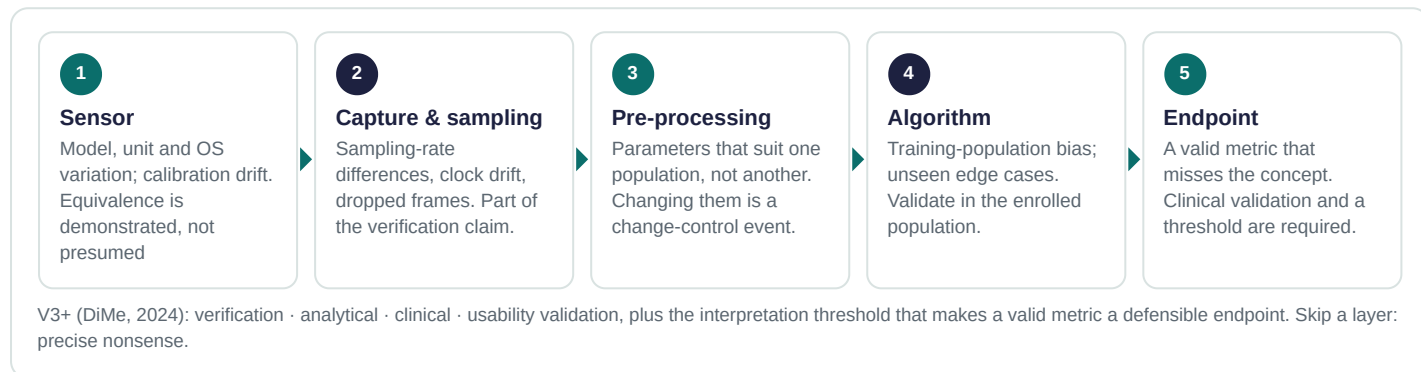


A sensor reading — from a wearable, a home instrument or a phone's own sensors — **is not an endpoint** until it is validated for the trial's own conditions.

Error enters at capture, pre-processing and the algorithm, and reliability alone is not enough. **Hold V3+ evidence for the enrolled population, the real conditions of use and the exact device, firmware and OS fleet — plus a pre-specified, patient-anchored meaningful-change threshold — before enrollment, not after lock.**

THE PICTURE Each link of the chain can distort the result; no one claim covers all



QOINTA'S POSITION Four positions that decide whether the endpoint survives submission

"The accelerometer works" is a hypothesis to test

Consumer sensors are capable, but capability in general is not performance for a specific measurement in a specific population on a specific fleet; accuracy degrades outside intended use.

An endpoint must be interpretable, not just valid

The measure must detect real change and carry a defined, patient-anchored meaningful within-patient change threshold — set before analysis and distinct from the treatment-effect test.

Fit-for-purpose is contextual, not absolute

Validated in supervised healthy adults is not valid for unsupervised, elderly, motor-impaired participants at home. The trial's own conditions are the test; the bar rises with endpoint role.

Outside the validated specification is unverified

Once models, firmware and OS range are specified, anything outside is unverified — live in BYOD, quieter in provisioned fleets. Updates are a change-control discipline (QPP-07).

FIVE DUTIES, ONE PER PARTY IN THE CHAIN — NONE IS DELEGABLE

- Sponsor: own the fit-for-purpose decision**, validation plan and interpretation threshold — accountability is not delegable.
- Vendor: generate and hold verification and analytical evidence** for capture, pre-processing and algorithm; control every update.
- Manufacturer: specify performance characteristics** and intended-use conditions; state plainly where use falls outside them.
- Biostatistics: treat device/OS heterogeneity and the threshold** as explicit analysis assumptions, not footnotes, and defend them.
- Engage the qualification route early** — FDA DDT or EMA Qualification of Novel Methodologies — as advice before full qualification.

4

validation questions in V3+:
verification, analytical, clinical,
usability

0

wearable endpoints qualified
under FDA COA or biomarker
programs, Sept 2026

1 May 2024

first DHT qualified under FDA's
MDDT program — Apple's
AFib History Feature

20 Jul 2023

CHMP qualified SV95C as a
primary endpoint in ambulant
Duchenne from age 4

Read with care. Risk likelihood and impact ratings are qointa's qualitative assessment for prioritization; the worked example is an illustrative composite; the FDA qualification count is stated "to our knowledge".

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-07 Change Control · QPP-09 Human Factors · QPP-15 Endpoint Qualification · QPP-17 Representativeness and Equitable Access



Summary of QPP-01 1.0 — the full paper, with sources and figures, is published at qointa.com.

FDA DHT guidance for Remote Data Acquisition (2023) · FDA PFDD guidance series · FDA-NIH BEST · FDA DDT and ISTDAND · EU MDR Annex II · ICH E6(R3) Annex 1 and 2 · EMA Qualification of Novel Methodologies · DiMe V3+

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