

A Generic TMF Fileplan: *Pipedream or Reality?*



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Eldin Rammell

Good Clinical Practice Records Managers
Association (GCP-RMA)

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GCP - RMA

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Current approaches to filing

- >260 TMF document types filed*
- Every sponsor files in a different way
- Most common approach:
 - Based around ICH GCP Ch. 8 list of essential documents
 - Files held by function (Monitor file, Data Mngt file, Project Mngt file etc)

* Number identified by DIA TMF Reference Model Working Team

How are we performing?

- 10% of MHRA inspection findings directly attributed as ‘archiving’ or ‘record keeping’*
- Much higher % *indirectly* attributable, including ‘quality system’, ‘IMP management’ and ‘contracts and agreements’ findings

* MHRA GCP Inspections Metrics Report, 1 Apr 07 – 31 Mar 08

How are we performing?

- Inability to locate documents
- Documents inconsistently filed
- Incomplete files
- Difficulty reviewing linked documents (to demonstrate process audit trail)
 - Which version of ICF did the EC approve?
 - Which site CVs were reviewed during last monitoring visit?
- Distributed document repositories

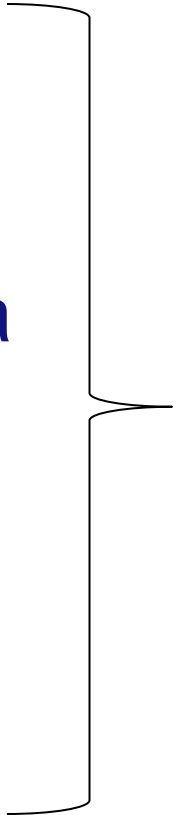
Is there a “best practice”?

Process/Activity based classification scheme

- UK National Archives
 - Business Classification Scheme Design
- National Archives of Australia
 - A Strategic Approach to Managing Business Information (DIRKS)
- International Standard ISO-15489-1
 - Information and documents: Records management

Clinical trial processes

- Initiate trial
- Organise drug
- Establish sites
- Test drug & capture data
- Monitor quality
- Close-out sites
- Analyse data
- Report findings
- Ensure good practice



54 sub-processes

Co-location of related documents

Proposal

Site initiation visit

- Visit report
- Correspondence
- Protocol signature page
- Investigator contract
- Financial disclosure
- Data processing form
- Indemnity form

Typical filing scheme

Documents filed under:

- *Monitoring visit reports*
- *Site correspondence*
- *Protocol*
- *Contracts/agreements*
- *Financial*
- *???*
- *Insurance*

Advantages

- Documents typically requested together – e.g. during inspections - are co-located
- Cuts across organisational structure: improves consistency and eliminates duplication
- More comprehensive contents list
- Independent of national and cultural differences and interpretations
- More stable through organisational, regulatory and cultural change
- **Consistency across sponsors, CROs and vendors**

How to implement

- Combine proposed scheme with TMF Reference Model
 - Comprehensive contents list with standard terminology (DIA)
 - Process/Sub-process added as metadata (GCP-RMA)
 - Provides an additional filing, search and retrieval mechanism

Is the investigator site suitably qualified to conduct the study?

ACME Document Management System

Trial: ADF-98-0001

Site: 045 Dr. Scroggins

Search

03 Establish trial sites

03.07 Site personnel qualifications

☐ Select document type

☒ Select activity

15 documents found:

Investigator meeting slides

Investigator meeting attendance

Dr. K.L. Allen CV

Ms. F.A. Smith CV

Mrs. T. Mahoney CV

Dr. A. Scroggins CV

Dr. S. Singh CV

Dr. S. Singh medical license

Click on a document to view

PRINT REPORT

SAVE LIST

MAIN MENU

Thank you

Any questions?

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