

The Inspection Lens

A companion reading on what an inspection of a digital trial actually examines — and where the evidence has to be built long before it

Prepared for	Sponsors, CROs and quality functions preparing for inspection — framed through the inspector's lens.
Subject	What an inspection of a digital trial examines, where the US and EU positions on device-side source data diverge, and the evidence a sponsor should hold before one is announced.
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Executive summary

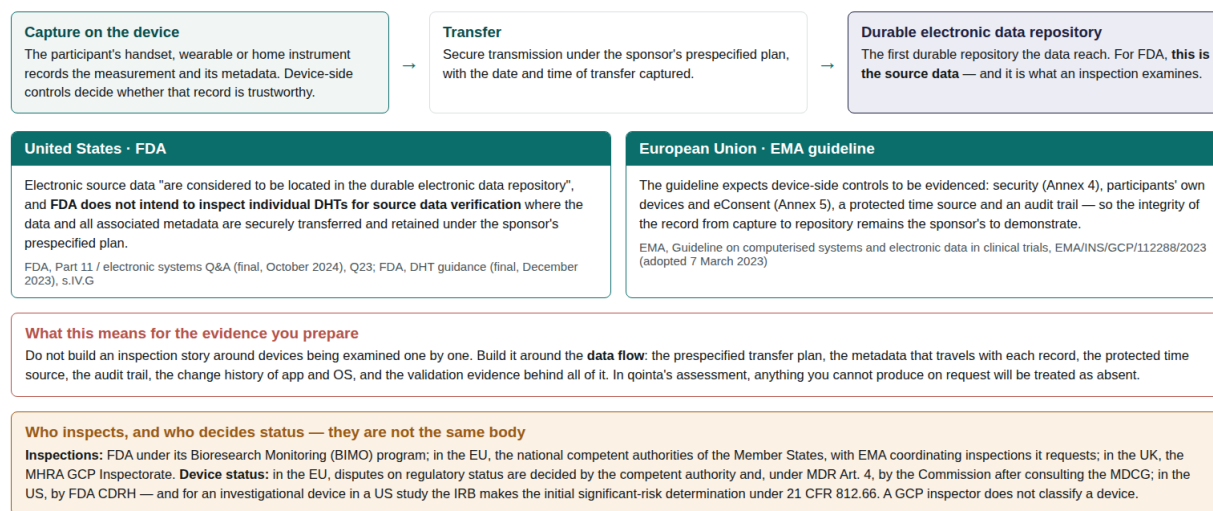
The answer. An inspection of a digital trial follows the record, not the device. Under FDA's position the source data are those held in the first durable electronic data repository, and FDA does not intend to inspect individual digital health technologies for source-data verification where the data and all associated metadata reach that repository under the sponsor's prespecified plan. The EU position is not identical: the EMA computerized-systems guideline expects device-side controls to be evidenced, so the integrity of the record from capture to repository remains the sponsor's to demonstrate.

What that means for preparation. Build the inspection story around the data flow — the prespecified transfer plan, the metadata that travels with each record, the protected time source, the audit trail, the change history of app and operating system, and the validation evidence behind all of it. Participants' own devices are inside the scope of the EMA guideline, so BYOD is not a gap you can leave undocumented.

What to do. Most of these properties are fixed months before an inspection is announced, and none of them can be reconstructed on the day. In qointa's experience the sponsors that inspect well are the ones that can produce the record and explain how it traveled — which is what the Trigger Register (QPP-08) is for.

Inspection follows the record, not the device — the source data sit in the durable repository, and the sponsor still has to evidence the journey there

What an inspection examines in a digital trial, and where the US and EU positions diverge.



Prepare the record and the story of how it traveled — not a demonstration of the device.

Illustrative composite — not a specific study. This figure sets out qointa's reading of published guidance; it does not represent the view of any regulator.

Figure 1 — Inspection follows the record, not the device: the source data sit in the durable repository, and the sponsor still has to evidence the journey there. Illustrative composite — not a specific study.

1. An inspection tests the record and the controls behind it, not the devices

This is a companion edition of qointa's position-paper series, read through the inspection lens. An inspection of a digital trial examines the trial record and the controls that produced it: the audit trail, the time source, the transfer plan, the change history and the validation evidence — including for data captured on participants' own devices.

It is written for sponsors, CROs and quality functions — **so the evidence is built before an inspection, not during it**. It describes qointa's reading of published expectations; it does not represent the view of FDA, any EU competent authority, the MHRA or any other regulator.

How this fits the full framework

This companion reads the series through the inspector's lens — the perimeters an inspection actually tests. The ties that matter most are:

- **QPP-06 — Inspection-Readiness.** The lens itself: what FDA (BIMO), EU competent authorities and the MHRA examine in a digital trial, and the evidence that answers it.
- **QPP-10 — Device-Side Data Integrity.** Audit trail, time source and attribution for data captured on a device — what the inspection examines.
- **QPP-07 — Change Control.** Whether app and OS updates were controlled and documented, or surface as an uncontrolled gap.
- **QPP-08 — Trigger Register.** What makes the assessment explicit, versioned and producible on demand — the record behind the evidence.

Regulatory basis

This edition summarizes the position set out in QPP-06 — Inspection-Readiness, QPP-07 — Change Control, QPP-08 — Trigger Register and QPP-10 — Device-Side Data Integrity; the sources are cited there in full. The load-bearing sources for the inspection position are:

- FDA, Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers (final, October 2024) — Q23: source data for a DHT are located in the durable electronic data repository; FDA does not intend to inspect individual DHTs for source-data verification.
- FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final guidance, December 2023) — s.IV.G (source data and the durable repository); s.IV.H.4 (changes to DHTs during a study).
- EMA, Guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023, adopted 7 March 2023) — written by the EU GCP Inspectors Working Group; Annex 4 (security), Annex 5 (specific systems, incl. participants' own devices and eConsent), s.5.5 (date and time), audit-trail requirements.
- ICH E6(R3) Principles and Annex 1 (Step 4, 6 January 2025; EU effective 23 July 2025) and Annex 2 (Step 4, 3 June 2026; EU effective 15 January 2027) — what GCP inspections are conducted against.
- Regulation (EU) 2017/745 (MDR) Art. 4 — regulatory-status determinations by the competent authority and the Commission after consulting the MDCG. 21 CFR 812.66 — the IRB's significant-risk determination in a US study.
- Who inspects: FDA under its Bioresearch Monitoring (BIMO) program; in the EU, the national competent authorities of the Member States (EMA coordinates the inspections it requests but does not itself inspect); in the UK, the MHRA GCP Inspectorate.

This edition describes qointa's reading of these published sources. It does not represent the view of any regulator or inspectorate.

2. Four things an inspection of a digital trial actually tests

- The record is examined; the device generally is not. For FDA the source data are those in the first durable electronic data repository, and individual DHTs are not inspected for source-data verification. The EMA guideline nonetheless expects the device-side controls — security, time source, audit trail, participants' own devices — to be evidenced.
- **BYOD is inside scope.** Participants' own devices fall within the EMA computerized-systems guideline, so the audit trail, attribution and time source must hold there as they do on provisioned handsets, wearables and gateways.
- **Device status is decided elsewhere.** A GCP inspector does not classify a device. In the EU, regulatory-status disputes are decided by the competent authority and, under MDR Art. 4, by the Commission after consulting the MDCG; in the US, by FDA CDRH, with the IRB making the initial significant-risk determination for an investigational device in a study.¹
- **Gaps cannot be closed on the day. The audit trail, the time source and the change history were fixed months before the inspection was announced, and none of them can be reconstructed retrospectively.**

¹ FDA, Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers (final, October 2024), Q23: "FDA does not intend to inspect individual DHTs for source data verification" and, for DHTs, "electronic source data are considered to be located in the durable electronic data repository". FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final guidance, December 2023), s.IV.G.

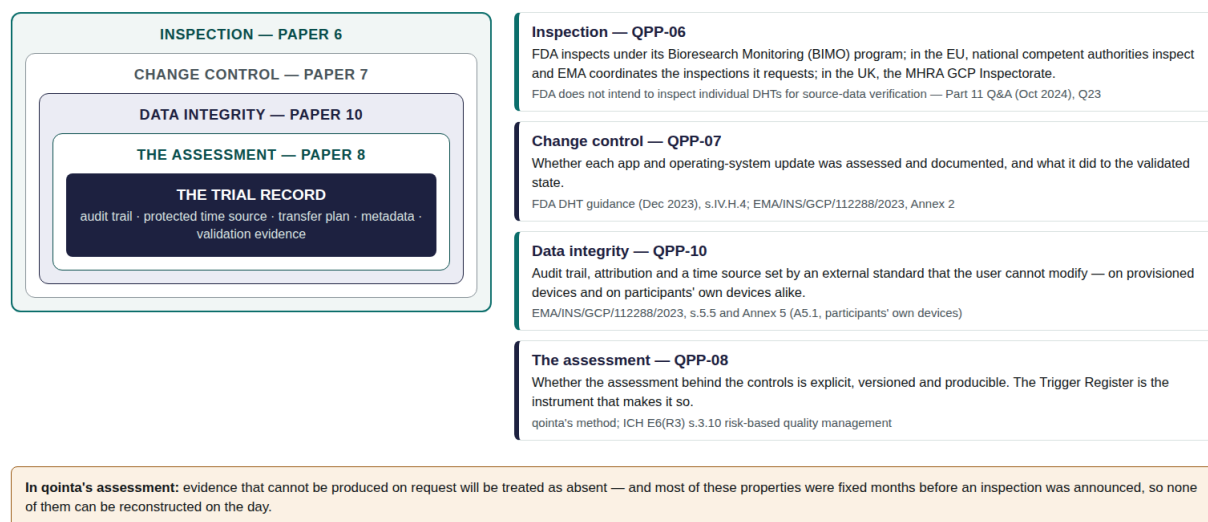
3. An inspection tests four perimeters at once, and each has a named evidence artifact

An inspection tests several perimeters at once, with the trial record at the center. Each maps to a paper, and to a named evidence artifact. The fourth column is **qointa's view of the evidence to hold**, not a statement of what any inspectorate will ask.

Perimeter / topic	What it covers	Paper	Evidence to hold (qointa's view)
Inspection	What FDA (BIMO), EU competent authorities and the MHRA examine in a digital trial.	6	The data flow and its controls: prespecified transfer plan, metadata, validation evidence — producible on request. FDA does not intend to inspect individual DHTs for source-data verification.
Data integrity	Device-side audit trail, time and attribution.	10	Audit trail (including participants' own devices), a time source set by an external standard and not user-modifiable, and clear attribution of each entry.
Change control	Whether updates were controlled and documented.	7	A documented trail for each app / OS change and its impact on the validated state.
The record	Whether the assessment is explicit, versioned and available.	8	An explicit, versioned assessment producible from the Trigger Register on request.

Four perimeters, one question: can you produce the record, and the control that made it?

An inspection reads every inner perimeter through the same outer lens. The artefact at the center is the trial record — not the device.



Prepare the record and the account of the control behind it; the device is not the exhibit.

Illustrative composite — not a specific study. This figure sets out qointa's reading of published guidance; it does not represent the view of any regulator.

Figure 2 — An inspection reads every inner perimeter through one outer lens: can the record, and the control behind it, be produced? Illustrative composite — not a specific study.

4. Three habits produce findings: excluding BYOD, holding no producible evidence, and improvising the account

- **Treating BYOD devices as out of scope.** Participants' own devices are within the EMA computerized-systems guideline; leaving the audit trail and attribution undocumented there is a gap by design.
- **No producible evidence.** In qointa's assessment, evidence that cannot be produced on request will be treated as absent — the ordinary GCP position that what is not documented was not done.
- **Improvising the account.** Explaining a control for the first time in the inspection room, with no documented basis behind it, invites the follow-up question you cannot answer.

5. Five preparations make the record producible before anyone asks for it

Five preparations make the trial record producible before anyone asks for it. The box below is the short form; it repeats nothing that is not here.

- **Bring BYOD inside scope** — participants' own devices must carry the same audit trail, attribution and time controls as provisioned ones (QPP-10 — Device-Side Data Integrity).
- **Make the record producible in advance** — audit trail, time source, transfer plan and validation evidence available on request (QPP-06 — Inspection-Readiness).
- **Document every change** — a controlled, assessed trail for each app / OS update (QPP-07).
- **Keep the assessment record current** — explicit, versioned and producible from the Trigger Register (QPP-08 — Trigger Register).
- **Be able to explain your controls** — a documented account of each control, its basis and its owner, so the explanation is read from the record rather than improvised.

Inspection-readiness checklist — the trial record

Five artifacts to have producible on request, built long before an inspection is announced (Figure 1):

- **Audit trail.** Who entered or generated what, and when — on every device, including participants' own.
- **Time-source evidence.** How the device clock is set and trusted, and how timestamps are bound.
- **Change documentation.** A trail for each app / OS change and its assessed impact on the validated state.
- **The assessment record.** Explicit, versioned, and producible from the trigger register (QPP-08).
- **The control account.** A documented explanation of each control and its basis, so the account given at inspection is read from the record.

6. What this means for the sponsor

The record an inspection examines is made months earlier, in the transfer plan, the time source, the audit trail and the change history. A sponsor that can produce those artifacts and explain how each was controlled has answered most of the inspection before it opens; one that cannot will be explaining

absences. The **Trigger Register (QPP-08)** is the instrument qointa uses to keep that assessment explicit, versioned and producible.

Contact qointa

To prepare the trial record and the control account before an inspection is announced, get in touch with the qointa team: **info@qointa.com**

Scope and status

This is a companion edition summarizing qointa's position-paper series from one stakeholder's perspective, keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). It summarizes the position set out in the numbered papers, where the sources are cited in full. It describes qointa's reading of published regulatory expectations and does not represent the view of FDA, any EU competent authority, the MHRA or any other regulator. It is not legal advice; the detail and the current framework references live in the numbered papers, and any specific position should be confirmed with qualified regulatory counsel.