



Multilingual Training & Onboarding for POC Devices in Decentralized Clinical Trials (DCTs)

In decentralized trials, devices aren't just tools—they are part of the clinical workflow. And yet, training is one of the top root causes of protocol deviations, audit findings, and data loss in device-enabled studies.

qointa TrainReady is a turnkey training and onboarding service designed to equip patients, caregivers, site staff, and vendors with the knowledge and tools they need to use POC devices safely, effectively, and in compliance with clinical and regulatory standards.

Built for global deployment, diverse populations, and regulatory scrutiny, TrainReady closes the training gap and future-proofs your device-enabled trials.

Why TrainReady Is Essential

In a recent audit of global decentralized studies, over 40% of device-related deviations were traced back to:

- Inadequate or outdated training materials
- Language or cultural mismatches
- Lack of documentation for inspection readiness

TrainReady directly addresses these challenges, reducing risk and ensuring readiness across all user groups.

“How are you currently ensuring that patients, caregivers, and site staff are trained consistently—and in their native language—on using POC devices?”

“Do you have audit-ready training logs for every user of every device in your trial?”

“What's your process for retraining when a protocol changes, a new site is added, or a device is updated?”

“Are you able to track training completion in real time across global sites, roles, and trial arms?”

“Have you ever faced an audit or ethics board query about device misuse, user error, or undocumented training?”

Risks we mitigate:

Risk	Regulatory Impact
• Untrained device users	• Data loss; GCP deviations
• Lack of training records	• Audit finding; TMF gap
• Language barriers	• User errors; device misuse
• No retraining on updates	• Noncompliance; increased support calls
• Training inconsistencies across geographies	• Ethics board rejection; brand risk

Regulators certify your trial—not your vendor. TrainReady makes that possible.

Our Comprehensive Services

1. Turnkey Training Content Development

- Develop comprehensive, study-specific training for: Patients, Caregivers, Site coordinators, CRO monitors, Third-party vendors

2. Multilingual & Localized Delivery

- Translate and localize content across regions, tailored to:
 - Language
 - Literacy level
 - Cultural context
 - Device familiarity

3. Human Factors-Informed Design

- Incorporate usability best practices (EN 62366-1)
- Adapt materials to populations such as elderly, pediatric, or remote users
- Simplify complex device instructions without losing clinical fidelity

4. Regulatory-Ready Documentation

- Generate training logs and completion records traceable to individual users and trial sites
- Align with ISO 13485:2016, 21 CFR Part 820, and GCP inspection criteria

- Populate TMF with validated training artifacts
- Training modules developed in TrainReady are tailored to the COA type being supported (e.g., performance outcomes vs. patient-reported outcomes), improving endpoint data quality and regulatory defensibility.

5. Learning Management System (LMS) Integration

- Deliver and track training via sponsor or CRO LMS platforms
- Provide real-time dashboards showing:
 - Completion status
 - Overdue modules
 - Retraining needs
- Optional white-label LMS support for turnkey rollout

6. Helpdesk Workflow & Escalation Design

- Define post-training support pathways for device users
- Create Tier 1 FAQs, Tier 2 escalation protocols, and vendor handoffs
- Integrate with site call centers and patient engagement teams

7. Training Lifecycle & Refreshers

- Schedule retraining for:
 - Protocol amendments
 - Device substitutions
 - Long-duration studies

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

With TrainReady, your devices don't just work—they work safely, work consistently, and stand up to inspection. Whether your device is going to Tokyo, Toronto, or Tampa, TrainReady ensures it's understood, accepted, and used correctly.

TrainReady = Right Training. Right User. Right Time.



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