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Catalan Clinical Audit
Network for Quality Improvement
in Radiotherapy

CAT·ClinART

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Catalan Clinical Audit Network for Quality Improvement in Radiotherapy

CAT-ClinART, 101161063

QUALITY ASSURANCE PLAN

D3.2

T3.2

WP3 members

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DOCUMENT HISTORY

Version	Date	By whom	Main area of changes
0.1	3 January 2025	Diego Jurado Bruggeman / Núria Jornet Sala	Template with main sections
0.2	8 February 2025	Diego Jurado Bruggeman / Núria Jornet Sala	Draft of design and content
0.3	21 February 2025	Diego Jurado Bruggeman / Núria Jornet Sala	Incorporating comments by WP members and project office
1.0	24 February 2025	Diego Jurado Bruggeman	Formatting and modifications from last review

SUMMARY SHEET

Project Name	CAT-ClinART
Title of the document	Quality Assurance Plan
Deliverable	D3.2
Work Package	3
Programme	EU4Health
Coordinator	Fundacio privada Hospital de la Santa Creu i Sant Pau
Website	www.catclinart.eu
Author	Diego Jurado Bruggeman, Núria Jornet Sala, Maria Lizondo
Status	
Dissemination level	Public
Reviewed by	WP3 members, Ismael Membrive, Dolors Segura
Submission date	March 2025
Starting date	January 2025
Summary	Deliverable 2 is the quality assurance plan. This document describes the procedures to ensure the results of the project meet the established quality standards. It acts as a roadmap for the implementation of quality assurance throughout the life cycle of the project.

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1. Executive Summary

1.1. Context

CAT-ClinART project aims to establish a rigorous evaluation of the project's performance and outcomes, ensuring continuous monitoring of its progress and adherence to defined quality standards. In this context, the Quality Assurance Plan provides the framework and the methodology to achieve this objective throughout the project's lifecycle. This document defines the objectives, evaluation methodology, and tracking mechanisms for tasks, deliverables, milestones, and key performance indicators (KPIs).

1.2. Objectives

The Quality Assurance Plan aims to ensure the systematic monitoring, evaluation, and continuous improvement of all project activities. The key objectives of this plan are:

- **Verification of work progress**: Establish mechanisms for continuous monitoring and evaluation to ensure that project tasks are completed on schedule and meet defined quality standards. Regular progress checks will be conducted to identify any deviations or inefficiencies, and corrective actions will be promptly implemented to address issues and maintain alignment with project goals.
- **Organize the review of project deliverables**: Define a structured review process to assess the quality, consistency, and accuracy of project deliverables. This process will involve peers, experts, and key stakeholders.
- **Preparation of project progress reports**: Compile and analyze project data to generate comprehensive progress reports that assess the project's achievements, identify challenges, and provide recommendations for continuous improvement.

1.3. Outline

Chapter 1: Executive Summary

This chapter provides an overview of the Quality Plan, summarizing its objectives, scope, and significance for the CAT-CinART project.

Chapter 2: Governance and Roles

This chapter outlines the CAT-ClinART governance structure and the roles of various bodies in relation to Quality Management. It specifically defines the Quality Committee (QC), detailing its composition, responsibilities, and interactions with other project entities to ensure effective evaluation and quality assurance.

Chapter 3: Quality Assessment methodology

This chapter presents the quality assessment methodology adopted in the project, structured to follow the chronological progression of work packages (WPs) and their planned deliverables, milestones, and key performance indicators (KPIs). It outlines the internal and external monitoring processes, specifying the roles of WP3 members and the external advisory board in ensuring adherence to quality standards, timely progress, and continuous improvement. Additionally, it describes the tools and procedures used for tracking and evaluating project outputs, including the dashboard system, reporting mechanisms, and quality control workflows for deliverables.

Chapter 4: Reporting

This chapter defines the reporting framework for the project, detailing the responsible parties, recipients, periodicity, and formats of key reports. It outlines the schedule for progress reports, quality checks, mid-term evaluations, and the final report, specifying their role in tracking project performance, identifying risks, and ensuring compliance with quality standards. Each report will follow a structured format, including an executive summary, evaluation metrics, analysis of findings, and corrective actions to support informed decision-making and continuous improvement.

The document also includes three appendices: Appendix A, which outlines the formal aspects that the Quality Committee (QC) will review within five natural days; Appendix B, which provides the reporting template from other WPs and groups to the QC to ensure consistency and clarity across all project reports; and Appendix C, which provides the reporting template for the periodic reporting of the QC.

2. Governance and roles

The general management structure of the project is presented in Figure 1, taken from the Description of Action (DoA) document:

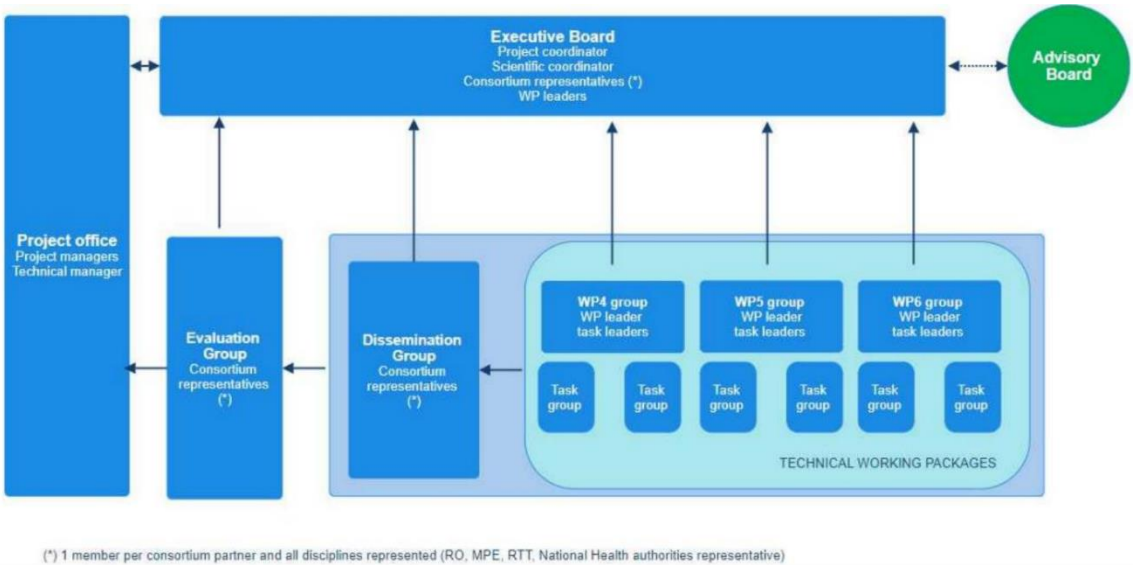

Figure 1. Project structure from the DoA document.

WP3 functions as the Evaluation Group, comprising one member per consortium partner to ensure representation across all disciplines. The members of WP3, together with the project manager and the quality technician, form the **Quality Committee** (QC). This committee is responsible for overseeing the evaluation and quality assurance processes across the project, ensuring adherence to established standards and continuous improvement.

WP3 interacts with multiple groups within the project to ensure a comprehensive and well-coordinated evaluation and quality assurance process. The nature and purpose of these relationships vary by group and are structured as follows:

- **WP leaders**. WP3 collaborates with the leaders and co-leaders of the other work packages to conduct periodic evaluations and ensure their tasks are progressing as planned.
- **Executive board**. WP3 provides progress reports, quality assurance updates, and evaluation outcomes to the Executive Board, which serves as the ultimate decision-

making authority within the project. Additionally, each member of the Executive Board is responsible for reviewing some specific deliverables.

- **External stakeholders and advisory board**. WP3 coordinates with external experts and stakeholders who independently evaluate project outcomes. Their feedback contributes to strategic recommendations for continuous improvement.
- **Dissemination group (WP2)**. WP3 works with the dissemination group to ensure that evaluation findings and quality assurance results are effectively communicated to relevant audiences, both within and outside the consortium.
- **Project office**. The project office supports WP3 in coordinating reviews, integrating risk management strategies, and communicating evaluation outcomes to the Executive Board for informed decision-making.

WP3 leaders serve as **Coordinators**. Their role is to establish and maintain a structured communication flow through WP3 members with the different WP and group leaders. They foster collaboration and coordination across all project components.

3. Quality assessment methodology

The quality management methodology will follow the chronological order of the WPs. It will be based on their planned tasks and measurable results: milestones, deliverables, and KPIs described in the DoA and presented below. Quality assurance and control measures will ensure that the project remains consistent during its lifetime and that the outputs from the project are of a continuous high level of quality.

3.1. Monitoring levels

The monitoring levels in the project can be grouped into Internal and External evaluations as follows:

- **Internal evaluations**. Conducted by the CQ members to ensure adherence to project plans, quality standards, and timely delivery of results. These evaluations will be performed monthly to track progress almost in real-time and detect any deviation sufficiently in advance to apply corrective measures and risk mitigation strategies. This document focuses on this internal monitoring.
- **External evaluations**. Conducted by the external advisory board to provide independent and unbiased assessments of the project's progress, effectiveness, and alignment with broader public health goals. The evaluation of the project's progress will rely on comprehensive reports provided by WP3. Two external audits will be performed: one mid-term (M18) to assess the project's evolution, and one final (M36).

3.2. Items to monitor and evaluate

The monthly internal evaluations will track the evolution of the project's tasks. To that aim, the monitoring will focus on specific indicators and performance metrics associated with these tasks: deliverables, milestones, and KPIs.

3.2.1. Deliverables

Table 1 includes a full list of expected deliverables with their characteristics:

Table 1. List of deliverables.

Deliverable Code	Deliverable Name	Related WP	Type	Dissemination level	Due Date
D1.1	Meeting minutes	WP1	Report	Sensitive	30 Sep 2027
D1.2	Evaluation Reports	WP1	Report	Public	30 Sep 2027
D1.3	Risk Management Framework	WP1	Report	Public	31 Mar 2026
D2.1	Dissemination and Exploitation Plan	WP2	Report	Public	31 Dec 2024
D2.2	CAT-ClinART Website	WP2	DEC	Public	31 Dec 2024
D2.3	Dissemination Report and Materials	WP2	Report	Public	30 Sep 2027
D2.4	Project leaflet	WP2	Report	Public	31 Dec 2024
D3.1	Guidance and standards within the project	WP3	Report	Public	30 Sep 2027
D3.2	Quality Assurance Plan	WP3	Report	Public	31 Mar 2025
D3.3	Progress on Specific Action-level Indicators	WP3	Report	Sensitive	30 Sep 2027
D4.1	Tools for quality audits	WP4	Report	Public	31 Aug 2025
D4.2	IT infrastructure for data collection and evaluation	WP4	DEC	Sensitive	31 May 2026
D4.3	Strategic plan for the project continuation and sustainability of clinical audit campaigns in RT	WP4	Report	Public	31 Jul 2027
D4.4	Manual for Dosimetry Audits	WP4	Report	Public	30 Sep 2025
D5.1	Course Programme and Auditors Training Materials	WP5	Report	Public	31 Jul 2025
D5.2	Survey Results and Course analysis	WP5	Report	Public	31 Mar 2026
D6.1	General Reports of Campaigns and Recommendations for the Health System	WP6	Report	Public	30 Sep 2027
D6.2	Update Planning of the Clinical Audit Campaigns	WP6	Report	Public	30 Sep 2027
D6.3	Workshop on the results of the 1st clinical audit cycle and feedback from audited centers and auditors	WP6	Report	Public	30 Sep 2027

3.2.2. Milestones

Table 2 includes a full list of milestones with their characteristics:

Table 2. List of milestones.

Milestone	Milestone name	Related WP	Means of verification	Due Date
MS1	Kick-off and annual meetings	WP1	D1.1	30 Sep 2027
MS2	Risk Assessment Completion	WP1	D1.2	30 Sep 2027
MS3	Kick-off workshop	WP2	Meeting Minutes	30 Nov 2024
MS4	Brand Materials Development	WP2	Materials published on the project website	30 Sep 2027
MS5	Website launch	WP2	Website accessible through the internet	31 Dec 2024
MS6	End of project workshop	WP2	Workshop participation, Dissemination materials	30 Sep 2027
MS7	Completion of Quality	WP3	Executive board meeting minutes	28 Feb 2025

	Assurance Plan			
MS8	Pilot Evaluation Run and Feedback Integration	WP3	Executive board meeting minutes	31 Dec 2026
MS9	Selection of the group of auditors	WP4	Call and selection process for clinical auditors	31 Dec 2024
MS10	Completion of the Clinical audit guidelines and templates	WP4	Publication of the guidelines and templates on the project website, Confirmation by project manager	30 Sep 2025
MS11	Delivery of the Clinical audit on RT course	WP5	List of participants, End of the course evaluation survey	30 Sep 2025
MS12	Run first audit	WP6	Audit report, evidence of data collection, feedback from the audited center, audit plan compliance, confirmation by project management	30 Nov 2025
MS13	Finalization of the audit cycle	WP6	Last audited center: Prepare the audit, collection of QI, auditor visit to the audited department and audit report completion	31 May 2027

3.2.3. KPIs

Table 3 includes a full list of KPIs with their characteristics:

Table 3. Key Performance indicators for quality assessment.

KPI No	Indicator Name	Measurement	Target
0	Collection of guidelines, templates, and standards for clinical audits in RT	Number of documents collected	Comprehensive collection of existing materials from experienced countries
1	Establishment of audit infrastructure	Percentage of components established	100% completion within the planned timeframe
2	Development of audit tools and resources	Number of tools developed (guides, checklists, etc.)	At least 9 audit tools created
3	Awareness improvement on clinical audits among RT professionals	Survey results before and after the project	60% improvement in awareness
4	Competency development in clinical audits	Self-assessment of acquired competencies by participants	30% increase in self-reported competencies
5	Completion of the first round of clinical audits	Number of hospitals participating and audits conducted	7 complete audits with 14 recommendations provided
6	Long-term sustainability of the audit system	Proposal for a permanent clinical audit mechanism	Submission of sustainability proposal to competent authorities
7	Dissemination and scalability of project results	7.1: % of project materials shared on website | 7.2: Number of conferences/events attended	7.1: 80% of materials published | 7.2: Attendance at 5 dissemination events

3.3. Tools

We will use a Dashboard built in Excel. This dashboard will be the central tool for tracking all key project elements. It will contain:

- Items to be monitored. For each item, information on:
  - Item characteristics (listed above).

- Status. Each item will be assigned a status (Pending, In Progress, Completed, Delayed) with corresponding temporal information to monitor progress against deadlines.
- Incidences. Track any delays, causes, actions taken, and ongoing monitoring.
- Quality control of the deliverables. Timeline and status of the validation workflow and quality control mechanisms.

- The dashboard will also serve to track the incidences/non-conformities.
- The dashboard will also serve to register and manage potential risks.
- The dashboard will also track the coordination and communication with the other WPs and groups.

3.4. Verification of work progress

The verification of work progress is outlined in the following diagram (Figure 2):

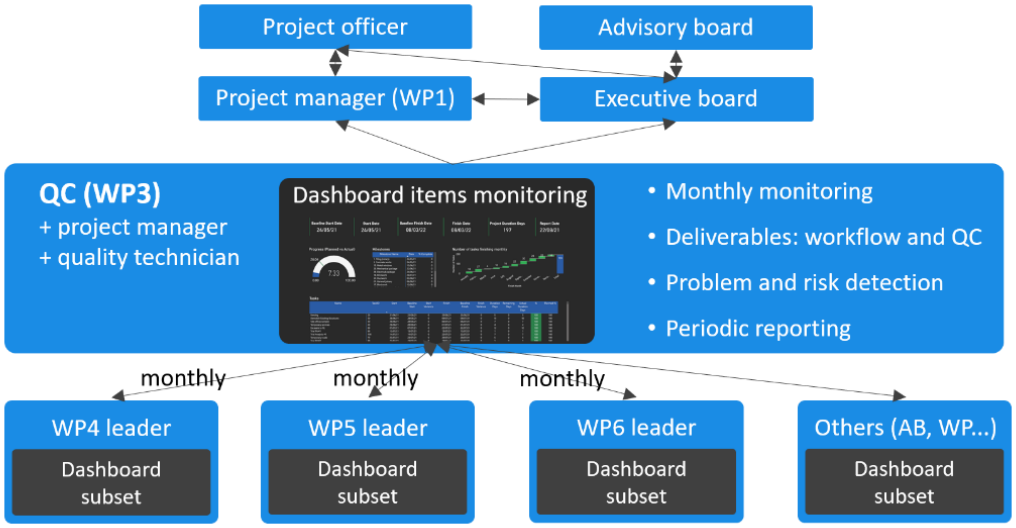

Figure 2. Workflow of the verification of work progress.

All communications between WP3 and other WPs and groups will be centralized by WP3 coordinators.

The QC will have a monthly meeting (online conference) to monitor the status and the progress of the items. To ensure data is updated, WP and group leaders and co-leaders will submit a progress report via email to WP3 coordinators before each meeting. This report will be based on the template provided in Appendix B and will include information on:

- On-going activities. Subset of the Excel overall dashboard including solely the items related to the specific WP or group. For the deliverables, this will also track the review and quality control processes.
- Issues/delays with the activities.

All reports from the different WPs and groups will be used to update the global dashboard that will serve as the basis for monitoring.

The CQ will evaluate if there are foreseeable difficulties in a WP in achieving objectives or deliverables. Additionally, the QC will assess if there are any obstacles and barriers causing delays, particularly if this can impact subsequent project activities or outcomes.

In case of issues or delays, the CQ will identify other tasks that can be affected and discuss and propose solutions to minimize the risks and possible consequences. These will include the need for harmonization of activities between and across WPs, and the need to relocate tasks within or among the WPs. The QC will inform the executive committee and the affected WPs of the issues detected and the analysis performed.

The results of the evaluations will be reported periodically to other groups according to the indications provided below in the specific section.

3.5. Monitoring the perception of project coordination among consortium members

To ensure effective collaboration, an annual survey will be conducted among consortium members to assess project coordination. The survey will evaluate meeting effectiveness, schedule, timing, participation, communication tools, documentation quality, and overall coordination.

Results will be analyzed, and a summary report will be shared to identify areas for improvement. Findings will guide adjustments to coordination strategies, enhancing efficiency and communication within the consortium.

3.6. Review and quality control of deliverables

The reviewing and quality control process is represented in Figure 3:

Figure 3. Quality control of deliverables process.

- **Step 1: related WP**. When applicable, the deliverable will be prepared using templates to ensure consistency and uniformity. The WP responsible for the deliverable will perform an internal peer-review process focused on the content before submitting it to the next step. This step must be finished 25 natural days before the deadline of the deliverable if it does not need to be reviewed by the advisory board, or 35 natural days before the deadline if the advisory board reviewing is necessary.
- **Step 2: QC**. The QC will have 5 natural days to review the formal aspects of the deliverable. These aspects are listed in Appendix A.
- **Step 3: advisory board**. Some specific deliverables will also be sent to the advisory board for their approval. These deliverables will require 20 additional natural days: 10 for reviewing and 10 more to allow the incorporation of the modifications required by the advisory board.
- **Step 4: executive board**. Two members of the executive board will review each deliverable. These members are chosen from a list where each member specifies what items they were willing to review. Their names will be documented in the "Reviewed by" item included in the Summary Sheet at the beginning of each deliverable. Final approval by the project coordinator and scientific coordinator.

- **Step 5: upload to the EU platform and publish it on the website if public**. The deliverable must be uploaded to the EU platform for the project before the deadline by the project office. All public deliverables will be submitted to the dissemination group (WP2) for their publication on the website. This publication will be also monitored.

The reviewers of the executive board, the need for a review by the advisory board, and the indication of publication on the website by the dissemination group are indicated for each deliverable in Table 4.

Table 4. Quality control information for the deliverables.

Deliverable Code	Deliverable Name	Executive board reviewers	Advisory board reviewing (Y/N)	Website (Y/N)
D1.1	Meeting minutes	A. Eraso, A. Herreros	N	N
D1.2	Evaluation Reports	A. Eraso, A. Herreros	N	Y
D1.3	Risk Management Framework	C. Montfà, D. Jurado	N	Y
D2.1	Dissemination and Exploitation Plan	- (delivered)	N	Y
D2.2	CAT-ClinART Website	- (delivered)	N	Y
D2.3	Dissemination Report and Materials	MC. Pujades, I. Membrive	N	Y
D2.4	Project leaflet	- (delivered)	N	Y
D3.1	Guidance and standards within the project	C. Muñoz, M. Mollà	N	Y
D3.2	Quality Assurance Plan	I. Membrive, D. Segura	N	Y
D3.3	Progress on Specific Action-level Indicators	J. Lozano, M. Beltrán	N	N
D4.1	Tools for quality audits	D. Jurado, M. Mollà	Y (QUATRO and B-QUATRO auditors)	Y
D4.2	IT infrastructure for data collection and evaluation	D. Jurado, J. Pérez	Y (Catalan Health System, ministerio sanidad)	N
D4.3	Strategic plan for the project continuation and sustainability of clinical audit campaigns in RT	J. Pérez, A. Eraso	Y (all members)	Y
D4.4	Manual for Dosimetry Audits	V. Hernández, C. Monfà	Y (QUATRO and B-QUATRO auditors)	Y
D5.1	Course Programme and Auditors Training Materials	MC. Pujades, M. Arenas	Y (QUATRO and B-QUATRO auditors)	Y
D5.2	Survey Results and Course analysis	J. Lozano, C. Monfà	Y (QUATRO and B-QUATRO auditors)	Y
D6.1	General Reports of Campaigns and Recommendations for the Health System	D. Segura, C. Muñoz	Y (all members)	Y
D6.2	Update Planning of the Clinical Audit Campaigns	V. Hernández, M. Beltrán	Y (QUATRO and B-QUATRO auditors)	Y
D6.3	Workshop on the results of the 1st clinical audit cycle and feedback from audited centers and auditors	M. Arenas, J. Pérez	Y (all members)	Y

4. Reporting

WP3 is responsible for preparing and submitting periodic reports to other project groups throughout the project's lifetime. These reports provide essential updates on progress,

evaluation results, and necessary corrective actions. Table 5 outlines the reports that WP3 must prepare, their recipients, and the corresponding delivery timelines.

Table 5. Reports from WP3.

Report Name	Recipient	Schedule
D3.3 Progress on Specific Action-Level Indicators	Executive Board, Advisory Board	M12, M24, M36 (Sep 2025, 2026, 2027)
Quarterly Quality Checks	Executive Board, WP Leaders	Every 3 months
Mid-term Evaluation Report	Executive Board, Advisory Board	M26 (Jul 2026)
Final Report	Executive Board, Advisory Board	M36 (Sep 2027)

The reports will follow a structured format including these sections:

- **Executive summary**. This section provides a high-level overview of the report, summarizing key findings, conclusions, and recommendations.
- **Evaluation metrics and indicators**. This section provides an assessment of the current progress and outcomes based on the predefined metrics and indicators. It offers a clear overview of performance status, highlighting key trends and any deviations from expected targets.
- **Analysis and findings**. A detailed examination of the evaluation results, identifying strengths, weaknesses, trends, and deviations from the expected standards. This section presents an evidence-based interpretation of the data collected, highlighting issues and areas for improvement.
- **Corrective actions and recommendations**. This part provides actionable steps and strategic recommendations for addressing the identified issues. It includes proposed solutions, prioritization of corrective actions, and an implementation timeline.

The deliverable reports will be based on the specific template for the deliverables, while all other reports will follow the template provided in Appendix C.

5. Conclusion

This document summarizes the procedures to ensure an effective evaluation of the progress of the project and the quality of its outcomes. Overall, the document will serve as a reference for all consortium partners during the project implementation.

APPENDIX A

Quality Committee checklist for deliverable review

Deliverable Code and version:

Date:

Reviewed by:

Item	OK / NO	Comment
Template used		
Document History section updated		
Summary Sheet section updated		
Table of Contents updated		
The first section Is the Executive summary		
Logo usage (see D2.1 - 2.2 Style guide)		
Colour scheme (see D2.1 - 2.2 Style guide)		
Typography (see D2.1 - 2.2 Style guide)		
Formating (see D2.1 - 2.2 Style guide)		

APPENDIX B

[WP#/Group] progress evaluation report

Date: DD/MM/YYYY

Author(s): [Full Name(s)] - [role(s)]:

On-going activities

Please find attached the updated information on the ongoing activities related to our group, as part of this month's periodic reporting to the Quality Committee.

Issues/Delays

Lorem Ipsum

Comments

Lorem Ipsum

APPENDIX C

[Title]specify one of the following: Quarterly quality checks; Mid-term evaluation report; Final evaluation report

Date: DD/MM/YYYY

Author(s): [Full Name(s)] - [role(s)]:

Executive summary

This section provides a high-level overview of the report, summarizing key findings, conclusions, and recommendations.

Evaluation metrics and indicators

This section provides an assessment of the current progress and outcomes based on the predefined metrics and indicators. It offers a clear overview of performance status, highlighting key trends and any deviations from expected targets.

Analysis and findings

A detailed examination of the evaluation results, identifying strengths, weaknesses, trends, and deviations from the expected standards. This section presents an evidence-based interpretation of the data collected, highlighting issues and areas for improvement

Corrective actions and recommendations

This part provides actionable steps and strategic recommendations for addressing the identified issues. It includes proposed solutions, prioritization of corrective actions, and an implementation timeline.