

The Smartphone in Digital Endpoints

Indispensable conduit, immature instrument — the phone's role in capturing, processing and submitting digital endpoint data

Scope note. This paper is a cross-cutting synthesis issued alongside the numbered series. It applies to the smartphone — and, by extension, to any tablet or dedicated gateway standing in the same position in the data path — positions developed in QPP-00 — Regulatory Impact Assessment (RIA), QPP-01 — Endpoint Validation, QPP-14 — Interoperability and QPP-15 — Endpoint Qualification. The other papers in the series are written for every device and system a trial relies on; this one owns the intermediate-device role. Its supporting evidence base is Annex D — FDA-Cleared Sensor DHT Landscape.

Prepared for	The sponsor's clinical, data-management and regulatory functions; the eCOA / ePRO and DHT vendors whose software sits in the endpoint data path; and the CRO and biostatistics teams who define and defend the endpoint
Subject	The two roles of the smartphone in digital endpoints — measuring instrument and data conduit — and the different evidence each demands
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1. Executive summary

Treat the phone as two things, not one. In a digital-endpoint trial the smartphone is sometimes the measuring instrument and far more often the conduit that carries another sensor's data to the sponsor. The two roles carry different evidence burdens, and conflating them is the costliest error in endpoint planning. qointa's position: separate **sensor** from **conduit** in every endpoint definition; validate the conduit as data integrity rather than as measurement; and reserve a full V3 evidence package — and any attempt at regulatory qualification — for phone-native measures that carry real program value.

What the evidence supports. On FDA's published list of sensor-based digital health technologies — 269 marketing decisions between 30 January 2015 and 13 March 2026, in the snapshot qointa took on 16 June 2026 (the list as updated by FDA on 4 September 2026 holds 279 decisions to 22 June 2026; the analysis here is stated at the March cut)¹ — qointa infers that **115 of the 269 devices (43%) route their data through a paired smartphone app**, rising to 133 (49%) if devices that are themselves phone or watch software are counted. That is an inference, not a finding: 90 of the 115 rest on a default assumption recorded as unverified, and 226 of the 269 rows carry low confidence. FDA decisions do not record connectivity, so confirming any single device means reading its decision summary. The defensible statement is that a paired phone is the most likely single data path for a substantial minority of cleared sensor devices — not that most depend on one.

What to do about it. Where a phone sits anywhere in the path, bring its conduit roles inside the sponsor's data-governance scope: verify capture, buffering and transfer; version-lock any edge algorithm

¹ FDA, "Medical Devices that Incorporate Sensor-based Digital Health Technology", fda.gov, Digital Health Center of Excellence. Snapshot taken by qointa on 16 June 2026; it covers decisions with final-decision dates from 30 January 2015 to 13 March 2026 (269 entries: 253 510(k) clearances, 13 De Novo grants, 3 PMA approvals). FDA states that the list is not a comprehensive resource of sDHT medical devices and is updated periodically; a later FDA update will give different totals. FDA content is in the public domain. All routing, modality grouping and confidence grades applied to the list are qointa's analysis.

as part of the endpoint definition; and evidence provenance end to end. Where the phone is the instrument, size the evidence to a full V3 package before the measure is proposed as primary. Neither judgment follows from the device's clearance status, and neither can be delegated away.

2. The phone plays two roles, and they carry different evidence burdens

The single word “phone” conceals two distinct functions that carry different evidentiary weight. Conflating them is the costliest error in endpoint planning, because it sizes the evidence to the wrong question.

One handset, eight roles: the phone stands between the sensor and the sponsor at every point where an endpoint can be lost

Two connectivity hops, three topologies — and only one of the eight roles is measurement

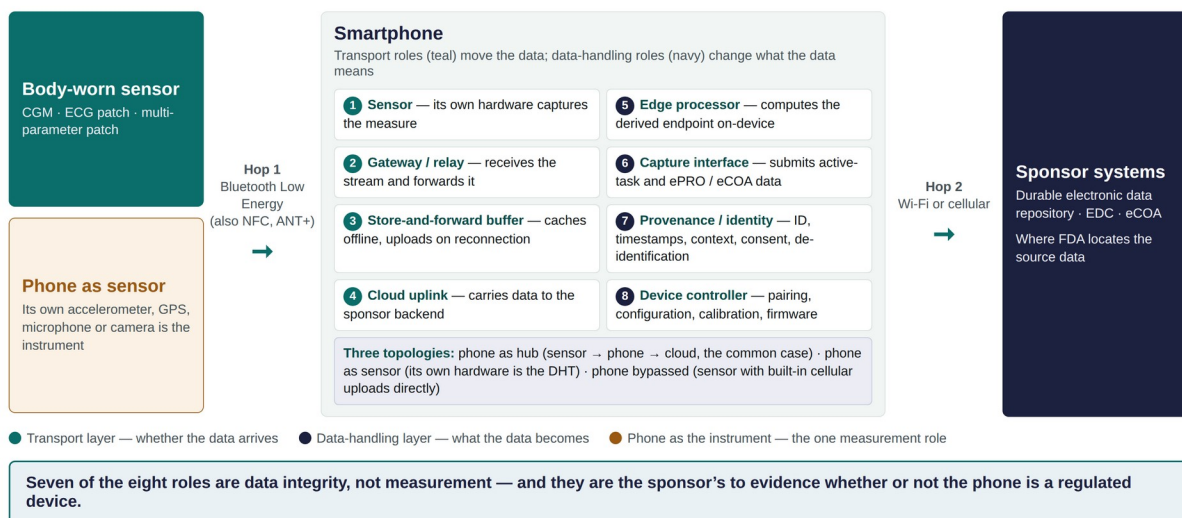


Figure 1 — Seven of the phone's eight roles are data integrity, not measurement.

2.1 As sensor, the phone is the instrument and attracts full measurement scrutiny

Here the phone's own hardware — accelerometer, GPS, microphone, camera — is the measuring instrument. The endpoint is generated by the device in the participant's hand, with no external sensor. This is the case that most resembles a novel medical measurement and therefore attracts the most validation scrutiny.

2.2 As conduit, the phone decides whether the endpoint arrives intact

Far more often the phone sits **between** a body-worn sensor and the sponsor's systems, filling up to eight separable roles across two connectivity hops (Figure 1). It relays the stream, buffers it offline, computes the derived endpoint, attaches identity and provenance, and uploads. The measurement originates in the sensor; the phone decides whether the data arrives intact, attributable and analysable. Under FDA's position the source data sit in the durable electronic data repository, and FDA does not intend to inspect individual DHTs for source-data verification²; the EMA computerized-systems guideline nonetheless expects device-side controls, so the record's integrity from capture to repository remains the sponsor's to evidence³.

² FDA, "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers" (final guidance, October 2024), Q23.

³ EMA, "Guideline on computerised systems and electronic data in clinical trials", EMA/INS/GCP/112288/2023, adopted by the GCP Inspectors Working Group 7 March 2023, effective September 2023 — Annex 4 (security) and Annex 5 (specific systems).

Whether the phone is the participant's own (BYOD) or provisioned by the sponsor does not change the roles it carries; it changes who controls them. On a provisioned, managed handset the sponsor sets the configuration, pins the app version and decides when the operating system updates, so the conduit roles can be validated and held under change control. On a participant's own phone none of that is in the sponsor's hands: the operating system, the pairing stack and the storage are whatever the participant has, and an update is a trigger the sponsor can only detect, not prevent (QPP-07). The evidence burden is the same; on BYOD the sponsor meets it through detection, version capture and reconciliation rather than through control.

3. The V3 framework turns the distinction into a defined evidence burden

The sensor / conduit split maps directly onto the digital-medicine field's de facto validation standard, the DiMe **V3 framework** — verification (does the sensor capture and store raw data accurately), analytical validation (does the algorithm convert that signal into the intended metric), and clinical validation (does the measure reflect a clinically meaningful state in the context of use), now extended to V3+ with usability validation.⁴ Using this lens turns a qualitative observation into a defined evidence burden.

V3 layer	Phone as sensor	Phone as conduit
Verification	Full burden — the phone's own sensor must be characterized for accuracy, precision, sampling	Limited — sensor verification sits with the body-worn device; the phone's capture/storage path still needs assurance
Analytical validation	Full burden — the on-device algorithm is the measurement	Applies where the phone does the edge computation; the algorithm version becomes part of the endpoint definition
Clinical validation	Full burden — the phone-derived measure must be shown clinically meaningful	Inherited from the endpoint, largely independent of the conduit
Usability (V3+)	High — participant operates the measuring device directly	Moderate — affects adherence and data completeness

The practical reading: phone-as-sensor must clear **all** V3 layers de novo, which is why so few phone-native endpoints reach primary status. Phone-as-conduit primarily implicates verification (of the data path) and data integrity — a lighter but non-zero burden that is too often left undocumented.

4. The phone can measure far more than sponsors ask it to

A modern smartphone is a dense sensor package: motion (accelerometer, gyroscope, magnetometer), optical (camera and flash for PPG, ambient light), audio (microphone), location (GPS/GNSS), touch (touchscreen, keystroke dynamics) and environmental (barometer), plus derived software signals. In principle these support endpoints across activity, sleep, cardiac, respiratory, cognitive, motor and behavioral domains. The table below is qointa's reference view of what each sensor can record and how far the measurement science has matured; it is professional judgment drawn from the published literature, not a count of trials.

In practice, adoption is thin. In qointa's assessment, phone-native measures remain a small minority of the sensor-derived endpoints used in registered trials, and none has been qualified by a regulator. The endpoint-library counts that previously quantified that minority are **withdrawn from this release**: the

⁴ Goldsack JC et al., "Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs)", npj Digital Medicine (2020). V3+ adds usability validation: DiMe / DATAcc announcement, 27 February 2024; Bakker JP et al., npj Digital Medicine 8:51 (2025). "De facto validation standard" is qointa's characterization, not a regulatory status.

library's terms of use grant a personal, non-commercial license only and bar redistribution and derivative works without written permission, which qointa does not hold⁵. The proportion stated here is therefore qointa's professional judgment and should be re-evidenced before a sponsor relies on it. The reason for the thinness is maturity: outside accelerometer-based activity and camera-PPG heart rate, most phone-native measures remain emerging or research-grade and lack the characterization a regulator expects of a primary or key secondary endpoint.

Phone sensor	Representative measures	Maturity
Accelerometer	Steps, activity, sleep/wake, tremor	Established
Camera + flash (PPG)	Heart rate, HRV, respiratory rate	HR established; BP/SpO2 research
Microphone	Cough, respiratory rate, voice biomarkers	Emerging
GPS / GNSS	Mobility, life-space, location patterns	Emerging
Touchscreen / keystroke	Reaction time, dexterity, typing dynamics	Emerging / research

5. Conduit roles are data-integrity obligations, not measurement obligations

When the phone is the conduit, its roles divide into a transport layer (moving the data) and a data-handling layer (transforming and contextualizing it). Each data-handling role is a point at which endpoint integrity can be strengthened or compromised — and each falls within regulators' data-integrity expectations under FDA's December 2023 guidance on digital health technologies for remote data acquisition⁶, 21 CFR Part 11 with the EMA computerized-systems guideline (EMA/INS/GCP/112288/2023), and ICH E6(R3)⁷.

Role	Layer	Why it matters for the endpoint
Gateway / relay	Transport	Sole link from sensor to the outside world (BLE/NFC)
Store-and-forward	Transport	Prevents data loss during disconnection
Cloud uplink	Transport	Delivers data to the sponsor backend (Wi-Fi/cellular)
Edge processing	Data-handling	Computes the derived endpoint — algorithm version is part of the definition
Provenance / identity	Data-handling	Timestamps, participant ID, consent, de-identification
Device controller	Data-handling	Calibration and firmware shape what is measured

5.1 FDA's device list cannot confirm how cleared sensors connect

Connectivity is not recorded in FDA decision data. qointa therefore inferred each device's route from its class, name and maker. **The inference has not been validated against the decision summaries**, and the reader should treat the distribution below and in Figure 2 as indicative: 226 of the 269 rows carry low confidence, and the largest single bucket — 90 devices assumed to use a smartphone-app hub — is

⁵ Digital Medicine Society, "Cookie and Terms of Use Policy", last updated 10 February 2026 — limited, non-exclusive, non-transferable, revocable licence for personal, non-commercial use; reproduction, distribution, republication, download and derivative works require written permission. qointa has not obtained that permission, so no count derived from the Library of Digital Endpoints is published in this release.

⁶ FDA, "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" (final guidance, December 2023), sections III (DHT selection, verification and validation regardless of device status), IV.G (source data and the durable electronic data repository) and IV.H.4 (changes to DHTs during a study).

⁷ ICH E6(R3) Good Clinical Practice: Principles and Annex 1 reached Step 4 on 6 January 2025 and took effect in the EU on 23 July 2025. Annex 2 reached Step 4 on 3 June 2026 and takes effect in the EU on 15 January 2027. The guideline describes itself as media neutral and states that digital health technologies, such as wearables and sensors, may expand the possible approaches to trial conduct.

recorded as an unverified default. Confirming the route for any one device requires reading its 510(k), De Novo or PMA summary. Annex D — FDA-Cleared Sensor DHT Landscape states the same limitation.

Inferred connectivity route	Devices	Confidence
Smartphone-app hub (default assumption, unverified)	90	Low
Standalone / gateway (own cellular, Wi-Fi or base station)	72	Low
Record-and-offload (stored, retrieved later)	64	Low
Smartphone-app hub (sensor pairs to phone app)	25	Medium
Phone / wearable software (device is the phone or watch)	18	Medium

The design consequence survives the uncertainty. For the 115 devices (43%) inferred to route through a paired phone — and for any device a sponsor confirms to do so — the handset is load-bearing in the data-integrity chain, whatever its regulatory status. Its conduit roles therefore belong inside the data-governance scope that ICH E6(R3) places on the sponsor, and the evidence for them should be planned before the first participant is enrolled, not assembled at inspection.

For most cleared sensor devices the paired phone is an inference, not a finding

269 FDA marketing decisions for sensor-based digital health technologies, routed by qointa from device class, name and maker

Inferred connectivity route	Devices	Confidence
Smartphone-app hub — default assumption, unverified	90	Low
Standalone / gateway — own cellular, Wi-Fi or base station	72	Low
Record-and-offload — stored on device, retrieved later	64	Low
Smartphone-app hub — sensor pairs to a named phone app	25	Medium
Phone / wearable software — the device is the phone or watch	18	Medium
All sensor-based DHT decisions on the FDA list	269	226 Low · 43 Medium

115 of 269 — 43%

inferred to route through a paired smartphone app; 133 (49%) if devices that are phone or watch software are counted.

90 of those 115

rest on a default assumption recorded in the source analysis as **unverified**. The inference has not been checked against decision summaries.

0 of 269

FDA decisions record connectivity. The agency's list does not hold the field; confirming any one device means reading its 510(k), De Novo or PMA summary.

Say "a substantial minority, unverified" — not "most". The design consequence is unchanged: where a phone is in the path, its conduit roles are in the sponsor's data-integrity scope.

Source: FDA, "Medical Devices that Incorporate Sensor-based Digital Health Technology" (US government, public domain), snapshot taken 16 June 2026, covering decisions 30 January 2015 to 13 March 2026. Routing and confidence grades are qointa's analysis. FDA states the list is not a comprehensive resource of sDHT medical devices.

Figure 2 — For most cleared sensor devices the paired phone is an inference, not a finding.

6. Digital endpoints are widely used and almost never qualified

Digital endpoints are widely used and almost never qualified. The one qualified digital endpoint relevant to this paper — **stride velocity 95th centile (SV95C)** — is wearable-derived, not phone-native, and it reached that status through two separate EMA opinions: qualification as a **secondary** endpoint in Duchenne muscular dystrophy in 2019, and a further opinion adopted by the CHMP on **20 July 2023** qualifying it as a **primary** endpoint in superiority studies in ambulant DMD patients aged four and over, as an alternative to the six-minute walk test, provided established endpoints are retained as secondary endpoints and give consistent findings, and provided the wearable used demonstrates adequate accuracy⁸. No phone-native endpoint has been qualified by either agency, and to qointa's knowledge as

⁸ EMA qualification opinion on stride velocity 95th centile as a secondary endpoint in Duchenne muscular dystrophy, EMA/CHMP/SAWP/178058/2019, adopted 26 April 2019; and the separate CHMP qualification opinion on SV95C as a primary endpoint in studies in ambulatory Duchenne muscular dystrophy, adopted 20 July 2023. The 2023 opinion is device-agnostic subject

at September 2026 no sensor-derived endpoint has been qualified through FDA's Drug Development Tool (DDT) program; FDA's list of qualified clinical outcome assessments holds patient-reported measures only⁹.

Author ity	Stance relevant to phone-derived endpoints
FDA	The December 2023 DHT guidance sets fit-for-purpose, verification, validation and data-integrity expectations regardless of device status. No DHT-derived endpoint has been qualified for drug trials through the DDT program; Apple's AFib History Feature was qualified under the separate MDDT program on 1 May 2024.
EMA	Qualified SV95C in Duchenne muscular dystrophy — as a secondary endpoint in 2019 and as a primary endpoint on 20 July 2023, subject to stated conditions. qointa has found no other EMA qualification opinion for a DHT-derived endpoint as at September 2026. Sponsors engage through the novel-methodologies qualification procedure.
ICH	E6(R3) is media neutral and states that digital health technologies such as wearables and sensors may expand the possible approaches to trial conduct, provided data integrity and traceability are preserved end to end. Annex 2 reached Step 4 on 3 June 2026 and takes effect in the EU on 15 January 2027.

6.1 Clearance enables measurement; it does not confer endpoint qualification

Device clearance enables measurement; it does not confer endpoint qualification, and a phone app in the data path does not lower the evidence bar. Where a phone-native measure is central to a program, its measurement properties must be established de novo, and the phone's edge-processing and provenance roles documented as part of that case.

7. The phone is not the device — a software function running on it can be

A phone is not a medical device by virtue of being a phone. FDA does not regulate the sale or conventional consumer use of smartphones or tablets, and does not treat platform makers as device manufacturers merely because their platforms can run a medical app. What can be regulated is the **software function** running on it, assessed one function at a time¹⁰. The decisive variables are intended use and claims, whether the function captures or relays data as against **interpreting or computing** a clinical result, its role in the trial, the risk if it malfunctions, and any commercial intent beyond the study.

Four questions must be kept apart.

- (1) Is the function a device?
- (2) Does it need its own authorization to be **used** in the trial — in the United States, whether an investigational device exemption is required and whether the investigation is significant-risk under 21 CFR Part 812¹¹?
- (3) Is the **endpoint** valid or qualified — a V3 and context-of-use question, independent of device status? (

to demonstrated accuracy.

⁹ FDA, "Qualified Clinical Outcome Assessments (COA)", fda.gov, content current as at 30 June 2026 — seven qualified COAs, all patient-reported. FDA did qualify Apple's AFib History Feature on 1 May 2024 under the separate Medical Device Development Tool (MDDT) program — the first digital health technology so qualified, and the closest precedent for a consumer-device-derived measure.

¹⁰ FDA, "Policy for Device Software Functions and Mobile Medical Applications" (guidance, 28 September 2022). The position is not absolute: a platform marketed with a device intended use can itself be regulated.

¹¹ 21 CFR Part 812 (investigational device exemptions), including the significant-risk / non-significant-risk determination and the categories of exempted investigations. FDA's DHT guidance does not decide device status; it states that verification and validation should be addressed regardless of whether the DHT meets the definition of a device.

(4) 4) Do data-integrity rules apply — 21 CFR Part 11, the EMA computerized-systems guideline and ICH E6(R3), all of which reach trial data whatever the device status?

Collapsing the four is how sponsors arrive at the wrong evidence package. A reminder app can be a non-device that must still meet data-integrity rules; a sensor app can be a device-grade measurement tool that, on the facts of a given study, needs no separate marketing authorisation to run in a trial — a judgment that turns on the Part 812 analysis, not on the app's sophistication.

Claims and trial role — not the technology — decide whether a phone function is a regulated device

The same handset runs functions at both ends of the spectrum; FDA assesses them one software function at a time

Not a device

Generally not a device

- Medication reminder or scheduling
- eDiary / ePRO capture
- Display or relay of sensor data
- BLE hub, store-and-forward
- Identity, timestamps, provenance
- eConsent and visit logistics
- General-wellness tracking

Still in scope of 21 CFR Part 11 and ICH E6(R3) data integrity if it produces trial data.

Depends on claims and role

Depends on claims and role

- Raw sensor capture feeding a measure
- Safety alert or clinical decision support (CDS carve-out test)
- Passive digital phenotyping
- Composite multi-sensor score
- Off-label use of a cleared consumer feature
- A reminder that adapts to the participant's data

Tips towards a device when it interprets data, drives a decision, or carries a clinical claim.

Regulated device

Generally a device

- On-device algorithm computing a clinical metric
- Active-task assessment (digital COA: tapping, cognition, voice)
- Camera diagnostic (skin, retina)
- Digital therapeutic — the app is the intervention
- Drug-device combination or companion function
- Adaptive dosing support

SaMD, classified by risk. US: 510(k), De Novo or PMA. EU: MDR Annex VIII Rule 11, read with MDCG 2019-11 Rev. 1.

Four questions, kept separate: is the function a device · does it need its own authorisation to be used in the trial (21 CFR Part 812) · is the endpoint valid or qualified · do data-integrity rules apply. The answers do not follow from one another.

The clinical-decision-support, AI-driven and passive-phenotyping boundaries move with guidance; classify against the text current on the date of the decision and record that date. In qointa's assessment the EU MDR pulls more software into the device net, and at higher risk, than the US framework.

Figure 3 — Claims and trial role, not the technology, decide whether a phone function is a regulated device.

7.1 Claims and trial role, not the technology, decide the verdict

The two anchor cases illustrate the range (Figure 3). An app using the phone's own sensors to derive a **primary endpoint** is near the regulated end: the deriving algorithm is a device software function, and primary status raises the validation bar to a full V3 package with the algorithm version locked. A **medication reminder** is a non-device — unless the trial is testing whether the reminder itself improves adherence or outcomes, in which case it becomes the investigational test article. Same technology, opposite verdicts, decided by claims and role.

Scenario	Likely status	What drives it
Sensor app deriving a primary endpoint	Device (the algorithm) + heavy validation	Interprets data; primary endpoint
Plain medication reminder	Not a device	Administrative; no clinical claim
Reminder whose effect is the endpoint	Test article / SaMD	The app is the intervention under study
Active-task assessment (tapping, cognition, voice)	Device (digital COA)	Administers a standardized assessment

Scenario	Likely status	What drives it
Camera diagnostic (skin, retina)	Device, often higher risk	Image interpretation for a medical purpose
Safety alert / decision support	Depends (CDS carve-out)	Whether a clinician can independently review
Digital therapeutic	Device / test article	The software is the treatment
Passive phenotyping (GPS, keystroke)	Depends; emerging	Novel construct; claim and interpretation
BLE hub / store-and-forward / eConsent	Generally not a device	Relay/logistics — but data-integrity rules apply
Off-label use of a cleared consumer feature	Re-opened	New context of use isn't inherited

Two boundaries move. Clinical decision support and anything AI-driven or based on passive phenotyping are being reshaped by successive FDA guidance, so a classification should be made against the text current on the date of the decision and that date recorded. In qointa's assessment the EU MDR pulls more software into the device net, and at higher risk, than the US framework, through the classification rules read with the Commission guidance on software qualification¹².

8. Six actions separate the two roles and size the evidence to each

qointa's recommendations follow from the sensor / conduit distinction, the V3 lens and the device-classification logic. They are ordered by how much evidence they save when applied at protocol design rather than at database lock.

#	Recommendation	Priority
1	Separate the phone's sensor role from its conduit role in every endpoint definition	High
2	Classify each phone software function early (device vs not) and keep the four questions separate	High
3	Validate the conduit roles — edge algorithm version, provenance, store-and-forward — as part of data integrity (FDA DHT guidance s.III; 21 CFR Part 11; EMA/INS/GCP/112288/2023; ICH E6(R3))	High
4	For phone-as-sensor, plan a full V3 evidence package; reserve phone-native primary endpoints for measures with established validation	High
5	Specify the connectivity topology, the failure modes and the reconciliation method in the protocol	Medium
6	Pursue qualification selectively for high-value phone-native candidates	Medium

8.1 The first question — sensor or conduit — sets the validation path

The first question — is the phone the sensor or the conduit — determines the evidence path.

¹² 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", read with MDR Annex VIII Rule 11. The comparison between EU and US breadth is qointa's professional judgment.

Ask one question first — is the phone the instrument or the conduit? — because it sets the whole evidence path

The two answers lead to different evidence packages, different owners and different failure modes

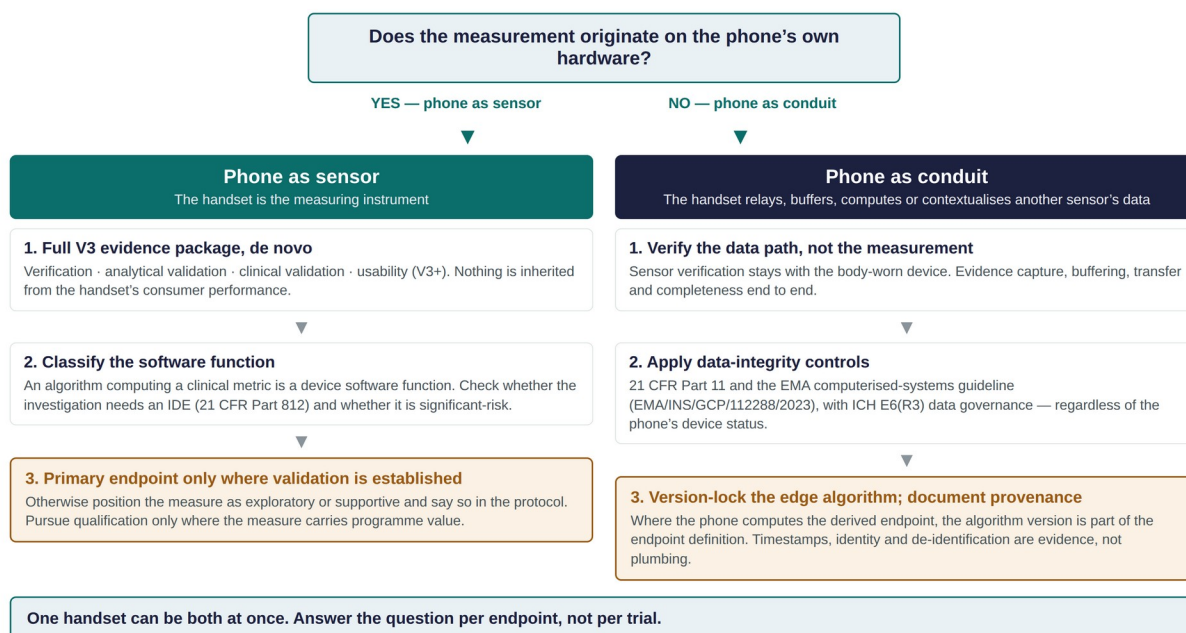


Figure 4 — The first question — instrument or conduit — sets the whole evidence path.

8.2 The heaviest risks sit on the edge algorithm and the phone-native primary endpoint

The principal risks cluster by the phone's role; mitigations map to the V3 layers and data-integrity controls.

Risk	Where it bites	Likelihood	Mitigation
Unvalidated phone-native measure used as primary	Phone as sensor	Medium	Full V3 package; downgrade to exploratory until validated
Edge-algorithm version drift changes the endpoint	Conduit (edge)	Medium	Version-lock; treat algorithm as part of endpoint definition
Data loss on disconnection	Conduit (transport)	Medium	Store-and-forward with reconciliation; completeness monitoring
Broken provenance / timestamps	Conduit (data-handling)	Low	Audit trails, synced clocks, E6(R3) data-governance controls
Qualification over-claim	Regulatory	Low	Scope claims to actual qualification status (SV95C precedent)

9. This paper rests on FDA's public device list and qointa's own analysis

This paper rests on two things: FDA's published list of sensor-based digital health technologies, which is US-government public-domain material, and qointa's own analysis of it. qointa classified each of the 269 entries by sensor modality and inferred a connectivity route from device class, name and maker; those classifications are **inferred, not audited**, and 226 of the 269 carry low confidence. They are fit for landscape framing and for shaping questions to a vendor; they are not fit to characterize a named device. FDA states that its list is not comprehensive and updates it periodically, so a later snapshot will give

different totals. The endpoint-library analysis that supported earlier drafts of this paper has been withdrawn pending written permission from the library's publisher; no count derived from it appears here, and the statements about how rare phone-native endpoints are stand as qointa's professional judgment until that permission is obtained. Regulatory positions are cited to the instruments named in the footnotes and were checked in September 2026; the classification boundaries for clinical decision support and AI-enabled functions are moving and should be re-checked at the date of any classification decision.

9.1 Sources

FDA, "Medical Devices that Incorporate Sensor-based Digital Health Technology" (snapshot 16 June 2026). FDA, "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" (final guidance, December 2023). FDA, "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers" (final guidance, October 2024). FDA, "Policy for Device Software Functions and Mobile Medical Applications" (28 September 2022). 21 CFR Part 11; 21 CFR Part 812. EMA, "Guideline on computerised systems and electronic data in clinical trials", EMA/INS/GCP/112288/2023. EMA qualification opinions on stride velocity 95th centile (EMA/CHMP/SAWP/178058/2019, secondary endpoint; CHMP opinion of 20 July 2023, primary endpoint). ICH E6(R3) Good Clinical Practice (Principles and Annex 1, Step 4 6 January 2025, EU effective 23 July 2025; Annex 2, Step 4 3 June 2026, EU effective 15 January 2027). MDCG 2019-11 Rev. 1 (June 2025). Goldsack JC et al., V3 framework, npj Digital Medicine (2020), extended to V3+ (DiMe / DATAcc, 2024; Bakker JP et al., npj Digital Medicine 8:51, 2025).