DEVELOPMENT AND VALIDATION OF A RADIOLOGY DIGITAL COMPETENCY PROFILE ALIGNED WITH THE EUROPEAN HEALTH DATA SPACE

A sequential framework-development study integrating evidence synthesis, regulatory mapping, and expert validation

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Dedication / Acknowledgements

I would like to express my sincere gratitude to all those who have accompanied and supported me throughout the development of this work.

This project has not only been an academic exercise, but also a journey of personal and professional growth, made possible by the generosity of those who shared their time, knowledge, and trust with me.

I would like to extend my special thanks to the subject matter experts who participated in the validation phase. Many of them did not know me personally beforehand, and yet they agreed to collaborate with admirable willingness. I deeply appreciate the time they devoted to me (often alongside demanding clinical responsibilities) to review, comment on, and enrich this research with their expertise and professional perspectives.

Their professionalism and their willingness to contribute selflessly were decisive in enabling this study to progress and achieve a higher level of rigor and relevance. I am sincerely grateful to all of them. Without their time and support, this work would not have been possible.

Abstract

The European Health Data Space (EHDS) introduces new interoperability, governance, and data use requirements that will directly affect radiology practice across Europe. However, existing digital competence frameworks for healthcare professionals do not adequately address EHDS-specific requirements within the context of medical imaging. This thesis aimed to develop and validate an EHDS-aligned, radiology-specific competency profile and associated learning outcomes, translating regulatory and interoperability expectations into operational educational targets.

A three-phase sequential design was applied. Phase 1 consisted of a structured scoping review to identify existing digital competence frameworks relevant to radiology. Phase 2 systematically extracted imaging-relevant operational requirements from the current EHDS Regulation, identifying radiology specific capability gaps. These findings informed the development of a draft radiology-specific competency profile overlay (RCPO) comprising 14 initial learning outcomes (LOs). Phase 3 involved expert validation with 11 European subject-matter experts (SMEs) using Likert scale appraisal (clarity, relevance, feasibility) combined with qualitative comments. Refinement was guided by a predefined combined quantitative–qualitative decision rule integrating median/ Interquartile range (IQR) thresholds with qualitative issue-pattern predominance to trigger structured review.

Following expert informed refinement, the final RCPO version retained eight core LOs, with removed items largely reflecting highly technical interoperability tasks more suited to informatics or technical roles than routine clinical radiologist practice. The resulting overlay is methodologically transparent, radiologist calibrated and aligned with EHDS implementation. By translating regulatory requirements into structured learning outcomes, this work provides a reproducible framework for integrating digital interoperability preparedness into radiology education and continuing professional development across Europe.

Keywords: EHDS, Interoperability, Digital Skills, Competency, Radiology

JEL Classification System: I18 Government Policy • Regulation • Public Health; O33 Technological Change: Choices and Consequences • Diffusion Processes

Index

Dedication / Acknowledgements ii

Abstract iv

Glossary ix

Introduction 1

Chapter 1 - Conceptual framework 4

1.1 Evidence base: peer-reviewed and grey literature as sources for digital competency domains and statements 4

1.2 Identification of EHDS/EEHRxF-related competencies relevant to medical imaging areas not covered by current frameworks 5

1.3 Definition of the initial version of RCPO 5

1.4 SME interviews as qualitative refinement and validation of the proposed professional-specific competency profile 6

Chapter 2 - Methodology 7

Chapter 3 - Results 10

3.1 Evidence synthesis (Phase 1) 10

3.1.1 Peer-reviewed literature 10

3.1.2 Grey literature and backward snowballing 14

3.1.3 Data extraction and synthesis (charting procedure) 18

3.2 EHDS/EEHRxF requirement operationalisation and mapping procedure (Phase 2) 20

3.2.1 EHDS/EEHRxF-derived competency needs extraction. 20

3.2.2 Mapping to Phase 1 evidence and gap analysis 21

3.2.3 Development of the RCPO v1 22

3.3 Interview with SMEs for RCPO v1 validation (Phase 3) 24

3.3.1 Sample characteristics 24

3.3.2 Completeness of ratings 26

3.3.3 Overall appraisal across learning outcomes 26

3.3.4 Cluster-level patterns 27

3.3.5 Learning outcome level results 27

3.3.6 Analysis of qualitative comments 27
3.3.7 Integration of quantitative and qualitative findings. 29
3.4 Final RCPO v2 29
3.4.1 Overview of refinement outcomes 29
3.4.2 Quantitative-qualitative convergence patterns 31
3.4.3 Resulting structural configuration of RCPO v2 31
3.4.4 Summary of outcomes 32
Conclusion 34
Bibliographic References and Sources 37
Annexes 41
Annex A – PubMed/MEDLINE search strategy and eligibility criteria 41
Annex B – Grey literature search strategy and eligibility criteria 43
Annex C – SME interview for RCPO v1 validation 45
Annex D – RCPOv2 Change Log 52
Annex E – Interview guide 55
Annex F – Full slide deck used for SME interviews 60

Index of tables and figures

Index of figures

Figure 1.0 Phased implementation timeline of the EHDS. 1
Figure 2.1 Study design and conceptual framework 7
Figure 3.1 PRISMA flow diagram 10
Figure 3.2 Radiology competency profile overlay v2 30
Figure C.1 RCPO refinement pipeline 51

Index of tables

Table 3.1 Synthesis of peer-reviewed literature. 12
Table 3.2 Synthesis of the grey literature. 15
Table 3.3 EHDS/EEHRxF needs extraction for medical imaging area 21

Table 3.4 Mapping and gap analysis 22

Table 3.5 RCPO v1 draft learning outcomes..... 24

Table 3.6 Profile of respondents to the interview 25

Table 3.7 Total ratings for the three different domains of RCPO v1..... 26

Table 3.8 SME ratings for RCPO v1 LOs (median and IQR). 26

Table 3.9 Theme labels mapped to the issue-type codebook 28

Table 3.10 Reassignment of general comments to issue types 28

Glossary

DICOM - Digital Imaging and Communications in Medicine standard

EEHRxF - European Electronic Health Record Exchange Format

EHDS - European Health Data Space

EHR - Electronic health record

EC – European Commission

EU – European Union

IQR - Interquartile range

LO - Learning outcome

PACS - Picture Archiving and Communication System

RCPO - Radiology Competency Profile Overlay

RIS - Radiology Information System

SME – Subject Matter Expert

Introduction

In May 2022, the European Commission (EC) presented to the European Parliament and the Council a proposal for a regulation on the EHDS (European Commission, 2022).

This initiative was part of the broader European data strategy, which aims to transform the European Union (EU) into a data-driven society by creating a single market for shared data, in which health is one of the nine strategic common European data spaces identified by the EC (European Commission, 2020).

In February 2025, the European Parliament and the Council of the EU definitively approved Regulation 327/2025 on the EHDS (EHDS Regulation). The EHDS Regulation entered into force on 26 March 2025 and will become applicable progressively in phases, supported by implementing acts (European Union, 2025). Under this multi-stage application framework, certain rules are expected to take effect within two years of entry into force, while others will be implemented gradually through successive milestones extending into the 2030s, when the regulation is scheduled to become fully operational (Figure 1.0)(European Commission, 2025).

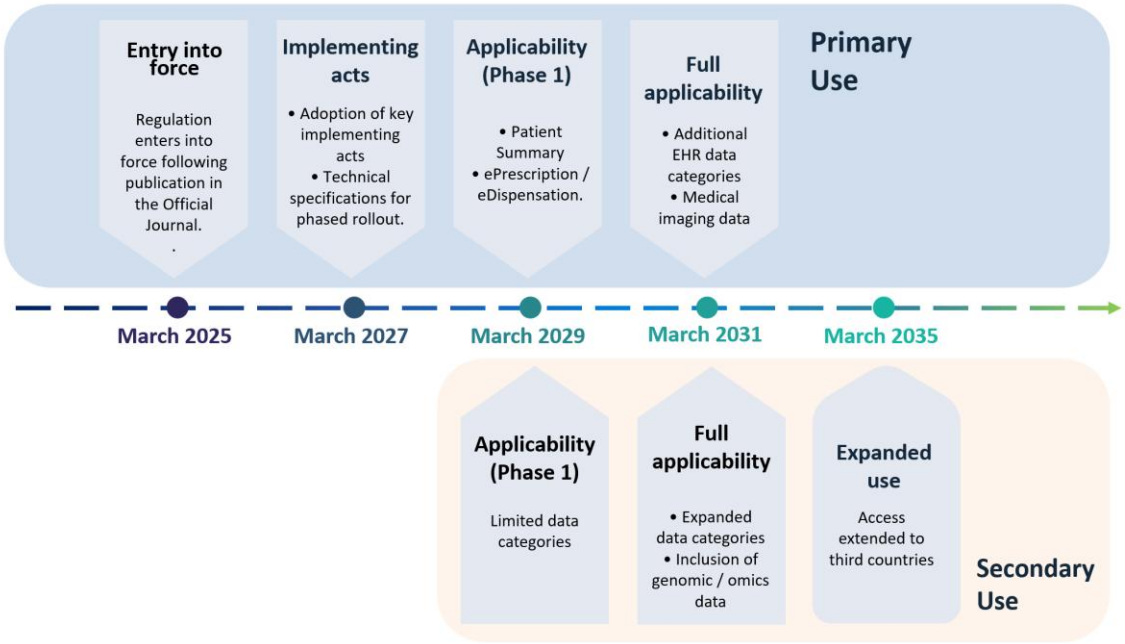


Figure 1.0 Phased implementation timeline of the EHDS.

Note. Author's synthesis based on EU Regulation 327/2025

In line with the fundamental purpose behind the creation of the EHDS, the main goal of the new regulation is to give European citizens greater control over their health data, facilitate cross-border data exchange, enhance the quality of care and patient safety, and foster personalised medicine. It also provides significant benefits for researchers and the healthcare industry by enabling the reuse of

health data to drive innovation and advance research. Additionally, by establishing a uniform legal and technical framework for electronic health record systems, EHDS Regulation supports the creation of a European Health Union.

The long-term transition period for the full implementation of the EHDS, reflects the technical, legal, ethical, and operational complexity of this initiative, which involves numerous stakeholders, including public authorities, industry, regulatory bodies, healthcare facilities, patients, and healthcare professionals, among others.

In Recital 89 of the EHDS Regulation, digital literacy is recognised as an essential component for the successful implementation of the new framework, both for patients and healthcare professionals. This emphasis is operationalised in Article 83, which requires Member States to establish specific training programmes for healthcare professionals "in order for them to understand and effectively carry out their role in the primary use of and in the accessing of electronic health data"(European Union, 2025, Article 83).

An appropriate level of digital literacy among healthcare professionals is a key component for the effective implementation of the EHDS, ensuring the meaningful use, secure sharing, and protection of health data.

Although the EHDS Regulation clearly underscores the importance of building such competences, there is still a limited systematic understanding of the current state of digital skills, particularly among health professionals. Another critical aspect is that this specific area of research is largely absent from peer-reviewed scientific literature, as many frameworks for digital literacy are documented exclusively in grey literature and are not always specifically tailored to healthcare professionals (Cosgrove & Cachia, 2025). Furthermore, given the intrinsic characteristics of the EHDS, specific competences in domains such as interoperability and the new European Electronic Health Record Exchange Format (EEHRxF) appear particularly relevant.

Addressing this gap is therefore critical to enable the effective implementation of the EHDS in clinical practice.

Radiology and medical imaging represent a particularly relevant use case for the EHDS, as imaging workflows depend on the secure and timely availability of structured clinical information, imaging metadata, and reports across organisational boundaries. Radiologists routinely interact with complex digital ecosystems (e.g., Radiology Information Systems (RIS), Picture Archiving and Communication Systems (PACS), Digital Imaging and Communications in Medicine standard (DICOM), electronic health records (EHRs), and local or regional archives) and are therefore directly exposed to interoperability challenges, data quality issues, access control requirements, and cross-border information exchange.

Consequently, beyond generic digital literacy, radiologists require role-specific competences aligned with EHDS requirements to perform their clinical responsibilities safely and effectively under the new regulatory framework.

Building on this rationale, the thesis draws on the current evidence base from both peer-reviewed and grey literature to develop and validate an EHDS-aligned radiology-specific competency profile through three sequential phases: a scoping review identifying the evidence gap (Phase 1); a requirement-led development and EHDS/EEHRxF alignment phase (Phase 2); and an expert validation phase leading to a training-oriented output (Phase 3).

The study is guided by the following research questions (RQ):

RQ1 (evidence synthesis)

How does the evidence base (peer-reviewed and grey literature) describe the digital and interoperability competences relevant to healthcare professionals and which are applicable or transferable to radiologists within the medical imaging ecosystem?

RQ2 (mapping and competency development)

Which EHDS/EEHRxF-relevant domains and competencies can be derived from existing general digital competence frameworks and the EHDS Regulation, and how can they be operationalised into an initial RCPO for the medical imaging ecosystem?

RQ3 (empirical refinement)

How do SMEs evaluate the clarity, relevance, and feasibility of the initial RCPO learning outcomes and domains, and what refinements are required to achieve a validated, training-oriented competency profile for real-world practice?

By combining evidence synthesis with expert input, this work moves beyond a review-only approach and produces a practical, traceable, and training-oriented competency profile. It is intended to support the design of targeted training programmes for radiologists, in line with the EHDS's emphasis on digital literacy and capacity building for healthcare professionals.

During the development of this thesis, AI tools were used, in accordance with the rules established in the Thesis Handbook for the ManagiDiTH Master's Programme, as support tools for tasks such as structuring the document, refining search strategies, performing predefined descriptive calculations in Excel, and improving language clarity. These tools were not used to generate original academic content, conduct literature screening or synthesis, or produce or modify research data. All outputs were critically reviewed and validated by the author, who retains full responsibility for the conceptual development, methodology, and final content of this thesis.

Chapter 1 - Conceptual framework

To address the main research questions of this master's thesis, a conceptual framework was developed. In building this framework, the definition provided by Ravitch and Riggan (2017)was followed. They describe the *conceptual framework* as the logical structure that connects all aspects of a research project, guiding its design, data collection, analysis, and interpretation.

This study is guided by a conceptual framework built on four interconnected components: (1) an evidence base combining peer-reviewed and grey literature as primary sources of digital competence domains and statements for healthcare professionals; (2) the digital competence needs derived by the EHDS Regulation and the introduction of the new EEHRxF standard, with particular emphasis on interoperability and cross-border data exchange; (3) a draft RCPO (RCPO v1) developed in response to the evidence gap identified in the existing peer reviewed and grey literature to ensure applicability of current general frameworks to radiology workflows; and (4) semi-structured SME interviews to validate and refine the competency statements and LOs within the RCPOv1, ensuring their relevance and feasibility for EHDS implementation in the medical imaging ecosystem. Operationally, these components are implemented through three sequential research phases: Phase 1 (evidence synthesis), Phase 2 (requirement operationalisation and mapping to develop the RCPO v1), and Phase 3 (expert interviews for validation and refinement).

1.1 Evidence base: peer-reviewed and grey literature as sources for digital competency domains and statements

Given the limited availability of peer-reviewed studies defining EHDS-aligned digital and interoperability competency frameworks for radiology or medical imaging, this work draws on combined evidence base from peer-reviewed and grey literature. Peer-reviewed publications provide academically validated constructs, while grey literature captures policy-driven and practice-oriented requirements that often emerge earlier across multiple channels, including institutional reports, implementation guidance, and technical documentation (Benzies et al., 2006).

In the present study, both evidence streams are used to extract competency statements and learning elements relevant to EHDS/EEHRxF implementation and to identify those that are applicable or clearly transferable to radiologists. Particular attention is given to competencies related to interoperability, secure access, data governance, data quality, and cross-organisational information exchange. This synthesis informs the development of an initial competency profile and a set of LOs for radiologists, which are subsequently refined through expert input.

1.2 Identification of EHDS/EEHRxF-related competencies relevant to medical imaging areas not covered by current frameworks

The EHDS regulation creates a direct legal obligation for Member States to develop training programs that provide healthcare professionals with the competencies required to manage and access electronic health data (European Union, 2025). This regulation also introduces new requirements related to interoperability and data stewardship, including the adoption of the EEHRxF standard, thereby reinforcing the need to identify competence domains that may not yet be formally integrated into existing general digital frameworks.

In the current study, these regulatory requirements serve as a foundation for identifying competence needs relevant to radiologists' EHDS readiness that are not addressed by existing competency frameworks. The focus is therefore not on generic digital skills, but on EHDS/EEHRxF-related competencies relevant to the specific medical imaging ecosystem.

1.3 Definition of the initial version of RCPO

The RCPO is defined as a role-specific, training-oriented set of competencies and LOs for radiologists.

It translates broad domains from general digital-competence frameworks for healthcare professionals into an actionable set of capabilities for everyday practice within the medical imaging ecosystem.

The RCPO is not conceived as a new generic digital competence framework for radiologists. Rather, it contextualises existing digital competence domains by identifying the competencies most relevant to routine radiological practice in the EHDS/EEHRxF context and by expressing them as clear, assessable LOs.

The initial version of the RCPO (RCPO v1) incorporates radiology-specific competency statements identified on the basis of the current available evidence. Where such statements are not available, it draws on transferable statements from general frameworks and aligns them with EHDS/EEHRxF implementation requirements relevant to medical imaging (e.g., interoperability and cross-border exchange). Where general frameworks remain non-specific to imaging, a minimal operationalisation layer is applied to specify how generic competencies translate into radiology workflows (e.g., DICOM-based study structure and study–report linkage), without introducing new high-level domains.

1.4 SME interviews as qualitative refinement and validation of the proposed professional-specific competency profile

Semi-structured SME interviews constitute the other component of the conceptual framework and provide the empirical mechanism through which the evidence-informed draft framework is contextualised to radiology practice within the medical imaging ecosystem. Because the EHDS/EEHRxF competence requirements relevant to medical imaging are often described at the health-workforce level and may not be explicitly articulated for radiologists, expert input is needed to assess the real-world relevance, completeness, and feasibility of the competencies derived from the literature and those identified as EHDS-specific needs.

The interviews are conceptualised as a mixed quantitative–qualitative refinement and validation step aimed at confirming which competency domains and LOs are most critical for EHDS readiness in radiology, and to identify missing or under-specified competencies not captured by existing frameworks or by the RCPOv1. This expert-informed refinement helps ensure that the final RCPO (RCPOv2) is not only evidence-informed but also practice-oriented and suitable for implementation across training and governance contexts.

Chapter 2 - Methodology

This study adopts a sequential framework-development design.

The overall study design and its three-phase structure are summarised in Figure 2.1.

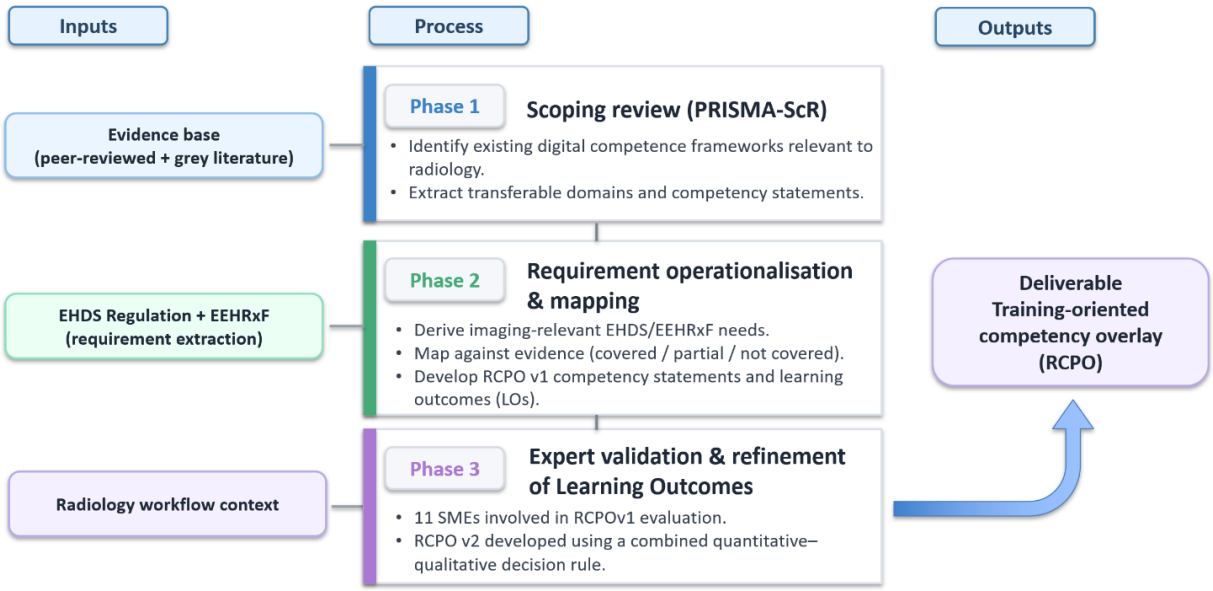


Figure 2.1 Study design and conceptual framework

Note. Author's own work (2026).

Phase 1 - Evidence synthesis

An evidence synthesis combining peer-reviewed and grey literature was conducted to identify existing digital-competence frameworks and competency statements relevant to healthcare professionals, with particular attention to interoperability and medical imaging, and was reported in accordance with PRISMA-ScR (Tricco et al., 2018). The review aimed to determine whether any sources provide explicit EHDS/EEHRxF-aligned and/or radiology-oriented competency profiles and LOs, and to extract transferable competency statements from general frameworks for subsequent analysis.

The initial phase followed the scoping review approach proposed by Arksey and O'Malley (2005). This methodology is particularly suited to mapping key concepts in areas where research is emerging, heterogeneous, and dispersed across multiple sources, including grey literature, which is especially relevant to this study. It enables the inclusion of policy documents, technical reports, and strategic frameworks that are not typically captured in conventional systematic reviews restricted to peer-reviewed studies.

To address both peer-reviewed evidence and policy-driven frameworks in the grey literature, two parallel search strategies were implemented. In addition, the backward snowballing technique was performed to identify potentially relevant documents that might not be retrieved through keyword-based searches (Wohlin, 2014).

Peer-reviewed literature was searched in MEDLINE via PubMed on 9 August 2025, restricted to 2015–2025 period, English-language records, and only to available abstracts. The strategy combined MeSH terms and free-text keywords to maximise sensitivity.

Grey literature was searched using Google.com on 21 October 2025, and the first 100 results were screened for relevance.

The full search strategies used for both peer-reviewed and grey literature, as well as the eligibility criteria, are provided in Annex A – PubMed/MEDLINE search strategy and eligibility criteriaand in Annex B respectively.

Screening and eligibility assessment were conducted by a single reviewer.

Phase 2 - EHDS/EEHRxF requirement operationalisation and mapping procedure

Imaging-relevant EHDS/EEHRxF needs were operationalised into structured needs statements (NS), which served as an external reference standard for radiology EHDS readiness. Competency domains and statements identified in Phase 1 were then mapped against the NS to classify coverage (covered/partially covered/not covered) and to identify gaps requiring radiology-specific elaboration. Based on this mapping, RCPO v1 and its corresponding LOs were constructed by selecting and adapting transferable statements from existing frameworks, applying a minimal medical-imaging operationalisation overlay only where general frameworks remained non-specific to imaging workflows.

Phase 3 - SME interviews and RCPOv1 validation

This phase was designed as a mixed quantitative-qualitative validation pathway aimed to empirically validate and refine the RCPO v1 and its associated LOs through SME semi-structured interviews (Kallio et al., 2016).

Expert input was used to assess LO-level for the following domains: (i) relevance to radiology practice in EHDS-relevant contexts, (ii) clarity of statement formulation (unambiguous, assessable wording), and (iii) feasibility (teachability and assessability within routine training constraints). The interviews were used to refine the proposed competency statements and LOs by evaluating these three dimensions and identifying context-specific gaps or inconsistencies.

This study is therefore more appropriately characterised as a semi-structured interview study with structured ratings than as a Delphi process (Hsu & Sandford, 2007), because it did not involve iterative

rounds or controlled feedback. This format supported a systematic review of RCPO v1 while allowing experts to highlight context-specific issues, including national implementation realities, organisational constraints, and workflow variability, and to suggest competencies not captured in the initial profile.

A detailed description of the SME interview methodology is provided in Annex C. This includes the sampling strategy and eligibility criteria, planned sample size rationale, interview materials and procedures, rating approach, quantitative and qualitative analytic framework, codebook structure, decision rules for LO refinement, and the integrated quantitative–qualitative refinement algorithm used to generate RCPO v2. The annex also documents the full audit trail linking SME feedback to LO-level modifications recorded in the Annex D.

Data management and analysis tools

Microsoft Office Excel 365 was used across phases to document the evidence synthesis, record needs-statement extraction, perform mapping and gap analysis, and capture SME responses. Descriptive and summary statistics were computed in Excel. Where needed, AI tools (e.g., ChatGPT) were used as technical support to suggest appropriate spreadsheet formulas or summary metrics; all analytical decisions, outputs, and interpretations remained the responsibility of the author.

Interview logistics

Interviews were conducted remotely via Microsoft Teams or Google Meet. Each interview was scheduled for 25 minutes, including a brief introductory overview of the EHDS (approximately 5 minutes). A short interview guide (see Annex E) and the supporting slide deck (see Annex F) were prepared using Microsoft PowerPoint (Microsoft 365) and the Gamma app. Integrated AI image-generation tools (e.g., Copilot and Flux) were used to create original illustrative visuals for the interview materials; these images were not used as research data and served only a communicative purpose.

Ethical considerations and data management

Participation was voluntary. Before each interview, participants received an invitation email containing the connection link, together with information about the purpose of the study and the processing of personal data for the purposes of this thesis. Oral informed consent was then obtained and verbally confirmed by the interviewer before proceeding with data collection. Personal identifiers were removed and were replaced with pseudonymous participant codes. Data were stored and were retained only for the period necessary to complete the thesis and any related publications. Findings were reported in aggregate, using anonymised excerpts to reduce re-identification risk.

Chapter 3 - Results

This chapter presents the results generated across the study phases. Section 3.1 reports the evidence synthesis from the scoping review (Phase 1), including the study-selection flow (Figure 3.1) and a descriptive summary of the included peer-reviewed and grey literature. Section 3.2 describes the operationalisation of EHDS/EEHRxF requirements into radiology-relevant competency needs, as well as the mapping and gap analysis against Phase 1 evidence that informed the development of RCPO v1.

Section 3.3 presents the expert interview findings used to validate and refine RCPO v1 (Phase 3), integrating quantitative Likert ratings with qualitative feedback. Finally, Section 3.4 summarises the resulting refinements and presents the final RCPO v2.

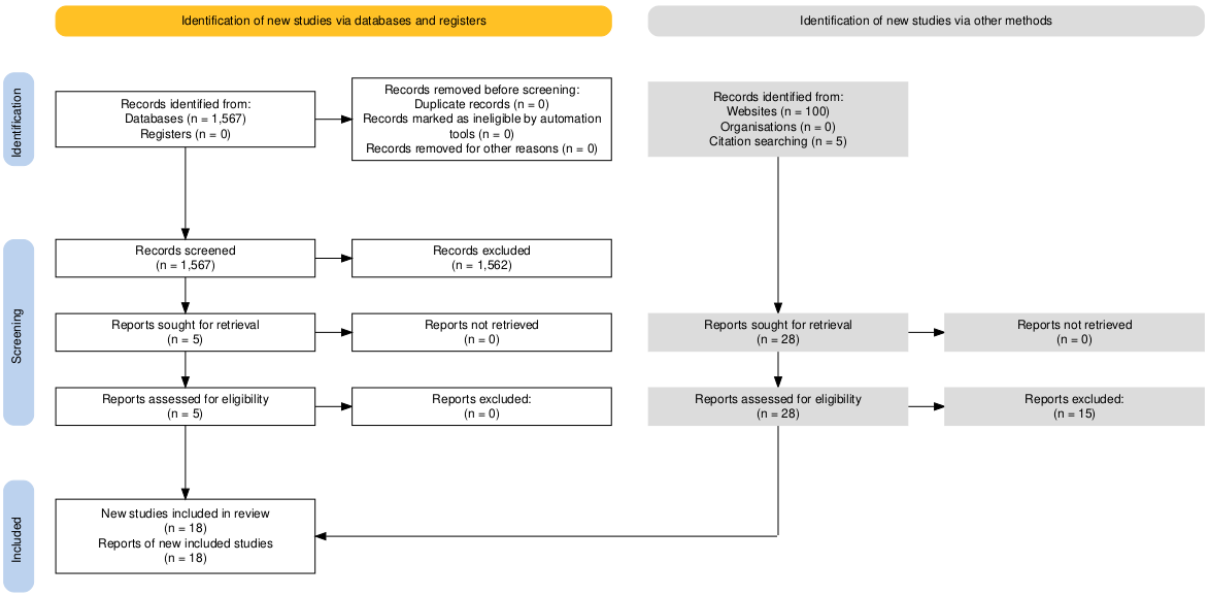


Figure 3.1 PRISMA flow diagram

Note. The diagram was generated using the PRISMA2020 R package and Shiny app (Haddaway et al., 2022), using the online tool available at: https://www.eshackathon.org/software/PRISMA2020.html

3.1 Evidence synthesis (Phase 1)

3.1.1 Peer-reviewed literature

The search of peer-reviewed literature using the query described in detail in Annex A, retrieved a total of 1,567 records from the PubMed database as of 09 August 2025. Many records referred to digital technologies applied in clinical settings and were not directly related to the digital competences of healthcare professionals. Therefore, all records were screened based on titles and the summary information displayed in the PubMed results list, and 1,439 records were excluded at this stage.

The remaining 128 records underwent a more detailed abstract-level screening using the full abstract text available in PubMed, resulting in a further 123 exclusions.

Five reports were therefore selected for full-text retrieval and assessed for eligibility. All five met the inclusion criteria and were included in the synthesis: four of these articles define new digital competence frameworks for healthcare professionals (Almalki et al., 2021; Brunner et al., 2018; Gutiérrez et al., 2025; Saigí-Rubió et al., 2024), and one was a scoping review of the frameworks previously published in the literature (Nazeha et al., 2020).

Across the included peer-reviewed literature, no publication explicitly targeted radiologists as a defined primary audience; any relevance to medical imaging appears via broader digital health or informatics competency structures rather than radiology-specific role definitions.

To identify explicit references to EHDS, interoperability, and imaging-related concepts, a targeted keyword/tag screening was applied to the retrieved reports using the following terms: interoperability; cross-border data exchange; EHDS; EEHRxF; medical imaging; radiology; radiologist(s); DICOM; PACS; RIS. Interoperability was explicitly mentioned in three publications. In contrast, cross-border data exchange, EHDS, and EEHRxF were not referenced in any included peer-reviewed article. With respect to imaging ecosystem terms, PACS and medical imaging appeared in two publications, whereas RIS appeared in one (see Table 3.1). No publication explicitly mentioned radiology, radiologists, or DICOM.

The scoping review of Nazeha et al. (2020). identified *“Imaging”* and *“Integration and interoperability”* as a competency domain across educational frameworks included in their review but did not provide granular competence statements attributable to a single, unified framework.

Table 3.1 Synthesis of peer-reviewed literature.

Title	Authors / Journal	Year	Document type	Target population	Structure / classification approach	Domains (count + list)	How competencies are defined	Number of competences	Found terms[11]	Competencies related to Medical Imaging/EHDS (main statements)	Targets radiologists / radiology or medical imaging ecosystem
Referential Competencies in Digital Health: A Necessity for the Digital Transformation of Future Clinical Professionals	Gutiérrez S.; Torres V.; Molina MM; Corvalán F.; García F.; Härtel S. / Studies in Health Technology and Informatics	2025	Conference proceedings paper	Four user groups: Decision Makers; ICT Personnel; Clinicians; Patients	Referential competency model using review literature as starting point, followed by focus group focus group to contextualize the competencies for the local healthcare setting.	9 domains: A: Digital Health Transformation Management; B: Process Architecture; C: Design, Development, and Implementation; D: Interoperability and Standards; E: Innovation and Digital Transformation in Health; F: Clinical Decision Support Systems; G: Secondary Use of Health Data; H: Telehealth; I: Ethical, Legal and Governance Aspects	Competency statements describing observable abilities	103 competencies across 9 domains for 4 different groups: Decision Makers, ICT Professionals, Clinicians, and Patients	interoperability; PACS; RIS	Generic reference to competences related to RIS/PACS and a dedicated domain on "Interoperability and Standards".	No
Design, Implementation, and Analysis of an Assessment and Accreditation Model to Evaluate a Digital Competence Framework for Health Professionals: Mixed Methods Study	Saigí-Rubió F.; Romeu T.; Hernández Encuentra E.; Guitert M.; Andrés E.; Reixach E. / JMIR medical education	2024	Peer-reviewed original article	Health professionals in Catalonia, segmented into 4 professional profiles	Iterative competence framework using scoping review as starting point followed by consultation with local experts.	4 competence areas: (1) data access, management, and analysis; (2) communication and collaboration; (3) digital awareness; (4) professional development	10 competences with indicators; assessment uses observable behaviors via contextualized scenarios	10 competences (under 4 areas) + indicators; assessment test: 28 questions/60 min per profile	None	No	No

[1] Searched terms within the documents: interoperability; cross-border data exchange; EHDS; EEHRxF; medical imaging; radiology; radiologist; DICOM; PACS; RIS.

An eHealth Capabilities Framework for Graduates and Health Professionals: Mixed-Methods Study	Brunner M.; McGregor D.; Keep M.; Janssen A.; Spallek H.; Quinn D.; Jones A.; Tseris E.; Yeung W.; Togher L.; Solman A.; Shaw T. / Journal of medical Internet research	2018	Peer-reviewed original paper; mixed methods / Delphi-style consensus	Health graduates and practicing health professionals	Capability framework: higher-level capability statements supported by performance cues	4 domains: (1) digital health technologies, systems, and policies; (2) clinical practice; (3) data analysis and knowledge creation; (4) technology implementation and codesign	4 capability statements (learning outcomes) + 40 performance cues illustrating how capabilities may be demonstrated	4 capability statements; 40 performance cues	None	No	No
A multi-perspective approach to developing the Saudi Health Informatics Competency Framework	Almalki M.; Jamal A.; Househ M.; Alhefzi M. / International journal of medical informatics	2021	Peer-reviewed original article	Health informatics professionals; regulator/registration body (SCFHS) for HI certification program	Iterative competency framework using scoping review as starting point, followed by stakeholder survey ranking, focus groups, and expert panel refinement	6 domains (22 subdomains): Core Principles; ICT; Health Sciences; Health Data Analytics; Education and Research; Leadership and Management	Competency statements consolidated from literature and locally validated/prioritized	92 competencies (grouped into 6 domains and 22 subdomains)	interoperability; medical imaging; PACS (included in Core Principle Health Informatics domain)	Includes an "Imaging" component (mentions biomedical imaging technologies and PACS) and references interoperability/integration of health IT applications (no EHDS/EEHRxF).	No
A Digitally Competent Health Workforce: Scoping Review of Educational Frameworks	Nazeha N.; Pavagadhi D.; Kyaw B.M.; Car J.; Jimenez G.; Tudor Car L./ Journal of Medical Internet Research	2020	Peer-reviewed Scoping review of existing frameworks	Digital health educational competency frameworks targeting health care workers (multiple professions/ settings)	Scoping review + thematic analysis synthesizing domains across included competency frameworks	28 digital health competency domains synthesized; includes (among others) "Integration and interoperability" and "Imaging"	Domain-level synthesis (competency domains) extracted from included frameworks; highlights HITCOMP as most comprehensive (covers 21/28 domains)	Not a single framework; domain synthesis across frameworks (28 domains identified)	interoperability; medical imaging	Identifies "Imaging" (knowledge of biomedical imaging digital technologies) and "Integration and interoperability" as competency domains; no EHDS/EEHRxF.	No

3.1.2 Grey literature and backward snowballing

From the first 100 results retrieved via the Google.com search engine on 21 October 2025, 23 documents were initially downloaded because they were considered potentially relevant. Following content review and duplicate removal, 10 documents met the inclusion criteria and were selected for full review(Australasian Institute of Digital Health, 2022; Australasian Institute of Digital Health & Australian Digital Health Agency, 2023; Australian Digital Health Agency, 2020; Blake & Blake, 2017; Cosgrove & Cachia, 2025; DigiCanTrain, 2024; Digital Health Canada, n.d.; Health Service Executive & Digital Health and Social Care Northern Ireland, 2022; NHS England, 2019; Williams et al., n.d.).

Furthermore, using backward snowballing technique, five additional potentially relevant documents were identified; three of these were ultimately included because they met the predefined eligibility criteria (Joint Action to support the eHealth Network, 2018; NHS England, 2018; TIGER Informatics Competencies Collaborative, 2009).

In total, 13 documents were included in the grey literature review.

With respect to target audience, seven documents addressed the health workforce in a broad or mixed scope (multi-professional and multi-actor coverage, including clinical and non-clinical roles), while five documents focused on specific professional groups (health informaticians/health informatics professionals, cancer-care professionals, allied health professionals, and nurses). One document, DigiComp 3.0 (Cosgrove & Cachia, 2025), targeted the general population and was retained because it is frequently used as a baseline for sector-specific adaptations, including healthcare. Across the included grey literature, no document explicitly targeted radiologists as a defined primary audience; radiology-related relevance appeared only implicitly or within broader occupational groupings (e.g., radiographers within allied health professionals).

In terms of structural approach, 10 documents provided a competency/capability framework, matrix, or repository structured in domains and descriptors or competence statements, whereas three documents were primarily strategy, maturity or profile-mapping oriented rather than domain-based competency frameworks. A detailed description of the grey literature is provided in Table 3.2 S.

Table 3.2 Synthesis of the grey literature.

Framework / Document name	Authors/ Organisation	Year	Document type	Target population	Structure/ classification approach	Domains (count + list)	How competencies are defined	Number of competences	Found terms[1]	Competencies related to Medical Imaging/EHDS (main statements)	Targets radiologists / radiology or medical imaging ecosystem
Health Informatics Professional Core Competencies	Digital Health Canada	n.d.	Report	Health informaticians	Professional competency framework (domain-based)	Domains (n=7): 1) Information Management; 2) Technology Ecosystem; 3) Clinical & Health Sciences; 4) Canadian Health System; 5) Healthcare Transformation; 6) Project Management; 7) Analysis & Evaluation.	Competency statements by professional domain.	56 competence statements	interoperability	Domain 1: A1.7 Demonstrate an understanding of relevant health information standards and their appropriate use (e.g. classifications, nomenclature, interoperability, standards, messaging, terminology, etc.) Domain 2: A2.5 Apply appropriate health informatics standards and enterprise models to enable system interoperability (e.g., terminology, data structure, system to system communication, privacy, security, safety, governance). Domain 2: A 2.9 Demonstrate an understanding of emerging technologies and their impact on healthcare, including addressing the interoperability challenges to sharing health data among systems and providers	No
DigComp 3.0 – The Digital Competence Framework for Citizens	Cosgrove M. & Cachia R.	2025	Policy report	General population (citizens); commonly used as baseline for sector-specific adaptations (including healthcare)	Competence framework (domain-based)	Domains (n=5): 1) Information search, evaluation, and management; 2) Communication and collaboration; 3)Content creation; 4) Safety, wellbeing and responsible use; 5) Problem identification and solving	Competence descriptors per domain	21 competence descriptors and 362 competence statements classified by proficiency level	____	Not Applicable (It isn't a classic domain-based competency matrix; provides role/profile-oriented expectations and capability development priorities to guide education, workforce planning, and implementation across horizons.)	No
BeWell Policy Brief – Digital Skills and Competency Matrix	BeWell project (with WHO Europe involvement)	2025	Policy brief and EU Project Deliverable	Healthcare workforce (broad), with training/upskilling focus	Competency matrix (DigComp-aligned)	Domains (n=5, DigComp-aligned): 1) Information & data literacy; 2) Digital teambuilding and communication ; 3) Digital content creation; 4) Safety and cybersecurity; 5) Digital problem solving	Competency matrix and sub-matrices aligned with DigComp (training-oriented)	Not stated (matrix and submatrix; item count not explicitly provided)	PACS, RIS	Submatrix 1.8: PACS, e-file, RIS	Implicit (terms mentioned; not a stated target group)

DigiCanTrain Digital Competence Framework (Cancer)	DigiCanTrain project consortium (EU-funded)	2024	Report	Healthcare professionals involved in cancer care (multi-professional; includes patient/caregiver)	Competence framework (domain-based)	Domains (n=5): 1) Communication, collaboration and participation; 2) Information technology and digital health systems; 3) Person-centred digital cancer care; 4) Digital interventions in cancer care; 5) Safety and ethics (digital interventions & data)	Learning outcomes/competencies by domain for cancer care digital context	Not Applicable	____	Not applicable	No
Australian Digital Health Capability Framework	Australasian Institute of Digital Health (Australia)	2024	Report	Health workforce (broad; clinical and non-clinical)	Capability framework (domain-based)	Domains (n=5): A) Digital professionalism; B) Leadership & advocacy; C) Data & information quality;D) Information-enabled care and services; E) Technology	Capability descriptors per domain	60 capability statements (12 for each domain)	interoperability	Interoperability (Domain E): Understands the principles of data and information governance, including privacy and security requirements and interoperability plans	No
All-Ireland Digital Capability Framework for Health and Social Care	HSE Ireland (Republic of Ireland)	2022	Report	Health and social care workforce (multi-professional; incl. learners/trainees)	Capability framework (domain-based)	Domains (n=5): 1) Digital professionalism; 2) Leadership and Advocacy; 3) Data & Information Quality; 4) Information-enabled care; 5) Technology	Competence descriptors per domain (often with progression levels)	80 competence statements across different domains	interoperability	Interoperability / Data sharing (Subdomain 1 of Domain 4): Understands the concepts relating to data linkage. Identifies the purposes, benefits and risks of aggregating clinical data from multiple sources. Understands the importance of data analytics and how they influence decision making and care delivery. Recognises the various data sources available and judges their quality, including patient/ consumer generated data	No
Australian Health Informatics Competency Framework (2nd ed.)	Australasian Institute of Digital Health (Australia)	2022	Report	Health informaticians	Professional competency framework (domain-based)	Domains (n=6): A) Health Sciences; B) Information Science; C) Information Technology; D)Leadership & Management;E) Social & Behavioural Sciences; F) Core Health Informatics	Competence statements by professional domain.	52 Competence Statements across different domains.	interoperability	Interoperability (Domain F): Health informaticians appraise the relevant standards, including messaging, exchange formats, and ontologies, to support safe and effective system interfacing and interoperability.	No
National Digital Health Workforce and Education Roadmap	Australian Digital Health Agency (Australia)	2020	Report	Healthcare workforce (broad)	Horizon roadmap (strategy) including the eight Digital Profiles	Not domain-based but Horizons Based: Horizon 1) Embedding safe, ethical and effective use of systems of record; Horizon 2) Integrating new technologies and ways of working; Horizon 3) Digital health transformation	Role-based digital profile expectations; strategic actions (not a granular competency list)	Not applicable	interoperability, cross-border data exchange, medical imaging, radiology, radiologist	Not Applicable (It isn't a classic domain-based competency matrix; provides role/profile-oriented expectations and capability development priorities to guide education, workforce planning and implementation across horizons.)	Implicit (terms mentioned; not a stated target group)

A Digital Framework for Allied Health Professionals	NHS England (UK)	2019	Report	Allied Health Professionals (AHPs) and AHP service leaders/staff in England.	Capability/competency framework (domain-based)	Not domain-based. Classification (n=3 ambitions): Digitally ready AHP services; Digitally mature AHP services; Data enabled AHP services.	Capability descriptors	Not applicable /Not defined	interoperability, Radiology	Ambition 1: Digitally ready AHP services. Ambition 2: Digitally mature AHP services. Ambition 3: Digitally ready AHP services	Radiographers (among the whole group of AHP)
JAseHN – Recommendations: common framework mapping health profession profiles (eHealth)	JAseHN / SPMS (Portuguese eHealth authority)	2018	EU Project deliverable / Report	Mixed healthcare professionals (non health/health/)	Profile mapping framework	No explicit competence domains. 3 main profiles identified: , 3 health, non-health and ICT.	Role/profile mapping to competence areas	52 competence organized in 6 main areas.	____	Not Applicable	No
A Health and Care Digital Capability Framework	NHS England (UK)	2018	Report	Healthcare workforce (broad; clinical and non-clinical)	Capability framework (domain-based)	Domains (n=6): 1) Communication, collaboration and participation; 2) Teaching, learning and self-development; 3) Information, data and media literacies; 4) Creation, innovation and research; 5) Technical proficiency; 6) Digital identity, wellbeing, safety and security	Capability descriptors per domain (often with progression levels)	Not stated	_____	Not Applicable	No
EU*US eHealth Work Project – HITComp (Competency Repository/Tool) – Deliverable D3.2	EU*US eHealth Work Consortium	2017	EU Project deliverable / Report (competency repository/tool web based)	All actors in eHealth/health IT workforce (clinicians, informaticians, ICT/IS specialists, administrators/management, research/biomedicine; etc)	Competency repository/tool (domain-tagged)	Domains (n=5): 1) Direct Patient Care; 2) Administration; 3) Engineering/Information Systems; 4) Informatics; 5) Research/Biomedical	Repository of competency statements mapped to roles; filtered by domain/level/quadrant/area	1050 competences	___-	Platform no longer available.	No
TIGER Informatics Competencies for Every Practicing Nurse	TIGER Initiative / TIGER Collaborative (Multinations)	2009	Report	Nurses (practicing and in training)	Competency framework (category-based)	Domains (n=3): 1) Basic computer competencies; 2) Information literacy; 3) Information management	Competency categories with guidance for nursing practice/education	187 competence statements across different domains	_____	Not Applicable	No

For each document, a targeted keyword and tag screening was conducted to identify explicit references to EHDS, interoperability, and imaging-related concepts. The EU–US HITComp deliverable (D3.2) (Blake & Blake, 2017) was considered not fully accessible for keyword screening because the original competency repository platform is no longer available; therefore, term frequencies are reported only for the 12 assessable documents. Across these documents, interoperability was explicitly mentioned in six sources, whereas cross-border data exchange appeared in one. No included grey literature documents explicitly referenced EHDS or EEHRxF.

Regarding imaging specificity (defined as explicit mention of medical imaging, radiology/radiologist(s), or imaging infrastructure terms such as PACS/RIS/DICOM), three documents contained imaging-/radiology-related terms: BeWell Policy Brief – Digital Skills and Competency Matrix (Williams et al., n.d.), mentioned PACS and RIS; the Australian National Digital Health Workforce and Education Roadmap (Digital Health Agency, 2020), mentioned medical imaging, radiology, and radiologists; and the Digital Framework for Allied Health Professionals (NHS England, 2019), mentioned radiology. No assessable documents explicitly mentioned DICOM.

Considering alignment with the thesis focus on the medical imaging ecosystem and radiologists, two documents emerged as the most directly relevant based on explicit imaging-related terminology and/or competency-oriented content: (1) the BeWell Policy Brief – Digital Skills and Competency Matrix (Williams et al., n.d.), due to explicit inclusion of PACS and RIS within a competency submatrix; and (2) the National Digital Health Workforce and Education Roadmap (Australian Digital Health Agency, 2020)because it explicitly referenced interoperability, cross-border exchange, medical imaging, radiology, and radiologists (noting that this source is strategic and does not provide a granular competency matrix). The NHS England framework for allied health professionals (NHS England, 2019) was considered adjacent rather than core to the present thesis focus, as its radiology references relate primarily to radiographers rather than radiologists.

3.1.3 Data extraction and synthesis (charting procedure)

For all included sources, data extraction followed the *"charting the data"* step described by Arksey and O'Malley (2005). A draft charting table was implemented as a spreadsheet and developed following the guidance and example extraction tables provided in the *JBI manual for evidence synthesis* (Aromataris et al., 2024). Charting variables were defined a priori and aligned with the study objective of identifying transferable digital and interoperability competency content relevant to radiologists' EHDS/EEHRxF readiness and to implementation needs within the medical imaging ecosystem. In line with Levac et al. (2010), the charting form was refined iteratively during extraction to improve fit with the emerging evidence base, including the addition of variables not considered at the outset.

For peer-reviewed literature, the following fields were charted: title, authors and journal, year, document type, target population, structure/classification approach (e.g., domain-based, level-based, role-based), domains (count and list), how competencies are defined (definition format and granularity), number of competencies, keywords identified (Found terms[1]), competencies related to medical imaging and/or EHDS (main statements extracted from the source), and whether the source explicitly targets radiologists, radiology, or the medical imaging ecosystem.

For grey literature, the charting procedure used a parallel structure, capturing: author/issuing organisation, year, document type, target population, structure/classification approach, domains (count and list), how competencies are defined, number of competencies, key terms identified (Found terms[1]), competencies related to medical imaging and/or EHDS (main statements), and whether the document explicitly targets radiologists, radiology, or the medical imaging ecosystem.

As part of data charting, each included document was screened for the explicit presence of pre-specified keywords related to (i) the medical imaging ecosystem, (ii) interoperability, and (iii) EHDS/EEHRxF. This keyword screening (Found terms[1]) was used for descriptive reporting and to support Phase 2 mapping and was not applied as an inclusion/exclusion criterion.

The keyword set included: interoperability; cross-border data exchange; EHDS; EEHRxF; medical imaging; radiology; radiologist; DICOM; PACS; RIS.

Following extraction, entries were reviewed for internal consistency. Competency statements and domains were extracted verbatim where available; no deduplication or terminology normalisation was performed at the extraction stage. Where competency statements were embedded in broader narrative text, the relevant statements were captured in their original phrasing when feasible or summarised conservatively when presented as high-level descriptions.

Keyword presence was assessed through targeted within-document search (e.g., PDF text search) complemented by contextual reading.

The resulting charted dataset, presented in Table 3.1 and Table 3.2, served as the basis for: (i) describing the characteristics of the evidence base; (ii) identifying gaps in explicit radiology EHDS/EEHRxF aligned competency content; and (iii) supporting Phase 2 requirement operationalisation and mapping through a traceable link between extracted statements and subsequent RCPO development.

3.2 EHDS/EEHRxF requirement operationalisation and mapping procedure (Phase 2)

Phase 2 translated EHDS/EEHRxF implementation into radiology-relevant competency needs and used these to identify gaps in the evidence-derived competency evidence from Phase 1, resulting in a RCPO v1 building.

Phase 2 included three sequential steps:

3.2.1 EHDS/EEHRxF-derived competency needs extraction.

Competency needs were derived through a directed regulatory content analysis of the EHDS Regulation, covering both primary use (care delivery and access to electronic health data) and secondary use (reuse of electronic health data under the EHDS framework) (Bowen, 2009; Krippendorff, 2019).

The analysis used Article 83 as the anchoring provision for health-professional training and role expectations in the primary use of and access to electronic health data. Relevant EHDS clauses were identified using an imaging-focused inclusion rule: clauses were retained if they (i) explicitly referred to medical imaging studies and/or related imaging reports as priority data categories for primary use and/or (ii) addressed access, interoperability, exchange, or governance conditions that operationally apply to imaging workflows (e.g., identity/authorisation, recording/updating, traceability/auditability, cross-organisational or cross-border use). Extracted clauses were normalised into concise need statements ("health professionals need to be able to…") and then operationalised into actionable capability statements ("is able to…", "can ensure…").

Capability statements were then grouped into workflow-aligned thematic clusters to support the subsequent mapping step, following an iterative document analysis process (Bowen, 2009).

Capabilities that were not operationally relevant to medical imaging workflows were excluded from the radiology-specific reference set. Transversal requirements (e.g., identity and authorisation, traceability and auditability, data governance, data protection requirements, and cybersecurity) were treated as enabling prerequisites for imaging access and exchange and were therefore incorporated as cross-cutting conditions rather than modelled as standalone imaging-specific competencies.

Based on the EHDS/EEHRxF operationalisation described before, the radiology-relevant reference set, four workflow-aligned thematic clusters were defined: 1) Interoperability and structured exchange, (2) Cross-organisational and cross-border clinical use, (3) Imaging workflow and systems integration, (4) Secondary use readiness and imaging data stewardship.

Across these clusters, eight generic EHDS/EEHRxF-derived needs were formulated (two needs per cluster) to serve as the reference standard for the mapping and gap classification (Table 3.3).

Table 3.3 EHDS/EEHRxF needs extraction for medical imaging area

Cluster name	Key EHDS anchors (cluster)	Definition for Medical Imaging Area	Generic need statement (cluster-level)	Use tag (Primary/Secondary/ Both)
Interoperability and structured exchange	Art. 15; Art. 14; Annex I	Interoperable exchange requirements (EEHRxF) as they apply to imaging studies, imaging reports and essential metadata.	Need to be able to apply EEHRxF interoperability requirements when exchanging imaging reports and essential imaging-related metadata.	Both
			Need to be able to maintain consistent identifiers and metadata enabling reliable study–report linkage across systems.	Both
Cross-organisational and cross-border clinical use	Art. 12; Art. 14; Annex I	Continuity-of-care use of imaging information across organisations/countries, including retrieval and safe clinical use of external records.	Need to be able to retrieve and use imaging studies/reports from other organisations or countries for continuity of care.	Primary
			Need to be able to reconcile externally sourced imaging information with local records to support safe clinical use.	Primary
Imaging workflow and systems integration	Art. 13; Art. 14; Annex I	Operationalisation within imaging workflows and system integrations (RIS/PACS/EHR), including study–report lifecycle and retrieval dependencies.	Need to be able to register, update and maintain imaging-related records (especially imaging reports) as part of care delivery.	Primary
			Need to be able to operationalise imaging system integration (RIS/PACS/EHR) to support retrieval and use of imaging data.	Both
Secondary use readiness and imaging data stewardship	Chapter IV; Art. 73; Art. 75	Stewardship and reuse-readiness of imaging-related data under EHDS secondary use governance and infrastructure.	Need to be able to support organisational imaging data stewardship for approved secondary use (reuse readiness).	Secondary
			Need to be able to operate within secondary-use governance and secure processing constraints when involved in reuse activities.	Secondary

3.2.2 Mapping to Phase 1 evidence and gap analysis

Competency statements and thematic clusters charted in Phase 1 were mapped against the EHDS/EEHRxF-derived competency needs using a traceable matrix to assess coverage.

For each EHDS/EEHRxF-derived need, Phase 1 evidence was classified as: (i) covered (explicitly addressed by an existing competency statement), (ii) partially covered (addressed only at a generic level without sufficient imaging/radiology operational detail), or (iii) not covered (no corresponding competency content identified). Items classified as partially covered or not covered were retained as priority gaps for overlay development and subsequent expert review.

No radiology or medical-imaging–specific interoperability competence frameworks explicitly aligned with EHDS/EEHRxF requirements were identified in the reviewed corpus (Table 3.4). Across the mapping exercise, the identified frameworks operated predominantly at a generic health-workforce level and therefore did not provide competencies that could be directly mapped to the medical imaging ecosystem or to EHDS/EEHRxF interoperability expectations for imaging content and exchange. As a result, the imaging-relevant needs extracted from the EHDS and captured in the mapping table were

classified as "*not covered*", indicating an absence of explicit, imaging-contextualised competence statements.

The gap pattern was consistent across all mapped clusters. Taken together, the mapping supports the need for a radiology-focused digital competence layer aligned to EHDS/EEHRxF, either as a dedicated competence profile or as an extension to existing health-workforce frameworks.

Table 3.4 Mapping and gap analysis

Cluster	Need	Need statement	Coverage classification	Peer-reviewed sources (Authors/Titles)	Grey literature sources (Author/Organization/Document titles)
Interoperability and structured exchange	1	Need to be able to apply EEHRxF interoperability requirements when exchanging imaging reports and essential imaging-related metadata.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
	2	Need to be able to maintain consistent identifiers and metadata enabling reliable study–report linkage across systems.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
Cross-organisational and cross-border clinical use	3	Need to be able to retrieve and use imaging studies/reports from other organisations or countries for continuity of care.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
	4	Need to be able to reconcile externally sourced imaging information with local records to support safe clinical use.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
Imaging workflow and systems integration	5	Need to be able to register, update and maintain imaging-related records (especially imaging reports) as part of care delivery.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
	6	Need to be able to operationalise imaging system integration (RIS/PACS/EHR) to support retrieval and use of imaging data.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
Secondary use readiness and imaging data stewardship	7	Need to be able to support organisational imaging data stewardship for approved secondary use (reuse readiness).	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified
	8	Need to be able to operate within secondary-use governance and secure processing constraints when involved in reuse activities.	Not covered	No explicit imaging-contextualised statement identified	No explicit imaging-contextualised statement identified

3.2.3 Development of the RCPO v1

Phase 2 mapping and gap analysis showed that existing general digital-competence frameworks provide limited and/or non-imaging-specific coverage of EHDS/EEHRxF-relevant imaging needs. On this

basis, RCPO v1 was developed to operationalise missing or under-specified competencies for radiologists in line with EHDS/EEHRxF requirements.

The overlay was primarily based on the extraction of needs within the medical imaging area, organized into clusters aligned with radiological workflows and classified according to the provisions of the EHDS (primary use, secondary use, or both), as reported in Table 3.3. For each need statement, radiology-contextualised competency statements were drafted as observable capabilities grounded in radiology workflows and the digital imaging environment, and then operationalised into a concise set of training-oriented learning outcomes (Table 3.5). These learning outcomes specify what radiologists should be able to demonstrate in practice to fulfil the corresponding competency under EHDS/EEHRxF conditions.

To ensure practical applicability, competency statements and LOs were contextualised to the operational realities of clinical imaging workflows and systems, including RIS/PACS–EHR interaction, imaging study and report linkage, metadata-driven retrieval, and controlled access to imaging content and reports across organisational boundaries. Where transversal requirements operationally condition imaging access and exchange (e.g., authorised access, consent status and auditability), these elements were embedded as enabling constraints within the relevant learning outcomes rather than modelled as separate learning outcomes or an independent cluster. Where general frameworks remained non-specific for imaging, a minimal medical-imaging operationalisation layer was applied to clarify how generic interoperability and digital-governance expectations translate into radiology-specific tasks and responsibilities.

The overlay content was structured according to the workflow-aligned thematic clusters derived from the EHDS/EEHRxF analysis (interoperability and structured exchange; cross-organisational and cross-border clinical use; imaging workflow and systems integration; secondary use readiness and imaging data stewardship).

The resulting draft RCPO v1 (Table 3.5), included *n* = 14 LOs distributed across the four imaging-relevant EHDS/EEHRxF clusters: interoperability and structured exchange (*n* = 4), cross-organisational and cross-border clinical use (*n* = 8), imaging workflow and systems integration (*n* = 1), and secondary use readiness and imaging data stewardship (*n* = 1).

Consistent with the Phase 2 mapping design, the transversal cluster *"professional access, governance and accountability"*, initially identified was treated as outside the radiology-specific scope of the learning-outcome set and therefore not included.

Table 3.5 RCPO v1 draft learning outcomes

EHDS/EEHRxF cluster	LO ID	Learning outcome
Interoperability and structured exchange	LO-01	Describe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging workflow.
	LO-02	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.
	LO-03	Explain how key imaging interoperability standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.
	LO-04	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.
Cross-organisational and cross-border clinical use	LO-05	Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.
	LO-06	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.
	LO-07	Prepare and share a complete, good-quality imaging package (images + clinical context) for cross-border second/expert opinions.
	LO-08	Retrieve and interpret relevant clinical history from the EHDS and integrate it into radiological decision-making, even when data originate from different healthcare systems.
	LO-09	Access, review, and integrate imaging studies performed at different sites into a unified radiology workflow to support continuity of testing.
	LO-10	Access and update contrast media allergies and prior reactions across hospitals through EHDS, ensuring that safety information is visible to all radiologists involved in the patient's care.
	LO-11	Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.
	LO-12	Evaluate the diagnostic suitability of cross-border imaging studies retrieved via EHDS, identifying and reporting technical deficiencies that make them clinically unsafe.
Imaging workflow and systems integration	LO-13	Identify interoperability gaps in radiology workflows that hinder clinical efficiency and communicate needs for improved tools and integration to IT and management.
Secondary use readiness and imaging data stewardship	LO-14	Use the EHDS as a source of secondary data for radiology research, collaborating with other institutions while complying with ethical, legal, and governance requirements.

3.3 Interview with SMEs for RCPO v1 validation (Phase 3)

3.3.1 Sample characteristics

A total of 11 SMEs completed the RCPO v1 validation template between 10 January 2026 and 02 February 2026 (Table 3.6). All participants provided informed consent to participate in the interview.

Table 3.6 Profile of respondents to the interview

Respondent ID	File Sheet	Role(s)	Country	Years of experience	Organization
SME-01	Interview Sheet_01.xlsx	Consultant Radiologist	Spain	>20	University Hospital
SME-02	Interview Sheet_02.xlsx	Industry Expert	Spain	>30	Contract Research Organization / Industry
SME-03	Interview Sheet_03.xlsx	Consultant Radiologist	France	>20	Private Hospital
SME-04	Interview Sheet_04.xlsx	Consultant Radiologist / Industry Advisor / Academic Professor	Spain	>30	University Hospital
SME-05	Interview Sheet_05.xlsx	Consultant Radiologist / PhD	Italy	6	University Hospital
SME-06	Interview Sheet_06.xlsx	Consultant Radiologist	Spain	15	Private Hospital
SME-07	Interview Sheet_07.xlsx	Consultant Radiologist	Spain	13	University Hospital
SME-08	Interview Sheet_08.xlsx	Training Radiologist	Spain	4	University Hospital
SME-09	Interview Sheet_09.xlsx	Radiologist and PhD	Netherlands	8	Research Institution
SME-10	Interview Sheet_10.xlsx	Consultant Radiologist /Academic Professor	Italy	9	University Hospital
SME-11	Interview Sheet_11.xlsx	Consultant Radiologist / Lecturer / Expert Advisor in Curriculum Design	Spain	>30	University Hospital / National Board for Specialist Training in Radiology

The panel included participants from Spain (*n*=7), Italy (*n*=2), France (*n*=1), and the Netherlands (*n*=1). Most respondents were primarily clinical stakeholders (*n*=8; 72.7%), with additional representation from industry stakeholders (*n*=3; 27.3%). Respondents demonstrated substantial professional seniority. Nearly half of the panel (45.5%) reported more than 20 years of experience, while 36.4% had up to 10 years of experience and 18.2% between 11 and 20 years. The dominant organisational setting was university hospitals (*n*=6), followed by private hospitals (*n*=2), with additional representation from a research institution (*n*=1), a national specialist training/governance body (*n*=1), and industry (*n*=1) (Table 3.6).

3.3.2 Completeness of ratings

SMEs rated each LO on 1–5 Likert scales (higher scores indicate more favourable appraisal) across clarity, relevance, and feasibility. Data completeness was high for clarity (154/154 ratings) and relevance (153/154 ratings), while feasibility had more missing responses (135/154 ratings), consistent with the context-dependent nature of feasibility judgements (Table 3.7). At LO level, the number of feasibility ratings ranged from *n*=7 to *n*=11 (lowest completion for LO-04 and LO-09, both *n*=7). Missing responses were marked as N/A as stated in Annex C.

Table 3.7 Total ratings for the three different domains of RCPO v1

Completeness totals (across all learning outcomes)	
Computed from:	
Number of SMEs (n)	11
Number of learning outcomes (LOs)	14
Total possible ratings per dimension	154

Metric	Total ratings	Total possible	Missing	% complete
Clarity	154	154	0	100,0%
Relevance	153	154	1	99,4%
Feasibility	135	154	19	87,7%

3.3.3 Overall appraisal across learning outcomes

Median scores and IQR were calculated for each LOs.

Across all SMEs and LOs, ratings were consistently high. Median scores were 4 (IQR 1; *n*=154) for clarity, 5 (IQR 1; *n*=153) for relevance, and 4 (IQR 1; *n*=135) for feasibility. Most ratings fell in the favourable range (scores 4–5): 81.8% for clarity, 78.4% for relevance, and 81.5% for feasibility. (Table 3.7 and Table 3.8).

Table 3.8 SME ratings for RCPO v1 LOs (median and IQR).

LO ID	Cluster	n Clarity	Clarity (median / IQR)	n Relevance	Relevance (median / IQR)	n Feasibility	Feasibility (median / IQR)
LO-01	Interoperability and structured exchange	11	4 (IQR 2)	11	4 (IQR 1.5)	9	4 (IQR 0)
LO-02		11	4 (IQR 1.5)	11	4 (IQR 1)	10	4 (IQR 0)
LO-03		11	4 (IQR 0.5)	11	4 (IQR 1.5)	11	4 (IQR 1)
LO-04		11	4 (IQR 1)	11	3 (IQR 1.5)	7	4 (IQR 1)
LO-05	Cross-organisational and cross-border clinical use	11	5 (IQR 0.5)	11	5 (IQR 0.5)	10	4.5 (IQR 1)
LO-06		11	4 (IQR 1)	11	4 (IQR 2)	9	3 (IQR 1)
LO-07		11	5 (IQR 1)	11	5 (IQR 2)	10	4.5 (IQR 1.8)
LO-08		11	5 (IQR 1)	11	5 (IQR 1)	11	5 (IQR 1)
LO-09		11	4 (IQR 1.5)	11	5 (IQR 1)	7	4 (IQR 1)
LO-10		11	5 (IQR 0)	11	5 (IQR 0)	10	5 (IQR 0.75)
LO-11		11	4 (IQR 1.5)	10	5 (IQR 1)	10	4 (IQR 1)
LO-12		11	4 (IQR 1)	11	5 (IQR 1)	10	4.5 (IQR 1)
LO-13	Imaging workflow	11	4 (IQR 0)	11	4 (IQR 1)	10	4 (IQR 0.8)
LO-14	Secondary Use	11	5 (IQR 0)	11	5 (IQR 0)	11	5 (IQR 1)

3.3.4 Cluster-level patterns

When aggregated by RCPO cluster, secondary use readiness and imaging data stewardship showed the strongest and most consistent endorsement across domains, with median 5 for clarity (IQR 0), relevance (IQR 0), and feasibility (IQR 1). Cross-organisational and cross-border clinical use also received strong appraisal, particularly for relevance (median 5; IQR 1), with clarity and feasibility both centred at median 4 (IQR 1). By contrast, interoperability and structured exchange showed comparatively lower relevance, with median relevance 4 (IQR 1.25), suggesting either perceived role-boundary issues (radiologist vs. informatics tasks) or limited immediate practical relevance in routine clinical work. Imaging workflow and systems integration was rated positively but with more moderate central tendency (median of 4 across domains).

3.3.5 Learning outcome level results

As shown in Table 3.8 at LO level the strongest endorsement was observed for LO-14 (secondary use and research enablement), which achieved a median score of 5 for both clarity and relevance with IQR 0 (indicating maximal agreement), alongside high feasibility (median 5; IQR 1). LO-10 also ranked highly, with feasibility median 5 (IQR 0.75). LO-05 scored consistently well (clarity median 5 [IQR 0.5]; relevance median 5 [IQR 0.5]; feasibility median 4.5 [IQR 1]).

In contrast, LO-04 received the lowest relevance appraisal (median 3 [IQR 1.5]) and showed the lowest feasibility completion (*n*=7). LO-06 showed the lowest feasibility central tendency (median 3 [IQR 1]; *n*=9), while cross-border collaboration outcomes (e.g., LO-07) exhibited the greatest dispersion (relevance IQR 2; feasibility IQR 1.75), indicating heterogeneous expectations and implementation readiness across settings. Finally, LO-11 and LO-12 retained high relevance (median 5; IQR 1) but showed comparatively lower clarity (median 4) with wider dispersion (IQR 1–1.5), consistent with wording/operational-definition issues rather than reduced perceived importance.

3.3.6 Analysis of qualitative comments

Qualitative comments were analysed as an action-oriented complement to the quantitative ratings and informed the transition from RCPOv1 to RCPOv2.

Across all LOs, qualitative analysis yielded a total of 100 coded comment instances. Comments were first condensed into Theme Labels and then mapped against an initial issue-type codebook (Clarity, Scope, Trainability), with a “Other” category used when mapping was not immediately possible (Table 3.9).

Table 3.9 Theme labels mapped to the issue-type codebook

Theme Label	Issue type
High Level Competence	Trainability
Unclear or ambiguous definition	Clarity
Provisional General Comment	Other
Time-consuming	Trainability
Too technical or Not relevant for end user	Scope
Hard to implement in training	Trainability
Provisional General Comment	Overlapping
Provisional General Comment	Implementation

The most frequent Theme Labels were “too technical / not relevant for end user” (n=34) and “unclear or ambiguous definition” (n=28), followed by feasibility-oriented constraints such as “time-consuming” (n=16), “hard to implement in training” (n=6), and “high level competence” (n=4).

During the initial coding process, some comments were provisionally assigned to a General category when their operational classification was not immediately clear. Following secondary analytical review, comments expressing recurrent clarity-related concerns were reassigned accordingly. Of the 14 comments initially retained within the General category, 9/14 (64.3%) were recoded into the pre-specified issue types (Clarity n=5; Scope n=2; Trainability n=2), while 5/14 (35.7%) required extension of the analytical framework through the operational creation of two additional issue types: Implementation (n=4) and Overlapping (n=1) (Table 3.10).

Table 3.10 Reassignment of general comments to issue types

LO ID	SME ID	General Comment_EN	Issue Type
LO-03	SME-10	It is not clear what 'how standards collaborate' means.	Clarity
LO-04	SME-10	The radiologist should not be the one doing this.	Implementation
LO-06	SME-06	Very complex to explain to clinical radiologists.	Trainability
LO-06	SME-10	Are we talking about primary or secondary use in the statement? What does 'without duplication' mean? It is also unclear why consent must be requested beforehand (it is a prerequisite), so mentioning it here is confusing. Needs more operational detail	Clarity
LO-07	SME-03	Language barrier issue.	Implementation
LO-07	SME-05	It sounds rare that a radiologist would request it abroad; it feels too futuristic/overly specific.	Implementation
LO-09	SME-05	It may be a repetition of other LOs.	Overlapping
LO-11	SME-03	Because the LO is unclear, the interviewee did not proceed to rate the other domains.	Clarity
LO-11	SME-09	Radiologists would use it whenever available, regardless of the situation; therefore it may not be a meaningful outcome. It is also very difficult to define general criteria given the wide range of clinical scenarios that may require access.	Scope
LO-11	SME-10	You would always access it; so it may not be a relevant outcome.	Scope
LO-12	SME-04	Rephrase the LO.	Clarity
LO-13	SME-04	Identify who should be informed about these gaps.	Clarity
LO-13	SME-08	This should not be taught to radiologists; instead there should be a button to simply flag that the study probably contains artefacts.	Implementation
LO-13	SME-10	A lot of time to explain.	Trainability

After reassignment, the overall distribution across all 100 coded instances was Scope 36%, Clarity 31%, Trainability 28%, Implementation 4%, and Overlapping 1%.

3.3.7 Integration of quantitative and qualitative findings.

Applying the pre-specified median and IQR thresholds (see Decision Rules in Annex C), 4 of 14 LOs were quantitatively flagged for revision. LO-01 was flagged due to disagreement in clarity (median 4; IQR 2). LO-04 was flagged due to low relevance (median 3; IQR 1.5). LO-06 and LO-07 were flagged due to disagreement in relevance (IQR 2), indicating heterogeneous perceptions across experts despite high central tendency in some cases (e.g., LO-07 median relevance 5).

No LOs met the criterion of median feasibility < 3, and no LOs met median clarity < 4, although some items demonstrated moderate dispersion below the predefined disagreement threshold. Quantitatively flagged items were subsequently subjected to structured qualitative review, with supporting rationales recorded in the RCPO v2 Change Log (Annex D).

Structural refinement review was triggered using the combined quantitative–qualitative decision rule defined in the Methods. Under this OR logic, LOs proceeded to structured review if they were either quantitatively flagged or met the qualitative trigger (≥3 distinct SMEs and ≥40% of SME-coded issues for that LO). Using this combined rule, 9 of 14 LOs met refinement trigger criteria (LO-01, LO-02, LO-03, LO-04, LO-06, LO-07, LO-09, LO-11, and LO-12). For each LO meeting the trigger criteria, a proposed refinement pathway was derived using the predefined refinement routes and recorded in the RCPO v2 Change Log (Annex D).

Proposed actions differentiate between:

I. editorial improvements to strengthen clarity and assessability;
II. recommendations for removal when content was judged too technical or outside the intended radiologist-focused competence scope;
III. narrowing, restructuring, or merging LOs when items were considered difficult to deliver within routine training constraints or substantially overlapping with other outcomes.

The resulting proposed changes are described in the following section.

3.4 Final RCPO v2

3.4.1 Overview of refinement outcomes

The refinement process produced Issue Type–specific actions as defined in the qualitative decision codebook. For reporting purposes, these actions are summarised into three overarching action families (Annex D), while preserving full traceability at LO level:

1. Editorial refinement to improve clarity (including simplification and, where needed, splitting compound outcomes or acronyms explication).
2. Removal of items considered outside the clinical radiologist competency scope or not feasible.
3. Structural narrowing, restructuring, merging and/or relocation of items where redundancy, limited deliverability, overlap, or strong implementation dependencies were identified.

   The resulting RCPO v2 framework reflects a more focused, radiologist-centred interpretation of EHDS preparedness, balancing interoperability awareness with realistic training feasibility.

Figure 3.2 presents the Radiology Competency Profile Overlay, integrating the refined learning outcomes into a layered digital competency framework.

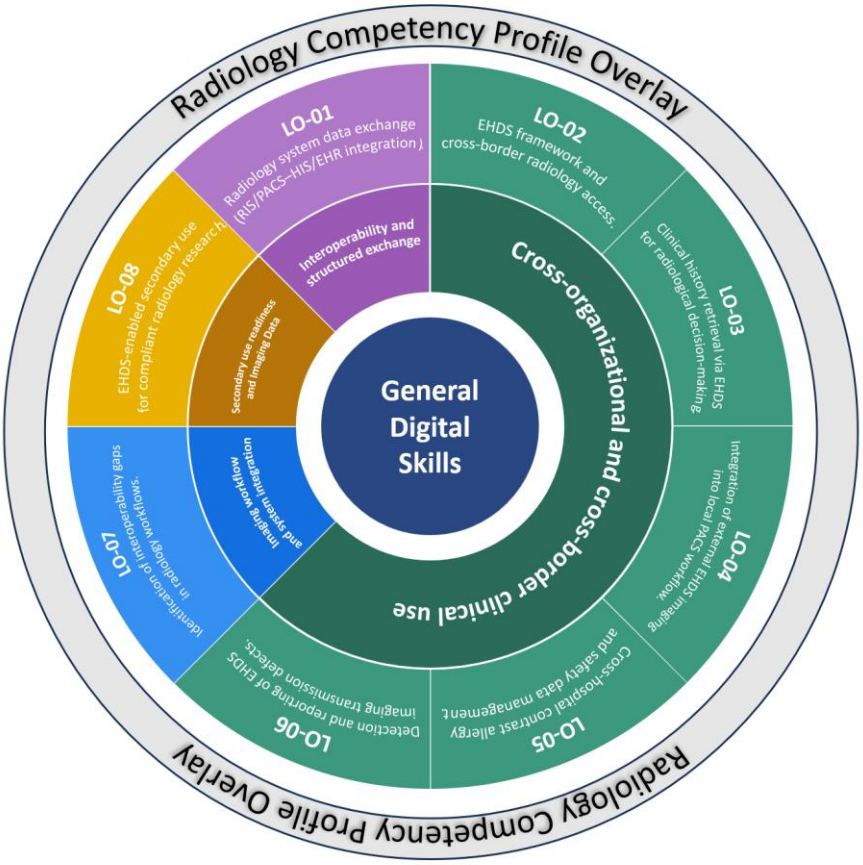


Figure 3.2 Radiology competency profile overlay v2

Note: Learning outcomes are presented in abbreviated form for visualization purposes. The full refined LOs are available in Annex D.

Author's own work (2026).

3.4.2 Quantitative-qualitative convergence patterns

Integration of quantitative ratings and qualitative Issue Types revealed three dominant refinement pathways: scope-led removal, clarity-led editorial refinement, and trainability-led removal.

Scope-dominant patterns (removal as out of scope)

Five LOs met the predefined qualitative predominance trigger for Scope (≥3 SMEs and ≥40% of LO-specific issue counts): LO-02, LO-03, LO-04, LO-06, and LO-07. These items were repeatedly framed by SMEs as misaligned with competencies expected of clinical radiologists in routine practice and/or excessively technical or operational in nature.

Quantitative flagging converged with this scope-led pathway in three outcomes (LO-04, LO-06, LO-07), which were also flagged by the median/IQR criteria. The remaining scope-triggered items (LO-02 and LO-03) were not quantitatively flagged but still met the qualitative action threshold and therefore followed the same removal pathway.

This pattern indicates that, while interoperability is central to EHDS implementation, tasks such as operational execution of cross-organisational exchange, technical data packaging, or system-level responsibilities were considered beyond the intended scope of radiologist competence development.

Clarity-dominant patterns

LO-01, LO-09, and LO-12 met the qualitative predominance trigger for Clarity and were prioritised for editorial refinement in RCPO v2 (Annex D). For LO-01, this pattern was reinforced by quantitative dispersion in clarity ratings (IQR = 2), indicating heterogeneous interpretation despite high central tendency. The resulting edits focused on simplification, definitional precision, and restructuring where compound elements reduced interpretability.

Notably, LO-02 also reached the Clarity trigger but was not refined editorially because it simultaneously met the Scope trigger and was removed from the radiologist-focused core framework.

Trainability-dominant pattern

LO-11 met the qualitative predominance trigger for Trainability and was removed as not realistically deliverable as a training outcome within routine specialist training and CPD contexts. This pathway captured recurring concerns such as “time-consuming,” “hard to implement in training,” and “high-level competence,” when these reached the formal action threshold.

3.4.3 Resulting structural configuration of RCPO v2

The refined RCPO v2 framework, therefore, reflects:

- Removal of six LOs from RCPO v1 that were deemed out of scope or not realistically deliverable as training outcomes, thereby reducing system-level and operational responsibilities not directly actionable by clinical radiologists.

- Greater emphasis on interpretive, governance-aware, and decision-oriented competencies.
- Clearer wording and improved interpretability of retained LOs, including definition/expansion or removal of acronyms and overly technical terminology where appropriate.

Overlapping and implementation-related concerns were identified in several LOs during qualitative coding. However, neither Issue Type met the predefined predominance threshold (≥3 SMEs and ≥40% of LO-specific issue counts) required to activate a formal qualitative refinement trigger.

Importantly, the refinement process did not reduce the conceptual ambition of the framework. Rather, it strengthened alignment between EHDS policy expectations and the realistic professional profile of clinical radiologists. All proposed modifications are fully traceable in the RCPO v2 Change Log (Annex D), which documents the link between SME feedback, predefined decision rules, and resulting framework adjustments.

3.4.4 Summary of outcomes

The final RCPO v2 represents an expert-informed and methodologically transparent refinement of RCPO v1. Through structured integration of predefined quantitative thresholds (median/IQR criteria) and qualitative predominance rules (≥3 SMEs and ≥40% of LO-specific issue counts), the framework evolved from an interoperability-comprehensive draft to a radiologist-calibrated competency profile aligned with realistic professional scope and training feasibility.

Starting from 14 draft learning outcomes in RCPO v1, RCPO v2 retained 8 outcomes and removed 6. In total, 9 LOs triggered structured refinement pathways based on the predefined decision rules.

Scope-led removal was activated for five outcomes (LO-02, LO-03, LO-04, LO-06, LO-07), which met the qualitative predominance threshold for Scope; three of these (LO-04, LO-06, LO-07) were also quantitatively flagged by the median/IQR criteria. These items were removed from the radiologist-focused core framework, reflecting consistent expert consensus that they represented system-level, operational, or overly technical responsibilities beyond routine radiologist competencies.

Clarity-led editorial refinement was activated for three retained outcomes (LO-01, LO-09, LO-12).

For LO-01, the qualitative clarity pattern was reinforced by quantitative dispersion in clarity ratings (IQR = 2), indicating heterogeneous interpretation despite high central tendency. Revisions focused on simplification, definitional precision, and restructuring where compound elements reduced interpretability. Although LO-02 also met the Clarity trigger, it was not refined editorially because it simultaneously met the Scope trigger and was removed.

Trainability-led removal was activated for LO-11, which met the qualitative predominance threshold for Trainability and was removed as not realistically deliverable as a training outcome within routine specialist training and continuing professional development contexts.

Overlapping and Implementation were identified during qualitative coding but did not reach the predefined predominance threshold required to activate formal qualitative triggers. Nevertheless, they informed proportional LO-level adjustments where relevant (e.g., minor consolidation to reduce redundancy and reframing of institution-dependent formulations). Overall, RCPO v2 reflects a more focused, structurally coherent, and professionally bounded framework that maintains alignment with EHDS interoperability objectives while remaining deliverable within routine training and CPD contexts.

All refinement decisions remain fully traceable in the RCPO v2 Change Log (Annex D), preserving transparency between SME input, predefined analytic rules, and final structural outcomes.

Conclusion

This thesis developed and refined a radiology-specific competency profile aligned with the emerging requirements of the EHDS and the EEHRxF. The aim was to translate high-level interoperability and data-governance expectations into operational LOs that are meaningful for radiology practice and training.

Using a structured scoping review and a systematic extraction of EHDS/EEHRxF-related requirement statements, this research identified imaging-relevant capability gaps that are not fully addressed by existing generic digital competence frameworks for healthcare professionals. These findings informed the development of the RCPO v1, which was subsequently validated and refined through expert interviews. A combined quantitative–qualitative decision rule integrating Likert ratings with structured thematic analysis supported the transition to RCPO v2, improving clarity and pedagogical coherence while maintaining alignment with regulatory expectations.

Limitations

This study has limitations. First, SME validation was conducted with a limited sample (n=11), which may not fully capture the diversity of radiology practice and organisational contexts across Europe; therefore, perceptions of relevance and feasibility may be context dependent.

Second, qualitative coding was undertaken by a single researcher. Although predefined categories and coding rules were used to guide the qualitative analysis, coding was performed by a single researcher, and no independent verification was conducted. This may introduce a degree of interpretative bias.

Third, the RCPO was developed during a transitional regulatory phase. While the EHDS Regulation has been adopted, several implementing acts and technical specifications relevant to medical imaging remain under development.

Consequently, some LOs reflect the best available interpretation of current regulatory texts rather than fully specified operational requirements.

Future research

Future work could expand validation through a larger and more geographically balanced expert panel, ideally using a multi-round Delphi process, and stratifying findings by organisational setting and digital maturity. Complementary approaches, such as a survey targeting European radiologists, could further assess relevance and feasibility at scale.

Pilot implementation within training programmes and microcourses would enable assessment of feasibility, workload implications, and learning outcomes using explicit competency assessment tools.

Once EHDS/EEHRxF implementing acts and imaging specifications are fully finalised, a remapping exercise should be conducted to confirm technical alignment. Finally, longitudinal evaluation could explore whether RCPO-aligned training contributes to improved interoperability-related outcomes, such as higher-quality structured data exchange, reduced duplication, and more consistent cross-border imaging continuity.

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Annexes

Annex A – PubMed/MEDLINE search strategy and eligibility criteria

The query, executed on 9 August 2025, was:

("Health Personnel"[MeSH Terms] AND (("digital"[Title/Abstract] OR ehealth[Title/Abstract] OR "e-health"[Title/Abstract]) AND ("skill"[Title/Abstract] OR "competenc*"[Title/Abstract] OR "literac*"[Title/Abstract] OR "training"[Title/Abstract] OR "education"[Title/Abstract])) AND ("Digital Health"[MeSH Terms] OR "Computer Literacy"[MeSH Terms] OR "Education"[MeSH Terms] OR "Curriculum"[MeSH Terms] OR "Surveys and Questionnaires"[MeSH Terms] OR "framework"[Title/Abstract] OR "frameworks"[Title/Abstract] OR "model"[Title/Abstract] OR "models"[Title/Abstract] OR "curriculum"[Title/Abstract] OR "curricula"[Title/Abstract] OR "questionnaire*"[Title/Abstract] OR "survey*"[Title/Abstract]) AND 2015/01/01:2025/08/09[Date - Publication]) AND english[Filter])*

A mixed approach was adopted, combining free-text terms (e.g., digital competences, digital skills, digital literacy, digital training, frameworks, models, curricula, healthcare professionals, health workforce, clinicians) with relevant Medical Subject Headings (MeSH)(National Library of Medicine, n.d.) such as Computer Literacy, Digital Health, Education, Curriculum, Surveys and Questionnaires, and the mandatory population descriptor Health Personnel.

This strategy was designed to maximise retrieval by capturing both indexed records and recent articles not yet fully indexed with MeSH terms.

The final PubMed query was developed with the assistance of the generative AI tool ChatGPT (OpenAI; accessed on 9 August 2025), used exclusively as technical support to refine Boolean logic and the combination of MeSH and free-text terms in accordance with PubMed's query syntax; no screening, extraction, or interpretation decisions were automated. The primary aim was to identify studies presenting, developing, or evaluating structured frameworks, models or curricula addressing digital competences intended for healthcare professionals.

In addition, the terms *survey* and *questionnaire* were included because several publications on digital skills report the use of questionnaires administered to healthcare professionals to self-assess their knowledge in this area.

However, it was not possible to fully eliminate irrelevant results ("noise") caused by the broad use of terms such as *digital*, which are also frequently applied in clinical research contexts involving patients and pathologies.

The search strategy was organised as follows:

- Block A – Concepts related to digital competences in healthcare

    - MeSH terms: Computer Literacy, Digital Health, Education, Curriculum, Surveys and Questionnaires
    - Free-text terms: digital literacy, digital skills, digital competences, digital competency, digital training, framework(s), model(s), curriculum(a), questionnaire(s), survey(s)
- Block B – Target population
    - MeSH term (mandatory): *Health Personnel*

Inclusion and exclusion criteria for peer-reviewed literature

Inclusion criteria

Only publications from the last ten years (2015–2025) were included, in order to capture the most up-to-date frameworks and developments aligned with the rapidly evolving landscape of digital health.

The search was limited to studies and documents available in English or accompanied by official English translations.

To be included in this review, peer-reviewed articles had to explicitly present, develop, or evaluate structured frameworks, models, or taxonomies of digital competences specifically intended for healthcare professionals.

Exclusion criteria

Studies focused solely on assessing individual digital literacy levels within a specific medical or healthcare professional subspecialty, or proposing digital literacy frameworks limited to such subspecialties, as well as studies addressing digital literacy in relation to a specific pathology, were excluded.

Articles focusing on healthcare professions not directly related to hospital or primary care settings—such as dentists, dental hygienists, pharmacists, and similar professions—were also excluded from the selection.

These criteria were applied systematically to ensure that the review remained focused on identifying comprehensive frameworks and models pertinent to enhancing the digital readiness of general healthcare professionals in alignment with the EHDS objectives.

Annex B – Grey literature search strategy and eligibility criteria

A targeted grey literature search was conducted on 21 October 2025 using Google Search (google.com) to identify non–peer-reviewed documents proposing, describing, or operationalising frameworks of digital skills/competences for the healthcare workforce. The search was performed using a structured query combining key synonyms related to digital competences, the health workforce, and competency frameworks, and restricted to downloadable documents:

("digital competence" OR "digital skills" OR "digital literacy" OR eHealth OR "e-health" OR "digital health") ("health professionals" OR "health workforce") (framework OR "competency framework" OR competence OR curriculum OR standard) filetype:pdf*

To mitigate search personalisation and improve transparency, the search was executed in an incognito/private browsing session with cookies disabled, using Google region settings set to Spain and the interface language set to English.

All search parameters (query string, date range, region, interface language, and browsing mode) were documented to ensure auditability.

Inclusion and exclusion criteria for grey literature

Inclusion criteria

Documents were included if they met all the following conditions:

1. *Authoritative source:* Published or hosted on institutional websites of recognised international or national bodies (e.g., EU institutions, WHO, OECD), national/regional/local health authorities, governmental agencies, and/or professional scientific societies/associations relevant to healthcare or health informatics.
2. *Content relevance:* Explicitly addressed digital skills/competences for health professionals/health workforce and presented a framework, competency model, curriculum, or standards-based structure (e.g., domains, levels, learning outcomes, or competency matrices).
3. *Accessibility:* Available as a full-text document suitable for assessment and extraction (PDF).
4. *Time window:* Published within the defined period (≥ 1 January 2015 and within the last 10 years).
5. *Language:* Available in English (consistent with the search interface language).

Exclusion criteria

Documents were excluded if any of the following applied:

1. *Peer-reviewed journal publications:* Items primarily published as academic journal articles (addressed separately in the peer-reviewed literature search).

2. *Unverifiable origin:* The issuing organisation could not be reliably identified, or the source could not be attributed with sufficient confidence (e.g., anonymous uploads, non-institutional repositories without clear authorship).
3. *Out of scope:* Documents focused primarily on (i) digital health technologies, (ii) surveys assessing current digital literacy skills, (iii) generic skills recommendations without defining a specific competency/skills framework, or (iv) policy/strategy documents without a substantive competency/skills framework component specifically addressing the healthcare workforce.

Screening and selection process of grey literature

The first 100 Google results (ranked by relevance) were screened. This threshold was selected a priori to balance feasibility and transparency while capturing the highest-ranked results that are more likely to include authoritative institutional outputs.

Screening followed a two-step approach:

Title and snippet screening: Each result was initially assessed using the title and snippet shown on the Google results page. Results were retained as potentially eligible when the title/snippet suggested relevance to digital competence/skills frameworks (or curricula/standards) for health professionals/health workforce and indicated an institutional or professional issuing body.

Full-text confirmation: When the title/snippet did not provide sufficient information to determine eligibility, the linked PDF was accessed and assessed at full text to confirm inclusion/exclusion criteria.

For temporal eligibility, the document's internal publication date (as stated in the PDF, e.g., cover page, footer, or publisher metadata) was used as the reference date, rather than the date displayed by Google or the hosting webpage. Only documents meeting all inclusion criteria were retained for subsequent data extraction.

Annex C – SME interview for RCPO v1 validation

Sampling strategy and eligibility criteria

A purposive sampling approach was used to recruit participants with demonstrable expertise in radiology workflows, radiology training, digital medical technologies, and/or imaging interoperability relevant to EHDS/EEHRxF implementation.

Eligibility included at least one of the following profiles: (i) consultant radiologists with experience in teaching and digital transformation; (ii) radiology specialists-in-training (residents) to capture the perspective of professionals currently undergoing training; (iii) imaging informatics or interoperability specialists involved in imaging data exchange standards; (iv) educators responsible for designing radiology training curricula; (v) industry experts (e.g., vendors, CROs, or health IT companies) involved in imaging systems, interoperability solutions, or EHDS-related implementation; and/or (vi) policy, regulatory, or academic professionals with direct involvement in EHDS/EEHRxF implementation affecting medical imaging.

To ensure heterogeneity of viewpoints, recruitment targeted variation across healthcare settings (academic hospitals, private hospitals, smaller clinics etc.) and, where feasible, across EU Member States.

Sample size

Given the bounded, framework-validation scope, an initial target of 8–12 SME interviews was planned to balance saturation of improvement feedback, stability of item-level judgements, and operational feasibility, consistent with evidence on qualitative saturation (Guest et al., 2006).

Interview materials

Participants received a PDF guide interview (Annex E) at least 24 hours in advance, including: (i) the scope and objectives of the interview; (ii) the interview protocol (structure and timing); (iii) a brief introduction to the EHDS; (iv) a short glossary defining key terms used consistently throughout the interview; and (v) the table containing the RCPO v1 competency statements and associated LOs.

Providing these materials in advance was intended to reduce interview time by allowing participants to familiarise themselves with the content beforehand, thereby lowering cognitive load during the session and enabling more discriminating and actionable feedback.

Procedure and interview guide

Interviews were conducted remotely (via videoconference) and lasted approximately 25 minutes. After obtaining oral informed consent, the interview followed a semi-structured guide (Annex F) organised into two core parts:

(1) **Item-level validation:** targeted review of the learning outcomes (LOs), focusing on perceived relevance, clarity, and feasibility.

(2) **Elicitation of omissions:** identification of missing competencies and/or overlooked imaging-workflow considerations.

Interviews were conducted in Italian, Spanish, or English. To ensure consistency in analysis across languages, the interviewer produced structured English summaries immediately after each session using a predefined template. Verbatim quotations were used selectively (as short key phrases) when translation could be performed confidently without loss of meaning.

Rating approach

To capture experts' judgements in a standardised way, a 5-point Likert-type scale was used (Jamieson, 2004; Likert, 1932)

Experts rated each LO on brief 5-point Likert-type scales across three dimensions: clarity (unambiguous wording expected to be interpreted consistently across experts), relevance (importance and applicability to radiology practice), and feasibility (realistic teachability within routine training and typical organisational constraints).

The rating dimensions were: (i) clarity (1 = unclear/ambiguous; 5 = very clear), (ii) relevance (1 = not relevant; 5 = essential), and (iii) feasibility (1 = not feasible in routine training; 5 = readily feasible). To support interpretability of ratings, experts were prompted to briefly justify any score of ≤ 3 on any dimension (clarity, relevance, or feasibility). These rationales were recorded as short free-text notes and were used alongside the quantitative summaries to guide LO revisions.

In addition, experts could provide optional free-text comments for LOs rated ≥4. These were coded as "*General comments"* in Theme label.

For LOs flagged by quantitative thresholds, associated comments were reviewed in a structured manner using the qualitative decision rubric (described later) and the resulting actions were documented in the RCPO v2 Change Log (Annex D).

Experts could select "Not able to rate/Not applicable (NA)" for any LO and/or dimension if they considered it outside their scope or lacked sufficient context for a meaningful judgment. NA responses were treated as missing values and excluded from median/IQR calculations; the number of valid ratings (n) per LO was reported. Where NA was selected, a brief reason was captured (e.g., out of scope, insufficient information, role-specific).

Decision rules for RCPOv1 refinement

1. **Quantitative analysis**

Given the ordinal nature of Likert data and the small expert sample, Likert ratings were summarised using the median and IQR, with IQR used as a robust measure of dispersion to characterise the degree of convergence in expert ratings (Shang, 2023; Sullivan & Artino, 2013).

On 5-point Likert scales, IQR ≤ 1 was interpreted as good convergence, 1 < IQR < 2 as moderate dispersion (suggesting contextual variability in interpretation), and IQR ≥ 2 as substantial disagreement requiring further review.

LOs were flagged for revision when they met at least one of the following criteria: (i) median relevance < 4; (ii) median feasibility < 3; (iii) median clarity < 4; or (iv) substantial disagreement indicated by IQR ≥ 2 on any scale.

Flagged items were reviewed alongside the qualitative rationale provided by experts to determine whether to: reword for clarity, split into separate outcomes, merge overlapping outcomes, relocate (to a different cluster), remove if judged non-essential or out of scope, reframe or remove if not realistically deliverable as a training outcome within routine clinical training (see Annex D for details).

Items with 1 < IQR < 2 were not automatically flagged; instead, where the median met predefined thresholds, the LO was retained and any dispersion was interpreted considering qualitative comments. Where an LO with 1 < IQR < 2 also fell below a median threshold on the corresponding scale, it was flagged for revision.

Newly proposed competencies were added only when traceable to an EHDS/EEHRxF operational requirement or to a clearly articulated imaging-workflow necessity relevant to EHDS-compliant practice.

2. **Qualitative analysis**

Selective capture of key segments and occasional verbatim key phrases was performed; full verbatim transcription was not systematic. English summaries and ratings were consolidated in a structured matrix (LOs × participants) to compare feedback across experts, document recurring issues and points of disagreement, and maintain an audit trail of changes and rationales.

Qualitative feedback was collected through two complementary routes: (i) brief, domain-specific comments elicited when an SME assigned a Likert score ≤ 3 for clarity, relevance, or feasibility for a given LO; and (ii) optional improvement suggestions also permitted when ratings were ≥ 4, recorded as LO-level “general comments”.

All qualitative entries were linked to their corresponding LO and appraisal domain.

Key phrases were occasionally captured verbatim to preserve nuance. When responses were extensive, interviewees were asked to summarise the key point in a few words, which was recorded and confirmed in real time to minimise researcher interpretation bias.

High ratings were interpreted as indicating overall acceptability, but not as precluding structural refinement needs such as overlap/duplication, redundancy, scope misalignment, among others.

To enable synthesis and standardise the use of qualitative input for RCPO refinement, each comment was retained in the analytic matrix and additionally condensed into a Theme Label, defined as a short paraphrase (≤8–10 words) capturing the primary change request or concern expressed by the SME.

Theme Labels were mapped to Issue Types defined in the codebook.

When a single SME comment contained more than one distinct concern, each concern was coded as a separate *"Theme Label"* for counting and aggregation.

Coding and mapping were performed by a single analyst.

For each LO, issue-type frequencies were computed based on unique SME counts (the number of distinct SMEs who raised at least one comment mapped to a given Issue Type). To identify recurrent patterns warranting systematic refinement, an operational predominance threshold was applied: an Issue Type was considered predominant for a given LO when it was raised by ≥3 SMEs and represented ≥40% of all SME-coded issues for that LO (the sum of SME counts across Issue Types within that LO).

These thresholds were not intended to establish formal consensus, but to distinguish isolated remarks from recurring concerns within a small expert sample.

Codebook and decision rubric

A codebook was used to operationalise qualitative coding and ensure consistent application of the refinement rules (White & Marsh, 2006).

It defined (i) the Issue Types, (ii) their operational definitions, and (iii) the default refinement actions linked to each Issue Type (decision rubric). An initial pre-specified set of Issue Types (clarity; scope; trainability) was defined and iteratively refined during analysis. A temporary "others" holding category was used during early coding and subsequently reassigned to existing Issue Types; where recurrent patterns were not captured by the initial scheme, additional Issue Types were introduced and applied consistently (Overlapping and Implementation).

However, comments coded as "*Implementation"*, primarily concerned operational readiness and governance/infrastructure dependencies for EHDS tool deployment rather than the educational scope of the competency overlay. Accordingly, "*Implementation"* was retained as a descriptive coding category for documentation purposes but was not linked to LO-level refinement actions in the decision

rubric. Operational actions were applied using a predefined qualitative decision rubric linking predominant Issue Types to LO-level edits:

- Clarity → rephrase for precision (define acronyms, remove ambiguity, simplify phrasing); split the LO if multiple actions were bundled in a single statement.
- Scope → address misalignment with the radiologist role; remove it when clearly out-of-scope.
- Trainability → reduce training burden by reframing content toward radiologist-facing knowledge; remove when the LO is not realistically deliverable as a training outcome in the intended context.
- Overlapping → address overlaps and duplication with other LOs, merging overlapping outcomes.

All resulting edits were recorded in the RCPO v2 Change Log (Annex D) to preserve traceability from raw comment to final action.

Combined refinement decision rule for radiology-specific competency overlay (RCPO v2)

Refinement actions were triggered using a combined decision rule integrating quantitative and qualitative criteria. LOs were refined if they met either of the following conditions:

1. They were quantitatively flagged according to the predefined median/IQR thresholds; or
2. A qualitative refinement trigger was activated, defined as a predominant Issue Type raised by ≥3 distinct SMEs and representing ≥40% of all SME-coded issues for that LO.

Both conditions were applied independently (OR logic); meeting either criterion was sufficient to initiate structured LO review. The qualitative double threshold was adopted to ensure proportionality and methodological consistency, preventing isolated comments from disproportionately influencing structural revisions.

Where more than one Issue Type met the qualitative trigger, LOs were treated as having co-triggered refinement pathways, and the final action was selected using the decision rubric and documented in the Change Log.

Generation of RCPO v2.

RCPO v2 was produced by applying the combined quantitative–qualitative decision rule to each LO, followed by structured LO-level edits guided by the decision rubric. Within each Issue-Type pathway activated for a given LO, proportional action selection was applied through structured LO-level assessment conducted by the analyst. The specific refinement action was determined through contextual evaluation of the LO's structural integrity, alignment with the intended professional scope, and degree of redundancy, overlap, or cluster misplacement within the framework.

Rewording and structural adjustments were informed by individual SME comments. Specific textual cues and examples provided by experts were systematically incorporated to refine terminology, clarify scope boundaries, and improve assessability, while maintaining alignment with the original EHDS-relevant intent of each LO (Annex D).

Editorial adjustments were implemented when concerns were primarily linguistic and the conceptual intent remained valid. Structural adjustments (splitting, merging, relocation, scope narrowing) were applied when redundancy, multiple assessable actions, or cluster misalignment were confirmed. Removal was reserved for LOs describing institutional, vendor-level, or non-radiologist responsibilities that could not be reformulated within the intended professional scope.

This two-level decision framework ensured methodological consistency while allowing proportional and context-sensitive refinement. All revisions (e.g., rewording, splitting, merging, relocation, acronym definition or removal, or removal), together with the triggering evidence (median/IQR flags and/or qualitative trigger metrics), were recorded in the RCPO v2 Change Log (Annex D).

Figure C.1 summarises the refinement pipeline from RCPO v1 to RCPO v2, including the SME interview workflow.

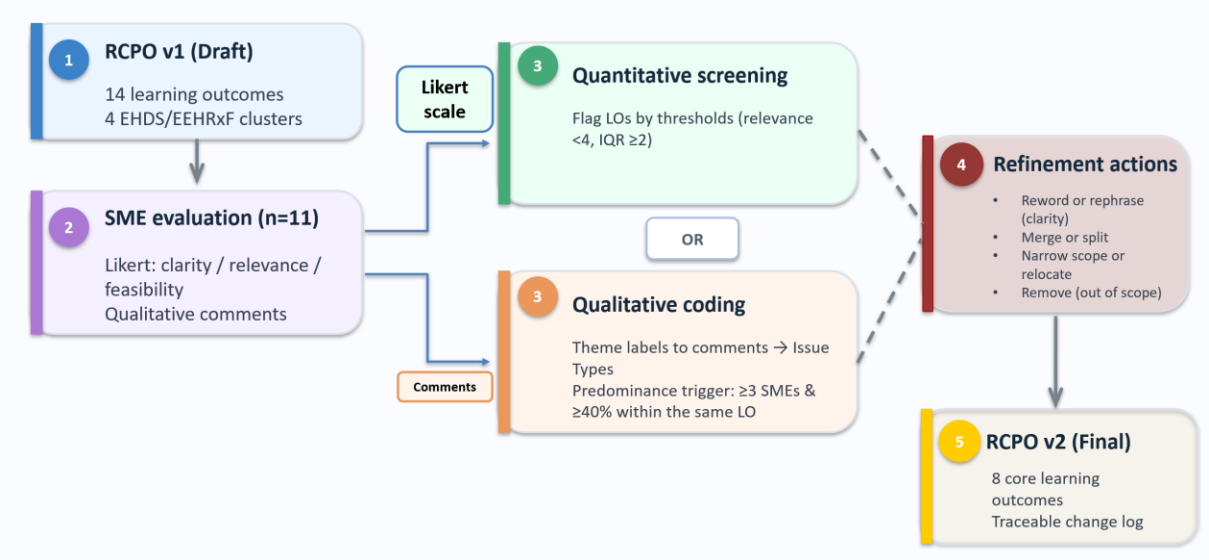


Figure C.1 RCPO refinement pipeline

Note: Author's own work (2026).

Annex D – RCPOv2 Change Log

RCPOv2 Change Log

LO ID	Cluster	Learning Outcome	Clarity median	Clarity iqr	Relevance median	Relevance Iqr	Feasibility median	Feasibility Iqr	Flagged	Flag reason	Issue Type(s) with SME≥3 (n)	Share for Issue Type(s) with SME≥3	Issue Type(s) meeting trigger (≥3 SMEs &	Top theme labels
LO-01	Interoperability and structured exchange	Describe, in language understandable to clinicians and managers, how RIS/PACS interfaDescribe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging	4	2	4	1,5	4	0	Yes	IQR ≥2 (Clarity)	Clarity=4; Scope=3	Clarity=44.4%; Scope=33.3%	Clarity (4; 44.4%)	Unclear or ambiguous definition (n=4); Too technical or Not relevant for end user (n=3); Time-consuming (n=2)
LO-02	Interoperability and structured exchange	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.	4	1,5	4	1	4	0	No		Clarity=3; Scope=3	Clarity=42.9%; Scope=42.9%	Clarity (3; 42.9%); Scope (3; 42.9%)	Unclear or ambiguous definition (n=3); Too technical or Not relevant for end user (n=3); Time-consuming (n=1)
LO-03	Interoperability and structured exchange	Explain how key imaging interoperability standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.	4	0,5	4	1,5	4	1	No	Evaluate the diagnostic s	Scope=5; Clarity=3	Scope=50.0%; Clarity=30.0%	Scope (5; 50.0%)	Too technical or Not relevant for end user (n=5); Unclear or ambiguous definition (n=3); High Level competence (n=2)
LO-04	Interoperability and structured exchange	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.	4	1	3	1,5	4	1	Yes	Median Relevance <4	Scope=6	Scope=54.5%	Scope (6; 54.5%)	Too technical or Not relevant for end user (n=6); Unclear or ambiguous definition (n=2); Time-consuming (n=2)
LO-05	Cross-organisational and cross-border clinical use	Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.	5	0,5	5	0,5	4,5	1	No					Too technical or Not relevant for end user (n=2); Time-consuming (n=1)
LO-06	Cross-organisational and cross-border clinical use	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.	4	1	4	2	3	1	Yes	IQR ≥2 (Relevance)	Scope=5; Trainability=3	Scope=45.5%; Trainability=27.3%	Scope (5; 45.5%)	Too technical or Not relevant for end user (n=5); Unclear or ambiguous definition (n=2); Time-consuming (n=3)
LO-07	Cross-organisational and cross-border clinical use	Prepare and share a complete, good-quality imaging package (images + clinical context) for cross-border second/expert opinions.	5	1	5	2	4,5	1,75	Yes	IQR ≥2 (Relevance)	Scope=4	Scope=57.1%	Scope (4; 57.1%)	Too technical or Not relevant for end user (n=4); General Comment (n=2); Time-consuming (n=1); Hard to implement in training (n=1)
LO-08	Cross-organisational and cross-border clinical use	Retrieve and interpret relevant clinical history from the EHDS and integrate it into radiological decision-making, even when data originate from different healthcare systems.	5	1	5	1	5	1	No					Unclear or ambiguous definition (n=1); Time-consuming (n=1)
LO-09	Cross-organisational and cross-border clinical use	Access, review, and integrate imaging studies performed at different sites into a unified radiology workflow to support continuity of testing.	4	1,5	5	1	4	1	No		Clarity=3	Clarity=50.0%	Clarity (3; 50.0%)	Unclear or ambiguous definition (n=3); General Comment (n=1); Time-consuming (n=1)
LO-10	Cross-organisational and cross-border clinical use	Access and update contrast media allergies and prior reactions across hospitals through EHDS, ensuring that safety information is visible to all radiologists involved in the patient's care.	5	0	5	0	5	0,75	No					Too technical or Not relevant for end user. (n=1); Time-consuming (n=1)
LO-11	Cross-organisational and cross-border clinical use	Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.	4	1,5	5	1	4	1,5	No		Trainability=4; Clarity=3	Trainability=44.4%; Clarity=33.3%	Trainability (4; 44.4%)	Unclear or ambiguous definition (n=3); General Comment (n=3); Hard to implement in training (n=3); Time-consuming (n=2)
LO-12	Cross-organisational and cross-border clinical use	Evaluate the diagnostic suitability of cross-border imaging studies retrieved via EHDS, identifying and reporting technical deficiencies tha…	4	1	5	1	4,5	1	No		Clarity=5	Clarity=71.4%	Clarity (5; 71.4%)	Unclear or ambiguous definition (n=5); Too technical or Not relevant for end user (n=2); General Comment (n=1)
LO-13	Imaging workflow and systems integration	Identify interoperability gaps in radiology workflows that hinder clinical efficiency and communicate needs for improved tools and integration to IT and management.	4	0	4	1	4	0,75	No		Clarity=3; Trainability=3	Clarity=30.0%; Trainability=30.0%		General Comment (n=3); Hard to implement in training (n=2); Too technical or Not relevant for end user (n=2)
LO-14	Secondary use readiness and imaging data stewardship	Use the EHDS as a source of secondary data for radiology research, collaborating with other institutions while complying with ethical, legal, and governance requirements.	5	0	5	0	5	1	No					

RCPOv2 Change Log triggered

LO ID	Original LO text	Predominant Issue Type(s) (triggering)	Proposed action	RCPO v2 final text
LO-01	Describe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging workflow.	Clarity	Rephrase; Acronyms elimination	Describe using plain language, how radiology information systems(RIS) and picture archiving and communication systems (PACS) exchange information with hospital electronic patient and health record systems (HIS/EHR).
LO-02	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.	Clarity, Scope	Remove as out of scope	
LO-03	Explain how key imaging interoperability standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.	Scope	Remove as out of scope	
LO-04	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.	Scope	Remove as out of scope	
LO-06	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.	Scope	Remove as out of scope	
LO-07	Prepare and share a complete, good-quality imaging package (images + clinical context) for cross-border second/expert opinions.	Scope	Remove as out of scope	
LO-09	Access, review, and integrate imaging studies performed at different sites into a unified radiology workflow to support continuity of testing.	Clarity	Rephrase	Integrate imaging studies retrieved via EHDS into the local radiology viewer and PACS enabling side-by-side comparison, relevant reconstructions, and interpretation within routine local radiological workflow.
LO-11	Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.	Trainability	Remove as not realistically deliverable as a training outcome	
LO-12	Evaluate the diagnostic suitability of cross-border imaging studies retrieved via EHDS, identifying and reporting technical deficiencies that make them clinically unsafe.	Clarity	Rephrase	Identify common transmission-related technical defects in imaging studies retrieved via EHDS (e.g., missing data, corrupted series, incomplete metadata) and report them to the appropriate hospital department.

Issue type codebook and decision rubric

Issue type	Operational definition (how it was used)	Default refinement action (guideline)
Clarity	Wording, ambiguity, undefined acronyms, overly broad or generic statements, compound outcomes.	a) Rephrase; b) Split if multiple actions; c) Acronyms elimination
Scope	Perceived misalignment with radiologist role; overly technical depth.	d) Remove if out-of-scope
Trainability	Training burden/time; difficult to deliver in routine training; too advanced for foundational level.	e) Reframe to radiologist-facing f) Remove if not realistically deliverable as a training outcome
Overlapping	Overlaps/duplication with other LOs; needs merge/split.	g) Merge
Implementation	Organisational/infrastructural constraints; governance or service dependencies; system readiness; local implementation context.	

Predominant share

LO_ID	Denominator (ΣSME_n)	Clarity SME_n	Clarity Share	Clarity Trigger?	Implementation SME_n	Implementation Share	Implementation Trigger?	Overlapping SME_n	Overlapping Share	Overlapping Trigger?	Scope SME_n	Scope Share	Scope Trigger?	Trainability SME_n	Trainability Share	Trainability Trigger?
LO-01	9	4	44,4%	Yes	0	0,0%	No	0	0,0%	No	3	33,3%	No	2	22,2%	No
LO-02	7	3	42,9%	Yes	0	0,0%	No	0	0,0%	No	3	42,9%	Yes	1	14,3%	No
LO-03	10	3	30,0%	No	0	0,0%	No	0	0,0%	No	5	50,0%	Yes	2	20,0%	No
LO-04	11	2	18,2%	No	1	9,1%	No	0	0,0%	No	6	54,5%	Yes	2	18,2%	No
LO-05	3	0	0,0%	No	0	0,0%	No	0	0,0%	No	2	66,7%	No	1	33,3%	No
LO-06	10	2	20,0%	No	0	0,0%	No	0	0,0%	No	5	50,0%	Yes	3	30,0%	No
LO-07	7	0	0,0%	No	2	28,6%	No	0	0,0%	No	4	57,1%	Yes	1	14,3%	No
LO-08	2	1	50,0%	No	0	0,0%	No	0	0,0%	No	0	0,0%	No	1	50,0%	No
LO-09	6	3	50,0%	Yes	0	0,0%	No	1	16,7%	No	1	16,7%	No	1	16,7%	No
LO-10	2	0	0,0%	No	0	0,0%	No	0	0,0%	No	1	50,0%	No	1	50,0%	No
LO-11	9	3	33,3%	No	0	0,0%	No	0	0,0%	No	2	22,2%	No	4	44,4%	Yes
LO-12	7	5	71,4%	Yes	0	0,0%	No	0	0,0%	No	2	28,6%	No	0	0,0%	No
LO-13	10	3	30,0%	No	1	10,0%	No	0	0,0%	No	2	20,0%	No	4	40,0%	Yes

Annex E – Interview guide



Validating Radiologists Learning Outcomes for the European Health Data Space (EHDS)

Expert validation (25-minute interview aprox.)

Interviewer: Alessandro Catanese - ManagiDiTH Master's

ARISTOTLE UNIVERSITY OF THESSALONIKI · iscte INSTITUTO UNIVERSITÁRIO DE LISBOA · LAUREA AMMATTIKORKEAKOULU University of Applied Sciences · ManagiDiTH ADVANCED DIGITAL SKILLS

Guide Content

a) Scope and objectives of the interview
b) Interview protocol (structure and timing)
c) Brief introduction to the EHDS;
d) Short glossary defining key terms used consistently throughout the interview;
e) Table containing the RCPO v1 competency statements and associated learning outcomes (LOs).

Scope and objectives of the interview

Aim

To validate and prioritise learning outcomes/competencies for radiologists in the context of the European Health Data Space (EHDS), as part of the **ManagiDiTh Master's thesis project**. Findings will inform EHDS-aligned radiology training and curriculum design and may support related European initiatives.

Interview Approach

Semi-structured format using open-ended questions

Ethics and confidentiality

Responses will be reported in aggregated/anonymized form;
Optional recording (with informed consent) for research purposes and auditability/traceability.

Interview Protocol

Optional recording with informed consent only for academic purpose and treaceability

1	**What you will be asked (4 segments):** a) Framework structure: clusters and language b) LO review: **relevance, clarity, feasibility** (with follow-up questions) c) Missing competencies + workflow constraints d) Prioritisation & sequencing for training deployment
2	**Rating task will be used for LOs : 5-point Likert scales (1 = low, 5 = high)** • Relevance (1–5): 1 not relevant ... 5 = essential • Feasibility (1–5): 1 = not feasible in routine training ... 5 = readily feasible • Clarity (1–5): 1 = unclear/ambiguous ... 5 = clear/assessable You will rate each LO and briefly explain the main reason for your rating.
3	**How inputs will be used:** • Ratings + brief rationale inform LO revisions (reword/split/merge/relocate/remove) • Summary consolidated in English





A brief overview of the EHDS

A Unified EU Health Data Framework

The EHDS stands as the first common EU data space exclusively dedicated to health data, aiming to harmonise the landscape of digital health across Member States.

Secure Cross-Border Data Sharing

Its core purpose is to establish a secure, standardised framework for the seamless sharing and reuse of electronic health data across national borders.

Supporting Primary and Secondary Use

The EHDS supports both primary use (direct patient care) and secondary use (research, innovation, and evidence-based policymaking), ensuring data serves multiple vital functions.

Glossary of Key Terms

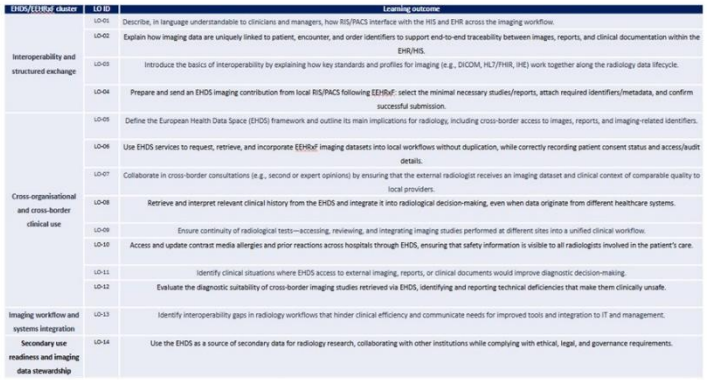
- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Competence (Competency):** An integrated combination of knowledge, skills, and attitudes that enables a professional to perform a task to an expected standard in a specific context. In this study, competencies relate to EHDS-compliant radiology practice and interoperability-enabled workflows.
- **EEHRxF (European Electronic Health Record Exchange Format):** A set of EU-level specifications that support cross-border exchange of electronic health record data by defining common information structures and interoperability requirements for priority health data categories.
- **EHDS (European Health Data Space):** An EU policy and regulatory framework intended to enable secure access, sharing, and use of health data across Member States for healthcare delivery and secondary use (e.g., research, innovation, policy), under common rules and governance.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.
- **Interoperability:** The ability of different information systems, devices, or applications to access, exchange, integrate, and use data in a coordinated way. In this study, it refers to imaging-relevant data exchange and the semantic/technical alignment needed for EHDS-compliant workflows.
- **Learning Outcome (LO):** A clear statement describing what a learner should be able to do after a training activity. Learning outcomes are written in observable, assessable terms and are used to guide curriculum design and evaluation.
- **Likert scale (5-point):** A rating scale used to capture judgments on an ordered continuum. In this study, experts rate each LO from 1 (low) to 5 (high) on three dimensions: relevance (1 = not relevant; 5 = essential), feasibility (1 = not feasible in routine training; 5 = readily feasible), and clarity (1 = unclear/ambiguous; 5 = clear/assessable).
- **Prioritisation and sequencing:** The process of determining which learning outcomes are most critical (prioritisation) and in what order they should be introduced or trained (sequencing), often to support staged deployment and manage prerequisites.
- **RCPO (Radiology Competency and Outcomes Framework – v1):** The initial version of the competency framework being assessed in this thesis, comprising competency statements and associated learning outcomes grouped into four clusters; it serves as the object of validation and prioritisation in Phase 3.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Skills gap:** Mismatch between current workforce competences and the competences required to perform expected tasks to the desired standard.
- **Workflow constraints:** Practical conditions that shape what can be implemented in real-world radiology settings (e.g., organisational roles and responsibilities, time and resource limitations, legacy IT systems, governance and access rules, and variability across sites or countries).

Table RCPO v1 Learning Outcomes

Learning outcomes mapped to EHDS/EEHRxF clusters (RCPO v1)		
EHDS/EEHRxF cluster	**LO ID**	**Learning outcome**
Interoperability and structured exchange	LO-01	Describe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging workflow.
	LO-02	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.
	LO-03	Explain how key imaging interoperability standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.
	LO-04	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.
Cross-organisational and cross-border clinical use	LO-05	Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.
	LO-06	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.
	LO-07	Collaborate in cross-border consultations (e.g., second or expert opinions) by ensuring that the external radiologist receives an imaging dataset and clinical context of comparable quality to local providers.
	LO-08	Retrieve and interpret relevant clinical history from the EHDS and integrate it into radiological decision-making, even when data originate from different healthcare systems.
	LO-09	Access, review, and integrate imaging studies performed at different sites into a unified radiology workflow.
	LO-10	Access and update contrast media allergies and prior reactions across hospitals through EHDS, ensuring that safety information is visible to all radiologists involved in the patient's care.
	LO-11	Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.
	LO-12	Evaluate the diagnostic suitability of cross-border imaging studies retrieved via EHDS, identifying and reporting technical deficiencies that make them clinically unsafe.
Imaging workflow and systems integration	LO-13	Identify interoperability gaps in radiology workflows that hinder clinical efficiency and communicate needs for improved tools and integration to IT and management.
Secondary use readiness and imaging data stewardship	LO-14	Use the EHDS as a source of secondary data for radiology research, collaborating with other institutions while complying with ethical, legal, and governance requirements.

Example questions

- **At a high level, does the RCPO structure make sense to you?**
- Are the four clusters appropriate and complete?
- **Is the language clear and consistent for your context?**
- Any terms that feel ambiguous or need standardisation?



EHDS/EEHRxF cluster	LO ID	Learning outcome
Interoperability and structured exchange	LO-01	Describe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging workflow.
	LO-02	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.
	LO-03	Introduce the basics of interoperability by explaining how key standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.
	LO-04	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.
Cross-organisational and cross-border clinical use	LO-05	Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.
	LO-06	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.
	LO-07	Collaborate in cross-border consultations (e.g., second or expert opinions) by ensuring that the external radiologist receives an imaging dataset and clinical context of comparable quality to local providers.
	LO-08	Retrieve and interpret relevant clinical history from the EHDS and integrate it into radiological decision-making, even when data originate from different healthcare systems.
	LO-09	Ensure continuity of radiological tests—accessing, reviewing, and integrating imaging studies performed at different sites into a unified clinical workflow.
	LO-10	Access and update contrast media allergies and prior reactions across hospitals through EHDS, ensuring that safety information is visible to all radiologists involved in the patient's care.
	LO-11	Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.
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Imaging workflow and systems integration	LO-13	Identify interoperability gaps in radiology workflows that hinder clinical efficiency and communicate needs for improved tools and integration to IT and management.
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Example question

"For **clarity**, please rate how clear and unambiguous this learning outcome is as written (i.e., whether a radiology clinician can immediately understand what is expected and how it would be demonstrated) on a **1 to 5** scale.
1 = very unclear, 3 = partly clear, 5 = completely clear."

"How relevant you believe this learning outcome is for the practical implementation of the European Health Data Space (EHDS) in radiology and imaging workflows—please rate it on a **1 to 5** scale.
1 = not relevant, 3 = moderately relevant, 5 = essential."

EHDS/EEHRxF cluster	Learning outcome
Interoperability and structured exchange	Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.

Annex F – Full slide deck used for SME interviews



Validating Radiologists Learning Outcomes for the European Health Data Space (EHDS)

Expert validation (25-minute interview)

Interviewer: Alessandro Catanese - ManagiDiTH Master's

ARISTOTLE UNIVERSITY OF THESSALONIKI · iscte INSTITUTO UNIVERSITÁRIO DE LISBOA · LAUREA AMMATTIKORKEAKOULU University of Applied Sciences · ManagiDiTH ADVANCED DIGITAL SKILLS

Scope and objectives of the interview

Aim

To validate, refine, and prioritise learning outcomes that support radiologists' readiness for the upcoming European Health Data Space (EHDS), as part of the ManagiDiTh Master's thesis project. Findings will inform the design of EHDS-aligned radiology education and training curricula and may support related European initiatives.

Interview Approach

Semi-structured format using open-ended questions

Ethics and confidentiality

Responses will be reported in aggregated/anonymized form;
Optional recording (with informed consent) for research purposes and auditability/traceability.



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Supporting Health Professionals: Article 83 Directives

Article 83 of the EHDS underscores the critical need to equip health professionals with the necessary knowledge and skills to navigate the new data landscape.

Training Programmes

Member States must develop and implement or provide access to dedicated training for health professionals.

Information Access

Ensure health professionals have access to relevant information regarding the EHDS and their roles.

Enhanced Data Literacy

Empower professionals to understand and effectively perform their roles in primary use and accessing electronic health data.

Commission Support

The European Commission will provide crucial support to Member States in these efforts, ensuring harmonised implementation.

Made with GAMMA

Interview Protocol

Optional recording with informed consent only for academic purpose and treaceability

1	**What you will be asked (4 segments):** a) Framework structure: clusters and language b) LO review: **relevance, clarity, feasibility** (with follow-up questions) c) Missing competencies + workflow constraints d) Prioritization & sequencing for training deployment
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	LO-04	Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.
Cross-organisational and cross-border clinical use	LO-05	Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.
	LO-06	Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.
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Starting the interview

Radiology Competency Profile Overlay (RCPO) v1

The Radiology Competency Profile Overlay (RCPO) is a crucial framework designed to articulate the specific skill sets and knowledge required for radiologists operating within the evolving European Health Data Space (EHDS). It provides a structured approach to identifying, developing, and assessing the competencies essential for modern radiological practice.

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Validadating Learning Outcomes (3 dimensions).

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Clarity
1 = unclear/ambiguous
5 = clear/assessable
This evaluates how well-defined and understandable the LO is, ensuring it can be effectively measured.

Relevance
1 = not relevant
5 = essential
This measures how pertinent the LO is to the daily practice and future needs of radiologists.

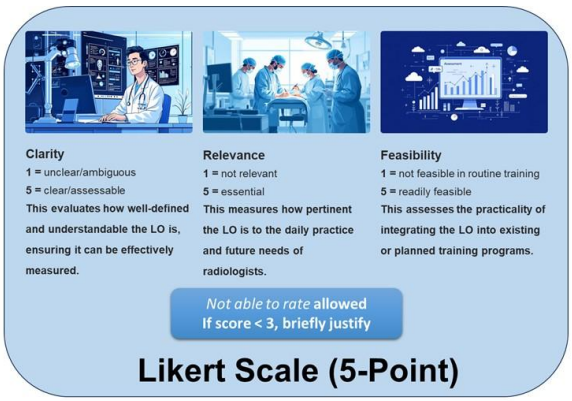
Feasibility
1 = not feasible in routine training
5 = readily feasible
This assesses the practicality of integrating the LO into existing or planned training programs.

Not able to rate **allowed**
If score < 3, briefly justify

Likert Scale (5-Point)

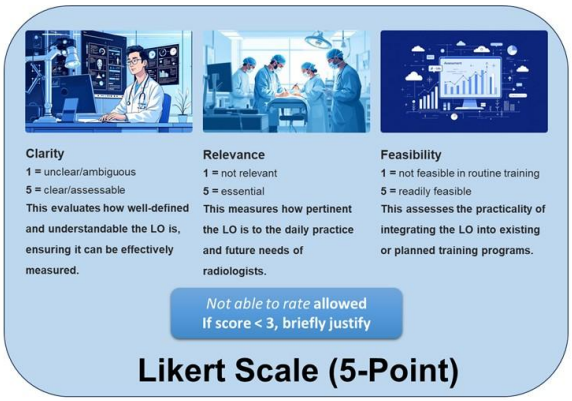
Interoperability and structured exchange	LO-01	**Describe, in language understandable to clinicians and managers, how RIS/PACS interface with the HIS and EHR across the imaging workflow.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
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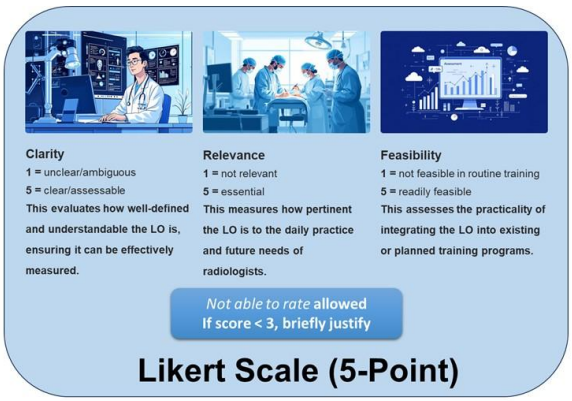
Interoperability and structured exchange	LO-02	**Explain how imaging data are uniquely linked to patient, encounter, and order identifiers to support end-to-end traceability between images, reports, and clinical documentation within the EHR/HIS.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Interoperability and structured exchange	LO-03	**Explain how key imaging interoperability standards and profiles for imaging (e.g., DICOM, HL7/FHIR, IHE) work together along the radiology data lifecycle.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Interoperability and structured exchange	LO-04	**Prepare and send an EHDS imaging contribution from local RIS/PACS following EEHRxF: select the minimal necessary studies/reports, attach required identifiers/metadata, and confirm successful submission.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-05	**Define the European Health Data Space (EHDS) framework and outline its main implications for radiology, including cross-border access to images, reports, and imaging-related identifiers.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-06	**Use EHDS services to request, retrieve, and incorporate EEHRxF imaging datasets into local workflows without duplication, while correctly recording patient consent status and access/audit details.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-07	**Prepare and share a complete, good-quality imaging package (images + clinical context) for cross-border second/expert opinions.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-08	**Retrieve and interpret relevant clinical history from the EHDS and integrate it into radiological decision-making, even when data originate from different healthcare systems.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-09	**Access, review, and integrate imaging studies performed at different sites into a unified radiology workflow.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
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- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



Cross-organisational and cross-border clinical use	LO-10	**Access and update contrast media allergies and prior reactions across hospitals through EHDS, ensuring that safety information is visible to all radiologists involved in the patient's care.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
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Cross-organisational and cross-border clinical use	LO-11	**Identify clinical situations where EHDS access to external imaging, reports, or clinical documents would improve diagnostic decision-making.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
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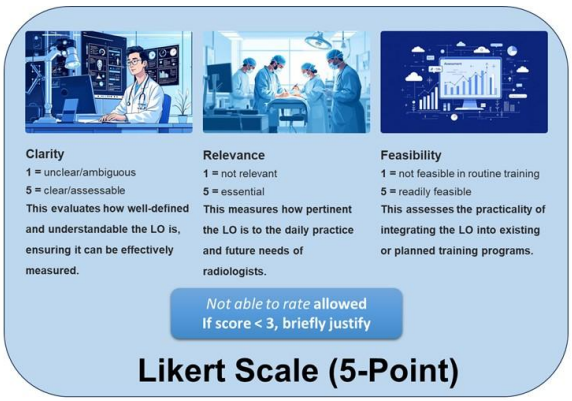
Cross-organisational and cross-border clinical use	LO-12	**Evaluate the diagnostic suitability of cross-border imaging studies retrieved via EHDS, identifying and reporting technical deficiencies that make them clinically unsafe.**

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- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



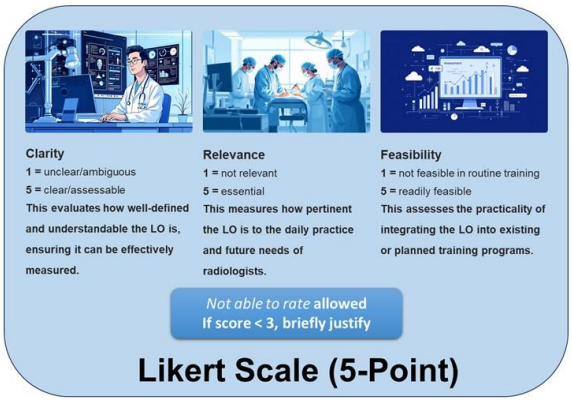
Imaging workflow and systems integration	LO-13	**Identify interoperability gaps in radiology workflows that hinder clinical efficiency and communicate needs for improved tools and integration to IT and management.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.



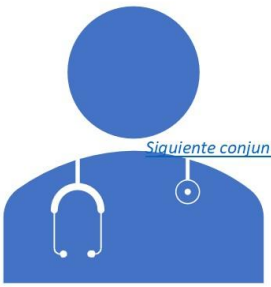
Secondary use readiness and imaging data stewardship	LO-14	**Use the EHDS as a source of secondary data for radiology research, collaborating with other institutions while complying with ethical, legal, and governance requirements.**

- **Clarity:** The degree to which a learning outcome is unambiguous, well-scoped, and stated in a way that can be consistently understood and assessed.
- **Relevance:** The degree to which a learning outcome is important and directly applicable to real-world radiology practice in the EHDS context.
- **Feasibility:** The degree to which a learning outcome can realistically be taught, implemented, and assessed within routine training and typical organisational/workflow constraints.





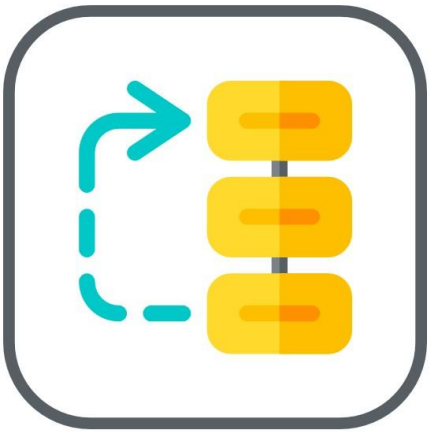
ANY COMMENT?



Siguiente conjunto de diapositivas

MISSING COMPETENCES?

- What competencies or LOs are missing in your opinion for a radiologist to operate safely in an EHDS/EEHRxF environment?
- Are there any clinical or operational risks not reflected?
- Any other comment?



PRIORITISATION AND SEQUENCING (optional)

- Can you select the most critical (must-have) learning outcomes for an initial rollout?
- Please, can you rank them in the order you would teach/train them ?