

DATA SHEET: Nucleus eTMF

Electronic Trial Master File: Improve visibility and readiness with Nucleus eTMF

An electronic master file or eTMF is a Trial Master File in electronic or digital format. It is a way of digitally capturing, managing, sharing and storing those essential documents and content from a clinical trial.

Nucleus eTMF allows your team to control submission documentation and maintain inspection readiness via a simple, intuitive layer on top of Nucleus Documents. Maintain your document accessibility and add regulatory compliance, standards based folder structures and improved visibility of eTMF information.

84%

of companies prefer an eTMF system to a paper TMF

How can Datatrial help your organisation?

Nucleus eTMF Configuration - Our standard folder structure uses the DIA reference model standard, so you can start adding your TMF content straight out of the box. We can also implement your organisations folder structure if so required.

Collaboration - Create multi-stage collaborations for document review and approval. Keeping documents, messaging and applications in one place means all stakeholders can access relevant information at the right time.

Quality and Compliance – Datatrial have a mature quality system and have been inspected by the MHRA in 2014. We have between 4-6 customer audits per year. Nucleus eTMF has been built to comply with 21CFR Part 11 compliance and EU Annex 11.

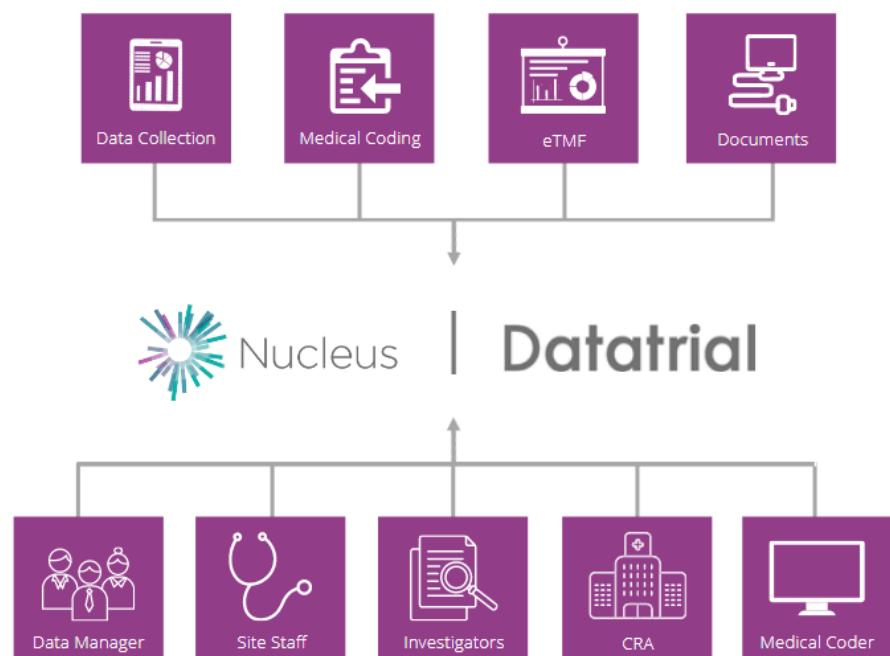
Nucleus Documents – Content management and version control for your study documentation. Control, manage, and share study specific content with ease whilst maintaining the highest level of compliance you demand.

Features and Benefits

64%

of companies currently use an eTMF as their primary document management solution

- **Reference Model Support:** TMF Reference Model structures are supported out of the box to enable fast study start-up. Customise and adjust the structure to your exact requirements for required or supplementary documents.
- **Drag and Drop Grab:** Drag and drop your document directly into the tree view. The document will automatically inherit the metadata for that folder structure.
- **Find information fast:** Powerful full content search, backed by Microsoft Azure, allows you to search inside your TMF documents and tags to quickly find the content you are looking for.
- **Remote monitoring and document review, permission management:** Allow multiple users simultaneous access to individual sections of the eTMF for document review or to allow instant access for remote monitoring.
- **Automatic Metadata:** Configure your own automated metadata schema to ensure consistency across your eTMF.
- **Document Versioning and History:** Track document versions over time to identify any changes and who has made them.
- **At a glance Document Listing and Exports:** Quickly export listing of all artefacts within your eTMF, as well as metadata assigned to them, allowing faster identification of empty sections.
- **Hosting:** Nucleus eTMF is hosted in Microsoft Azure, UK South datacentre.



Challenges and Solutions

Accessible – Nucleus eTMF can resolve the challenge of accessibility whilst remote working and on site

Scalable – Nucleus eTMF has the ability to scale up easily as you become established particularly important in the international arena

Configurable – Nucleus eTMF allows you to configure a folder structure that suits your way of working

Compliant – Be inspection ready from the get go with a system built to the DIA reference model

Efficient – Save time and money with everything just at the click of a button. Upload your files using the drag and drop functionality and find what you need using the search bar, gone are the days of routing through folder after folder.

About Datatrial

At Datatrial we strive to make software that makes people's lives easier. With 20 years of experience in the life science industry our vision is to advance global healthcare using our data expertise, our innovative technology platform, and through striving to form collaborative relationships with the people we work with.

Datatrial provide software solutions enabling clinical organisations to better collaborate and safely capture, store, and analyse their trial data and information. We are passionate about both privacy and authenticity, and work with each of our commercial partners to ensure your data remain secure for the lifetime of your research.

Learn more at: <https://www.datatrial.com/nucleus/etmf/>

Sources: <https://www.veeva.com/resources/veeva-2016-paperless-tmf-survey/>