

Improving the Quality of Data

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ABSTRACT

At Covance the quality of the data we provide to internal and external clients is very important. As one of the main outputs from the clinical trial process, our clients expect us to deliver high quality data that is accurate and on-time.

This paper will show how the Biometricians at Covance have used *SAS Stored Processes*® along with the *SAS Add-In for MS Office*® application to help our Data Management colleagues improve the quality of the clinical trial database. These techniques and software enable the Biometrician and Data Manager at Covance not only to save time and be more productive, but also improves the relationship with our clients by providing quality data of the highest standards, in a timely manner.

INTRODUCTION

Before clinical trial data can be summarised into tables, figures and listings (TFLs), the data has to be cleaned to ensure that any discrepancies have been queried and resolved. The more thorough this process is, the more discrepancies are identified, queried and resolved, and ultimately the cleaner the data is.

A recent upgrade to the *SAS Enterprise Intelligence Platform*® is enabling the Biometricians at Covance to assist in the validation process beyond the levels previously possible. The Biometrics and Data Management departments have always worked together to develop edit checks in SAS to identify discrepancies as the study progresses, in addition to those created within the clinical trial database. However, the new opportunities provided by the *SAS Enterprise Intelligence Platform* have enabled the execution process to be automated, removing a time limiting hand-off between the two functions. Now, SAS generated edit checks can be run by Data Managers at regular intervals (or as required) and queried as soon as discrepancies appear. This, in turn, improves the timeliness and quality of data we provide to our clients.

This paper will explain what a *SAS Stored Process* is, how it is created and how the Biometricians and Data Managers at Covance are using it in conjunction with the *SAS Add-In for MS Office* application to take full advantage of these software products.

SAS STORED PROCESSES

SAS Stored Processes are SAS programs that are stored centrally on a server so that they can be accessed from anywhere within the organisation. The advantage of *SAS Stored Processes* over other approaches is in the ability to centrally maintain and manage code. They provide better change control, enhanced security and application integrity, and ensure that every client application executes the latest version of code.

Another advantage of using *SAS Stored Processes* is that the program can be invoked by end users, in our case the Data Manager. The code is not embedded into client applications and therefore can be invoked from multiple applications at a given time (the results being returned to the invoking client application). *SAS Stored Processes* also allow the user to input parameters for dynamic execution. The security and application integrity are also ensured through Metadata accessed on demand and therefore changes are immediately reflected.

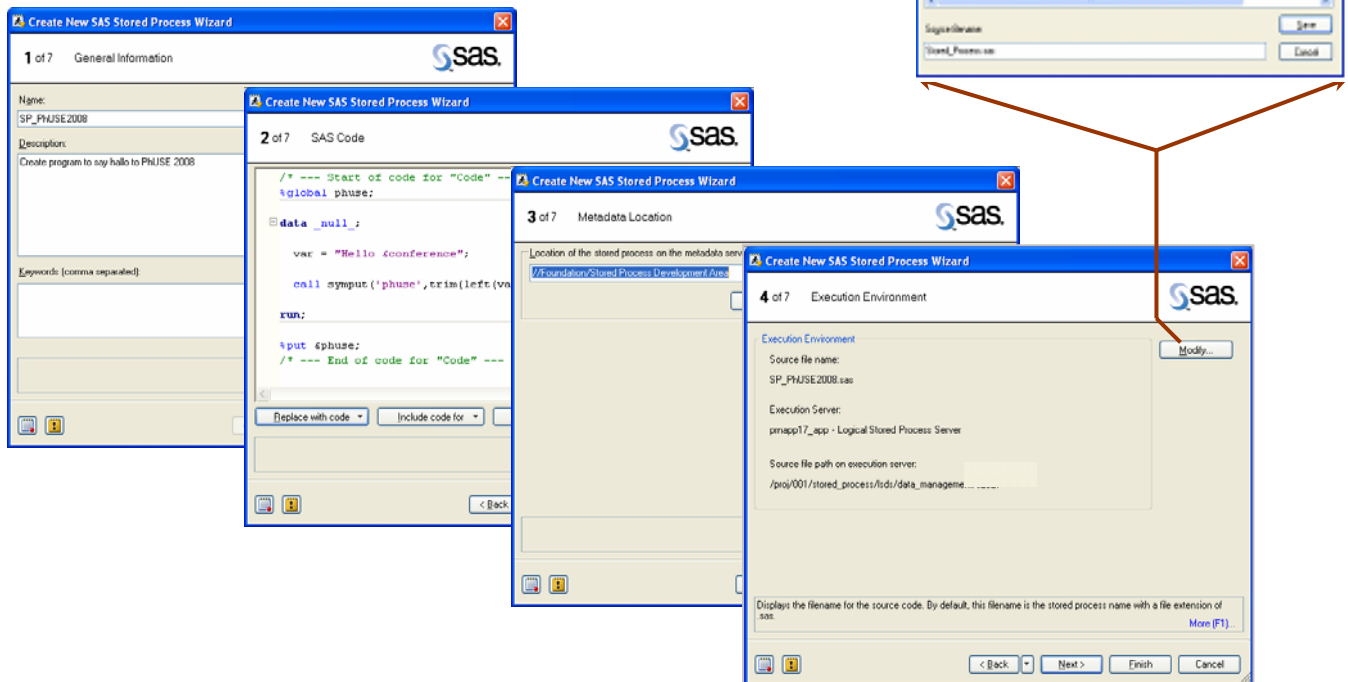
HOW ARE SAS STORED PROCESSES CREATED?

At Covance, we create *SAS Stored Processes* using *SAS Enterprise Guide*® (EG). Our edit check is written as a SAS program and EG is used to modify this to include the code required to create a *SAS Stored Process Macro*. The *SAS Stored Process* is then saved on the central server. EG has a very helpful wizard menu that aids in the creation of a *SAS Stored Process* from the initial SAS program.

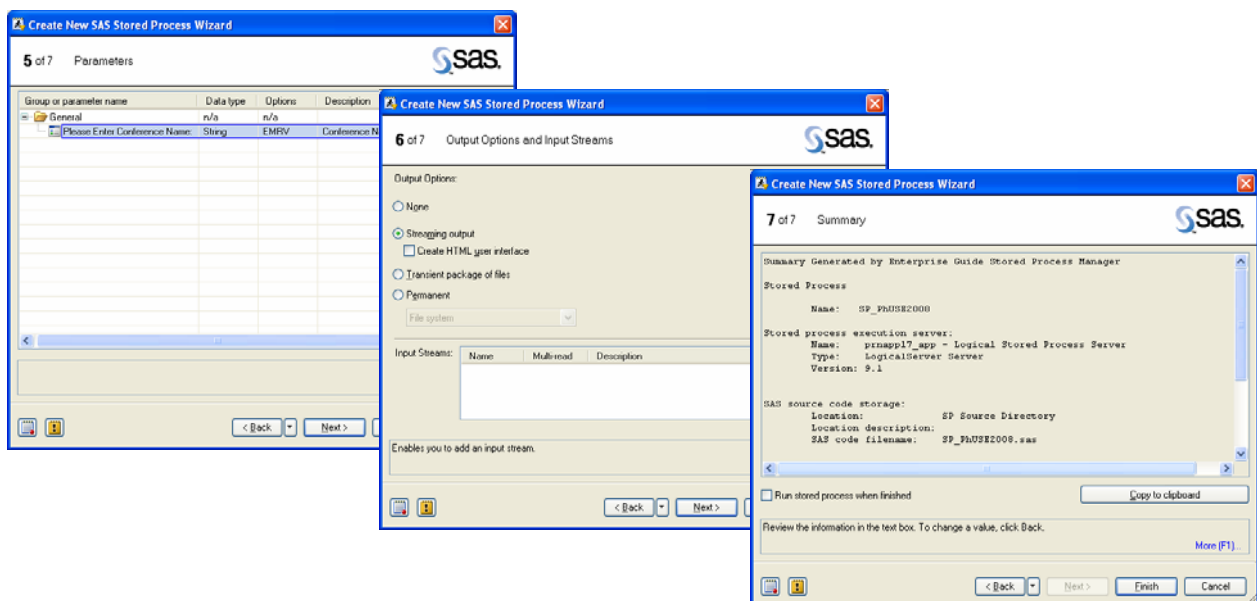
CREATING A SAS STORED PROCESS USING THE WIZARD MENU

The Wizard menu is easy to use and broken down into seven steps:

- 1) Name the SAS Stored Process and provide a description of what it will be doing
- 2) Define the SAS code
- 3) Select the Metadata location where the SAS Stored Process will be stored
- 4) Review the execution environment and modify if necessary



- 5) Specify parameters used in the SAS code (step 2)
- 6) Select output options and input streams
- 7) Review the summary before finalising the SAS Stored Process



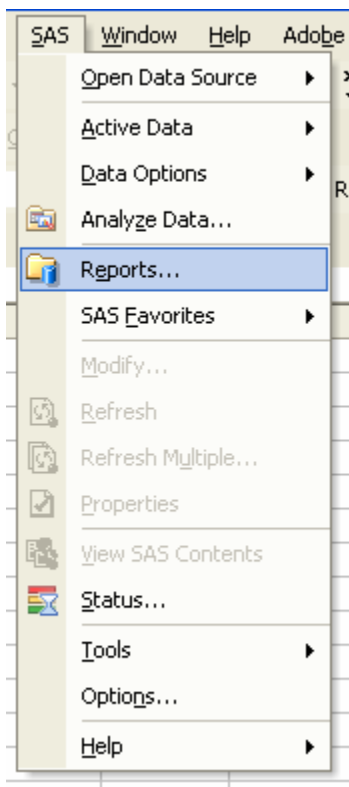
EXECUTING STORED PROCESSES WITHOUT ACCESSING SAS

Covance decided to utilise the *SAS Add-In for MS Office* application, to fully take advantage of *SAS Stored Processes*. In Microsoft Office applications such as MS Word®, MS Excel® and MS PowerPoint®, the SAS dropdown menu is added when the *SAS Add-In for MS Office* application is installed. By selecting the reports option from the SAS dropdown menu, our Data Management colleagues can run *SAS Stored Processes* that we create for them. The system will then prompt for credential verification to ensure security is maintained.

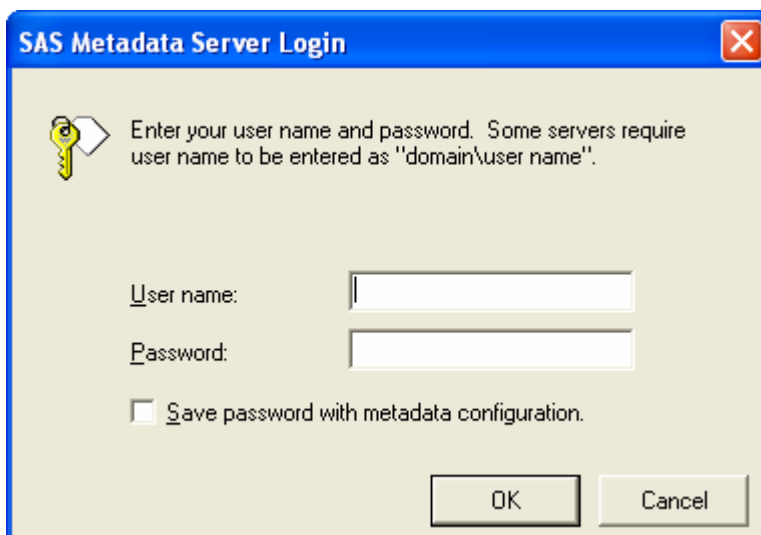
Once the user's credentials have been checked against the Metadata server, the list of available *SAS Stored Processes* will appear. Data Managers can select the Stored Process to be run and wait for the results to appear in the chosen MS Office® application.

AN EXAMPLE OF RUNNING A SAS STORED PROCESS BY USING THE ADD-IN APPLICATION FOR MS EXCEL

In MS Excel, select Reports... from the SAS dropdown menu.



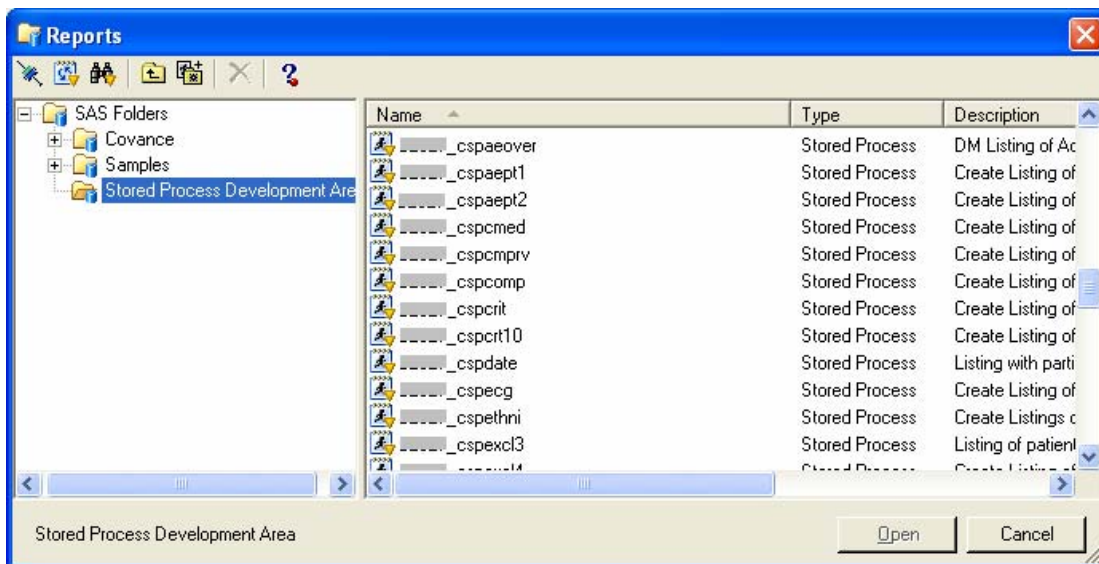
The system will then prompt you to enter your UNIX username and password:



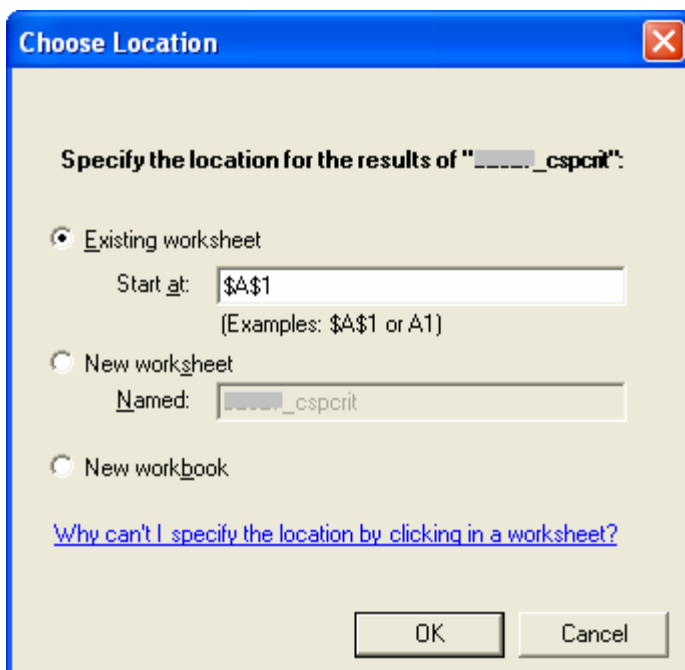
This window will appear briefly while connecting to the SAS Metadata Server and verification of your credentials take place.



After successful login, the Reports window will then be displayed. First you need to select the central server where the *SAS Stored Processes* are kept, in this example "Stored Process Development Area" (on the left side of the window). Then select the stored process you want to run (on the right side of the window) and click on Open. Note that each stored process has a description to further assist the end user.



Next, MS Excel will ask you to choose the location of where you would like the data displayed.



While running the stored process you selected, you will briefly see the following windows appear.



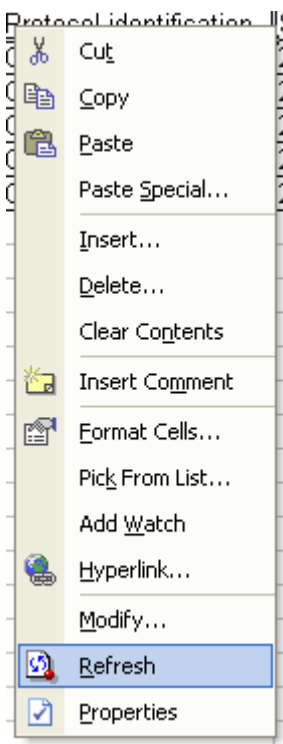
The output will be displayed in MS Excel.

The screenshot shows the Microsoft Excel interface with the following data in the worksheet:

	A	B
1	Listing of patients that did not meet the criteria at baseline, without at least one	
2	Inclusion=NO or Exclusion=YES	
3	NOOBS	
4	No data matching the listing characteristic.	
5		
6		

REFRESHING A STORED PROCESS OUTPUT

If the data is already in MS Excel for example, and needs to be updated, simply right click on the data and select Refresh from the pop-up menu.



Again, the system will ask for credential verification and then submit the *SAS Stored Process*. The data in MS Excel will automatically be updated with the latest query output.

WHAT ELSE CAN YOU DO WITH A *SAS STORED PROCESS*?

SAS Stored Processes are very flexible and can deliver output to a Web browser or other media, such as HTML, PDF, RTF, XML, CSV, GIF and PNG. Also, it can use Web reporting, Analytics and other Web applications. In future, we might use some of these reporting techniques to give external clients the choice of being more involved in the clinical trial database cleaning process.

CONCLUSION

New opportunities to improve the overall quality of clinical trial data are arising all the time. By using *SAS Stored Processes* we are at the forefront of many of the current initiatives. We are embracing the technological advantages available to us to save money, advance productivity and inevitably improve the quality of data!

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CONTACT INFORMATION

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