



arkivum

Bringing archived data to life

Arkivum: eTMF Archiving and Preservation Solution



Is your eTMF Inspection ready?

Adhering to regulatory and GxP requirements outlined by the FDA, EMA or MHRA is challenging.

The eTMF and related clinical trial documents need to be retained and inspection ready for decades. This means the data must be secure, findable, accessible and readable for the entire retention period.

The sponsor and the investigator shall archive the content of the clinical TMF for at least 25 years after the end of the clinical trial. – Regulation (EU) No 536/2014 (57).

Storing data for that period of time creates a number of organizational challenges, including:

- Ensuring the data is stored in a cost-effective manner.
- Employing measures to prevent data loss or corruption.
- Preparing for file format changes (and obsolescence) over time.
- Ensuring data is indexed correctly so it can be easily found.
- Providing secure access to the data.
- Capturing a complete audit trail of who has accessed the data and when.

Placing this valuable data in a backup or existing live system will not solve these challenges and could put your organization at risk of large fines, reputational damage and delays to drug development.

An effective archiving and preservation solution as part of your fully integrated eTMF approach will ensure that you are compliant and inspection ready.

The Solution

Arkivum provides a fully validated digital archiving and preservation solution for clinical trial sponsors and contract research organizations (CROs). Easy to setup, our digital archiving system provides the protection our regulated customers require, no matter where they are in the clinical trial process.

The solution is fully aligned to the TMF Reference Model and supports the Exchange Mechanism Standard (EMS).

We ensure that your eTMF is secure, accessible and usable for the whole retention period, guaranteeing you are inspection ready.

As part of our commitment to our regulated customers, we regularly deliver validated (CSV) releases of our software and place a great importance on our Quality Management System (QMS) and related SOPs. We are confident in our quality processes and fully welcome customer audits.

On top of this, you will also have access to a personalized dashboard which works across the entirety of the solution - think of this as your admin management center. Through this you'll be able to assign user permission-based control, search your data, download/export and access reports, including audit trails.

75% of life sciences organisations plan to invest significantly in technology. – TMF Futures report, 2021.



"Arkivum offered the best package for the solution we are looking for. Their team was knowledgeable, very helpful and responsive from beginning to end. We are looking forward to working with the team for subsequent eTMF archiving needs."

NEURALY

Archiving

Archiving your data ensures that it remains secure, searchable and accessible within the archive, for as long as you need it.

Our archiving capability includes:

- 100% data integrity guarantee: Stored in three separate geographic locations, aligning with any data sovereignty requirements.
- No vendor lock-in: EMS support and third storage location is in Escrow for easy customer access and exit.
- Automated validation: Checks on upload and throughout the retention period to identify any corrupted or damaged files.
- Data immutability: Ensure valuable assets cannot be modified after upload.
- Full chain of custody: Peace of mind during data transfer, from upload through to archival in our system.
- Users Access Control: User access is role-based, and roles are determined by their delegated responsibilities to ensure the right people have access to the right data.

Preservation

Whilst archiving ensures that your data is safe, findable and accessible, preservation endeavours to make it usable and readable. The automated digital preservation of your data means that your files can be read and used in the future - regardless of how long they are archived for and what device is used. Within our solution, preservation is achieved through:

- The generation of a preservation copy of to ensure long-term readability.
- Original files maintained in line with ALCOA+.
- Generation of Archival Information Package (AIP) in line with Open Archival Information System (OAIS).

Compliance

This element has been specifically designed for customers operating within highly regulated sectors to aid compliance with regulations and standards by the FDA, GxP, EMA and MHRA, to name a few.

Compliance features include:

- Retention Policy Management: Set automatic rules for how long specific data is retained for within the archive.
- Legal Holds: Hold or un-hold any retention rules in the case of legal challenges or queries on specific data.
- eSignatures included and recorded as part of the upload.
- All data deletions have to be approved by administrators so you can rest easy knowing that your data will not be accidentally deleted.



The Benefits

Our solution guarantees that your data is:



Secure

Our solution provides peace of mind that your data is safe.



Findable

Easily locate the right information when you need it.



Accessible

Ensure you can download the data at any given time in the future.



Readable

Avoid file obsolescence with automatic format updates and identify and fix any corrupted data.



Auditable

A complete audit trail of every document and file.



Compliant

Adhere to changing industry requirements and regulations.

Arkivum recently published a new eBook on the basics of eTMF archiving and preservation. It provides a detailed overview of what sponsors should consider when planning for the long-term management of the eTMF, as well as answers to questions you may have.

Download this free [eBook](#) to find out more.

Some of our Customers



About Arkivum

Arkivum is the trusted software and service partner for long-term data lifecycle management and digital preservation. We serve organisations around the world in data-intensive, regulated markets, including pharmaceutical, life sciences and healthcare.

Arkivum provides an end-to-end, managed service to deal with the complexity of preserving your data while guaranteeing 100% data integrity and immediate access. Our vendor-neutral technology means you can use Arkivum across your existing platforms and various deployment models, and you own your data at all times as there is no data lock-in.

Speak to a member of the team today!

Contact us

For more information about the product, or to arrange a demo, please email us on hello@arkivum.com or visit www.arkivum.com



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