CLAUD·IT

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CLAUD·IT

D1.3 Third update report on planning clinical audit campaigns

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Executive summary

CLAUD-IT is an EU co-funded project with the main objective to implement clinical audit in radiology and nuclear medicine in EU Member States. This report presents project achievements to-date, reviews the project timeline for potential delays, presents up-to-date risk analysis, and outlines next steps for the consortium.

The project is currently on track, with minor delays. The next upcoming deliverables and milestones are expected to be accomplished on time with the exception of D5.2 (postponed from M20 to M21) and MS4 (postponed from M18 to M21). No new or major risks for the project have been identified. The main achievements during the M13–M18 are:

- Completion of the remote training in the 1st round hospitals; and
- Finalisation of the audit methodology.

Abbreviations

BEN	Beneficiary
CA	Consortium Agreement
C&D	Communication and Dissemination
DoA	Description of the Action
EAB	External Advisory Board
EANM	European Association for Nuclear Medicine
ESR	European Society of Radiology
EU	European Union
GA	Grant Agreement
HaDEA	European Health and Digital Executive Agency
IB	Implementation Board
KPI	Key Performance Indicator
MB	Management Board
MS	Milestone
PCO	Project Coordinator
SC	Steering Committee
SCO	Scientific Coordinators
WP	Work Package
WPL	Work Package Leader

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1. Introduction

CLAUD-IT is a 36-month project (September 2024 – August 2027) co-funded by the EU under the EU4Health programme 2021–2027, specifically EU4H-2023-PJ-05 action grants concerning implementation of the agenda for medical ionising radiation applications (SAMIRA action plan). The project focuses on organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising radiation and brings together 13 beneficiaries and one affiliated entity from 10 Member States.

The objectives of CLAUD-IT are to improve clinical audit practice in EU Member States, foster implementation of clinical audit in radiology and nuclear medicine and thus improve quality and safety of patients.

The bi-annual progress reports on planning clinical audit campaigns provide comprehensive insight into the project's progress according to its timeline, highlight achievements and outline next steps.

First, the project timeline will be revised to check whether all milestones and deliverables were completed on time and account for any possible delays as early as possible to mitigate their possible effect on the project's success.

Next, progress updates will be presented for each WP, highlighting achievements against targets defined in the GA. If achievements were not possible to reach, a throughout explanation of the issues will be provided.

In the following section, the project's progress will be verified against the list of possible risks. Each will be reviewed regarding their probability of occurrence and possible impact on the project. Mitigation measures will be reviewed and adapted if needed. Finally, if any new risks were identified, they will be added to the list, including their probability of occurrence, impact and mitigation measures.

The last section will focus on the next steps for each WP. If any delays were identified, mitigation measures will be proposed in this section. Additionally, if the progress analysis shows that some of the targets may not be achieved on time or difficult to reach, alternative solutions will be proposed.

The reports will serve as a comprehensive overview of the project's status and progress. Bi-annual reports will allow careful monitoring of the progress.

2. Project timeline revision

The project launched on the 1st of September 2024 and is planned to last for 3 years (36 months). It is split into six WPs, five of which launched at the beginning of the project, and one started in month 16 (December 2025). During the first year the project focused on revising existing guidelines and practices, and developing own guidelines, which will be easily adaptable by hospitals in different EU Member States. Additionally, a repository of audit materials, guidelines, and regulations were created, as a one-stop-shop for all needed information on clinical audit in radiology and nuclear medicine. Moreover, preparations for the first round of audit took place, with the first audits in month 16 (December 2025).

From September 2025 (month 13) until the end of February 2026 (month 18) the project ran on time with a few slight delays. All delays were caused either by external factors, or practical reasons. The adaptations in the workplan are independent from other aspects of the project, therefore the full project timeline is not subject to any major delay.

The following changes to the timeline have been applied:

- MS12 has been completed in M17 (instead of planned M16) due to external factors,
- MS4 has been postponed from M18 to M21 to allow for a better preparation of the multi-stakeholder workshop,
- D5.2 has been postponed from M20 to M21 due to external factors.

In M13 - M18 the CLAUD-IT consortium successfully achieved the following milestones:

- MS12 – Completion of remote training

Additional to the accomplishment of planned milestones, the following deliverables were completed and submitted.

- D1.3 - Third update report on planning of clinical audit campaigns
- D1.4 - Activity Report of External Advisory Board and Implementation
- D3.1 - Report with comprehensive overview of ”national procedures” and comparison with current status, identifying gaps and suggesting action plans
- D5.1 - Report on developed training material, including clinical audit “cookbook”

The following tasks were completed with the end of M12.

- T5.2 Setup of related training materials and selection of audit templates for the internal clinical audit
- T5.3 Training of the local multidisciplinary teams by external experts.

The project tasks are on track. Concrete next steps for each WP have been described in section 5 of this report.

3. Completed actions per WP

3.1. WP1: Project Management and Coordination

EIBIR as the project coordinator and lead of WP1 is conducting and monitoring all activities in WP1 with support from the SCOs. The consortium’s project management bodies (SC and MB) are in full

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operation since the start of the project. Additionally, external bodies, the IB and EAB, continue their operations through regular meetings and e-mail updates. The IB met twice between M13 and M18, in September and December 2025.

During the period between M13 and M18 there were no changes in the composition of the IB and EAB. A complex report on the IB and EAB activities during the first half of the project was featured in D1.4.

The Management Board (MB) conducts regular monthly meetings. Meeting minutes are submitted first to the MB members for review and then shared with the Steering Committee (SC) members and the whole consortium to support transparency and information flow.

An SC meeting was organised in M13 (September 2025). During this meeting the general progress updates were discussed, and the SC agreed on the steps for the next 12 months. Following the SC meeting, a plenary consortium call was organised. During this meeting the consortium was presented with the highlights from each WP and the most important plans for the upcoming months. The next SC and Consortium meetings have been scheduled for 26 and 27 of March 2026.

3.2. WP2: Dissemination

The consortium continued their communication and dissemination efforts. The CLAUD-IT project has been continuously promoted via LinkedIn. At the end of M18, the LinkedIn page had 317 followers, and the content has achieved ~7 500 impressions (between M13 and M18).

The project was promoted at EANM 2025, which took place from October 4–8, 2025, in Barcelona, Spain. The project had a dedicated session within the newly created EANM "EU Affairs Track," where Scientific Coordinator Prof. Laura Evangelista, together with colleagues, presented the challenges of CLAUD-IT, focusing on the nuclear medicine aspects and the development of NuCline. The session was freely accessible to all congress participants onsite. Additionally, EARL/EANM showcased the project at their booths, presenting the project leaflet, sharing information about NuCline, and actively engaging with conference attendees.

The table below presents a progress overview of communication KPIs. Only KPIs relevant to the current stage of the project are presented.

Review of communication KPIs		
KPI	Target	Achieved by end of M12 (cumulative)
Conference Presentations and Posters	15	7
Virtual media presence (including social media)	10.000 per year	37.868 impressions on LinkedIn 1162 impressions on EIBIR's website

In July 2025 (M11) ESR with support of the CLAUD-IT consortium launched the Young Audit Prize - a competition dedicated to young radiologists with the main objectives to popularise clinical audit among young radiologists and spread awareness on importance of clinical audit for safety in radiology. Additionally, through the Young Audit prize, ESR and the Consortium aim to further disseminate AUDITRAD. The participants were asked to conduct a clinical audit under guidance of AUDITRAD and submit a completed form with an audit template. It is recommended to use one of the templates included in AUDITRAD, or develop an own template based on an empty template included in the AUDITRAD. The audits were evaluated by a committee nominated by ESR's Audits and Standards

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Subcommittee. To boost interest and number of applications from the EU Member States, information about the Young Audit Prize has been shared with the consortium members, EAB, IB, and is actively promoted through CLAUD-IT's communication channels. The Young Audit Prize Committee, which partly consists of the consortium members, selected 7 audits which will be presented and graded during a dedicated session at ECR 2026.

3.3. WP3: Evaluation

The report providing a comprehensive overview of "national procedures" and a comparison with the current status, identifying gaps and proposing action plans, was finalised (D3.1) and submitted by the end of November 2025. The first part of the report (*Current state of clinical audit in participating countries and comparison with the QuADRANT project*) presents the current status of clinical audit and a comparison with the QuADRANT findings, the current status of audits of justification in radiodiagnostic procedures, and a national gap analysis with proposed action plans. The second part of the report (*Overview of current status in participating core hospitals*) presents the results of the survey conducted in hospital radiology and nuclear medicine departments across nine participating countries.

Based on data collected using specially developed evaluation sheets, the assessment of progress on action-level indicators was performed and evaluated during the consortium meeting held in September 2025 (Task 3.3).

In January 2026, in collaboration with WP5, work started on the development of a questionnaire to be used in a survey to be conducted after completion of the clinical audits in the first-round hospitals, with the aim of collecting feedback on experience with the clinical audit process, including lessons learned, challenges encountered, and suggestions for improving the clinical audit methodology (Task 3.3 and Task 5.4).

3.4. WP5: Preparation of Clinical Audit and Related Education & Training Material Followed by First Round of Audit

T5.3 (M14-M16 = 01.10.2025 – 31.12.2025)

Experts from various European countries were recruited for the online training courses with the local multidisciplinary audit teams and the respective test audits. After being assigned to the individual consortium hospitals, the online training courses were largely completed by 31 December 2025 (see the table below). The only exception was the cancellation of one external expert, which we were able to compensate for with another, but this caused a slight delay in the schedule.

Partner	Auditor RAD	Auditor NucMed	Date Training RAD	Date Training NM
Klincka bolnica Dubrava	Michael Walz	Michel Koole	22.12.2025	30.12.2025
Fondazione Policlinico Universitario A. Gemelli	Petro Julkunen	Francesco Giammarille	16.12.2025	01.12.2025
LINAC-PET Scan Opco Ltd (GOC)	Peter Mildenberger	Luísa Paldo Pereira	12.12.2025	27.11.2025
Humanitas Mirasole SPA	Petro Julkunen	Francesco Giammarille	19.12.2025	10.12.2025

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Institute of Oncology Cluj-Napoca	Rebecca Greenhalgh	Luísa Paldo Pereira	21.11.2025	21.11.2025
Universitätsklinikum Essen	Michael Walz	Francesco Fraioli	Online training both teams together with M.Walz - 09.01.2026	
University Hospital Schleswig-Holstein	Peter Mildenberger	Francesco Fraioli	Online training both teams together with P.Mildenberger - 17.11.2025	
University Medical Centre Ljubljana	Graciano Paulo	Michel Koole	26.11.2025	26.11.2025
University Hospital St. George Plovdiv	Rebecca Greenhalgh	Luísa Paldo Pereira	24.11.2025	26.11.2025
Panepistimio Kritis	Peter Mildenberger	n/a	13.11.2025	n/a
Hospital Clinic de Barcelona	Graciano Paulo	Francesco Giammarille	18.12.2025	18.12.2025

MS12 (remote training completed): postponed from December 2025 to January 2026 for those hospitals which reported issues due to illnesses or experienced trouble due to changes of the responsible experts.

T5.4 (M16-M20 = 01.12.2025 – 30.04.2026)

Audit templates from the AUDITRAD and NuCline guidelines are used in every partner hospital:

> Radiology - Audit 18
> = Appropriate completion of radiology request forms for X-rays and CT scans
> Nuclear medicine – Audit 13
> = Is there a declaration of consent for patients undergoing diagnostic nuclear medicine procedures?

In this instance, too, appointments had to be postponed due to illness, but the new dates have now been set and will be completed by mid-February. The reporting deadline has been postponed to the end of May with the approval of the PO.

Audit reports are currently being evaluated and compared. A questionnaire is also being used in the consortium hospitals (see 3.3 WP3 above) to determine the degree of understanding of QM in order to continue and consolidate the audit system.

In the course of WP5, a steadily growing interdisciplinary commitment has been observed. Over the past few months, all participants have reported a continuous potential for improvement in training activities and the provision of materials for setting up and maintaining an audit system. The process is still very dynamic and continues to evolve. All input is discussed in the responsible teams and, for final decision-making, in the Management Board and Implementation Board.

3.5. WP6: Clinical Audit Campaigns in Hospitals across Europe

The first coordination meeting with 2nd round hospitals was held to recap the project objectives, timeline, and assigned tasks of the WP (19/01/2026). During the meeting, participating centers from 2nd round hospitals received instructions on the upcoming activities, including guidance on the composition of the local audit teams. A written summary was subsequently circulated to all sites, outlining the key points discussed and the next steps. The deadline of 31/03/26 was set for hospitals to communicate the composition of their local audit teams.

4. Risk analysis – review

Initial risk analysis has been conducted at the application stage. At the project start, the risk analysis has been re-evaluated and updated. No new risks connected with the project have been identified. Additionally, at the start of the project, a risk assessment has been conducted. The risk analysis has been done using the following methodology:

> For each risk, a probability (P) of its occurrence has been estimated (on scale 1 to 9, where 1 – 3 is low probability, 4 – 6 is medium probability, and 7 – 9 high probability). Next, an impact (I) of each risk on the project has been determined (on scale 1 to 9, where 1 – 3 is minimal impact, 4 – 6 is medium impact, and 7 – 9 high impact). In the following step, the result of the probability factor was multiplied by the impact factor, to determine the result.

The results of the risk assessment, as well as current risks to the project are presented in the table below. The mitigation measures have been already introduced, where applicable:

- Each WP has a person supporting the WP leader, well informed about the current tasks and goals (R1, R2),
- MB conducts monthly online meetings which include update from each WP and review of project progress (R2),
- Project management platform has been established and has been shared with the consortium (R2),
- Involvement of national societies and the IB in the evaluation of the status quo (R4),
- Partner representatives support the project partners in direct contact with representatives of national societies and authorities when needed (R5),
- Meetings within working groups conducted (R6),
- Regular meetings of the nuclear medicine group conducted (R7),
- Idea for the repository aligned with ESR experts; External, free of charge platform specialised in publishing scientific results selected to host the repository (Zenodo) (R8),
- External audit experts reconfirmed their participation at the start of the project (R10),
- A number of 2nd round hospitals have already been recruited (R11),
- Project timeline and next steps for each WP reviewed during monthly MB meetings (R14).

Due to successful completion of the D4.2 – ESPERANTO 1st edition for nuclear medicine – risk R7 (Delay in creating the ESPERANTO 1st edition for nuclear medicine due to difficulties in consensus about template content**)** has become obsolete and is therefore marked as completed. Completion of the open access repository removed the possibility of materialisation of the risk R8 (Unforeseen problems with the technical infrastructure and repository set up).

Risk	P	I	Result	Mitigation	Affected WPs
R1: Potential absence of a critical team member (e.g., WP lead) during this short project due to illness, etc.	1	1	1	Appointment of deputy for each WP during first MB meeting	All WPs
R2: Lack of responsiveness of consortium members	3	3	9	Monthly online meetings of the MB to detect issues early on; online communication and project management platform for project members, appointment of deputies for key roles (WP lead)	All WPs, WP1
R3: Low interest in stakeholder workshop	1	2	2	Early planning and promotion, online character to facilitate participation; use of ESR/EANM and national society communication channels, as well as HERCA and SGQS; IB members and personal contacts to disseminate information and promote the workshop	WP2
R4: Translation of some specific regulations or guidelines in English unavailable	8	5	40	Engagement of experts from specific participating country	WP3
R5: Lack of responsiveness of national radiology and nuclear medicine societies of the 9 participating countries	5	5	25	Already assured full support from national radiology and nuclear medicine societies documented through letters of support. Close follow-up through ESR/EANM and direct personal contacts	WP3
R6: Delay in achieving milestones in WP4, WP5 and WP6 resulting in scarce evaluation report	2	4	8	Regular consortium meetings during which potential obstacles would be identified and remedial actions planned, regular review of risk register in MB meetings	WP4, WP5, WP6
~~*R7: Delay in creating the ESPERANTO 1st edition for nuclear medicine due to difficulties in consensus about template content*~~	~~*3*~~	~~*6*~~	~~*18*~~	~~*Initial and clear timeline definition. Regular meetings and communications with EANM experts and with external experts in audits. Timely follow up by the coordinators.*~~	~~*WP4*~~
~~*R8: Unforeseen problems with the technical infrastructure and repository set up*~~	~~*1*~~	~~*4*~~	~~*4*~~	~~*Seek advice from ESR/EANM who have experience setting up this type of online repository; start planning and communication with technical experts from beginning of the project*~~	~~*WP4*~~
R9: Difficulty to reach consensus on audit methodology	1	4	4	Methodology has been already preliminarily discussed with the consortium at proposal stage. Implementation Board will advise and support finding consensus taking into account local specificities and requirements	WP5

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R10: Insufficient availability of external experts for 1st round audits	1	2	2	External experts were already identified at proposal stage and a list of potential backup experts has been set up in case of issues.	WP5
R11: Problems to recruit hospitals for the 2nd round of audit	2	5	10	Implementation Board to reach out to hospitals that have already agreed to participate at proposal stage, recruit additional hospitals as needed. Intensify recruitment campaigns at the earliest sign of under-recruitment through various strategies (activating personal contacts, recruitment campaigning via national societies as well as ESR and EANM.)	WP6
R12: Participants of the 2nd round audit already have their own internal and structured auditing procedure	5	3	15	The CLAUD-IT methodology will be used and adapted to the local setting and requirements. Information on methodology and related training material will be shared early on with participating hospitals.	WP6
R13: Delays in setting up, performing or reporting of the1st and 2nd audit rounds	3	4	12	For the 1st round audits, the setting up of the local audit team will start right at the beginning of the project to allow sufficient preparatory time, with regular jour fixe meetings scheduled. The external experts will support the WP5-6 leads in identifying issues/delays early on so that potential barriers can be identified and resolved in a collaborative way. Analysis and reporting of the 1st round audit will be supported and guided by the external auditors who are experienced and have committed to that role already during proposal phase, hence no issues are expected regarding a timely reporting. For 2nd round audits, in case of issues with pre-identified 2nd round hospitals, the consortium already has a back-up list of potentially interested hospitals who can be approached instead. The Implementation Board will also play an active role in ensuring buy-in of the centres and timely implementation of the 2nd round audits. Analysis and reporting will be overseen by UKSH and EIBIR and regular interaction is foreseen to recognize potential issues early on and offer support from the 1st round auditors as needed	WP5, WP6
R14: Delays in project deliverables and interim and final reporting	2	3	6	EIBIR and UKSH with support of the Management Board will closely monitor the implementation of the work plan and related timelines. In case of early indications of delays in deliverables, dialogue will be sought with the partners concerned to identify issues and to develop support strategy from other consortium members. The interim and final reporting will be coordinated by EIBIR with extensive experience in European projects and sufficient lead time for partners to prepare their input. Briefing meetings/webinars will be organized for all partners to alert them to the reporting requirements and related templates.	All WPs

5. Next steps

5.1. WP1:Project Management and Coordination

The Coordination Team will continue monitoring the progress and status of the project in close cooperation with the management bodies (SC and MB). The fourth SC meeting (in person) is planned in March 2025 and will be followed by a plenary meeting with all consortium members (hybrid). Regular progress updates and meetings with the IB and the EAB members will be conducted.

5.2. WP2: Dissemination

CLAUD-IT will be present at the ECR 2026 with a dedicated talk by Prof. Roman Klöckner on the project's progress. ECR 2026 will feature a dedicated session organised by CLAUD-IT – an "ask me anything" format with a panel of experts. Two posters have been submitted by the CLAUD-IT consortium to the EuroSafe Imaging exhibition at ECR 2026. Additionally, ESR will for the first time feature a poster competition dedicated to clinical audit in radiology - the Young Audit Prize. WP2 will support ESR's communication efforts to promote this initiative as well as AUDITRAD. Last but not least, with the premiere of the "audit cookbook" planned in November 2025, WP2 will conduct a promotional campaign to promote this valuable resource in participating countries and other EU Member States.

The consortium will continue promoting the project online and at professional conferences and meetings. An abstract has been submitted to the Italian Congress of Nuclear Medicine (May 2026).

The dedicated stakeholder workshop is being organised together by EIBR and EARL with support of the professional societies ESR and EANM. The workshop will take an online format and take place in May 2026.

5.3. WP3: Evaluation

Using specially developed evaluation sheets, the necessary data and information will be collected, and the assessment of progress on action-level indicators for the following project year will be carried out and evaluated during the first subsequent consortium meeting.

5.4. WP5: Preparation of Clinical Audit and Related Education & Training Material Followed by First Round of Audit

The final activities in WP5 are planned for M19-M21. Clinical partners and external audit experts provide reports on the training mock audits, and the first round of audits, as well as fill a survey to provide feedback on the methodology. The results will be carefully analysed, and the WP5 will conclude with a report on the 1st round of audits and the methodology.

5.5. WP6: Clinical Audit Campaigns in Hospitals across Europe

The next phase will focus on supervising the formal appointment of local audit teams by 2nd round hospitals. The specific Task T6.1 (Setup Local Audit Teams) will continue until April 2026, with the deadline of 31 March 2026 for the 2nd round hospitals and a reminder planned for February 2026.

Preparatory activities for T6.2 (Remote Training, April–July 2026) will be initiated, including the identification and appointment of relevant experts, as well as continued alignment and refinement of training materials. These points will also be discussed and refined during the consortium meeting on 26–27 March 2026.

A further coordination meeting with 2nd round hospitals is planned to support this phase.

Following completion of the previous tasks, T6.3 (Conduct 2nd Round Audit) will be conducted between August 2026 and April 2027.

Subsequently, T6.4 (Review and Future Direction) will take place from April to August 2027, focusing on the evaluation of audit outcomes and the definition of future actions.