

The Update You Ship Is a Trial Event

A companion reading from the OS / firmware vendor seat — why your release is the sponsor's change event, and what only you can tell them about it

Prepared for	Operating-system and firmware vendors, and the trial teams whose devices run them.
Subject	Why an operating-system or firmware release is the sponsor's change event, what the sponsor must do about it, and what only the vendor can supply.
Status / Date	Final — 1 September 2026
Version	1.0
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Executive summary

The answer. No GCP rule binds an operating-system or firmware vendor. Every duty your release creates belongs to the sponsor — and the sponsor cannot discharge it without facts that exist only on your side. FDA requires changes to a digital health technology during a study to be assessed for their effect on the data;¹ the EMA computerized-systems guideline requires the change to be controlled and the system revalidated where the assessment requires it.² Both obligations are blind without a release note that says what actually changed.

What is at stake. A single release can move sampling, sensor behavior, permissions or APIs, and it rolls out unevenly, so a study holds two or more device states at once. In qointa's experience these changes are announced as build numbers rather than behavioral deltas, which is why the sponsor usually learns of them after the data has moved. The trial cannot control your cadence; it can only plan around what it can see.

What to do. Publish a release calendar and forced-update deadlines, state the behavioral delta and which models it touches, declare end-of-support dates against study timelines, and say whether an update can be deferred or a version pinned. That costs a template. Not doing it makes you the dependency a sponsor writes a risk around.

¹ FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final guidance, December 2023), s.IV.H.4 (changes to DHTs during a study) and s.III (verification and validation of the DHT for its use in the investigation, regardless of the DHT's regulatory status).

² EMA, Guideline on computerised systems and electronic data in clinical trials, EMA/INS/GCP/112288/2023 (GCP IWG, 7 March 2023), Annex 2 (validation and change control) and Annex 4 (security).

A release you consider routine lands in the trial as a change that must be assessed

The obligation is the sponsor's; the facts it needs to discharge it exist only on your side

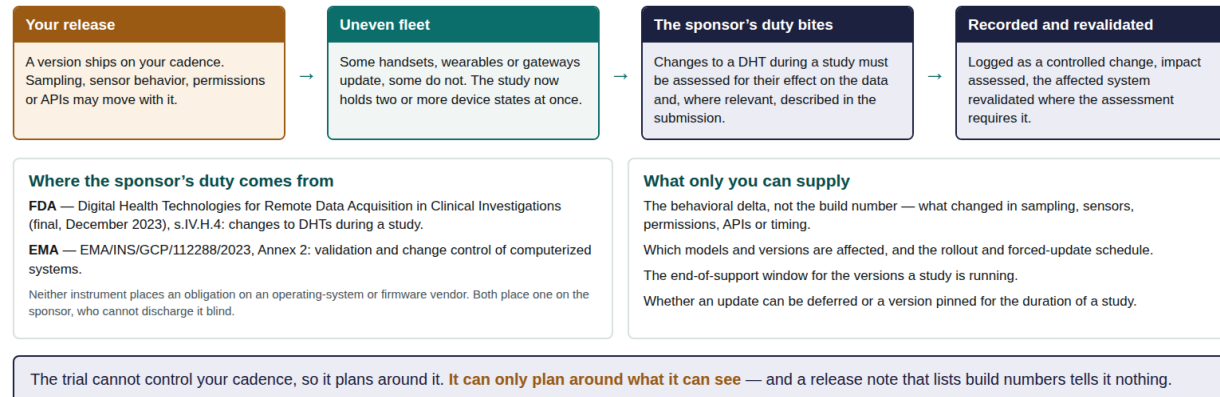


Figure 1 — A release you consider routine lands in the trial as a change the sponsor must assess — and only you hold the facts.

1. Your release is the trial's change event, and the trial never contracted with you

This is a companion edition of qointa's position-paper series, read from the operating-system or firmware vendor's seat. **Updates you ship can change a device's behavior mid-study** — and the sponsor must assess that change whether or not it was told about it. This edition summarizes the position set out in QPP-07 — Change Control; the sources are cited there in full.

It is addressed to OS and firmware vendors and to the trial teams whose devices depend on them. **The trial does not control your release cadence**, which is exactly why it has to plan around it (Figure 2).

How this fits the full framework

This companion is keyed to Section 12 of the Regulatory Impact Assessment (QPP-00 — Regulatory Impact Assessment (RIA)). The numbered papers carry the detail — the ties most relevant to an OS or firmware vendor are:

- **QPP-07 — Change Control.** Your core perimeter: an update is a change event that can break the validated state mid-study.
- **QPP-01 — Endpoint Validation.** A silent sampling or sensor change can move a sensor-derived measure.
- **QPP-05 — Cybersecurity.** Patch cadence and end-of-support set the security exposure the study inherits.
- **QPP-16 — PCCP.** Where predetermined change control plans sit — with the manufacturer of an AI-enabled device software function, not with you.
- **QPP-08 — Trigger Register.** Where the sponsor records your release as a controlled change — if it is visible to them.

Regulatory basis

The positions in this edition rest on the following sources. Pin-cites are in the footnotes; the full argument is in the numbered papers.

- **FDA**, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final, December 2023), s.III and s.IV.H.4 — verification and validation of the DHT, and assessment of changes during a study.
- **EMA/INS/GCP/112288/2023**, Annex 2 (validation and change control) and Annex 4 (security).
- **ICH E6(R3)**, s.3.6 — sponsor oversight of service providers; Annex 2 (Step 4, 3 June 2026; EU effective 15 January 2027).
- **FDA**, Marketing Submission Recommendations for a Predetermined Change Control Plan for AI-Enabled Device Software Functions (final December 2024; re-issued 18 August 2025) — applies to marketed AI-enabled device software functions, not to operating systems.
- Neither the FDA nor the EMA instrument places an obligation on an operating-system or firmware vendor. The duties described here are the sponsor's; the inputs are yours.

2. Four facts about your releases that a sponsor has to work around

- **Your update is the trial's change event.** A routine OS push can alter a measure or a permission.
- **You are an uncontracted dependency.** The sponsor relies on a party it never contracted with.
- **Behavioral changes are announced as build numbers.** In qointa's experience, sampling, sensor and permission changes reach release notes as version strings, if at all.
- **End-of-support forces a choice.** Update and accept behavioral drift, or stay on an unsupported version and carry the security exposure.

3. One release, four duties — and all four of them are the sponsor's

A single release reaches several of the sponsor's obligations at once. Each maps to a paper — and to a concrete disclosure on your side (Figure 2).

Perimeter / topic	What it means for you	Paper	Vendor action / evidence
Change control	Updates can break the validated state mid-study.	7	Publish a release calendar and change notices the sponsor can plan around.
Endpoint validation	A sampling change can alter a sensor-derived measure.	1	Flag changes to sampling, sensors or signal processing in the release notes.
Security	Patch cadence and end-of-support drive security exposure.	5	Declare patch cadence and end-of-support dates against study timelines.
Predetermined change control plans	A PCCP is held by the manufacturer of an AI-enabled device software function — not by you.	16	Say what you ship and when, so the sponsor can plan; do not expect a change plan to pre-authorize it.

No GCP rule binds you — every duty in this table is the sponsor's, and every input is yours

The commercial case for a change notice is not compliance; it is that the sponsor cannot discharge its own obligation without you

What moves	Why the trial cares	Whose duty it is	What you supply
A version ships	The state the sponsor validated is no longer the state in the field.	Sponsor — change control and revalidation (EMA/INS/GCP/112288/2023, Annex 2; QPP-07).	A release calendar and forced-update deadlines.
Sampling or sensor behavior changes	A sensor-derived measure can shift without a clinical announcement.	Sponsor — verification and validation of the DHT for its use in the study (FDA DHT guidance, s.III; QPP-01).	The behavioral delta in the release notes, not the build number.
The permission model changes	The app may lose access to data the protocol depends on.	Sponsor — assessment of changes to DHTs during the study (FDA DHT guidance, s.IV.H.4).	Which models and versions, and when.
Support ends	Patch and risk drift, or stay unpatched and carry the security exposure.	Sponsor — security of the trial record (EMA guideline, Annex 4; QPP-05).	End-of-support dates, early enough to reconcile with the study timeline.

One thing this edition does not say. A predetermined change control plan is a marketing-submission instrument held by the manufacturer of an AI-enabled device software function. An operating-system vendor does not hold one, and cannot pre-authorize its releases through one. See QPP-16 — PCCP.

Publishing what changed, what it touches and when costs you a template. Not publishing it makes you the dependency a sponsor writes a risk around.

Figure 2 — No GCP rule binds you: every duty in the table is the sponsor's, and every input is yours.

4. Three changes that reach a trial without announcing themselves

- **Silent sensor or sampling changes.** A background change can shift a mobility or signal measure.
- **Permission-model changes.** An OS update can alter what the app may access.
- **End-of-support timing.** A support window can close inside a study that is still recruiting.

5. Five moves turn an uncontracted dependency into a predictable one

Five moves let a sponsor plan around a cadence it cannot control. The template below turns them into a single release notice (Figure 1).

- **Publish a release calendar** — give the study a forward view of your cadence and forced-update deadlines.
- **Flag behavioral deltas, not just build numbers** — call out changes to sampling, sensors, permissions or timing.
- **Declare end-of-support dates early** — so support windows can be reconciled with study timelines (QPP-05 — Cybersecurity).
- **Offer a defer-or-pin path where your platform allows one** — a way to delay an update or hold a version for the duration of a study. In qointa's assessment this is the single most valuable thing a vendor can offer a trial; it is a recommendation, not a legal requirement.
- **Say what a change plan will not cover** — a predetermined change control plan sits with the manufacturer of an AI-enabled device software function, not with an operating-system vendor (QPP-16 — PCCP).

OS / firmware change-notification template

A release notice a sponsor can act on answers six questions (Figure 1):

- **What changed** — the component, version and the behavioral delta, not just the build number.
- **What it touches** — sampling, sensors, permissions, APIs or timing the trial may rely on.
- **Who is affected** — which device models / OS versions in the fleet, and the rollout schedule.
- **When** — release date, staged-rollout window, and any forced-update deadline.
- **End-of-support** — the support window for affected versions against the study timeline.
- **How to defer or pin** — whether the update can be delayed or a version pinned for the study.

6. Predictability is the whole of what a trial needs from you

The OS or firmware vendor is the uncontracted dependency every digital trial carries. **Predictable, documented change behavior is what lets a sponsor plan around it** — and it is the only thing in this edition that costs you anything at all.

How qointa can help

qointa drafts release-notice and end-of-support templates that answer what a sponsor's change assessment actually asks, and reviews a release program against the change-control expectations trial teams work to. **info@qointa.com**

Scope and status

This is a companion edition summarizing qointa's position-paper series from one stakeholder's perspective, keyed to Section 12 of the Regulatory Impact Assessment (QPP-00 — Regulatory Impact Assessment (RIA)). The sources for the positions taken here are cited in the footnotes and in the Regulatory basis box; the full treatment is in the numbered papers. It is not legal advice, and any specific position should be confirmed with qualified regulatory counsel.