A Socio-Technical Assessment of AI-Driven Clinical Data Structuring for the EEHRxF

The Implementation Wall

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Date: 28/02/2026

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Dedication / Acknowledgements

I would like to express my sincere gratitude to my supervisors, Prof. Panagiotis Bamidis, and Dr. Alexander Berler, for their guidance, expertise and support throughout the development of this research. I am also deeply thankful to Prof. Henrique Martins for his insightful contributions and day-to-day mentorship. Special thanks to EHTEL/Marc Lange for linking this work to the EHTEL Symposium 2026 in Helsinki and permitting the writing and presenting of a working paper on a related topic.

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Abstract

The European Health Data Space (EHDS) establishes the European Electronic Health Record Exchange Format (EEHRxF) as the foundation for cross-border interoperability. While technical specifications are formalising, a significant "Implementation Wall" persists: the challenge of transforming unstructured clinical narratives into structured, interoperable formats. In parallel, a "Technological Push" driven by Large Language Models (LLMs) offers new possibilities for automated clinical structuring.

This thesis evaluates the socio-technical feasibility of AI to meet EHDS mandates. Using a dual-methodological approach, it synthesises a systematic review of 103 peer-reviewed AI articles (2020–2025) and an empirical analysis of 357 European stakeholders. Capabilities are evaluated against "First Group" priority categories (Patient Summaries, eP, eD) mandated for March 2029.

Findings reveal a stark misalignment between technical potential and organisational capacity. While AI models frequently exceed F1-scores of 0,90 in lab environments, they remain restricted by a "Retrospective Trap". Notably, over 60% of surveyed stakeholders report zero proficiency in SNOMED CT and HL7 FHIR governance, rendering the assumed "Human-in-the-Loop" architecture a structural misconception. The research concludes that successful 2029 implementation depends on shifting policy focus from algorithmic performance to "Organisational Pull," specifically through investments in workforce semantic literacy and localised IT infrastructure.

Keywords: European Health Data Space (EHDS); European Electronic Health Record Exchange Format (EEHRxF); Generative Artificial Intelligence (GenAI); Semantic Interoperability; Workforce Readiness; Socio-Technical Analysis.

JEL classification codes: I18 – Health: Government Policy; Regulation; Public Health and O33 – Technological Change: Artificial Intelligence; Automation; Innovation.

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Glossary

Acronym / Term	Meaning
Artificial Intelligence (AI)	A field of computer science dedicated to creating systems capable of performing tasks that typically require human intelligence, such as visual perception, speech recognition, and decision-making. In this study, AI specifically refers to machine learning and deep learning models used for structuring clinical text.
Automation Bias	The tendency of human users to favor suggestions from automated decision-making systems and to ignore contradictory information made without automation, even if it is correct.
Clinical Note	An unstructured or semi-structured narrative recorded by healthcare professionals during a clinical encounter, containing diagnoses, physical findings, and treatment plans.
Electronic Dispensation (eD)	The electronic record of the fulfilment of an e-prescription by a pharmacy, including the specific medicinal product delivered and the date of supply.
Electronic Health Record (EHR)	A digital version of a patient's paper chart, containing the medical and treatment history of the patients in one practice.
Electronic Prescription (eP)	A digital prescription generated by a healthcare provider using an electronic system, allowing for the interoperable exchange of medication orders.
European Electronic Health Record Exchange Format (EEHRxF)	A set of technical and semantic specifications designed to enable the interoperable exchange of personal health data across EU Member States.
European Health Data Space (EHDS)	A legally binding framework (Regulation) established by the EU to facilitate the secure and interoperable exchange of health data for primary (care) and secondary (research) use.
F1-Score	A statistical measure of a model's accuracy that considers both precision and recall, commonly used to evaluate the performance of clinical NLP models.
Generative AI (GenAI)	A subset of artificial intelligence, such as Large Language Models (LLMs), capable of generating new content (text, code, structured data) based on patterns learned from training data.
HL7 FHIR (Fast Healthcare Interoperability Resources)	A standard describing data formats and elements and an application programming interface for exchanging electronic health records.
Human-in-the-Loop	A model of interaction where an AI system provides suggestions or outputs that must be reviewed, validated, or corrected by a human expert before implementation.
Implementation Wall	A socio-technical barrier where advanced technical tools (the Push) exist, but the organisational structures, standardised data formats, and workforce proficiencies (the Pull) required to utilise them are absent.
Interoperability Paradox	A condition where the proliferation of overlapping technical standards increases system complexity, potentially decreasing actual interoperability and creating "semantic blindness" for the workforce.
Large Language Model (LLM)	A type of AI model trained on vast amounts of text data, capable of understanding and generating human-like language for tasks like clinical summarisation and coding.
Natural Language Processing (NLP)	A branch of AI that focuses on the interaction between computers and human language, specifically the ability of computers to process and analyse large amounts of natural language data.
Organisational Pull	The institutional and human capacity—including skills, infrastructure, and governance—required to successfully absorb and sustain a new technology.
Patient Summary (PS)	A standardised dataset containing a concise set of basic medical data (e.g., allergies, current medications, major past illnesses) to ensure continuity of care across borders.
Retrospective Trap	A gap in evidence where AI models demonstrate high accuracy on historical, static datasets (lab validation) but fail to maintain performance in "live," fragmented clinical environments.

Semantic Literacy	The specific competency of a workforce to comprehend, audit, and govern the structured clinical terminologies and standardised formats (e.g., SNOMED CT, HL7 FHIR) generated by AI systems.
SNOMED CT	A comprehensive, multilingual clinical healthcare terminology used for the consistent representation of clinical content in electronic health records.
Technological Push	Advancements in digital transformation driven primarily by R&D and rapid technical innovation rather than immediate organisational demand or readiness.

Introduction

Digital health transformation and the interoperability challenge

Over the past two decades, European healthcare systems have undergone a fundamental transition toward digital-first delivery. This transformation—catalysed by demographic aging, the rising prevalence of chronic conditions, and sustained pressure on workforce capacity—has seen electronic health records (EHRs), telemedicine, and remote monitoring become core components of system management. Historically, this shift has been framed as a "Technological Push[1]", where the adoption of digital tools was expected to automatically yield public value in the form of improved safety, equity, and efficiency (Zmud 1984).

However, the reality of European digital health remains one of profound fragmentation. Most initiatives have developed within institutional or regional silos, relying on proprietary architectures that lack the interoperability required for a borderless European Health Data Space (EHDS). This fragmentation creates a "Socio-Technical Implementation Wall": a barrier where sophisticated digital tools exist, but the organisational structures, standardised data formats, and workforce proficiencies required to utilise them at scale are absent (Lewerenz, Moen, and Martins 2025; Li et al. 2019). Consequently, patients and professionals continue to encounter significant discontinuities in care, undermining the vision of a coherent, citizen-centred health data journey.

Structured health data: a pillar of the European Health Data Space

The EHDS Regulation, formally adopted in 2025, represents a landmark regulatory intervention designed to dismantle these silos by establishing a legally binding framework for health data exchange (European Health Data Space Regulation 2025). Central to this framework is the European Electronic Health Record Exchange Format (EEHRxF), which recognises that meaningful exchange depends not merely on technical connectivity, but on the availability of structured, semantically interoperable data.

Currently, a vast majority of clinically significant information is trapped in "computationally dark" formats—narrative free text, scanned PDFs, or idiosyncratic local codes (Gu et al. 2025; Wu et al. 2022). Even within mature EHR systems, heterogeneity remains

[1] Technological Push: Advancements in digital transformation driven primarily by R&D and rapid technical innovation rather than immediate organisational demand or readiness

the norm, with divergent terminologies and documentation practices coexisting without centralised governance (Palm et al. 2025). From a system perspective, this lack of structure is no longer just a technical inefficiency; it is a regulatory liability. Structured data, aligned with global standards like SNOMED CT and HL7 FHIR , is a prerequisite for the clinical decision support, quality analytics, and cross-border continuity of care envisioned by the EHDS.

Following the FAIR principles (Findable, Accessible, Interoperable, Reusable), the EEHRxF provides the mandatory "exchange layer" required to make European health data machine-actionable (Dugas et al. 2024; Wilkinson et al. 2016). However, as the 2029 regulatory deadline for the first wave of priority data (Patient Summaries and Medication records; See EHDS Art. 105) approaches, the challenge shifts from *defining* these standards to *populating* them from legacy and live systems—a task that increasingly relies on the capabilities of Artificial Intelligence (AI).

Artificial Intelligence as a Strategic Catalyst for EHDS Implementation

Addressing the Unstructured Legacy at Scale

The ambitious regulatory timeline for the EHDS—specifically the 2029 mandate for the first group of priority categories—presents a scalability challenge that traditional manual data-entry and legacy mapping methods cannot resolve. The "Technological Push" of AI has therefore emerged as a core strategic enabler for the digital transformation of European health systems. By providing the capacity to automate the transformation of "computationally dark" legacy information into structured, standard-compliant formats, AI is positioned as the primary bridge to the machine-actionable requirements of the EEHRxF.

Recent research indicates that AI-based approaches can now perform high-utility tasks such as named entity recognition (NER) and terminology mapping with significant statistical performance. This transition represents a paradigm shift from rigid, rule-based architectures—which were often "socio-technically fragile" and required constant manual maintenance —to Transformer-based models capable of contextual reasoning. However, the role of AI is no longer a matter of future speculation; it is actively being integrated into the current preparatory phase of the EHDS to ensure that Member States can meet upcoming application deadlines.

AI in EHDS Preparatory Strategies: FAIRification and Validation

Current implementation frameworks and thought leadership identify AI as a critical tool for "FAIRification"—ensuring that health data is Findable, Accessible, Interoperable, and Reusable—which is a prerequisite for any meaningful exchange within the EHDS (Xt-EHR and Lange 2026). Beyond simple data extraction, AI is being considered for large-scale validation of Electronic Health Record (EHR) outputs against specific EHDS profiles (Lewerenz, Berler, and Lange 2026). This includes providing automated classification of HL7 FHIR conformance errors, conducting root cause analysis of profile violations and offering "smart recommendations" for corrective mappings to ensure regulatory compliance.

Strategic discussions such as within the EHTEL's EHDS Implementers' Task Force[2] or the i2X Project[3] are already weighing whether the deployment of advanced clinical decision support tools should be conditioned on the prior use of AI-driven data quality and FAIRification tools. Furthermore, there is an urgent focus on identifying "quick-win" AI tools that can be deployed the quickest to support EHDS processes by healthcare professionals and IT managers alike. This preparatory focus underscores that AI is viewed by the ecosystem as a necessary component of the technical infrastructure required to manage the transition from legacy systems to the EHDS and for instance the EEHRxF.

The Need for Socio-Technical Evaluation

While the technical maturity of AI models—particularly Large Language Models (LLMs)—continues to advance rapidly, their successful integration into clinical workflows remains a significant socio-technical challenge (Lewerenz, Berler, et al. 2026; Rodrigues and Lopes 2025; Xt-EHR and Lange 2026). Models have demonstrated the ability to map clinical narratives to standardised terminologies like SNOMED CT, LOINC, and RxNorm , and even transform raw text into fine-grained, HL7 FHIR -compatible representations (Dandala et al. 2020; Harris et al. 2023; Herman Bernardim Andrade et al. 2024; Nath, Lee, and Lee 2023; Noor et al. 2022; Patel, Tanwani, and Patidar 2021; Van Veen et al. 2023; Wang et al. 2020, 2023). However, these capabilities are often validated in narrow domains or single datasets or institutions, leaving a gap in understanding their feasibility for the diverse, multilingual requirements of the EHDS.

[2] See: https://www.ehtel.eu/18-articles/301-ehtel-s-european-health-data-space-ehds-implementation-task-force.html
[3] See: https://www.uphillhealth.com/i2x

The central challenge for implementation is no longer just the algorithm's ability to generate code, but the organisational and workforce capacity to govern it. This creates a critical need for an evaluation that aligns AI's technical capabilities with the practical "Organisational Pull"[4] of European healthcare systems. It is this disconnect—between the strategic promise of AI and the practical readiness of the workforce to audit and validate it—that defines the research gap addressed by this thesis.

Problem statement and research gap

Recent advances in AI, particularly within the realms of LLMs and Generative AI (GenAI), have introduced transformative possibilities for extracting, structuring, and semantically normalising clinical information (Chen et al. 2023; French and McInnes 2023; Hu et al. 2026; Kang et al. 2021; Lee et al. 2019; Weeks et al. 2020; Xu et al. 2020). An expanding corpus of research demonstrates promising technical results in high-utility tasks such as clinical entity recognition, terminology mapping, and multilingual processing. However, this body of literature is characterised by significant heterogeneity and remains largely disconnected from the specific semantic and structural mandates defined by European interoperability frameworks.

The primary research gap lies in the absence of a systematic synthesis that evaluates AI-based structuring methodologies against the "First Group" of priority electronic health data categories—Patient Summaries, e-Prescription, and e-Dispensation—as defined by the EHDS. Current AI research often prioritises model-centric metrics, such as F1-scores on historical benchmarks, while neglecting the rigorous regulatory and deployment constraints emerging under the EHDS.

This disconnect creates a critical "Semantic Gap": while AI may technically succeed in structuring a clinical note, its output may fail to meet the EHDS-specific "regulatory-grade" precision and specification frame required for cross-border continuity of care. With the legal provisions for the first wave of priority data set to enter into force on March 26, 2029, there is an urgent need to determine whether the "Technological Push" of AI is compatible with the EEHRxF. Furthermore, there is a lack of empirical evidence regarding whether the European health workforce possesses the "Semantic Literacy" required to govern these automated

[4] Organisational Pull: The institutional and human capacity—including skills, infrastructure, and governance—required to successfully absorb and sustain a new technology.

processes—a prerequisite for the high-risk AI governance mandated by the EU AI Act (AI Act – Regulation - EU - 2024/1689 - EN - EUR-Lex 2024).

Aim and research questions

Therefore, the overall aim of this thesis is to synthesise recent AI research on clinical data structuring and to assess its socio-technical feasibility for implementing the EEHRxF across its first group of priority domains. By evaluating both the technical state-of-the-art and the current state of workforce readiness, this research seeks to identify the specific misalignments that constitute the "Implementation Wall".

Main research question:

> *How do recent AI-based approaches (2020–2025) for structuring clinical data align with the technical, organisational and workforce capabilities required to implement the European Electronic Health Record Exchange Format (EEHRxF) for the first group of priority electronic health data categories under the European Health Data Space (EHDS)?*

Sub-questions guiding reflection:

1. What AI-based methods have been proposed for extracting and coding clinical data relevant to the first group of EEHRxF priority categories, and what levels of technical maturity and methodological patterns do they demonstrate?
2. What levels of workforce capability and readiness exist within the European healthcare sector to deploy, validate, and govern AI-based clinical data structuring solutions in line with EEHRxF requirements?
3. Where do gaps or misalignments emerge between AI technical capabilities and organisational readiness, and what do these gaps imply for the 2029 EEHRxF implementation deadline and future AI-enabled interoperability initiatives?

The research questions are intentionally framed to capture the interaction between algorithmic performance and the human conditions required for sustainable deployment in regulated European environments.

Chapter 1 –Contextual Review and Regulatory Landscape

1.1 The European Health Data Space and the European Electronic Health Record Exchange Format

European digital health policy has historically positioned interoperability as a foundational pillar for the delivery of safe, efficient, and patient-centred care. For over two decades, the European Commission has facilitated numerous initiatives aimed at exploring the technical, semantic, and organisational dimensions of cross-border health data exchange (Lewerenz, Chronaki, et al. 2026). However, despite this sustained **"**Technological Push", the European digital health landscape remains profoundly fragmented. Most initiatives have been implemented in institutional or regional silos, often tethered to proprietary platforms that fail to communicate across national borders.

This fragmentation is particularly evident in domains such as telemedicine. Recent evidence suggests that documented instances of cross-border telemedicine data exchange within the European Union (EU) remain scarce, reflecting a significant gap between policy ambitions and operational reality (Lewerenz, Zanini, and Martins 2024; Martins et al. 2025). The resulting patchwork of localised infrastructures creates a historical "implementation wall" where data cannot effectively follow the citizen, undermining the vision of a coherent, pan-European health data journey. From a socio-technical perspective, this lack of sustainable success can be attributed to an underdeveloped "Organisational Pull", where the technical tools for interoperability were not matched by the workforce readiness or infrastructural maturity required to absorb them.

The EHDS represents a pivotal regulatory shift, introducing the first legally binding framework designed to govern both the primary and secondary use of health data across the EU. While the secondary use of data focuses on research, innovation, and evidence-based policymaking, the primary use mandate aims to ensure that citizens have immediate, secure, and interoperable access to their health data during clinical encounters, regardless of their location within the EU (Ahmed et al. 2025). To operationalise this vision, the EHDS relies on the EEHRxF, a set of technical and semantic specifications designed to bridge disparate national systems while respecting the administrative autonomy of individual Member States.

The EEHRxF does not emerge in a vacuum; rather, it represents the strategic consolidation of a decade-long lineage of EU-funded research and implementation pilots

(Lewerenz, Chronaki, et al. 2026). This lineage began with pioneering efforts such as epSOS (2008–2014)[5], which established the initial specifications for cross-border patient summaries and e-prescriptions. Subsequent initiatives, including Trillium-II[6], Smart4Health[7], and InteropEHRate[8], progressively refined these standards by exploring citizen-centred exchange and the integration of diverse data sources. More recently, the transition toward a formal regulatory instrument has been accelerated by consolidation projects like X-eHealth[9], XpanDH[10], xShare[11], and the joint action Xt-EHR[12]. These projects collectively developed the governance models, testing methodologies, and semantic resources that form the backbone of the current MyHealth@EU[13] infrastructure (Misheva et al. 2025).

By codifying these legacies into a formal EU legal instrument, the EEHRxF shifts interoperability from a voluntary technical objective to a mandatory regulatory requirement. Rather than prescribing a single, monolithic EHR architecture for all of Europe—an approach that would be politically and logistically unrealistic—the EEHRxF specifies a common "exchange layer". This layer defines the data structures, terminologies, and value sets necessary for machine-readable communication between systems. This architectural choice places a significant weight on healthcare providers to transform their legacy data into compliant formats. However, it also exposes a potential socio-technical gap: while the exchange layer is now legally and technically defined, the internal capacity of organisations to populate these structures remains a critical implementation challenge.

1.2 Priority health data categories and EEHRxF domains

In its current scope, the EEHRxF targets specific priority categories of personal electronic health data that are both clinically central and cross-cutting across healthcare use cases. Defined under Article 14 of the EHDS Regulation, these categories are subject to a phased regulatory

[5] (Cross-border health project epSOS: What has it achieved? | Shaping Europe's digital future 2014)
[6] (Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary 2017)
[7] (Citizen-centred EU-EHR exchange for personalised health | Smart4Health | Project | Fact Sheet | H2020 | CORDIS | European Commission n.d.)
[8] (Interoperable EHRs at user edge | InteropEHRate | Project | Fact Sheet | H2020 | CORDIS | European Commission n.d.)
[9] (X-eHealth: eXchanging electronic Health Records in a commom framework | X-eHealth | Project | Fact Sheet | H2020 | CORDIS | European Commission n.d.)
[10] (Expanding Digital Health through a pan-European EHRxF-based Ecosystem | XpanDH | Project | Fact Sheet | HORIZON | CORDIS | European Commission n.d.)
[11] (Expanding the European EHRxF to share and effectively use health data within the EHDS | xShare | Project | Fact Sheet | HORIZON | CORDIS | European Commission n.d.)
[12] (Project Overview - Xt-EHR n.d.)
[13] MyHealth@EU is the cross-border digital infrastructure that enables the secure exchange of health data, such as Patient Summaries and ePrescriptions, between participating European Union Member States.

rollout designed to allow Member States and healthcare providers amongst other stakeholders sufficient time to align their digital infrastructures. The EHDS identifies two primary waves of application: the first group, namely patient summaries, electronic prescriptions, and electronic dispensations, is mandated for cross-border exchange by 2029; the second group, comprising medical imaging, laboratory results, and discharge reports, follows in 2031[14].

The selection of these categories is far from arbitrary. It is the result of a rigorous, decade-long legal and technical evolution rooted in the 2011 Directive on the application of patients' rights in cross-border healthcare (European Parliament and Council of the European Union 2011) and the subsequent 2019 Commission Recommendation on a European Electronic Health Record Exchange Format (European Commission 2019). This historical trail stems from the foundational work of the eHealth Network[15] (eHN) and its thematic subgroups, which identified the information most critical for EU citizens, travellers and mobile patients. The eHN published guidelines directing the electronic exchange of health data under Cross-Border Directive 2011/24/EU for each data domain (eHealth Network 2022, 2024, 2025). By building upon these recommendations, the EHDS transforms previously voluntary guidelines into a binding legal requirement for a machine-readable, citizen-centred data journey.

This thesis focuses specifically on the first group of priority categories (2029). These domains represent the most immediate "implementation wall" for European providers. Patient summaries are characterised by high semantic density, requiring AI to extract core clinical profiles from narrative text, while medication data demands an absolute precision mandate to ensure patient safety and pharmacovigilance in cross-border e-prescribing. By centring the analysis on this initial wave, the research evaluates the feasibility of AI-driven semantic mapping at the point of greatest regulatory urgency.

1.3 Artificial intelligence for clinical text structuring: the generative pivot

The realisation of a vision such as that of the EHDS is fundamentally obstructed by the "unstructured legacy"—the vast quantities of clinical narrative, PDF summaries, and scanned documents that currently remain "computationally dark" and inaccessible for cross-border exchange (Holmes et al. 2021). Historically, the effort to structure this data relied on Natural

[14] See: EHDS Regulation, Art. 105.
[15] The eHealth Network is a voluntary network established under Article 14 of Directive 2011/24/EU that connects national eHealth authorities across EU Member States to facilitate cooperation and technical interoperability for cross-border health data exchange.

Language Processing (NLP) systems built on rigid, rule-based architectures. While these systems provided high precision within narrow domains, they were "socio-technically fragile," requiring constant manual maintenance by specialised informaticians to account for linguistic variations and local documentation idiosyncrasies (de Mello et al. 2022). This high barrier to entry has historically exacerbated the fragmentation of the European data landscape, as only resource-rich institutions could sustain the technical "push" required for semantic consistency.

The emergence of Transformer-based architectures and LLMs represents a paradigm shift from "feature engineering" to "contextual reasoning" (Singhal et al. 2023). Unlike their predecessors, these foundation models are pre-trained on massive multilingual corpora, allowing them to ingest the messy, non-linear logic of clinical notes and transform them into structured, standard-compliant formats—such as HL7 FHIR resources—with minimal local fine-tuning (Van Veen et al. 2023). This "Technological Push" offers a seductive solution to the "Retrospective Trap"[16], promising to automate the population of the EEHRxF for the 2029 mandate without the prohibitive cost of manual retrospective re-coding.

However, this shift replaces a technical maintenance problem with a semantic governance problem. As AI moves from simple entity extraction to complex, generative semantic mapping, the underlying logic becomes increasingly opaque. For safety-critical domains like e-Prescription and Patient Summaries, where the precision mandate is absolute, the reliance on generative outputs introduces the risk of 'structured hallucinations'—outputs that appear technically valid and standard-compliant but contain semantically incorrect clinical content (Singhal et al. 2023).

In this new paradigm, the primary bottleneck to EHDS implementation shifts from the algorithm's ability to "write" the code to the human workforce's ability to "read" and audit it. The transition to GenAI thus creates an immediate, yet largely unmet, demand for Semantic Literacy—the specialised skill set required to validate AI-structured data against controlled terminologies like SNOMED CT and LOINC and derive real-world contextual meaning. Consequently, the very technology intended to bridge the interoperability gap may inadvertently widen the socio-technical divide, as the rapid technological advancement of

[16] Retrospective Trap: A gap in evidence where AI models demonstrate high accuracy on historical, static datasets (lab validation) but fail to maintain performance in "live," fragmented clinical environments.

LLMs outpaces the organisational capacity of a workforce prepared to govern them (Sittig and Singh 2010).

1.4 Opportunities, risks, and governance considerations

The integration of AI-supported clinical data structuring presents a duality of profound opportunity and significant risk for the implementation of the EEHRxF. Primarily, AI offers a mechanism to accelerate the population of standardised datasets by automating the extraction and normalisation of clinical information from legacy infrastructures. This "Technological Push" potentially lowers the barrier to entry for Member States, allowing fragmented, unstructured EHR systems to align with EHDS requirements without the prohibitive cost of total system replacement. Furthermore, by providing automated data-quality checks and multilingual terminology mapping, AI systems can enhance the reliability and machine-readability of data exchanged via the MyHealth@EU infrastructure, fulfilling the EHDS's objective of creating a high-quality data foundation for both primary and secondary use.

However, the deployment of these technologies in a clinical context introduces substantial risks that require a robust regulatory and security framework (Schmidt et al. 2024). Under the EU's AI Act, AI systems intended for healthcare applications—particularly those influencing clinical information processing—are classified as high-risk. This classification mandates stringent obligations for risk management, technical documentation, and, crucially, human oversight (Vardas, Marketou, and Vardas 2025). AI-based tools used to transform raw clinical text into EEHRxF-compliant structures fall directly under this regime, as errors in entity extraction or terminology binding could have direct, adverse effects on patient safety and continuity of care.

The intersection of the AI Act and the EHDS creates a unique "dual compliance" challenge. While the EHDS mandates the *ends* (interoperable, structured health data), the AI Act governs the *means* (the deployment of the algorithms). This regulatory overlap raises critical questions regarding liability and accountability when AI-generated structured data is exchanged across borders. For instance, if an LLM incorrectly maps a medication dosage in a Patient Summary that is later dispensed in another Member State, the resulting liability chain involves the developer of the AI tool, the healthcare provider who deployed it, and the professional who failed to audit the output (Aboy, Minssen, and Vayena 2024).

From a security perspective, AI systems operating on sensitive health data introduce new attack surfaces. Beyond traditional data leakage risks, these systems are vulnerable to model manipulation and prompt injection, which could compromise the integrity of EEHRxF-compliant datasets. These concerns are amplified by the "black box" nature of contemporary large language models, where the opacity of the structuring process poses challenges for explainability and professional trust. Without clear mechanisms for auditability, AI-supported structuring risks undermining the very confidence in cross-border exchange it was intended to facilitate.

In summary, the implementation of the EEHRxF via AI is not merely a technical task but a governance mission. The central challenge lies in ensuring that the "Technological Push" of AI is managed within a framework that prioritises transparency, security, and human accountability. As this thesis will demonstrate through its empirical analysis, the ability to meet these high-risk governance standards is intrinsically linked to the "Organisational Pull", specifically the semantic literacy of the workforce tasked with maintaining human oversight in an increasingly automated data ecosystem.

1.5 The EEHRxF as a Standardised Target for AI Outputs

Beyond its role as a regulatory mandate, the EEHRxF provides a unified, machine-readable target format that fundamentally reshapes the development of clinical AI. Historically, the field of clinical NLP has been fragmented by a lack of shared output objectives; models were often trained to populate idiosyncratic, institution-specific data schemas, which severely limited their cross-border utility. The EEHRxF addresses this by offering a stable, pan-European "ground truth" for AI outputs. By defining specific profiles (e.g., HL7 FHIR) and terminology bindings (e.g., SNOMED CT for Patient Summaries), the format provides AI developers with a clear objective function, enabling the transition from "generic" clinical extraction to "policy-aligned" data generation.

The implications of this standardised target are two-fold. First, it enables the benchmarking and portability of AI models across Member States. Because the EEHRxF defines the final "shape" of the data, a model developed to extract e-Prescriptions in one jurisdiction can, in theory, be deployed in another with minimal architectural reconfiguration, provided it is adapted to the local language. This effectively creates a "Single Market" for

interoperability-ready AI tools, accelerating the Technological Push at EU scale by reducing the R&D costs associated with proprietary data mapping.

Second, and more critically for this thesis, the existence of a common target format alters the governance burden placed on the workforce. While a standardised output simplifies the *technical* task for the algorithm, it creates a more rigid *semantic* requirement for the human auditor. When AI maps a narrative note to a precise EEHRxF-mandated SNOMED CT code, the "margin for error" disappears; a slight misclassification that might be overlooked in a free-text system becomes a structural, legal error in a machine-readable exchange. Consequently, the EEHRxF as a target format essentially steepens the Implementation Wall. It demands a level of semantic precision that the human workforce may find increasingly difficult to validate or correct in real-time.

Chapter 2 – Analytical framework

This thesis adopts a socio-technical analytical framework designed to evaluate recent AI-based approaches for structuring clinical data through the balanced lenses of technical capability and organisational readiness. The framework is positioned at the intersection of clinical informatics and European health policy, specifically addressing the requirements of the EHDS and the EEHRxF. This approach is grounded in the *Eight-Dimensional Socio-technical Model* introduced by Sittig and Singh (2010), which posits that health information technology success is predicated on the dynamic interaction between hardware/software, clinical content, human-computer interfaces, and organisational policies.

The scope of the framework is intentionally restricted to the "First Group" out of two groups of priority electronic health data categories: patient summaries (PS), electronic prescriptions (eP), and electronic dispensations (eD). This focus reflects the regulatory sequencing of the EHDS, where these domains represent the earliest mandatory targets for cross-border interoperability.

The core assumption of this framework is that technical performance is a necessary but insufficient condition for digital transformation. While traditional literature prioritises model-centric metrics (accuracy, F1-score), this framework evaluates whether AI-generated outputs are "interoperability-ready"—meaning they are semantically consistent, standard-compliant, and governable by the human workforce in view of their scaled implementation and adoption.

As illustrated in Figure 2.1, the framework integrates four complementary layers:

1. *The Clinical Data Layer***:** Analyses the semantic density and safety-critical nature of PS, eP, and eD data.

2. *The AI-Based Structuring Layer***:** Evaluates the methodological paradigms (from rule-based to GenAI) and their degree of automation.

3. *The Performance and Robustness Layer***:** Moves beyond accuracy to evaluate semantic correctness and safety-relevance.

4. *The Interoperability and Readiness Layer***:** Assesses alignment with EEHRxF standards (HL7 FHIR /SNOMED CT) and measures the "Workforce Pull" through empirical survey data.

By combining these layers, the framework provides a structured methodology to identify the asymmetry between AI technical maturity (the "Technological Push") and human organisational capacity (the "Organisational Pull"). This distinction is rooted in classic innovation theory, which distinguishes between "technology-push" (advancements driven by R&D) and "demand-pull" (solutions driven by identified user needs and organisational readiness) (Zmud 1984).

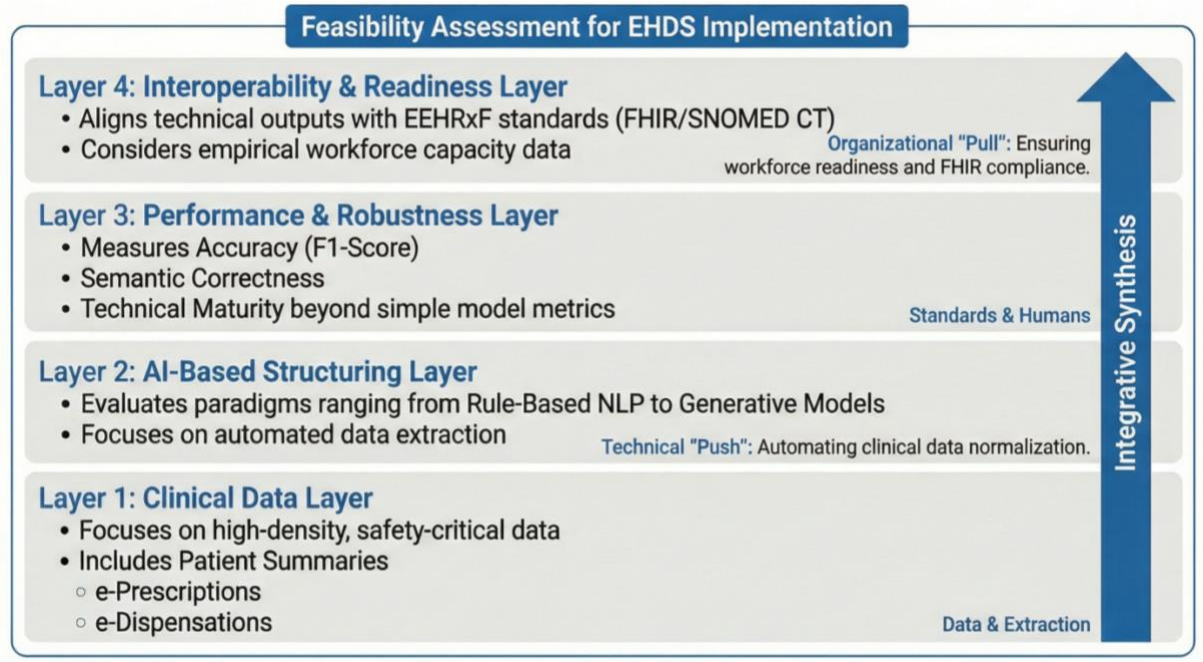


Figure 2.1. Multi-layered socio-technical framework for AI–EEHRxF alignment. (Source: Author's own.)

2.1 Clinical data domains as analytical units

To ensure analytical coherence and regulatory relevance, this thesis adopts the clinical data domains corresponding to the "First Group" of EEHRxF priority categories as its primary units of analysis. These domains—Patient Summaries (PS), e-Prescriptions (eP), and e-Dispensations (eD)—are defined under the EHDS Regulation for primary use and represent the most mature use cases within the MyHealth@EU infrastructure.

Anchoring the analysis in these specific domains allows AI-based structuring approaches to be evaluated not as abstract technical exercises, but against the concrete semantic and safety-critical conditions legally required for cross-border exchange.

2.1.1 Patient Summaries (PS): The Semantic Density Challenge

The Patient Summary is our most heterogeneous unit of analysis. It typically aggregates narrative clinical information—including diagnoses, allergies, and social history—derived from unstructured discharge letters or consultation notes.

- *Structuring Requirement*: AI models in this domain must perform complex Named Entity Recognition (NER) and subsequently map these entities to standard ontologies like SNOMED CT or ICD-10/11.

- *Socio-Technical Implication*: The high semantic density and contextual dependency of PS data create a high risk for AI "hallucinations" or misinterpretations of negation (e.g., misidentifying "no history of diabetes" as a diagnosis). This necessitates a "Human-in-the-Loop" governance structure, as AI struggles with the nuanced contextual interpretation of free-text clinical notes (Sittig and Singh 2010; Suenghataiphorn et al. 2025).

2.1.2 e-Prescriptions (eP) and e-Dispensations (eD): The Precision Mandate

In contrast to the narrative nature of PS, medication-related data, i.e., eP and eD data demands absolute semantic precision and temporal consistency.

- *Structuring Requirement*: AI tasks in these domains centre on the accurate identification of active substances, dosages, routes, and frequency, often requiring mapping to the ISO IDMP (Identification of Medicinal Products) standards or ATC (Anatomical Therapeutic Chemical) classification.

- *Socio-Technical Implication*: Because medication errors have immediate life-safety implications, the technical "Performance and Robustness" layer (Layer 3) of this framework must be prioritised. The reliance on precise terminology mapping creates a steep "Workforce Pull" for pharmacists and clinicians who must validate that the AI-structured dosage matches the clinical intent.

2.1.3 Domain-Specific Interoperability Requirements

The selection of these three domains reflects a strategic alignment with the EEHRxF datasets. For example, each domain maps to specific HL7 FHIR artifacts where HL7 FHIR is foreseen to support the EEHRxF:

- *PS* maps to the *Composition* and *ClinicalImpression* resources.
- *eP/eD* map to *MedicationRequest* and *MedicationDispense* resources.

By treating these domains as discrete analytical units, the framework enables a domain-sensitive assessment of why an AI model that succeeds in extracting entities from a Patient Summary may fail in the high-precision environment of an Electronic Prescription. This distinction is critical for identifying exactly where the workforce lacks the proficiency to govern automated clinical workflows.

2.2 AI-based structuring dimensions

To enable a systematic and policy-relevant evaluation of the literature, this thesis conceptualises AI-based clinical data structuring along a set of stable analytical dimensions. These dimensions are designed to be largely technology-agnostic, allowing approaches ranging from advanced rule-based NLP to contemporary generative models to be assessed within a common socio-technical frame. Rather than focusing on specific algorithms, the analytical emphasis is placed on how these methods operationalise the transformation of clinical information into structured, interoperable representations feasible for EEHRxF implementation.

The first dimension concerns the methodological paradigms associated with the "Technological Push" observed in the recent literature. This spectrum includes knowledge-driven systems relying on hand-crafted clinical lexicons, classical machine learning architectures, and more recent foundation models that leverage zero-shot or few-shot learning. The framework examines the underlying data dependencies of these paradigms, specifically how they adapt to the semantic constraints of patient summaries and medication records. A critical point of analysis is whether an approach relies on extensive, domain-specific feature engineering—common in legacy medication parsing—or whether it uses pre-trained representations that can be adapted across the diverse institutional and linguistic contexts of the EHDS.

The second dimension addresses the depth of the input-output transformation, which is critical for identifying the "Interoperability Paradox." In health informatics, this paradox suggests that a plethora of overlapping standards can paradoxically decrease interoperability by increasing system complexity (Tsafnat et al. 2024). In the context of this thesis, the paradox is redefined: as AI automates semantic normalisation into standards like HL7 FHIR , it creates

"semantic blindness" in a workforce that can no longer audit the underlying logic. This axis tracks the progression from surface-level named entity recognition to deep semantic normalisation and, ultimately, standard-compliant data generation. For the clinical domains in scope, this distinction is analytically vital: while simple extraction may support local decision support, the implementation of the EEHRxF requires outputs that can populate standardised datasets. The framework therefore distinguishes between AI outputs that remain as annotated text and those transformed into structured representations compatible with HL7 FHIR artifacts, as the latter signal a significantly higher level of technical maturity.

A third dimension evaluates the degree of automation and the intended governance structure, specifically focusing on the role of the "Human-in-the-Loop". Some architectures are explicitly designed to support augmented intelligence, where AI provides suggestions that must be validated by clinicians or pharmacists to ensure safety. Others aim for end-to-end automation with minimal human intervention. This distinction is particularly salient for medication-related data, where regulatory and liability considerations may constrain the permissible extent of automation. The framework treats human involvement not as a technical limitation, but as a deliberate design choice that must be reconciled with the workforce proficiency levels measured in the empirical portion of this study.

Finally, the framework incorporates deployment and contextual maturity as a cross-cutting dimension. This dimension assesses whether AI-based structuring approaches have been evaluated beyond controlled "Retrospective Lab" environments. It distinguishes between studies using historical, anonymised benchmarks and those demonstrating robustness across multiple institutions, languages, or "live" clinical settings. By identifying the "Retrospective Trap"—the potential drop in performance when moving from experimental datasets to the fragmented reality of European Hospital Information Systems—this dimension provides a structured basis for assessing the realistic feasibility of AI-driven interoperability initiatives.

2.3 Performance and robustness criteria

The evaluation of AI-based clinical data structuring requires a multidimensional set of criteria that extends beyond conventional, model-centric metrics. While quantitative indicators such as accuracy, precision, recall, and the F1-score remain fundamental for benchmarking, they are insufficient for determining whether AI-generated outputs are reliable and fit for purpose within the regulated EHDS. In the context of the EHDS and the operationalisation of the EEHRxF, performance must be interpreted through the lenses of semantic integrity, clinical safety, and

long-term operational viability, particularly when processing safety-critical domains like patient summaries and medication records.

The primary criterion of the framework remains *technical performance*, which serves as the foundational "Technological Push" metric. This involves standard evaluation methods typically derived from comparisons with manually annotated "gold standard" corpora. To provide the granularity required for EEHRxF alignment, this framework distinguishes between entity-level performance (e.g., the correct extraction of a drug name) and document-level structural integrity. For patient summaries, this includes the accurate identification of core clinical elements, whereas for e-prescription and e-dispensation data, the focus shifts to the precise extraction of substances, dosages, and temporal attributes. However, these metrics are treated merely as necessary precursors to deeper qualitative evaluations of reliability.

The second criterion addresses *semantic correctness and safety relevance*, which are paramount for the "First Group" of priority health data. From an interoperability and safety perspective, it is insufficient for an AI system to extract text strings accurately; the resulting data must preserve the physician's original clinical intent and meaning (Wei et al. 2024). This necessitates appropriate terminology binding and consistency in semantic granularity when mapping to the code systems mandated by the EEHRxF. In medication-related domains, semantic errors—such as the incorrect interpretation of a dosage frequency or an ambiguous mapping of a substance—represent significant clinical risks. Misalignment at this level undermines cross-border reuse and patient safety, even when surface-level F1-scores appear high.

A third criterion focuses on *robustness and generalisability*, evaluating the stability of AI-based approaches across variations in clinical language, documentation styles, and institutional contexts. Robust systems must demonstrate "cross-contextual performance," maintaining accuracy when applied beyond the original training environment. Given the linguistic diversity and fragmented organisational landscape of European healthcare, generalisability is a core indicator of feasibility for EEHRxF implementation. The framework therefore examines whether AI approaches can cope with the "Retrospective Trap"—the drop in performance observed when moving from a controlled, historical dataset to the messy, real-world multilingual documentation practices found in European hospitals (Gaschi et al. 2023; Rodrigues and Lopes 2025).

Finally, the framework incorporates *operational robustness and oversight feasibility*. This dimension evaluates the transparency of AI outputs and the practicality of human intervention. It considers whether systems provide confidence indicators or traceable decision logic that allows a human auditor to detect and correct errors efficiently. Systems that are opaque or lack error-detection mechanisms pose a high risk of "Automation Bias," particularly in environments where the workforce lacks advanced technical proficiency. By applying these criteria jointly, the analytical framework enables a nuanced assessment of whether an AI system is merely a successful laboratory experiment or a viable component of a trustworthy, interoperable health data infrastructure.

2.4 EEHRxF alignment criteria

A central objective of the analytical framework is to assess the extent to which AI-based clinical data structuring approaches are aligned with the requirements of the EEHRxF. In the context of the EHDS, interoperability is no longer a voluntary design choice but a regulatory obligation for the exchange of priority electronic health data. Consequently, this thesis treats alignment with EEHRxF specifications as a *core analytical criterion*, rather than as an optional or downstream implementation consideration.

The scope of this assessment is intentionally limited to the first group of EEHRxF priority electronic health data categories, namely patient summaries, e-prescription, and e-dispensation. These categories represent the earliest mandatory use cases for cross-border exchange and therefore provide the most relevant benchmark for evaluating the practical contribution of AI-based structuring approaches to EEHRxF implementation.

The first alignment criterion concerns *structural compatibility*. AI-based structuring approaches are assessed on whether their outputs can be represented within the standardised information models expected under the EEHRxF for the domains in scope. This includes the ability to populate defined datasets for patient summaries and medication-related exchanges, and to support representation through established exchange standards such as HL7 FHIR . Thus, approaches that remain at the level of annotated text, ad hoc data tables, or proprietary formats are considered less mature from an EEHRxF perspective, even where reported technical performance is high.

The second criterion relates to *semantic interoperability and regulatory fitness*. Alignment with EEHRxF requires that structured outputs preserve clinical meaning in a manner

that is consistent across systems and jurisdictions. The framework therefore examines whether AI-based approaches explicitly address terminology binding, concept normalisation, and semantic disambiguation using recognised code systems and value sets relevant to patient summaries and medication workflows. Particular attention is given to medication-related domains, where real-time semantic precision is essential for safety and legal compliance, and where misalignment may undermine cross-border reuse despite apparent technical success.

A third criterion addresses *domain specificity and prioritisation*. EEHRxF implementation follows a phased approach centred on defined priority categories. AI-based structuring approaches are therefore assessed on whether they explicitly target patient summaries, e-prescription, or e-dispensation data, and whether their outputs correspond to data elements that are meaningful within these cross-border exchange scenarios. Studies addressing generic clinical text processing tasks without clear linkage to the data structures required for these priority domains are analytically distinguished from those that demonstrate direct relevance to EEHRxF datasets.

The fourth criterion concerns *traceability and governance readiness*. Within a regulated interoperability environment, structured health data must be traceable to their source and generated through processes that can be audited, validated, and governed, e.g., for conformity assessments under the EU AI Act for high-risk clinical systems. The framework therefore considers whether AI-based approaches provide mechanisms for provenance tracking, confidence estimation, or explainability that could support conformity assessment, clinical oversight, and accountability. Although such aspects are often underreported in technical studies, their presence or absence is treated as analytically significant when assessing feasibility for EEHRxF deployment.

Finally, the framework evaluates *implementation plausibility in real-world settings*. This includes consideration of whether AI-based structuring approaches are designed with integration into existing electronic health record systems and medication management workflows in mind. Approaches that explicitly discuss deployment within EHR environments, cross-border infrastructures, or regulated clinical processes are considered more closely aligned with EEHRxF objectives than those evaluated solely in experimental or laboratory contexts.

By applying these EEHRxF alignment criteria, the analytical framework distinguishes between AI-based structuring approaches that are technically promising in isolation and those

that are realistically capable of supporting interoperable, regulated exchange of patient summaries and medication data in Europe. This distinction is essential for identifying gaps and misalignments between AI technical capabilities and organisational or workforce readiness, and for drawing implications for EEHRxF implementation and future AI-enabled interoperability initiatives.

2.5 Workforce and organisational readiness

The final layer of the analytical framework addresses the enabling conditions required to translate AI-based structuring from a laboratory environment into a sustainable clinical reality. In the context of the EHDS and the implementation of the EEHRxF, readiness serves as the "Organisational Pull" that determines whether the technological push of AI can be safely absorbed by European healthcare systems. This framework conceptualises readiness not as a monolithic state, but as a dynamic interaction between workforce competencies, institutional infrastructure, and governance arrangements. By situating human and organisational capacity at the core of the evaluation, the thesis moves beyond model-centric performance to assess the socio-technical feasibility of this digital transformation.

Workforce readiness refers here to the availability and distribution of the specific competencies required to deploy, validate, and govern AI-based structuring solutions throughout their lifecycle. This dimension acknowledges that the implementation of the EEHRxF demands a highly differentiated set of skills across diverse stakeholder roles, ranging from the 208 frontline healthcare professionals identified in the empirical cohort to specialised IT managers and policymakers. Within this framework, readiness is operationalised through a focus on semantic literacy—the ability of the workforce to comprehend and audit the structured standards and terminologies (such as SNOMED CT and HL7 FHIR) that AI models generate. The framework assumes that if a workforce suffers from "semantic silence," the risk of Automation Bias—the tendency to favour suggestions from automated systems even when they are incorrect—increases significantly (Goddard, Roudsari, and Wyatt 2012).

Organisational and infrastructural readiness represents the institutional capacity to host and maintain AI-enabled workflows. While often underreported in technical AI literature, this dimension is critical for overcoming the "Retrospective Trap." It encompasses the availability of interoperable technical environments, such as localised Clinical Data Warehouses (CDWs), and the ability of an organisation to adapt its existing electronic health record (EHR) systems to accommodate AI-supported processes. This framework treats infrastructure not merely as a

hardware requirement, but as a strategic asset that determines whether a hospital can host privacy-preserving, localised models or must rely on external, cloud-tethered architectures that may conflict with European data sovereignty and GDPR mandates.

Finally, the framework incorporates governance and accountability readiness as the ultimate failsafe for AI-driven interoperability. This component evaluates the existence of mechanisms for human oversight and the practical feasibility of the “Human-in-the-Loop” architecture. It posits that for safety-critical data like patient summaries and medication records, technical accuracy is secondary to the auditability of the system. Governance readiness is therefore measured by the workforce's proficiency in data quality management and their capacity to assume clinical liability for AI-generated structures. By integrating these readiness dimensions, the analytical framework provides the necessary theoretical bridge to interpret together the results from our systematic review of literature and from the secondary analysis of survey data, allowing for a rigorous diagnosis of the “Implementation Wall” that separates AI potential from EHDS reality.

Chapter 3 – Methodology

This chapter outlines the mixed-methods design employed to address the thesis objectives: (i) a systematic literature review (SLR) on AI-based approaches for structuring health data relevant to the EEHRxF's first group of priority data categories, and (ii) a secondary analysis of empirical survey data assessing European workforce and organisational readiness. This sequential explanatory approach contextualises the technical maturity of current AI models against the practical realities of EHDS implementation.

3.1 Systematic literature review (SLR)

3.1.1 Review Design and Research Questions

The SLR was conducted in accordance with PRISMA 2020 guidelines to ensure reproducibility and rigor. The objective was to synthesise peer-reviewed research on AI-based methods for transforming unstructured clinical data into standardised formats. The primary research question was:

> *What AI-based approaches are reported in the academic literature for extracting and structuring clinical data relevant to the EEHRxF first group of priority data categories?*

Secondary questions explored the specific AI techniques used (e.g., deep learning, large language models), their performance, the targeted data categories (Patient Summary, Electronic Prescription, Electronic Dispensation), and the models' technical readiness for clinical integration.

3.1.2 Data Sources and Search Strategy

The search was conducted in the Web of Science Core Collection, targeting English-language, peer-reviewed articles published between 2020 and 2025. This timeframe corresponds to the rapid maturation of transformer architectures in clinical NLP. The search strategy combined three concept blocks: (i) AI methods, (ii) data structuring tasks, and (iii) EEHRxF priority health data domains, that directly informed the terms belonging to the search string. The foundational literature supporting these terms is detailed in Table 3.1.

Table 3.1. Foundational Literature Supporting Search Strategy Concept Blocks.

Block	Search Term	Key scientific source
(i) AI Methods	Artificial intelligence, Deep learning, Machine learning	(Golder et al. 2025; Makhni et al. 2025)
	Large language model, Transformer	(Yang et al. 2022)
	Natural language processing	(Golder et al. 2025; Hu et al. 2026; Wieland-Jorna et al. 2024)
(ii) Structuring Tasks	Information extraction, Named entity recognition	(Chen et al. 2023; Hu et al. 2026)
	Automated clinical coding, Biomedical entity linking, Biomedical text mining	(Dong et al. 2022; French and McInnes 2023; Lee et al. 2019)
	Concept normalisation, Medication extraction, Terminology mapping	(Chen et al. 2023; Kang et al. 2021; Weeks et al. 2020; Xu et al. 2020)
(iii) Health Data Domains	Clinical note	(Wang et al. 2018)
	Electronic prescription	(Lester et al. 2022)
	Medication extraction	(Weeks et al. 2020)
	Patient summary	(Zhao et al. 2023)
	Prescription	(Lester et al. 2022; Yao, Rao, and Padman 2025)

Following iterative piloting to optimise sensitivity for medication and patient summary terminology, the final search string applied was:

TS = (“artificial intelligence” OR “deep learning” OR “large language model*” OR “machine learning” OR “natural language processing” OR “transformer*”)

AND TS = (“information extraction” OR “automated clinical coding” OR “biomedical entity linking” OR “biomedical text mining”OR “concept normaliz*” OR “medication extraction” OR “named entity recognition” OR “terminology mapping”)

AND TS = (“clinical note*” OR “electronic prescription*” OR “medication extraction” OR “patient summar*” OR “prescription*”)

3.1.3 Eligibility Criteria

Records were evaluated against strict eligibility criteria to ensure relevance to the EHDS framework:

- *Inclusion criteria*:
  (1) Addresses at least one EEHRxF priority category;
  (2) Uses AI-based methods (e.g., ML, DL, LLMs) to structure, extract, or normalise clinical data from unstructured sources;
  (3) Produces structured representations (e.g., mapped to SNOMED CT) rather than solely descriptive outputs; and
  (4) Uses real or realistic clinical data in a healthcare context.

- *Exclusion criteria*:
  (1) Outside timeframe (2020–2025);
  (2) Not AI-based (e.g., purely rule-based NLP);
  (3) No structuring or coding task performed;
  (4) Not relevant to priority EHDS categories (PS, eP, eD); and
  (5) Full text unavailable for retrieval.

3.1.4 Study Selection and Synthesis

Titles and abstracts were initially screened, followed by a full-text assessment of records against the eligibility criteria. Studies which met all eligibility criteria were included in the final review. Data from the included articles were extracted into a structured Microsoft Excel template to capture study characteristics, specific AI techniques, targeted EEHRxF categories, and evaluation outcomes. A qualitative and descriptive quantitative synthesis was performed to identify patterns in technical maturity, multilingual capabilities, and semantic interoperability readiness.

3.2 Secondary data analysis: workforce readiness for EEHRxF implementation

In addition to the systematic literature review, this thesis incorporates a secondary analysis of existing empirical data to contextualise the technical findings within the organisational and human capacity landscape of the European digital health ecosystem. This responds to the

concern that technical feasibility alone is insufficient for successful large-scale implementation of interoperability frameworks such as EEHRxF.

3.2.1 Data Source and Instrument

To contextualise technical AI capabilities within the European organisational landscape, this thesis incorporates a secondary analysis of empirical data from the XiA Project[17] (Deliverable D3.2[18]). The source data originates from a large-scale, cross-sectional survey administered via the EU Survey platform, targeting healthcare professionals, industry representatives, and public-sector actors across Europe. The instrument assessed self-reported competencies and training needs across 28 digital health skill areas and 13 interoperability standards.

3.2.2 Variables of Interest and Selection Rationale

For the purposes of this study, a targeted subset of the 28 available skills was selected based on their direct relevance to the data structuring and AI tasks identified in the systematic review. The analysis focuses on items related to:

- *Interoperability Standards*: Knowledge of frameworks supporting health data exchange.
- *Data Management and Structuring*: Competencies in ensuring data quality and semantic transformation.
- *Advanced Technologies*: AI-related skills and the capacity to use automated tooling.

This focus ensures the analysis moves beyond mere tooling to examine the actual human capacity required to manage the lifecycle of structured health data.

3.3 Ethical Considerations and Limitations

The systematic review relied exclusively on publicly available academic literature, requiring no ethical approval. The secondary analysis used anonymised, aggregated data collected by the XiA project in compliance with EU data protection requirements; no personal data were processed for this thesis.

[17] See: https://xia-project.iscte-iul.pt/ and https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/43353764/101187650/ERASMUS2027?order=DESC&pageNumber=1&pageSize=50&sortBy=title&isExactMatch=true&topicAbbreviation=ERASMUS-EDU-2024-PI-ALL-INNO-BLUEPRINT

[18] Deliverable has been submitted but awaits formal approval and is thus not yet publicly available.

Methodological limitations include potential publication bias in the systematic review due to the rapid evolution of LLM technologies. Furthermore, the secondary data relies on self-reported competencies, which may be subject to social desirability or overestimation bias. Despite these limitations, this dual-method approach provides a balanced, socio-technical perspective on EHDS implementation feasibility.

Chapter 4 –Findings

4.1 Systematic Review Results

4.1.1 Study Selection

The systematic literature search across the selected databases yielded a total of 240 unique records. During the initial screening phase, the titles and abstracts of all 240 records were evaluated against the predefined inclusion and exclusion criteria, resulting in the exclusion of 95 records that lacked relevance to the application of AI in clinical healthcare contexts or did not address data structuring.

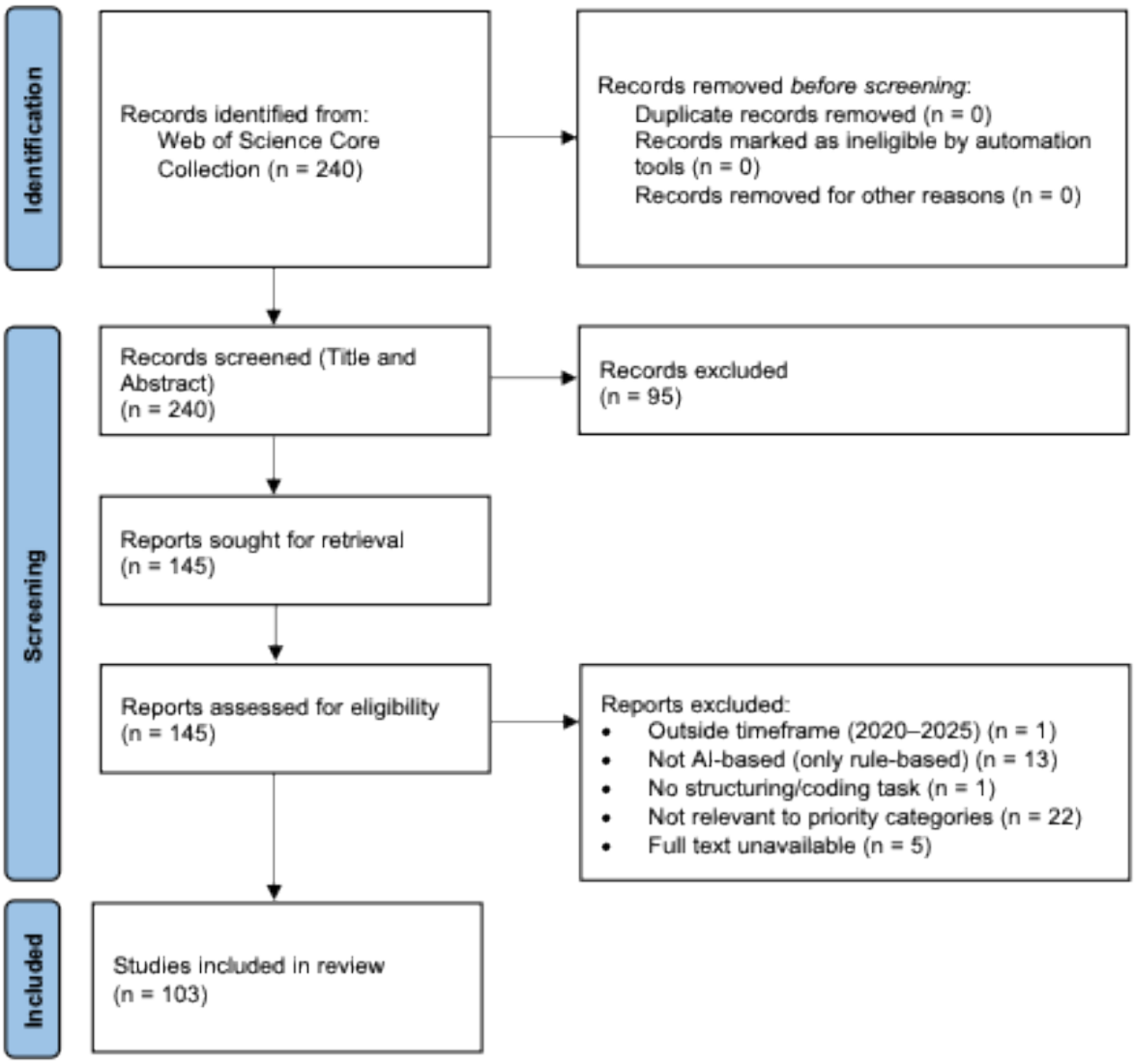


Figure 4.1. PRISMA flow diagram. (Source: Author's own.)

The remaining 145 reports were sought for retrieval and subjected to a rigorous full-text eligibility assessment. During the full-text screening, 42 records were excluded. The primary reasons for exclusion at this stage were: studies not relevant to the first group of priority

EEHRxF categories ($n = 22$); reliance on purely rule-based or non-AI methodologies ($n = 13$); the full text being unavailable for review ($n = 5$); studies focusing on non-structuring tasks such as text de-identification ($n = 1$); and publication outside the target 2020–2025 timeframe ($n = 1$).

The final qualitative synthesis included 103 peer-reviewed studies. The detailed study selection process is illustrated in the PRISMA flow diagram (see Figure 4.1).

4.1.2 Study Characteristics and Relevance to EHDS Priority Categories

The 103 included studies demonstrated a significant global effort to automate the extraction and structuring of clinical narratives. The records were categorised based on their alignment with the EEHRxF first group of priority data categories: Patient Summary, Electronic Prescription and Electronic Dispensation .

A substantial portion of the included studies ($n = 53$) produced structured data applicable to multiple EEHRxF categories simultaneously. This reflects the highly interconnected nature of clinical data; for example, the AI-driven extraction of medication names, dosages, and administration routes can directly inform both the medication list within a Patient Summary and the structured logic required for an Electronic Prescription.

When evaluating the categories in aggregate (accounting for overlapping applicability), the vast majority of the research supported the Patient Summary ($n = 99$). These AI models successfully extracted unstructured social history observations related to health (e.g., alcohol and tobacco use), physical findings, family history, and complex diagnostic data into structured formats. Research addressing Electronic Prescriptions was also prominent ($n = 54$), focusing on active medications, dosage modifications, and adverse drug events. Furthermore, nearly a third of the studies ($n = 32$) generated outputs applicable to

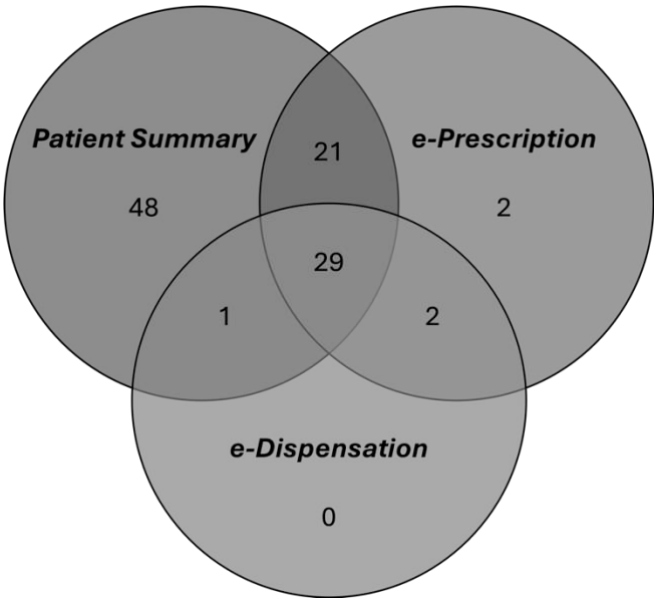


Figure 4.2. Venn Diagram: Number of Included Studies per EHDS Priority Data Category. (Source: Author's own.)

Electronic Dispensation, largely in conjunction with prescription data to support medication reconciliation and fulfilment tracking. Table 4.1 provides a granular breakdown of the specific category combinations targeted by the included literature, also illustrated in Figure 4.2.

Table 4.1. Number and Percentage of Included Studies per EHDS Priority Data Category.

EHDS Data Category Alignment	Number of Studies (n=103)	Percentage (%)
Single Category Focus	50	48,5%
Patient Summary (PS) Only	48	46,6%
Electronic Prescription (eP) Only	2	1,9%
Electronic Dispensation (eD) Only	0	0,0%
Multiple Category Focus	53	51,5%
Patient Summary + Electronic Prescription	21	20,4%
Patient Summary + Electronic Dispensation	1	1,0%
Electronic Prescription + Electronic Dispensation	2	1,9%
Patient Summary + eP + eD	29	28,2%

4.1.3 AI Methodologies for Clinical Data Structuring

Analysis of the technical approaches across the included studies revealed a dominant paradigm shift toward deep learning architectures for clinical information extraction and named entity recognition (NER).

Transformer-based architectures were the most frequently used models, featuring in over 75% of the included studies ($n = 78$). Within this category, BERT and its clinical variants (e.g., ClinicalBERT, BioBERT, RoBERTa) served as the foundational architecture for the majority of the structuring tasks ($n = 66$). Furthermore, an emerging subset of studies ($n = 20$) leveraged standalone generative LLMs, such as GPT-2, GPT-4, and Llama, to generate structured outputs—such as SOAP notes and JSON-formatted medication lists—directly from free text. A critical component of the EHDS framework is semantic interoperability. Within the included dataset, 27 studies explicitly paired their AI extraction methods with terminology normalisation, mapping unstructured text to standardised international ontologies such as SNOMED CT, ICD-10, LOINC, or RxNorm. This demonstrates a decent level of technical readiness for integrating these AI models into interoperable EHR systems across European borders.

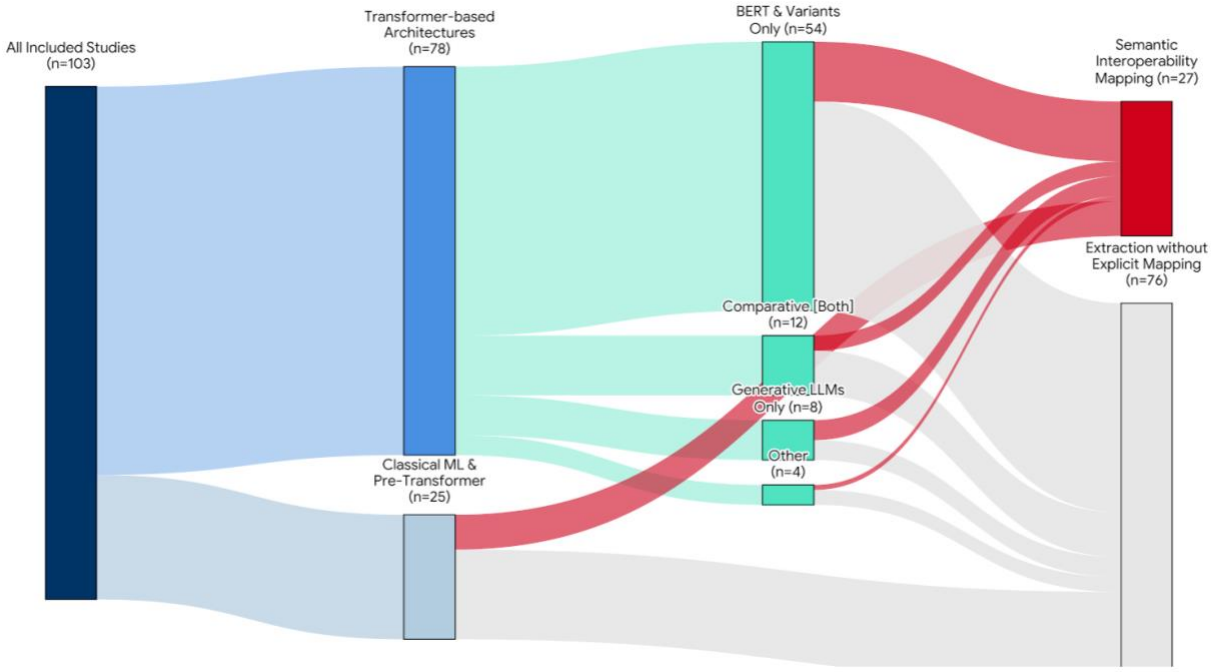


Figure 4.3. Sankey Diagram: flow of AI Methodologies to Semantic Interoperability.
(Source: Author's own.)

Figure 4.3 description: The diagram visualises the proportional distribution of AI architectures and their corresponding alignment with EHDS-mandated output formats. The width of the bands represents the number of studies. The massive divergence into "Extraction Only" (grey flows, $n = 76$ visually demonstrates the "Interoperability Gap," highlighting that despite the prevalence of advanced Transformer architectures, the vast majority of current research stops short of explicit terminology normalisation (red flows, $n = 27$).

The visual flow of the literature, as illustrated in Figure 4.3, reveals a significant methodological bottleneck characterising the current state of clinical NLP. While the "Technological Push" has successfully saturated the research landscape with advanced Transformer models, the vast majority of these implementations (73,8%, $n = 76$) remain confined to the extraction phase, failing to cross the finish line of explicit terminology normalisation. A nuanced insight emerges when comparing the architectural pathways: although BERT-based models represent the largest volume of extraction efforts, they most frequently function as localised solutions without standard-compliant outputs. In contrast, the emerging subset of Generative LLMs demonstrates a higher proportional alignment with direct structural generation, with 50.0% of studies utilising standalone generative models successfully bridging the gap from raw narrative to structured ontologies or JSON/FHIR-formatted representations; keeping mindful of the small absolute sample subset discussing Generative LLMs ($n = 8$). Yet, this could suggest that while technical maturity for "reading" clinical text

is widespread, the specific capacity for "writing" interoperable, EHDS-compliant data remains a concentrated and emerging competency within the field.

4.2 Secondary Data Analysis Results

4.2.1 Respondent Characteristics

The secondary analysis evaluated empirical data from a pan-European cohort of health professionals ($N = 357$). The cohort represented a comprehensive cross-section of the targeted workforce tasked with operationalising the EHDS. As shown in Table 4.2, the sample was distributed across the following primary stakeholder categories: healthcare professionals and hospital personnel excluding IT ($n = 208$; 58,3%), IT professionals working within healthcare institutions ($n = 55$; 15,4%), managers or heads of departments in healthcare entities ($n = 41$; 11,5%), managers in IT/IS companies or departments ($n = 21$; 5,9%), and other specified roles ($n = 32$; 9,0%).

Table 4.2. Sample distribution of primary stakeholder categories.

Primary stakeholder category	**n (%)**
Healthcare professionals and hospital personnel excluding IT	208 (58,3)
IT professionals working within healthcare institutions	55 (15,4)
Managers or heads of departments in healthcare entities	41 (11,5)
Managers in IT/IS companies or departments	21 (5,9)
Other specified roles	32 (9,0)

Within the survey's detailed skills assessment module, valid and complete responses were recorded for 295 participants across 24 European countries. The findings below (summarised comprehensively in Table 4.3) reflect this subset's self-reported current proficiencies and future skill needs.

Table 4.3. Current Proficiency and Future Skill Needs Across Key EEHRxF Competencies.

Skill Area	Metric	None (%)	Basic (%)	Average (%)	Expert (%)
Proficiency in clinical terminologies	Current Proficiency	8,5	31,2	40,0	20,3
	Future Skill Need	4,7	14,2	41,0	40,0
Governance and infrastructure for SNOMED CT	Current Proficiency	63,7	20,0	13,6	2,7
	Future Skill Need	19,3	32,9	30,8	16,9
Standards and interoperability, usability	Current Proficiency	34,6	29,5	24,1	11,9
	Future Skill Need	12,2	23,1	35,6	29,2
Integration of HL7 FHIR resources into workflows	Current Proficiency	64,1	18,6	12,9	4,4
	Future Skill Need	21,4	28,1	30,5	20,0

Ensuring interoperability across HIS platforms	Current Proficiency	56,3	22,0	13,6	8,1
	Future Skill Need	16,3	29,2	32,9	21,7
AI and ML in healthcare	Current Proficiency	40,0	41,0	16,9	2,0
	Future Skill Need	9,2	16,9	42,7	31,2

Note. Due to rounding, percentages may not perfectly sum to 100%. Data sourced from the XiA Project's pan-European survey.

4.2.2 Competency in Data Structuring and Terminology Management

The systematic literature review demonstrated a high degree of technical readiness for AI-driven data structuring, particularly regarding the mapping of unstructured text to standardised ontologies. However, the survey results indicate a contrasting reality regarding human capacity. While respondents reported moderate competency in general clinical terminologies (40,0% "Average" and 20,3% "Expert"), severe skill gaps emerge when evaluating advanced semantic governance.

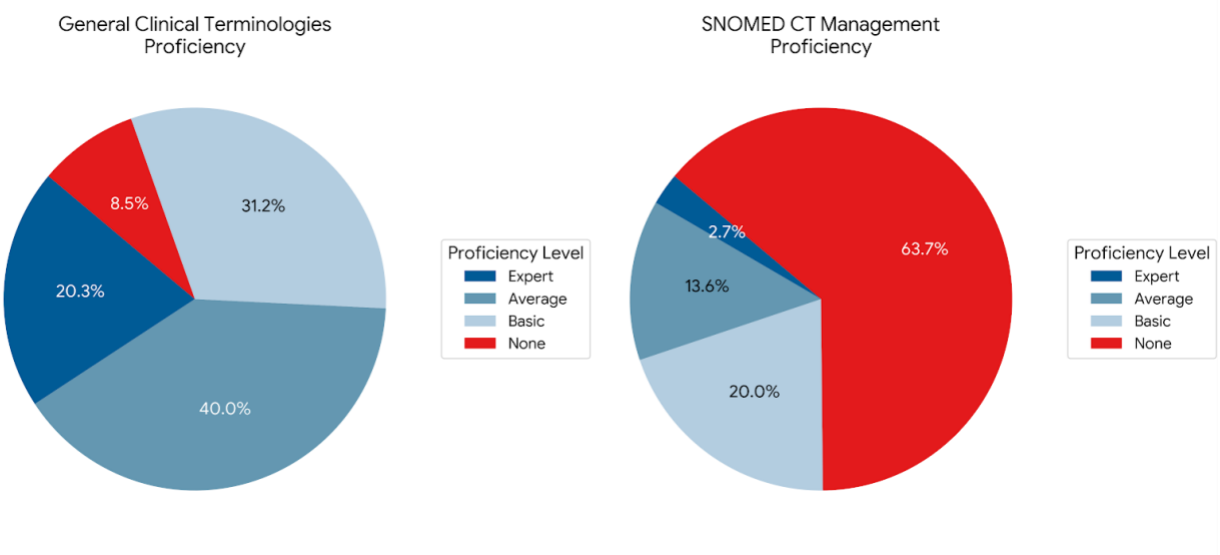


Figure 4.4. Contrast in Workforce Semantic Literacy. (Source: Author's own.)

Figure 4.4 description: A comparison of self-reported proficiency in General Clinical Terminologies versus SNOMED CT Management. While a majority report functional literacy (Basic to Expert) in general terminologies, nearly two-thirds (63,7%) of the workforce lack any proficiency in the specific governance and infrastructure required for SNOMED CT management, highlighting a critical socio-technical gap for AI deployment.

Specifically, regarding the *Governance and infrastructure for SNOMED CT management*, nearly two-thirds of the workforce (63,7%) reported having zero ("None") proficiency, with only 2,7% identifying as "Experts." This reveals a critical disparity: while

contemporary AI models are technically capable of standardising clinical notes to SNOMED CT, the current human workforce overwhelmingly lacks the foundational capacity to manage, validate, or govern these structured outputs.

4.2.3 Competency in Interoperability Standards

A similar discrepancy was identified in the context of interoperability, which is central to cross-border data exchange under the EHDS. When assessing general *Standards and interoperability*, 34,6% of respondents reported zero proficiency.

This deficit is highly pronounced regarding the technical standards explicitly required for the EEHRxF. For the *Integration of HL7 FHIR resources into clinical workflows*, an overwhelming 64,1% of respondents indicated zero proficiency, with merely 4,4% reporting "Expert" levels. Furthermore, more than half of the cohort (56,3%) reported no proficiency in *Ensuring interoperability across HIS platforms*. Conversely, the perceived need for these skills is exceptionally high, with exactly 50,5% of respondents indicating a need for either "Average" (30,5%) or "Expert" (20,0%) training in HL7 FHIR integration to fulfil their future roles.

4.2.4 Advanced Digital Technology Skills

The disparity between the technical potential of AI (established in Section 5.1) and actual workforce capacity is most pronounced in the domain of advanced digital technologies. Regarding proficiency in *AI and ML in healthcare*, 40,0% of respondents reported having zero current proficiency, and 41,0% rated themselves at a "Basic" level. Only 2,0% of the European stakeholder cohort identified as "Experts." Despite this low baseline, a cumulative 73,9% of the respondents stated they will require "Average" (42,7%) or "Expert" (31,2%) training in AI and ML to safely operationalise these technologies.

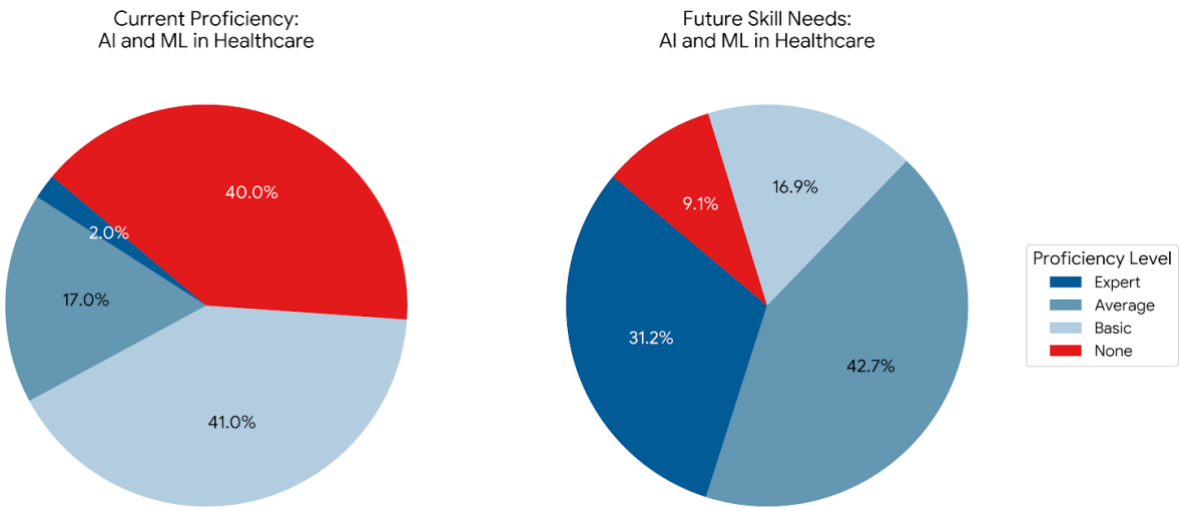


Figure 4.5. The AI and Machine Learning Capability Gap. (Source: Author's own.)

Figure 4.5 description: A comparative visualisation of the European healthcare workforce's current proficiency in AI/ML versus their self-reported future training needs. While 81,0% currently operate at a "Basic" or "None" proficiency level, the data reveals a massive anticipated shift, with nearly three-quarters (73,9%) stating they will require "Average" or "Expert" training to safely operationalise these technologies moving forward.

4.2.5 Synthesis of Readiness for EEHRxF Implementation

These empirical findings suggest that the primary bottleneck to implementing the AI-driven structuring approaches identified in the literature may not be technological, but organisational. The reported foundational skills gaps—specifically the lack of proficiency in SNOMED CT governance, HL7 FHIR resource integration, and applied AI—emphasise an urgent need for targeted capacity-building programs. Without significant investment in digital health education (literacy), the automated extraction of Patient Summaries, Electronic Prescriptions, and Electronic Dispensations cannot be sustainably governed or integrated into European clinical workflows.

Chapter 5 –Discussion

The integration of AI into clinical data structuring presents a profound socio-technical challenge for modern healthcare systems. This chapter synthesises the findings from the SLR and the XiA survey to address the primary research question: how recent AI-based approaches align with the technical and organisational capabilities required for EEHRxF implementation. The findings reveal that while algorithmic capability is high, an "implementation wall" is constructed from a stark misalignment between the technical prerequisites of AI and the current proficiency of the European workforce.

5.1 The 'Interoperability Paradox'

The systematic review demonstrates that contemporary AI models for clinical data structuring are fundamentally anchored to rigid semantic standards. To achieve reliable named entity recognition and semantic normalisation, algorithmic architectures explicitly rely on standardised global ontologies—notably SNOMED CT, the Unified Medical Language System (UMLS), MedDRA, and RxNorm—to force highly variable, idiosyncratic clinical text into strict ontological boundaries (Dandala et al. 2020; Harris et al. 2023; Herman Bernardim Andrade et al. 2024; Nath et al. 2023; Noor et al. 2022; Patel et al. 2021; Wang et al. 2020, 2023). However, literature demonstrates that being fundamentally anchored to rigid semantic standards does not universally guarantee high accuracy. In practice, relying strictly on dictionary-based mapping to SNOMED CT or UMLS can artificially lower model recall and introduce bias, as these global ontologies often lack comprehensive coverage of specialised clinical sublanguages, local jargon, or unstructured social determinants (Fan et al. 2021; Harris et al. 2023; Wang et al. 2023). Despite these limitations in direct entity matching, advanced NLP systems designed for cross-institutional interoperability and live clinical deployment remain heavily dependent on structured data exchange frameworks. Specifically, systems extracting complex diagnostic, medication, and prescription data across multiple healthcare facilities demand mapping these extracted entities to stringent protocols, such as HL7, openEHR, and HL7 FHIR specifications, to successfully communicate complex attributes to broader EHR ecosystems and ensure efficient clinical decision support (Jiang-Kells et al. 2025; Wang et al. 2020). However, viewing this technical necessity through a socio-technical lens exposes a stark implementation wall, illustrated in Figure 5.1. While the algorithms require these highly standardised, hierarchical formats—such as MedDRA's five-level logical structure—to compute and interoperate (Herman Bernardim Andrade et al. 2024), expecting

frontline clinical staff to comprehend, reconcile, and manually audit outputs formatted to strict SNOMED CT and HL7 FHIR parameters imposes a severe cognitive burden. This architectural requirement assumes a level of semantic literacy and informatics training that the existing workforce simply may not possess, transforming the pursuit of perfect technical interoperability into a significant barrier to practical human governance.

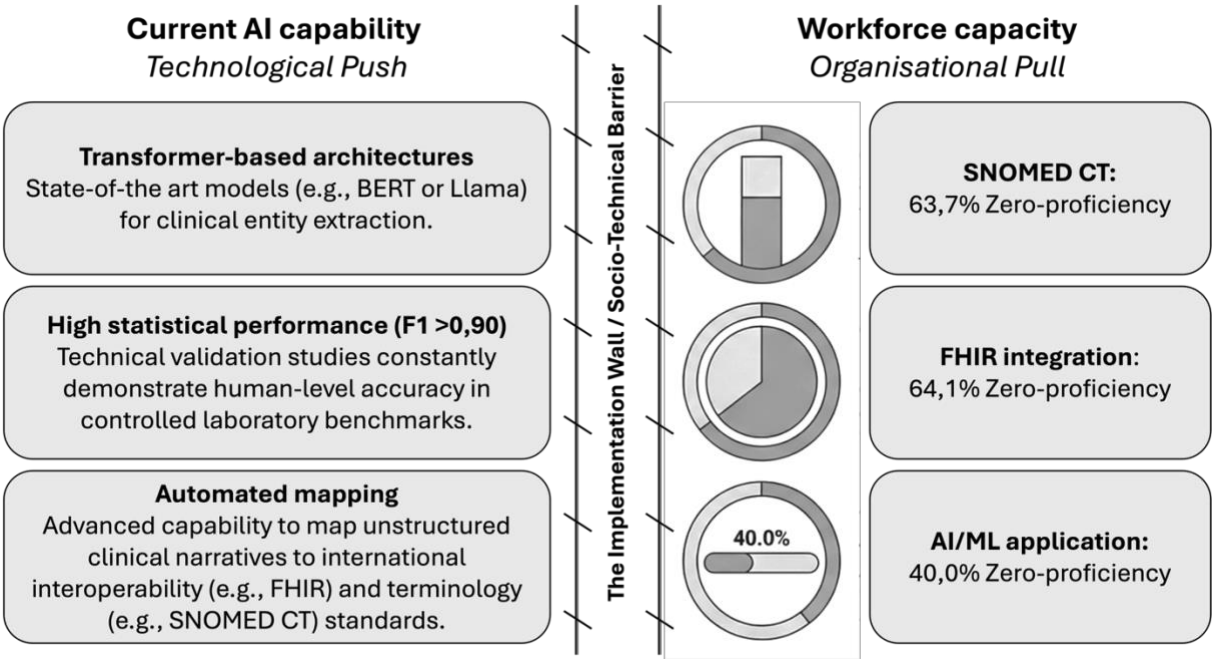


Figure 5.1. Socio-technical asymmetry in front of EEHRxF implementation. (Source: Author's own.)

Indeed, the empirical survey data reveals a contrasting reality. When assessing the governance and infrastructure for SNOMED CT management, nearly two-thirds of the European workforce cohort (63,7%) report zero proficiency. Similarly, 64,1% of respondents indicate zero proficiency in the integration of HL7 FHIR resources. This disparity exposes the "Interoperability Paradox": while the 55 specialised healthcare IT professionals in the cohort may grasp these systems, the 208 frontline clinical staff and 41 managers lack the semantic literacy required to govern them. If AI autonomously generates standard-compliant code that the human workforce cannot audit, the clinical workforce is rendered "semantically blind." The automated mapping of extracted entities to strict standards remains prone to normalisation errors that require human intervention to mitigate safety risks that the current workforce—including the 32 "Other" stakeholders like researchers and social workers—is not equipped to provide.

In fact, the algorithmic expansion and normalisation of free-text clinical narratives to rigid ontologies is inherently fragile due to the idiosyncratic, highly compacted, and often ungrammatical nature of routine clinical documentation (Isaradech et al. 2024; Kim and Meystre 2020). Because clinical notes are frequently authored hastily under severe time pressure, they are characterised by high information density, the omission of words, and dense medical jargon (Ruis et al. 2020; Schäfer et al. 2023). This highly unstructured text exhibits extreme linguistic variability, including a prevalence of ungrammatical sentences, inconsistent punctuation, spelling errors, and a multitude of specialised abbreviations and acronyms (Giraldo-Forero et al. 2025; Rubio-Martin et al. 2025; Ruis et al. 2020). Consequently, this heterogeneous linguistic environment introduces significant ambiguity and misinterpretation, fundamentally limiting the efficacy of traditional NLP techniques and making algorithmic matching to strict ontological dictionaries exceptionally difficult (Kocaman et al. 2025).

Physicians typically record symptoms, diagnoses, and medication regimens using domain-specific vernacular, dense abbreviations, and descriptive shorthand rather than standardised terminology, creating a fundamental mismatch between natural clinical expression and strict ontological boundaries (Azizi, Hier, and Wunsch 2022; Jaber and Martínez 2022; Schäfer et al. 2023; Sharma et al. 2024). Because misunderstanding clinical abbreviations or extracting incorrect medication data can directly cause patient safety issues, absolute precision is mandated over broad algorithmic recall in healthcare contexts (Isaradech et al. 2024; Jaber and Martínez 2022; Ruis et al. 2020). Consequently, these technical limitations force health systems to rely on 'human-in-the-loop' interfaces as a mandatory safety firewall to reject false positives and resolve ambiguities (Jiang-Kells et al. 2025; Ruis et al. 2020). While this human-in-the-loop approach drastically improves precision with limited time investment, relying on human workers as ultimate validators introduces a different systemic vulnerability: inter-annotator disagreement. Because algorithmic architectures demand strict, standardised formats like UMLS or HL7 FHIR , even highly trained medical experts struggle to consistently classify complex, ambiguous clinical narratives into these rigid semantic boundaries, making perfect human validation inherently difficult to achieve (Fabacher et al. 2025; Giraldo-Forero et al. 2025; Ruis et al. 2020).

5.2 Automation vs. Governance: The Human-in-the-Loop Delusion

The automation of clinical entity extraction consistently relies on a mandatory 'human-in-the-loop' architecture to guarantee safety, functioning less as autonomous AI and more as a digital

assistant that optimises, yet ultimately still requires, clinical oversight (Jiang-Kells et al. 2025). The literature overwhelmingly depends on highly trained domain experts—such as senior clinical pharmacists, psychiatrists, and neurologists—to establish the baseline ground truth, manually curate training data, and adjudicate model outputs (Botero-Aguirre and García-Rivera 2025; Chen et al. 2021; ten Hoope et al. 2025; Rubio-Martin et al. 2025; Weissenbacher et al. 2024). Because clinical annotation requires deep semantic literacy that standard crowdsourcing cannot provide, building and maintaining these systems imposes massive cognitive and temporal demands on the medical workforce. In practice, leveraging rare clinical expertise to manually label data is notoriously expensive, labour-intensive, and constitutes a severe developmental bottleneck (Abbas et al. 2024; Fan et al. 2021; Isaradech et al. 2024; Jouffroy et al. 2021). Furthermore, even when deployed to enhance high-stakes processes like medication reconciliation or allergy verification, these technical systems derive their safety justifications from the assumption that a clinician will continuously audit, correct, and verify the AI-generated suggestions before they are committed to the permanent electronic health record (Botero-Aguirre and García-Rivera 2025; Jiang-Kells et al. 2025; Noor et al. 2022). This exposes a critical friction point at the implementation wall: while algorithmic extraction provides a necessary foundation, the technological architecture still mandates a level of continuous manual governance and verification for real-time data needs that an overwhelmed human organisational capacity may be unable to sustain (Kopacheva et al. 2025; Wang et al. 2020).

This theoretical assumption of human oversight collides starkly with the empirical reality of the XiA survey findings. With 40,0% of respondents reporting zero proficiency in AI/ML and 41,0% reporting only basic proficiency, relying on a 'human-in-the-loop' framework becomes a structural misconception. These health professionals are expected to act as failsafes against AI 'hallucinations'—instances where models invent, distort, or misclassify clinical attributes not present in the source text (Fu et al. 2024; Isaradech et al. 2024). Yet, without the foundational capacity to evaluate advanced algorithmic reasoning, the workforce is highly susceptible to automation bias, risking the blind acceptance of unverified AI outputs because they lack the technical governance skills to challenge the machine. This vulnerability is especially dangerous given that NLP architectures frequently struggle with complex but clinically critical relation categories (Kim and Meystre 2020). The literature demonstrates a severe performance drop when models transition from simple named entity recognition (NER) to relation extraction (RE); for example, extracting nuanced causal relationships—such as

identifying that a specific treatment actively worsens a medical problem or triggers an adverse drug event—yields significantly lower accuracy, higher false-positive rates, and severe error propagation compared to standard entity extraction (Fu et al. 2024; Kopacheva et al. 2025; Shen et al. 2021; Zuo et al. 2024). If the frontline clinical workforce cannot comprehend these algorithmic blind spots, they cannot effectively audit these specific failures. Without expert human oversight capable of bridging this semantic gap, these algorithmic misclassifications will seamlessly propagate into the EEHRxF, transforming a known technological limitation into a severe clinical liability at scale (Haaker et al. 2024; Rybinski et al. 2021).

5.3 The ‘Retrospective’ Trap: Infrastructure Over Algorithms

Our systematic review of the literature reveals that the vast majority of clinical AI research remains trapped in the 'retrospective validation' stage, overly reliant on historical, localised, and highly sanitised datasets such as MIMIC and i2b2/n2c2 (Dandala et al. 2020). While models trained on these curated datasets perform well in controlled environments, literature demonstrates that their performance frequently degrades when applied to noisy, real-world clinical corpora (Fabacher et al. 2025). The transition from isolated pilot studies to live clinical production is rarely paralysed by algorithmic inadequacy; rather, it collides with the 'implementation wall' of health system IT infrastructure (Jiang-Kells et al. 2025). When attempting to deploy these models into real-world workflows, researchers face severe infrastructural and regulatory constraints. Because clinical data is highly sensitive and subject to strict privacy regulations, health systems are often explicitly prohibited from using external APIs or transmitting data over the internet for cloud computing (Fabacher et al. 2025; Giraldo-Forero et al. 2025; Herman Bernardim Andrade et al. 2024). This strict data governance necessitates local, on-premise deployment. In practice, this forces advanced model training and deployment to occur on standard machines or CPU-based setups, as specialised graphics processing units (GPUs) are generally unavailable within standard hospital IT environments (Kocaman et al. 2025). Furthermore, these facilities lack the computational memory and VRAM required to host, scale, and maintain state-of-the-art generative large language models, rendering them entirely impractical for these low-resource setting (Fabacher et al. 2025; Jiang-Kells et al. 2025; Woo et al. 2025). Consequently, the socio-technical gap between what advanced algorithms can theoretically achieve in the cloud and what constrained legacy hospital infrastructures can practically and securely support renders the pilot-to-production pipeline structurally deficient.

The empirical survey data confirms this operational bottleneck: 56,3% of the cohort report zero proficiency in ensuring interoperability across diverse Hospital Information System (HIS) platforms. This human skill deficit is exacerbated by severe infrastructural constraints at the implementation wall; the literature underscores that modern generative transformer-based models demand immense computational complexity and large VRAM requirements, making them highly impractical for low-resource environments (Fabacher et al. 2025; Tavabi et al. 2024; Woo et al. 2025). Consequently, healthcare and IT managers face a stark deployment barrier: strict internal privacy regulations and data protection laws frequently prohibit the use of external cloud-based APIs, forcing practitioners to execute complex model fine-tuning locally on standard, constrained on-premise hardware (Fabacher et al. 2025; Giraldo-Forero et al. 2025; Herman Bernardim Andrade et al. 2024). Furthermore, the profound predominance of English-language corpora in clinical NLP research leaves non-English texts heavily unexplored, severely limiting the 'out-of-the-box' readiness of these models for the multilingual requirements of the EHDS (Akhtyamova et al. 2020; Fabacher et al. 2025; Frei and Kramer 2022; Giraldo-Forero et al. 2025; Sharma et al. 2024). Because developing models for other languages faces significant resource scarcity (Gérardin et al. 2022; Sharma et al. 2024), and because simple automated translation of clinical notes induces a significant loss in extraction performance (Gérardin et al. 2024), localising these algorithms demands extensive, language-specific domain adaptation and manual fine-tuning (Giraldo-Forero et al. 2025; Lentzen et al. 2022). Ultimately, this creates a complex socio-technical gap that the current European IT workforce, operating under infrastructural constraints, is structurally ill-equipped to bridge.

5.4 Policy Recommendations for the EHDS

To bridge this socio-technical gap, the following evidence-based actions are proposed, mindful of the considerable magnitude represented by the problem at stake:

1. **Mandatory Semantic Literacy Programs:** Policy frameworks must move beyond general “digital literacy” to topical and role-specific education such as in SNOMED CT and HL7 FHIR. This must prioritise the clinical staff and managers who act as the ultimate clinical auditors of AI outputs, without leaving aside the IT professionals working in health sectors.

2. **Socio-Technical Usability Audits:** Regulatory bodies should evaluate AI tools not just on F1-scores, but on their “Human-in-the-loop” feasibility. Tools requiring continuous

manual curation by physicians are unsustainable given current European clinician shortages.

3. **Investment in Localised, Privacy-Preserving AI:** To escape the retrospective trap, funding should favour lightweight, open-source models that can operate on existing hospital hardware. This empowers the internal IT professionals and industry managers to build localised CDWs that comply with the EHDS and GDPR without relying on cloud-tethered APIs.

5.5 Synthesis Statement

The primary socio-technical challenge facing the European Health Data Space is that the technological sophistication of AI has drastically outpaced the semantic literacy, governance capacity, and infrastructural readiness of the human workforce. The "implementation wall" is fundamentally human; without immediate investment in digital health education and localised IT modernisation, the automated extraction of clinical data cannot be safely governed within European clinical workflows. At the same time, policy response ought to remain mindful of issues of ownership, governance and value distribution (Lewerenz, Martins, et al. 2026).

5.6 Study limitations

While this thesis provides a socio-technical evaluation of AI-driven interoperability, several methodological limitations must be acknowledged. The secondary analysis used XiA project data, which is not a statistically representative census of the entire European health workforce. The cohort may exhibit selection bias, as participants in EU-funded initiatives may be more digitally engaged than the general population. Additionally, the reliance on self-reported proficiencies introduces potential social desirability or Dunning-Kruger biases, where respondents may over- or under-estimate their actual technical skills in complex domains like HL7 FHIR or SNOMED CT governance. Regarding the systematic review, the extreme velocity of development in Generative AI results in a potential publication lag. Many state-of-the-art LLM advancements are documented in pre-prints that were excluded from this peer-reviewed synthesis. Furthermore, the predominance of English-language clinical corpora in the literature limits the direct generalisability of these findings to the multilingual documentation realities of the EHDS. Finally, this research processed only anonymised secondary data. Ethical approval was secured by the original XiA project, and since no new personal data were gathered for this study, further ethical approval was not required for this dissertation.

Chapter 6 – Conclusion

The overall aim of this thesis was to evaluate the alignment between recent AI research for clinical data structuring and the organisational readiness required to implement the EEHRxF within the European Health Data Space. By synthesising evidence from 103 peer-reviewed articles and empirical data from a cross-sectoral cohort of 357 European stakeholders, this study identifies a significant "implementation wall."

This wall is characterised by a fundamental socio-technical asymmetry: while the "technological push" has produced AI models capable of high-accuracy semantic mapping, the "organisational pull" is constrained by a workforce that lacks the foundational proficiency to govern, audit, and sustainably integrate these automated outputs into the clinical workflow.

While algorithmic approaches for clinical entity extraction routinely surpass F1-scores of 0,90, evaluating these metrics without a socio-technical lens leads directly into the "retrospective trap". Current technical maturity remains largely restricted to sanitised, historical datasets, failing to represent the complexities of live clinical workflows. Furthermore, this algorithmic sophistication masks a profound implementation wall, exacerbated by a severe English-language bias in existing foundational models and research corpora. Consequently, the transition from controlled laboratories to the messy, multilingual realities demanded by the EHDS remains structurally unresolved. Ultimately, health systems cannot govern deployment based solely on retrospective laboratory metrics; until these models can safely process live, idiosyncratic documentation without exacerbating the cognitive burden of the human workforce, their readiness for real-world clinical production remains unproven.

The analysis of the XiA survey results reveals a profound readiness gap across the European workforce. The data indicates a state of "semantic silence" regarding the technical cornerstones of the EEHRxF. Specifically, over 60% of the 357 respondents—spanning 208 healthcare professionals, 55 IT specialists, 41 managers, and 53 other key stakeholders—report zero proficiency in the management of SNOMED CT and HL7 FHIR resources. This lack of foundational literacy suggests that the human workforce is currently unable to fulfil the governance roles required by modern AI systems.

The primary misalignment identified is the "Human-in-the-Loop Misconception." The technical literature consistently assumes a baseline of expert human oversight to validate AI outputs and mitigate hallucinations. However, the empirical results show a workforce that lacks the semantic and technical proficiency to act as this critical failsafe. The implication for the

EHDS is a high risk of “Automation Bias,” where structurally valid but clinically inaccurate data could be propagated across European borders, potentially compromising patient safety and diagnostic liability.

The primary contribution of this research is the demonstration that the “bottleneck” to the EHDS is not algorithmic, but human and organisational. The transition to a structured, interoperable healthcare ecosystem is a socio-technical challenge that cannot be solved through technical refinement alone.

If the human workforce cannot comprehend the structured code that the AI generates, the safety and sustainability of the EEHRxF are compromised. This thesis concludes that for the EHDS to move from a technical possibility to an organisational reality, European policy must pivot its focus away from the “tool” and toward the “system”—prioritising human semantic literacy and localised IT infrastructure as the necessary prerequisites for a successful digital transformation.

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Annexes

Annex A – Statement of Originality and Authorship

Statement of Originality and Authorship

I, Simon Luca Lewerenz, hereby declare that this thesis, titled "The Implementation Wall: A Socio-Technical Assessment of AI-Driven Clinical Data Structuring for the EEHRxF", is my own original work, conducted under the supervision of Prof. Panagiotis Bamidis and Dr. Alexander Berler.

In accordance with academic integrity standards, I confirm the following:

- Authorship: I am the sole author of this manuscript and have assumed full responsibility for its intellectual content.
- Originality: All research, analysis, and conclusions presented herein are the result of my own independent investigation, except where otherwise explicitly indicated by proper citation.
- Sources: Every contribution to this work from the research of others—including published articles, white papers, and technical standards—has been clearly attributed and cited according to the APA 7th Edition formatting guidelines.
- Previous Submission: This work has not been previously submitted, in whole or in part, for another degree or qualification at any other university or institution of higher education.

I acknowledge that any failure to accurately represent authorship or the use of external sources constitutes a violation of academic regulations and may lead to disciplinary action.

Date: February 28, 2026

Signature: 

Simon Luca Lewerenz

Annex B – Supervisor's Declaration Prof. Bamidis

Supervisor's Declaration of Readiness for Public Defense

I, **Prof. Panagiotis Bamidis**, in my capacity as the primary supervisor of the Master's thesis titled "The Implementation Wall: A Socio-Technical Assessment of AI-Driven Clinical Data Structuring for the EEHRxF", submitted by Simon Luca Lewerenz, hereby declare the following:

- Review and Approval**:** I have reviewed the final manuscript and confirm that the research has been conducted in accordance with the established academic standards for graduate studies.
- Originality and Rigor**:** The work demonstrates a sufficient level of originality, methodological rigor, and critical analysis.
- Research Objectives Compliance**:** I verify that the candidate has addressed the challenges of clinical data structuring and alignment with European interoperability frameworks as outlined in the research objectives.
- Readiness for Examination**:** I certify that this thesis meets all the necessary formal and substantive requirements to be presented and defended in a public examination.

Consequently, I authorise the submission of this work to the examination committee for the final public defense.

Date: February 28, 2026

Supervisor's Signature: Panagiotis Bamidis 28.02.2026 19:24 UTC

Prof. Panagiotis Bamidis
Professor of Medical Physics and Informatics
Aristotle University of Thessaloniki

Annex C – Supervisor's Declaration Dr. Berler

Supervisor's Declaration of Readiness for Public Defense

I, **Dr. Alexander Berler**, in my capacity as the supervisor of the Master's thesis titled "The Implementation Wall: A Socio-Technical Assessment of AI-Driven Clinical Data Structuring for the EEHRxF", submitted by Simon Luca Lewerenz, hereby declare the following:

- Review and Approval**:** I have reviewed the final manuscript and confirm that the research has been conducted in accordance with the established academic standards for graduate studies.
- Originality and Rigor**:** The work demonstrates a sufficient level of originality, methodological rigor, and critical analysis.
- Research Objectives Compliance**:** I verify that the candidate has addressed the challenges of clinical data structuring and alignment with European interoperability frameworks as outlined in the research objectives.
- Readiness for Examination**:** I certify that this thesis meets all the necessary formal and substantive requirements to be presented and defended in a public examination.

Consequently, I authorise the submission of this work to the examination committee for the final public defense.

Date: February 28, 2026

Supervisor's Signature: ALEXANDROS OR ALEXANDER BERLER Digitally signed by ALEXANDROS OR ALEXANDER BERLER Date: 2026.02.28 23:50:41 +02'00'

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