Extended EHR@EU Data Space for Primary Use - Xt-EHR

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EHR Data Requirements for AI-based Clinical Decision Support
(Work Package 5 – Task 5.2)

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Author(s)

Name	Surname	Country	Organisation	Role of the Organisation
Prof. Christos N	Schizas	Cyprus	NeHA	CO
Dr. Andreas	Neocleous	Cyprus	NeHA	CO
Dr. Andreas	Menikou	Cyprus	NeHA	CO
Prof. Pattichis	Costas	Cyprus	UCY	AE
Dr. Theodoros	Kyprianou	Cyprus	UCY	AE
Dr. Maria	Papaioannou	Cyprus	UCY	AE
Prof. George	Spyrou	Cyprus	CING	AE
Prof. Kyproula	Christodoulou	Cyprus	CING	AE
Prof. Carolina	Sismani	Cyprus	CING	AE
Dr. Menelaos	Pipis	Cyprus	CING	AE
Dr. Marios	Tomazou	Cyprus	CING	AE
Dr. Athina	Theodosiou	Cyprus	CING	AE
Styliana	Menelaou	Cyprus	CING	AE

ABBREVIATIONS

EHR	Electronic Health Record
AI	Artificial Intelligence
EHDS	European Health Data Space
CDSS	Clinical Decision Support Systems
FAIR	Findable, Accessible, Interoperable, Reusable
FHIR	Fast Healthcare Interoperability Resources
NeHA	National eHealth Authority
CING	Cyprus Institute of Neurology and Genetics
UCY	University of Cyprus
IG	Implementation Guide

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1 INTRODUCTION

Task 5.2 explores how Electronic Health Record (EHR) data can be effectively and safely used by Artificial Intelligence (AI) tools that assist clinicians in decision-making. It defines what types of health data AI systems need as inputs and how their outputs—such as alerts, risk scores, or recommendations—should be represented and recorded back into EHRs.

Building on the **X-eHealth** results and aligned with the **European Health Data Space (EHDS)** Regulation, this work ensures that health data across Europe remains structured, interoperable, and reusable for both clinical care and research.

Using **HL7 FHIR (Fast Healthcare Interoperability Resources)** as the interoperability backbone and following **FAIR data principles** (Findable, Accessible, Interoperable, Reusable), Task 5.2 establishes the technical and semantic foundations that connect EHRs with AI-based Clinical Decision Support Systems. It also defines how AI-generated outputs can be represented in standard FHIR resources—ensuring transparency, explainability, and clinician oversight.

Through the **Gen2EHR** initiative, the task further explores the integration of genomic and bioinformatics data into EHRs, paving the way for **AI-enabled precision medicine**.

Together, these efforts create a trusted framework for linking AI, genomics, and EHR systems—bringing the EHDS vision of smarter, safer, and more personalized healthcare closer to reality.

1.1 Objective

Task 5.2 explores how health data from EHRs can be used effectively and safely by AI tools that support clinicians in making informed decisions.

It defines the types of health data that AI systems require as inputs and how their outputs (such as alerts, risk scores, or recommendations) should be represented and recorded back into patient records.

This milestone builds upon the outcomes of the **X-eHealth project** and directly supports the objectives of the EHDS Regulation, ensuring that health data across Europe remains structured, interoperable, and usable for both clinical care and research-driven innovation.

2 KEY HIGHLIGHTS

Connecting EHRs with AI Tools

The task defines the **technical and semantic requirements** that enable seamless communication between EHR systems and AI-based **Clinical Decision Support Systems (CDSS)**.

All interactions and data exchanges between these systems are built upon the **HL7 FHIR** standard, which provides a **common, secure, and interoperable framework** for health data exchange across Europe.

By adopting the **FAIR data principles**, this work ensures that the data used by AI systems is accurate, traceable, and reusable. This is a key enabler of trustworthy AI in healthcare.

2.1 EHR Data as Input for AI

AI systems rely on standardized and structured data to produce reliable, explainable outputs. This work (Xt-EHR Milestone 16) specifies how different categories of EHR data should be represented, harmonized, and exchanged using **HL7 FHIR** as the interoperability backbone and a set of international terminologies and coding systems, including:

- **Demographics:** ISO and FHIR-based patient identifiers and structures.

- **Laboratory results:** LOINC and UCUM for universal test codes and measurement units.
- **Vital signs:** Standardized through FHIR Observation profiles and recognized terminologies.
- **Medications:** ATC, IDMP, and EDQM for consistent prescribing data.
- **Diagnoses:** ICD-10 and SNOMED CT for semantic precision.
- **Unstructured text:** Processed via Natural Language Processing (NLP) techniques.
- **Imaging and time-series data:** Using DICOM and ISO timestamp standards.

By combining these standards under the FHIR exchange model, health data becomes interoperable and machine-readable. This enables AI-driven innovation across borders while maintaining clinical safety and transparency.

2.2 AI Outputs and Their Representation in EHRs

AI-generated insights (such as alerts, risk predictions, and treatment recommendations) must be **clear, auditable, and clinically interpretable**.

This task defines how these outputs should be represented using standardized FHIR resources, including **RiskAssessment**, **GuidanceResponse**, and **DiagnosticReport**.

This ensures that:

- Every AI-generated recommendation is **traceable and explainable**;
- Clinicians can understand **why and how** an alert was generated;
- Both AI outputs and clinician decisions are **recorded for accountability and learning**.

This approach reinforces clinician oversight and builds trust in AI-assisted decision-making.

2.3 Integrating Bioinformatics and Genomic Data

As healthcare transitions toward precision medicine, genomic and bioinformatics data are becoming essential for both clinical practice and AI-driven decision support. This task, through the **Gen2EHR initiative**, explored how such complex datasets can be securely and meaningfully integrated into EHR systems.
The **Gen2EHR Workshop**, co-organized by the **Cyprus Institute of Neurology and Genetics (CING)**, the **University of Cyprus (UCY)**, and the **National eHealth Authority (NeHA)** of Cyprus, gathered experts from across Europe to define practical steps toward genomic data integration.

3 KEY OUTCOMES OF THE GEN2EHR WORKSHOP

- **National "Genomics-in-EHR" Specification:** Agreement to establish a genomic data specification under Xt-EHR Work Package 5, with **Cyprus as a pilot site**. This specification defines how genomic test results can be securely stored and exchanged within EHRs following **HL7 FHIR Genomics** and **EHDS** standards.
- **Technical and Semantic Standards:** Participants recommended adopting international standards for consistency and interoperability:

- **HGVS** and **HGNC** for variant notation and gene identifiers
- **ACMG/AMP** for variant classification (pathogenic, VUS, benign, etc.)
- **HPO**, **OMIM**, and **Orphanet** for phenotype and disease representation
- **LOINC** and **UCUM** for test coding and measurement units

These standards enable a structured, computable representation of genomic data that AI tools and EHR systems can interpret automatically.

- **Laboratory Integration and Data Flow:** Labs will produce both **human-readable PDF reports** and **machine-readable FHIR bundles** containing key elements such as variant data, genomic study metadata, and phenotype observations. This dual format supports immediate usability while laying the groundwork for full digital interoperability.
- **Privacy and Data Protection:** Strong emphasis was placed on **GDPR compliance**, anonymization (de-identification), pseudonymization, secure data transmission, and role-based access controls to ensure patient trust and ethical data use.
- **Dynamic Data and Continuous Updates:** The workshop highlighted that genomic data must be **dynamic**, allowing EHRs to reflect reclassifications of variants and evolving scientific knowledge automatically. This shift moves healthcare from static reports toward a **continuously learning system**.
- **Path Toward EU-wide Adoption:** The Cyprus pilot will serve as a **model for other Member States**, supporting the eHealth Network and EHDS vision of a Europe-wide, interoperable infrastructure for genomic and clinical data exchange.

4 GENOMIC REPORTING IMPLEMENTATION GUIDE (HL7 FHIR)

The HL7® FHIR® Genomics Reporting Implementation Guide (IG) provides profiles and guidance to represent genomic test results in a computable, interoperable way—enabling safe integration of genomics into EHRs and AI-assisted clinical workflows. The IG is maintained by the HL7 Clinical Genomics Work Group. FHIR Build

What it covers (highlights)

- GenomicReport (profile on *DiagnosticReport*) plus related Observation profiles for variants, haplotypes, genotypes, pharmacogenomics, and more.
- GenomicStudy and GenomicStudyAnalysis to capture study and analysis metadata for traceability and reuse.
- Targeted extensions (e.g., Genomic Risk Assessment, Follow-up Recommendation) to convey clinical implications and next steps. FHIR Build+1

Where to find it

- Artifacts summary (continuous build, v4.0.0-ballot): shows the full list of current profiles, extensions, examples, and value sets. *(Note: content may change.)* FHIR Build

- Current published version (v3.0.0 STU3): stable release for production implementations, with core profiles and narrative guidance. HL7

Why it matters for Xt-EHR

- Establishes a common, FHIR-based schema for genomic results exchange across Member States.
- Supports AI/CDSS by making genomic findings structured, explainable, and auditable alongside clinical data. FHIR Build

5 OUTCOME AND IMPACT

Milestone 16 delivers a concrete roadmap for connecting **AI, genomics, and EHRs** in a secure and interoperable manner.
By combining **technical standards**, **semantic harmonization**, and **ethical governance**, these efforts lay the foundation for **AI-enabled, personalized medicine across Europe**.
This milestone brings the vision of the **European Health Data Space** closer to reality, where patients' **clinical, genomic, and lifestyle data** work together to support smarter, safer, and more personalized healthcare for all Europeans.

6 CONCLUSION

Task 5.2 establishes the foundation for safe and interoperable use of AI within clinical workflows. By defining clear data requirements, technical standards, and semantic models, it enables EHR systems and AI tools to communicate seamlessly and transparently.
Through initiatives like **Gen2EHR**, this work also extends interoperability to genomic and bioinformatics data—unlocking new possibilities for **AI-driven precision medicine**.
Together, these efforts strengthen Europe's capacity to deliver trustworthy, data-driven healthcare and bring the vision of the **EHDS** closer to reality.