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Bringing archived data to life

ETMF RETENTION REQUIREMENTS: COMPLYING WITH EU REGULATION 536/2014

Introduced
2014: EU Regulation 536 published

Go-live
Jan 2022: EU Reg 536 comes into affect

Mandated/Inspected
Jan 2023: EU Reg 536 **mandated** for all trials

Retention Requirements:

Who is responsible for retaining the eTMF?	At the conclusion of the trial both the drug sponsor and investigator must retain their trial master file for the stated period.	**Arkivum supports clinical sponsors to comply with EU Regulation 536**
How long do I need to keep the eTMF for?	Both sponsor and investigator to archive the TMF for at least 25 years after the conclusion of the trial.	
Records should be 'readily available and accessible'	Archived data needs to be 'inspection-ready' throughout the retention period. Have you considered: • How will future staff find digital records 10 or 20 years from now? • How will they gain access to those records? Or access the system they are stored in?	
The TMF (and the media is stored on) must remain 'complete & legible'	Records should be safeguarded against corruption, loss and obsolescence. Digital preservation can ensure records are readable (i.e. legible) for the entire retention period. Are you: • Storing copies in multiple locations? • Regularly checking data integrity has been maintained? • Maintaining records in long-term formats to be readable by future tech?	
'The clinical trial master file shall be traceable'	Sponsors and sites should ensure that they are capturing an audit trail of who has accessed the records, what they accessed and what they do. Any system which doesn't achieve this is not fit for purpose.	

Read the full blog post here.

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