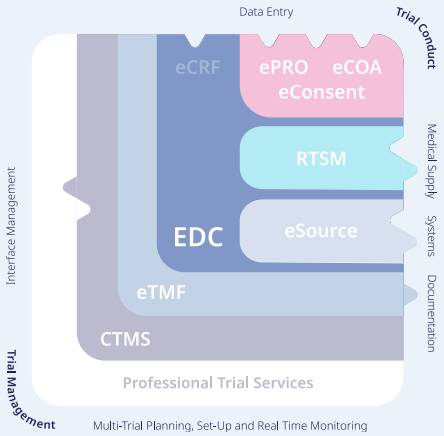
# oomnia EDC




## PRECISE AND FAST DATA CAPTURING WITH OOMNIA EDC

**Streamline your data collection, ensuring analysis-ready datasets the moment they are entered**

EDC and eCRFs are an integral part of oomnia. Data integration capabilities, customized dashboards, and real-time reports enable you to oversee and manage your clinical trial efficiently. Moreover, you can use customized dashboards to facilitate clinical trial data and operational oversight. Comprehensive capabilities allow the creation of any type of EDC form, including eCRF, SAE report form, protocol deviation logs, and many more.

- ✓ Data integration capabilities
- ✓ Convenient user interface
- ✓ Real-time data validation
- ✓ Customizable dashboards

## BENEFITS OF OUR UNIFIED EDC

**Harness the full potential of clinical data**

### PROTOCOL DEVIATION

A centralized protocol deviation log enables streamlined tracking of deviations and manages protocol non-compliance. Our data-driven insights ensure potential improvements in protocol adherence.

### DATA QUALITY

Our EDC system minimizes data entry errors. Real-time validation checks during data entry ensure accuracy. Audit trails and data tracking further ensure data integrity and compliance.

### DATA COLLECTION

Automated EDC forms save time and money by minimizing error-prone manual data entry, reducing reconciliation. Efficient data capture processes lead to quicker and more accurate data analysis.

### ERROR REDUCTION

We offer a well-designed eCRF that significantly lowers manual entries and data entry errors: Up to 67% decrease in manual queries due to reduced data entry errors.

### TIME SAVINGS

The setup, deployment, and validation of eCRFs is possible in weeks instead of months. Our proper initial setup reduces future problems and avoids later interventions.

### COST SAVINGS

Our unified EDC can automatically map data across modules and EDC documents thereby reducing double entries, reconciliation, and data reviews. Pre-validated design processes without programming minimize EDC form development.

# ADVANCED FEATURES OF OOMNIA EDC

**Unlock the full potential of your clinical trials**

## STUDY MILESTONE AND ENROLLMENT MANAGEMENT

| FEATURES | DESCRIPTION |
|---|---|
| **Flexible data capture form creation** | • Flexible no programming drag-and-drop design tools enable fast and easy creation of EDC forms<br>• Ensure CDISC compliance with a built-in CDISC Metadata Browser for eCRF or other form creation<br>• Choose whether SDV applier to an EDC form or even fields within a form<br>• Create templates or simply copy and paste elements to accelerate eCRF or any other form design |
| **Any data capture form** | • Much more than eCRF, create electronic CRFs, PD Logs, SAE Report Forms, Monitoring Visit Reports and more<br>• Templates or simply copy and paste elements to accelerate eCRF or any other form design<br>• Assignment of EDC forms and any version of the forms to participants or organizations |
| **Adaptive data collection** | • Quickly and easily modify data collection forms during trial conduct, without compromising timelines or data integrity<br>• Add and remove fields and change validation behavior on the fly within minutes<br>• Include full exportable listing of changes |
| **Advanced digital signatures** | • Compliant with 21 CFR Part 11, EU Annex 11, and EU Regulation No 910/2014<br>• Apply one or more digital signatures to an entire EDC document (eCRF), Visit, Page, Field Group, or individual field level<br>• Create predefined complex rules for single or multiple signatures with or without a predefined sequence |
| **Automated SAE Report Form generation** | • Immediate notification of SAEs for chosen Roles<br>• Autogenerated SAE Report Form and prepopulated from a participant eCRF and their AE<br>• Automatically create follow-up and final SAE Report Forms that are linked to the participant's AE<br>• Data is automatically mapped from participant's eCRF to the SAE Report |

## DATA VALIDATION

| FEATURES | DESCRIPTION |
|---|---|
| **Automatic data cleaning** | • Create dependent field behavior for fields within unscheduled visits that depend on answers to question in scheduled study visits<br>• Data cleaning is automatically performed by oomnia system resulting in up to 67% fewer queries than industry standard software |
| **Real-time data validation** | • Advanced real-time data validation checks for any EDC document type without any programming<br>• Univariate and multivariate soft edit checks for number fields, dates, times, including partial dates and partial times<br>• Participant and site specific edit checks for laboratory assay results<br>• In minutes adapt univariate or multivariate edit and data discrepancy checks while the study is in progress |
| **Dramatically reduced reconciliation** | • Create mapping rules between Pages, Fields, or Field Groups between documents without programming<br>• Save time and money by automatically transferring data from the eCRF to the SAE Report Form, ePDL, or any other form<br>• Automatically prepopulate the MVR from participant eCRFs or other EDC forms in the system |

## REAL-TIME REPORTING

| FEATURES | DESCRIPTION |
|---|---|
| **Integrated graphical reports** | • Create graphical or tabular reports from any data or metadata, including audit trials, from or between any EDC documents in the system<br>• Template, name and give Role based permissions to reports |
| **Templated data listings** | • Granularly create and export data captured in any EDC document (data dumps or reports)<br>• Select and template exports by choosing visits, pages, or single fields in any combination, and in any combination of countries, sites, participants and much more |