

Digital Trials and the Device Perimeter: A Regulatory Primer

A plain-language entry point to the regulatory questions raised by the devices and systems a clinical trial relies on — wearables and sensors, home and point-of-care instruments, apps and eCOA platforms, clinical systems, and the phones and tablets that connect them

Prepared for	Anyone new to the regulatory questions that digital health technologies raise in clinical trials.
Subject	A plain-language primer to the device-perimeter view of digital and decentralized trials, and a guide to the series.
Status / Date	Final — 1 September 2026
Version	1.0
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Executive summary

Assess, rather than assume: a trial device's regulatory status follows what it does, not what it is — and most assessments return a light-touch result that is then defensible. Teams most often misjudge the regulatory perimeter of the devices and systems a trial relies on. A participant's phone is waved through as "just a phone"; a provisioned eCOA handset as "just the vendor's phone"; a cleared spirometer or wearable as finished business because it is "already a device" — and the questions that actually attach get missed.

One device or system can play several roles at once, so its obligations stack across seven regulated perimeters — medical device, GxP and computerized systems, data protection, human factors, configuration, economic operator and protocol design. They add up; they do not cancel out — and the stack differs per device and per deployment (Figure 1).

What to do: for each device and system, establish its role, decide which perimeters it touches, record the controls and the reasoning, and reopen the assessment when the device, its software, its connection or the protocol changes. This primer names the seven perimeters and shows how the stack differs across three typical trial devices (Figure 1); Section 5 points to the paper that works each perimeter through, and QPP-00 — Regulatory Impact Assessment (RIA) sets out the method.

The stack differs per device — and the measuring device is often not the transmitting one

Three typical trial devices read against the seven perimeters. Which perimeters bite, and how hard, follows from the role each device plays in the protocol and from who controls it — not from what it is.

Perimeter	Provisioned smartphone running the eCOA app Sponsor-supplied handset, locked down by MDM · daily symptom diary · no measurement of its own · uploads to the eCOA platform	Wrist-worn wearable paired to the participant's own phone Wearable measures the secondary endpoint · phone (BYOD) relays, buffers and uploads · sponsor controls the wearable, not the phone	Home spirometer paired to a provisioned cellular gateway CE-marked / FDA-cleared instrument · pairs by Bluetooth to a sponsor-provisioned cellular hub · no phone in the path · feeds a secondary endpoint
1 · Medical device Is the device, the app or the measure MDSW?	LIGHT — RECORD WHY A diary app that only captures and transmits answers is usually not medical device software.	ASSESS The wearable and any on-device algorithm may be a device or MDSW; check that the cleared intended use covers this use.	FULL A medical device with an intended purpose — confirm it covers the protocol's use and population.
2 · GxP & computerized systems Does it hold or move GCP records?	FULL Holds ePRO source records; audit trail and validated state on the handset and the platform.	FULL Endpoint data; integrity must be evidenced from sensor through the phone to the repository.	FULL Source data; integrity from the instrument through the gateway to the repository.
3 · Data protection Where does the data travel, on what basis?	FULL Personal data; lawful basis, residency, deletion.	FULL Personal data on a device the sponsor does not own; transparency and deletion on the phone.	FULL The gateway's cellular route sets where the data travels and resides.
4 · Human factors Can these participants use it reliably?	FULL Usability of a single known device; missing entries are missing data.	FULL Wear compliance and pairing across many phone models.	FULL A technique-dependent measure; coaching and acceptability rules.
5 · Configuration Is the deployed state controlled through change?	FULL The MDM profile is the validated state; app and OS updates are controlled events.	SPLIT Wearable firmware under change control; the phone is not locked down, so an OS update is a trigger.	FULL Instrument firmware and calibration, and the gateway's firmware and pairing, under change control.
6 · Economic operator Who is manufacturer, importer, distributor?	ATTACHES Provisioning hardware across borders can make the sponsor or its logistics vendor an importer or distributor.	ATTACHES TO THE WEARABLE Whoever sources and ships it may inherit operator duties; none for the participant's phone.	FULL Kitting, import and country activation of instrument and gateway assign operator duties by operation of law.
7 · Protocol design What duties does the protocol create?	LIGHT Not an endpoint feed — unless an amendment makes it one.	FULL Secondary endpoint: validation and qualification evidence (QPP-01, QPP-15).	FULL Endpoint feed; every change reopens the assessment.
Who transmits the data?	The handset itself — the device that captures is the device that uploads.	The participant's phone — a device the sponsor neither measured with nor controls carries relay, buffering, provenance and upload roles (QPP-C).	The provisioned gateway — an intermediate device the sponsor controls; its relay and upload roles are validated like any other system component.

■ Full obligation ■ Assess — depends on function or on who controls it ■ Light-touch — record the reasoning ■ Transmission path

Obligations stack rather than substitute, and the stack is set per device and per deployment. Provisioned devices pull in configuration and economic-operator duties; participant-owned devices (BYOD) move the control problem to a device the sponsor does not own. Where a phone, tablet or gateway carries data it did not measure, it is load-bearing for data integrity — the conduit role QPP-C works through; whether the sponsor controls that device decides how the role is evidenced.

Illustrative only — which perimeters apply to a given device is a matter for structured assessment (QPP-00 — Regulatory Impact Assessment); most assessments return a light-touch result that is then defensible.

Figure 1 — The stack differs per device: three typical trial devices read against the seven perimeters. The measuring device is often not the transmitting one. Illustrative only.

1. The moment a device or system carries trial data, regulatory questions attach to it

Digital and decentralized trials move data collection out of the clinic and onto devices and systems in participants' hands and homes: wearables and biosensors, home spirometers and glucose monitors, eCOA apps on sponsor-provisioned or participants' own phones, eConsent platforms, and the clinical systems — EDC, RTSM, CTMS, eTMF — that receive what they produce. That shift is operational, but it is also regulatory: the moment a device generates, carries or signs trial data, regulatory questions attach to it. This primer is a plain-language entry point to those questions.

It does not try to cover decentralized trials in general — it covers what teams most often misjudge: the regulatory perimeter of the devices and systems a trial relies on. It is written for someone new to the topic, and it ends by pointing to the fuller papers in the series.

2. A device's regulatory status follows what it does, not what it is

A participant's phone is not exempt because it is "just a phone," a sponsor-provisioned eCOA handset is not exempt because the sponsor owns it, and a CE-marked spirometer or FDA-cleared wearable is not finished business because it is "already a device." What matters is the role the device plays in the study and the conditions it meets. The frameworks say the same in their own words. FDA expects a sponsor to address verification and validation of a digital health technology "regardless of whether the DHT meets the definition of a device." ICH E6(R3) expects the computerized systems used in a trial to be fit for purpose, whatever they run on. Under the EU Medical Device Regulation, software is a medical device by its intended purpose,

not by the hardware it runs on. Because one device can play several roles at once, its obligations can stack across several perimeters simultaneously. They add up; they do not cancel out.¹²³

Two consequences follow. The measuring device is often not the transmitting one: a wearable or home instrument usually hands its data to a smartphone or a provisioned gateway, which then carries roles of its own — relay, buffering, provenance, upload — and QPP-C — The Smartphone in Digital Endpoints works that conduit role through. And whether a device is provisioned by the sponsor or brought by the participant (BYOD) changes which perimeters bite hardest: provisioning pulls in configuration and economic-operator duties, BYOD moves the control problem to a device the sponsor does not own (Figure 1).

3. A trial device can fall into seven regulated perimeters at once

Any device or system in the study — a wearable, a home instrument, a phone or gateway, an eCOA platform or an EDC system alike — can sit inside several regulated perimeters at the same time. The series organizes them into seven, and calls the boundary of each a perimeter — hence “one device, several perimeters.” The third column says why each matters in a trial — the practical consequence if the question is missed.

Perimeter	The question it asks	Why it matters in a trial
Medical device	Is the device, the app, or a measure it produces, a medical device or medical device software (MDSW)?	Sets whether medical-device duties and endpoint validation apply.
GxP and computerized systems	Does the device hold or move GCP records, with the integrity duties that brings?	Determines data-integrity and validation obligations for the records.
Data protection and privacy	Where does participant data live and travel, and on what lawful basis?	Drives lawful basis, residency, transparency and deletion rights.
Human factors	Can the actual participants use it reliably and safely?	Use-error and non-adherence become missing or wrong data.
Configuration	Is the device locked down, modified or instrumented out of “general purpose” — and is it provisioned by the sponsor or the participant’s own?	Configuring a device for a medical, regulated-record or controlled purpose can change its status; a provisioned device is the sponsor’s to configure, a participant’s own device is not (QPP-00, Section 5).
Economic operator	Who is the manufacturer, importer or distributor in this supply chain?	Assigns operator duties under MDR Articles 13, 14, 16 and 22 — often inherited silently along the chain.
Protocol design	What obligations does the protocol itself create?	The protocol can add duties beyond what the hardware implies.

¹ FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final guidance, December 2023), section IV.C.

² ICH E6(R3), Good Clinical Practice (Step 4, 6 January 2025; effective in the EU from 23 July 2025).

³ Regulation (EU) 2017/745, Article 2(1); MDCG 2019-11 Rev. 1 (June 2025), Guidance on qualification and classification of software.

Where the rules come from: the GxP perimeter rests on ICH E6(R3), 21 CFR Part 11 and the EMA guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023);⁴ data protection on the GDPR, read with the EDPB's guidance on clinical trials;⁵ human factors on IEC 62366-1:2015 + A1:2020; and the economic-operator perimeter on the MDR articles above. Configuration and protocol design have no single instrument of their own — they are the choices that pull the other five in.

4. Assess, rather than assume — and record the reasoning

The practical move the series recommends is simple to state. For a given device or system in a given study, ask what role it plays and which conditions it meets, decide what controls follow, and — crucially — record the reasoning.

A documented “**we assessed it and here is why minimal controls suffice**” is a strong position; an undocumented “*we assumed it didn't apply*” is the weakest. In qointa's experience most assessments return a light-touch result; the value is that the result is now defensible.

Two example assessments — one provisioned instrument, one participant-owned phone

Example A — a home spirometer paired to a sponsor-provisioned cellular gateway, feeding a secondary endpoint. Walking the seven perimeters:

- **Medical device?** Yes — a CE-marked / FDA-cleared device. Check that the cleared intended use and performance cover the way the protocol uses it, and that the measure is validated for this context of use (QPP-01, QPP-15).
- **GxP / data protection?** Yes — source data relayed through the gateway; integrity must be evidenced from the instrument to the repository, and the gateway's cellular route decides where the data travels (QPP-02).
- **Human factors?** Yes — a technique-dependent measure; coaching, acceptability criteria and the participants who will actually use it (QPP-09).
- **Configuration / economic operator?** Yes — instrument firmware and calibration, and the gateway's firmware and pairing, under change control (QPP-07); kitting, import and country activation of both can make the sponsor or its logistics vendor an importer or distributor (QPP-03).
- **Protocol design?** Yes — an endpoint feed, so every material change reopens the assessment.

Result: a full profile — but most of it is already owed by the manufacturer. The sponsor's task is to evidence that the manufacturer's obligations exist, apply to this use, and are watched for change.

Example B — a daily symptom questionnaire through an app on the participant's own phone (BYOD). Walking the same perimeters:

- **Medical device?** A questionnaire app that only captures and transmits answers is usually not medical device software — but record why.
- **GxP / data protection?** Yes — it holds GCP records and personal data; integrity and lawful basis apply.
- **Human factors?** Yes — usability across the real range of participants' phones matters for data quality.
- **Configuration / economic operator?** Light — the phone is not locked down and no one is importing hardware; an operating-system update is nonetheless a trigger. (If the app itself were medical device software, importer or distributor duties could still attach to it.)

⁴ 21 CFR Part 11; EMA, Guideline on computerised systems and electronic data in clinical trials, EMA/INS/GCP/112288/2023 (adopted 7 March 2023).

⁵ Regulation (EU) 2016/679 (GDPR), Articles 6, 9 and 28; EDPB Opinion 3/2019 on the interplay between the Clinical Trials Regulation and the GDPR (23 January 2019).

- **Protocol design?** Light — the questionnaire is not an endpoint feed. If a later amendment makes it one, the assessment reopens.

Result: a light-touch profile — documented and defensible rather than assumed. Same method, opposite weight: the device's role and who controls it decide the result.

Illustrative composite — not a specific study.

Quick decision questions

- What does the device actually *do* in this study (its role)?
- Which of the seven perimeters does that role touch?
- What controls follow — and is the reasoning written down?
- What change would reopen the assessment (a firmware, app or OS update, a new data route, a new endpoint, a switch between provisioned and participant-owned devices) — and is it in the Trigger Register?

5. Start with QPP-00, then read the perimeters that match your devices and systems

This primer is the shallow end. The series goes deeper: QPP-00, twenty-four numbered papers and fourteen Stakeholder Editions. Here is a recommended reading path.

Step	Read	Why start here
1	QPP-00 — Regulatory Impact Assessment (RIA)	The entry point: makes the case for assessing rather than assuming.
2	Your high-priority perimeters	Use the perimeter table in Section 3 — and the catalogue in QPP-B — Series Overview — to find the perimeters your device's role touches, and read those papers first.
3	The remaining numbered papers (1–24)	Endpoints and their qualification, data residency, operator roles, AI and PCCPs, security, inspection, change control, human factors, integrity, eConsent, interoperability, decommissioning, labelling, EHR integration, monitoring, equitable access, global reconciliation and QMS integration.
4	The discipline papers, then your Stakeholder Edition	QPP-12 — Vendor Qualification and Oversight and QPP-08 — Trigger Register keep the assessment current and inspection-ready. Stakeholder Editions S01–S14 then apply Section 12 of QPP-00 to one party each — sponsor, CRO / sites, eCOA / ePRO vendor, IRB, participant and more.

Quick-start path

Start with QPP-00 → read the two or three perimeters that match the role of each device and system → finish with QPP-08 — Trigger Register and QPP-12 — Vendor Qualification and Oversight to keep the assessment current → read your Stakeholder Edition. QPP-B — Series Overview maps all of them and is the best place to choose where to read next.

Scope and status. This is an introductory primer to qointa's position-paper series. It is deliberately simplified, is not legal advice, and is not a comprehensive treatment of decentralized-trial regulation. The detail, current framework references and caveats are in the numbered papers, and any specific position should be confirmed with qualified regulatory counsel.