

Easy CSR In-Text Table Automation, Oh My

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ABSTRACT

Your medical writers are about to embark on creating the narrative for the clinical study report (CSR). They are tired of asking the programmers to re-run the in-text tables and then cutting and pasting them into the report. And each time that the report needs to be updated, they need to copy and paste the in-text tables again. Isn't there a better way to do this in a more automated fashion? This paper will show you that using your CSR template along with SAS® Enterprise Guide with stored processes and SAS® Add-in for Microsoft Office, this becomes an easy task for the medical writers.

INTRODUCTION

After the data is cleaned, after the transformation to CDISC standards and after the full set of tables, listings, figures and in-text tables have been completed it is time to begin to put together the Clinical Study Report (CSR). Over the years, a great deal of effort has been put into the creation of the in-text tables. These tables needed to be cut and pasted into the CSR. What happens when the in-text tables are changed? Every time the data is updated, every time there is a change to a title or footnote, the tables must be rerun and cut and paste into the draft and then the final document. This has been a very manual process in the past. Now there are many tools that we have in our toolbox with which we can automate the process. The programmer can work with the clinical staff to create the tables and then put them in the shell of the CSR. Once that is done, the clinician can refresh the tables right in Microsoft Word without needing to cut and paste anything ever again. The result is a cleaner, less error prone CSR.

To do all the steps in this process, you will need to have SAS® Office Analytics with the SAS Add-In for Microsoft Office. With the add-in, you will have a SAS tab on the menu. This will give you the ability to run SAS stored processes within The Microsoft Office products Excel, Word and PowerPoint. You will have the ability to refresh the reports with changes and/or updated data.

THE STORED PROCESS - DEFINITION

A stored process is a SAS program that is stored on a server and can be executed as required by requesting applications. You can use stored processes for Web reporting, analytics, building Web applications, delivering packages to clients or to the middle tier, and publishing results to channels or repositories. Stored processes can also access any SAS data source or external file and create new data sets, files, or other data targets supported by SAS.

The ability to store your SAS programs on the server provides an effective method for change control management. For example, instead of embedding the SAS code into client applications, you can centrally maintain and manage this code from the server. This gives you the ability to change your SAS programs and at the same time ensure that every client that invokes a stored process will always get the latest version available.¹

SAS ADD-IN FOR MICROSOFT OFFICE

SAS Add-In for Microsoft Office provides you with seamless direct access to SAS reports, data engines, data management, reporting, and analytic tasks from Microsoft Excel, Word, and PowerPoint. SAS is well suited for this type of processing through the SAS add-in. When you use

the SAS add-in, SAS content and data sources are centrally maintained and can be dynamically synchronized with your SAS server to ensure that all analysts in your company are accessing “one version of the truth.”² In the pharmaceutical, biotechnology and medical device industries this is a very important part of validated and compliant environments.

THE PROGRAMMER

The first step in the process is to create the in-text tables that will go into the CSR. The programmer will work with the clinical team to create the tables. I suggest that the programming interface used here is SAS® Enterprise Guide (EG). Whether you enjoy using the graphical user interface (GUI) with the tasks that are provided or prefer to write the programs using SAS code directly, this is the first step in the process. Here is a simple example of the code that was used to create a demographic frequency table (seen in Figure 1) in EG using the One-Way Frequency task .

```

PROC SQL;
  CREATE VIEW WORK.SORT AS
    SELECT T.ARM, T.SEX, T.RACE
    FROM CSR.AE_DM as T
;
QUIT;

TITLE;
TITL1 "Demographic Frequencies";
FOOTNOTE;
FOOTNOTE1 "Generated on %TRIM(%QSYSFUNC(DATE(), NLDATE20.)) at %TRIM(%SYSFUNC(TIME(), TIMEAMP12.))";
PROC FREQ DATA=WORK.SORT
  ORDER=INTERNAL
;
  TABLES ARM / SCORES=TABLE;
  TABLES SEX / SCORES=TABLE;
  TABLES RACE / SCORES=TABLE;
RUN;
/*-----
   End of task code
-----*/
RUN; QUIT;
%_eg_conditional_dropds(WORK.SORT);
TITLE; FOOTNOTE;

```

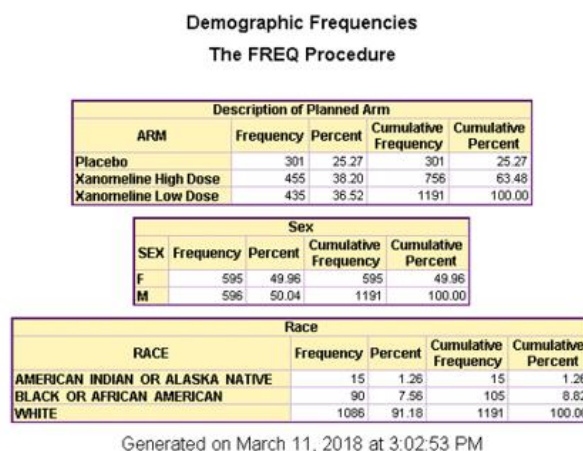


Figure 1

The table is now complete and the next step is to create the stored process for the table. This can easily be done in EG. There is a wizard that will guide you through the steps to create the

stored process. As you can see in Figure 2, there are six steps to create the stored process. Going window by window, the information is filled in by you as you complete all the steps. You will need one stored process for each in-text table that will be going into the CSR. Each stored process must have a unique name.

Once the code is complete for each stored process, the programmer needs to get a copy of the most current template that is being used for the for the CSR. There is no need to have any input from the clinical team other than the template. The only thing that is needed is the shell of the report so that the programmer can place a marker in each section of the CSR for each table, listing or figure. See Figure 2 for an example of the first window of the stored process wizard.

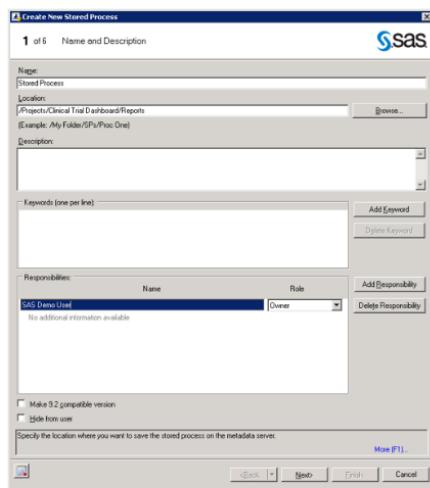


Figure 2: Stored Process Wizard

Here is an example of an in-text table that we are going to be using. As you can see it is the shell of the summary of adverse events.

* 1.1. → Adverse-Events¶

* 1.1.1. → Brief Summary of Adverse Events¶

¶

* **Table 2: → Overview of Adverse Events¶**

* Category ^{a,b}	Number of Subjects (%) ^a			
	Trial drug (n=>) ^a		Control (n=>) ^a	
All Adverse Events ^a	>>	(>) ^a	>>	(>) ^a
All Serious Adverse Events ^a	>>	(>) ^a	>>	(>) ^a
Withdrawals ^a	>>	(>) ^a	>>	(>) ^a
Due to Adverse Event ^a	>>	(>) ^a	>>	(>) ^a
Not Due to Adverse Event ^a	>>	(>) ^a	>>	(>) ^a
Deaths ^a	>>	(>) ^a	>>	(>) ^a
During Treatment, Due to Adverse Event ^a	>>	(>) ^a	>>	(>) ^a
During Follow-Up, Due To Adverse Event ^a	>>	(>) ^a	>>	(>) ^a
During Treatment or Follow-up, not Due to Adverse Event ^a	>>	(>) ^a	>>	(>) ^a

^aReference: <<Table or Listing No.>>¶

^bSubjects may fall into more than 1 category¶

¶

Figure 3: Sample Table Shell

The next step for the programmer is to add all the stored processes to the shell of the clinical study report. The first thing to do is open the CSR in Microsoft Word. Click on the SAS tab to see the options that are available within MS Word. This can be seen in Figure 4. You will need to have this open to add in a pointer for each In-text table. Place the cursor at the space you would like to add the in-text table. Then click on the REPORTS icon on the SAS ribbon. Browse to the file

that contains the sorted process for the in-text table. Once you find it, run the stored process. To run the stored process, double-click on the file. When the stored process is finished running, the in-text table will open into the space after the cursor in the document. You need to do this for every in-text table that you want to add to the CSR. When you have completed this, the programmer's work for this phase of the report process is done. If there are any changes to the program that creates the in-text table (most likely changes to the titles and footnotes), the programmer will need to step in to make those changes. The programmer can do this in EG. Open the project that created the stored process. If you right click on the stored process, you can click on the **MODIFY TASK** menu item. Figure 5 is a picture of the stored process manager. Any changes can be made here. Once the changes have been made, the stored process must be

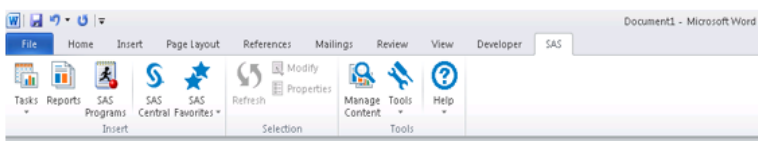


Figure 4: SAS Ribbon in Microsoft Word

saved and run again. This is the way to update the stored process.

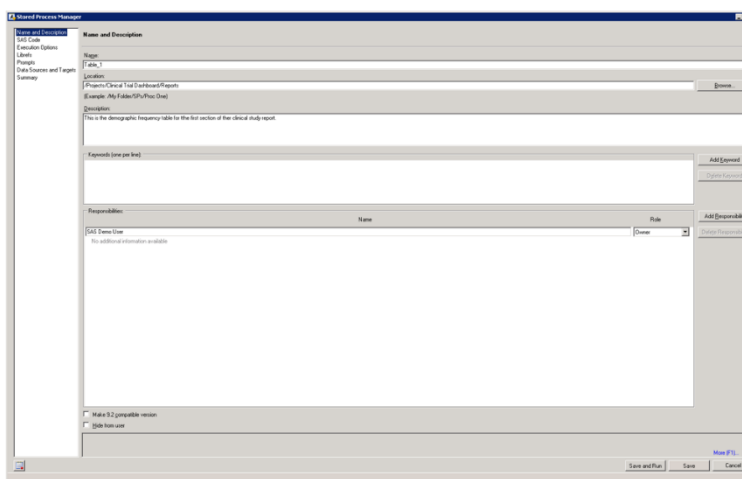


Figure 5

THE CLINICAL TEAM

When the programmer is finished, the clinician can start writing the text for the CSR into the MS Word document. The steps to update the data in the in-text tables is easier than cutting and pasting each table that needs to be refreshed in the document. To refresh the tables, the clinician must look for the SAS tab on the ribbon. Click on the **MANAGE CONTENT** icon. That will open a window which can be seen in Figure 5. All the stored processes will have an entry in the open window. As you can see, the clinician can choose to update one table, several tables or all the tables. Once the tables that need to be refreshed have been chosen, click **REFRESH** and all of the stored processes for those tables will run and be refreshed. When the refresh of the tables has been completed, click **CLOSE** to close the window. The next time the tables need to be updated, repeat the above procedure.

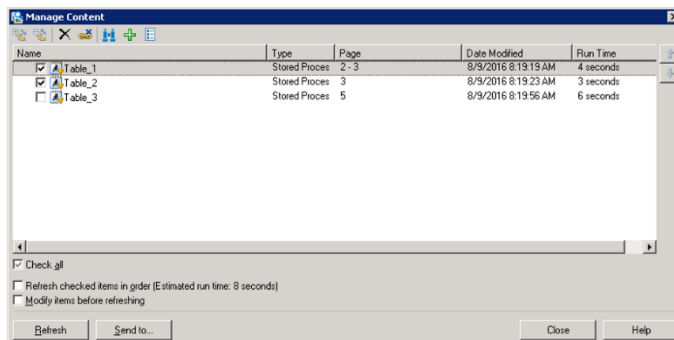


Figure 6: Manage Content Window

HOW IT CAN BE USED

Creating the in-text tables for the CSR is only one of the many uses of stored processes in the SAS Add-In for Microsoft Word. The add-in can be used in MS Excel, MS PowerPoint and MS Word. You can create a PowerPoint presentation that can be refreshed with new data. You can add SAS content to an MS Excel spreadsheet. Most of the functionality for the Add-In is the same for each of the MS Office products. You can run analyses and reports as well as add content. You can access SAS data sources or any data source that is available from your SAS server as the input to your analysis. You can run stored processes that were developed by others in your company leading to collaborative efforts on projects.

SUMMARY

Creating the clinical study report is a joint effort of the biostatistics team and the clinical team. The programmers and statisticians will create the analysis of the data and the programs for the tables, listings, figures and in-text tables for the report. The clinicians, along with the statisticians will create the table shells and the CSR shell in Microsoft Word. Then the programmers will create the placeholders in the word document for the in-text tables. When all of that is done, the clinicians go to work writing the CSR. This is usually done as the subjects are still enrolling to the study. Along the way, tables will be updated and the data needs to be refreshed to capture the most up-to-date information.

CONCLUSION

The purpose of this paper was to show how to update the in-text tables in the clinical study report without the major effort of cutting and pasting each table back into the report when tables are changed or that data needs to be refreshed. Using SAS Enterprise Guide and the SAS Add-in for Microsoft Office this can be done much more easily. The old methodology can be error prone and needs to have multiple iterations of review to make sure that the correct table was replaced and that the new data is correct. When the process is automated there is more efficiency, greater speed and more accuracy in the product.

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RECOMMENDED READING

- *Base SAS® Procedures Guide*
- *SAS® For Dummies®*
- *The Little SAS® Enterprise Guide Book*
- *SAS® Programming for Enterprise Guide Users, Second Edition*

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