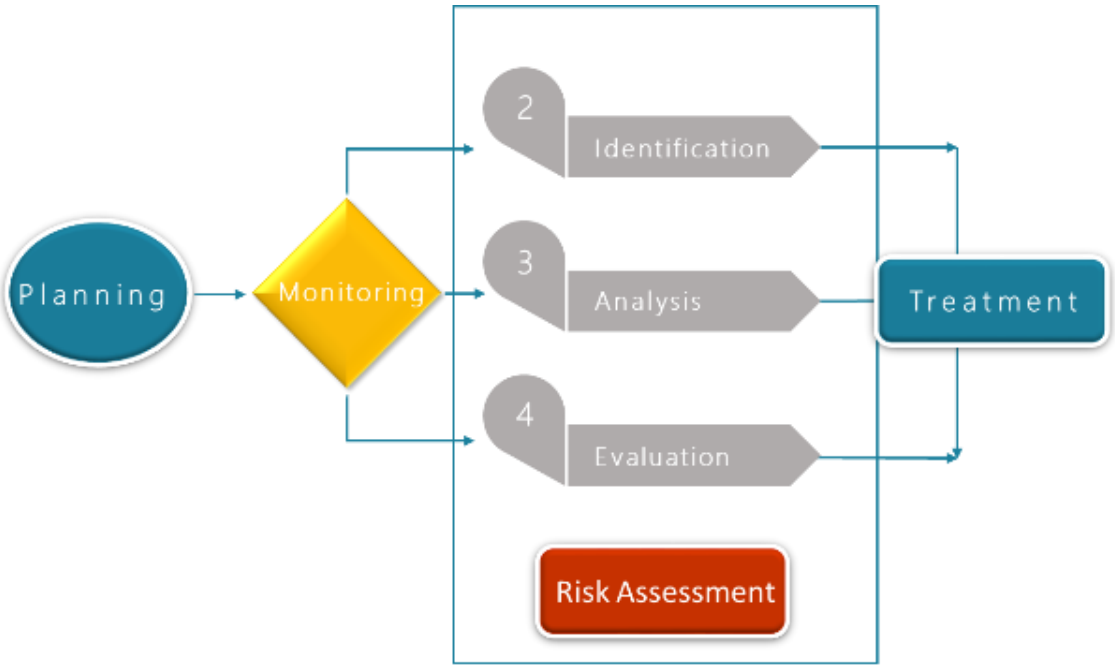

Figure 4. *Risk Management Process.*

When managing the risks, clear roles and responsibilities are necessary:

- Risk owner: the person responsible for managing, monitoring and controlling all aspects of a particular risk.
- Risk responsible: the person assigned to carry out a risk response action/s to respond to a particular risk.

5.4.2 Risk Register

The risk register should be updated regularly, and updates can happen anytime. However, to ensure that the register is actively reviewed and updated, a scheduled process should be in place by Management Team to maintain effective monitoring.

There are three processes outlined which should attach to the maintenance of the register:

- Updating existing risks on the register
- Identifying and adding risks to the existing register
- Reviewing the entirety of the register

The Risk Register will keep track of risk management actions. The Project Management Team will evaluate and update the Risk Register as part of their project control efforts.

It is recommended that the risk register should be reviewed on a two-month basis at the relevant Management Team meeting but at a minimum every quarter.

A preliminary Risk Register structure (see Figure 5) is recommended during the kick-off meeting, which will be detailed in the Project Risk Management Plan.

#	Risk Title	Risk Description / Impact	Status	Owner	Identified Date	Risk Category	Risk Rating
001	New Hirings	Possible delays in appointment of personnel (low/low)	Open	1	1-May-21	Organizational	Low
002	Departure of key personnel	Departure of key personnel from participants (low/low)	Open	All	1-May-21	Organizational	Low
003	Imaging	Unsatisfactory compatibility of UQ-FWI images for diagnosis (medium/high)	Open	2, 4	1-May-21	Resource	High
004	Hardware	Delays in production of USCT hardware (low/high)	Open	3	1-May-21	Project	Medium
005	Ethical Aprooval	Delays in approval of the ethics committee of Vall d'Hebron hospital regarding clinical feasibility study (low/medium)	Open	4	1-May-21	Environment	Low

Figure 5. *Initial Risk Register.*

An initial table of potential risks and mitigation actions was already provided in the proposal (Table 7). Those risks will be reevaluated, as well as new risks added to the Risk Register.

Critical risks (likelihood/severity)	WPs involved	Proposed mitigation measures
Possible delays in the appointment of personnel (low/low)	1	The search for personnel and publication of job advertisements will be performed as soon as the project is accepted to minimise the likelihood. We will employ as many available resources as possible to mitigate hiring delays' impact.
Departure of key personnel from participants (low/low)	All	All institutions are well-staffed, and research groups belong to highly active departments. Replacements are likely to be found internally in a short time.
Unsatisfactory compatibility of UQ-FWI images for diagnosis (medium/high)	2, 4	The methods might not be sufficiently mature, clear or adaptable for clinical diagnostic purposes. The results, in any case, will have a high scientific value, and an analysis of the diagnosis suitability can still proceed with multiparameter 3D FWI, which, in itself, is a very high-impact technological development. Additionally, we will employ HPC to brute-force produce UQ of our models as an additional measure.

Delays in production of USCT hardware (low/high)	3	Due to electronic supply shortages or unexpected technical problems, the 3D-USCT-III device might suffer a delay in its assembly, transport and installation. In that case, KIT is in contact with other hospitals that can provide data on their clinical studies with 3D-USCT-II devices so that we can obtain partial conclusions and complement the necessarily shorter clinical feasibility study by VHIR.
Delays in approval of the ethics committee of Vall d'Hebron hospital regarding clinical feasibility study (low/medium)	4	We will start an approval request prior to the project's start in order to accelerate the process. If there are delays in the approval at the hospital, the measures will be similar to those exposed for the previous risk.

Table 7 – *Critical risks for implementation.*

5.4.3 Re-Rating Risk

After completing some or all steps, the rating may be reevaluated to see if the likelihood or impact score has decreased.

Whilst under active management, a risk has the status of being 'open'. After all, activities have been completed, and the risk has been mitigated, the status can be changed to either 'follow up'; or 'closed'.

6. Reporting and reviews

During the QUSTom execution period (from the 1st of April 2022 until the 31st of March 2024), the Consortium will have to submit one Final Report. In compliance with the Horizon Europe rules specified in Article 21.2 of the QUSTom Grant Agreement, the report must be submitted within 60 days following the end of the reporting period.

The report consists of a technical and a financial part describing the technical activities and costs incurred over the corresponding period specified above.

The PM will create a guide for QUSTom reporting, shared with all Consortium members and made available on the B2DROP repository. The guide includes screenshots and detailed instructions for adequate technical and financial reporting. If needed, additional webinars will be organised prior to the end of the reporting period.

6.1. Technical Report

The technical report is made of two parts:

1. PART A can be updated at any time during the project's lifetime. This has to be done through the Funding and Tenders portal under the Continuous Reporting Module. It consists of the following sections:

   - Summary for publication,
   - Deliverables, Ethics, DMP, Other Reports,
   - Milestones,
   - Critical Risks,
   - Publications,
   - Dissemination & Communication Activities,
   - Patents (IPR),
   - Innovation,
   - Open Data,
   - Gender,
   - ABS Regulation.

The Project Manager (PM) and all the other partners will be responsible for collecting and introducing the information in the appropriate sections for Continuous Reporting. Regarding the dissemination and exploitation of results, the Dissemination Manager (DM) will keep track of the project dissemination activities for the purpose of reporting. Participants will be asked regularly to send updates on any dissemination activity related to QUSTom. The DM will integrate all the available information in a general dissemination register.

2. PART B is the core part of the report and follows the template made available by the European Commission. It has to be uploaded to the grant management tool as a single document, including the following:

   - Details of the work carried out by all beneficiaries during the reporting period as per WP; and
   - An overview of the progress towards the project objectives, justifying any difference between the work described in Annex I (DoA) and the work actually performed.

The Project Coordinator, in close collaboration with the project partners, will be responsible for elaborating the Part B of the Periodic Technical Report and uploading the file to the Portal.

The final report must also include a 'Final technical report' with a summary for publication containing the following:

- an overview of the project results and their exploitation and dissemination,
- the conclusions on the action, and
- the socio-economic impact of the action.

6.2 Financial Report

6.2.1 QUSTom eligible costs

For incurred project costs to be eligible and therefore approved by the Funding Agency, they must fulfil the following general conditions:

- They must be incurred by the beneficiary.
- They must be incurred during the project's duration, except for costs relating to submitting the periodic report for the last and final reporting period.
- They must be indicated in the estimated overall budget in Annex II.
- They must be actual and necessary for carrying out the QUSTom implementation.
- They must be identifiable, verifiable and recorded in the participants' accounts.
- They must be registered in accordance with the usual accounting practices of the participant.
- They must comply with the applicable national law on taxes and social security.
- They must be reasonable, justified and comply with the principle of sound financial management, particularly regarding economy and efficiency.

6.2.2 Financial Statements for each beneficiary

The Financial Report is composed of Individual Financial Statements for each beneficiary, together with an explanation of the use of resources. Financial statements are specific documents in which each participant declares all the costs incurred over the corresponding reporting period.

The justification of costs is done through the Funding and Tenders Portal using the Periodic Reporting Module (made available to the participants after the end

of the corresponding reporting period by the Project Officer). Each beneficiary must fill in and detail their own expenses. Once the input information is complete, the beneficiary must electronically sign the Financial Statement. Only users with the role of Project Financial Signatory (PFSIGN) can perform this action. Once all Financial Statements have been signed by all beneficiaries (including the Coordinator), the Coordinator will check that all information is correct and include the Financial Statements in the Periodic Report composition.

The 'Final financial report' will also contain the following:

- A 'final summary financial statement', created automatically by the electronic system, and including the request for payment of the balance; and
- A 'certificate on the financial statements for each beneficiary who requests a total contribution of EUR 430,000 (excluding indirect costs) or more as reimbursement of actual costs and unit costs.

6.2.3 Explanation of the deviations from the planned budget

In addition to the financial statements for each beneficiary, an explanation of any significant deviation from the costs forecasted in Annexes I and II of the Grant Agreement should be provided in Part B of the Periodic technical report. Moreover, information on unforeseen subcontracting and unforeseen in-kind contributions provided by third parties (if any) should also be provided and properly justified. The PM will be responsible for collecting and compiling the information from all beneficiaries. To that end, every six months, the PM will monitor the effort and costs incurred by all partners as described in section 5.1 of this document.

6.2.4 Report submission

The Coordinator is responsible for approving the Financial Statements of each beneficiary and revising all information included in the Technical Report (Part A and Part B). Once all information is complete, the Coordinator will submit the Periodic Report to Funding Agency through the Funding and Tenders Portal.

6.3 Reviews

The Funding Agency conducts checks and reviews on the proper implementation of the action (including assessment of deliverables and reports). Reviews normally refer mainly to the project's technical implementation (i.e., its scientific and technological relevance) but may also cover financial and budgetary aspects

or compliance with other obligations under the Grant Agreement. The QUSTom reviews are scheduled for Month 13 (May 2023) and Month 25 (May 2024) in Brussels. However, dates and locations are tentative and subject to changes based on the flexibility and availability of the Project Officer, the selected reviewers, and the project partners, as well as the health recommendation at the respective time.

7. Specific rules for EIC actions

EIC Programme Managers and beneficiaries must communicate via the EIC Market Place; see Annex 5 MGA for more details.

When implementing EIC actions, the beneficiaries acknowledge and accept that they must attend regular (normally six-monthly) progress meetings if organised by the granting authority.

In addition, the beneficiaries must provide the granting authority with regular data and information on the implementation of the action (normally every three months) if requested by the granting authority and via the EIC Market Place.

The beneficiaries acknowledge and accept that EIC actions are part of (one or more) EIC Portfolio(s) managed by the granting authority and the EIC Programme Managers and, therefore, subject to the following specific portfolio-related conditions:

Programme Manager may:

- Request participation in EIC Portfolio activities (such as conferences, workshops, EIC Portfolio or networks meetings, experience and data sharing activities, and EIC Business Acceleration Service events, etc.)
- Propose or accept the organisation of EIC additional Portfolio activities (for EIC Pathfinder actions: the possibility of additional funding of up to EUR 50 000 to cover the related costs).

Appendix 1: Definitions

These definitions are predominantly based on the terms and definitions from the International Risk Management Standard ISO 31000:2009.

Controls	A mechanism, process, procedure or action that can be verified seeks to reduce a risk's likelihood and/or consequence. Controls include any process, policy, device, practice, or other actions which modify risk. They can exist or be required as additional in order to mitigate the risk further.
Impact	The outcome or consequence of an event affecting objectives. It can be expressed either qualitatively or quantitatively, being a loss, disadvantage or gain. There may be a range of possible outcomes associated with an event.
Likelihood	The chance of something happening (also described as the probability or frequency of an event occurring).
Monitor	To check, supervise, observe critically or record the progress of an activity, action or system regularly to identify change.
Operational Risk	Operational risks relate to the day-to-day delivery of activities, operational business plans and objectives. Operational risks typically have a short-term focus. Whilst they may affect a number of areas of the service, this does not necessarily, make them a strategic risk. Operational risks may have the ability to impact strategic and other operational risks.
Project Risk	Project risks relate to achieving and delivering the project objectives and outcomes. The majority of project risks are short-term in nature and exist for the term of the project, whilst some will be ongoing and re-classified at the end of the project. Projects can be defined as temporary to deliver outcomes within a specified timeframe.
Risk	Risk is the effect of uncertainty on objectives. It is measured in terms of consequences and likelihood.
Risk Categories	The categories used by the organisation to group similar opportunities or risks to report and assign responsibility
Risk Criteria	Terms of reference against which the significance of a risk is evaluated.
Risk Identification	A systematic process applied to the organisation's objectives and activities to identify possible risk sources and causes and potential consequences or impacts should a risk occur.
Risk Management	Coordinated activities to direct and control an organisation with regard to risk.
Risk Matrix	Tool for ranking and displaying risks by defining ranges for consequence and likelihood

Table 8 – *Risk Management Standard.*