# A Generic TMF Fileplan: *Pipedream or Reality?*



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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



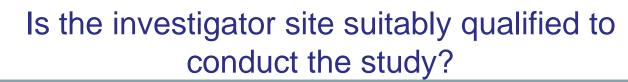
### **Advantages**

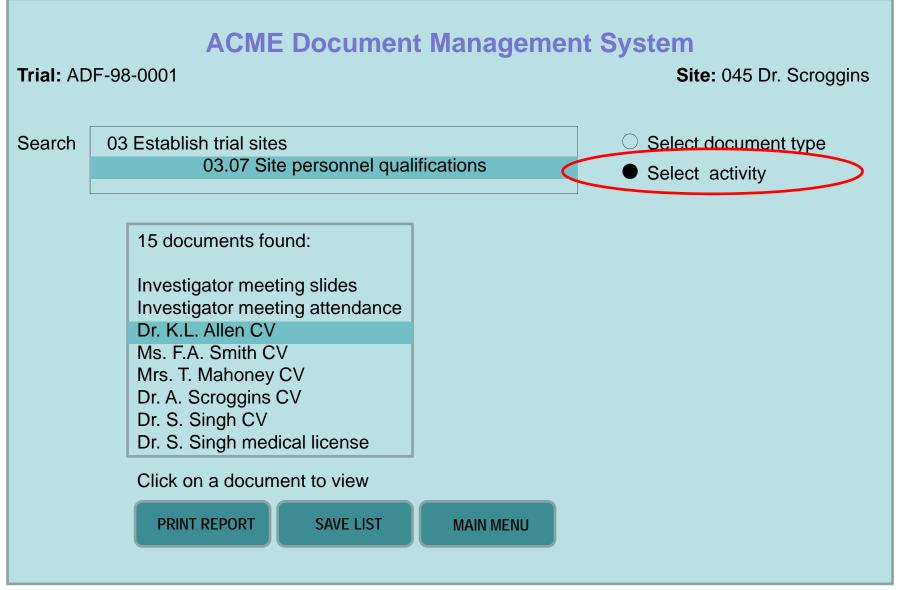
- Documents typically requested together e.g. during inspections are co-located
- Cuts across organisational structure: improves consistency and eliminates duplication
- More comprehensive contents list
- Independent of national and cultural differences and interpretations
- More stable through organisational, 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 <u>added as metadata</u> (GCP-RMA)
  - Provides an additional filing, search and retrieval mechanism







### Thank you

Any questions?

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http://www.gcp-rma.org