

An inspection of a digital trial follows the record, not the device — and the sponsor still has to evidence the journey from capture to repository.

For FDA the source data sit in the first durable repository, and FDA does not intend to inspect individual DHTs where data and metadata arrive under the prespecified plan; the EMA guideline still expects device-side controls evidenced, BYOD included. **Build the inspection story around the data flow months ahead — none of it can be reconstructed on the day.**

THE PICTURE Inspection tests four perimeters at once, each with a named artifact

Perimeter	What it covers	Evidence to hold (qointa's view)
Inspection	What FDA (BIMO), EU competent authorities and the MHRA examine	The data flow and its controls: transfer plan, metadata, validation
Data integrity	Device-side audit trail, time and attribution	Audit trail incl. own devices; external, non-modifiable time source
Change control	Whether updates were controlled and documented	A trail for each app / OS change and its impact on the validated state
The record	Whether the assessment is explicit, versioned and available	A versioned assessment producible from the Trigger Register on request

The evidence column is qointa's view of what to hold, not a statement of what any inspectorate will ask. Illustrative composite — not a specific study.

QOINTA'S POSITION Four things an inspection of a digital trial actually tests

The record is examined; the device generally is not

FDA does not intend to inspect individual DHTs for source-data verification. The EMA guideline nonetheless expects device-side controls — security, time source, audit trail — evidenced.

BYOD is inside scope

Participants' own devices fall within the EMA computerized-systems guideline, so audit trail, attribution and time source must hold there as on provisioned handsets, wearables and gateways.

Device status is decided elsewhere

A GCP inspector does not classify a device: in the EU the competent authority and, under MDR Art. 4, the Commission after consulting the MDCG; in the US FDA CDRH, with the IRB making the initial SR determination.

Gaps cannot be closed on the day

Audit trail, time source and change history were fixed months before the inspection was announced; evidence that cannot be produced on request will be treated as absent.

FIVE PREPARATIONS MAKE THE RECORD PRODUCIBLE BEFORE ANYONE ASKS

- Bring BYOD inside scope** — participants' own devices must carry the same audit trail, attribution and time controls as provisioned ones.
- Make the record producible in advance** — audit trail, time source, transfer plan and validation evidence available on request.
- Document every change** — a controlled, assessed trail for each app / OS update and its impact on the validated state.
- Keep the assessment record current** — explicit, versioned and producible from the Trigger Register.
- Be able to explain your controls** — a documented account of each control, its basis and its owner, read from the record, not improvised.

Read with care. This is qointa's reading of published expectations, not the view of FDA, any EU competent authority, the MHRA or any other regulator. That unproducible evidence counts as absent is qointa's assessment of the GCP position.

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