


The Role of the Clinical Trial Archivist



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SAG/ICR Joint Meeting

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Agenda



- Historical perspective
 - Recent changes
 - Who could be the 'archivist'?
 - What is the archivist responsible for?
 - Benefits of having a dedicated archivist
 - On site archiving vs off site storage
 - Further help available
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Historical Perspective

- GLP regulations have for many years required a 'named' archivist, with clear accountabilities
 - GCP did not mandate an archivist role.
 - Ambiguity of GCP guidelines does not stipulate how records should be kept
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Recent changes

EU Directive 2005/28/EC (8th April 2005)

Article 19

The sponsor shall appoint individuals within its organisation who are responsible for archives.

Access to archives shall be restricted to the named individuals responsible for the archives.

As a result, organisations are now identifying /appointing GCP archivists



Who would be an “archivist”!?

- Almost anybody....
 - CTA, CRA, Admin staff
 - Librarian
 - Dedicated Archivist

 - Part time/full time etc as business need dictates

 - May be a need for additional archive staff in larger organisations
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What is an archivist responsible for?

- ❑ Day to day operation and management of the archive
- ❑ Monitoring conditions in the archive and addressing issues
- ❑ Indexing and controlling deposited records
- ❑ Controlling access
- ❑ Tracking/documenting record retrievals, loans, transfer and destruction

...following documented procedures

...supported by training to show competence



Benefits of having a dedicated archivist

- Consistency of archiving processes
 - Potential involvement throughout study (not just at the end)
 - Develop expertise in the role within the organisation
 - Especially valuable during inspections
 - Allows sufficient time for archiving work, training etc
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On site archiving vs offsite storage

- Size and number of clinical studies increasing, creating more records
 - Some electronic records, but predominately still paper
 - Onsite space often limited
 - Often not ideal for use as a long term archive
 - Offsite storage
 - It's not “archiving”, the archivist role still required
 - The contract/service level is key
 - Need to monitor performance/quality
 - Archiving CROs
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Further help available

- Publications
 - SAG GCP Guidance
 - Conferences/training events
 - Become a member of SAG!
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Thank you

