

Introducing Arkivum Trust

What is Arkivum Trust?

Arkivum Trust is a digital archiving solution designed to store the TMF and other related clinical documents for sponsors and clinical research organisations (CROs). As a specialist TMF archiving service, Arkivum Trust complements existing eTMF and CTMS systems, ensuring the long-term, end-to-end integrity, security and viability of clinical trial data, whatever its source and format.

By storing large volumes of trial data in a live archive, always accessible and ready for regulatory inspection, the solution helps to effectively manage both current and future requirements. Our solution helps organisations:

- Respond to inspectors and auditors efficiently
- Avoid any potential fines or reputational impact
- Maximise the value obtained from data.

Arkivum, chosen by organisations across the globe, is committed to best practice in data governance and management, specialising in the archiving and digital preservation of valuable data and assets.



Why is eTMF archiving so important?

Effective digital archiving and preservation is so much more than simply maintaining a backup of your data.

Regulatory requirements from around the world require pharmaceutical organisations to keep and maintain TMF data for the long-term; in 2019 the European Medicines Agency (EMA) set the requirement to store the TMF for at least 25 years.

To comply, archived trial data needs to be complete, reliable, accessible and readable. It is vital that data integrity exists, and it is possible to reconstruct a clinical trial if required.

Archiving should also deliver strategic value to organisations. This can be in areas such as post marketing approval when a sponsor may want to make formulation changes in order to extend the patent or look for new indications. In these instances, it is crucial that the sponsor can easily and reliably access the early trial data.

eTMF archiving is not simply about storing data, it's about ensuring you are maximising the value from it. Whether this is part of a wider digital transformation effort, or simply about staying competitive, effective eTMF archiving can be a strategic differentiator for pharmaceutical and life sciences organisations today.

Arkivum Trust customers



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The Arkivum Trust Solution

Arkivum TRUST is a modular solution that scales with its customers' requirements, from entry level to an enterprise solution. It helps customers predict, plan for and manage costs at every stage of their long-term management and preservation efforts.

The main elements of the solution include;

- **COMPLIANCE:** secure access to your data, audit trails in a validated environment and easily managed retention periods
- **DIGITAL SAFEGUARDING:** a secure cloud based managed service ensure that all data is safely stored in multiple locations. This data is also regularly checked for integrity and accessibility
- **DIGITAL PRESERVATION:** automated preservation ensures that all files are kept up to date to the latest formats so that all data can be easily accessed, years into the future
- **SECURE SHARING:** safely share sensitive data with the right individuals and organisations to improve collaboration across the business.

The top screenshot displays the 'Overall System Status' dashboard. It features a bar chart comparing data across two locations, 'Location 0' and 'Location 1'. The legend includes Metadata, Audit Trail, Normalized Files, Files, and Dissemination data. To the right, the 'Data Usage' section shows a circular gauge at 0.01% and a bar indicating 1.94MB of 2.0TB used.

The bottom screenshot shows the 'Current Processing' section with a 100% completion bar. Below this, two processes are listed: 'IA Ingestion and Integrity Checks' and 'PAE Packaging and Encryption', both at 100% completion. The 'Search' results table below shows a list of items with columns for ID, Type, and Start Date. The 'Metadata Details' panel on the right shows fields for ObjectMetadata (rmfobject), Objectid, SiteSystemid, Siteid, Uniqueid, ArtifactNumber, and ArtifactName.

ID	Type	Start Date
TestProtocol1	C	2020-02-12
900000000018	O	2020-02-12
900000000017	O	2020-02-12
900000000019	O	2020-02-12
900000000020	O	2020-02-12
/etmf/12df0b91-b639-4...	F	2020-02-12



Arkivum Trust Benefits

Effective eTMF archival offers a range of benefits for any organisation responsible for the management of sensitive trial data. These include;

- **Ensure compliance and reduce risk:** Effectively manage both current and future regulatory requirements by guaranteeing your clinical data is easily accessible for up to 25 years (and beyond). Your organisation will be able to respond to inspectors and auditors efficiently and avoid non-compliance findings which could lead to potential fines or reputational impact
- **Inspection and audit ready:** Easily access your sensitive data, when you need it. Enable collaboration with a powerful front-end interface for (authorised) IT administrators, archivists, clinical and data managers, thus facilitating search, discovery and access
- **Obtain strategic value from your data:** shift your data management focus beyond just compliance by ensuring that it is easily accessible to leverage for future opportunities such as post marketing approval formulation changes or mergers and acquisitions
- **Oversight and quality control:** Consolidate all your eTMF data in a secure and unified location. Shift your archived data to be an operational and reputational asset, and demonstrate your focus on quality
- **Reduce total cost of ownership (TCO):** Efficiently consolidate your data in a single archive to reduces maintenance costs for servers, operating systems, and application software, notably where legacy solutions are involved. Pricing for storage is transparent and calculated per study.

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 securely for the long-term, while guaranteeing 100% data integrity and immediate access to your data so that you can bring your archived data to life. 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 one of the team! Contact us today

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