

A DHT does not shed its obligations once deployed — but which reporting route it carries turns on **what the device is** in that study.

Settle the position first; the route, the reporter and the clock follow from it. **Hold one safety plan that records each device's position, names the legal reporter for every applicable route and prints the deadline that attaches to it.** Closing an event under the protocol does not close it under vigilance.

THE PICTURE Four positions, not two regimes; in one the Regulation swaps the route

POSITION 1

Device under investigation

MDR Arts 62–82; 21 CFR 812.
Deficiencies and serious adverse events reported under Art. 80 or 21 CFR 812.150.

POSITION 2

CE-marked device in a PMCF investigation

Within intended purpose, Art. 80(5)–(6) routes the sponsor to vigilance (Arts 87–90), not Art. 80 — one route.

POSITION 3

Marketed device used as a trial tool

Trial safety reporting (CTR Arts 41–42; 21 CFR 312.32) and manufacturer vigilance run at once — two clocks.

POSITION 4

Not a medical device at all

Most trial phones, tablets, gateways and eCOA apps. No device reporting duty — a conclusion to document.

Which route or routes apply to a given device and study is a matter for structured assessment, not a reading of the figure. Deadlines are calendar days unless the instrument says otherwise.

QOINTA'S POSITION Obligations stack — except where the Regulation displaces one

Meeting one route does not discharge another

Protocol adverse-event reporting does not satisfy device vigilance, and a manufacturer's post-market surveillance does not cover an investigational device's deficiencies.

Two clocks run on a marketed device used as a trial tool

A cleared wearable capturing an exploratory measure keeps its manufacturer's vigilance duties while trial safety reporting covers participant harm. Both run; make the interface explicit.

Roles can be inherited by operation of law

Kitting, provisioning and import can place manufacturer, importer or distributor reporting duties (MDR Arts 13, 14 and 16) on a party that never signed up for them.

A signal closes only when every route is satisfied

Capture, classify against the device's position, route to the right reporter and start the clock at awareness, act on FSQA, feed back into change control and decommissioning.

SIX READINESS MOVES, FROM DEVICE POSITION TO LIFECYCLE FEEDBACK

- 1 Settle each device's position** — under investigation, PMCF within intended purpose, a tool in a medicinal-product trial, or not a device.
- 2 Name the legal reporter for each route** in contracts and the safety plan, including duties inherited through kitting or import.
- 3 Record the clock for every route** — which deadline applies, from what moment of awareness, and who holds it.
- 4 Stand up capture and triage**, including telemetry that surfaces silent failures, with a documented triage decision behind every signal.
- 5 Pre-agree FSQA mechanics** — who issues notices, how, and how reach to the field is evidenced.
- 6 Wire feedback into change control**, the validated state and decommissioning at study close.

2 / 10 / 15 days

EU vigilance, MDR Art. 87 — threat / death or serious deterioration / other

7 / 15 days

SUSAR under CTR Arts 41–42 — fatal or life-threatening / all other

10 working days

US IDE unanticipated adverse device effect under 21 CFR 812.150(b)

30 / 5 days

US Medical Device Reporting, 21 CFR 803 — 5 work days if remedial action needed

Read with care. The UK position is still moving: strengthened PMS in force in GB since 16 June 2025, clinical-trials amendments effective 28 April 2026, pre-market device reform still draft. EUDAMED vigilance modules are not yet mandatory.

READ NEXT

QPP-03 Economic-Operator Roles · QPP-00 Regulatory Impact Assessment · QPP-07 Change Control · QPP-10 Data Integrity · QPP-13 Decommissioning · QPP-21 Risk-Based Monitoring



Summary of QPP-18 1.0 — the full paper, with sources and figures, is published at qointa.com.

MDR Arts 62–82, 80(5)–(6), 83–92 · CTR Arts 41–42 · 21 CFR 812.150 · 21 CFR 803 · 21 CFR 312.32 · ISO 14155:2020 · SI 2024/1368 reg. 44ZH · SI 2025/538

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