

The Sponsor's Accountability Map

A companion reading from the sponsor's seat — what you can delegate the work of, and what you answer for regardless

Prepared for	Sponsor leadership, clinical development, regulatory affairs, QA and vendor management.
Subject	The sponsor's accountability across the regulatory perimeters of a digital trial.
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Executive summary

You can transfer every activity in a digital trial. You cannot transfer the answer you give at inspection. ICH E6(R3) puts the ultimate responsibility for the reliability of the trial data with the sponsor, whoever performs the work — so the perimeters this series describes are, from your chair, a single map of obligations you own across every device maker, vendor, CRO and site.

Treat "no obligation" as a conclusion you can produce, not an assumption from the hardware label. A consumer handset, a CE-marked wearable, a home instrument on a cellular gateway and an eCOA app each raise a different question, and each setup answers it differently; one party's assessment does not discharge yours. An inspector will not ask what you believed about the device — FDA (BIMO), the EU national competent authorities and the MHRA all ask what you assessed, when, and on what basis.

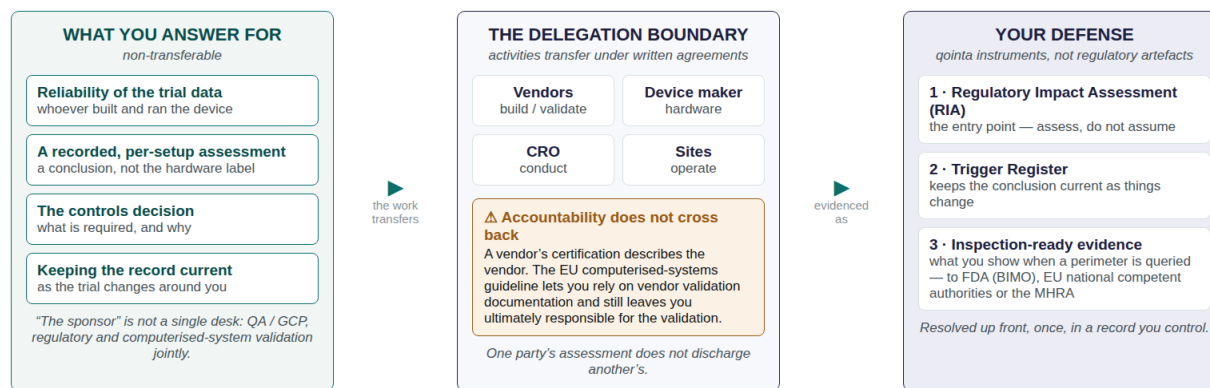
Do four things. Run a Regulatory Impact Assessment (RIA) before the controls are fixed, so every "no obligation" is a dated conclusion. Own vendor oversight as your own activity, because a vendor's certification describes the vendor and you remain ultimately responsible for the validation of the systems you use.¹ Keep a Trigger Register so a model, routing or scope change reopens the right assessment rather than surfacing as an inspection finding. And name internal owners across QA / GCP, regulatory affairs and computerized-system validation, because "the sponsor" is not a single desk.

¹ ICH E6(R3), Annex 1 s.3.6.6 (Step 4, 6 January 2025; EU effective 23 July 2025): a sponsor may transfer any or all of its trial-related activities to a service provider, "however, the ultimate responsibility for the sponsor's trial-related activities, including protection of participants' rights, safety and well-being and reliability of the trial data, resides with the sponsor." Principle 10.1 is to the same effect. Verified at https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf. In EU law the same rule is Art. 71 of Regulation (EU) No 536/2014 (the sponsor may delegate tasks but remains responsible). Annex 2 to E6(R3), which covers decentralized and pragmatic elements and real-world data, reached Step 4 on 3 June 2026 and takes effect in the EU on 15 January 2027.

The work crosses the delegation boundary; the accountability does not

You can transfer every activity in a digital trial. You still answer for the data at inspection.

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"No obligation" is a conclusion you can show, not an assumption from the hardware label.

The RIA and the Trigger Register are qointa instruments; no framework requires either by name. Which obligations and evidence apply to a given setup is a matter for structured assessment.

Figure 1 — The work crosses the delegation boundary; the accountability does not.

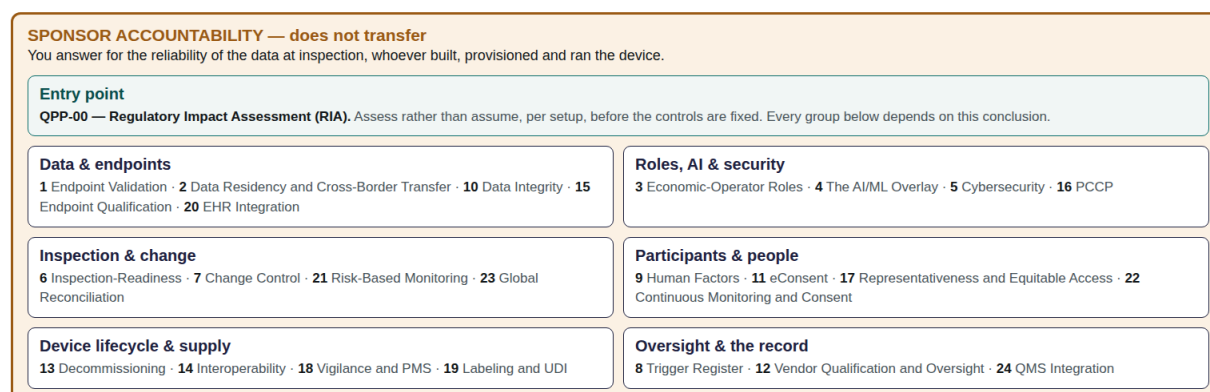
1. The perimeters are one map, and you hold all of it

This edition reads the series from the sponsor's seat. The instruments it recommends — the Regulatory Impact Assessment and the Trigger Register — are qointa's, not regulatory artifacts: no framework requires either by name. What the frameworks require is that the sponsor can show the assessment behind its controls and keep it current, and these are the two documents that do it.

It is written for sponsor leadership, clinical development, regulatory affairs, QA and vendor management. Inside the sponsor the assessment is owned jointly across QA / GCP compliance, regulatory affairs and computerized-system validation (CSV): **"the sponsor" is not a single desk**. Figure 2 sets out the whole series as your map.

Every paper in the series is work you can delegate — inside one band you cannot

The 25 papers of the series, grouped as the sponsor's map of obligations. Each group is execution someone else can perform; the band around them is the sponsor's ultimate responsibility under ICH E6(R3) Annex 1 s.3.6.6.



The map is the sponsor's, whoever does the work: no group below the band is delegable out of your answer at inspection.

Illustrative grouping by qointa. Which papers bear on a given study depends on the setup; one party's assessment does not discharge another's.

Figure 2 — Every paper in the series is work you can delegate — inside one band you cannot.

2. Four propositions decide how a device question ends at inspection

- **Responsibility does not transfer.** You answer for the data at inspection, whoever built, provisioned and ran the device — ICH E6(R3)'s "ultimate responsibility", cited in the summary above.
- **"No obligation" is a conclusion, not an assumption.** It comes from an assessment you can show, not the hardware label.
- **Each setup and stakeholder differs.** One party's assessment does not discharge another's.
- **The record is the defense.** A dated, owned assessment is what converts a belief about the device into evidence an inspector can test.

3. Every perimeter is delegable work wrapped in accountability you keep

Each perimeter is work you can delegate, wrapped by accountability you keep. The added column names the **sponsor action and the evidence** that discharges it — what you do, and what an inspector would expect to see. The assess-vs-assume row is flagged because it is the entry point on which every other row depends.

Perimeter / topic	What it means for you	Sponsor action / evidence	Series paper
Assess vs assume	An assessment was performed and recorded before controls were set.	Complete and date a Regulatory Impact Assessment before controls are fixed.	QPP-00
Endpoints / data	Sensor-derived measures validated; residency and integrity assured.	Hold V3 evidence — verification, analytical validation and clinical validation — plus a data-residency and integrity record. ²	QPP-01, QPP-02, QPP-10
Operator roles, AI and security	Economic-operator roles assigned; where a model runs on or behind the device, AI obligations stack on top of the device ones; security controls owned.	Record who is manufacturer, importer, distributor or system / procedure pack producer for each configuration; record the AI and security controls and their owners.	QPP-03, QPP-04, QPP-05
Inspection / change	Device-side evidence exists and updates are controlled.	Keep device-side evidence; bring updates under change control.	QPP-06, QPP-07
Consent, human factors and decommissioning	Valid eConsent, use-safety and end-of-life device handling.	Evidence valid eConsent, human-factors work and a decommissioning plan.	QPP-09, QPP-11, QPP-13
Oversight / record	Vendors qualified and overseen; the assessment kept current.	Qualify and oversee vendors; maintain a current trigger register.	QPP-08, QPP-12

² EMA, "Guideline on computerised systems and electronic data in clinical trials" (EMA/INS/GCP/112288/2023, adopted 7 March 2023): the responsible party may rely on validation documentation provided by the vendor, but "remains ultimately responsible for the validation of the computerised systems used in clinical trials". https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf

4. Three habits turn a manageable question into an inspection finding

- **Treating a vendor's certification as your oversight.** A certification describes the vendor. Oversight is your own activity, and the validation of the systems you use remains your responsibility however much of the documentation the vendor supplies.
- **Assuming "already a medical device" is settled.** A known device still needs a per-setup assessment.
- **Discovering a crossed perimeter at inspection.** Silent app and operating-system updates and changes to data routing surface at inspection, when they cost the most to fix.

5. Six records evidence accountability before a study opens

Six records evidence accountability before a study opens and keep it current. The completed answers are the record that becomes your defense.

Checklist item	Evidence that it is done
A Regulatory Impact Assessment is complete and dated.	Signed Regulatory Impact Assessment covering each perimeter, dated before the controls were set.
Each "no obligation" is a recorded conclusion.	Assessment rationale, not a reliance on the hardware label.
Vendor oversight is your own activity.	Oversight plan and records distinct from vendor certifications.
Validation and integrity evidence is held.	V3 evidence (verification, analytical validation, clinical validation), data-residency and integrity records on file.
A trigger register keeps the result current.	Register with owners and dates, updated as the trial changes.
Accountability ownership is assigned internally.	Named owners across QA / GCP, regulatory affairs and computerized-system validation (CSV).

RIA-to-trigger-register workflow

How the entry-point assessment stays a live defense rather than a one-off document:

- **Assess (RIA):** perform and record the per-setup assessment across every perimeter, before controls are set.
- **Decide & control:** set the controls the assessment requires, with the rationale captured.
- **Register triggers:** list the changes that would reopen the assessment (model change, routing change, scope change), each with an owner.
- **Monitor & re-assess:** when a trigger fires, reopen the RIA for that perimeter and re-date the record — keeping it current and inspection-ready.

6. The sponsor owns all 25 papers of the series, not a subset

How this edition fits the qointa series

This edition is keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). The sponsor is accountable for every paper in the series, not a subset; they group as follows (Figure 2):

- **Entry point — QPP-00 — Regulatory Impact Assessment (RIA).** Assess rather than assume, per setup, before the controls are fixed.
- **Data and endpoints — QPP-01, QPP-02, QPP-10, QPP-15, QPP-20.** Endpoint validation and qualification, data residency, device-side data integrity and EHR integration.
- **Roles, AI and security — QPP-03, QPP-04, QPP-05, QPP-16.** Economic-operator roles, the AI/ML overlay, cybersecurity and predetermined change control plans.
- **Inspection and change — QPP-06, QPP-07, QPP-21, QPP-23.** Inspection-readiness, change control, risk-based monitoring and global reconciliation.
- **Participants and people — QPP-09, QPP-11, QPP-17, QPP-22.** Human factors, eConsent, representativeness and equitable access, continuous monitoring and participant burden.
- **Device lifecycle and supply — QPP-13, QPP-14, QPP-18, QPP-19.** Decommissioning, interoperability, vigilance and post-market surveillance, labelling and UDI.
- **Oversight and the record — QPP-08, QPP-12, QPP-24.** The Trigger Register, vendor qualification and oversight, and QMS integration.

Regulatory basis

The sources behind this edition. The detail, and the rest of the citations, are in the numbered papers.

- **ICH E6(R3)**, Principle 10.1 and Annex 1 s.3.6.6 (Step 4, 6 January 2025; EU effective 23 July 2025) — activities transfer; ultimate responsibility for data reliability resides with the sponsor. Annex 2 (decentralized and pragmatic elements, real-world data) reached Step 4 on 3 June 2026; EU effective 15 January 2027.
- **Regulation (EU) No 536/2014** (Clinical Trials Regulation), Art. 71 — the sponsor may delegate tasks but remains responsible.
- **EMA/INS/GCP/112288/2023** (adopted 7 March 2023) — the responsible party may rely on vendor validation documentation and remains ultimately responsible for the validation.
- **FDA**, *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations* (final, December 2023) and *Conducting Clinical Trials With Decentralized Elements* (final, September 2024).
- **FDA**, *Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers* (final, October 2024), Q23 — for DHTs, source data are located in the durable electronic data repository, and FDA does not intend to inspect individual DHTs.
- **V3 / V3+**: Goldsack et al., *npj Digital Medicine* 3:55 (2020); Bakker et al., *npj Digital Medicine* 8:51 (2025).

The **Regulatory Impact Assessment** and the **Trigger Register** are qointa instruments, not regulatory artifacts. Everything in this edition that is not attributed to a source above is qointa's professional assessment.

7. Resolve it once, up front, in a record you control

The four actions below are the cheapest form of the same answer: resolve the device questions once, up front, in a record you control, rather than under inspection pressure with a study already running.

- **Run the RIA before fixing controls** so every “no obligation” is a recorded conclusion, not an assumption.
- **Own oversight as your own activity** so a vendor's certification never stands in for your evidence.
- **Maintain a live trigger register** so a model, routing or scope change reopens the right assessment, not an inspection finding.
- **Assign internal owners** so accountability is held jointly across QA / GCP, regulatory and CSV — not left to one desk.

Example oversight statement

A framing a sponsor can record and stand behind at inspection — usable only where each sentence is true of the study, because an inspector will test it against the evidence:

“For each device configuration in this study we performed and recorded a Regulatory Impact Assessment across every perimeter before setting controls. Execution is delegated to qualified vendors under our oversight; accountability for data reliability is retained by the sponsor and owned jointly across QA, regulatory and CSV. A trigger register is maintained so that any change reopens the relevant assessment, keeping the record current.”

8. How qointa can help

qointa runs the Regulatory Impact Assessment with sponsor teams — across device status, endpoints, data residency, operator roles, AI, security, change control and decommissioning — and leaves behind a dated record with named owners and a Trigger Register that keeps it current. We also write the vendor-oversight plan that sits behind it, and rehearse the questions FDA (BIMO), EU national competent authorities and the MHRA ask about device-derived data.

Scope and status. This is a companion edition summarizing qointa's position-paper series from one stakeholder's seat, keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). It summarizes positions set out in full, with sources, in the numbered papers. It is not legal advice; any specific position should be confirmed with qualified regulatory counsel.