Clinical QMS

Simplify Studies with Streamlined and Optimized Clinical Management

Life Science organizations need an efficient solution for clinical data management that allows them to holistically manage data, documentation and regulatory activities across the different clinical stages.

Dot Compliance's Clinical solution combines Clinical Trial Management Software (CTMS) with QMS to optimize clinical documentation, quality, and compliance. Risk is reduced and communication between sponsors, Contract Research Organizations (CROs), and sites are streamlined to help to increase visibility into the clinical trial process.

Streamline end-to-end processes
Easily access, plan, benchmark, report, bill, and track clinical trial data in a single, centralized location.

Drive efficiency
Document, organize, and evaluate all data and processes involved in a clinical trial using Dot Compliance's Binders.

Improve collaboration
Increase visibility for all parties involved, enabling easy access to study information, Electronic Trial Master Files (ETMF), clinical documents and tasks.

Key capabilities include:

Clinical Trial Record

Management of clinical trial record from initial stages till study closeout. Management of clinical site initiation process including the communication with study team, site contacts, and patients (blinded or un-blinded).

Trial Master File (TMF)

Document management for trial master file.

Submission Management

Tracking of submission to Site IRB/EC, related correspondence, and tasks.

Subject Screening and Enrollment

Track the stages of patient screening and enrollment and related activities.

Monitor Visit Tracking

Management of site monitoring visits including planning, assignments, and status tracking. Track visit summary report and associated medical activities.

Patient Medical Event/Activities

Tracking of planned and actual clinical activities and events. Manage the monitoring status and completeness of data and payment authorization and schedule.

Study Portal

Allow access to external parties to a defined subset of data. Coming Soon.

Electronic Data Collection (Electronic Forms)

Create validated electronic forms on demand.