

Secure, Compliant, and AI-Ready Integration for Digital Health Technologies (DHTs) in Clinical Trials

Ensuring Ongoing Compliance for Life Sciences Systems

In decentralized and hybrid trials, Digital Health Technologies (DHTs)—including wearables, SaMD, sensor-based tools, and provisioned or BYOD devices—must do more than just collect data. They must connect, sync, and report securely and traceably across clinical systems such as eCOA, EDC, eSource, and CTMS.

qointa DeviceConnect is a consulting and implementation service purpose-built for regulatory-grade integration of DHTs. It ensures every data point is time-synced, traceable, encrypted, and audit-ready, fully aligned with FDA, EMA, PMDA, NMPA, and global health authority expectations.

Why DeviceConnect Is Critical

As DHTs become trial-critical, so do their integration challenges:

- SaMD and platform APIs change frequently, risking unvalidated endpoints.
- Sync failures and data silos compromise data integrity and audit trails.
- AI/ML-enabled tools require version traceability and explainability documentation.

DeviceConnect eliminates these risks by embedding integration governance, system compatibility, and regulatory documentation across the device lifecycle.

DeviceConnect = From Connection to Compliance

“How do you ensure that your POC devices seamlessly integrate with your eCOA, EDC, and eSource platforms—without compromising data integrity or audit trails?”

“Are you confident that every data point captured by your devices is time-synced, traceable, and properly tagged for endpoint mapping?”

“What happens when your device firmware updates or your API version changes mid-study—do you have a validated change control process in place?”

“Are your device data flows secure, encrypted, and compliant with ISO 27001, 21 CFR Part 11, and GDPR?”

“If your device includes AI or algorithm-driven scoring, how are you documenting explainability, traceability, and compliance with FDA PCCP or the EU AI Act?”

“Are your DHTs technically integrated and regulatorily defensible across your eClinical platforms?”

“Can your team trace every AI-driven data point to the algorithm version and source timestamp?”

Risks we mitigate:

Risk

- Mismatched timestamps
- Unsecure API transmission
- Firmware/API incompatibility
- No audit trail for device logs
- AI/ML drift without controls

Regulatory Impact

- Invalid data for primary endpoints
- Data breach or HIPAA/GDPR violation
- Data loss; repeat visits; protocol deviation
- GCP noncompliance; regulatory finding
- Invalid scoring or endpoint misclassification

Our Comprehensive Services

1. System Architecture & Data Flow Mapping

- Design validated system architectures supporting real-time or batched data ingestion.
- Map DHT integrations with: eCOA/ePRO, EDC/eCRF, eSource and eConsent, SaMD and AI-enabled companion apps
- Deliver system diagrams and interface protocols for Design History Files (ISO 13485:2016 Clause 7.3.4).

2. Metadata Standardization & Endpoint Mapping

- Assign structured metadata: device ID, firmware, calibration, geolocation, timestamp.
- Link DHT outputs to protocol-defined endpoints and CRFs.
- Document data lineage and chain-of-custody per ALCOA+ and ICH E6(R3).
- DeviceConnect ensures that metadata schemas and endpoint mappings clearly delineate COA classifications, supporting structured data review and audit readiness.
- DeviceConnect supports integration of RWE-derived metadata models (e.g., baseline variability, environment-of-use factors) to enhance interpretability and statistical alignment of digital endpoints.

3. Time Synchronization & Data Integrity Controls

- Prevent timestamp drift across devices, APIs, and platforms.
- Normalize time zones and apply offset corrections for global consistency.
- Ensure real-time and event-driven data are reliably captured for endpoint use.
- Align with 21 CFR Part 11.10(e) and EU GMP Annex 11 (Section 9).

4. SaMD/API Validation & Lifecycle Documentation

- Validate APIs and firmware using ISO/IEC 62304, FDA SaMD, and IEC 82304-1.
- Manage change control across device software, firmware, and platform APIs.
- Maintain integration test logs and API version control trackers.

5. Cybersecurity & Data Privacy Assurance

- Assess encryption, buffering, and API tokenization (TLS 1.3 preferred).
- Align with ISO/IEC 27001:2022, ISO/IEC 27701, and NIST SP 800-53/800-82.
- Implement audit trails, identity management, and endpoint authentication.
- Comply with HIPAA, GDPR, and MDR Annex I (Cybersecurity).

6. AI/ML Traceability & Algorithm Governance

- Trace data from AI-driven DHTs across inputs, model version, and scoring outputs.
- Document model explainability, risk controls, and drift thresholds.
- Align with FDA PCCP, EU AI Act Articles 10–13, and IMDRF SaMD Risk Framework.
- Maintain audit logs and performance monitoring for each deployed algorithm version.

7. Change Management & Interoperability Validation

- Support sponsor Change Control Boards (CCBs) and platform version updates.
- Update risk files, test reports, and validation logs per ISO 13485 Clause 7.3.9 and FDA 21 CFR 820.30(i).
- Deliver performance benchmarks pre- and post-integration.

Why Choose quinta?

01 Regulatory Mastery

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

02 Quality Excellence

quinta 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 quinta to Ensure Ongoing Compliance

quinta DeviceConnect bridges the gap between tech enablement and regulatory confidence. From source timestamp to API schema, it ensures that DHT data is not just connected, but validated, traceable, and secure. Because in clinical trials, integration isn't optional—it's regulated.

Let DeviceConnect be your compliant pathway from bedside to database.



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