

You can transfer every activity in a digital trial. You cannot transfer the answer you give at inspection.

ICH E6(R3) puts ultimate responsibility for the reliability of trial data with the sponsor, whoever performs the work — so the perimeters are one 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.**

THE PICTURE Every perimeter is delegable work wrapped in accountability you keep

Perimeter / topic	Sponsor action / evidence	Series paper
Assess vs assume	Complete and date a Regulatory Impact Assessment before controls are fixed	QPP-00
Endpoints / data	Hold V3 evidence plus a data-residency and integrity record	QPP-01, QPP-02, QPP-10
Operator roles, AI and security	Record who is manufacturer, importer, distributor or pack producer; record AI and security controls and owners	QPP-03, QPP-04, QPP-05
Inspection / change	Keep device-side evidence; bring updates under change control	QPP-06, QPP-07
Consent, human factors, decommissioning	Evidence valid eConsent, human-factors work and a decommissioning plan	QPP-09, QPP-11, QPP-13
Oversight / record	Qualify and oversee vendors; maintain a current trigger register	QPP-08, QPP-12

The assess-vs-assume row is the entry point on which every other row depends. The RIA and the Trigger Register are qointa's instruments, not regulatory artifacts: no framework requires either by name, but every framework requires that you can show the assessment behind your controls and keep it current.

QOINTA'S POSITION 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".

"No obligation" is a conclusion, not an assumption

It comes from an assessment you can show, not the hardware label. FDA (BIMO), the EU national competent authorities and the MHRA ask what you assessed, when, and on what basis.

Each setup and stakeholder differs

A consumer handset, a CE-marked wearable, a home instrument on a cellular gateway and an eCOA app each raise a different question. One party's assessment does not discharge yours.

The record is the defense

A dated, owned assessment converts a belief about the device into evidence an inspector can test. A vendor's certification describes the vendor; oversight is your own activity.

FOUR ACTIONS: RESOLVE THE DEVICE QUESTIONS ONCE, UP FRONT, IN A RECORD YOU CONTROL

- 1 Run the RIA before fixing controls** so every "no obligation" is a recorded, dated conclusion, not an assumption.
- 2 Own oversight as your own activity** so a vendor's certification never stands in for your evidence; validating the systems you use stays yours.
- 3 Maintain a live Trigger Register** so a model, routing or scope change reopens the right assessment, not an inspection finding.
- 4 Assign internal owners** so accountability is held jointly across QA / GCP, regulatory affairs and CSV — "the sponsor" is not a single desk.

25

papers in the series — the sponsor owns all of them, not a subset

6

records that evidence accountability before a study opens and keep it current

4

actions that resolve the device questions once, up front, in a record you control

3

internal functions that jointly own the assessment: QA / GCP, regulatory affairs, CSV

Read with care. Companion edition keyed to Section 12 of QPP-00; it summarizes positions set out in full, with sources, in the numbered papers. The example oversight statement is usable only where each sentence is true of the study — an inspector will test it against the evidence.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-02 Data Residency · QPP-03 Economic-Operator Roles · QPP-06 Inspection-Readiness · QPP-07 Change Control · QPP-08 Trigger Register · QPP-12 Vendor Qualification and Oversight



Summary of S03 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) · FDA (BIMO) inspection · EU national competent authorities · MHRA

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