eDOCS manager
powered by cara

EXTEDO
eRegulatory Affairs

Product Information

The Clinical Module

From EXTEDO eDOCSmanager™ powered by CARA™

Create accurate eTMF documents on the fly

Management of Electronic Trial Master File (eTMF) documents is a daily, time-consuming activity for life science companies. Organizations that can prepare eTMF documents quickly and accurately consistently beat their competitors to market and whilst remaining compliant. The power to achieve this is now within your grasp with the Clinical Module from eDOCSmanager.

Benefits

- **Reduce data duplication and errors –** the Clinical Module is your single source of truth for all operational Clinical Trial data and workflows.
- **Use dashboards and reporting based on metadata –** manage all of your eTMF information from user-friendly dashboards powered by the most up-to-date data.
- **Create rapid TMF files –** use drag-and-drop functionality, dedicated templates, and automated workflows to create eTMF files quickly.
- **Manage the entire eTMF lifecycle from start to finish from one location –** with full visibility and complete control via one window instead of multiple siloed locations.
- **Gain access to easy-to-use eTMF template structures –** to ensure compliance, efficiency, and approval.
- **Digitally collaborate with your team –** use simultaneous authoring with your team or third parties with secure version control.

With the Clinical Module from eDOCSmanager, you can create inspection-ready electronic TMF documents and records quickly and easily. It streamlines your clinical regulation and life science management activities, boosting productivity and eliminating human error organization-wide.

Compliance collaboration at its finest

- Role-based security and access
- Web-based, digital collaboration
- Full auditing and review capabilities
- Trail-specific requirement access templates

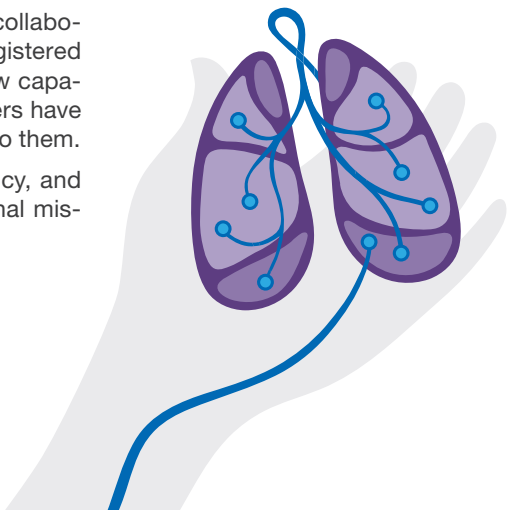
Managing documents is challenging, and it becomes even more complicated with teams working from different locations or with external suppliers. Duplicate content and a lack of visibility into regulatory activities increase the risk of non-compliance and confuse your workforce and your projects.

The core concept behind the Clinical Module from eDOCSmanager is effective collaboration between clinical stakeholders. It provides secure and fast access for all registered users through web-based, remote access and also delivers full auditing and review capabilities to the organizational owner. In addition, role-based access ensures that users have the correct permissions and visibility for the information and documents assigned to them.

The Clinical Module enables organizations to gain complete oversight, transparency, and team cohesion without the security and organizational risks associated with internal mishaps or third-party access.

Master eTMF Management

- Bulk uploading capabilities for internal and external documents
- Seamless integration and access with regulatory, safety, and quality data
- Easy indexing and filing
- Based on the TMF Reference Model



eTMF organization can quickly become overwhelming. With multiple products, authorities, and regions, submissions can grow in unmanageable quantities. The Clinical Module from eDOCSmanager is a single repository in which to take control of your eTMF data.

The Clinical Module from eDOCSmanager enables you to bulk upload internal documents as well as documents from other systems. Since the Clinical Module is part of eDOCSmanager, all information is seamlessly available in all modules, enabling regulatory, safety, quality, and enterprise data to be accessed and managed when needed.

With the Clinical Module, you'll never lose track of your documents again, no matter how many you have. All eTMF files are based on the TMF reference model for easy indexing and filing of documentation. All document information, including dates and details, is automatically captured and stored in metadata. This information is then immediately accessible for reporting purposes.

A Reliable Single-Source-of-Truth

- Advanced version control and history
- Full digital signature support
- Multiple quality control applications
- Dedicated copy certification and validation tools

The Clinical Module acts as the single source of truth for your operational data, integrating multiple systems and processes. Advanced version control is applied to every eTMF document, with the version history retained and easily viewed on-demand. When the document is finalized, users have the option to lock versions to ensure integrity.

The Clinical Module also offers support for digital signatures ensuring swift and straightforward approval. In addition, the module provides a timestamp for all events related to the creation, upload, approval, and changes.

Finally, quality control processes can be performed as part of defined QC workflows, with the ability to update, reject correct, and QC-approve items and documents, along with dedicated copy certification tools like MD5 checksums.

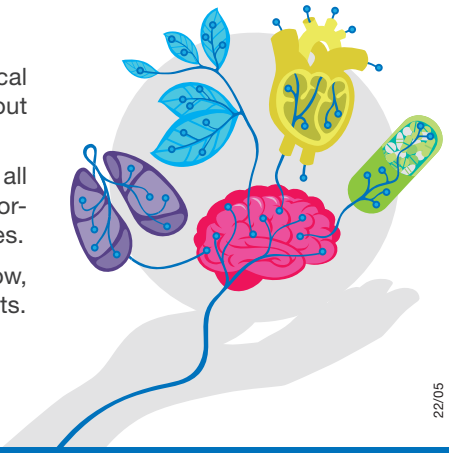
Streamlined eTMF submissions

- Cover all aspects of clinical trails – planning, reporting, data sharing, and tracking via a single platform
- Use pre-certified eTMF templates
- Connect all trial clinical operation workflows through a streamlined solution
- Integrate multiple systems and processes towards your eTMF production

Beat the competition to market with a fast and efficient eTMF process. With the Clinical Module, you can manage Clinical Trials from Protocol Approval to the Study Closeout through the EXTEDO platform.

With the Clinical Module from eDOCSmanager, you can connect data flows from across all your activities, wherever they are located, and for whatever purpose. Liberate siloed information with end-to-end visibility across your planning, recruitment, and logistics activities.

Now you finally can view and manage multiple clinical trials effectively via a single window, resolve issues promptly and proactively keeping pace with evolving regulatory requirements.



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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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