Decision Note

Document 1 · Dr Kai U. Heitmann · Release 1.54.1 – 7 September 2026

Written for: Hospital boards, commercial leadership and political decision-makers.

The decision

Clinical software must, among other things, do two different things with patient data. **Exchange** is the standardised representation in which data leave one system and can be processed by another. **Storage** concerns the model in which an organisation retains its clinical data. For the European data exchanges examined here, the implementation work on the European Health Data Space (EHDS) and the German specifications use HL7 FHIR without prescribing the internal storage model. The authoritative record may be held in a proprietary model, in FHIR, in openEHR, or in an architecture that combines these models.

The recommendation

> **For genuinely new infrastructure, FHIR should be the common storage and exchange model. An additional openEHR model is justified only where a demonstrated benefit in clinical modelling or governance outweighs the continuing burden of transformation, validation and maintenance.**

Every governed conversion between clinical models must be specified, maintained and clinically validated. It creates continuing effort and another possible point of semantic failure. The number of conversions is an architectural indicator, not a measure of cost or safety: one badly governed conversion can be more hazardous than two well-governed ones.

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

Using FHIR for both at once can remove one cross-standard boundary where the stored representation is compatible with the required exchange profile. It does not remove source-system mappings or differences between FHIR profiles.

The default also reflects FHIR's stronger regulatory anchoring and its broader present ecosystem of implementations, tooling and skills. Those advantages bear on procurement and operation.

This is a reasoned judgement, not a finding of superiority. Persistent FHIR repositories and operational openEHR platforms have both been demonstrated at scale, and no comparative study of clinical outcomes or complete lifecycle costs was identified for equivalent architectures.

Where it does not apply

- **Existing systems.** Replacing a functioning architecture may cost more and create more risk than improving its interfaces and governance. Its internal model alone is not sufficient reason for replacement.
- **Not every new project.** A newly funded or tendered project that writes into an existing store has no open storage decision.
- **Secondary platforms.** Where data are copied out for research or reporting, one conversion is needed in any case.

Three questions for the decision

1. How many **governed conversions** lie between clinical capture and use, and **is each one necessary**?
2. How are the **models**, the **terminology** and every **conversion validated**, so that defined safety-critical meaning is preserved and stays **consistent** across **versions**?
3. After a change of supplier, do the **data** and the **models** needed to interpret them remain **available**?

The answers belong in the contract: clinical validation, version maintenance, data export and long-term model availability.

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