Transform Clinical Operations with CONFORM™ - CTMS

Integrated, Intelligent Solutions for Effective Trial Management

About CONFORM™ CTMS

The CONFORM™ Clinical Trial Management System (CTMS) is an advanced, integrated solution for managing the operational aspects of clinical trials. As part of the CONFORM™ eClinical Platform, our CTMS ensures that clinical trial operations are optimized, streamlined, and compliant with industry standards—enhancing the efficiency and quality of your entire trial management process.

CONFORM™ CTMS is uniquely designed to integrate seamlessly with other CONFORM™ modules, offering a fully unified platform for managing everything from data capture to patient engagement, compliance, and risk.

Why Choose CONFORM™ CTMS?

Integrated, End-to-End Platform for Clinical Success

CONFORM™ CTMS is part of the larger CONFORM™ Platform, which includes EDC, RTSM, Safety/PV, eTMF, eDiary/ePRO/eCOA, Informatics, and Central and Risk-Based Monitoring. This end-to-end integration eliminates silos, reduces redundant processes, and ensures that every aspect of your trial is seamlessly managed from start to finish. Here's how CONFORM™ CTMS integrates across the platform:

Electronic Data Capture (EDC)

Real-time data synchronization between CTMS and EDC ensures that clinical data is instantly available for operational tracking, allowing teams to see enrollment updates, site progress, and data collection status all in one place.

Randomization and Trial Supply Management (RTSM)

Manage patient enrollment, randomization, and treatment assignment while leveraging CTMS to track subject milestones and site activities.

Safety and Pharmacovigilance (PV)

Coordinate with the Safety Module for automated tracking of serious adverse events (SAEs) and other safety signals, ensuring safety and regulatory compliance.

electronic Trial Master File (eTMF)

Seamlessly maintain essential trial documents within the eTMF module to meet regulatory requirements and ensure audit readiness at all times.

eDiary/ePRO/eCOA

Capture patient-reported outcomes in real time, with CTMS providing site and study coordinators immediate access to ePRO data, enabling improved patient follow-up and issue resolution.

CONFORM™ Informatics

Leverage powerful analytics through CONFORM™ Informatics to gain insights into site performance, data trends, and operational metrics that enhance decision-making.

Central and Risk-Based Monitoring

CONFORM™ CTMS is tightly integrated with Central and Risk-Based Monitoring, enabling targeted monitoring efforts based on real-time key risk indicators (KRIs), central surveillance data, and risk mitigation strategies.

Comprehensive Quality, Compliance, Operation, and Risk Management

CONFORM™ CTMS provides a single platform for managing quality, compliance, operational efficiency, and risk:

- **Quality and Compliance:**
  The integration with eTMF ensures that all essential documents are maintained, version-controlled, and audit-ready, while Safety/PV integration guarantees that safety events are tracked and reported in compliance with regulatory requirements.
- **Operational Oversight:**
  Manage every aspect of your clinical trial—from site activation and patient enrollment to monitoring visit schedules and closeout activities—through a centralized, intuitive interface. Real-time integration with EDC and RTSM ensures seamless tracking of site and patient activities.
- **Risk Management:**
  Utilize Central and Risk-Based Monitoring to focus monitoring efforts on high-risk sites and data points. Risk indicators, such as enrollment lag or high protocol deviation rates, are highlighted in the CTMS dashboard for proactive issue resolution.

Integrated Site and Study Dashboards

CONFORM™ CTMS offers an intuitive dashboard that consolidates data from across the platform, providing a holistic view of study progress, site performance, compliance status, and risk metrics. Key benefits include:

- **Real-Time Data Visibility:**
  Get instant updates on patient enrollment, site performance, monitoring activities, and data collection—all within a centralized dashboard.
- **Site Management Tools:**
  Manage site-level activities, including activation milestones, contract tracking, payments, and monitoring visit schedules, all from one platform.
- **Risk Alerts and Notifications:**
  Integrated with risk-based monitoring to provide real-time alerts and notifications for critical risk indicators, ensuring that study teams stay on top of potential issues.

Centralized Access and Streamlined Workflow

- **Centralized Portal Access:**
  Access all study components—including eTMF, EDC, RTSM, and Safety—through a single portal, ensuring that team members can efficiently collaborate and manage tasks without switching systems.
- **Eliminate Redundant Data Entry:**
  Seamlessly integrate data across modules to eliminate duplicate data entry and transcription errors, which reduces workload and improves data accuracy.

Flexible, User-Friendly Interface

- **User-Friendly Interface:**
  The intuitive user interface is designed to simplify complex trial management tasks, providing easy access to information, navigation, and functionality.
- **Support for Adaptive Trials:**
  CONFORM™ CTMS supports adaptive study designs and dynamic workflows, ensuring that changes in study protocols are smoothly incorporated and tracked.

Proven Success in Complex Trials

Extensively Validated:
CONFORM™ CTMS has been tested in over 700 clinical studies, including large, late-stage Phase 3 pivotal trials, providing a robust and reliable solution for managing the operational complexities of clinical trials.

Accelerate Study Start-Up and Ensure Compliance

- **Fast Study Start-Up:**
  By integrating study start-up activities across CTMS, RTSM, and eTMF, CONFORM™ enables faster site activation and patient enrollment, reducing the time to first patient in.
- **Comprehensive Document and Compliance Management:**
  Integration with eTMF ensures that essential documents are compliant and readily available for audits, inspections, and regulatory submissions.

Integration Across the Entire CONFORM™ Platform

CONFORM™ CTMS is designed to work in tandem with other CONFORM™ eClinical modules, creating a unified solution that covers the full lifecycle of a clinical trial—from start-up, randomization, data capture, and patient engagement to safety, monitoring, and regulatory compliance.

The Benefits of Integration Include:

Real-Time Data Flow:
Eliminate silos by having real-time synchronization of patient and site data between CTMS, EDC, RTSM, Safety, and Monitoring.

Comprehensive Monitoring:
Utilize data-driven insights from Risk-Based and Central Monitoring integrated directly with CTMS to improve quality and reduce operational risks.

Scalable Platform:
The integrated modules ensure that as your trial grows in complexity, CONFORM™ scales with you, supporting more sites, patients, and data points.

Partner with EDETEK for Comprehensive Trial Management Excellence

CONFORM™ eClinical - CTMS is your central hub for managing all clinical trial operations. Integrated across multiple modules, our CTMS ensures that your trial runs smoothly, compliantly, and efficiently. With features that address quality, compliance, risk management, and operational efficiency, CONFORM™ CTMS empowers your clinical team to achieve