



Fit-for-Purpose Technical and Clinical Validation for Digital Health Technologies (DHTs) in Clinical Trials

Ensuring Ongoing Compliance for Life Sciences Systems

Deploying Digital Health Technologies (DHTs)—including wearables, connected sensors, and Software as a Medical Device (SaMD)—in clinical trials is not just about device availability. It's about ensuring that every DHT is clinically valid, technically accurate, usable by the intended population, and fit-for-purpose in supporting protocol-defined endpoints.

Why DeviceFit Is Essential

qointa DeviceFit is a specialized validation and risk management service designed to ensure DHTs meet regulatory, clinical, and operational expectations across global trials. It aligns with ISO 14971, IEC 62366-1, FDA QSR, EU MDR Annex I, and ICH-GCP standards.

Many DHTs are cleared for consumer or general medical use—but not necessarily validated for your trial population, endpoint accuracy, or clinical setting. Misuse or under-validation leads to:

- Data exclusions by regulators (e.g., FDA, EMA, PMDA)
- IRB/EC pushback or study delays
- Safety risks from poor usability or insufficient performance

DeviceFit enhances validation with RWE inputs that reflect true real-world variability, environmental factors, and demographic differences not captured in controlled bench testing or vendor claims.

DeviceFit eliminates these risks by providing end-to-end validation of technical, clinical, and operational suitability.

DeviceFit = Validation Without Compromise

“How do you confirm that your POC devices are clinically valid and technically accurate for your specific trial population and endpoints?”

“Have you evaluated whether consumer-grade wearables (e.g., Fitbit, Apple Watch) meet clinical-grade accuracy and regulatory expectations for your study?”

“What’s your process for assessing usability risks for elderly, pediatric, or multilingual users in global trials?”

“When device firmware or companion apps are updated, do you revalidate performance and recheck regulatory compliance?”

“Are your devices mapped to protocol endpoints with documented accuracy, traceability, and clinical performance metrics?”

“Is your DHT validated to support primary or secondary endpoints?”

“Can you demonstrate equivalence of consumer-grade devices vs. medical-grade alternatives?”

“Do your devices meet usability, risk, and performance standards across global populations?”

“Do you have revalidation processes when firmware or app updates occur?”

Risks we mitigate:

Risk	Regulatory Impact
• Using unvalidated consumer devices	• Endpoint data exclusion by regulators
• Poor usability in elderly/ pediatric users	• Protocol deviations and site burden
• No risk file or ISO 14971 compliance	• Audit findings or ethics board rejection
• Software updates without reassessment	• Data loss, traceability failure
• Inaccurate device performance	• Misleading primary/ secondary endpoint results

Our Comprehensive Services

1. Fit-for-Purpose Validation

- Match device outputs to study endpoints, patient populations, and data models.
- DeviceFit provides validation packages to ensure clinical significance of DHT-derived endpoints is demonstrated and supported.

2. Usability & Human Factors Testing

- Evaluate usability per IEC 62366-1 and FDA Human Factors Guidance.

3. ISO 14971 Risk Management

- Generate a device-specific Risk Management File.
- Identify use-related hazards in decentralized or hybrid settings.
- Recommend mitigations for integration into protocol, SOPs, or training.
- DeviceFit integrates revalidation triggers for firmware and software updates, aligned with FDA's position on software change impact under the DHT Framework and MDR Rule 11. Each update initiates a new hazard/risk profile review.

4. Software/Connectivity Risk Review

- Classify software under FDA SaMD, MDR Rule 11, and IMDRF frameworks.
- Evaluate data security, audit trails, and API behavior.
- Assess companion app functionality and update risks.
- Supports change tracking and version control for AI/ML-based features in SaMD, referencing FDA PCCP guidance and EU AI Act traceability mandates.

5. Endpoint-Specific Technical Evaluation

- Validate device output against endpoint definitions in the protocol.

6. Interoperability & Platform Compatibility

- Confirm integration with EDC, eCOA, eSource, or SaMD platforms.
- Validate timestamp, sync logic, and metadata traceability.
- Align output with CRFs and data models for regulatory submission.

**Validated devices yield valid data.
Fit-for-purpose validation powers fit-for-
approval outcomes.**

Why Choose qointa?

01 Regulatory Mastery

We excel in understanding and navigating complex regulatory requirements, ensuring compliance and product approval.

02 Quality Excellence

qointa is committed to helping you maintain the highest standards of quality throughout your operations.

03 Customized Solutions

We tailor our services to your specific needs, ensuring a personalized and effective approach.

04 Global Expertise

Our team has extensive experience in dealing with regulatory standards and compliance across the globe.

05 Holistic Approach

Our services cover every aspect of quality and regulatory support, offering a one-stop solution for your needs.

Partner with qointa to Ensure Ongoing Compliance

qointa provides the expertise and flexibility to help Life Sciences organizations maintain the compliance of their systems, ensuring continued product quality and patient safety. Let us handle the complexities of validation and compliance so you can focus on your core business.

With DeviceFit, you don't just deploy a device—you defend it. You validate it for science, for safety, and for global regulatory scrutiny.



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