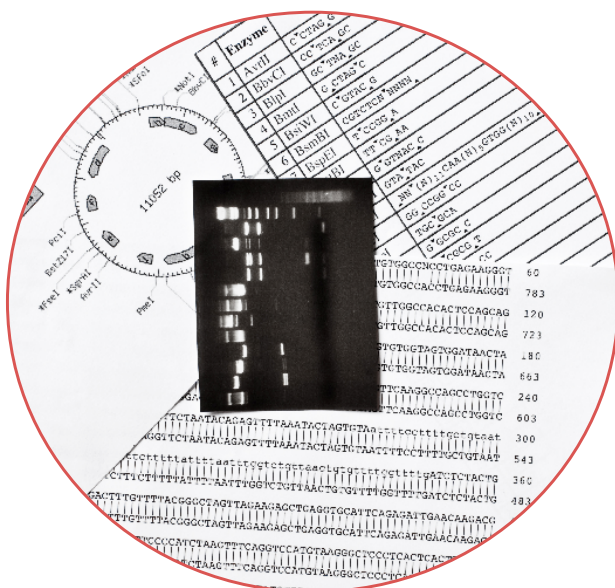


Arkivum TRUST: Case Study

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 records 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 and 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 TRUST

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.

PhlexEarchive was initially utilised by the company for ten trials across phases I – IV, and five compounds. The trial records 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 records 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, Arkivum TRUST.

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

2016

Arkivum TRUST 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% data 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 TRUST solution by the pharmaceutical 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 PhlexView 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 PhlexView 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.



The TMF Experts®

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 a leading provider of compliance-driven, long-term data safeguarding and usability solutions serving regulated, data intensive markets worldwide. Arkivum's solution helps organizations safeguard and preserve their most valuable digital content to the highest level, adhere to intensified regulation of digital records management, economically cope with increasing data volumes and make archived data usable and accessible.

Arkivum provides a safe, secure, compliant and accessible digital archiving solution for any type of data, structured and unstructured, with a unique 100% data integrity guarantee and a built-in escrow service. The Arkivum solution brings archived data to life by enabling users to explore the vast, usually untapped value of their archived repository.

Since 2012 Arkivum has been serving more than 100 clients worldwide across industries and is accredited and certified for ISO 27001.

Talk to us

To find out more about our solutions and to start securing your data today and for the future, please contact us on + 44 (0) 1249 405060 or + 1 617 306 4563, or send us an email at hello@arkivum.com.

