

A DHT is **not demographically neutral**: device, connectivity, interface and provisioning decide who takes part — and exclusion is a data-validity problem first.

A measure that under-samples older adults or people with low literacy or poor connectivity may not generalize to the population the product is for. **Define the target population, map who the device cannot reach, design for access, test for differential performance, and record it in the RIA with the validation evidence.**

THE PICTURE Five design choices decide whether a deployment narrows or widens reach

Design choice	How it narrows reach	How it widens reach
BYOD vs provisioned	BYOD assumes a suitable device and data plan	Provisioning removes the ownership barrier — if logistics reach everyone
Connectivity model	Always-online apps exclude low-connectivity participants	Offline-tolerant capture with later sync reaches rural / intermittent users
Language and literacy	Single-language, text-heavy interfaces exclude many	Multilingual, low-literacy and audio-supported designs broaden access
Accessibility	Small targets and no assistive support exclude impaired users	Accessible design and assistive-tech support include them
Support model	Self-service only assumes digital confidence	Human and helpline support keeps less-confident participants enrolled

Each choice is tied to a regulatory hook: ICH E6(R3) 1.4, CTR Recital 14, the HMA/EC/EMA recommendation paper v02, FDA DHT guidance s.IV.A.1, IEC 62366-1:2015 + A1:2020. Illustrative — which choices matter is a matter for assessment of the specific population.

QOINTA'S POSITION Four positions that move representativeness out of the equity annex

Device choice is a population choice

The wearable, home instrument, phone or tablet — with its connectivity, interface and provisioning route — decides who can realistically take part, and therefore who the data describe.

Exclusion is a validity problem, not only an equity one

An endpoint from a device that under-samples part of the target may not generalize to it; a label claim resting on it is, to that extent, unsupported. Context of use includes the population.

Representativeness has a durable anchor in GCP and EU law

ICH E6(R3) Principle 1.4 requires selection representative of the groups the product is intended to benefit; the CTR asks the same at assessment (Recital 14; Art. 6(1)(b)(i)).

"Available to everyone" is a conclusion to be evidenced

Broad ownership is not broad access. Provisioning moves the step rather than removing it; each assumption falls hardest on the groups trials most often under-represent.

FIVE STEPS, FROM TARGET POPULATION TO RECORDED RATIONALE

- 1 Define the target population** — the population the product is actually for, the reference against which representativeness is judged.
- 2 Map device-driven exclusion** — who the device, connectivity and interface cannot reach: age, literacy, language, connectivity, disability.
- 3 Design for access** — BYOD vs provisioned, offline tolerance, language, accessibility and support models that widen reach.
- 4 Check for measurement bias** — whether the measure or any model behind it performs differently across groups.
- 5 Document the rationale** in the RIA alongside the validation and qualification evidence — not in a separate equity annex.

Read with care. The US Diversity Action Plan duty (FDORA 2022) is enacted but not in effect: FDA's June 2024 guidance remains a draft (checked 1 September 2026), the June 2025 deadline was missed, and the duty starts 180 days after final guidance.

READ NEXT

QPP-00 RIA · QPP-01 Endpoint Validation · QPP-02 Data Residency · QPP-04 AI/ML Overlay · QPP-08 Trigger Register · QPP-09 Human Factors · QPP-15 Endpoint Qualification · QPP-16 PCCP



Summary of QPP-17 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) Principle 1.4 · CTR Recital 14, Art. 6(1)(b)(i) · FDORA (2022) Diversity Action Plans · FDA draft DAP guidance (June 2024) · HMA/EC/EMA recommendation paper v02 · FDA DHT guidance · IEC 62366-1:2015 + A1:2020

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