

The source record is the repository, not the device — which puts **your integration boundary**, not the device, at the center of the evidence.

Under FDA the source data live in the durable electronic data repository and FDA does not intend to inspect individual DHTs; the EMA guideline still expects device-side controls. **Either way the interface is in validation scope, not just the systems it connects** — provenance, timing and audit context must survive the handoff.

THE PICTURE Four perimeters meet at the handoff, and each has an evidence artifact

Perimeter	What it means for you	Vendor action / evidence
Data integrity	Provenance, timestamps and audit trail across the handoff	Map and validate provenance fields; reconcile the two audit trails
Interoperability	The integration boundary is part of the system	Bring the interface into the validated system boundary
Inspection	The handoff is examined as evidence for the record	Hold boundary evidence — mapping, tests, reconciliation — ready
Change control	Interface changes on either side are change events	Treat interface changes as change events; revalidate

The data-integrity row is flagged because provenance lost at the boundary cannot be recovered downstream. Read from the EDC, eCOA and RTSM / IRT seat — the platforms that receive device data.

QOINTA'S POSITION Four facts about the handoff decide whether your platform is defensible

The interface is in scope

The integration between the device and your system must be validated, not only the systems at either end.

Provenance must survive the handoff

Source, original capture time and attribution cannot be lost in transit — and silent metadata loss must be tested for, not assumed away.

Two audit records meet at the seam

In qointa's assessment device-side and system-side records should be reconcilable; no instrument prescribes the method.

You inherit upstream integrity

A validated platform can still receive data it cannot account for — and the sponsor remains ultimately responsible for the trial data either way.

SIX MOVES, IN ORDER OF WHAT BREAKS FIRST

- 1 Bring the boundary into validation scope** so the interface is validated, not just the endpoints it connects.
- 2 Map provenance field by field** so source, time and attribution survive the handoff rather than dropping silently.
- 3 Test for silent metadata loss** with negative tests confirming no drop of timestamps or audit context in transfer.
- 4 Reconcile the two audit trails** so device-side and system-side records align at the seam.
- 5 Treat interface changes as change events** so an integration change never breaks provenance unnoticed — revalidate.
- 6 Hold the boundary evidence package ready** — mapping, tests, reconciliation and change records — for audit or GCP inspection.

Read with care. Reconciling device-side and system-side audit records is qointa's recommendation, not a requirement: no instrument prescribes the method. The EU position differs from FDA's — the EMA guideline expects device-side controls.

READ NEXT

QPP-00 Regulatory Impact Assessment (Section 12) · QPP-20 EHR Integration · QPP-10 Data Integrity · QPP-14 Interoperability · QPP-06 Inspection-Readiness · QPP-07 Change Control

