openEHR and HL7® FHIR® in Europe

Evidence, Architecture and Procurement Implications

Executive Brief

Document 2 · Dr Kai U. Heitmann · Release 1.54.1 – 7 September 2026

Written for: Health-system executives, CIOs, chief medical information officers, enterprise architects, procurement leaders and clinical informatics specialists.

For the decision in one page see Document 1. The derivation is in Document 3 and the graded source ledger in Document 4. The full set is listed at the end of this brief.

Contents

Introduction

Clinical software must, among other things, do two different things with patient data. The two are connected, but they should not be confused.

KEEPING DATA	HANDING DATA ON
The model in which an organisation retains clinical information over time – stores it.	The standardised representation in which one system makes information available to another – exchanges it.

For the European data exchanges examined in this assessment, current EHDS implementation work, cross-border specifications and German requirements use HL7 FHIR. This establishes the exchange method for them. It does not prescribe the model in which every organisation keeps its clinical record.

The storage decision therefore remains open. The authoritative record may be held in a proprietary model, in FHIR, in openEHR, or in an architecture that combines these models. Each additional governed representation creates obligations for transformation, validation, change management and maintenance. A later change of the authoritative model is a migration, not a configuration change.

Decision in brief

What is being decided is which clinical model holds the data authoritatively, not whether HL7 FHIR or openEHR is the better standard. The recommendation below applies where that model can still be chosen, and its scope is set out under *Scope of the recommendation*.

> **For genuinely new infrastructure, FHIR should be the common storage and exchange model. An additional openEHR layer is justified only where a demonstrated domain benefit outweighs the continuing transformation, validation and maintenance obligations.**

The default rests on more than removed model boundaries. FHIR has a clear lead in regulatory adoption, implementation breadth, size and engagement of its community, tooling and workforce availability. Those are material procurement and operating considerations, and they are not evidence of greater clinical effectiveness (§ 1.2, Finding 3).

Existing estates, secondary-use platforms and environments with established openEHR capabilities may reasonably reach a different conclusion. The decision should therefore be based on the authoritative storage of the clinical content, the required conversions and their lifecycle consequences, not on a general contest between standards.

Interoperability is more than this decision. Exchanging data in a standard format, or storing them in one, is only one aspect of interoperability. It also takes

- the preservation of clinical meaning,
- models constrained tightly enough to be testable and implemented consistently,
- governed terminology,
- validated transformations,
- tested conformance,
- receiving processes that can use the information safely, and
- adequate governance for the production of specifications and the quality assurance of implementations.

This assessment examines the conditions that the choice and governance of clinical data models materially affect: the authoritative storage model, the number of governed model boundaries a record crosses, profiling depth, terminology binding, mapping validation, portability and lifecycle governance. Workflow integration, usability and clinical outcomes are not evaluated here. They depend on applications, configuration and professional practice as much as on standards.

Two standards, different purposes

FHIR and openEHR overlap, but they start from different design priorities:

- **FHIR** structures health data for exchange and application use. It is also used for persistent repositories.
- **openEHR** structures longitudinal clinical records through a stable reference model and governed clinical content models.

The practical question is therefore not simply *openEHR or FHIR?* It is where clinical data are first written, which model remains authoritative and how many governed model boundaries the data must cross before use.

Five architectural arrangements

The following five arrangements are useful ideal types. They cover the principal combinations examined here but are not an exhaustive taxonomy of clinical systems.

	AUTHORITATIVE CAPTURE AND PERSISTENCE	PATH TO THE REQUIRED FHIR REPRESENTATION	MINIMUM GOVERNED CONVERSIONS	EVIDENCE STATUS
A	Clinical content is captured and retained in a proprietary model	Proprietary model → FHIR when required	**1, transient**	Common architecture in existing installations
B	A proprietary source remains authoritative and is replicated into a persistent FHIR repository	Proprietary model → FHIR store	**1, persisted**	Demonstrated at infrastructural scale and commercially offered
C	Clinical content is captured and retained authoritatively in FHIR	Direct use of the authoritative FHIR representation	**0**, if compatible with the required exchange profile	Testable requirement; one vendor states that it has established this method, but this is not demonstrated independently
D	A proprietary source remains authoritative and is replicated into openEHR before FHIR is produced	Proprietary model → openEHR → FHIR	**2:** one persisted and one transient	Documented in particular integration paths, not as a universal openEHR pattern

	AUTHORITATIVE CAPTURE AND PERSISTENCE	PATH TO THE REQUIRED FHIR REPRESENTATION	MINIMUM GOVERNED CONVERSIONS	EVIDENCE STATUS
E	Clinical content is captured and retained authoritatively in openEHR	openEHR → FHIR when required	**1, transient**	A major Norwegian development programme is documented; broad market availability is not established

Five architecture options and how many governed conversions each carries

Each amber arrow is one conversion between separately governed clinical models. Software layers, caches and transport steps are not counted. Every conversion has to be mapped, validated and version-managed for as long as both sides keep changing.

A and E carry the same count and differ only in whose model the store speaks — the case for openEHR is not made on the exchange side. Because exchange is FHIR, a record kept in openEHR is always converted at least once. That follows from the regulatory position, not from technical merit.

Figure 1 — Where the clinical record is written and retained, and the minimum governed conversions needed for the required FHIR representation.

The count concerns conversions between separately governed clinical models, not software layers, caches or transport steps. A conversion counts when an explicit mapping must preserve clinical meaning between independently specified and versioned representations.

Arrangements A and E each require one cross-standard conversion to produce FHIR, and for a receiving system they are indistinguishable at that boundary. A conformant FHIR payload does not by itself reveal which internal model produced it. The architectures are not otherwise equivalent. **The case for openEHR must therefore rest on a demonstrated advantage in modelling depth, governance, reuse or long-term stability.**

For the European data exchanges examined here, the required FHIR representation creates an asymmetry: data held in openEHR must be converted at least once for FHIR exchange, while data held in FHIR can avoid that particular boundary. This follows from the regulatory and procurement context. It does not establish technical superiority.

What the evidence supports — and where it stops

- Large FHIR repositories and operational openEHR platforms demonstrate that both storage approaches are feasible. They do not establish comparative clinical effectiveness.

- Each additional governed model boundary creates continuing effort for mapping, terminology alignment, testing, clinical validation and change management. Published long-term cost evidence is scarce.
- Every conversion introduces a possible source of error and a corresponding validation obligation. No comparative study identified here establishes that two conversions cause more patient harm than one.
- No head-to-head study identified for this assessment compares clinical outcomes or full lifecycle costs of equivalent FHIR-native and openEHR-plus-FHIR architectures.
- Large FHIR repositories do not in themselves demonstrate comprehensive primary documentation, that is, data stored directly as FHIR resources. In most of the examined cases, data originate in primary systems and are extracted and converted into FHIR. One vendor, however, states that it uses direct storage in FHIR as primary documentation; this has not been independently demonstrated so far.
- Deployed scale and product availability establish feasibility to the extent documented. Regulatory adoption adds planning relevance. Neither establishes superior effectiveness.

These limits matter because architectural considerations can conceal the organisational challenges of keeping mappings clinically correct over time. What counts is not only whether a conversion works once, but whether it remains **governed, testable and maintainable** while source systems, profiles and terminologies may change over time.

Mapping is not a one-off project. It is a durable architectural decision.

Scope of the recommendation

Here, **genuinely new infrastructure** means an environment in which the organisation is not constrained by an established clinical repository, entrenched application models or prior contractual commitments, and can still choose its authoritative data model.

The recommendation may not apply in three situations:

- **Existing systems:** Replacing a functioning architecture may cost more and create more risk than improving its interfaces and governance.
- **Secondary platforms:** Research, analytics and cross-organisational platforms may justify a separate canonical model because their purpose differs from primary documentation. The resulting secondary representation and its continuing maintenance should be explicit.
- **Dedicated or specialised environments:** Established openEHR capabilities or a demonstrated need for its modelling and governance approach may outweigh the additional FHIR boundary.

Questions for a procurement decision

1. Where is the authoritative clinical record?

Identify the model in which each clinical fact is first committed and from which the other representations can be reconstructed.

2. How is every conversion clinically validated?

Require representative sets of clinical test data, named responsibility, regression testing and controlled treatment of unmappable content. Demand evidence that changes in source models, profiles and terminology bindings do not go unnoticed.

3. How precisely are profiles and terminologies governed?

Require enforceable field constraints, versioned value sets, explicit bindings and automated validation. Formal conformance without sufficient profiling does not ensure usable interoperability.

4. Can the organisation terminate the contract and take both data and meaning with it?

Secure export and continued use of data, profiles, templates, mappings and terminology assets. Vendor neutrality depends on governance, intellectual-property rights, skills and exit provisions, not on the standard alone.

5. What obligations arise over ten years?

Compare the full cost of modelling, mapping, validation, upgrades, migration and supplier change. Initial implementation cost alone does not carry the architectural choice.

What would change this recommendation

The recommendation should be reconsidered if comparative evidence shows lower lifecycle costs, better model reuse, greater clinical completeness or better long-term stability for an openEHR-plus-FHIR architecture, or if FHIR-internal complexity removes the assumed advantage. A material change in European exchange requirements would also alter the regulatory basis of the judgement.

Evidence and method

The supporting evidence register, architecture analysis and procurement criteria are set out in Documents 3 to 5 of the separately published assessment set. Document 6 records what the standards communities, specification bodies and researchers would have to supply to close the evidence gaps this brief has to state as open.

The assessment distinguishes demonstrated operation from claimed benefit, separates architectural feasibility from comparative effectiveness and records material evidence gaps. Product and deployment examples are used to establish that an arrangement exists, not to infer clinical superiority. Conclusions are intentionally limited to the evidence and European policy context available at the release date.

The assessment set

	DOCUMENT	WRITTEN FOR
1	**Decision Note**	boards, commercial and political leadership — the decision in one page
2	**Executive Brief**	CIOs, CMIOs, enterprise architecture, informed procurement
3	**Assessment**	interoperability and standards specialists, and anyone checking the derivation
4	**Evidence Annex**	reviewers checking cases, source criticism and the graded source ledger
5	**Technical Report: German FHIR Profile Governance**	the German FHIR profiling and terminology teams, and those responsible in governance structures
6	**Desiderata**	the standards communities, specification bodies, vendors, researchers and funders

Documents 1, 2, 5 and 6 are also available in German.

Method, and the use of a large language model. The literature search, the collation of sources, the drafting, and the consistency and readability checking across versions of this set were carried out with the assistance of a large language model. The editorial pass that set paragraph and sentence structure was made after the findings were fixed and did not change them. Not all of the cited literature was read in full: for part of it a summary extract was the working basis, and Appendix G of Document 4 records source by source which basis applies. Document 4 also states the limits of the method in full, including what a re-derivation of the evidence grades can and cannot establish. The grading rule, its application, the assessment and the conclusions are the author's, as is responsibility for any error that remains.

Transparency. The author is CEO of HL7 Deutschland, a Senior Expert and Community Event Manager at HL7 Europe, and a member of the ART-DECOR Expert Group. Those roles bear on a document that recommends a FHIR-native default, and they are stated for that reason. ***The assessment presented here is his personal professional view as an interoperability expert and does not represent an official position of HL7 Deutschland or HL7 Europe.***

The assessment aims at fair treatment of both standards, states the limits of the evidence explicitly on both sides, and marks the point at which description ends and the author's judgement begins.