eNNOV
Software for Life

Ennov CTMS
Clinical Trial Management System

The CTMS that provides true transparency and clarity for all of your clinical processes

The CTMS Challenge

The information needed to run your clinical trials efficiently may be found in many places in your organization: clinical data management systems, document management systems, databases and spreadsheets. What if you could unify this information in a consolidated, metrics-driven system that provides you with instant insight into status, risks, and priorities?

Ennov CTMS is a true Business Process Management (BPM) solution that automates, controls and measures your clinical business process. Workflow, data and documents are seamlessly connected to each other and to your users, across the enterprise. Processes and insights support both Risk Based Quality Management (RBQM) and Risk-Based Monitoring (RBM). Dashboards and micro-alerts help users in each role to understand their tasks and priorities at a glance. As a result, users can focus their attentions where they are needed the most.

A Unified Clinical Platform

A unified clinical process requires a unified platform. CTMS is a key element of that unified platform. The Ennov CTMS drives efficiency and accuracy in eTMF by triggering the creation of placeholders, automating the creation of monitoring visit documents that are automatically filed in eTMF, and coordinating the handling of protocol deviations and the management of associated documents.

Unification with EDC provides detailed insights into site operations and risk factors. Ennov EDC drives CTMS dashboards with up-to-date information on recruitment, trial subjects status, deviations, and SAEs.

Unification workflows even extends to Ennov RIM to ensure that the Regulatory team knows when protocol amendments occur, new investigators and added, or changes to registries are needed.

Key Benefits

Single source of truth for all your clinical trial management processes and data
Reduces effort and complexity by requiring only the necessary information for your study based on phase, therapeutic area, and more
Provides integrated CAPA processes for management of deviations and other issues
Improves decision making based on true insight into status, workflow and risk
Pre-integrated with Ennov's eTMF and EDC – enter data once and ensure consistency without the need for custom integrations

Important Features

| |
|---|
| Manages studies, sites, IRB/IECs, labs, site staff, study timeline, and more |
| Manages monitoring visits and automates the production of monitoring visit documents |
| Supports clinical trial registries and provides alerts when updates are needed |
| Supports Risk-Based Monitoring, including TransCelerate risk-based processes |
| Monitors recruiting, SAEs, protocol deviations, and other follow-up/risk areas |
| Provides an extensive collection of out of the box dashboards and reports to drive insight and reduce risk |

Cloud-based or On Site

Multi-Platform

ISO

ISO 9001:2015 Certified

Scales to Work Perfectly for Your Trial

Different trials require different levels of data collection, reporting and process. Ennov CTMS is designed to support each trial by enforcing only those process and data requirements needed for the type of trial – meaning you don't need to enter unneeded data or execute unnecessary processes.

Combined with risk-based monitoring processes, this not only saves time but allows you to focus your limited resources on where they provide the most benefit. The result: a CTMS a system your users actually enjoy working with.
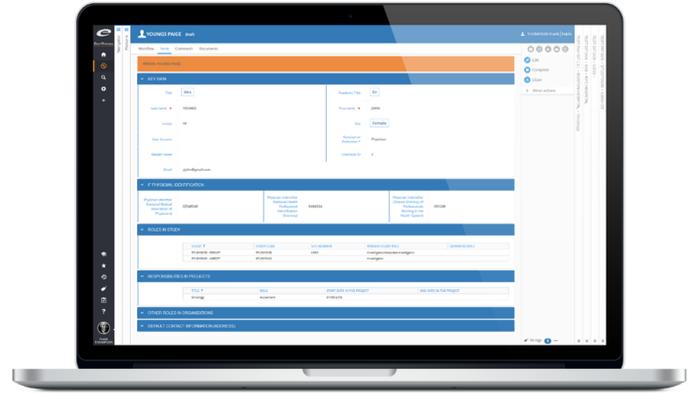
Ennov CTMS – Part of the Ennov Clinical Suite
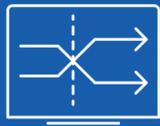
Ennov EDC   Ennov RTSM   Ennov ePRO   Ennov CTMS   Ennov eTMF   Ennov eLearning

Why Choose Ennov?

Hundreds of companies trust Ennov

- **Over 15 years of experience providing Clinical solutions**
  200+ life sciences customers, many more in other industries.

- **Modern architecture and user interface**
  100% web-based, Highly scalable. User-centric design.

- **Our commitment to your success**
  Very high customer satisfaction. 98.5% of projects delivered on time and within budget.

Providing you freedom of choice

- **Available as cloud-based or on-premises deployment**
  You can switch between deployment options at any time.

- **We make you autonomous**
  System configuration and management require no IT skills.

- **Improved security and optimized performance**
  Data is hosted locally for total flexibility. Single tenancy minimizes business interruptions

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

Quality   Clinical   Regulatory   Pharmacovigilance   Commercial