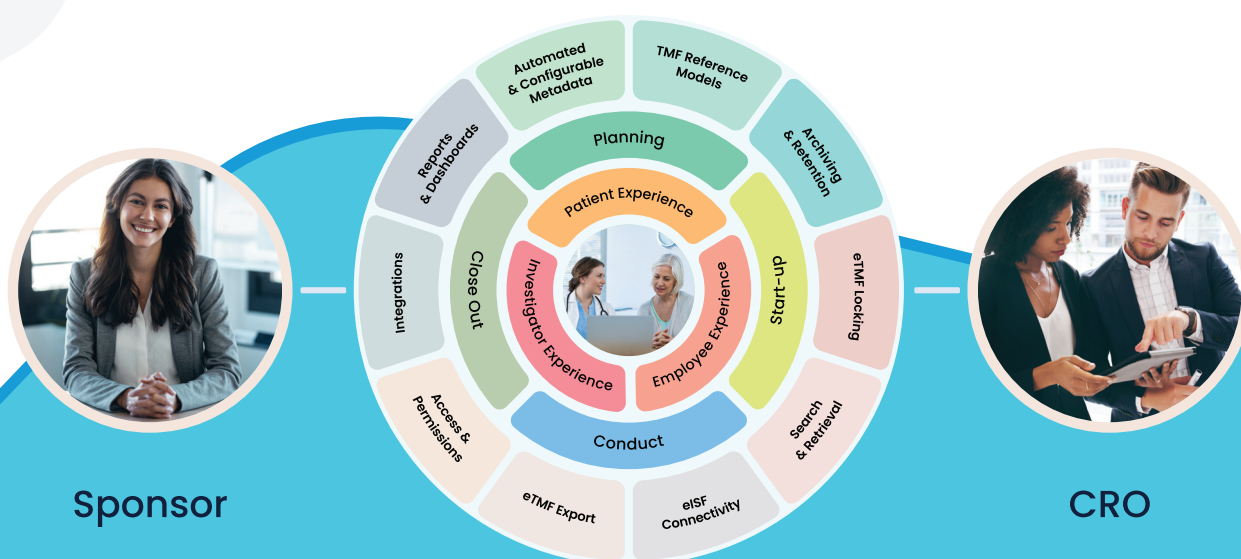




DATA SHEET

eTMF

Cloudbyz eTMF solution offers a cloud-based repository of all clinical trial documents including files, images, information, etc. Digitally store, manage, and share all clinical trial-related documents with a centralized overview. Manage essential trial documents, stay inspection ready, and enable real-time visibility for CROs, sponsors, monitors, and other stakeholders in a clinical trial.



Key Features

eTMF Export

Cloudbyz eTMF enables export of Study documents for both ongoing and completed studies, along with the document metadata and audit history.

Automated & Configurable Metadata

The solution provides a comprehensive view of documents and their respective metadata to help research teams and stakeholders eliminate errors within the data. Additionally, it enables users to customize, define, and store metadata. Auto-populate a document's metadata to its maximum extent as per industry standards.

TMF Reference Models

Utilize the latest version of the widely used, built-in DIA TMF reference model, or work with a custom model. Add or remove folders from the built-in models and apply the model directly to a study according to the study-specific TMF plan and index.

Actionable Notifications

Built-in workflow rules route documents through a review process with a click of a button. Assign statuses to documents as well as send and receive customized notifications at each step of the review process. Customize the workflow based on the type and nature of the clinical research study.

eTMF Locking

Once ready for study close out, lock the eTMF to ensure no further updates can be made to the documents or the metadata.

Search and Retrieval

Find and retrieve folders and documents using a search engine that's effective for both file names and metadata. Create custom list views with numerous available filters. It also provides auditors, inspectors, and users with a powerful and dynamic search capability to retrieve documents quickly.

eISF Connectivity

Cloudbyz Investigator Portal seamlessly connects sponsor and site operations. It allows sites and/or CRAs to upload essential documents and to maintain ISFs in the system, which are seamlessly connected to the TMF folder.

Real Time Collaboration

The solution provides timely, contextually relevant notifications to complete tasks, such as document reviews within the system, and cross-functional communication within the team using the in-built chat functionalities. Set automatic rule-based notifications to ensure timely actions on missing or expiring documents.

TMF Health Check

The eTMF dashboard provides an overview of the health of all folders. See at a glance what documents are pending review, or which are expired. This results in improved efficiency and effectiveness of your TMF management.

Inspection Readiness

Digitally track, manage, share, and store all essential trial documents and stay inspection ready. Our eTMF solution enables real-time visibility for CROs, sponsors, monitors, and other stakeholders in a clinical trial.

Milestone Tracking

Through Milestone tracking, the Cloudbyz eTMF enables the users to review the state of progress for documents, providing a measure of completeness throughout study execution.

Unified with CTMS, EDC, and Safety & PV

All Cloudbyz solutions are natively built on the Salesforce platform and leverage a common data model to ensure seamless integration between the systems. Additionally, users can leverage the template-based approach to accelerate their trial operations. Our solutions span across the entire life cycle of clinical trials and help customers to stay fully compliant with global industry regulations.

Benefits

Cloudbyz eTMF is built on the cloud, enabling Sponsors, CROs, and Sites to manage their trial documents with the highest levels of efficiency and integrity. The solution benefits are listed below –

- Secure, reliable & scalable
- Compliant & inspection ready
- Flexible & easy to use
- Real-time visibility of TMF completeness
- Collaboration with Site/ Sponsor/CRO

Cloudbyz eTMF solution is designed and built to be highly scalable, secure, and reliable, providing a robust and comprehensive solution for Trial Master File management. Our platform is built on cutting-edge Salesforce cloud technology and is fully compliant with global regulatory standards. The cloud platform benefits are listed below –

- Real-time analytics using reports & dashboards
- Robust data security through fine-grained access control
- Seamless processes through workflow orchestration

- Scalable data processing & storage with audit trail
- Ease of integration through open APIs

System Requirements

- Internet Connection:** The solution requires a stable internet connection to access the cloud-based platform.
- Browser:** The solution supports the latest versions of Google Chrome, Mozilla Firefox, Microsoft Edge, and Apple Safari.
- Device:** The solution is compatible with desktops, laptops, tablets, and smartphones running on Windows, MacOS, iOS, or Android.

Pricing

Cloudbyz eTMF solution offers a subscription-based pricing model, which is based on the module and the number of users per year.

Compliance

All Cloudbyz products and solutions are regulatory compliant. Security, privacy, compliance, and transparency are foundational pillars of our software development

process and we ensure rigorous implementation of the same through several international standards, regulations and guidelines.

Our products and services meet below listed Standards, Frameworks and Guidelines. It includes national, regional, and industry-specific requirements governing the collection and use of data.

- ISO/ IEC 27001:2013
- ISO 9001
- Good Clinical Practice (GCP)
- Good Automated Manufacturing Practice (GAMP 5)
- Health Insurance Portability and Accountability Act (HIPAA)
- 21 CFR Part 11
- General Data Protection Regulation (GDPR)
- California Consumer Privacy Act (CCPA)

Support

Cloudbyz eTMF solution provides 24/7 customer support through phone, email, and online chat. The solution also offers training and implementation services to ensure seamless deployment and adoption.

