

You hold no clinical-trial obligations — and the trial's regulated evidence is **built on what you publish** about your hardware.

Where trial software runs on your handset, the software manufacturer answers for your hardware's safety, performance and reproducibility in combined use — and can only do so with what you disclose. **An unnotified sensor change invalidates a validated measure mid-study; the study running on your hardware is the one that stops.**

THE PICTURE Each perimeter is someone else's obligation, discharged with your hardware

Perimeter	What it means for you	Why it matters to your roadmap
Endpoint validation (QPP-01)	Sensor specifications feed the V3 evidence chain	Spec stability across SKUs decides whether a validated measure survives a refresh
Change control (QPP-07)	Hardware / sensor change-notification lets the trial manage drift	Notification turns model-year updates into managed events, not stranded studies
Device status and scope (QPP-00)	Qualification follows the software maker's intended purpose, not your hardware	Capability plus published end-of-sale / end-of-support dates set which studies you can support
Interoperability (QPP-14)	Where your handset hubs other devices, its behavior is part of the system	OS / connectivity behavior you ship becomes part of someone's validated system

The change-control row is flagged because an unnotified change is the fastest way to strand a study. Your hardware sits at the core of all four perimeters, upstream of every perimeter others build around the device.

QOINTA'S POSITION Four things you ship decide whether a study can use your range

Sensor specifications are the input to V3 evidence

Performance characteristics per model feed the verification and analytical-validation work a sponsor must complete before a measure supports a claim.

Change notification turns a surprise into a scoped revalidation

Advance notice of a component or model-year change is what separates a managed event from a study-stranding one, months after it shipped.

SKU-to-sensor mapping is the trial's heterogeneity problem

Variation across your range decides which participants a BYOD study can enrol at all.

Lifecycle dates let a sponsor plan a refresh, not discover one

Published end-of-sale and end-of-support dates stop a validated configuration being stranded mid-study.

FOUR DISCLOSURES THAT COST A PUBLISHED DOCUMENT AND A NAMED MAILBOX

- 1 Publish and version sensor specifications** so others can cite a stable source in their validation.
- 2 Notify measurement-affecting changes in advance** so a model-year update is a managed event, not a stranded study.
- 3 Map SKUs to sensor stacks and publish lifecycle dates** so studies can plan around heterogeneity, end-of-sale and end-of-support.
- 4 Name a clinical / regulatory point of contact** so sponsors and vendors have a route to ask and get answers.

Read with care. None of these disclosures is a certification or a compliance cost, and qointa offers no badge. The gait-measure scenario is an illustrative composite, not a specific study. This is not legal advice.

READ NEXT

QPP-00 Regulatory Impact Assessment (s.12) · QPP-01 Endpoint Validation · QPP-04 AI/ML Overlay · QPP-07 Change Control · QPP-14 Interoperability



Summary of S01 1.0 — the full paper, with sources and figures, is published at qointa.com.

MDCG 2023-4 (Oct 2023), Option 3 · MDCG 2019-11 Rev. 1 (June 2025) s.3.1 · FDA DHT guidance (Dec 2023) s.III · EMA/INS/GCP/112288/2023 s.6.1.3 · Regulation (EU) 2024/2847 (Cyber Resilience Act) Arts 2(2), 14 · V3 / V3+ (Goldsack 2020; Bakker 2025)

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