

In a decentralized trial the device is both a risk to the data and the richest source of monitoring signal — its telemetry belongs **inside the monitoring plan**.

Uptime, sync, completeness, sensor health, version drift and capture timing are all observable continuously; none is monitoring until someone owns the indicator and a breach has somewhere to go. **Name the device risks, give each an owned indicator with a pre-specified range, and wire every breach to action.**

THE PICTURE Six device indicators: none is monitoring until it is owned and routed

INDICATOR 1

Device uptime

Risk: non-use and data loss. An absent signal is ambiguous — failure or non-use — and the plan resolves it.

INDICATOR 2

Sync success

Risk: data stranded on the device or its relay. Drives reconciliation before lock.

INDICATOR 3

Completeness

Risk: capture below schedule. Drives query activity in data management.

INDICATOR 4

Sensor self-test

Risk: drift or fault. Where the DHT is a medical device, may be a device deficiency or reportable incident.

INDICATOR 5

Version inventory

Risk: validated-state drift. Routes to the Trigger Register and change control as the early warning.

INDICATOR 6

Capture timing

Risk: adherence. Tells the study when, not only whether, the participant captured.

Every acceptable range is derived from this study's risk assessment (E6(R3) s.3.10.1.3); the values shown in the paper's Figure 3 are qointa's illustration and have no regulatory or empirical status.

QOINTA'S POSITION Telemetry is monitoring only as an owned indicator with a routed action

Risk-proportionate monitoring includes device risks

ICH E6(R3) requires monitoring whose extent and nature follow the identified risks (s.3.11.4); nothing in it excludes the device that generates the data.

Decentralization changes the instrument, not the duty

A connected device yields a continuous, time-stamped record of its own operation — continuous rather than sampled, contemporaneous rather than reconstructed — that a site visit never could.

The instrument has known limits, and the plan states them

Telemetry is silent when a device is off or suspended; a participant's own handset narrows collection; central review can unblind; the analytics are a validated computerized system.

A breach that routes nowhere is decoration, not monitoring

Version drift goes to the Trigger Register and change control; sensor-health signals to vigilance where the DHT is a device; completeness and sync to data management before lock.

FIVE STEPS, FROM DEVICE RISK TO ROUTED SIGNAL

- 1 Identify device-side risks** — which device behaviors threaten safety or data reliability in this decentralized setup.
- 2 Define the indicators** — turn each risk into a named indicator with an owner and a data definition.
- 3 Instrument the telemetry** — capture uptime, sync, completeness, sensor health and version data in a controlled, traceable way.
- 4 Set acceptable ranges and actions** — pre-specify the range for each indicator from this study's risks, and the action a breach triggers.
- 5 Feed the register and lifecycle** — route signals into the Trigger Register (QPP-08), change control (QPP-07) and vigilance (QPP-18).

Read with care. ICH E6(R3) uses neither 'risk-based monitoring' nor 'key risk indicator'; reading device telemetry into its risk-proportionate frame is qointa's position, not a regulator's instruction. EMA/269011/2013 is superseded.

READ NEXT

QPP-08 Trigger Register · QPP-12 Vendor Qualification and Oversight · QPP-07 Change Control · QPP-18 Vigilance and PMS · QPP-10 Data Integrity · QPP-22 Continuous Monitoring



Summary of QPP-21 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) s.3.10, 3.10.1, 3.10.1.3, 3.11.4; Annex 2 (Step 4, 3 June 2026) · FDA risk-based monitoring guidance (2013) and Q&A guidance (2023) · EMA/INS/GCP/112288/2023 · HMA/EC/EMA Recommendation paper, Version 02

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