Catalan Clinical Audit
Network for Quality Improvement
in Radiotherapy

Introduction to the course: Clinical Audits in Radiation Oncology: Training for Auditors and Auditees

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Hospital Clínic Barcelona

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Welcome and Opening Remarks

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Course Director: Núria Jornet, Principal Investigator of CAT Clin-ART:

- for her vision and dedication to this collaborative project.
- for her leadership that has been essential in shaping this course.

Representatives of each partner center and the Faculty:

- Your expertise will enrich this course and will help drive the future of clinical audits in Catalonia.

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Frame CA within a Quality Management System (QMS):

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Introduction to the course:

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- Course overview
- Faculty

Brief introduction to the CAT ClinART project

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To provide background

- Radiotherapy high complexity demands rigorous quality assurance to ensure patient safety.
- Clinical audits have emerged as a vital tool, enabling systematic evaluation of clinical practices and fostering continuous improvement.
- Despite European Directive 2013/59 mandating clinical audits, their implementation across Member States has been inconsistent.
- In Catalonia, only a limited number of audits have been conducted in radiotherapy departments over the past two decades, often lacking technical depth and multidisciplinary involvement.
- This has hindered the harmonisation of practices and the establishment of a robust quality culture.

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CAT-CLINART (Catalonia Clinical Audit in Radiotherapy) is a regional initiative designed to address this gap. It is inspired by successful models such as QUATRO (Quality Assurance Team for Radiation Oncology) and B-QUATRO in Belgium.

Main objectives

- **Develop a standardized methodology** and a solid infrastructure to perform comprehensive clinical audits in Radiotherapy in Catalonia following the QUATRO model.
- **Create an IT structure** to regularly collect Quality Indicators in Radiotherapy as a complement/support to the clinical audits.
- **Raise awareness** in the radiation therapy community concerning the importance of incorporating clinical audits as a tool to increase the quality and safety of radiotherapy procedures.

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Secondary objectives

- Design and create a training course following QUATRO methodology for clinical audits.
- Generate a set of QI for quality monitoring and improvement.
- Organize and conduct a first round of comprehensive pathology-based (prostate cancer) clinical audit campaign.
- Develop a robust communication and dissemination strategy.
- Prepare a proposal for a permanent clinical audit mechanism in Radiotherapy in Catalonia (Long Term **sustainability**)
- Use the lessons learnt in this experience to extend the model to other regions.

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Partners of the consortium of this Collaborative Project in the Autonomous Community of Catalonia

main

satelite

Clinical partners	staff
HSP	10+1
ICO-H	3+1
ICO-B	3
ICO-G	4
VHUH	3
HCB	7
HMar	2
IISPV	4
ICS-lleida	4
CST	4

Non Clinical partners	Focus	staff
Quality department - Departament de Sanitat Generalitat de Catalunya	Sustainability model	3
Centro Nacional de dosimetria (Valencia)	Dosimetry audits	2

Total: **51** professionals
RO
MPE
RTT
Project managers
IT experts
Health departament staff

10 Radiotherapy Departments
36 Linacs

Objectives:

- Provide training to 9 auditors
- Conduct 10 clinical audits, one in each clinical partner radiotherapy department by the end of this three-year project

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Expected outcomes

- **Improved Treatments:** Enhanced quality and safety of radiotherapy treatments.
- **Enhanced Collaboration:** Better teamwork and knowledge sharing among professionals of different partners.
- **Harmonized Practices and scalability:** Standardized radiotherapy practices in Catalonia, and beyond.

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Rationale for the focused approach...in only one site

Why do we start clinical audits in **only one site: prostate**? Because...

- It is a high incidence disease.
- There are clear guidelines and standards at national and international levels.
- We have previous **group** experience in defining QI for prostate treatments.
- We don’t expect large differences between the consortium clinical centres that will be audited.

In conclusion, starting CA in **only one site** will increase the probability of project success.

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Rationale for the focused approach... In one geographical region

Starting clinical audits in only **one geographical region** allows:

- Pilot testing under a more controlled situation
- With no language barriers
- The perfect environment for building expertise

In summary, starting clinical audits in a focused manner allows for a more strategic and effective approach, ensuring success in the initial stages and laying the groundwork for scalability and sustainability in the future.

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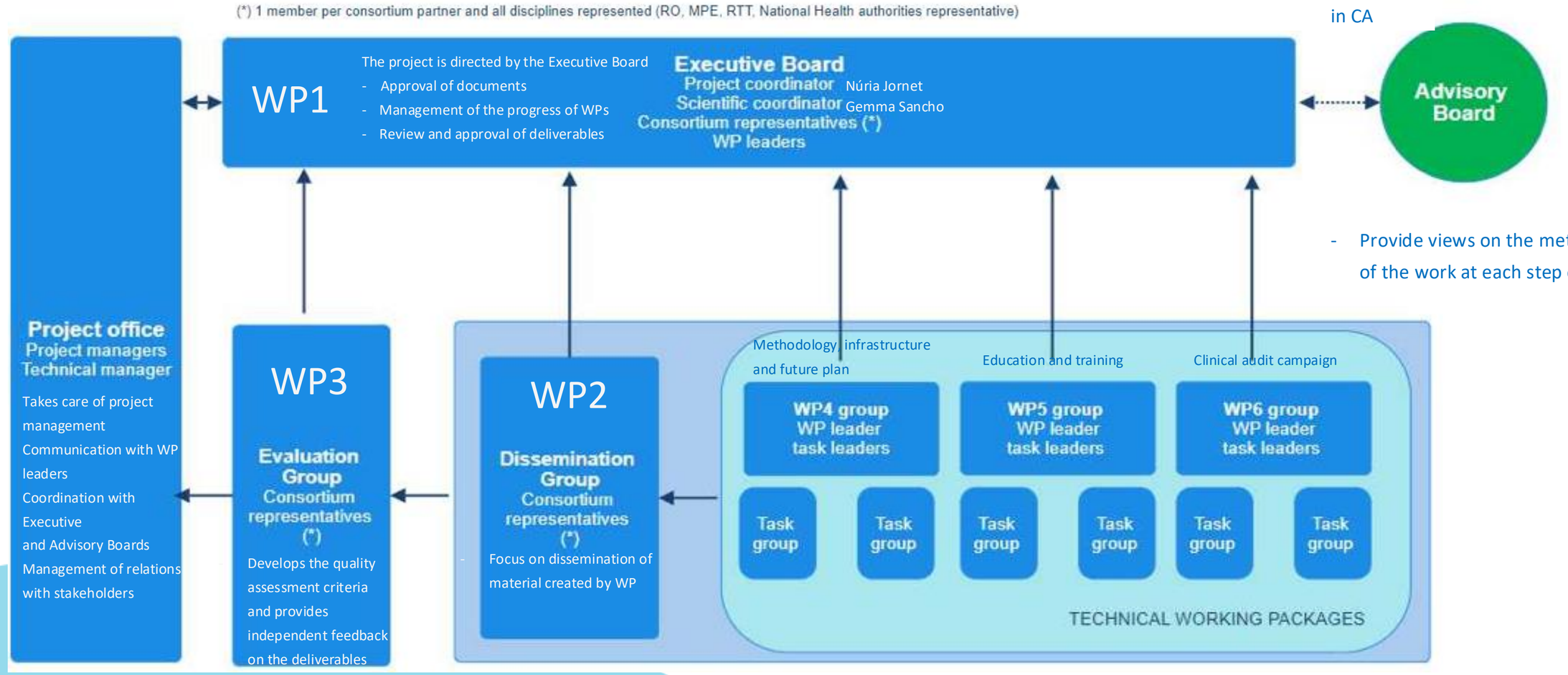
Leadership and Coordination between different Working Packages (WPs)



Composed by national and international experts in CA

- Provide views on the methodology and results of the work at each step of the project.

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Project Plan

WP4 oversees the development of methodology and audit tools like:

1. Clinical audit manuals including checklists and templates.

2. Definition of quality indicators and standards (focused on prostate treatments).

3. Dosimetry audits for clinical auditing.

4. IT solutions for data management including automation of the extraction of QI from medical records and oncology information systems.

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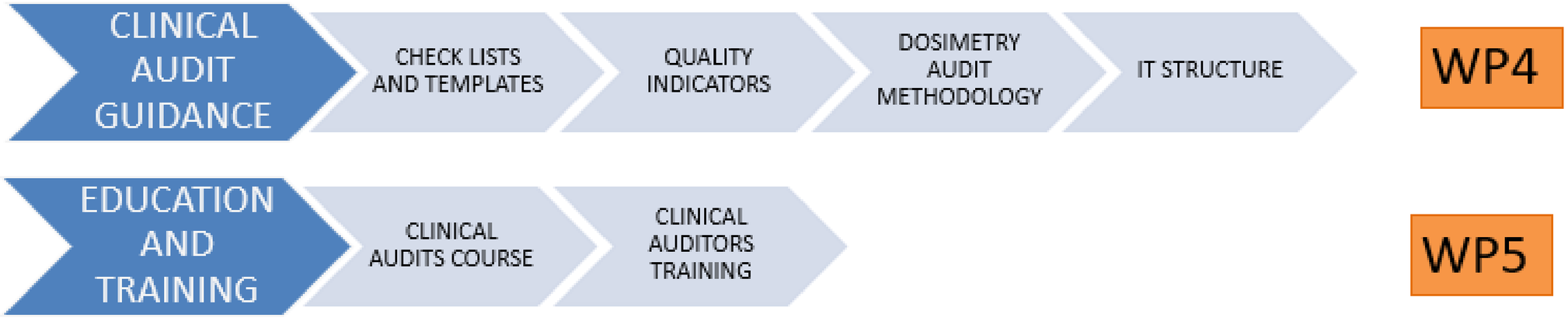
Project Plan



WP5 includes not only training of auditors but also of auditees.

By involving trainees in real-world training scenarios, we aim to ensure that our auditors are well prepared and equipped to be able to conduct CA on their own.

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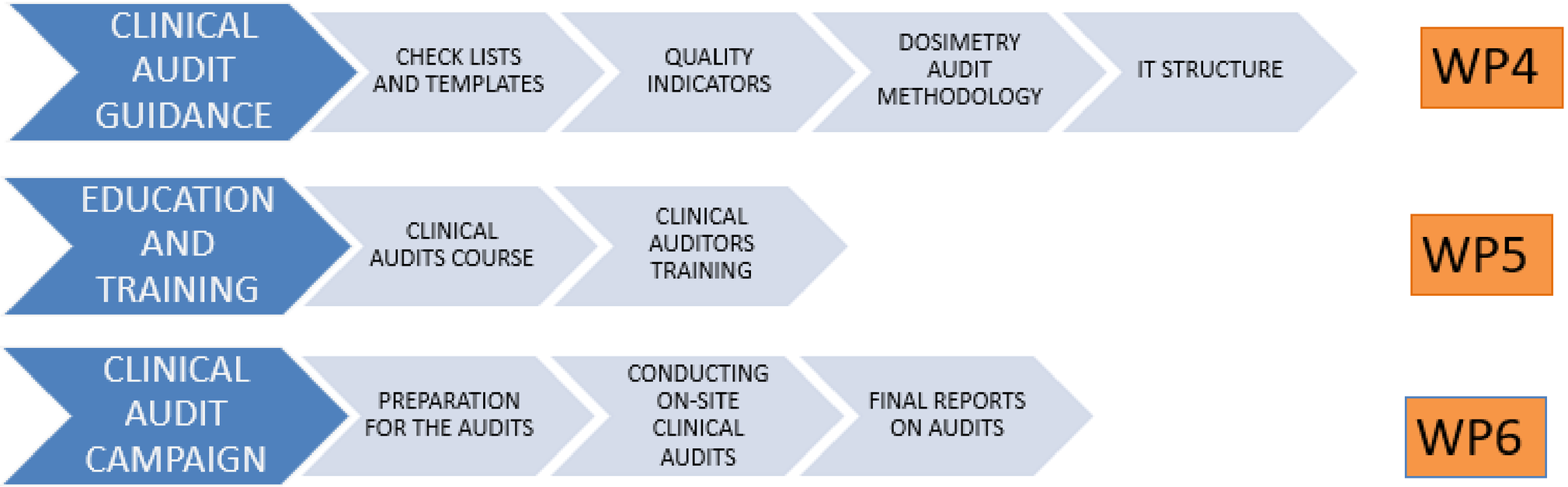
Project Plan



The pinnacle of our project will be the comprehensive CA pilot by **WP6**, focused on prostate treatment, to be conducted **by our auditors** in all the clinical centres of our Consortium.

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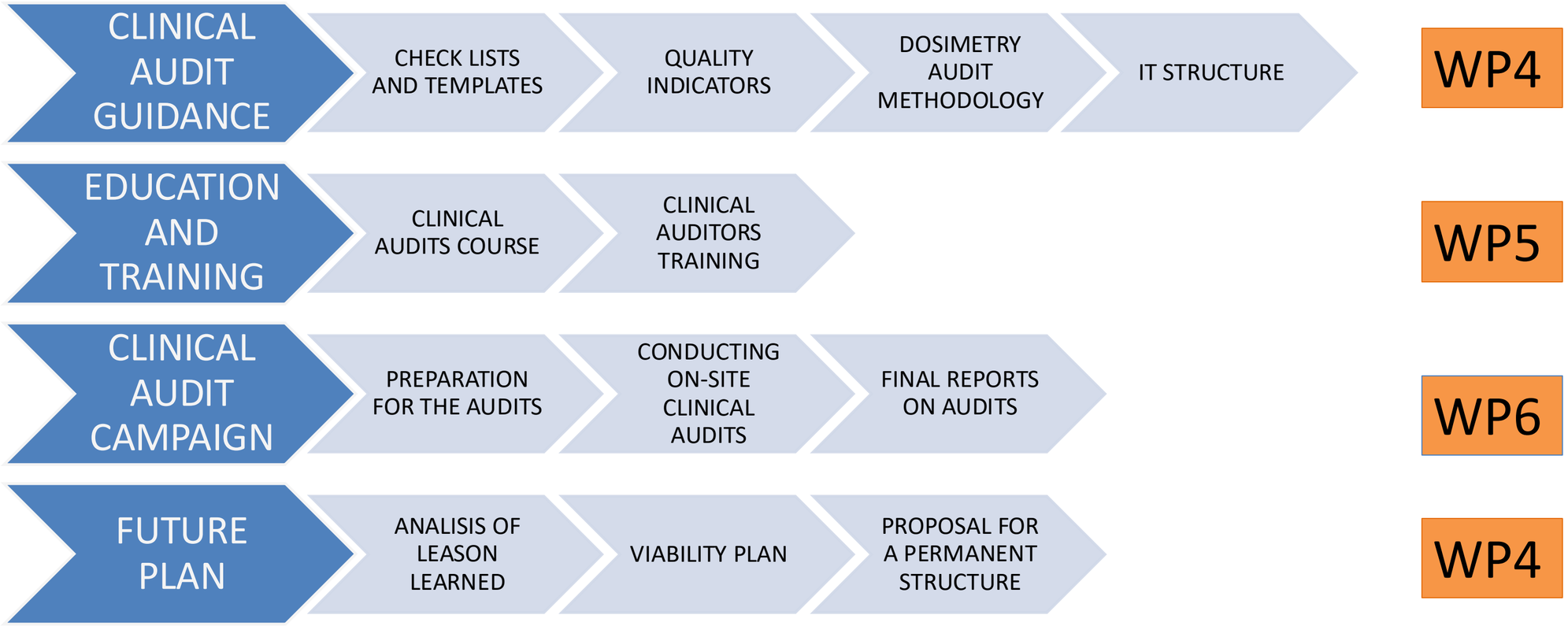
Project Plan



To secure the project's sustainability and continuation beyond the funding period, we will compile the results and gather feedback from auditors and audited centres.

We will then develop a viability plan encompassing critical aspects such as financial considerations, personnel requirements, and organizational components, for a permanent structure.

Frame within a Quality Management System

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Frame within a Quality Management System

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Quality Management System (QMS)

Definition:

The search for efficiency is the scope of a QMS which aims for **continuous improvement** within an organisation by the achievement of objectives based on the Plan-Do-Check-Act methodology.

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Components of a QMS

A QMS in radiotherapy typically includes:

- **Quality assurance:** Ensuring equipment and procedures function correctly.
- **Risk management:** Identifying and mitigating potential hazards.
- **Regulatory compliance:** Adhering to national and international standards.
- **Continuous improvement:** Using the mentioned Deming cycle.

Although we all know that regular **audits** enhance performance, in the past, it was not common to include regular **audits** in our QMS (like ISO 9001).

The implementation of **clinical audits** has been even less frequent despite Directive 2013/59/Euratom and its transposition Royal Decree 601/2019.

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What is an Audit?

Definition (ISO 9001:2015):

An audit is a **systematic**, **independent**, and **documented** process for obtaining objective evidence and evaluating it to determine the extent to which the audit criteria are fulfilled.

Systematic:

- Meaning: The audit follows a structured and organized approach.
- Importance: Ensures consistency and reliability in the audit process. It involves planning, executing, and reporting in a methodical manner.
- Example: An auditor uses a checklist to ensure all aspects of the quality management system are reviewed.

Independent:

- Meaning that: The audit is conducted by individuals who are not directly involved in the activities being audited.
- Importance: Maintains objectivity and impartiality, reducing bias and ensuring a fair assessment.

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What is an Audit?

Definition (ISO 9001:2015):

An audit is a **systematic**, **independent**, and **documented** process for obtaining objective evidence and evaluating it to determine the extent to which the audit criteria are fulfilled.

Documented:

- Meaning: The audit process and findings are recorded in written form.
- Importance: Provides a clear record of the audit process and results, which can be used for future reference and improvement.
- Example: The auditor prepares a detailed report outlining the findings, non-conformities, and recommendations.

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And a “Clinical” Audit?

Council Directive 2013/59/Euratom defines a **Clinical Audit** as:

a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against **agreed standards** for good medical procedures.

So, the **agreed standards** of a Clinical Audit are the **audit criteria** from ISO 9001 audit definition.

Improve quality is explicitly stated in the definition of **Clinical Audit.** This is the scope of the QMS definition: continuous improvement. Remember that ISO 9001 audit objective is to determine the extent to which the audit criteria are fulfilled, not to improve these audit criteria. In conclusion, Clinical Audits are a necessary tool for **improvement, and an essential part of QMS**.

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Why do we need to perform Clinical Audits?

Because it is a **regulatory requirement** indicated in Council Directive 2013/59/Euratom

17.1.2014 EN Official Journal of the European Union L 13/1

II

(Non-legislative acts)

DIRECTIVES

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

Article 58

Procedures

Member States shall ensure that:

(a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;

(b) information relating to patient exposure forms part of the report of the medical radiological procedure;

(c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;

(d) in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

(e) clinical audits are carried out in accordance with national procedures;

And in its transposition Royal Decree 601/2019 and recent Royal Decree 391/2025.

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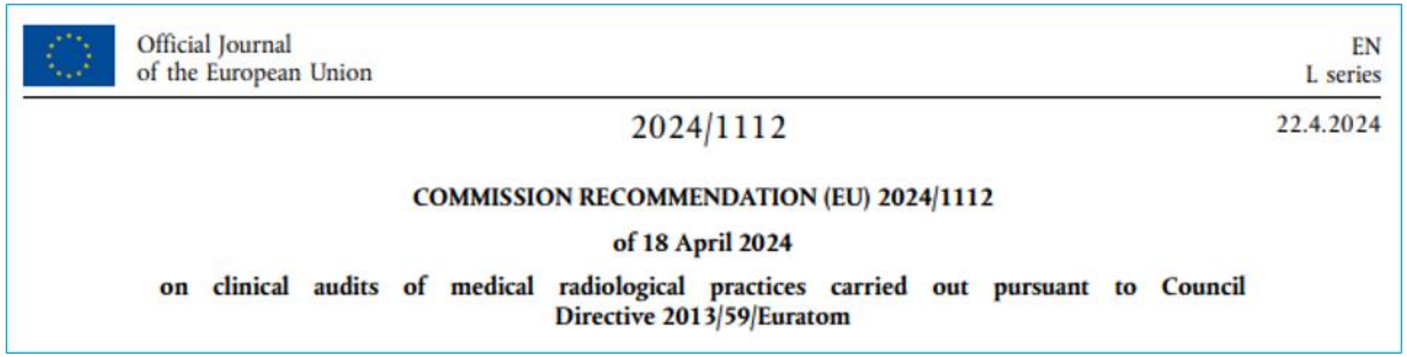
Why do we need to perform Clinical Audits?

But recent Commission Recommendation 2024/1112

includes these **other reasons**:



Official Journal of the European Union

EN
L series

2024/1112

22.4.2024

COMMISSION RECOMMENDATION (EU) 2024/1112

of 18 April 2024

on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom

For **improvement purposes,** it states that:

CA of medical radiological procedures are an essential tool within clinical governance that ensures continuous quality improvement.

For **harmonization** at Community level, it states that:

It is appropriate to make recommendations for harmonising the provisions applicable in the Member States regarding the implementation of the provisions of Directive 2013/59/Euratom on CA, to promote a more harmonised approach at Community level.

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Why do we need to perform Clinical Audits?

Commission Recommendation 2024/1112 also states that Member States should assign the following **responsibilities** to the appropriate body at National level**:**

- Define clinical audit **responsibilities** and allocate available **financial, human and technical resources.**
- Provide **administrative support** to the implementation of CA.
- Develop **audit guidelines and manuals** and **share** these and good practices among entities involved in CA.
- Provide effective **tools for the collection of data** for CA by functional **IT** solutions.
- Ensure access to **training programmes** for auditors carrying out CA.
- Develop appropriate **educational resources** in CA.
- Compare and **benchmark results** of CA.

Technical WPs Objectives of

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The benefits of Clinical Audits include...

Ensuring Patient Safety by:

- Identifying areas of improvement.
- Verifying accuracy of radiation doses and equipment functionality.
- Ensuring staff training and adherence to best practices: uncovering discrepancies and implementing corrective actions.

Enhancing Treatment Efficacy by:

- Assessing adherence to best treatment protocols and guidelines.
- Harmonizing quality standards among hospitals.
- Evaluating the entire treatment process.

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The benefits of Clinical Audits include...

Ensuring Continuous Quality Improvement by:

- Encouraging regular review and refinement of practices.
- Facilitating identification of best practices and areas for improvement.
- Promoting collaboration and knowledge sharing among teams.

Complying with Regulatory Standards by:

- Ensuring compliance with Directive BSSD 2013/59/Euratom and Commission Recommendation 2024.

The Course

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What are the benefits of this Course?

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What are the benefits of this Course?

This course will provide specialized training to equip us with:

- the **skills to conduct and participate in CA** effectively

- and the necessary **skills to drive continuous improvement**

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Objectives

- Understand the **principles and benefits of CA** in radiotherapy.
- Learn the **QUATRO methodology**.
- Develop **practical skills** to perform CA.
- Gain **hands-on experience** through case studies and real-life audit simulations.
- Introduction to **quality indicators, standards, and benchmarking** to foster a culture of continuous quality improvement.
- Understand the **legal framework**, including compliance with the Basic Safety Standards Directive 2013/59/Euratom, its transposition Royal Decree 601/2019, 2024 Commission Recommendation and Royal Decree 391/2025.
- **Networking**: Enhancing collaboration between multidisciplinary teams.
- **Expert Insights**: Learning from leading experts in clinical audits.

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Faculty – European Leading Experts

Aude Vaandering
RTT and Quality Manager
Position: Quality manager in the Radiotherapy Department.
Current workplace: Cliniques Universitaires St Luc, Brussels, Belgium.
Co-chair of the Belgian Association of Quality Managers in Radiotherapy.
Coordinator of the B-QUATRO audits in Belgium.

Dirk Verellen
Medical Physicist
Position: Director Medical Physics Department and Prof. Biomedical Physics.
Current workplace: Iridium Netwerk, GZA Ziekenhuizen, Antwerp University, Antwerp, Belgium.
Expert member of the working group External Audits for the Federal Agency for Nuclear Control (FANC) and member of the Steering Committee BELdART.
Auditor for B-QUATRO (Peer review commission radiation oncology and medical oncology, Belgium).

Primoz Strojan
Radiation Oncologist
Position: Consultant Radiation Oncologist.
Current workplace: Institute of Oncology Ljubljana, Slovenia.
Member of various QUATRO teams.
Auditor for QUATRO.
Participated in the QuADRANT project of the European Commission.

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Faculty – local Experts

Núria Jornet

Medical Physicist

Position: Clinical Chief. Medical Physics Department.

Current workplace: Hospital de la Santa Creu i Sant Pau. Barcelona, Spain.

Participated in the QUADRANT project.

Expert on QUATRO audits methodology.

Principal Investigator of CAT-ClinART project.

Director of this course.

Carles Muñoz

Medical Physicist

Position: Director of Medical Physics Department.

Current workplace: Institut Català d'Oncologia, Girona, Spain

Member of the ICO ISO 9001:2015 Quality Board and Radiotherapy Process Harmonization Group.

Hospital Consortium- IROCA-Improving Radiation Oncology through Clinical Audits-**Principal Investigator**-Varian Medical Systems

Hospital Consortium-IROCATES-Improving Quality Assurance in Radiation Oncology through Clinical Audits-Training and Education for Standardization-**Principal Investigator**-No funding

Xavier Maldonado

Radiation Oncologist

Position: Director of Radiation Oncology Department.

Current workplace: Hospital de la Valle Hebron, Barcelona, Spain.

Related to quality: ISO 9001:2015 and OECI Quality certification.

Related to safety: Member of the radiation therapy patient safety core

Gemma Sancho

Radiation Oncologist

Position: Director of Radiation Oncology Department.

Current workplace: Hospital de la Santa Creu i Sant Pau. Barcelona.

Member of the multicentric Spanish group of clinically localized prostate Cancer. Participated in four important prostate cancer studies.

Scientific coordinator of CAT-ClinART project.

Jordi Sáez

Medical Physicist

Position: Chief of the Medical Physics Section.

Current workplace: Hospital Clínic. Barcelona, Spain.

Member of the ISO 9001:2015 Quality Board in Radiotherapy.

Member of WP4 Task group on dosimetry audits.

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Course Overview – Day 1

9:45-10:15	**Current situation of Clinical Audits in RT: Summary of QUADRANT results** Explain the results of the QUADRANT report on Clinical Audits in RT	QuADRANT Núria Jornet
10:15-10:45	**Audit vs Inspection** Herca position statement on the differences between a clinical audit and an inspection	Núria Jornet
10:45-11:15	**QUATRO and B-QUATRO audits: Commonalities and differences** Overview of QUATRO and B-QUATRO focusing on the commonalities and differences	Aude Vaandering
11:15 - 11:45	*Coffee Break*	
11:45 - 12:15	**QUATRO terminology** Introduce the terminology used in QUATRO, including terminology used in the checklists	Primoz Strojan
12:15 - 12:45	**Audit components** Go through the different components such as infrastructure, Patient Procedures, Equipment Procedures, Quality Management Structure	Aude Vaandering
12:45 - 13:15	**Audit methodology: Checklists, standardized forms, observation and interviews** Introduction to the different tools for auditing	Primoz Strojan
13:15-13:45	**Audit methodology B-QUATRO** B-QUATRO excel collection sheets and spider diagrams, the role of the Quality manager	Aude Vaandering

You will probably have noticed that the course programme has been slightly modified because, It was not possible for Dirk Verellen to join us today, because he is part of an audit commission for a training program for RTT in Brussels.

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Course Overview – Day 2

9:00 - 9:30	**QUATRO team** Introduction to the components of the QUATRO team, importance of team work and the roles of each component and the role of the team leader	Dirk Verellen
9:30 - 10:00	**QUATRO Structure** Introduction to the audit temporal structure; Preparation, Auditors visit and Final report	Aude Vaandering
10:00 - 10:30	**Entrance and exit meetings** What should be covered in the entrance and exit meetings and to whom they are addressed	Dirk Verellen
10:30 - 11:00	*Coffee break*	
11:00-11:30	**The role of the MPE** Explain the role of the MPE including the dosimetry audits	Dirk Verellen
11:30-12:00	**The role of the RO** Explain the role of the RO, including the attendance to MDT meetings, clinical record review, etc	Primoz Strojan
12:00-12:30	**The Role of the RTT** Explain the role of the RTT, including the observation of practice at treatment units, education and training of RTTs, etc	Aude Vaandering
12:30 – 13:15	**Auditors code of conduct and required skills** Overview of the ethical principles, professional responsibilities, and key competencies required for auditors.	Primoz Strojan
13:15 - 14:15	*Lunch*	
14:15 - 15:00	**Dosimetry audit BQUATRO and QUATRO** Description of the dosimetry audits conducted during QUATRO audits and Dosimetry audits in BQUATRO through BeldART	Núria Jornet and Dirk Verellen
15:00 - 15:30	**Dosimetry audit CAT-ClinART** Description of the dosimetry audit in CatClinART	WP4 Task group on dosimetry audits
15:30-16:30	**Clinical case audit** Demo on how the review of a clinical case would be performed	Primoz Strojan, Dirk Verellen, Aude Vaandering
20:00-22:00	**Faculty Dinner**	

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Course Overview – Day 3

9:00 - 9:15	**Infrastructure checklists** Introduction to the practical exercise	Primoz Strojan
9:15 - 10:15	**Practical in groups: Infrastructure checklists** 45 min of team work filling in the checklist followed by a discussion	Primoz Strojan, Dirk Verellen, Aude Vaandering, Núria Jornet
10:15 - 10:45	*Coffee Break*	
10:45-11:00	**Patient related procedures checklists** Introduction to the practical exercise	Aude Vaandering
11:00-12:00	**Practical in groups: Patient related procedures checklists** 45 min of team work filling in the checklist followed by a discussion	Primoz Strojan, Dirk Verellen, Aude Vaandering, Núria Jornet
12:00-12:30	**What to do when we do not have standards?** Discussion on how to proceed when there are no standards	Dirk Verellen
12:30 - 14:30	*Lunch*	
14:30 - 14:45	**Equipment and IT related checklists** Introduction to the practical exercise	Dirk Verellen
14:45 - 15:45	**Practical in groups: Equipment and IT related checklists** 45 min of team work filling in the checklist followed by a discussion	Primoz Strojan, Dirk Verellen, Aude Vaandering, Núria Jornet
15:45-16:00	**Quality management related checklists** Introduction to the practical exercise	Aude Vaandering
16:00- 17:00	**Practical in groups: Quality management related checklists** 45 min of team work filling in the checklist followed by a discussion	Primoz Strojan, Dirk Verellen, Aude Vaandering, Núria Jornet

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Course Overview

9:00– 9:30	**Writing the final report: dos and don'ts** How the final report should look like including practical examples	Primoz Strojan
9:30 – 10:00	**Experience B-QUATRO** Explain lessons learnt from B-QUATRO audits and the feedback from auditors and auditees	Aude Vaandering
10:00-10:30	**How to maintain a permanent audit service** Experience from Belgium and B-QUATRO will be explained	Dirk Verellen
10:30 - 11:00	*Coffee break*	

11:00 - 12:30	**Quality Indicators** Introduce the concept of quality indicator, types and how they are defined.	Aude Vaandering
12:30 - 13:00	**Presentation of CAT-ClinART QI** Describe the QI that will be collected within CAT-ClinART clinical audit pilot	Xavier Maldonado
12:30 - 13:00	**Collection and benchmarking of QI in CAT-ClinART** Description and demonstration of the tools for QI reporting	Carles Muñoz
13:00-13:30	**Final conclusions** Wrap up and messages to take back home	Gemma Sancho

We wish you an enriching experience.

Thanks!

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