

Fund a summative usability evaluation of every critical task, on representative participants and the real device range, **before enrollment.**

Use-error in a participant-facing DHT is a regulated safety and data-quality risk, not polish — and it concentrates in the participants the trial most needs to hear from. **Identify the critical tasks, set the evidence depth in the RIA, test on real users and real devices, and detect use-error in the field.**

THE PICTURE Five triggers raise the human-factors weight; each names its evidence

If this is true of the deployment...	...the weight rises because	Evidence / mitigation
Participants self-administer a task that affects safety	Use-error can cause harm; critical-task analysis is engaged	Identify the critical tasks; run summative evaluation on them
The device captures data used in the analysis	Use-error degrades endpoint quality directly	Validate data-entry tasks on representative users; track missing data
The population is older, impaired, paediatric or low in literacy	The usability bar and evidence expectations rise	Representative users in formative and summative tests; accessibility
Use is unsupervised and remote	No site staff catch or correct use-errors	Error-tolerant flows and in-app guidance; monitor use-error signals
The app runs on a heterogeneous BYOD fleet	The validated interface is not the one each participant sees	Validate across the device / OS range; test accessibility settings

Each trigger feeds the RIA (QPP-00) and the Trigger Register (QPP-08). Task criticality and population difficulty set how much evidence a trial DHT needs — proportionate, not one-size-fits-all.

QOINTA'S POSITION Four positions that move usability from “polish” into the evidence plan

Use-error is a safety and a data-quality issue at once

One mis-tap is three failures: a safety event, a missing or wrong data point in the endpoint, and a representativeness problem — use-error concentrates in the participants who struggle most.

Device rules make it a design duty; trial rules a data duty

IEC 62366-1 and MDR Annex I bind devices used by lay users. Where the DHT is not a device, FDA's DHT guidance still requires a usability evaluation for the trial population.

The population sets the bar

A design a young, supervised, digitally fluent user navigates without error can defeat an older, impaired, paediatric or low-literacy participant using the device unsupervised at home.

BYOD multiplies the interfaces that must be covered

Screen size, OS version, font-scaling, dark mode and accessibility settings change what each participant sees. A summative evaluation on one reference device does not cover the fleet.

SIX ACTIONS THAT PRODUCE PROPORTIONATE, DEFENSIBLE EVIDENCE

- 1 Identify the critical tasks** — separate the interactions that can cause harm or corrupt a key measurement from the rest.
- 2 Right-size the evidence in the RIA** — scale formative and summative work to task criticality and population difficulty.
- 3 Test on real users and real devices** — summative evaluation with representative participants across the BYOD range, not proxies.
- 4 Specify and review the usability-engineering file** — users, environment, use-related risk and evaluation record (QPP-06).
- 5 Build a field path to detect use-error** and feed it back into design and the Trigger Register (QPP-08).
- 6 Protect representativeness** — treat use-error as an equity issue so the data reflects the participants who struggle most (QPP-17).

5

triggers raise the human-factors weight of a deployment

8

questions set the human-factors evidence depth in the RIA

3

failures per mis-tap: safety event, data defect, representativeness

2

evaluation stages: formative before design lock, summative on the final interface

Read with care. The field case is an illustrative composite. FDA has two human-factors guidances in play: the 2016 Applying Human Factors guidance (revised 3 Aug 2026) and the submission-content guidance (final May 2026). Evidence depends on device, tasks and population.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-06 Inspection-Readiness · QPP-08 Trigger Register · QPP-17 Representativeness and Equitable Access



Summary of QPP-09 1.0 — the full paper, with sources and figures, is published at qointa.com.

IEC 62366-1 · ISO 14971 · EU MDR Annex I · FDA Applying Human Factors guidance (2016, revised Aug 2026) · FDA HF submission-content guidance (final May 2026) · QMSR · FDA DHT guidance · FDA decentralized-trials guidance · ICH E6(R3)

Annex 2 · EMA computerized-systems guideline

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