Object oriented document management/creation: The merging of a Cro’ S SOPS and client’s SOPs to create working procedures

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1 Introduction

In being a contract research organisation, AnalyticA has the opportunity to work alongside numerous laboratories. One of the major problems of coordination concerns the adaptation of internal procedures with reglementary and contract requirements. Moreover, with a multitude of projects running simultaneously, it is important to have coherent and flexible methods which are adaptable and applicable to each and every trial. That is why a structured management system of SOPs and more generally of the documentation of a study became necessary. The management product and programming support is SAS®6.09 on UNIX. Its implementation of graphical interface, transportability and system links make it a perfect base for the development of such an application. The development method used is the object orientated approach. This is applicable not only to the language used but also to the structure of the documents and to the nature of the development. So the elements of a document are considered as objects composing of functionalities, attributes and methods. The presentation will attempt to explain the approach, the technical aspect, and the advantages gained from such a development.

2 Generalities

In terms of programming the goal of such an application is to manage via the intermediary of a graphical interface convivial and intelligible an application to build and manage documents.

There are differing aspects within the application. On one hand there is SAS®, with its graphical interface, database management and link with external products. On the other hand there is the document itself, both composition and treatment.

To summarise the principle of the application, we could say it is an application of document construction managed by SAS® and a text formatter. The figure 1 page 7 describes the application in its principle element i.e. the building of a document. We can take a look inside a database to see how the data represents the elements of the document. These elements match with files editable (or not) by external products. Finally SAS® transforms these files to make them integrable by the text formatter.

Finally the document “Text formatter” is compiled to be visualisable or printable. The format of visualisation and printing is postscript® (You can in the figure 2 page 8 see a session of visualisation).

3 Database organisation

The databases are organised in a hierarchical manner. At the top level of the list of documents we have a dataset which contains all the references concerning the document itself, title, code, stability... From the information contained in this file we find a dataset containing the references of the objects present in the document. Finally, for each of these
objects, we have a database containing every attribute of the object. The objects are linkable. Let’s take for example a reference document containing an object representing an organigram. This organigram may be applicable to instanciations of the reference and must evolve in the same way in applications and in references. There is also the possibility of logical link which is given to the application administrator. A diagram page 9 shows in a simplified way the organisation of these databases.

4 Document management

4.1 Document coding

To classify sops, it has been necessary to find an efficient coding system. The purpose of the document must be derivatable by the four level name which has been used to code it.

- 1st field: The domain of the SOP. It can be the department, the service, or the study (The word itself is an application domain)...

- 2nd field: The support of the SOP. It can be the fax, the electronic mail, or CRF, or databases...

- 3rd field: The induced action of the procedure. This can be a circuit, an audit, a proposition ...

For example, let’s take a procedure concerning the writing of the protocol to be used in a therapeutical trial.

The first field will be “STUDY”, it is the domain of application.

The second field will be “PROTOCOL”. It is the support of the procedure.

The third field will be “DEVELOPMENT” or also “WRITING”, as it is the concerned action.

The last field concerns the procedure indentation. Because many procedures can touch the same subject. You can see in the figure 2, page 8 a screen showing the coding criterias and the document visualized.

4.2 Notion of application (or instanciation)

There are two types of document. Those defining internal procedures and specific applications for some SOP's in terms of the particular trial in question. This can be an adaptation but also an integration of the procedure of the laboratory. Note, an internal SOP can match with different procedures within different trials. Let’s take, for example, a drug management procedure. The procedure, internally applicable has not been constucted taking into account that the laboratory itself manages the drug supplies to
centres and not Analytica. So we must make an application of the reference procedure to the study where the the drug management will be the domain of the laboratory. In terms of the document format the difference is designated by the header. As well as the header’s colour (red for the reference, green for the application), the application’s header incorporates the name of the study and the sponsor for which the document has been made (Example figure 4, page 10).

4.3 Security

Security is critical for a company working in this area. The databases are protected by SAS/Share®. The documents are, constantly protected with read and write access.

Not all the procedures are of interest to everybody. Moreover the application of procedures to a specific study only concerns the people who are in charge of the project. Therefore it is necessary to manage access via read and write privilege. For this reason, a link to the information centre has been necessary. The SOP creators are not only responsible for the design of the SOPs but also for designating the levels of access for the document.

5 Management of the document by objects

5.1 Object notion

A document is composed of several objects, the notion of each object being sequential. For example, a document may be composed, firstly of a landscape object, i.e. the page format of the document will, until another page format object, be in landscape format. This object will be followed by an “image” object (importation of a file created by SAS/GRAPH® or a graphic editor). The various objects, come from not only SAS®, but also form external products. It can be from a graphic editor, text processor scannerised pages, or printed results that can come from any of the products generating postcript®. Each of the objects are automatically parametered, implying that like an object (in object oriented languages) the module of the document has attributes. Just as for an image, we will find as attributes, the size the referencing, title place and eventually the relevant font etc ...

5.2 Methods and products

The correct vocabulary concerning the object would not be complete if we did not use the term “method”, as for each class of an object there match several methods. A build method (attribute definition), an edition method (call, display of the text processor, graphic editor, or other product), an integration method (It means an eventual transformation of the file and placement in the CANVA of the document).
6 Conclusion, Possibilities ...

The possibilities and advantages offered by a management system

- Document standardization: The headers, page formats, fonts, automatically integrated in the document are generated at each visualization. This means that the users immediately have the ideal working environment. Only the realization method changes. In this context all the documents are standardized in their form.

- Compilation: It is possible, for a given study, to produce reports, by compiling several procedures into one document. The interest of this functionality is, for example, for a particular study to make a package for concerned people of all the concerned procedures. To build such a report is extremely simple. The administrator chooses his documents (in the references as in the instantiations), arranges the order of the documents and gives the order in which to generate it. A contents table, figure list and an index can be generated automatically if required.

- Information processing: As the documents are organised via a database, it permits us to managed the whole document building process.

If we finally consider the value of the development as a whole, it is clear that we can separate the required processes. A few people can be typing text or reproducing simple diagrams, while others may be allocated the job of integrating these documents (i.e. the naming of each document or importing relevant graphics). A sound working practice can therefore be established.
Figure 1: General organisation

Document building
Methods are managed or controlled by SAS/FRAME®

Database Structure of the document
Object* text formatter
Object* graphic editor
Object* text processor
Object* SAS® listing
Object* scannerised

EDITION
by user

TEXT FORMATTER

ASCI1 file. text formatter Structure of the document
Input "Predefined style"
Input "Draw"
Input "Text"
Input "listing SAS®"
Input "scannerisation"

TRANSFORMATION

Formatted for integration in text formatter
Can be:
- Transformation into POSTSCRIPT® format
- Transformation into ASCII format
- Transformation into TIFF format
- Transformation into formatting commands
Everything is done in batch, and is therefore invisible to the user

COMPILATION

VISUALISATION OR PRINTING (Transformation in POSTSCRIPT® FORMAT)

* Physically match to a file
Figure 2: SOP visualisation
Figure 3: Reference document CANVA and application

**DOCUMENT DE REFERENCE**

**OBJECT LANDSCAPE**
Formatting of the document in landscape

Object IMAGE 12x15 cm
Enclosed, no page breaks after the object
Object Text processor
No page break
Default font

**APPLICATION TO STUDY XXXXXX**

**OBJECT LANDSCAPE**
Formatting of the document in landscape

Object IMAGE 12x15 cm
Enclosed, no page breaks after the object
Object Text processor
No page break
Default font


- Punctual link (done at the moment of the creation of the document)
- Constant link (The object in its instanciation cannot be modified during the document construction. The applied version looks searches for the reference)

Figure 4: Headers examples
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