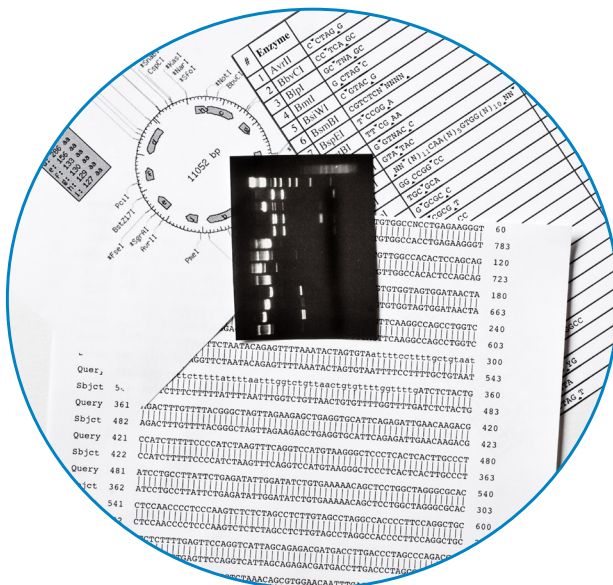


Arkivum TRUST: Case Study

Delivery of an efficient and secure electronic archive solution for eTMF documents

Phlexglobal and Arkivum have partnered to implement a regulatory compliant electronic-archiving solution resulting in a reduction in eTMF maintenance costs. The solution uses Arkivum and PhlexView to manage millions of pages from a growing number of clinical trials.



The company, a Japanese top 10 pharmaceutical company, required a solution for the long-term archiving of their electronic documents and associated metadata stored in their eTMF via Phlexglobal's best of breed solution, PhlexView.

This company is planning to process around 5 million pages from over 200 trials into PhlexView.

Data archiving & eTMF

The electronic archiving (e-Archiving) of clinical trial data is a regulatory requirement for many authorities: UK S.I. 2006 No. 1928, Trial Master File and archiving; EU Rules governing medicinal products, Vol.10, Ch.5 recommendation on the content of the Trial Master File and archiving, and the principles as defined by the FDA for Electronic Records and Electronic Signatures (21 CFR Part 11).

PhlexEarchive and Arkivum

Phlexglobal has developed a secure e-Archiving system, PhlexEarchive, which enables the long-term preservation of electronic content whilst reducing maintenance costs for servers, operating systems, and application software.

Implemented in 2014, PhlexEarchive was initially utilised by the company for ten trials across phases I – IV, and five compounds. The trial documents were transformed to PDF/A and XML (for the associated metadata) to assure long-term readability. PhlexEarchive is able to perform the transformation of TMF documents into PDF/A format and create a standard XML backbone for the associated metadata fully automatically. Both of these archive format files are then stored nearline or offline with Phlexglobal's partner Arkivum, using their managed data archiving service.

When the EU Clinical Trials Regulation (CTR) EU No.536/2014 comes into force that defines the 25-year retention period for eTMF.



Arkivum's Service meets the key requirements of 21CFR part 11 and has been certified to ISO 27001, which includes a detailed risk assessment of the integrity, availability and confidentiality of company assets in their possession.



100% integrity

Phlexglobal chose Arkivum as their eTMF partner because Arkivum provides an insurance-backed 100% data integrity guarantee for the full 25-year eTMF retention period as specified in the EU Clinical Trials Regulation (CTR) EU No.536/2014 that comes into force early in 2016.

The number of clinical trials archived in the Arkivum Service by the Asian company via PhlexEarchive.

200

The archived trial documents are available for retrieval from PhlexEarchive within 24 hours (Monday to Friday) of the request from the client being made. Once the retrieved files have been retrieved from the archive, they are available to the company via the archive module of PhlexEview with full search capabilities. Upon completion of the review the retrieved archive is deleted for security purposes. The original data is never removed from the off-line eArchive at retrieval time (a copy is taken).

PhlexEarchive allows for the import of data from PhlexEview to provide a full electronic archiving solution for the company that improves security by reducing the chance of accidental or deliberate damage, change or loss of eTMF content. correct format.

About Phlexglobal

Phlexglobal is a specialist provider of technology-enabled, Trial Master File (TMF & eTMF) document management solutions and other support services to the global clinical research market.

The company offers a unique combination of clinical trial knowledge, document management skills, regulatory understanding and technical expertise to deliver a range of flexible, targeted solutions to meet business needs.



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, financial services, higher education and heritage.

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.

Talk to us

To find out more about our solutions to start securing your data today and for the future, please contact us on:

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