

A verified and validated digital measure is not, by that fact alone, ready to carry a regulatory endpoint: qualification is a separate decision for a stated context of use.

Getting it wrong is rarely recoverable — a COU too broad or a population mismatched at submission cannot be repaired with data already collected. **Define the context of use before the evidence, size verification, analytical and clinical validation to it, choose the pathway, and fix the COU and the bar with the regulator before pivotal data.**

THE PICTURE

There is no single route: the pathway follows the context of use and whether qualification must be reusable

FDA · S.507

Drug Development Tool qualification

Formal public programme — Biomarker, COA, Animal Model and ISTAND — fixing a COU other programmes may rely on.

EMA · CHMP

Qualification of novel methodologies

Qualification opinion, advice or letter of support for a specified COU; source of the only qualified digital endpoint, SV95C.

FDA · CDRH

Medical Device Development Tool

Device-side counterpart; the precedent is Apple's Atrial Fibrillation History Feature, qualified 1 May 2024.

SINGLE TRIAL

Study-specific endpoint justification

Justified for one trial through a formal Center meeting or EMA scientific advice; still built to the COU.

LOWEST EFFORT

Reliance on a qualified measure

Available only where the COU matches exactly.

SV95C, captured by an ankle-worn wearable, was qualified twice for ambulant Duchenne: as a secondary endpoint (EMA/CHMP/SAWP/178058/2019) and, on 20 July 2023, as a primary endpoint in superiority studies — escalated only on new evidence.

QOINTA'S POSITION Four assertions that separate a validated measure from a qualified endpoint

Validation answers a different question from qualification

Validation asks whether the measure is trustworthy; qualification asks whether it may decide this regulatory question. "Validated" is a property of the measure; "qualified" of its use for a stated COU.

The context of use is the unit

A measure is never qualified in general — only for this concept, population, disease, decision and stage. Change the COU and the qualification does not automatically follow.

Evidence is built to the bar, not assumed to clear it

V3 — verification, analytical and clinical validation, plus V3+ usability — is the structure; the COU sets how much of each. A primary-endpoint or label-claim COU attracts the fullest package.

Qualification is maintained, not granted once

A device or sensor change, an algorithm update, population or COU drift, or real-world deployment conditions can disturb the binding and should trigger re-confirmation.

FIVE STEPS, IN THE ORDER THE QUALIFICATION IS BUILT

- 1 Define the context of use** in six fields: measure, concept, population and disease, decision, development stage, conditions of use.
- 2 Map evidence to the COU** — verification, analytical validation, clinical validation and usability, sized per the V3+ framework.
- 3 Choose the pathway:** FDA DDT, FDA MDDT on the device side, EMA qualification, study-specific justification or reliance.
- 4 Engage the regulator early** — a formal Center meeting, DDT interaction, EMA qualification advice or scientific advice — before generating data.
- 5 Maintain the qualification:** re-confirm whenever the measure, device, population or COU changes.

1

digital endpoint formally qualified for medicinal-product trials in the EU as at September 2026 — SV95C

0

DHT-derived endpoints qualified under the s.507 DDT programmes for drug trials, to qointa's knowledge

2

qualifications of the same measure — secondary endpoint in 2019, primary endpoint on 20 July 2023

7

readiness questions a sponsor must answer before relying on the measure

Read with care. The evidentiary ladder in Figure 1 is qointa's assessment of relative burden, not a regulator's scale. The two case outcomes are illustrative composites, not specific studies; the SV95C history is the documented precedent.

READ NEXT

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Summary of QPP-15 1.0 — the full paper, with sources and figures, is published at qointa.com.

s.507 FD&C Act (DDT: Biomarker, COA, Animal Model, ISTAND) · FDA MDDT · EMA qualification of novel methodologies · EMA/CHMP/SAWP/178058/2019 · FDA DHT guidance (s.IV.C.3) · FDA patient-focused drug development guidance series · V3 / V3+ framework

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