

ENNNOV CLINICAL SUITE

Ennov EDC Electronic Data Capture

The EDC that simplifies and streamlines eCRF design, creation of database rules and data capture.

The EDC Challenge

Organizations may have clinical data management challenges ranging from use of paper CRFs to data cleanliness and quality problems to legacy systems that are cumbersome and difficult to use. Ennov EDC is designed to solve all of these challenges—just ask our clients.

Ennov EDC is a comprehensive CDMS that allows clinical research personnel to easily define EDC studies and collect subject data, significantly decreasing missing and inaccurate data. Data can be entered in a browser or using EDC Mobile in an online or offline mode.

Configurable edit checks allow you to build in database rules without advanced programming skills. Computed fields, calculated intervals. A configurable library of allowable values (harmonized with CDISC, CDASH and SDTM standards) provide Ennov EDC with the flexibility re-quired to support even the most sophisticated and complex study designs.

Add CDMS Modules on Your Schedule

Ennov RTSM is a comprehensive solution that manages both randomization and clinical trial supplies. Ennov RTSM allow statisticians to define complex randomization schemes and supports patient randomization using standard algorithms such as minimization and stratification (variable lists). It also manages the IMP (investigational medicinal product) from the initial shipment to the investigating centers to dispensing and replenishment.

Ennov ePRO facilitates the direct capture of electronic patient data. Patients enter their data using an intuitive and user-friendly web application. The data is immediately checked for validity, consistency and completeness and is made available to the investigators and site personnel responsible for monitoring patient compliance and safety.

> CORE CAPABILITIES

Design, deploy, and capture clinical trial data with one comprehensive solution—even for complex, multi-center trials

Reduce effort and increase consistency with built-in medical coding (MedDRA, WHO Drug)

Decrease preparation time by reducing set-up to just a few weeks

Support clinical trials of any type, including large global trials, post-marketing trials, cohort trials, health surveillance, Phase I-IV trials and epidemio-logical trials

Pre-integrated with Ennov's eTMF and CTMS—enter data once and ensure consistency without the need for custom integrations

> KEY FEATURES

Graphical design tools that take the complexity out of creating eCRFs—no IT skills needed

Built-in CDISC, CDASH and SDTM compliance

Streamlined clinical data capture

Configurable edit checks

Localized to many languages—others easily added

Connects to EDC Mobile, RTSM and ePRO



Cloud Based or On Premises



Multi-Platform



ISO 9001:2015 Certified

Maximum Flexibility with Minimal Complexity

As much as you would like to standardize, clinical data is different for almost every trial. Employing programmers to create CRFs and implement edit check rules is expensive and time consuming. With Ennov EDC, you can use graphical design tools to create CRFs with no programming skills needed, and configure the edit checks and rules you need for clean data.



Ennov EDC - Part of the Ennov Clinical Suite



Why Choose Ennov?

HUNDREDS OF COMPANIES TRUST ENNOV	PROVIDING YOU FREEDOM OF CHOICE
<p>20 years and 300+ Life Science customers, with many more in other industries.</p>	<p>Available as cloud-based or on-premises deployment: You can switch between deployment options at any time.</p>
<p>Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.</p>	<p>We make you autonomous: System configuration and management require no IT skills.</p>
<p>Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.</p>	<p>Improved security and optimized performance: Data is hosted locally for total flexibility. Single tenancy minimizes business interruptions.</p>

Learn more about our unified content and information management platform to support the entire Life Sciences product development continuum at www.ennov.com



QUALITY

Our comprehensive QMS improves operational efficiency and ensures regulatory compliance



CLINICAL

Our total solution for capturing and managing Clinical Trial information streamlines clinical operations



REGULATORY

Our world-class Regulatory content and information management software accelerates HA approvals



PHARMACOVIGILANCE

Our end-to-end solution for collecting, reporting and analyzing human and vet PV data minimizes risk



COMMERCIAL

Our complete management of professional events ensures DMOS, EFPIA, HCP and COI compliance