

The handoff from a trial DHT into an EHR, EDC or RTSM is itself in regulatory scope: a validated interface with its own mapping, test evidence and audit trail — not plumbing.

Attribution, original capture time and audit trail must survive the transfer, not be regenerated on arrival. **Map every element from capture to each handoff, name one system of record per element, bring the interface and its semantic mapping into computerized-system validation, and keep the interface inside change control.**

THE PICTURE Five boundaries recur — each with a named risk and the deliverable that retires it

Boundary	Common risk	Validation deliverable
Device → EDC	Receipt time overwrites capture time	Validated mapping + transfer audit record
Device / site → EHR	Mismatched patient identity	Verified identity mapping + reconciliation log
EHR → EDC (eSource)	Transferred data diverge from the care record	Validated transfer spec + traceability matrix
Device → RTSM / IRT [decisional]	Late or wrong trigger fires	End-to-end validation with timing and failure-mode tests
System → eTMF / CTMS	Incomplete record transfer	Completeness check + index reconciliation

The device → RTSM / IRT row carries the highest consequence if timing or correctness fails. Which boundaries exist in a given study is a matter for structured assessment of that data architecture.

QOINTA'S POSITION Four positions that turn a data feed into a regulated boundary

The interface is the unit, and the transfer must be validated

Validation cannot stop at the two systems it connects; the boundary and the mapping across it are in scope

(EMA/INS/GCP/112288/2023 s.6.1.2; ICH E6(R3) s.4.2.5).

Standards fix the structure, not the meaning

FHIR packages and requests data; it does not guarantee a field means the same thing, in the same units and coding, on each side. A correctly transported, wrongly mapped value arrives looking valid.

Exactly one system of record per element

Every other copy is traceable to it through a validated transfer, with a certified-copy procedure where a copy replaces an original. In qointa's experience, ambiguity here is the most common root of reconciliation failure.

The principle is common; the source-location rule is not

FDA locates DHT source data in the durable repository and does not intend to inspect individual DHTs; the EMA guideline expects device-side controls and records both capture and save time.

SIX STEPS, IN THE ORDER THE EVIDENCE IS BUILT

- 1 Map the data flow** — trace each element from capture on the device through every handoff into EHR, EDC, RTSM and beyond.
- 2 Classify the source** — name the system of record per element and where the record becomes source in each region.
- 3 Validate the interface** — bring the boundary and its semantic mapping into computerized-system validation, not just the endpoints.
- 4 Preserve provenance** — carry attribution, original capture time and the audit trail across the transfer, ALCOA++ intact.
- 5 Use fit interoperability standards** — apply FHIR where the receiving system exposes it, then validate the mapping, not just the transport.
- 6 Keep the interface inside change control** — with revalidation triggers covering the mapping as well as the connection.

Read with care. Validation depth follows consequence — decisional and endpoint feeds attract the fullest validation — but this is qointa's application of the risk-proportionate approach in ICH E6(R3) s.4.3 and the EMA guideline; neither sets a tariff.

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Summary of QPP-20 1.0 — the full paper, with sources and figures, is published at qointa.com.

EMA/INS/GCP/112288/2023 · ICH E6(R3) and Annex 2 · 21 CFR Part 11 · FDA Part 11 Q&A (Oct 2024) · FDA DHT guidance · HL7 FHIR · ONC/ASTP HTI-1 · 21st Century Cures Act · European Health Data Space Regulation · GDPR

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