

Treat the phone as **two things, not one**: sometimes the measuring instrument, far more often the conduit that carries another sensor's data.

The two roles carry different evidence burdens, and conflating them is the costliest error in endpoint planning. **Separate sensor from conduit in every endpoint definition; validate the conduit as data integrity, not as measurement; and reserve a full V3 package — and any attempt at qualification — for phone-native measures that carry real programme value.**

THE PICTURE The same V3 lens, two very different burdens

Phone as sensor — the instrument

- Its own accelerometer, camera, microphone or GPS generates the endpoint
- Verification, analytical and clinical validation all fall on the phone — a full V3 package, de novo
- Usability burden high: the participant operates the measuring device directly
- Outside accelerometer activity and camera-PPG heart rate, most phone-native measures are emerging or research-grade

vs

Phone as conduit — the data path

- Up to eight roles: relay, store-and-forward, cloud uplink, edge processing, provenance, device controller
- Seven of the eight are data-integrity obligations, not measurement obligations
- Edge-algorithm version becomes part of the endpoint definition — version-lock it
- BYOD does not change the roles; it changes who controls them — detect, capture and reconcile instead of control

V3: verification · analytical validation · clinical validation (Goldsack et al., 2020), extended to V3+ with usability. Clinical validation is largely inherited from the endpoint whichever role the phone plays.

QOINTA'S POSITION Four questions sponsors collapse into one — and must keep apart

Is the function a device?

A phone is not a device by virtue of being a phone. The software function running on it can be — assessed one function at a time, on intended use and claims.

Does it need its own authorisation to run in the trial?

In the US, whether an IDE is required and whether the investigation is significant-risk under 21 CFR Part 812 — a judgment on the facts, not on the app's sophistication.

Is the endpoint valid or qualified?

A V3 and context-of-use question, independent of device status. Clearance enables measurement; it does not confer endpoint qualification.

Do data-integrity rules apply?

Always. 21 CFR Part 11, EMA/INS/GCP/112288/2023 and ICH E6(R3) reach trial data whatever the device status — a reminder app included.

SIX ACTIONS, ORDERED BY THE EVIDENCE THEY SAVE AT PROTOCOL DESIGN

- 1 **Separate sensor from conduit** in every endpoint definition — the first question sets the whole evidence path.
- 2 **Classify each phone software function early** (device or not) and keep the four questions separate.
- 3 **Validate the conduit roles as data integrity**: edge-algorithm version, provenance, store-and-forward and reconciliation.
- 4 **Plan a full V3 package for phone-as-sensor**; reserve phone-native primary endpoints for measures with established validation.
- 5 **Specify the connectivity topology**, failure modes and reconciliation method in the protocol.
- 6 **Pursue qualification selectively** — only for high-value phone-native candidates.

43%

of 269 FDA-listed sensor devices inferred to route data through a paired phone app

7 of 8

phone conduit roles are data-integrity, not measurement, obligations

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qualified digital endpoint relevant here — SV95C (EMA) — wearable-derived, not phone-native

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phone-native endpoints qualified by FDA or EMA as at September 2026

Read with care. The 43% is an inference, not a finding: FDA decisions do not record connectivity; 90 of the 115 rest on an unverified default and 226 of 269 rows carry low confidence. Fit for landscape framing, not for characterising a named device.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-07 Change Control · QPP-14 Interoperability · QPP-15 Endpoint Qualification · Annex QPP-D FDA sensor landscape



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

FDA DHT guidance (Dec 2023) · FDA Device Software Functions policy (2022) · 21 CFR Part 11 and Part 812 · EMA/INS/GCP/112288/2023 · ICH E6(R3) · MDCG 2019-11 Rev. 1 · EMA SV95C qualification opinions (2019, 2023) · © qointa 2026 — Public — Uncontrolled when printed · Not legal advice; this summary does not classify any device.

qointa · DHT governance for clinical trials
sales@qointa.com · qointa.com