

What the Trial Needs From the Handset Maker

A companion reading from the phone manufacturer / OEM (original equipment manufacturer) seat — what the trial needs from you, and why none of it is your obligation

Prepared for	Smartphone / handset manufacturers and OEMs, and the trial teams that depend on their hardware.
Subject	Why hardware specification, sensor performance and change-notification feed the regulatory evidence other parties must produce.
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Executive summary

You hold no clinical-trial obligations — and the trial’s evidence is built on what you publish. A smartphone sold as a consumer product is not a medical device and its maker is not a manufacturer under the EU Medical Device Regulation or the US Federal Food, Drug, and Cosmetic Act. But where trial software runs on that handset, the software manufacturer becomes responsible for the safety, performance and reproducibility of your hardware in its combined use¹ — a responsibility it can discharge only with what you disclose.

An unnotified sensor change invalidates a validated measure mid-study. Your sensor specifications feed the verification and analytical-validation evidence a sponsor must hold before a measure counts²; the EU computerized-systems guideline requires directly captured data to travel with device metadata — device version, identifiers, firmware version, last calibration³. A change you do not document therefore surfaces as a gap in someone else’s trial record, months after it shipped, and the study that was running on your hardware is the one that stops.

Four disclosures make a handset range trial-ready: publish and version sensor specifications; notify measurement-affecting changes before they ship; map SKUs (stock-keeping units) to sensor stacks and publish end-of-sale and end-of-support dates; and name a clinical / regulatory point of contact. None is a certification and none is a compliance cost. They are what lets a sponsor choose your hardware, defend it to an inspector and keep it in the study through a model-year refresh.

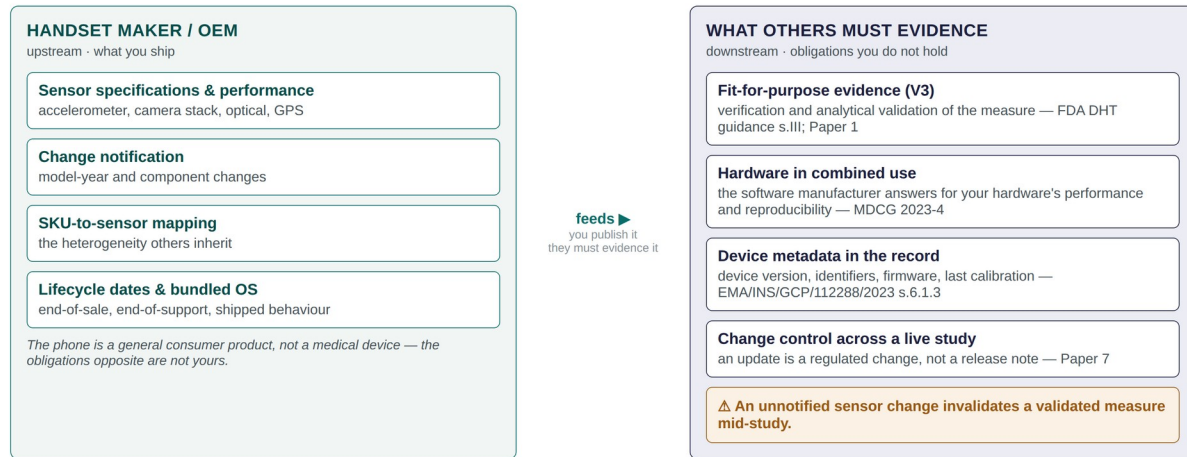
¹ MDCG 2023-4, “Medical Device Software (MDSW) – Hardware combinations” (October 2023), Option 3: where MDSW is intended to run on general consumer hardware with no medical purpose, “the MDSW manufacturer becomes responsible for the safety, performance and reproducibility of the hardware or hardware component in its combined use with the MDSW in all intended configurations”. https://health.ec.europa.eu/system/files/2023-10/md_mdcg_2023-4_software_en.pdf

² J.C. Goldsack et al., “Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs)”, *npj Digital Medicine* 3:55 (2020) (<https://www.nature.com/articles/s41746-020-0260-4>); extended to V3+ with usability validation, Bakker et al., *npj Digital Medicine* 8:51 (2025). FDA, “Digital Health Technologies for Remote Data Acquisition in Clinical Investigations” (final guidance, December 2023), s.III, requires verification and validation of the DHT whatever its device status.

³ EMA, “Guideline on computerised systems and electronic data in clinical trials” (EMA/INS/GCP/112288/2023, adopted 7 March 2023), s.6.1.3 (direct capture): such data “should be accompanied by metadata concerning the device used (e.g. device version, device identifiers, firmware version, last calibration, data originator, timestamp of events)”. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf

You hold no trial obligations — and every one of them is built on what you publish

Four things the handset maker ships; four evidence obligations other parties must discharge using them.



Transparency upstream is the differentiator downstream: the clearer your specification and change behaviour, the cheaper it is to keep your hardware in the study.
Which inputs matter for a given study is a matter for structured assessment with the sponsor and its vendors.

Figure 1 — You hold no trial obligations — and every one of them is built on what you publish.

1. You build a consumer product; the trial builds regulated evidence on it

A handset sold as a consumer product carries no medical-device obligations: qualification and classification follow the intended purpose declared by the manufacturer of the software, not the capability of the hardware it runs on, and the operating system or environment does not affect that qualification at all.⁴ You do hold one live obligation in this space: as the manufacturer of a product with digital elements, the EU Cyber Resilience Act has required you to report actively exploited vulnerabilities and severe incidents since 11 September 2026.⁵

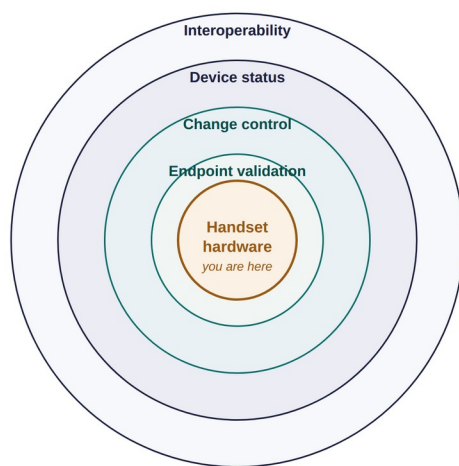
This edition is written for OEM product and regulatory teams, and for the sponsors and vendors who build on their hardware. The series' central view — one device, several perimeters (Figure 2) — locates you at the hardware core, upstream of every perimeter others build around the device.

⁴ MDCG 2019-11 Rev. 1 (June 2025), "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR", s.3.1: "These operating systems, servers, or virtual environments do not impact the qualification of a software"; "the intended purpose, as described by the manufacturer of the software is relevant for the qualification and classification of any device". https://health.ec.europa.eu/document/download/b45335c5-1679-4c71-a91c-fc7a4d37f12b_en?filename=mdcg_2019_11_en.pdf

⁵ Regulation (EU) 2024/2847 (Cyber Resilience Act): reporting obligations apply from 11 September 2026, the main obligations from 11 December 2027; devices covered by the MDR and IVDR are excluded by Art. 2(2), so a consumer handset is in scope.

One device, four perimeters — and your hardware sits at the core of all of them

Each ring is an obligation another party must satisfy. None is yours; each is built on the handset you ship.



Handset hardware & sensors — this edition

Your specifications, SKU mapping, lifecycle dates and change notices seed every ring.

Endpoint validation (V3)

Verification and analytical validation of the measure run on your sensor performance.

Paper 1 — Endpoint Validation

Change control & drift

A model-year change is a regulated study event; your notice is what makes it manageable.

Paper 7 — Change Control

Device status & scope

Qualification and classification follow the software manufacturer's intended purpose, not your hardware — your capability decides feasibility.

MDCG 2019-11 Rev. 1 s.3.1 · Paper 0 — Regulatory Impact Assessment (RIA)

Interoperability & system behaviour

Where the handset hubs other devices, the OS and connectivity behaviour you ship is part of someone's validated system.

Paper 14 — Interoperability

You hold none of these obligations — every one of them is discharged with inputs only you can give.

Illustrative. Which perimeters apply to a given study is a matter for structured assessment.

Figure 2 — One device, four perimeters — and your hardware sits at the core of all of them.

2. Four things you ship decide whether a study can use your range

- **Sensor specifications.** Performance characteristics per model are the input to the verification and analytical-validation work a sponsor must complete before a measure supports a claim.
- **Change notification.** Advance notice turns a component or model-year change from a study-stranding surprise into a scoped revalidation.
- **SKU-to-sensor mapping.** Variation across your range becomes the trial's heterogeneity problem, and in bring-your-own-device (BYOD) studies it decides which participants can be enrolled at all.
- **Lifecycle dates.** Published end-of-sale and end-of-support dates are what let a sponsor plan a device refresh instead of discovering one.

3. Each perimeter is someone else's obligation, discharged with your hardware

Each perimeter below is an obligation another party must satisfy using your hardware as an input. The third column names the product decision on your side that the perimeter turns on. The change-control row is flagged because an unnotified change is the fastest way to strand a study.

Perimeter / topic	What it means for you	Why it matters to your roadmap	Series paper
Endpoint validation	Sensor specifications feed the V3 evidence chain (verification, analytical validation, clinical validation).	Spec stability across SKUs determines whether a validated measure survives a refresh.	QPP-01

Perimeter / topic	What it means for you	Why it matters to your roadmap	Series paper
Change control	Hardware / sensor change-notification lets the trial manage drift.	A change-notification process turns model-year updates into managed events, not stranded studies.	QPP-07
Device status and scope	Qualification and classification follow the software manufacturer's intended purpose, not your hardware; your capability decides feasibility.	Capability, plus published end-of-sale and end-of-support dates, sets which studies your range can support.	QPP-00
Interoperability	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.	QPP-14

4. Three roadmap events can strand a running study

- **Undocumented sensor changes between model years.** A changed accelerometer or camera stack can shift a measure with no notice.
- **Discontinued models.** End-of-sale and end-of-support can strand a validated configuration mid-study.
- **Bundled OS / firmware behavior.** Behavior you ship but do not fully control still reaches the trial.

5. Six disclosures make a handset range trial-ready

A short, repeatable checklist for making a handset range **trial-ready**. It is not a certification and qointa offers no badge: these are the inputs that let others build defensible evidence on your hardware.

Checklist item	What good looks like
Published, versioned sensor specifications.	Performance characteristics per model, with version history.
Change-notification for hardware / sensor changes.	Advance notice of component or model-year changes that affect measurement.
Model / configuration mapping.	Clear map of which SKUs share which sensor stack.
End-of-sale and end-of-support dates.	Published timelines so studies are not stranded.
Bundled OS / firmware behavior documented.	Known behaviors that reach measurement, even if third-party.
A named point of contact for clinical / regulatory queries.	A route for sponsors and vendors to ask and get answers.

Recommended disclosure template (illustrative)

A lightweight per-model disclosure others can build evidence on:

- **Model & SKUs:** *[model] — [SKUs sharing this sensor stack]*
- **Sensors & performance:** *[sensor] — [range, resolution, sampling, known tolerances]*
- **Change since last version:** *[what changed, when, and any measurement impact]*
- **Lifecycle:** *[release date · end-of-sale · end-of-support]*
- **Contact:** *[named clinical / regulatory point of contact]*

6. This edition condenses five papers of the series

How this edition fits the qointa series

This edition reads the series from the OEM seat. The hardware you ship is the input behind these papers:

- **QPP-00 — Regulatory Impact Assessment (RIA).** Section 12 keys the stakeholder editions and sets device status and scope.
- **QPP-01 — Endpoint Validation.** Your sensor specs feed the V3 verification and analytical-validation chain.
- **QPP-04 — The AI/ML Overlay.** Where a model runs on the handset, the compute and operating-system behavior you ship becomes part of an AI system someone else must document.
- **QPP-07 — Change Control.** Your change-notification is what lets the trial manage drift across model years.
- **QPP-14 — Interoperability.** Where your handset hubs other devices, its behavior is part of the validated system.

Regulatory basis

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

- **MDCG 2023-4** (October 2023), *MDSW – Hardware combinations*, Option 3 — where trial software runs on general consumer hardware, the software manufacturer answers for that hardware's safety, performance and reproducibility in combined use.
- **MDCG 2019-11 Rev. 1** (June 2025), s.3.1 — qualification and classification follow the software manufacturer's intended purpose; the operating system or environment does not affect qualification.
- **FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations** (final guidance, December 2023), s.III — verification and validation of the DHT regardless of its device status.
- **EMA/INS/GCP/112288/2023** (adopted 7 March 2023), s.6.1.3 — directly captured data must be accompanied by device metadata: device version, identifiers, firmware version, last calibration, timestamp.
- **Regulation (EU) 2024/2847** (Cyber Resilience Act), Arts 2(2) and 14 — vulnerability and incident reporting for products with digital elements, applicable since 11 September 2026; MDR/IVDR devices excluded.
- **V3 / V3+:** Goldsack et al., *npj Digital Medicine* 3:55 (2020); Bakker et al., *npj Digital Medicine*

8:51 (2025).

Everything in this edition that is not attributed to a source above is qointa's professional assessment.

7. Transparency upstream is a commercial advantage downstream

The four actions below cost a handset maker a published document and a named mailbox. They decide whether a sponsor can defend a measure taken on your hardware — and therefore whether it specifies your range next time.

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

One change notice turns a stranded study into a scoped revalidation

A sponsor validates a gait measure on your current flagship. A year later the accelerometer supplier changes with no notice. The validated measure now runs on a sensor it was never validated against, and the sponsor must either revalidate or treat the data as suspect. A single change notice would have turned a study-stranding surprise into a planned, scoped revalidation — at far lower cost to everyone, and with your hardware kept in the study.

Illustrative composite — not a specific study.

8. How qointa can help

qointa builds the disclosure package described above — the per-model specification sheet, the change-notification trigger criteria and the SKU-to-sensor map — and tests it against what sponsors and eCOA vendors actually have to evidence under the MDR, the FDA DHT guidance and EMA/INS/GCP/112288/2023. We also sit on the other side of that conversation, helping sponsors qualify a handset range, so the questions you will be asked are ones we have written.

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 QPP-01 — Endpoint Validation, QPP-07 — Change Control and QPP-14 — Interoperability. It is not legal advice; any specific position should be confirmed with qualified regulatory counsel.