SOPs OF DATA MANAGEMENT

TOPICS COVERED

- SOP of data management plan
- Using data management plan

SOP

- Every data management group should have a process for documenting how a study was conducted
- The process must be described formally in either an SOP or a department guideline
- For most companies, the way to document a study will be to create a DMP-type document as described
- A few companies, typically small ones with little variation across studies, may choose not to have a DMP but to have instead a detailed document on study files (similar to the technique used widely in the past)

- When using a DMP, the associated SOP must clearly define a point at which the DMP for a given study must be in place For the DMP to be a plan, rather than a report at the end of the study, and to provide the value of thinking through a study before data comes in, a draft or an initial version typically needs to be in place before any substantial work is performed on data for the study
- It is not unusual to use a point of first patient in or first data in as the trigger around which the DMP must be final The SOP must also state the circumstances under which the DMP must be revised and what signatures are required Along with an SOP for creating and maintaining a DMP, there should be a blank template document or an outline for the plan to assure consistency across studies

- Each section in the template should have instructions on what kind of information and what level of detail is expected An example of a completed DMP used in training of new CDM staff is especially helpful Because the DMP and study files are so closely linked, it is a risk to have two separate SOPs for these topics
- Many companies have made the mistake of having the DMP requirements specified in one SOP (with a template) and a separate SOP describing contents and maintenance of the study files Because the DMP is in constant use, the template is updated to change contents of the study files, but the SOP on study files is not

- An auditor looking at the SOP on study files will find one list of contents or folders and a different list in the DMP template—and some unknowable final result in the actual study file New data managers will also be confused because they will have a document required in the DMP and no obvious place to file it in the study files

Use of DMP

- To overcome the natural, strong reluctance to spend time planning or documenting anything when there is “real” work to be done, the value of the effort must be recognized To get more than minimal compliance from staff, that value has to be more than “because so-and-so tells us we have to” or “the FDA requires it ” A DMP actually does have benefits that can be recognized by every data manager

- These benefits include:

- The work to be done and responsibilities are clearly stated at the start of the study so that everyone knows what is expected
- The expected documents are listed at the start of the study so they can be produced during the course of, rather than after, the conduct of the study
- The document helps everyone fulfill regulatory requirements
- Data management tasks become more visible to other groups when the DMP is made available to the project team
- The DMP provides continuity of process and a history of a project This is particularly useful for long-term studies and growing data management groups

References

- Society for Clinical Data Management, Good clinical Data Management Practices version 3. Sep 2003
- Colleen M Cox. Planning the data Management Process for a clinical trial, Technology and Data Management. Monitor, Sep 2005.
- Louis Pozzo, Glen de Vries. Applied Clinical Trials, Oct 5 2005
- Paul Bliecher, Applied Clinical Trials, Apr 1, 2005
- Rondel, R. Varley, S. Webb, C. Clinical Data Management. New York: John Wiley and Sons LTD. 2000