

A Web Interface for Efficient Clinical Trial Program Development

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ABSTRACT

In order to improve the efficiency of code programming in clinical trial, an interface in web page form is developed to contribute several important functions to reduce unnecessary time.

There are two parts are included in the interface. One is hyperlink to required documents, such as protocol, sap, TLG shells and programming tracking sheet. The program can automatically create the link by identifying the key words to locate and get these documents' path. It also can be recreated if related documents are updated. The other is a Shortcut to utility tools, which includes batch-run, compare-result, check difference and etc. These functions could make programming process more efficient. The Web interface could be generated by using SAS with a few parameters. It's very easy to implement at the start of a project .Functions of this interface could also be extended.

INTRODUCTION

Many essential documents such as **blankcrf**, **Protocol**, **SAP**, **TLG shell**, **Dataset Specification** and **Programming Tracking Sheet** are very helpful and required in processing programming work for clinical programmer, so as to some utility tools which used for batching run, checking log and doing validation work.

The problem is that when documents or utility tools showed above needed to be invoked, user usually has to open folders by folders, until get to the destination where they locate, which is somehow time wasting.

This presentation illustrates core concepts to create an interface by SAS code that can hyperlink to necessary documents and those utility tools directly. Using the interface enables us to cover the question mentioned above, which is to yield the minimum time cost.

STANDARD FOLDERS

In a company, the study folders usually share one standard structure, special documents are usually with regular file naming rule and located in the specified folder. In the example below (Table 1), all programming related documents are stored under ...\\csr\\doc folder.

Project Name	Document Name	The Pathway Where Stored(Folder)
Study-001	Protocol	csr\\doc\\protocol
Study-001	CRF/blankcrf	csr\\doc\\CRF
Study-001	spec/tracking sheet	csr\\doc\\programming
Study-001	SAP/TLG shells	csr\\doc\\statistics
Study-001	Toc	csr\\doc\\other

Table 1. Document Paths

Here is a list of some instructions for the related document names:

- **CRF**: Case Report Form.
- **Blankcrf**: Annotated Case Report Form.
- **SAP**: Statistical Analysis Plan
- **Spec**: Dataset Mapping Specification, including SDTM spec and ADaM spec.
- **TLG Shells**: Tables, listings and Graphs shells
- **Tracking Sheet**: project tracking sheet, a file to capture assignment and status for the project.
- **Toc**: Table of Contents, a file including all titles and footnotes for programming usage.

HYPERLINK TO NECESSARY DOCUMENTS

Based on their regular names and pathways mentioned above, using those as key words, to locate the documents with DOS command or SAS X command. Take one project study-001 as example. Below figure shows the output after running the Marco (*%find*),

```
%find (folder=statistics);
```

As the output 1 showing, all the document related information under ...doc\statistics\ folder are listed.

doc	folder
Study-001_SAP signed Sponsor signature page.pdf	doc\statistics\
Study-001_Signature page.docx	doc\statistics\
Study-001_Figure_Shell_Final_v1.0.docx	doc\statistics\
Study-001_Figure_Shell_Final_v1.0_clean.docx	doc\statistics\
Study-001_Listing_Shell_Final_v1.0.docx	doc\statistics\
Study-001_Listing_Shell_Final_v1.0_clean.docx	doc\statistics\
Study-001_SAP_Final.docx	doc\statistics\
Study-001_SAP_Final.pdf	doc\statistics\
Study-001_SAP_Final_CRO_Signature_Page.pdf	doc\statistics\
Study-001_SAP_Final_v1.0.docx	doc\statistics\
Study-001_Table_Shell_Final_v1.0.docx	doc\statistics\
Study-001_Table_Shell_Final_v1.0_clean.docx	doc\statistics\
Archive.rar	doc\statistics\
getname.bat	doc\statistics\
random subj and block test.sas	doc\statistics\
~\$udy-001_Figure_Shell_Draft_v0.2.docx	doc\statistics\
~\$udy-001_Listing_Shell_Final_v1.0.docx	doc\statistics\
~\$udy-001_Listing_Shell_Final_v1.0_update.docx	doc\statistics\
~\$udy-001_SAP_Draft_v0.1.doc	doc\statistics\
~\$udy-001_SAP_Final.docx	doc\statistics\
~\$udy-001_Table_Shell_draft_v0.2_team_comments.docx	doc\statistics\
~\$udy-001_Table_Shell_draft_v0.2_trackchange.docx	doc\statistics\
~\$udy-001_Table_Shell_Final_v1.0.docx	doc\statistics\
~\$udy-001_Table_Shell_Final_v1.0_update.docx	doc\statistics\

Output 1. All the Documents Under ...lcsr\doc\statistics folder.

After locating and getting all the documents, user need to make some trade-offs. First, under all the files list above, only word or PDF documents are included; Second, based on the key variables, such as **protocol**, **spec**, **shell**, the documents whose names are identified by those key variables are preferred; Last, some documents are excluded from the hyperlink list, since they are helpless to programming work .For example, business files with the key word 'Signature' and unexpected temporary documents with '~\$' will be removed.

Below is the sample code how to drop temporary documents and get SAP not the signature for SAP involved.

```
data namelist;  
  set namelist : toc;  
  length a $256;  
  where substr(doc,1,2) ne '~$';  
  path=strip(folder)||strip(doc);  
  if index(lowercase(doc),'sap')>0 and  
  index(lowercase(doc),'signature')=0 then do;  
    a='<b> SAP </b>';  
    order=10;  
    output;  
  end;
```

After that, all the necessary documents about SAP are collected (see output 2 display as below).

doc	folder
Study-001_SAP_Final.docx	doc\statistics\
Study-001_SAP_Final.pdf	doc\statistics\
Study-001_SAP_Final_v1.0.docx	doc\statistics\

Output 2. The Necessary Documents about SAP Under ...\.csr\doc\statistics Folder.

Users can get other related documents by setting the parameters as required and run the Marco (*%find*) as mentioned above. For example, with 'folder= programming\ads' user will obtain all the necessary documents about ADaM specification. According to this, finally, user can gain all the necessary documents together.

But there is one thing worth noting, as we know, for the convenience of timely updating, documents like **protocol, CRF, SAP, TLG shells** often display in unshared mode. So once programmer is opening these documents, it will be a trouble for statistician who is required to modify these documents. Hence, in the program, we add a new step (refer to code display as below) to copy those latest documents into doc\user folder under the project, the corresponding hyperlink pathway also point to the documents under the folder, which cause no effect on updating of the origin documents. However, no such action demanded for those shared documents, such as **toc, tracking sheet**.

```

data copy;
  set namelist;
  where order<30;
  copy="put 'copy /y &rootcsr.'"||strip(folder)||' "'||strip(doc)||' "'||"
&rootcsr.user\&SYSUSERID.\"||' "'||strip(doc)||' "'||'";
  folder0=folder;
run;

proc sql noprint;
  select copy into:copy separated by ' '
  from copy;
quit;
data _null_;
  file "&rootcsr.doc\copy.bat" ;
  put "@echo off " ;
  put "if not exist &rootcsr.user\&SYSUSERID. md
&rootcsr.user\&SYSUSERID.;"
  &copy.;
  put "exit" ;
run;

  options xwait xsync ;
  X "&rootcsr.doc\copy.bat" ;
  options noxwait noxsync;
  X "del &rootcsr.doc\copy.bat" ;

data namelist;
  set namelist;
  if order<30 then folder="user\&SYSUSERID.\";
run;

```

The results of running the above code are presented in Figure 1, all the unshared documents are copied to the new created folder (folder="user\&SYSUSERID."). This solved the trouble which affect the statistician updating these documents. As for those shared documents, the hyperlink pointed to their original pathways.

Name	Size	Type	Date Modified
Study-001 Protocol 2mal052915	376 KB	Microsoft Office Wo...	6/18/2015 12:59 PM
Study-001_Figure_Shell_Final_v1.0	52 KB	Microsoft Office Wo...	4/29/2016 11:26 AM
Study-001_Figure_Shell_Final_v1.0_clean	50 KB	Microsoft Office Wo...	4/29/2016 11:23 AM
Study-001_Listing_Shell_Final_v1.0	101 KB	Microsoft Office Wo...	4/21/2016 1:18 PM
Study-001_Listing_Shell_Final_v1.0_clean	92 KB	Microsoft Office Wo...	4/29/2016 11:19 AM
Study-001_SAP_Final	149 KB	Microsoft Office Wo...	10/21/2015 2:57 PM
Study-001_SAP_Final	626 KB	Adobe Acrobat Doc...	10/21/2015 2:57 PM
Study-001_SAP_Final_v1.0	115 KB	Microsoft Office Wo...	10/8/2015 5:58 PM
Study-001_Table_Shell_Final_v1.0	83 KB	Microsoft Office Wo...	4/29/2016 11:37 AM
Study-001_Table_Shell_Final_v1.0_clean	83 KB	Microsoft Office Wo...	4/29/2016 11:34 AM

Figure 1. All the Necessary Documents are Copy to New Folder: ...\.csr\user\ SYSUSERID.

HYPERLINK TO UTILITY TOOLS

In our programming process, after coding part is done, the following steps should be performed before passing your work to review or deliver:

1. Batch run all the development and validation programs.
2. Check log to make sure it is clear with following SAS messages/note in log file.
 - ❖ Error
 - ❖ Warning
 - ❖ Uninitialized Variable.
 - ❖ Merge by more than on value
 - ❖ Missing value generated
 - ❖ Character/numeric conversion
3. Compare results to ensure the validation results goes well.

For these functions, the corresponding code are called "batch run", "mchklog", "chk_proc_compare", details refer to figure 2, which all stored under ...\.csr\dev\pglother folder.

In fact, to make the code as user friendly as possible, check log and compare results are both involved in batch run, which means user only need to call "batch run", then "mchklog" and "chk_proc_compare" will be carried out .

	batchrun	7/13/2016 10:13 PM	SAS System Progr...	6 KB
	chk_proc_compare	7/13/2016 9:54 PM	SAS System Progr...	6 KB
	mchklog	7/13/2016 9:54 PM	SAS System Progr...	6 KB
	batchrun	7/26/2016 10:45 PM	Windows Batch File	1 KB

Figure 2. The Related Code We Call For On the Server.

CREATE THE WEB INTERFACE BY SAS

With all the prepared data and resources, by using HTML language and Proc report function (code displaying as below).

```

title1 " ";
title2 "<b> Hyperlinks for Necessary Documents </b>";
title3 "<A HREF='%UNQUOTE(&rootcsr) ' > &project </A>";

ods listing close;
ods html body="&rootbat..html" headtext="&project programming interface by
UserID=&SYSUSERID on &now.;" ;

proc report data=namelist nowindows;
    column order a folder doc ;

```

```

define order/group noprint;
define a/group display 'Filetype' style(column)=[cellwidth=25% ];
define doc/order 'Filename' style(column)=[cellwidth=70% ];
define folder/noprint;

compute doc;
  link = "&rootcsr."||strip(folder)||strip(doc);
  call define(_col_, 'url', link);
endcomp;

run;

title2 "<b> Hyperlinks for Utility Tools </b>";
title3 " ";
proc report data=tools nowindows;
  column folder dv pg ;
  define dv/ 'Role' style(column)=[cellwidth=20% ];
  define pg/ 'Program' style(column)=[cellwidth=70% ];
  define folder/noprint;

  compute pg;
    link = "&rootcsr."||strip(folder)||strip(pg);
    call define(_col_, 'url', link);
  endcomp;

run;
ods html close;
ods listing;

```

After running the giving code, the web interface is available as below (Figure 3).

Study-001 programming interface by UserID=ping_ni on 2016-09-01;

Hyperlinks for Necessary Documents Study-001

Filetype	Filename
PROTOCOL	Study-001 Protocol 2mal052915.docx
SAP	Study-001_SAP_Final.docx
	Study-001_SAP_Final.pdf
	Study-001_SAP_Final_v1.0.docx
Shell	Study-001_Figure_Shell_Final_v1.0.docx
	Study-001_Figure_Shell_Final_v1.0_clean.docx
	Study-001_Listing_Shell_Final_v1.0.docx
	Study-001_Listing_Shell_Final_v1.0_clean.docx
	Study-001_Table_Shell_Final_v1.0.docx
	Study-001_Table_Shell_Final_v1.0_clean.docx
Tracking	Study-001-ADaM_TLG_Programming_Status_tracking_sheet.xls
Spec	Study-001-ADaM-Data-Specification.xlsx
Toc	toc.xls

Hyperlinks for Utility Tools

Role	Program
Dev	batchrun.bat
	runall_ads.bat
	runall_tables.bat
	runall_listings.bat
Val	batchrun.bat
	runall_ads.bat
	runall_tables.bat
	runall_listings.bat

Figure 3. The Layout of Final Web Interface.

By clicking the related hyperlink as show in figure 3, the corresponding document will display in front of you. Meanwhile, the utility tool showing on the lower part also works well. At the top of the web interface, user can get the information about when the interface was created and the user information.

SHORTCUT TO GENERATE THE WEB INTERFACE

Last, when the code for creating this web interface is ready, for your convenience, suggest using **GSUBMIT** function to add an icon to the tool bar. Here is the customized tool bar.



When needed in the programming, user can just click the icon in red box with your mouse, which can reach to the web interface as show in figure 3, then choose then files you need.

CONCLUSION

The aim of this paper is to explore how to create a web interface to make our daily work easier. After testing, it is easy to create with SAS 9.3. The functions of this interface could be extended within different project with just a little extra parameters updated. Hopefully this paper offers you impressive and usefully information.

REFERENCES

Xin Wang, (2016), "Using GSUBMIT command to customize the interface in SAS®", PharmaSUG China 2015.

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