



Appendix 2 to SOP S-1032 UoL Archiving Electronic Aspects of the TMF

The following advice from the MHRA Forum should be taken into consideration:

The use of electronic systems for such activities as data management, statistical analysis, reporting, trial management systems and eTMFs means that electronic documentation and data is likely to need to be retained. The data may be on a server or on transportable media, e.g. USB drives, CDs, tapes etc. It is recommended that more than one copy of the data is retained, for example where the data is archived in a specific server, this should be subject to back up, with the back up media stored in a separate location. Consideration may be given to storing the data in differing formats on different types of media or even on the same media from different manufacturers.

Access to archived data must be suitably restricted, either by user access levels to the archive area of a server or by controls to access the storage area where the media are retained (as for paper). Additionally, the electronic documents or data that have been archived must be protected from unauthorised changes to maintain authenticity.

It is important that future access to records and data is maintained. This could include maintaining the system (hardware and software) to access the data in its original format or the use of a new system to emulate the old software or migration of the data into a new format to ensure continual access with new software. This issue should be addressed by the organisation via formal procedures.

Media used to store the data may potentially deteriorate or become obsolete, for example, during a recent inspection a paper file contained a 3.5" floppy diskette containing the randomisation schedule. At the current time, PCs with ability to use such media are rare and future potential access would not be guaranteed, thus transfer to an alternative would need to be considered. The media should be stored under appropriate conditions. The transfer of data to new media as technology advances would need to be considered by the organisation. It is also recommended that periodic test retrieval or restores are undertaken to confirm that ongoing availability to the data is being maintained.

Where data is required to be migrated to new media or a new format, then the transfer should be validated and fully documented, so that it can be subject to audit, to ensure and demonstrate that there has been no loss, changes or corruption to the data or meta data and that authenticity is maintained.