



THE CDM QUALITY & SECURITY FRAMEWORK: THE ZILLA STANDARD

How Zilla Clinicals Deploys Audit-Ready Clinical Data Management Pods Using Proprietary Simulation Training and Global Delivery Excellence.



1. The Human–Technology Synergy

Traditional Clinical Data Management outsourcing models focus on staffing availability. Zilla Clinicals focuses on proven proficiency.

Our framework is built on the belief that high-quality data outcomes are achieved when well-trained people operate within rigorously tested systems. To achieve this, Zilla Clinicals developed Zilla EDC – a proprietary Electronic Data Capture platform used exclusively to train, validate, and certify Clinical Data Management professionals before they ever touch a live client study.

Every Zilla CDM professional completes over 500 hours of structured simulation covering database builds, data entry, query management, external data reconciliation, and database lock scenarios. This removes the traditional learning curve and ensures immediate execution upon deployment.



2. The Three Pillars of Quality Control

Pillar 1: Integrity-First Validation

Zilla operates a strict maker-checker methodology across all data activities. All critical data points are reviewed by a senior resource prior to final submission.

All staff undergo recurring ICH-GCP (E6 R2) training, SOP refreshers, and protocol-specific briefings to ensure compliance is embedded into daily operations, not treated as a checklist.

Pillar 2: Security & Data Privacy

Zilla Clinicals operates under GDPR- and HIPAA-aligned data protection principles.

Access to client systems is controlled through encrypted VPN connections, multi-factor authentication, role-based access controls, and monitored hardware usage. Client data is never stored locally and remains the exclusive property of the sponsor.

• Pillar 3: Zero-Lag Communication

- Our Nigerian delivery hub provides overlapping business hours with both U.S. and European teams, enabling same-day query resolution and continuous study momentum.

- Each CDM Pod is led by a dedicated Pod Lead who serves as the single point of contact, eliminating communication delays common in traditional outsourcing models.



3. The Zilla CDM Pod Deployment Model

Zilla Clinicals does not deploy individuals. We deploy high-performance CDM Pods.

A standard CDM Pod consists of:

- One Lead Clinical Data Manager (5+ years experience; Medidata/Veeva proficient)
- Two to three Zilla-certified Clinical Data Associates
- Fractional Quality Assurance oversight

Pods are assigned to specific studies or programs and operate as an extension of the client's internal data management team.



4. Audit Readiness & SOP Alignment

Audit readiness is a continuous process at Zilla Clinicals.

Training records, simulation performance logs, and certification outcomes are maintained for every CDM professional. These records can be made available to clients as part of vendor qualification or audit support.

Zilla Pods can operate under Zilla's Quality Management System or rapidly adopt client-specific SOPs within 48 hours of onboarding.



Your Next Step

Zilla Clinicals delivers more than outsourced Clinical Data Management — we deliver peace of mind.

To learn how a Zilla CDM Pod can support your upcoming studies, we invite you to schedule a 15-minute Capability Audit with our team.



QUESTIONS ?

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