

Case Study

The implementation and ongoing management of a global eTMF for a top 30 global pharmaceutical company

Client Scenario

UCB, a newly merged global pharmaceutical organisation, was facing the challenges of integrating legacy and disparate trial management systems and filing structures, whilst maintaining 'business as usual'. UCB was looking for an appropriate outsourcing model which would result in a new global eTMF enabling office based or remote access by internal and contract staff. Anticipated to continue over 5 years, the project will include ongoing management of both the paper and electronic TMF documents.

Implementation of a global eTMF system

Incorporating 3 disparate filing structures

£12m over 5 years

Pilot using a Phase I study

200 users accessing PhlexEview

Phlexglobal Solution

Following an initial pilot period using a completed Phase I study, the global roll-out of the eTMF was performed according to a controlled and phased plan. By January 2010 all three of UCB's filing structures had been implemented (2 legacy and 1 current) in PhlexEview, Phlexglobal's end-to-end eTMF, and in excess of 200 users had access to the system.

Trial master file documentation is now categorised according to 'backlog' or 'ongoing' criteria before being processed – a procedure involving the scanning, indexing and QC of documents according to predefined conventions – within contractually agreed timeframes.

In addition to the usual expected benefits of centralised eTMF documentation, the eTMF has enabled the delivery of significant other advantages. Perhaps most beneficial is the management oversight PhlexEview provides, giving key UCB users complete overview of which study documents are present, or more importantly missing, at any one point in time. This feature is invaluable when preparing for any regulatory inspection. Document throughput and CRO contribution can be carefully reviewed allowing for earlier intervention where required.

Throughout the planning, design and implementation phases of this project, UCB and Phlexglobal have worked in close partnership, allowing for the development of a bespoke solution which continues to meet all of UCB's goals and objectives.