

Case Study

Delivery of a complete records management solution including implementation of a global eTMF for a top 25 global pharmaceutical company

Client Scenario

Our client, a European affiliate of a global pharmaceutical company, required a solution to resolve their problems with lack of compliant TMF storage, decentralised documents, lack of in-house resource, no quality control before archive and the need to incorporate CRO documentation. The longer term vision was to implement a global eTMF that would support international alignment and, through file reviews, audits and inspections.

Implementation of global eTMF system

Over 100 studies & 1.5 million documents loaded into PhlexEview

Over 300 global PhlexEview users

Mapping of CRO to client filing structures

Full TMF support

Phlexglobal Solution

Following a period of in-house consultancy in 2006, Phlexglobal implemented an eTMF solution to issues such as a lack of compliant storage, lack of in-house resource, CROs files in different filing structures etc. A phased approach was adopted to ensure that the PhlexEview end to end offered the solution our client was looking for. Planning and design included understanding requirements involving User Acceptance Testing (UAT) of a pilot study and assessing initially 65 global studies. Process mapping and re-engineering looked at workflow requirements and TMF restructure, streamlining of current process and secure storage, CRO partnerships and effective processing of over 250,000 retrospective documents into PhlexEview.

Since 2006, PhlexEview has been rolled out to our client's CROs and documents have been received from disparate locations across a number of studies. PhlexEview has been used to facilitate a number of audits and file reviews and also provided our client with documents to assist with writing clinical study reports and eCTD submission.

Over 3 years after the successful implementation of PhlexEview, our client is ready to utilise PhlexEview in a truly global manner by employing the same approach in the US.

Through effective global project and operational management, our client and Phlexglobal maintain a close partnership which ensures bespoke PhlexEview development and continual improvement to meet client needs.