E-Site Files: The Pros & Cons.

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Introduction

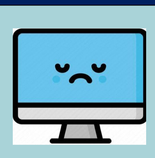
The Investigator Site File consists of trial documents from the initiation to closeout and preserves data relating to a study before, during, and after research trials according to Good Clinical Practice requirements. There are lots of versions of documents when a trial continues for the years, and considering the bulk of papers and handling of documents in traditional paper ISFs, it can be difficult to pace and track everything.

Since the advancement of new technologies, and the impact of COVID and virtual work environments, electronic site files are increasingly becoming the norm. But these types of site files are not without their problems either.

Our Swansea Bay R&D team conducted literature searches, and discussed with colleagues the pros and cons of using e-site files. We summarise these findings, and identify future implications and training suggestions.

Pros & Cons

- Improves speed and compliance across sites.
- Centralising and simplifying trial oversight.
- Conduct remote site monitoring.
- Up to date study documents. Real-time site file maintenance.
- “Going Green” Less impact on the environment, e.g. fuel emissions used for transporting files back and forth.
- Less cost on archiving providers, as some providers have a for each paper site file per day.
- Less storage required for hard/paper copies of files.
- More accessible amongst colleagues in same Trust but different sites.
- Less time manually destroying and shredding the files
- More secure, limited access to files, less likely to change data after data lock.



- Staff confidence/trust in new technology.
- Competence in use, human errors.
- Safe storage of patient details. Cyber security, password protected documents, delays in gaining role-based permissions.
- Issue when study set up and consent requires wet ink signatures.
- Challenges for GCP inspection e.g. actual size documents, read-only view, requires efficient system, availability of e-archiving guidelines.
- Issue with limited length of file names and issue if lots of sub folders then unable to open on computer.
- Technology is constantly changing. Staff must place the e-files on a modern storage device.

Summary

E-Site files are a useful way to store trial specific essential documentation in a more efficient and “greener” way. They can improve compliance across research sites and simplify trial oversight.

On the other hand, this modern way of working identifies areas that still need to be addressed, such as consistent structure and format, and e-archiving guidance.

Discussion with our teams have shown that staff can be mistrusting of new technology and confidence in the use of e-site files needs to be increased. A useful way that this can occur is to train new staff, and re-train existing staff, in the management of essential documents electronically.

References

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