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ENNOV CLINICAL SUITE

Ennov eTMF
Electronic Trial Master File

The solution built to enable efficiency, compliance and inspection readiness—whether you are a large pharma company, a small biotech just starting your first trials, or a CRO.

The eTMF Challenge

eTMF is a non-negotiable regulatory requirement. But with every new study, more and more resources are needed to plan the TMF, upload and quality check documents, and monitor TMF health.

Your eTMF should be designed to plan, maintain and archive a high-quality TMF while minimizing your operational burden and need for resources. Ennov's eTMF combines unified and streamlined processes and intelligent automation to reduce your operational burden.

Imagine an eTMF that plans your studies based on their unique characteristics. Ennov eTMF generates the document placeholders you need, tagged with the information users need to file accurately. Documents are uploaded in a moment, and QC processes optimized to achieve the best results with the fewest resources.

Dashboards and micro-alerts help users in each role to understand their tasks and priorities at a glance. TMF health becomes a team effort.

The Only eTMF with Basic CTMS

Some organizations need an eTMF now, but aren't ready for a Clinical Trial Management System (CTMS) project. Ennov eTMF includes the ability to manage information about studies, countries, sites, visits, investigators and other site personnel, IRBs/IECs, and other committees. Smart Templates automatically plan the documents required in your TMF each time a new entity is created.

Basic CTMS also includes the automated generation of monitoring visit reports. Basic CTMS can be upgraded to Ennov's full CTMS, or you can integrate the CTMS of your choice—at the same time as your eTMF project, or later when you are ready.

> CORE CAPABILITIES

- Provide access to business users worldwide—including CRO or sponsor partners
- Ensure completeness and inspection-readiness with automated planning processes and one-click dashboards
- Support hands-on TMF inspections by health authorities
- Streamline upload and QC—fewer steps, faster processing, less resources
- Easy to navigate—find any document in your study in just a few clicks

> KEY FEATURES

- TMF Reference Model ready configuration—adaptable to your needs
- Smart Templates that automatically plan the contents of your TMF based on specific conditions of your study
- Streamlined drag and drop upload process
- Risk-based, sampled and tracked QC process
- Extensive collection of out of the box dashboards and reports to drive inspection readiness and reduce risk
- Complete authoring, approval and electronic signature capability

Cloud Based or On Premises | **Multi-Platform** | **ISO 9001 and 27001 Certified**

Transparency + Insight Support Optimized Processes

eTMF health is as much about the documents you are missing as it is about the quality of the documents you do have. Ennov eTMF provides the planning processes you need to precisely define the documents you need for each trial—without cumbersome editing of document lists. Insights into com-pleteness, quality and timeliness allow you to adjust your TMF for accuracy and efficiency as the trial unfolds. And our dashboards don't just display information—they help you understand priorities, issues, and risks.

Ennov eTMF - 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	PROVIDING YOU FREEDOM OF CHOICE
Over 25 years' experience, and 450+ 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 manage-ment of professional events ensures DMOS, EFPIA, HCP and COI compliance