CONFORM™ EDC

Revolutionize Your Clinical Trial Conduct: Seamless, Intelligent, and Scalable

Unlock the Potential of Your Clinical Trials with a Turn-Key, End-to-End System

EDETEK's CONFORM™ eClinical System is a robust, integrated solution that offers everything you need for clinical trials—from EDC to RTSM, Trial Supply Management, CTMS, Safety, eTMF, Payments, eDiary, ePRO/eCOA, Patient Profiles, and more—all within a single platform.

Why Choose CONFORM™ EDC?

Intuitive Interface & Easy Operation

Navigate your clinical trial effortlessly with our intuitive and responsive user interface. The task summary panel and dashboard provide easy tracking of outstanding activities and comprehensive access to all aspects of your studies. Navigation to study, site, subjects, visits, and forms has never been easier.

Comprehensive CRF Support

Our system provides dynamic CRF features that adapt to your trial's needs, with support for:

- **Dynamic (Conditional) Questions, Forms, Visits, Cycles:** Customize CRFs based on patient responses.
- **Form Versatility:** Supports standard, log, and grid forms.
- **Dynamic Cycle Management:** Allows for flexible study designs, including cycle groups.
- **Hierarchical Folder Structures & Unscheduled Visits:** Easily organize study data and manage unscheduled
- **Web-Based GUI Study Designer:** Build and manage CRFs using an easy-to-use GUI with version control.
- **Built-In CDASH and SDTM Support:** Standardize data collection with CDASH and easily transform datasets to SDTM format for regulatory compliance.
- **CRF Library & Standardization:** Easily reuse and standardize CRFs for multiple studies.
- **ODM, SDM Import/Export:** Support for standards-driven study design ensures seamless integration of data from multiple sources.

Local Lab and External Data Management

Our platform handles local lab ranges, standardizations, and unit conversions to SI or conventional units. Easily auto-populate normal lab ranges, calculate lab toxicity grades, and reconcile external data, all while supporting direct data uploads into CRFs.

Comprehensive Reporting for Full Study Oversight

Generate key reports for streamlined trial management:

- **Patient Tracker** based on subject calendar for clean patient tracking.
- **Query Reporting** with hyperlinks for efficient follow-up.
- **Dynamic Cycle Management:** Allows for flexible study designs, including cycle groups.
- **Enrollment, Payment, and Financial Reports** to track patient recruitment and financial activities.
- **Raw Data Validation Reports** to ensure data quality throughout the study.

Advanced SAE Reporting & Medical Coding

Manage serious adverse events seamlessly:

- **SAE Reporting Support:** Automatically populate customizable SAE reports and facilitate E2B R3 XML SAE exports.
- **Medical Coding Support:** Automated coding generation using industry-standard dictionaries, with support for MedDRA and WHO-Drug coding and versioning.

*Tested in over **700 clinical studies**, including large, late-stage **Phase 3 pivotal global trials**. Supports complex study designs, including adaptive trials.*

Notification Support for Proactive Trial Management

Keep teams and investigators informed:

- **Alerts and Notifications:**
  Receive alerts for key activities like subject enrollment, dosing, and SAE events.
- **Notification Center:**
  Aggregate important information across all modules for better oversight.
- **Reminders for Scheduling and Visits:**
  Ensure compliance through subject calendars and visit reminders.

Full Life-Cycle Management

Manage the full lifecycle of your clinical trials, from development to production:

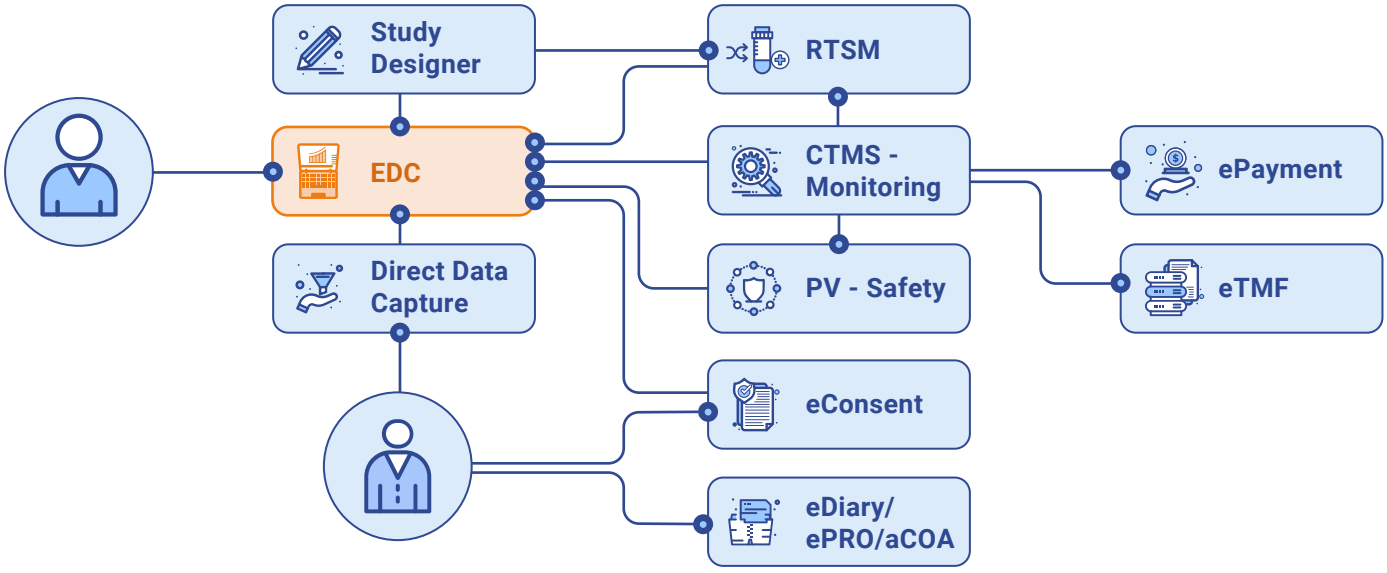
- **Full Version Control** ensures that all changes are documented and traceable.
- **CRF Rollout** at study, site, or subject levels.
- **Complete Lifecycle Management:**
  Support for development (Dev), User Acceptance Testing (UAT), and production environments.
- **Migration Environment for Validation:**
  Automated validation and change analysis during lifecycle transitions.

Integration with the Full CONFORM™ Suite

Leverage the power of integration with the CONFORM™ suite to streamline every aspect of your trial:

- **CONFORM RTSM and Trial Supply Management:**
  Prediction-based resupply, randomization, and treatment management.
- **CONFORM CTMS:**
  Operational reporting, data-driven monitoring, and protocol deviation tracking.
- **Risk-Based/Central Monitoring:**
  Real-time KRI reporting for effective risk management.
- **CONFORM eTMF:**
  Efficiently track essential documents and manage the Trial Master File.
- **CONFORM PV/Safety:**
  Automated ICSR intake, queries, and reconciliation for safety management.
- **CONFORM eDiary/eCOA:**
  Support real-time data ingestion and compliance tracking for patient-reported outcomes.
- **CONFORM ePayment:**
  Manage activity tracking, contract supervision, and financial reporting.
- **CONFORM eConsent:**
  Handle subject consent/re-consent management, including changes related to protocol amendments.
- **Open Architecture and API Support:**
  Integrate easily with third-party systems, including IRT, CTMS, and IP management tools.

eClinical Sub-System



Study Conduct

Your Partner in Clinical Trial Success

EDETEK's CONFORM™ eClinical Sub-System is designed to meet the evolving demands of modern clinical trials. Whether managing early-stage or large-scale late-phase studies, CONFORM™ delivers the tools to optimize efficiency, ensure data quality, and enhance patient safety.