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ENNOV CLINICAL SUITE

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.

> CORE CAPABILITIES

- 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

> KEY 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 Premises | **Multi-Platform** | **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 CTSM | ENNOV eTMF | ENNOV eLearning

Why Choose Ennov?

HUNDREDS OF COMPANIES TRUST ENNOV	PROVIDING YOU FREEDOM OF CHOICE
20 years and 300+ Life Science customers, with many more in other industries.	**Available as cloud-based or on-premises deployment:** You can switch between deployment options at any time.
Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.	**We make you autonomous:** System configuration and management require no IT skills.
Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.	**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

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