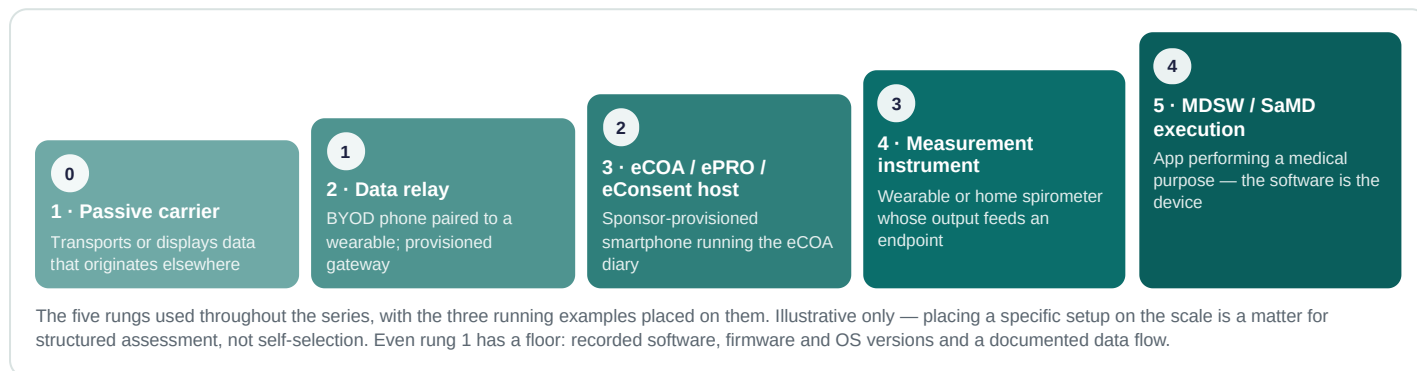


Every device and system a trial relies on needs a Regulatory Impact Assessment — and for most deployments that assessment is short and returns minimal controls.

"It's just a phone", "just the modem", "already a cleared device" are conclusions the assessment can reach; none is an exemption from performing one. **Assess rather than assume: place each device on the role scale, test the triggers, record the controls decision per stakeholder, and re-run it on every material change.**

THE PICTURE Regulatory weight rises with the device's role, not with its hardware



QOINTA'S POSITION Four principles that turn "no RIA needed" from an assumption into a finding

"No RIA needed" is an output, not an input "Merely carries the study" is itself a classification. Only an assessment of the deployment's role and triggers can confirm it; skipping it leaves the risk undetermined and the decision undocumented.	Function, not form factor, sets the obligations The same smartphone is a passive carrier in one study and a measurement instrument or MDSW host in another. One device can sit inside several perimeters at once — obligations stack, they do not substitute.	"Not a device" does not mean "no controls" FDA's 2023 DHT guidance expects verification and validation regardless of whether the DHT meets the device definition; ICH E6(R3) expects computerized systems to be fit for purpose and recorded.	The RIA is proportionate, per-stakeholder and lifecycle Effort scales to the risk found; a sponsor's RIA does not discharge its eCOA, connectivity or MDM vendor's; and the assessment is re-run on material change, not signed off once.
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RECORDED STEPS FIRST, THEN THE PRACTICAL NEXT STEPS

- 1 Identify every device and system** the trial relies on in a non-investigational capacity — phones, gateways, wearables, platforms.
- 2 Establish the role** of each on the five-rung scale and **test the nine triggers** — own-sensor measurement, endpoint feed, medical purpose, eConsent, GCP source data, updates.
- 3 Record the controls decision** — minimal, standard or full device and GxP controls — with its rationale and the owning stakeholder.
- 4 Enter the material-change triggers in a Trigger Register** (QPP-08) and re-assess at each one: updates, new endpoints, new vendor, route or country.
- 5 Keep the sponsor accountable throughout:** under ICH E6(R3) s.3.6 ultimate responsibility for data reliability stays with the sponsor, however much is transferred.

5

rungs on the role scale, from passive carrier to MDSW / SaMD execution

9

triggers that move a deployment up the scale, drawn from seven regulatory perimeters

2 Aug 2028

AI Act device-embedded high-risk obligations apply (Regulation (EU) 2026/1744)

14

Stakeholder Editions (S01–S14) apply the per-party matrix to each role in the chain

Read with care. Not legal advice; the paper does not itself determine device classification. Frameworks cited centre on the EU, US and ICH GCP; likelihood and impact ratings in the exposure table, and Member-State variation, are qointa's judgment and experience.

READ NEXT

QPP-08 Trigger Register · QPP-03 Economic-Operator Roles · QPP-04 AI/ML Overlay · QPP-05 Cybersecurity · QPP-10 Data Integrity · QPP-06 Inspection-Readiness · QPP-23 Global Reconciliation · S01–S14



Summary of QPP-00 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) and Annex 2 · FDA DHT guidance (Dec 2023) · FDA decentralized elements (Sept 2024) · HMA/EC/EMA DCT paper v02 · EU MDR 2017/745 Arts 10–16, 22 · IVDR 2017/746 · MDCG 2019-11 Rev. 1 · AI Act 2024/1689 · Reg. 2026/1744 · 21 CFR Part 11 · EMA/INS/GCP/112288/2023 · GDPR

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