AI, FHIR, EHDS & the AI Act: Impacts on Healthcare Software and Standards

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Introduce myself

CTO of Strategic Planning Office

Fondazione Bruno Kessler (FBK) - Trento

Secretary of HL7 Italy & Digital Health Expert

Involved in strategic planning of digital health ecosystems that bridge research and public health implementation. (FBK)

- **National Strategy:** he was scientific consultant for the Italian Digital Transformation Department on the "Fascicolo Sanitario Elettronico" (FSE 2.0). Now scientific consultant of Autonomous Province of Trento
- **Standards Leadership:** Active in HL7 Europe Working Groups, focusing on AI certification and EHDS interoperability.
- **Innovation:** Leads projects on AI as Software as a Medical Device (SaMD) and citizen-centric digital health platforms.

Agenda

- Objective of this meeting
- Standard and AI development: European context
- HL7 community: challenges and contributions
- Round table: our feedback, interests and expertise
- Next step: what we can do together

Objective of this meeting

Assess the interest on the topic “relationship between AI and application of standard” and learn about our expertise

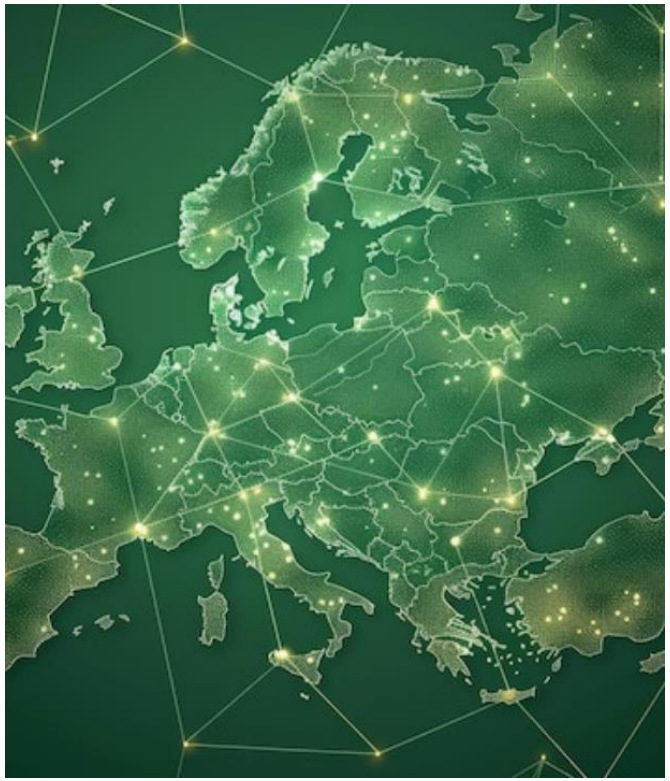
Discuss How FHIR can support EHDS & the AI Act compliance for secondary use of the data

Identify actions and topics that could be addressed by HL7 community next year

Standard and AI development: European context

Standard HL7 and AI Development: The European Context

The "Dual-Compliance" Challenge



What is the possible role of the standardization bodies? What is the role of HL7?

The European healthcare landscape is changing because of the introduction of AI

The convergence of the **EU AI Act** and the **European Health Data Space (EHDS)** creates a complex regulatory environment.

AI in Clinical Practice: Process Transformation

Diagnostic Triage

AI algorithms pre-screen and flag critical radiological findings before human review.

CHANGE: SHIFT FROM FIFO QUEUES TO RISK-PRIORITIZED WORKFLOW.

Predictive Monitoring

Real-time analysis of vital signs to predict adverse events like sepsis hours in advance.

CHANGE: SHIFT FROM REACTIVE TREATMENT TO PROACTIVE PREVENTION.

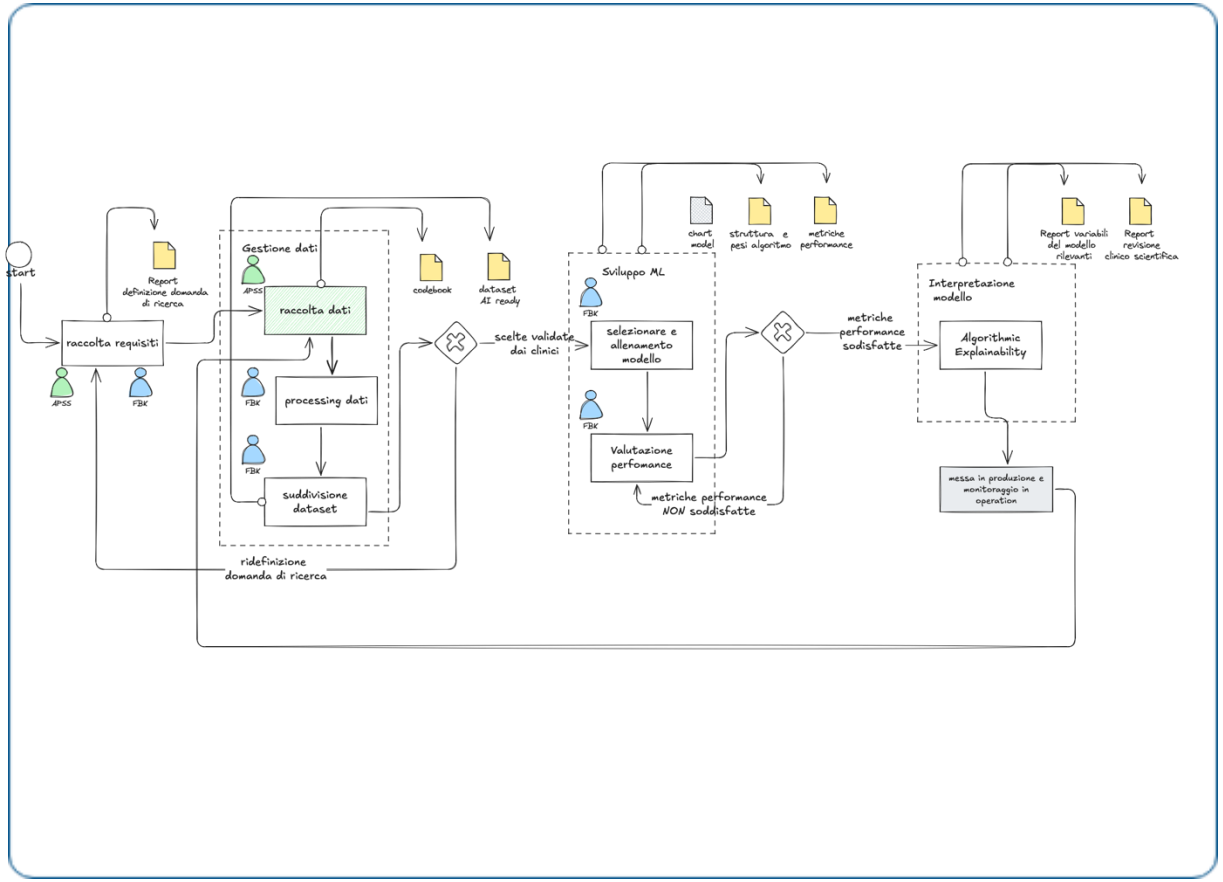
Precision Medicine

Correlating vast genomic datasets with clinical outcomes to identify optimal therapies.

CHANGE: SHIFT FROM TRIAL-AND-ERROR TO TARGETED PRECISION DOSING.

What is the possible role of standardization body?

- Leveraging **EHDS Secondary Use** mandates to transform isolated clinical data into high-value AI training assets.
- **Semantic Interoperability for RWD:** Utilizing FHIR as anormalization layer to convert heterogeneous Real-World Data(RWD) into standardized datasets (e.g., mapping FHIR to OMOPCDM) for robust model training.
- **Anonymization Pipelines:** Implementing standard-based de-identification profiles to ensure GDPR compliance while retaining longitudinal clinical value for research cohorts.
- **Reproducible AI:** Standardizing "Metadata" and "Provenance" resources to document data lineage, ensuring that AI research models are transparent and reproducible across EU borders.



Optimizing AI Data Lifecycle with FHIR

Data Acquisition

Standardized Ingestion: FHIR APIs enable unified data extraction (e.g., Patient, Observation) from heterogeneous EHRs, reducing preparation time.

Curation & Labeling

Quality Assurance: Using Provenance to track data lineage and QuestionnaireResponse for structured ground-truth labeling and validation.

Model Training

Cohort Definition: Utilizing Group resources to define precise training populations and Consent resources to manage data usage rights.

Deployment Loop

Continuous Learning: Capturing model inference via RiskAssessment and clinical outcomes for drift detection and retraining.

Strategic Imperatives for Decision Makers

HL7 Italia

Harmonized Compliance

Aligning vertical AI Act safety controls with horizontal MyHealth@EU data flows. This harmonization reduces regulatory friction and prevents the need for separate compliance silos.

Trust Architecture

Leveraging open HL7 standards to build explainable, transparent AI systems. Standardized data provenance acts as a trust signal for clinicians and patients across borders.

Cross-Border Scale

Preparing infrastructure for the EHDS. Adopting AI-ready standards today ensures seamless, secure health data exchange across EU member states tomorrow.

Focus on euopean regulation

Why AI Act & EHDS Matter for Healthcare AI

European Health Data Space (EHDS)

Focuses on health data governance (primary and secondary use). Defines **how we access data**.

AI Act

Focuses on AI models and systems. AI systems used in healthcare are almost always classified as high-risk, triggering strict requirements on data managment, transparency, human oversight and data management.

Technical Standards

Provide "operational translations" of legal requirements, and are expected to be used as evidence of compliance ("presumption of conformity")

AI Act: High-Risk Healthcare AI and Data Governance

Regulates the development, placing on the market, and use of **AI systems in the EU**, with a risk-based approach; most clinical AI falls under "high-risk" systems (e.g. AI-enabled medical devices).

Many of these obligations explicitly rely on detailed technical standards and structured documentation – an area where HL7 FHIR-based models for AI transparency, provenance and data lifecycle can provide concrete implementation artefacts.

Key lifecycle obligations for high-risk systems (selected):

- Art. 9 – Continuous risk management system across the whole lifecycle.
- Art. 10 – Data & data governance: training/validation/test datasets must be relevant, representative, free of errors and complete, with documented governance and management practices.
- Art. 11–12 – Technical documentation and logging to ensure traceability and post-hoc analysis.
- Art. 13–15 – Transparency, human oversight, accuracy, robustness and cybersecurity with declared performance metrics.
- Art. 16–17, 72–73 – Quality management system, CE conformity assessment, and post-market monitoring/incident reporting.

European Health Data Space (EHDS) main principles

EHDS regulates **access and use of electronic health data**, creating a legal and technical framework for both primary (care) and secondary use (research & innovation, including AI development).

- **Allowed**: for secondary use, EHDS explicitly includes “development, training, testing and validation of AI algorithms” aimed at improving public health and healthcare quality;
- **Denied**: uses such as marketing or discriminatory insurance pricing are excluded.

Access occurs only inside secure processing environments:

- Data are anonymous or pseudonymous by default;
- Raw source data never leave the environment;
- Only non-identifying aggregate outputs or trained models can be exported;
- All operations are logged for accountability.
- Data access is mediated by national Health Data Access Bodies, which issue time-bound data permits specifying which data can be used, for which purpose, and under which conditions.

HL7 community: challenges and contributions

HL7 AI Office: A Strategic Umbrella (July 2025)

Key Objectives:

- **Standardization:** Creating frameworks for safe, transparent, and interoperable AI.
- **Global Forum:** gather technology experts, clinicians, and regulators to shape the future of AI in healthcare
- **Responsible Innovation:** Ensuring ethical AI that improves patient outcomes.

Operational Pillars:

- **AI Innovation Lab:** An incubator for accelerating standards.
- **Community Excellence:** Tools for responsible adoption.

HL7 international AI Office: A Strategic umbrella launched in July 2025

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HL7 international focus group– Artificial Intelligence

Activitities

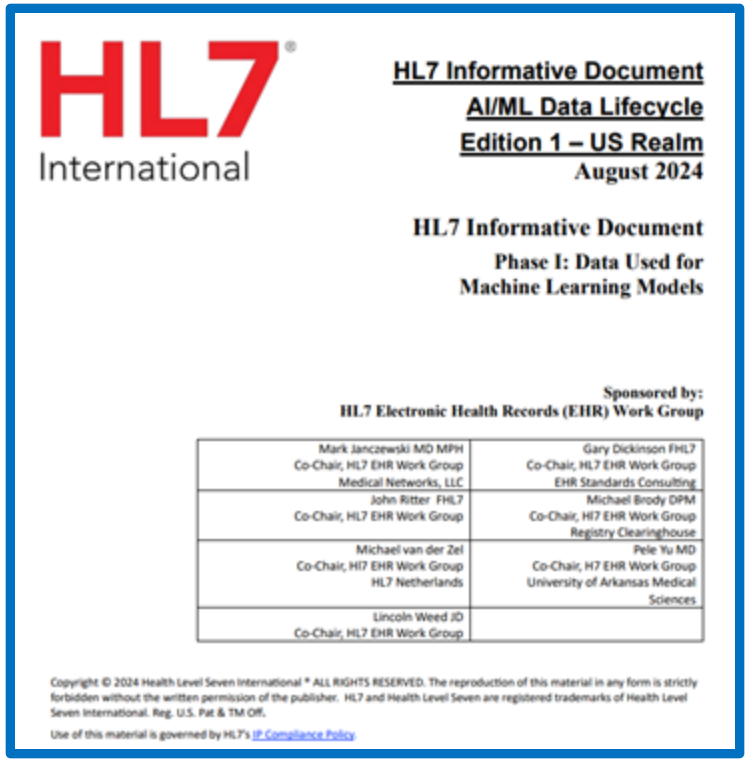
- **HL7 EHR Work Group/Artificial Intelligence Focus Team**
- Informative Document on data used foro machine learning models (August 2024)

Reference:

Gary Dickinson

HL7 EHR Work Group - Artificial Intelligence Focus Team - Confluence Page

Data life cycle for Machine Learning models



HL7 International

HL7 Informative Document
AI/ML Data Lifecycle
Edition 1 – US Realm
August 2024

HL7 Informative Document

Phase I: Data Used for Machine Learning Models

Sponsored by:
HL7 Electronic Health Records (EHR) Work Group

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HL7 Europe: areas of possible interest

- **Interoperability of AI System:** support standard extension and new profiles that allow AI models trained on standardized data to be deployed in different organizations without retraining.
- **Federated Learning /validation:** it is feasible when FHIR standards ensure data consistency (it mitigates privacy concerns in data training). Without this alignment, the aggregation of results becomes heterogeneous and unreliable. This issue is particularly relevant when datasets reside in different Countries.
- **Regulatory Compliance:** how standards can support compliance with emerging EU AI regulations, with a focus on Transparency and eXplainable AI (XAI)
- **Data enrichment for secondary use (data lifecycle support):** how FHIR can support the data preparation pipeline from real world data to AI-ready data

Round table: our feedback, interests and expertise

Open discussion

Sharing experience – some contributions

- Flavio Ragni, researcher and data scientist, Fondazione Bruno Kessler - Italy
- Ignacio Jauregui, Senior Interoperability Standardization Manager , Philips – Netherlands
- Roberta Gazzarata, member of HL7 Italy directive, leader WG Cancer Common Model
- Stefano Lotti, President of HL7 Italy

Next step

- Collect our contacts, expertise
- List working group we are involved in: which implementation guide is relevant addressing these aspects? Which ones?
- Something else?

WGM HL7 Europe Cologne AI FHIR EHDS and AI Act folder

Thanks

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https://www.fbk.eu/en/

https://www.hl7.it