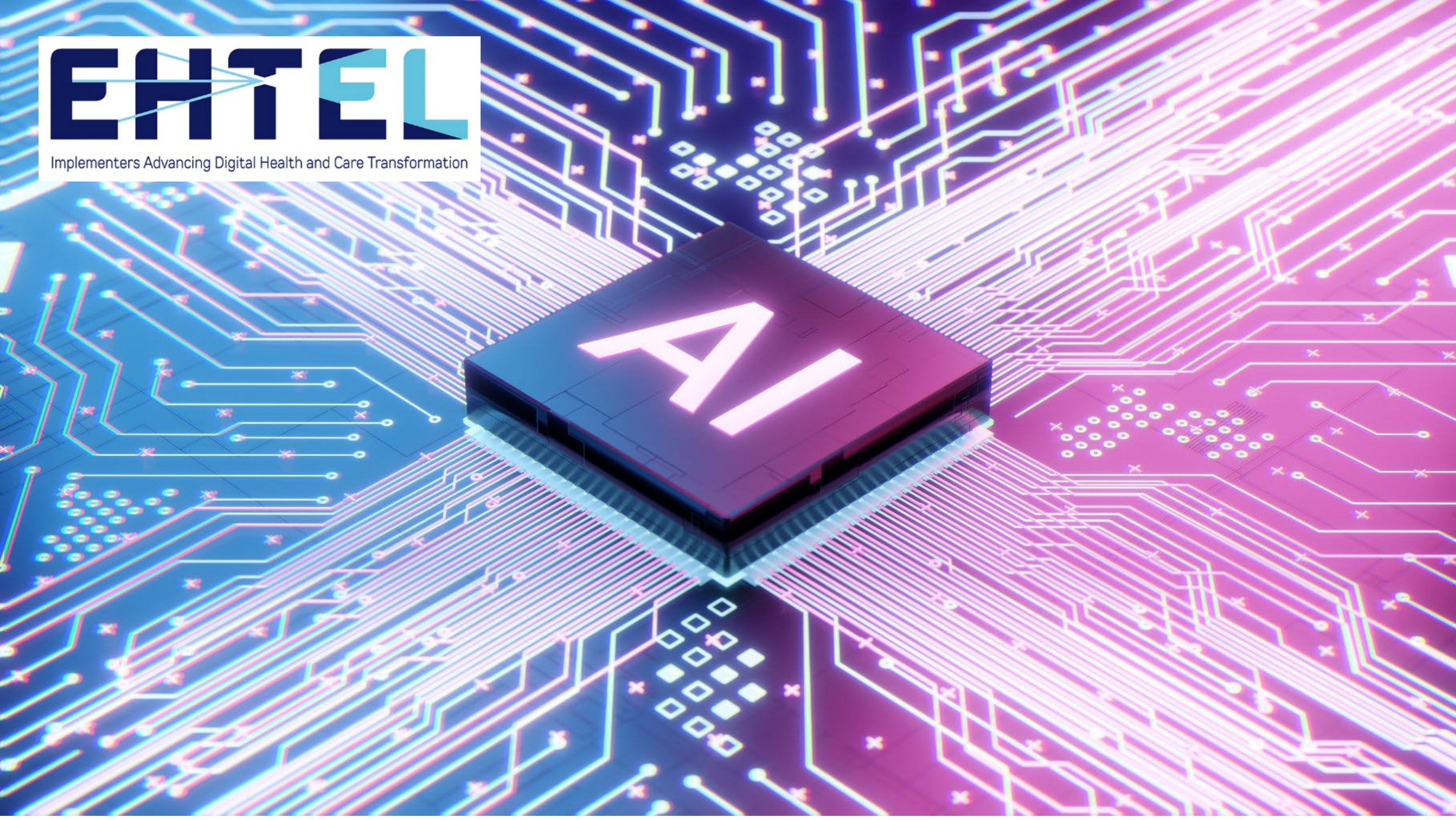

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Increasing the availability of high-quality and structured health data, the potential of AI

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XiA

in collaboration with the EHTEL EHDS Implementers Task Force

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Contents

1 Introduction and objectives

The European Health Data Space (EHDS) establishes a **common syntactic framework** for cross-border data exchange, centred on formats such as HL7 FHIR®, DICOM, and HL7 CDA. While this regulatory shift provides a necessary foundation, it does not in itself resolve the deeper challenge of ensuring consistent **semantic meaning** across heterogeneous health data. This challenge has long been recognised: already in the 1960s, Dr. Lawrence L. Weed argued that the field of medicine was limited not by a lack of knowledge, but by the absence of structured, standardised representations of clinical problems and observations.[1] Today, many health systems still rely on a fragmented mix of terminologies, locally defined codes, and variable documentation practices. As a result, the availability of structured, high-quality data remains uneven, and large parts of the clinical record are still produced as unstructured text. In this working paper, artificial intelligence (AI) is considered primarily as a tool for enhancing **technical and semantic interoperability** – e.g., automated structuring, coding, mapping, and validation – not as a general enabler of clinical decision support[2].

Most **current tools** addressing these gaps – such as terminology services, rules-based extract-transform-load (ETL) engines, and native-to-FHIR® converters – are non-AI and require substantial human configuration. They improve syntactic alignment but only partially address semantic variability because of the complexity of clinical modelling and syntax. At the same time, rapid advances in AI, particularly in natural language processing (NLP), speech recognition, and image understanding, are creating **new opportunities** to automate structuring, coding, and validation of clinical data. These technologies can simplify data workflows and increase the availability of semantically consistent, computable health data when combined with appropriate human oversight and organisational governance. AI automates parts of structuring, but semantic quality ultimately emerges from the interaction between tools, trained professionals, and coherent governance processes.

The aim of this working paper is to examine how AI and related tools can **complement the EHDS agenda** by strengthening the semantic layer and accelerating the production of reliable, structured data. The analysis draws on scientific literature, insights from implementers involved in EHDS-related projects (including **Xt-EHR**[3],

[1] Weed, L. L. (1968). Medical records that guide and teach. *N Engl J Med*, *278*(11), 593-600. www.taylorfrancis.com/chapters/edit/10.1201/b17819-8/medical-records-guide-teach-lawrence-weed

[2] This challenge is the subject of another EHTEL working paper: “How can EHR system clinical users make the best of algorithm-based tools?” released in parallel to this paper.

[3] https://www.xt-ehr.eu/

myHealth@myHands[4], **xShare**[5], **i2X**[6] and **XiA**[7]), and on ongoing implementation experiences (i.e., implementer perspectives).

The paper also formulates provisional **recommendations** and **discussion points** (questions for debate). Given the fast pace of AI evolution, EHDS implementation strategies must remain valid even as AI systems become capable of automating tasks traditionally carried out manually; however, their safe integration depends on building adequate capacity, maintaining human validation, and having organisational structures that preserve semantic integrity. Understanding this **trajectory** is essential to avoid policies that may become rapidly outdated or that constrain innovation in areas where automation may soon outperform manual processes, while still ensuring fit and integration into organisations and social value frameworks.

2 Understanding the challenge: Syntax and semantics in the EHDS era

An exploration follows of the relevant literature and various implementer-related challenges to help understand the challenge of what may happen to **semantics and syntax** in the upcoming EHDS era.

2.1 What does the literature say

The literature consistently shows that syntactic interoperability – ensuring data are exchanged in formats such as HL7 FHIR® or CDA – solves only a small part of the **interoperability** problem. Even when systems exchange structurally valid resources, semantic interoperability remains fragile because meaning, context, and standardised terminology use are highly inconsistent across organisations and countries. Studies emphasise that the "unbroken chain" of meaning often breaks at the point(s) of coding, classification, or metadata definition, leading to data that is technically shareable but operationally unusable for clinical, public health, or research purposes.[8]

Recent systematic reviews highlight that semantic misalignment persists even in settings where FHIR® is implemented. Variability in **terminology adoption** (e.g., SNOMED CT, LOINC, ICD-10), local coding conventions, and profile extensions routinely undermine the

[4] https://myhealthmyhands.eu/
[5] https://xshare-project.eu/
[6] https://www.uphillhealth.com/i2x
[7] https://xia-project.iscte-iul.pt/
[8] Facile R. et al. (2025). "Standards in sync: five principles to achieve semantic interoperability for TRUE research for healthcare." *Front. Digit. Health*. https://doi.org/10.3389/fdgth.2025.1567624

utility of exchanged data.[9,10] A classic example comes from laboratory data: despite shared use of LOINC identifiers, institutions still differ in units, acronyms, and result expressions, requiring extensive synonym tables and manual conversion.[11] Such findings confirm that syntax alone cannot compensate for heterogeneity in underlying semantic practices.

Technically, **several factors** drive these gaps: uneven uptake of standard vocabularies, lack of governance to synchronise terminology use across FHIR® profiles, incomplete or unstable mappings between coding systems, and the absence of robust metadata standards.[12] Contextual information – such as units, provenance, or clinical intention – is often missing, further limiting semantic clarity. These issues reduce data quality by harming correctness, completeness, conformance, and consistency across systems.[13]

The **consequences** are visible in both clinical workflows and secondary use. Semantic inconsistencies introduce inefficiencies, manual reconciliation, and potential misinterpretation during care transitions, referrals, or medication reconciliation. They also degrade the reliability of aggregated datasets and complicate AI development, as heterogeneous coding inflates noise and forces extensive preprocessing.[14] Ontology-driven approaches can mitigate this, but they require technical capability and coordinated governance that remain uneven across Europe.

In effect, **semantic misalignment** becomes a hard ceiling on Europe's capacity to scale personalised care. Strengthening semantic interoperability therefore does not only support administrative harmonisation; it is a precondition for delivering equitable and evidence-based personalised medicine across the European Health Union.

2.2 Challenges from the field: Implementer perspective

Experiences from hospitals, national authorities, and European Union (EU)-funded **projects** show that the main challenge in EHDS implementation is not the adoption of standards such as FHIR® or CDA, but the persistent variability in how clinical concepts are documented, coded, and interpreted because international standards allow variations

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[9] Amar F. et al. (2024). "Electronic Health Record and Semantic Issues Using FHIR: Systematic Mapping Review." *JMIR*. https://doi.org/10.2196/45209
[10] Ambalavanan R. et al. (2025). "Challenges and strategies in building a foundational digital health data integration ecosystem: a systematic review and thematic synthesis." *Front. Digit. Health*. https://doi.org/10.3389/frhs.2025.1600689
[11] Lin M-C. et al. (2011). "Investigating the semantic interoperability of laboratory data exchanged using LOINC codes." *AMIA Proc.* https://pubmed.ncbi.nlm.nih.gov/22195138/
[12] Palojoki S. et al. (2024). "Semantic Interoperability of Electronic Health Records." *JMIR Med Inform*. https://doi.org/10.2196/53535
[13] Wu Y. et al. (2025). "Semantics-driven improvements in electronic health records data quality." *BMC Med Inform Decis Mak*. https://doi.org/10.1186/s12911-025-03146-w
[14] Ambalavanan R. (2025). "Ontologies as the semantic bridge between artificial intelligence and healthcare". *Front. Digit. Health*. https://doi.org/10.3389/fdgth.2025.1668385

and optionality. **Pilot sites** repeatedly report that syntactic compliance can be achieved through incremental upgrades or middleware, while semantic alignment requires multi-stakeholders' involvement, co-creation processes, organisational commitment, new competencies, and sustained clinical involvement.

Projects such as **Trillium II**[15] demonstrated that even well-defined artefacts, like the International Patient Summary, require intensive work on terminology mappings and clinical agreement. **XpanDH**[16] and **xShare** further confirmed that the current state of local data models, legacy systems, and inconsistent coding across specialties may limit the reuse of data for structuring, coding, validation, and any downstream reuse. Implementation sites point to the gap between nominal syntactic conformity and the actual usability of data for automated semantic processing, quality assurance, and compliant data exchange.

A **key lesson** is that semantic standardisation cannot be outsourced to technical teams alone: instead, it emerges from AI-assisted tooling, continuous human expertise, and stable organisational governance acting together. Sites that succeed treat semantic interoperability as a co-produced, co-created outcome: where AI suggests and accelerates, professionals curate and validate, and governance structures maintain coherence over time. Smaller providers often lack this capacity, and rely on manual coding or partial mappings, leading to heterogeneous outcomes even when using the same standards. Across initiatives, implementers agree that syntax is only the visible layer of interoperability. Value emerges when data carry consistent meaning, and this depends on governance, clinical buy-in, and the availability of robust semantic tooling – not only on regulatory compliance.

To contribute to this improvement, the **Xt-EHR** joint action is developing a **logical, vendor-neutral semantic model** built on HL7 FHIR® resources and data obligations, designed to support semantic interoperability across heterogeneous electronic health record (EHR) systems[17].

3 Existing tools for structuring and coding health data

An exploration of the relevant literature and various implementer-related challenges helps to understand what tools can be used to structure and code health data.

[15] https://cordis.europa.eu/project/id/727745/results
[16] https://cordis.europa.eu/project/id/727745/results
[17] https://www.xt-ehr.eu/artifacts-logicalmodels/

3.1 What does the literature say

Literature reviews show that NLP and AI advances and the potential for supporting automated structuring and coding of health data for EEHRxF implementation, while they highlight the opportunities, limitations, and governance risks that arise when semantic quality and oversight are insufficient.

3.1.1 From rule-based systems to GenAI

NLP and AI techniques have for many years been applied to clinical text, from simple keyword extraction to sophisticated named-entity recognition and concept normalisation[18]. Traditionally, many systems rely on rules and lexicons tailored to specific institutions or languages, which limits their portability and requires intensive maintenance[19].

The arrival of transformer architectures and large language models (LLMs) has fundamentally changed this landscape[20,21,22]. Foundation models pre-trained on vast corpora can be adapted to clinical tasks with relatively modest amounts of fine-tuning of data and can handle a range of tasks including information extraction, semantic normalisation, and conversion of free text into structured, coded representations[23,24].

When combined with domain ontologies, terminologies and structured templates (e.g., HL7 FHIR® Resources), such models promise to support semi-automated structuring of clinical documents into coded data[25].

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[18] Chowdhary, K.R. "Natural Language Processing," *Fundamentals of Artificial Intelligence*, pp. 603–649, 2020, https://doi.org/10.1007/978-81-322-3972-7_19

[19] de Mello B.H. et al., "Semantic interoperability in health records standards: a systematic literature review," *Health Technol (Berl),* vol. 12, no. 2, pp. 255–272, Jan. 2022, https://doi.org/10.1007/S12553-022-00639-W

[20] Yoon D. et al., "Redefining Health Care Data Interoperability: Empirical Exploration of Large Language Models in Information Exchange," *J Med Internet Res 2024;26:e56614* https://www.jmir.org/2024/1/e56614 vol. 26, no. 1, p. e56614, May 2024, https://doi.org/10.2196/56614

[21] Singhal K. et al., "Large language models encode clinical knowledge," *Nature 2023 620:7972*, vol. 620, no. 7972, pp. 172–180, Jul. 2023, https://doi.org/10.1038/s41586-023-06291-2

[22] Harnoune A., M. Rhanoui, M. Mikram, S. Yousfi, Z. Elkaimbillah, and B. El Asri, "BERT Based Clinical Knowledge Extraction for Biomedical Knowledge Graph Construction and Analysis," *Computer Methods and Programs in Biomedicine Update*, vol. 1, Apr. 2023, https://doi.org/10.1016/j.cmpbup.2021.100042

[23] Van Veen D. et al., "Clinical Text Summarization: Adapting Large Language Models Can Outperform Human Experts," *Res Sq*, Oct. 2023, https://doi.org/10.21203/RS.3.RS-3483777/V1

[24] Builtjes L., J. Bosma, M. Prokop, B. van Ginneken, and A. Hering, "Leveraging open-source large language models for clinical information extraction in resource-constrained settings," *JAMIA Open*, vol. 8, no. 5, Sep. 2025, https://doi.org/10.1093/JAMIAOPEN/OOAF109

[25] Riquelme Tornel Á., P. Costa Del Amo, and C. Martínez Costa, "Large Language Models for Automating Clinical Data Standardization: HL7 FHIR Use Case," Jul. 2025, Accessed: Nov. 27, 2025. [Online]. Available: https://arxiv.org/abs/2507.03067v1

3.1.2 Opportunities and risks for EEHRxF implementation

AI-supported structuring of health data offers clear **opportunities** for EEHRxF implementation. First, it could accelerate the population of EEHRxF-compliant records from existing unstructured data, reducing manual burdens for clinicians and health information departments. Second, it may facilitate adoption of common standards by providing tooling that integrates into documentation workflows rather than requiring separate coding efforts. Third, it can support secondary use of data by producing structured datasets that are more amenable to analytics and research. However, implementers emphasise that AI's value depends on the presence of trained professionals who can supervise coding decisions, and on organisational governance that maintains terminology, mappings, and workflows.

Continuity of care across primary care, hospitals, rehabilitation, and chronic disease follow-up relies on coherent, interpretable, and longitudinal patient data. Once semantic consistency is ensured, AI tools can also assist continuity of care – e.g., by generating structured summaries, reconciling medications, or surfacing missing follow-up events. These functions rely entirely on the semantic layer and are only possible once automated structuring and coding have been achieved. AI cannot reliably summarise what is inconsistently coded, incomplete, or semantically ambiguous. Strengthening semantic interoperability therefore directly strengthens AI's capacity to support safe, uninterrupted care pathways.

At the same time, AI introduces new **risks** and concerns that cannot be ignored:

- **Accuracy and bias.** Errors in extraction or coding may be propagated through semantic processing, quality assurance, and subsequently into clinical or analytical uses. If models are trained on biased or unrepresentative data, they may perform poorly for minority populations or less common languages, exacerbating digital health inequities[26].
- **Opacity and trust.** Stakeholders already express concerns about digital health tools compromising established professional roles, patient-clinician relationships, and data security[27]. Introducing AI systems that are not transparent or explainable may further erode trust.
- **Governance and accountability.** It is unclear how responsibility should be allocated when AI-generated structuring leads to errors in cross-border EHR

[26] Hasanzadeh F., C. B. Josephson, G. Waters, D. Adedinsewo, Z. Azizi, and J. A. White, "Bias recognition and mitigation strategies in artificial intelligence healthcare applications," *npj Digital Medicine 2025 8:1*, vol. 8, no. 1, pp. 154-, Mar. 2025, https://doi.org/10.1038/s41746-025-01503-7

[27] Hogg H. D. J. et al., "Stakeholder Perspectives of Clinical Artificial Intelligence Implementation: Systematic Review of Qualitative Evidence," *J Med Internet Res*, vol. 25, 2023, p. e39742, 2023, https://doi.org/10.2196/39742

exchange[28,29]. Governance models for digital health emphasise co-creation and public value but have yet to fully internalise the implications of AI-driven data processing[30].

Recent large-scale transformer models trained on longitudinal population health records provide strong empirical evidence that AI systems amplify the semantic and data-quality characteristics of the data they process. Shmatko and colleagues[31] show that models trained on standardised diagnostic codes (ICD-10) learn not only clinical patterns but also inconsistencies in coding practices, "missingness", and data-source bias, which directly shape model outputs. This demonstrates that AI does not automatically compensate for weak semantic interoperability; rather, it operationalises existing semantic fragmentation at scale. These findings reinforce the need to prioritise semantic consistency, provenance, and quality assurance upstream, before AI-assisted structuring, coding, or reuse can be considered reliable in the EHDS context.

In short, AI is both a potential enabler and a potential source of new governance problems. The challenge is to understand, in a structured and evidence-based way, what current AI research can realistically offer to EEHRxF implementation across the priority data domains, and where significant gaps remain.

3.2 Implementer perspective

Experiences from hospitals, national programmes, and EU-funded projects indicate that the maturity of tools for structuring, coding, and converting health data varies widely across categories. Commercial solutions – particularly speech-to-text, clinical NLP, and text-to-code engines – are the most mature, with several vendors offering integrated modules embedded in EHR workflows. These systems perform reliably for transcription and basic semantic extraction tasks, but implementers repeatedly highlight limits in domain specificity, multilingual coverage, and the stability of automated coding across clinical contexts. Accuracy often drops when confronted with local documentation styles,

[28] Rowland S. P., J. E. Fitzgerald, M. Lungren, E. (Hsieh) Lee, Z. Harned, and A. H. McGregor, "Digital health technology-specific risks for medical malpractice liability," *npj Digital Medicine 2022 5:1*, vol. 5, no. 1, pp. 157-, Oct. 2022, https://doi.org/10.1038/s41746-022-00698-3

[29] Nouis S. C. E., V. Uren, and S. Jariwala, "Evaluating accountability, transparency, and bias in AI-assisted healthcare decision- making: a qualitative study of healthcare professionals' perspectives in the UK," *BMC Med Ethics*, vol. 26, no. 1, pp. 89-, Dec. 2025, https://doi.org/10.1186/S12910-025-01243-Z/TABLES/4

[30] Lewerenz S., A. Moen, and H. Martins, "Public value and digital health: The example of guiding values in the national digital health strategy of France," *Int J Med Inform*, vol. 196, p. 105794, 2025, https://doi.org/10.1016/j.ijmedinf.2025.105794

[31] Shmatko, A., Jung, A.W., Gaurav, K. et al. Learning the natural history of human disease with generative transformers. *Nature* 647, 248–256 (2025), https://doi.org/10.1038/s41586-025-09529-3

abbreviations, or specialty-specific terminology, requiring manual validation and ongoing configuration.

Open-source tools show strong innovation – especially around FHIR® conversion, terminology services, and rule-based extract-transform-load (ETL) pipelines – but their deployment still requires significant in-house technical capacity. Hospitals report good results with FHIR® converters for structured modules (e.g., for labs, medications) yet note persistent constraints when processing unstructured text or mapping heterogeneous legacy codes. **Terminology servers** (e.g., SNOMED-enabled services) are seen as essential enablers, but smaller providers often lack the expertise to maintain them effectively.

Research prototypes in NLP, image-to-code models, and multimodal AI provide promising results in controlled environments, particularly for extracting key clinical concepts or generating structured outputs aligned with FHIR® resources. However, most remain difficult to operationalise at scale. Issues include limited explainability, unstable performance across sites, and the absence of robust benchmarking datasets representing European languages and documentation traditions. Implementers caution that such **tools** can be valuable for pre-processing and quality assurance but are not yet dependable for fully autonomous coding in routine care.

Across all categories, implementers consistently observe that AI tools alone cannot secure semantic quality: meaningful outputs arise only when automated extraction is complemented by trained professionals and by organisations with mature terminology governance, quality monitoring, and workflow alignment. Even high-performing systems struggle when upstream workflows are inconsistent or when semantic standards are only partially implemented. This reinforces the need for **mixed approaches** – combining automation with clinician oversight – and for strong governance to ensure that AI-generated or AI-assisted structured data remains clinically trustworthy.

Twelve **examples of tools** that are currently available are:

- **Apelon DTS / Apelon Semantic Platform**[32] providing machine learning-assisted terminology mapping and normalisation, code system alignment (SNOMED, LOINC, ICD), semantic normalisation pipelines, FHIR integration, and more.
- **AWS HealthLake**[33] provides a comprehensive data infrastructure for healthcare applications, advanced analytics, machine-learning models, and generative AI innovations, while maintaining enterprise-grade security and eliminating infrastructure management overhead.

[32] See https://apelon-dts.sourceforge.net/
[33] See https://aws.amazon.com/healthlake/

- **cTAKES / MedCAT / spaCy-Clinical research** initiatives[34]
- **eHealthPass™** [35] is a remote patient management platform, a personal health records, a digital therapeutics solution that incorporates LLMs and other AI algorithms to promote quality enabled treatment and prevention. It incorporates smart ChatBots, openAI tools and more to streamline patient-clinician collaboration.
- **FHIR Workbench and LLM-based evaluation tools**[36] is a large language model (LLM)-based reasoning over FHIR® resources tool. FHIR®-Workbench provides standardised benchmarks to evaluate LLM performance on healthcare interoperability tasks.
- **IHE's Gazelle**[37] tests tools automation and undertakes model-based validation of FHIR® documents. IHE Gazelle is an open-source interoperability testing platform central to IHE Connectathons, Projectathons and Plugathons, providing tools for validating healthcare systems, including robust support for HL7 FHIR® validation through integrated components. One example is Matchbox, which uses official validators (like HAPI FHIR and IHE profiles) to check FHIR® message conformance, structure, and adherence to specific implementation guides, crucial for ensuring that data exchange standards are met in national and international health initiatives.
- **IQVIA Patient Experience Platform**[38] is a next-generation digital solution that reimagines how patients engage with support programmes throughout their treatment journey. It addresses long-standing challenges in patient support – including low engagement, poor adherence, and fragmented digital ecosystems – by delivering personalised, behaviourally informed experiences powered by real-world data. Built on a secure, compliant infrastructure, IQVIA Patient Experience (PX) Platform integrates with wearables, EHRs, and case management systems to enable real-time interventions and outcome tracking. With capabilities spanning onboarding, adherence support, and evidence generation, it empowers patients and providers to drive measurable improvements in satisfaction, persistence, and health outcomes.

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[34] See https://arxiv.org/html/2508.02556v1; https://www.researchgate.net/figure/Step-by-step-implementation-of-clinical-natural-language-processing-NLP-pipeline-Step_fig1_370154080; https://medcat.readthedocs.io/en/latest/autoapi/medcat/meta_cat/; https://nuchange.ca/2020/04/nlp-for-clinical-notes-tools-and-techniques.html
[35] See https://ehealthpass.eu/
[36] See https://github.com/UMEssen/FHIR-Workbench
[37] See https://ihe-catalyst.net/test-system-gazelle/
[38] See https://www.iqvia.com/solutions/commercialization/commercial-engagement-services/iqvia-patient-experience-platform

- **InterSystems IRIS for Health**[39]**,** with machine learning services, is a comprehensive, cloud-first digital health development platform that provides all the building blocks needed to work with any healthcare data standard, including HL7 FHIR®.
- **OHDSI / OMOP AI Harmonisation Tools**[40] OHDSI offers a wide range of open-source tools to support various data-analytics use cases on an observational patient-level data. What these tools have in common is that they can all interact with one or more databases using the Common Data Model (CDM). Furthermore, these tools standardise the analytics for various use cases.
- **Ontoserver**[41] is a next-gen FHIR® terminology server developed by the Australian e-Health Research Centre, CSIRO, providing semi-automated mapping and terminology services.
- **Snowstorm**[42] are SNOMED CT and terminology-centric AI Tools providing assisted mapping, terminology maintenance, and semantic validation.
- **Text2Node**[43] is a cross-domain mapping system capable of mapping medical phrases to concepts in large taxonomies (such as SNOMED CT). The system is designed to generalise from a limited set of training samples and to map phrases to elements of the taxonomy that are not covered by training data.

AI tools for semantic interoperability are already deployed in terminology services, FHIR® platforms, and national EHR infrastructures, while AI-assisted conformance testing and cross-border semantic mediation are transitioning from advanced prototypes to operational pilots. In the current EHDS era, AI acts as an accelerator for standards-based interoperability, and not as a replacement for HL7 FHIR®, EEHRxF, or governance frameworks.

4 Organisational, human, and other enablers of interoperability

Semantic interoperability is not produced by tools alone. It emerges from the combined action of AI systems capable of automating structuring and coding; professionals who validate, correct, and refine semantic representations; and organisations that maintain the governance structures, terminology services, and cultural conditions needed for consistency over time. This **tripartite interaction** i.e., tools plus people, governance, and

[39] See https://www.intersystems.com/products/intersystems-iris-for-health/
[40] See https://www.ohdsi.org/software-tools/
[41] See https://www.ontoserver.csiro.au/site/
[42] See https://github.com/IHTSDO/snowstorm
[43] See https://arxiv.org/abs/1905.01958

consensus[44] – forms the operational backbone of semantic interoperability in the EHDS era.

4.1 What does the literature say

The literature identifies several **inter-linked domains** critical to semantic interoperability: organisational readiness, governance and leadership, human-AI collaboration, and professional culture. Across studies, one finding is consistent: semantic interoperability emerges when automation, human expertise, and organisational governance reinforce each other. None of these components is sufficient on its own.

4.1.1 Organisational readiness

Readiness for digital health interoperability requires more than just technical infrastructure. For example, de Mello et al. found that semantic interoperability is hindered by weak organisational arrangements around terminology governance, mapping services and interdisciplinary coordination.[45] Organisational models typically emphasise leadership buy-in, stakeholder alignment, training, resource allocation, and change management.[46] **Readiness frameworks** for AI and digital health emphasise that without process alignment, workforce capability and executive sponsorship, investments in interoperability yield limited returns.[47]

4.1.2 Governance and leadership models

Good **governance** is consistently cited as a pre-condition for semantic interoperability. Clear accountability for terminology adoption, data stewardship, version control, and mapping responsibilities is required. In the context of AI and data reuse, emerging governance frameworks emphasise transparency, data ethics, stakeholder engagement and continuous monitoring of algorithms.[48] In the context of the EHDS, Hussein et al note that, even with shared technical specifications, variable governance across countries undermines reuse and secondary use of data. Integrating the Healthcare Enterprise (IHE) has provided a use case-based methodology to implement a National eHealth

[44] This interaction can also be referred to as tools + people + governance + consensus.

[45] de Mello BH, et al. "Semantic interoperability in health records standards." *BMC Med Inform Decis Mak*. 2022. https://doi.org/10.1007/s12553-022-00639-w

[46] Babšek M, Murko E, Aristovnik A. "Organisational AI Readiness for Public Administration: A Comprehensive Review." Int J Econ Bus Admin. 2025. https://doi.org/10.35808/ijeba/894

[47] Hussein R, Gyrard A, Abedian S, Gribbon P, Martínez S. "Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework–Based Standards Compliance Toolkit for AI-Driven Projects." *J Med Internet Res 2025*;27:e69813 https://doi.org/10.2196/69813

[48] Ribeiro D, Rocha T, Pinto G, et al. "Toward Effective AI Governance: A Review of Principles." 2025. https://doi.org/10.48550/arXiv.2505.23417

Interoperability Framework.[49] Hussein et al also discuss the challenges of properly implementing interoperability standards for secondary use of data.

4.1.3 Human-AI collaboration and professional culture

Semantic interoperability initiatives invariably require **collaboration** between clinicians, informaticians, terminologists, and IT software architects and developers. The literature on human-AI collaboration observes that successful models embed AI as **a partner** in semantic processes – suggesting codes, identifying gaps, and assisting validation – rather than replacing human judgement.[50] **Professional culture** plays a major role: data-capture behaviour, coding discipline, terminology uptake, and willingness to engage with structured workflows vary widely across specialties and institutions. The inertia of clinicians to change documentation habits, combined with perceived burden and limited immediate benefit, remains a recurring barrier.

4.1.4 In summary

Achieving semantic interoperability is as much **an organisational and cultural challenge** as a technical one. Without readiness (resources, skills, processes), governance (terminology services, data stewardship) and a culture aligned with structured, reusable data workflows, even well-specified syntactic frameworks (e.g., FHIR®) will under-deliver. The literature thus points to the need for an integrated socio-technical approach: tools, governance, workforce, and culture must evolve in concert.

4.2 Implementer perspective

Implementers across hospitals, regional systems and national authorities report that semantic interoperability fails not because of technical shortcomings alone, but because organisational and human **processes remain uneven**.

Implementers emphasise that AI can accelerate structuring only when professionals validate outputs and organisations maintain the semantic backbone through stable governance processes. **Progress** depends on early investment in terminology services, stable data-governance arrangements and cross-disciplinary teams that can maintain mappings and coding practices over time. Sites with centralised terminology governance – bringing together clinical informatics, IT, coders and quality staff – describe fewer inconsistencies and less semantic drift, whereas those relying on informal or fragmented arrangements experience recurring divergence between departments. Clinicians' documentation habits remain a decisive factor because they determine the availability and

[49] Bourquard K. and A. Berler, "Use-Case Driven Approach for a Pragmatic Implementation of Interoperability in eHealth", *International Journal of Reliable and Quality E-Healthcare (IJRQEH)* 6(3), IGI Global, 2017 Pages pp 52-62, https://doi.org/10.4018/IJRQEH.2017070104

[50] Karapanagiotis P. "Enabling interoperable human-AI teaming for automation." *Int J Hum-Comput Stud*. 2025. https://doi.org/10.1016/j.jii.2025.100962

quality of content that automated structuring and coding tools can process. Smaller providers face additional asymmetries, depending heavily on vendor defaults or national mapping repositories, and they are lacking the capacity to manage their own terminology pipelines. Across settings, implementers converge on **a common insight**: semantic interoperability becomes sustainable only when governance, culture, AI-assisted workflows, and everyday professional practice evolve together.

Addressing these entrenched gaps requires systematic capacity building rather than ad hoc training. Recent European initiatives illustrate workable models. The **XiA project** provides modular, role-specific learning pathways that build interoperability competencies among developers, deployers and end-users. Its structured micro-content approach supports consistent coding behaviour, strengthens the understanding of standards and terminologies, and helps embed semantic practices into routine workflows. Such programmes reduce variation in documentation, improve uptake of FHIR®-based profiles, and equip staff to work responsibly with AI-assisted structuring tools. Complementary efforts such as the **SUSA project**[51] integrate interoperability and data-literacy skills into broader digital-skills curricula for health and social care professionals. These initiatives highlight that capacity building is not peripheral: without sustained, organisation-wide education, even well-designed semantic tools and governance models struggle to deliver consistent, high-quality structured data.

Governing interoperability is a key component for successful implementation. Embedding interoperability across the full system lifecycle has the following **benefits**. It:

- Enhances outcomes and user experience by enabling safe, seamless data exchange across care settings and over time.
- Improves efficiency and reduces costs by avoiding bespoke integrations and unnecessary duplication, while promoting reuse of data and solutions.
- Supports data reuse by enabling information to be captured once and used for multiple purposes.
- Stimulates innovation and healthy competition – particularly benefiting small and medium-sized enterprises – through the adoption of open standards and transparent conformance mechanisms.
- Strengthens public value by promoting transparency, accountability, and long-term sustainability of digital health systems.
- Helps reduce inequities by enabling accessible, person-centred services and supporting cross-border cooperation.

[51] See SUSA. https://susacampus.eu/

An example of a well-established **national interoperability framework** is the French eHealth Interoperability Framework[52].

5 Recommendations and questions for debate

The analysis presented in this working paper confirms that **semantic interoperability cannot be delivered by technology alone**. It emerges from the combined action of:

1. **AI-assisted tools** that automate structuring, coding, mapping, and validation.
2. **Professionals** who supervise outputs, adapt documentation behaviour, and sustain semantic accuracy.
3. **Organisations** that maintain governance, terminology services, training, and quality processes.

The following **recommendations** consolidate all the insights outlined in previous sections of the working paper into five strategic clusters. The recommendations follow the principle that semantic interoperability is co-produced by AI tools, professional expertise, and organisational governance. Ensuing actions should therefore **target all three dimensions** (i.e., AI-assisted tools, professionals, and organisations) simultaneously.

5.1 AI-assisted semantic enablement tools

Recommendations

Prioritise public investment in tools that directly enhance semantic interoperability, including:

- **Automated extraction and structuring systems** able to convert free text into coded, EEHRxF-compliant data.
- **Terminology services and mapping engines** that maintain stable links between local expressions and SNOMED CT, LOINC, ATC, ICD, and domain-specific vocabularies.
- **Multilingual and cross-lingual AI models** to ensure equitable interoperability across all EU languages, including minority languages.
- **Quality-assurance and conformance-checking tooling** that flags missing mandatory fields, implausible combinations, and semantic inconsistencies.
- **Transparent and auditable AI components** to reduce dependency on opaque vendor ecosystems and allow cross-site validation.

[52] See https://esante.gouv.fr/produits-services/ci-sis

Questions for debate

1. Which classes of AI tools should receive structural EU-level support due to their public-good nature?

2. What minimum benchmarking and validation frameworks are needed for AI tools that perform semantic tasks?

3. How should the EHDS ensure that AI-generated semantic content remains traceable and auditable?

5.2 Organisational and governance enablers

Recommendations

Establish robust organisational governance models that institutionalise semantic interoperability, including through:

- Establishing stable **terminology governance structures** in organisations, with explicit roles for stewardship, version control, and mapping ownership.
- Requiring **semantic governance teams** that combine clinical, informatics, terminology, and IT profiles.
- Implementing **continuous processes** to detect and correct semantic drift across departments.
- Promoting **governance models** that define shared accountability between AI outputs, professional oversight, and organisational processes.
- Establishing **digital health interoperability frameworks** that include semantic task forces and the necessary testing continuum to strengthen the implementation processes.
- Enabling **co-creation processes** involving all stakeholders at the design phase of digital strategies and implementation projects.

Questions for debate

1. Should the EHDS standard bundle include guidelines for organisational governance of semantics and human-AI collaboration workflows?

2. What constitutes "semantic maturity" for organisations participating in EHDS data flows?

3. How can governance models account for liability when AI tools participate in structuring and coding?

4. How can AI tools enhance better testing and conformance processes taking into account both the EHDS regulation and the AI Act?

5.3 Workforce, training, and culture

Recommendations

Invest in sustained, role-adapted capacity-building and AI literacy programmes that embed semantic competencies into daily practice, incentivise high-quality documentation, and enable professionals to effectively supervise AI-assisted structuring and coding:

- Develop **sustained capacity-building programmes** covering standards literacy, terminology, semantic quality, and AI-assisted structuring.
- Promote **role-specific, modular learning** (e.g., micro-learning) that fits into clinical and operational workflows.
- Support **peer-to-peer and practice-integrated training models** to improve uptake and consistency of structured documentation.
- Strengthen **AI literacy** to ensure that professionals understand how automated coding works, when it needs verification, and what its limitations are.
- Incentivise **documentation behaviours** that increase semantic quality – e.g., through demonstrable clinical value, reduced duplication, or workflow simplification.

Questions for debate

1. How can Europe scale semantic and AI literacy training without adding burdens to clinical staff?
2. Which training formats (e.g., micro-learning, simulation, peer-led sessions) have proven most effective in healthcare settings?
3. How can training programmes be harmonised across Beveridgian and Bismarckian systems while respecting local contexts?
4. How can we make stakeholders of different backgrounds collaborate together and create common knowledge and capacity building?

5.4 Vendor collaboration and interoperability-ready systems

Recommendations

Strengthen market and procurement conditions to ensure vendor openness by mandating standards-based interoperability, enabling third-party semantic components, supporting shared semantic assets, and fostering experimentation through interoperability labs :

- Address structural vendor lock-in by requiring EHR vendors to support **international standards** and IHE profiles, open interfaces, third-party semantic modules, and transparent mapping logic.
- Encourage **procurement frameworks** that prioritise interoperability-ready systems with demonstrable semantic capabilities.
- Organise **interoperability labs** to enable semantic interoperability experimentation to improve the standardisation and profiling processes, educate the vendors, enable early adopters and promote innovation into national and cross border digital transformation in healthcare strategies.
- Promote **shared, public repositories** of semantic assets, mapping tables, and AI training artefacts to avoid duplication and fragmentation.

Questions for Debate

1. Should the EHDS introduce vendor-level obligations to ensure interoperability of third-party semantic tools?
2. How can Europe develop shared "semantic commons" (terminology resources, multilingual datasets) that vendors must interoperate with?
3. What would be an acceptable semantic-friendly, open interoperability architecture?
4. Are the current interoperability architectures consistent enough at the European level to enable proper data quality and semantic maturity?

5.5 Implications for EHDS governance

Recommendations

Embed semantic interoperability as a core EHDS governance objective by:

- Positioning semantic interoperability as **a governance priority** in EHDS implementation – not merely a technical requirement.
- Integrating AI-assisted structuring into future **implementing acts**, ensuring traceability, validation expectations, and performance monitoring.
- Encouraging Member States to adopt **national semantic governance frameworks**, aligned with EU-wide terminology policies.

- Launching pan-European **monitoring mechanisms for semantic quality**, including indicators for errors, drift, completeness, and coding alignment.
- Extending concepts and lessons learned from the **MyHealth@EU initiative**.
- Enabling **a use case-based model** to enhance common implementation processes across Member States.

Questions for debate

1. How can EHDS governance ensure long-term alignment between semantic standards, evolving AI capabilities, and organisational readiness?
2. Should the EHDS define a Europe-wide methodological baseline for "semantic quality monitoring"?
3. What is the right balance between EU-level prescription and Member State autonomy in governing semantic workflows?

6 Annex: Supporting semi-automated structuring of clinical documents into coded data for EEHRxF compliance

In the European context, these developments intersect with the EEHRxF in several ways:

- **Automated extraction from free text.** AI models can identify problems, medications, laboratory values and other entities in clinical notes, discharge summaries or imaging reports, and map them to EEHRxF elements[53,54,55,56].
- **Terminology mapping and normalisation.** NLP can assist in mapping local terms to standard codes (e.g., LOINC, SNOMED CT) and flag inconsistencies or missing codes[57,58].

[53] Yang X. et al., "A large language model for electronic health records," *npj Digital Medicine 2022 5:1*, vol. 5, no. 1, pp. 194-, Dec. 2022, https://doi.org/10.1038/s41746-022-00742-2

[54] Jiang-Kells J. et al., "Design and implementation of a natural language processing system at the point of care: MiADE (medical information AI data extractor)," *BMC Med Inform Decis Mak*, vol. 25, no. 1, pp. 365-, Oct. 2025, https://doi.org/10.1186/S12911-025-03195-1/TABLES/4

[55] Eguia H. et al., "Clinical Decision Support and Natural Language Processing in Medicine: Systematic Literature Review," *J Med Internet Res 2024*. https://doi.org/10.2196/55315

[56] Reichenpfader D., H. Müller, and K. Denecke, "A scoping review of large language model based approaches for information extraction from radiology reports," *npj Digital Medicine* 2024 7:1, vol. 7, no. 1, pp. 222-, Aug. 2024, https://doi.org/10.1038/s41746-024-01219-0

[57] Hristov A. et al., "Clinical Text Classification to SNOMED CT Codes using Transformers Trained on Linked Open Medical Ontologies," pp. 519–526, https://doi.org/10.26615/978-954-452-092-2_057

[58] Au Yeung J. et al., "Natural language processing data services for healthcare providers," *BMC Med Inform Decis Mak*, vol. 24, no. 1, pp. 356-, Dec. 2024, https://doi.org/10.1186/S12911-024-02713-X/FIGURES/8

- **Multilingual support.** Multilingual or cross-lingual models can help bridge language barriers, supporting translation and coding across EU languages[59,60].
  - **Quality assurance and compliance.** AI can detect missing mandatory fields, implausible combinations or data quality issues relative to EEHRxF constraints[61].
  - **AI-assisted FHIR® and EEHRxF conformance testing**[62]. AI can support large-scale validation of EHR outputs against EHDS profiles, providing automated classification of FHIR® conformance errors, root cause analysis of profile violations, and smart recommendations for corrective mappings.

These capabilities are not speculative; a growing body of research demonstrates the potential of AI and GenAI for structuring clinical narratives, though often in narrow domains, single institutions, or non-European settings. The maturity and limitations of these methods vary substantially across data types and clinical contexts.

[59] Gaschi F., X. Fontaine, P. Rastin, and Y. Toussaint, "Multilingual Clinical NER: Translation or Cross-lingual Transfer?," *Proceedings of the Annual Meeting of the Association for Computational Linguistics*, pp. 289–311, Jun. 2023, https://doi.org/10.18653/v1/2023.clinicalnlp-1.34

[60] Jo E., et al., "Domain and Language adaptive pre-training of BERT models for Korean-English bilingual clinical text analysis," *BMC Medical Informatics and Decision Making 2025 25:1*, vol. 25, no. 1, pp. 428-, Nov. 2025, https://doi.org/10.1186/S12911-025-03262-7

[61] Röchner P. and F. Rothlauf, "Unsupervised anomaly detection of implausible electronic health records: a real-world evaluation in cancer registries," *BMC Med Res Methodol*, vol. 23, no. 1, pp. 125-, Dec. 2023, https://doi.org/10.1186/S12874-023-01946-0/FIGURES/5

[62] See https://al-kindipublishers.org/index.php/jcsts/article/view/9889