Catalan Clinical Audit
Network for Quality Improvement
in Radiotherapy

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Risk Management Framework

D1.3

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DOCUMENT HISTORY

Version	Date	By whom	Main area of changes
0.1	February 11, 2026	Anna Ponce	Template with main sections.
0.2	March 4, 2026	Núria Jornet	Several items have been added and the risks have been revised.
0.3	March 18, 2026	Carlota Monfà and Diego Jurado	Executive board revision.

SUMMARY SHEET

Project Name	CAT-ClinART
Title of the document	Risk Management Framework
Deliverable	D1.3
Work Package	WP1
Program	EU4Health
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Summary	Deliverable 1.3 outlines a comprehensive risk management framework that encompasses risk identification, assessment, and mitigation strategies for priority risks. It defines a structured approach to addressing potential challenges and opportunities, thereby strengthening decision-making processes and supporting the successful implementation of the project.

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1. Executive Summary

1.1. Introduction

The implementation of the project may be affected by critical risks, uncertainties, and operational challenges that could compromise timelines, deliverables, or overall objectives. This document identifies the main risks associated with the project and outlines the corresponding mitigation strategies. For each identified risk, the risk score, the potential impact, and the likelihood of occurrence are assessed using a three-level scale (high, medium, low). This structured approach ensures transparency, strengthens accountability, and facilitates proactive decision-making throughout the project lifecycle.

Uncertainty and unforeseen events are inherent to any organisation, regardless of its level of performance or governance maturity. Conducting a systematic risk analysis enables early identification of potential barriers that may delay or hinder project activities. Implementing a robust risk management strategy is therefore essential to minimise disruption, enhance organisational resilience, and ensure effective and timely project execution.

1.2. Objectives

The objective of Deliverable 1.3 is to establish a comprehensive and systematic Risk Management Framework that supports effective project governance and implementation. Specifically, it aims to:

- Ensure the structured identification and categorisation of risks that may affect the achievement of the project's objectives and expected results.
- Assess the likelihood and potential impact of identified risks using a transparent, consistent, and clearly defined methodology.
- Define appropriate mitigation and contingency measures for priority risks.
- Support evidence-based decision-making by the Project Management and Steering structures.
- Enable continuous monitoring, review, and updating of risks throughout the project lifecycle.

1.3. Outline

Critical risks and mitigation measures of the CAT-ClinART project are summarised here and described in greater detail in this document, including their potential impact, likelihood, and proposed mitigation measures.

- **Missed deadlines and/or deliverables**

Risk of delays in project activities or unmet deliverables due to unforeseen challenges, resource limitations, or technical issues, potentially impacting the overall timeline and project objectives.

- **Work Package (WP) leader unavailability**

Risk that a WP leader becomes unavailable, potentially disrupting coordination and affecting timelines and project.

- **Development of wrong audit procedures**

Risk of designing or implementing audit procedures misaligned with project objectives, leading to ineffective data collection, inaccurate assessments, and reduced project credibility

- **Technical challenges**

Risks of technical issues in dosimetry audits and automated Quality Indicators (QIs) extraction, including equipment availability, data variability, system integration, and scalability, potentially affecting timelines and data variability.

- **Lack of candidates for clinical auditors**

Initially identified risk of limited auditor availability, now largely mitigated through the training of 11 auditors and involvement of project coordinators; remaining constraint related of limited Radiation Therapy Technologists (RTTs) availability.

- **Lack of experts' engagement for training and conducting the first supervised audits**

Initial risk of limited expert availability, now mitigated through successful completion of most supervised audits and reduced dependency on external experts.

- **Stakeholders' resistance**

Risk of limited participation from healthcare professionals or institutions, potentially restricting data access, delaying activities, and affecting project outcomes.

- **RTTs not allowed to act as auditors**

Risk that RTTs may not obtain permission to participate as auditors due to clinical workload constraints, potentially impacting audit implementation and project objectives

2. Critical Risks and Mitigation Measures

The key project risks, along with the corresponding WP to which each risk pertains, are summarised below. Each risk is described in detail in this section, including its potential impact, likelihood, and proposed mitigation measures.

1. **Missed deadlines and/or deliverables**
   - WP1/2/3/4/5/6
2. **WP leader unavailability**
   - WP1/2/3/4/5/6
3. **Development of wrong audit procedures**
   - WP4
4. **Technical challenges**
   - WP4
5. **Lack of candidates for clinical auditors**
   - WP4
6. **Lack of experts' engagement for training and conducting the first supervised audits**
   - WP5
7. **Stakeholders' resistance**
   - WP6
8. **RTTs not allowed to act as auditors**
   - WP4/6

2.1. Missed Deadlines and/or deliverables

There is a risk that project activities may experience delays or that deliverable deadlines may not be met due to unforeseen challenges, resource constraints, or technical difficulties. Depending on the affected WP, such delays could compromise the overall project timeline and the achievement of project objectives.

- **Risk Score:** Medium
- **Impact:** High
- **Probability:** Low

2.1.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Implement a robust progress monitoring system to track tasks and milestones across all WPs. The first level of oversight will be ensured within WP3, with escalation to WP1 when higher-level coordination or intervention is required.
- Conduct regular schedule assessments to identify deviations early and implement corrective actions as necessary.
- Map task dependencies and identify critical paths to prioritise monitoring and coordination efforts.
- Ensure close coordination of independent tasks to prevent delays cascading across the project.

2.2. WP Leader Unavailability

There is a risk that a WP leader may be unable to continue participating in the project due to unforeseen circumstances. Such unavailability could temporarily disrupt project coordination and may affect timelines and the achievement of project objectives.

- **Risk Score:** Low
- **Impact:** Low
- **Probability:** Low

2.2.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Identify and appoint a co-leader for each WP to ensure continuity of leadership and maintain effective coordination in the event of a WP leader's unavailability.
- Monitor and address this risk within WP3 as part of overall project follow-up
- Maintain clear documentation of responsibilities and ongoing tasks to facilitate seamless handover if required.
- Ensure regular communication and reporting between the WP leader and co-leader to minimise the impact of any unexpected absence.

2.3. Development of Wrong Audit Procedures

There is a risk that clinical audit procedures may be developed or implemented in a manner that is not fully aligned with project objectives. Such procedures could lead to ineffective data collection, inaccurate assessments, overlooked issues, and potential loss of credibility for the project.

- **Risk Score:** Low

- **Impact:** Medium
- **Probability:** Low

2.3.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Establish a dedicated assessment team to promptly identify and evaluate any issues arising from incorrect audit procedures, implement corrective actions, and ensure thorough documentation of the process.
- Maintain clear and timely communication with all relevant stakeholders regarding corrective actions and updates.
- Organise regular training sessions and workshops for consortium members to ensure they remain up-to-date on correct audit procedures, methodologies, and best practices.
- Conduct structured debriefing meetings are organised after each audit cycle to mitigate the risk of deviation from the established clinical audit guidelines and methodology. These meetings bring together the auditors and representatives of the audited department, with a specific focus on reviewing the *application of the audit methodology* rather than discussing audit results.

  The objective is to critically assess whether the audit was conducted in full alignment with the agreed QUATRO-based framework, checklists, and procedural standards developed in WP4. Any inconsistencies, ambiguities, or practical challenges encountered during implementation are systematically identified and documented.

  If methodological gaps or the need for clarification are detected, corrective actions are defined early. This may include refining checklists, updating guidance documents, or adjusting procedural elements. Any revised components of the methodology are subsequently tested and validated in the following audit cycle before formal consolidation.

  This structured feedback mechanism ensures continuous methodological alignment, prevents drift from agreed standards, and strengthens the robustness, reproducibility, and long-term sustainability of the regional clinical audit model.

2.4. Technical Challenges

Technical risks may arise in the implementation of dosimetry audits and in the automatic extraction of QIs. For dosimetry audits, delays may occur due to pelvis phantom availability or potential equipment malfunction. Regarding QIs, challenges related to data variability, system integration, data quality, and scalability across centres may affect timelines and the reliability of collected data. These issues could delay project activities and impact methodological robustness if not proactively managed.

- **Risk Score:** Medium

- **Impact:** Medium
- **Probability:** Medium

2.4.1. Proposed Risk-Mitigation Measures

To mitigate operational risks in the dosimetry component:

- A formal agreement has been secured with the pelvis phantom manufacturer to guarantee availability within the required audit timeframe, thereby minimising the risk of scheduling delays.
- An intercomparison exercise has been successfully performed with dosimetry equipment from another participating centre. This ensures technical compatibility and enables rapid deployment of alternative equipment in case of breakdown or malfunction, safeguarding continuity of audit activities. Any technical challenges identified will be communicated to WP3 and WP1 for their respective follow-up and handling.

Automatic extraction of QIs. In line with the project's Risk Management Framework, the following measures have been established to address potential technical challenges related to QI extraction:

- Hire a dedicated IT specialist with experience in medical record data extraction to oversee technical implementation and ensure data quality.
- Explore opportunities to involve volunteers or interns from academic institutions who can contribute their technical skills with reduced cost.
- Engage IT experts from participating institutions to provide technical guidance, support problem-solving, and validate solutions.
- Monitor technical workflows regularly to identify and address potential bottlenecks or errors promptly.

2.5. Lack of Candidates for Clinical Auditors

At the proposal stage, there was a potential risk related to the limited availability of qualified clinical auditors, which could have affected the timely implementation of audit activities and the overall quality of the process.

However, this risk has been significantly mitigated. Currently, 11 auditors are undergoing structured training, creating a sufficiently large and flexible pool of qualified professionals. This number provides adequate redundancy to accommodate unforeseen events such as illness, scheduling conflicts, or institutional constraints.

In addition, the two project coordinators, a Radiation Oncologist and a Medical Physics Expert, have also completed auditor training and are available to act as replacements, if necessary, further strengthening resilience and operational continuity.

The only remaining structural constraint concerns the availability of Radiation RTTs, as their clinical workload may limit their capacity to travel to other centres for on-site audits.

- **Risk Score:** Medium
- **Impact:** High
- **Probability:** Low

2.5.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures were defined:

- Initiate the identification and recruitment of potential clinical auditors at the start of the project to secure an adequate pool of qualified personnel.
- Establish a supportive network of auditors, including international participants, to facilitate peer learning, knowledge sharing, and collaboration.
- Offer incentives and recognition for auditors, such as professional development opportunities, to increase participation and retention.
- Plan audit schedules well in advance and strengthen centre-level coordination to mitigate the risk that recruited RTTs may not be available to support the clinical audits. This will help facilitate the allocation of protected time whenever possible.
- Identify and communicate any shortage of auditors from specific staff categories or centres to WP1, where all consortium members and staff categories are represented, to ensure the issue can be addressed in an equitable manner.

2.6. Lack of Experts' Engagement for Training and Conducting the First Supervised Audits

At the proposal stage, a potential risk was identified regarding the availability and engagement of experienced international experts to deliver the training course and supervise the first clinical audits. Their participation was considered critical to ensure methodological fidelity, consistency with QUATRO principles, and high-quality implementation of the initial audit cycle.

To date, this risk has been effectively mitigated. Two of the three planned supervised training audits have already been successfully conducted with the direct involvement and contribution of the identified international experts. Their participation ensured appropriate knowledge transfer, validation of the methodology in practice, and hands-on mentoring of the newly trained auditors.

At present, only one supervised training audit remains pending. Given the experience gained during the first two audits, the strengthened capacity of the trained auditor pool, and the consolidation of procedures, the dependency on external experts has significantly decreased.

While expert availability always carries some degree of scheduling uncertainty, the project is now substantially less vulnerable to this risk.

- **Risk Score:** Medium-Low
- **Impact:** Medium
- **Probability:** Low

2.6.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Initiate early identification and engagement of suitable experts, including those serving on the Advisory Committee, and secure their commitment to contribute to the auditors' training program.
- Clearly define and communicate expectations, roles and responsibilities, highlighting the added value of their contribution to the project's success.
- Provide financial support to cover travel, accommodation, and related expenses, in line with project budget provisions.
- Prepare a shortlist of alternative qualified experts who could be mobilised if initially identified experts become unavailable.
- Build the progressive capacity of local auditors during the first two supervised audits thereby reducing reliance on external experts for subsequent activities.
- Develop an internal expertise (including trained project coordinators) capable of ensuring continuity should expert availability become constrained.

Given the successful completion of two supervised audits and the strengthened internal capacity, this risk is now considered largely controlled and unlikely to compromise project implementation.

2.7. Stakeholders Resistance

There is a risk that healthcare facilities or healthcare professionals may be reluctant to participate in clinical audit activities. Such resistance could limit stakeholder engagement, reduce access to relevant data, and delay the implementation of planned audit tasks. This may ultimately affect the timely achievement of project objectives and the overall effectiveness of the project.

- **Risk Score:** Low
- **Impact:** Medium
- **Probability:** Low

2.7.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Develop and implement engagement strategies to address potential concerns and secure buy-in from participating partners.
- Clearly communicate the objectives, benefits, and added value of the clinical audit process to all involved partners.
- Promote transparent and continuous dialogue to build trust and foster collaborative relationships.
- Share good practices and early positive results to encourage broader participation and sustained engagement.

2.8. RTTs Not Allowed to Act as Auditors

There is a risk that RTTs, who are essential for the daily operations of the radiotherapy department, may face challenges in obtaining permission to participate as auditors in clinical audit activities. Their absence from the department could compromise the continuity of patient care and the timely delivery of treatments, potentially impacting both departmental performance and the achievement of project objectives.

- **Risk Score:** Medium-High
- **Impact:** Medium
- **Probability:** Medium

2.8.1. Proposed Risk-Mitigation Measures

In line with the project's Risk Management Framework, the following mitigation measures have been defined:

- Plan audit activities well in advance and schedule them to avoid conflicts with holidays or peak workload periods.
- Communicate the importance of RTT involvement as auditors to hospital management and department heads, emphasising how their participation contributes to quality improvement and patient safety.
- Provide temporary coverage or replacements for RTTs during their absence to ensure continuity of patient care.
- Monitor RTT participation and workload regularly to identify potential conflicts early and adjust schedules as necessary.
- Communicate any deviations to WP1 so that corrective measures can be implemented at the affected centre.

3. Conclusion

The Risk Management Framework presented in this deliverable provides a systematic and structured approach to identifying, assessing, and mitigating the critical risks associated with the project. Through the detailed analysis of eight key risks across the project's Work Packages, the framework ensures that potential challenges are anticipated and addressed proactively.

The implementation of targeted mitigation measures—including the appointment of co-leaders, engagement of experts, recruitment of qualified auditors, technical support, and stakeholder engagement strategies, strengthens the resilience of the project and supports the achievement of objectives, timelines, and deliverables.

Continuous monitoring, regular review, and timely adaptation of mitigation strategies are essential to maintain effective risk management throughout the project lifecycle. By fostering transparency, clear communication, and collaborative coordination among all partners, the framework enhances decision-making and promotes a culture of proactive risk awareness.

Overall, this Risk Management Framework provides the consortium with a robust foundation to anticipate uncertainties, minimise disruption, and ensure the successful implementation of project activities. It serves as a practical tool to support governance, guide operational decisions, and safeguard the overall quality and impact of the project.