Paper CT12

Advance SAS® techniques to generate Automated Topline RTF Reports, daily use of PMs

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ABSTRACT:

Before moving to final CSR, it is very important for the project managers (PMs) to review the Topline results on a regular basis for every single Dry-Run. The process of populating TLFs, updating TLF numbers, cross-references and incorporating results in Topline reports is laborious, time consuming and potentially error prone.

An automated technique is presented in this paper which uses SAS® and literate programming concept to generate study topline reports with specified text, TLFs, and cross-references with Table of Contents (ToC). Literate programming efficiently combines the text and statistical analysis in one single SAS® source file, which can be reused and updated multiple times without applying any changes. This process will significantly reduce the amount of time to produce the study topline reports in RTF format.

The goal of this process is to complete the final CSR, which is the final milestone of any clinical trial.

Keywords: Automation, Topline, CSR, TEMPLATE, ODS RTF, LISTING.

INTRODUCTION:

The final milestone in any clinical trial is Clinical study report (CSR). A CSR typically consists in study background, results interpretation, tables, listings, and figures (TLFs) with appropriate Table of Contents (ToC). To deliver the quality CSR in one source file the Project Managers (PMs) have to complete the topline results in different layer of safety checks. The repetitive tasks need to be performed in every single Dry-Run as follows:

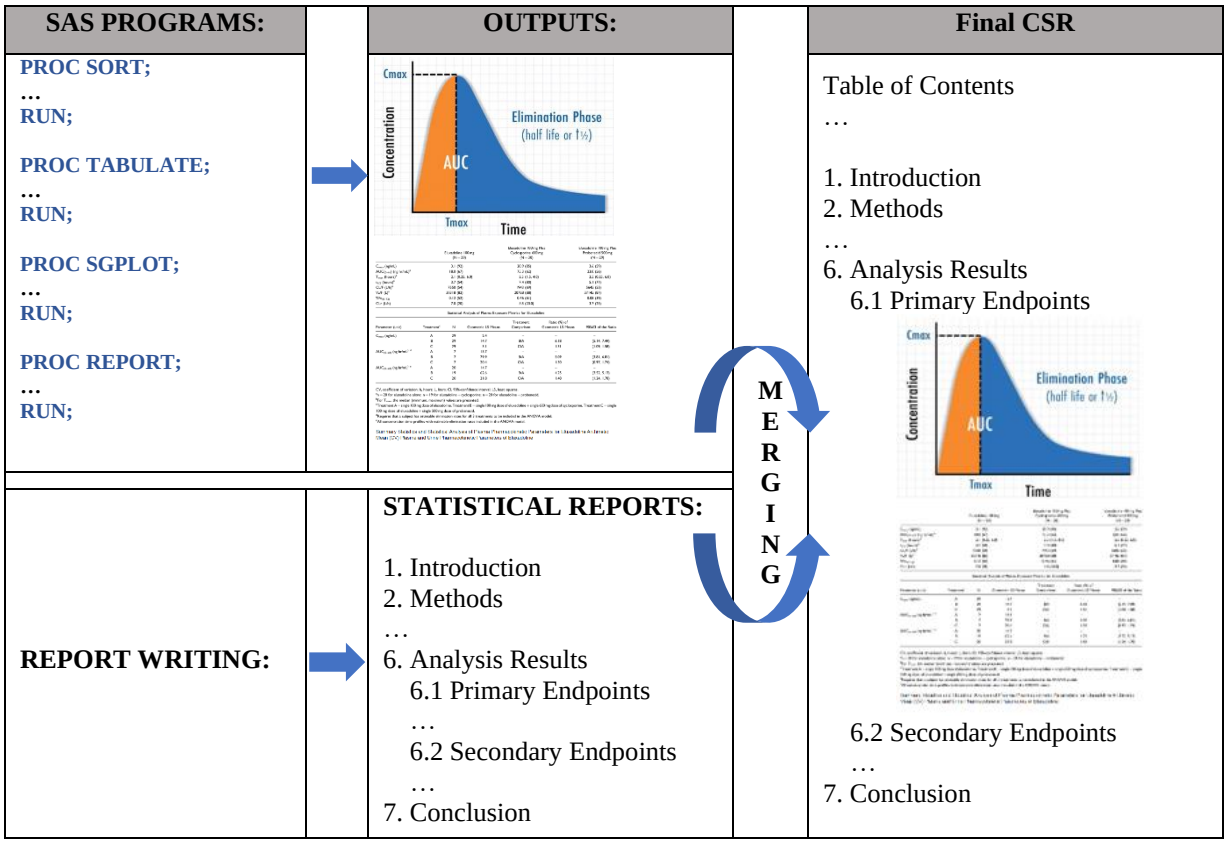


Figure 1: Traditional way of completing CSR.

The reason of writing the Topline report by the PMs is very much like development of research papers. They need to be prepared with the topline results every time after each Dry-Run, where the authentication input is required with the open texts. They also require the summary tables, listings, and figures to complete the reports. The PMs need to perform these tasks on a regular basis, and there is a lot of rush in doing this challenging tasks. These tasks are very important and time consuming to every PMs.

Being motivated as a SAS® programmer, focusing on quality, efficiency, and reproducibility I adopted the advance SAS® programming approach. The idea is to intermingle plain text and SAS® code in one single file to create statistical report. I applied advance ODS programing and reproducible research principles within a SAS® environment. The SAS® programs that create the statistical outputs and write the statistical report are exported to an RTF file. These are achieved by;

a) Design and write the program in an easily readable fashion.
b) Making sure there is a transparency and traceability embedded in the executable code within program.
c) User friendly environment and time saving.

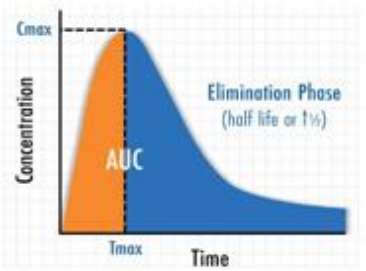
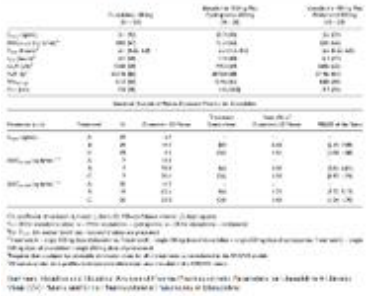
SH_Topline.sas		Topline Report
%INCLUDE inout(sh_macros); %***sh_start***(); %***sh_title***(title=**1** Introduction); %***sh_texts***() %***sh_title***(title=**2** Methods); %***sh_texts***() … %***sh_title***(title=**6** Analysis Results); %***sh_texts***(); %***sh_title***(title=**6.1** Primary Endpoints); %***sh_image***(); **DATA;** **PROC SQL;** **QUIT;** **PROC SGPLOT;** **PROC REPORT;** **RUN;** %***sh_ftnote***() %***sh_title***(title=**6.2** Secondary Endpoints); … %***sh_title***(title=**7** Conclusion); %***sh_texts***(); %***sh_stop***;	F9 .RTF	Table of Contents … 1. Introduction 2. Methods … 6. Analysis Results 6.1 Primary Endpoints   6.2 Secondary Endpoints … 7. Conclusion

Figure 2: Automated Topline results approach.

PROCESS OVERVIEW:

In Clinical Trial reporting, the analyses and the topline results are conveyed through tables, listings, and figures (TLFs). Depending upon the study milestone, the number of tables, listings, and figures may vary from study to study. However, it is extremely useful to complete all the required tables, listings, and figures using SAS, into a single file with a table of contents (ToC).

Traditionally, these outputs would be compiled either manually or by using Stored Word VBA process. The disadvantage of these methods is that they are either prone to errors or time consuming. Although output methods vary, reports generated in Rich Text Format (RTF) have gained popularity. Since RTF files are in one-way plain text files, we can utilize the powerful ODS features of SAS to gather the required information needed for creating ToC and complete the file.

Prerequisites:

With the clinical trial knowledge, the end user (PMs) should have to have the knowledge of SAS. Considering the outlook of the Topline file the user should make sure the availability of the external

images (e.g: Company logo, external images to be considered, …). These will allow you to start the process with full of confidence.

Initialization:

To start the process the setup of the project is important. Considering the background and availability of sources you will have to make sure the setup is perfectly done with the inclusion of Topline SAS macro file. Here is an example:

```
LIBNAME source "source";
LIBNAME inout ".";
FILENAME inout ".";
%INCLUDE inout(sh_macros);
```

Start of the process:

A macro is designed with the help of two sub-macros focusing on the outlook template, the header (both for the first and following pages) and footer (e.g: page number). This macro consists of PROC TEMPLATE (creating a style Template), ODS PATH (controls where ODS stores new templates that you create and where ODS finds the templates that your programs use), ODS ESCAPECHAR (representative character to be used in output strings), ODS NOPROCTITLE (to write the title that identifies the procedure that produces the results in the output) and ODS RTF TEXT (opens, manages, or closes the RTF destination, which produces output written in Rich Text Format for use with Microsoft Word) procedure in SAS. You need to assign the Topline file name (you would prefer) within macro parameter. It has default features with the option of customization ToC text, image, and orientation. The following is an example;

```
%sh_start (outfile=%SYSFUNC(PATHNAME(inout))\SH07015_Topline
          ,preimage=%SYSFUNC(PATHNAME(inout))\SH_Logo.png);
```

TABLE OF CONTENTS:

Figure 3: Header of ToC page.

Figure 4: Header and Footer of Topline results.

Section/Sub-Section:

A macro consists of ODS RTF STARTPAGE (to control page breaks) and ODS RTF TEXT is being developed. The purpose of this macro is to identify the title and sub-title text (as needed) of the section and sub-section to complete the ToC with/without the numbers. It has default features with the option of customization front style, weight, and color of the title/ sub-title texts. Following is an example:

%sh_title (title=**1** INTRODUCTION);

1 INTRODUCTION

1 INTRODUCTION

Summary Section:

A macro consists of ODS TEXT (specifies the text) to insert the paragraph as a plain/style texts needed to complete the report. It has default features with the option of customizing the style, weight, color, decoration, lists and spaces.

%sh_texts (text=%STR(There was a Statistically Significant Difference Observed/No Statistically significant difference observed between Active Drug and Placebo for number of severe Asthma Exacerbations Sensitivity.
^n The following sensitivity analysis were performed:
^n^n &bullet. ^{style[font_style=italic textdecoration=underline] Table for key sensitivity analysis}));

There was a Statistically Significant Difference Observed/No Statistically significant difference observed between Active Drug and Placebo for number of severe Asthma Exacerbations Sensitivity.
The following sensitivity analysis were performed:

- *Table for key sensitivity analysis*

Footnote:

The purpose of this process is to complete the footnote (as needed) as per specified TLFs. This macro consists of ODS RTF STARTPAGE=NO (to control page breaks) and ODS TEXT in SAS. It has default features with the option of customizing the style, size, color, weight, and decoration.

%sh_ftnote (ftnote=%STR(Note: CI = confidence interval.
&nl. For Censor Patients: If none exacerbation is observed during the study, data on time to first asthma exacerbation will be censored at the last asthma exacerbation assessment of the concerned patient.
&nl. Time to First Asthma Exacerbation Duration = Date of first documented Asthma Exacerbation – date of first treatment intake + 1.
&nl. [a] Percentages are based on the number of subjects per treatment group in the FAS population.
&nl. [b] Estimates are from a Kaplan-Meier analysis. Minimum and Maximum include censored time to event.
&nl. [c] The hazard ratio and associated 95&percent. Confidence Interval comes from proportional hazards modelling.));

Note: CI = confidence interval.
For Censor Patients: If none exacerbation is observed during the study, data on time to first asthma exacerbation will be censored at the last asthma exacerbation assessment of the concerned patient.
Time to First Asthma Exacerbation Duration = Date of first documented Asthma Exacerbation – date of first treatment intake + 1.
[a] Percentages are based on the number of subjects per treatment group in the FAS population.
[b] Estimates are from a Kaplan-Meier analysis. Minimum and Maximum include censored time to event.
[c] The hazard ratio and associated 95% Confidence Interval comes from proportional hazards modelling.

Internal Reporting:

In-between the process, you can use the program as plain SAS Editor window. You have full of freedom writing SAS code and complete the reporting as required for Topline report. There seems to have no restrictions of producing the summary report and complete the graphical analysis. You can play with any SAS procedures in-between START and STOP.

%sh_title (title=3.1.1.1 Table: Summary of Demographic and Baseline Characteristics - ITT);

```
DATA source.t3_1_1_1;
 LENGTH col1txt $30 trt1 trt2 trt99 $20;
 mord=1;
 DO col1txt ="Sex","Male","Female","Age","N","Mean (SD)","Min","Median","Max";
  IF col1txt ="Sex" THEN DO;
   trt1="“; trt2="";trt99="";
  END;
  IF col1txt ="Male" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="80 ( 66.67)";trt2="40 ( 50.00)";trt99="120 ( 60.00)";
  END;
  IF col1txt ="Female" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="40 ( 33.33)";trt2="40 ( 50.00)";trt99="80 ( 40.00)";
  END;
  IF col1txt ="Age" THEN DO;
   mord=2; trt1="";trt2="";trt99="";
  END;
  IF col1txt ="N" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="120";trt2=" 80";trt99="200";
  END;
  IF col1txt ="Mean (SD)" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="60.9 (11.33)";trt2=" 62.4 ( 8.33)";trt99="61.7 (10.02)";
  END;
  IF col1txt ="Min" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="37.0";trt2=" 36.0";trt99="36.0";
  END;
  IF col1txt ="Median" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="60.0";trt2=" 62.0";trt99="61.0";
  END;
  IF col1txt ="Max" THEN DO;
   col1txt ="A0A0"x|| col1txt; trt1="81.0";trt2=" 82.0";trt99="82.0";
  END;
  OUTPUT;
 END;
```

```
RUN;

%LET itta=120;
%LET ittp=80;
%LET ittt=200;

PROC REPORT DATA=source.t3_1_1_1 NOWD SPLIT='@' HEADLINE HEADSKIP;
  COLUMNS mord col1txt trt1 trt2 trt99;

  DEFINE mord     / ORDER NOPRINT;
  DEFINE col1txt / "Demographic Parameter" STYLE={WIDTH=15% textalign=LEFT} FLOW;
  DEFINE trt1      / "Active Drug@(N=%left(&itta.))@n (%)" STYLE={WIDTH=10% textalign=CENTER} FLOW;
  DEFINE trt2    / "Placebo@(N=%left(&ittp.))@n (%)" STYLE={WIDTH=10% textalign=CENTER} FLOW;
  DEFINE trt99 / "Total@(N=%left(&ittt.))@n (%)" STYLE={WIDTH=10% textalign=CENTER} FLOW;

  BREAK AFTER mord/SKIP;
RUN;
```

%sh_ftnote (ftnote=%STR(Note: Std = Standard deviation. Percentages are computed based on the Intent to Treat Population in each treatment group));

3.1.1.1 Table: Summary of Demographic and Baseline Characteristics - ITT

Demographic Parameter	Active Drug (N = 120) n (%)	Placebo (N = 80) n (%)	Total (N = 200) n (%)
Sex			
Male	80 (66.67)	40 (50.00)	120 (60.00)
Female	40 (33.33)	40 (50.00)	80 (40.00)
Age			
N	120	80	200
Mean (SD)	60.9 (11.33)	62.4 (8.33)	61.7 (10.02)
Min	37.0	36.0	36.0
Median	60.0	62.0	61.0
Max	81.0	82.0	82.0

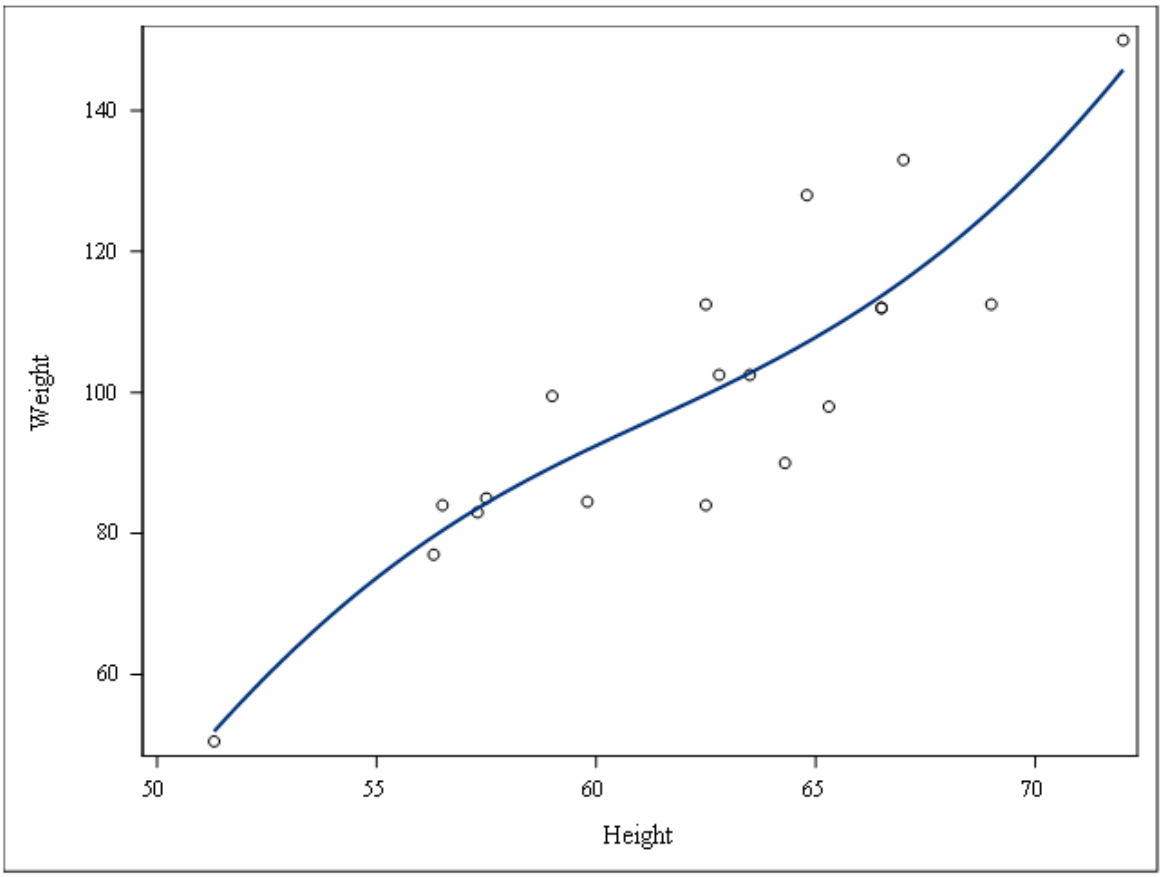
Note: Std = Standard deviation. Percentages are computed based on the Intent to Treat Population in each treatment group

%sh_title (title=7.1.1.1 Figure: Correlation between Weight vs Height of the Students);

```
TITLE;
PROC SGPLOT DATA=sashelp.class NOAUTOLEGEND;
  PBSPLINE Y=weight X=height;
  FOOTNOTE;
RUN;
```

%sh_ftnote (ftnote=%STR(Note: SG Procedure Examples));

7.1.1.1 Figure: Correlation between Weight vs Height of the Students



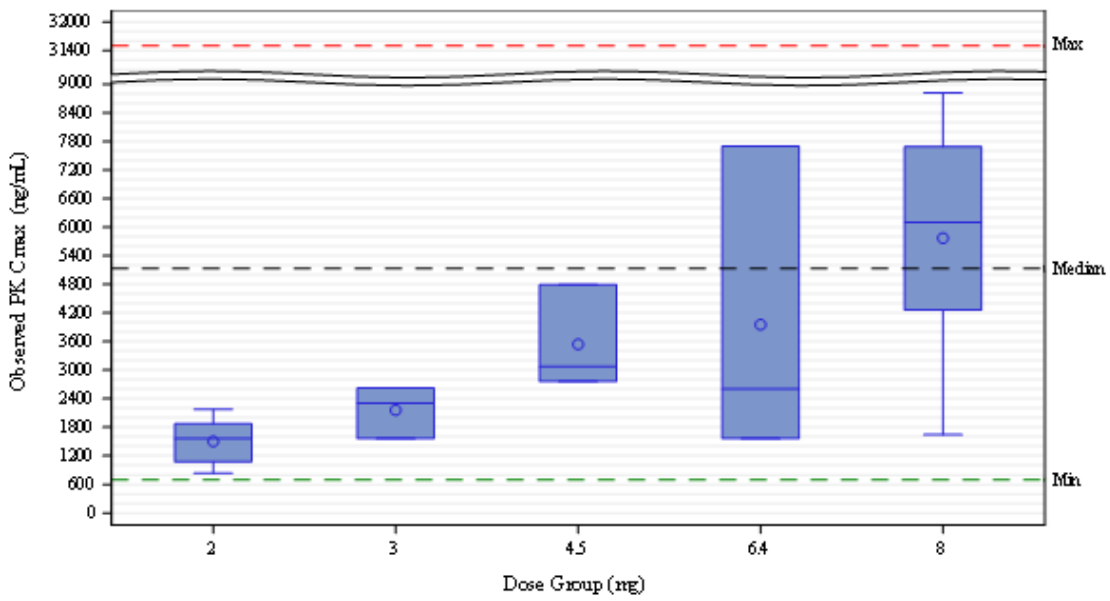
Note: SG Procedure Examples

External Image:

To complete the Topline report graphical representation is very much essential. The source could be both internal and external. Considering the uses of external images, a macro consists of ODS TEXT has being developed. The principle of this macro is to use the images as texts. It has default features with the option of customizing the justification and width. Following is an example:

%sh_title (title=6.1.1.3 Figure: Comparison of observed Cmax of Pediatric with expected Cmax with Adults.);
%sh_image (image=%SYSFUNC(PATHNAME(inout))\PK_Cmax.png);
%sh_ftnote (ftnote=%STR(Note: PK = Pharmacokinetics Concentration));

6.1.1.3 Figure: Comparison of observed Cmax of Pediatric with expected Cmax with Adults.



Note: PK = Pharmacokinetics Concentration

End of process:

This is a simple macro consists of ODS _ALL_ CLOSE and ODS LISTING (to open, manage, or close the LISTING destination) statement in SAS. It is designed to close the process of Topline RTF report.

%sh_stop;

Rendering Table of Contents:

After the successful run of SAS program, the topline RTF file will be generated, but you will not immediately see the ToC. To render the ToC keep the mouse in appropriate ToC position and then press F9 to create the ToC. Since the ToC entries were specified as hyperlinks, you can press Ctrl+click to follow the link to the appropriate location in the document. If there needs to reshuffle the ToC after the initial review, you can do it normally by Update Field option.

TABLE OF CONTENTS:

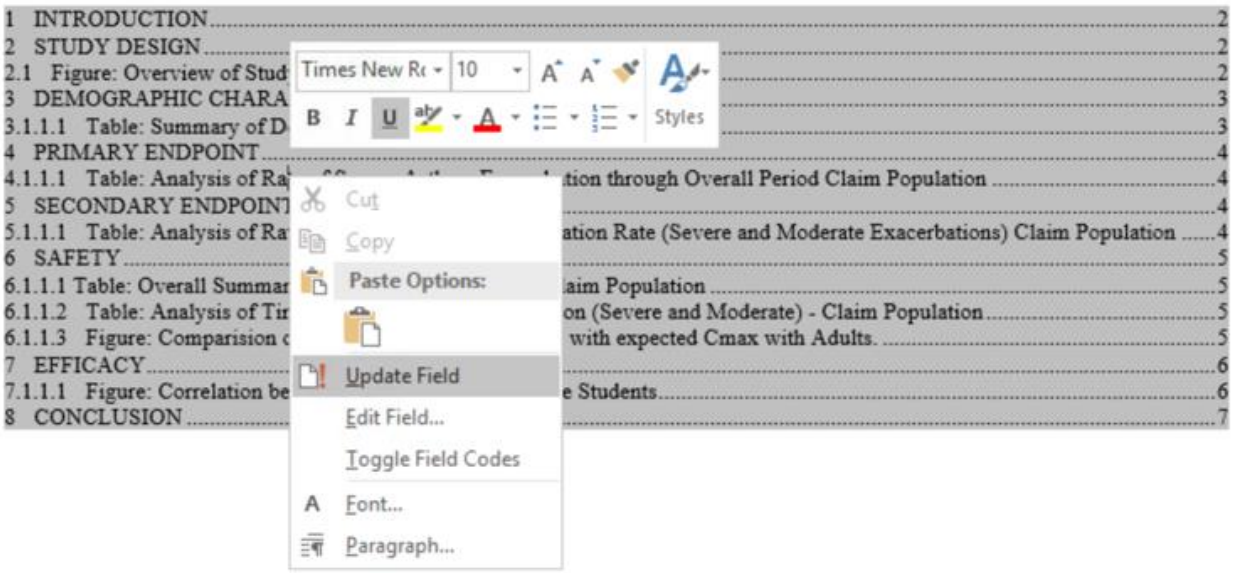


Figure 5: Table of Contents

CONCLUSION:

The automated reporting system only requires clinical trial and SAS® experiences. The developed template SAS program will help the Project Managers (PMs) in three axes:

Quality: The automation of the routine tasks allows the PMs to focus on important aspects of safety and efficacy analysis, interpretation of results which increases the quality of the topline reporting. It reduces the manually made mistakes (copy-paste) while completing the report.

Efficiency: The generation of listings, tables, figures, and cross references are automated in the Topline program. In case of data updates, it would suffice to re-run the SAS® programs to produce the updated report. No additional time is required for copy and paste.

Reproducibility: The file provides complete transparency and traceability. Since it acts as a single source file that integrates programming and writing, anyone can easily modify and re-run the program. No worries of breakdown the consistency.

To make sure the extensive use and complete the final CSR, it should be explored to include more dimensions.

REFERENCES:

- TEMPLATE Procedure: https://support.sas.com/documentation/cdl/en/odsug/65308/HTML/default/viewer.htm#n1l2gcv43fk5e2n15szl4ii5ovpb.htm
- ODSTEXT Procedure: https://documentation.sas.com/doc/en/pgmsascdc/9.4_3.5/odsproc/n03l6kzsr7pzrsn1fy1tftbt0j3f.htm
- Unicode and Special Characters: https://support.sas.com/documentation/cdl/en/statug/63962/HTML/default/viewer.htm#statug_templt_a0000000058.htm
- Color Schemer Online: https://www.colorschemer.com/online/
- PharmaSUG 2017 - Paper AD02: https://www.lexjansen.com/pharmasug/2017/AD/PharmaSUG-2017-AD02.pdf
- Paper 238-2008: https://support.sas.com/resources/papers/proceedings/pdfs/sgf2008/238-2008.pdf
- Paper 215-2010: https://support.sas.com/resources/papers/proceedings10/215-2010.pdf

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CONTACT INFORMATION:

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Web: www.syneoshealth.com

APPENDIX:

```
*Setup details;
*Include all macros;
/*%INCLUDE "%SYSFUNC(PATHNAME(inout))/sh_macros.sas";*/
LIBNAME source "source";
LIBNAME inout ".";
FILENAME inout ".";
%INCLUDE inout(sh_macros);
```

```
*Starting;
%sh_start(outfile=%SYSFUNC(PATHNAME(inout))\SH07015_Topline
          ,preimage=%SYSFUNC(PATHNAME(inout))\SH_Logo.png);

*1 INTRODUCTION;
%sh_title(title=1  INTRODUCTION);
%sh_texts(text=%STR(This Document describes the top line results for the Asthma Study
SH07015.));

*2 STUDY DESIGN;
%sh_title(title=2  STUDY DESIGN);
%sh_texts(text=%STR(^n This is the prospective, multicenter, randomized, double-
blind, placebo-controlled, two treatment arm parallel groups, Phase 3 study.
^n^n&bullet.  Group 1: 120 patients will receive Active Drug at 6 mg/kg/day
^n&bullet.  Group 2: 80 patients will receive placebo
^n^nThe study consists of the three following periods:^n^));
%sh_title(title=2.1  Figure: Overview of Study Design);
%sh_image(image=%SYSFUNC(PATHNAME(inout))\Study_Design.png);

%sh_ftnote(ftnote=%STR(Abbreviations: AE = adverse event; C1D1 = Cycle 1 Day 1; IV
= Intravenous;));

*3  DEMOGRAPHIC CHARACTERISTICS;
%sh_title(title=3  DEMOGRAPHIC CHARACTERISTICS);
%sh_texts(text=%STR(^n A total of XX patients were enrolled in the study. Of these
XX patients, YY(&percent.) percentage were
females and ZZ(&percent.) were males. Majority of patients were in the age group of
(XX,XX).));
%sh_title(title=3.1.1.1  Table: Summary of Demographic and Baseline Characteristics
- ITT);

DATA source.t3_1_1_1;
      LENGTH col1txt  $30 trt1 trt2 trt99 $20;
      mord=1;
      DO col1txt ="Sex","Male","Female","Age","N","Mean (SD)","Min","Median","Max";
            IF col1txt ="Sex" THEN DO;trt1="";trt2="";trt99="";END;
            IF col1txt ="Male" THEN DO;col1txt ="A0A0"x||col1txt ;trt1="80 (
66.67)";trt2="40 ( 50.00)";trt99="120 ( 60.00)";END;
            IF col1txt ="Female" THEN DO; col1txt ="A0A0"x||col1txt ;trt1="40 (
33.33)";trt2="40 ( 50.00)";trt99="80 ( 40.00)";END;
            IF col1txt ="Age" THEN DO;mord=2;trt1="";trt2="";trt99="";END;
            IF col1txt ="N" THEN DO;col1txt ="A0A0"x||col1txt ;trt1="120";trt2="
80";trt99="200";END;
            IF col1txt ="Mean (SD)" THEN DO;col1txt ="A0A0"x||col1txt ;trt1="60.9
(11.33)";trt2=" 62.4 ( 8.33)";trt99="61.7 (10.02)";END;
            IF col1txt ="Min" THEN DO;col1txt ="A0A0"x||col1txt ;trt1="37.0";trt2="
36.0";trt99="36.0";END;
            IF col1txt ="Median" THEN DO;col1txt ="A0A0"x||col1txt
;trt1="60.0";trt2=" 62.0";trt99="61.0";END;
            IF col1txt ="Max" THEN DO;col1txt ="A0A0"x||col1txt ;trt1="81.0";trt2="
82.0";trt99="82.0";END;
            OUTPUT;
      END;
RUN;

%LET itta=120;
```

```
%LET ittp=80;
%LET ittt=200;

PROC REPORT DATA=source.t3_1_1_1 NOWD SPLIT='@' HEADLINE HEADSKIP;
  COLUMNS mord col1txt  trt1 trt2 trt99;
  DEFINE mord  / ORDER NOPRINT;
  DEFINE col1txt   / "Demographic Parameter"              STYLE={WIDTH=15%
textalign=LEFT}   FLOW;
  DEFINE trt1  / "Active Drug@(N = %left(&itta.))@n (%)" STYLE={WIDTH=10%
textalign=CENTER} FLOW;
  DEFINE trt2  / "Placebo@(N = %left(&ittp.))@n (%)"   STYLE={WIDTH=10%
textalign=CENTER} FLOW;
  DEFINE trt99  / "Total@(N = %left(&ittt.))@n (%)"     STYLE={WIDTH=10%
textalign=CENTER} FLOW;
  BREAK AFTER mord/SKIP;
RUN;
%sh_ftnote(ftnote=%STR(Note: Std = Standard deviation. Percentages are computed
based on the Intent to Treat Population in each treatment group));

*4 PRIMARY ENDPOINT;
%sh_title(title=4  PRIMARY ENDPOINT);
%sh_texts(text=%STR(^n The primary endpoint, Severe Asthma Exacerbations was
defined as, Severe Asthma exacerbation is defined as an asthma worsening that
requires an increase from stable maintenance dose of total corticosteroid
(Intramuscular, Intravenous and oral) for at least three days and /or
hospitalization because of Asthma.));
%sh_title(title=4.1.1.1  Table: Analysis of Rate of Severe Asthma Exacerbation
through Overall Period Claim Population);
*Need to insert report;
%sh_ftnote(ftnote=%STR(Abbreviations: n= Subject has at least one severe
exacerbations; E=Number of Events; D= Duration of Exposure.
&nl. Note: Severe asthma exacerbation is defined as an asthma worsening that
requires an increase from the stable maintenance dose of oral corticosteroids, for
at least 3 days and/or a hospitalization because of asthma. For consistency,
increased courses of corticosteroids separated by 1 week or more will be treated as
separate severe exacerbations. Poisson regression model will be performed on
observed data, and test statistic will be provided along with p-value. Exposure
duration is calculated as the date of last dose of study medication - date of first
dose of study medication + 1.));
%sh_texts(text=%STR(^n There was a Statistically Significant Difference Observed/No
Statistically significant difference observed between Active Drug and Placebo for
number of severe Asthma Exacerbations Sensitivity.
^n The following sensitivity analysis were performed:
^n^n &bullet. ^{style[font_style=italic textdecoration=underline] Table for key
sensitivity analysis}));
%sh_texts(text=%STR(^n Interpretation: There was a Statistically Significant
Difference Observed/No Statistically significant difference observed between Active
Drug and Placebo for number of severe Asthma Exacerbations.));

*5 SECONDARY ENDPOINT;
%sh_title(title=5  SECONDARY ENDPOINT);
%sh_texts(text=%STR(^n The key secondary endpoints were as follows:
^n^n a&right. Overall Asthma Exacerbations (Severe and Moderate Exacerbations)));
%sh_title(title=5.1.1.1  Table: Analysis of Rate of Overall Asthma Exacerbation
Rate (Severe and Moderate Exacerbations) Claim Population);
*Need to insert report;
```

```
%sh_ftnote(ftnote=%STR(Abbreviations: n= Subject has at least one severe
exacerbations; E=Number of Events; D= Duration of Exposure.
&nl. Note: Severe asthma exacerbation is defined as an asthma worsening that
requires an increase from the stable maintenance dose of oral corticosteroids, for
at least 3 days and/or a hospitalization because of asthma. For consistency,
increased courses of corticosteroids separated by 1 week or more will be treated as
separate severe exacerbations. Poisson regression model will be performed on
observed data, and test statistic will be provided along with p-value. Exposure
duration is calculated as the date of last dose of study medication - date of first
dose of study medication + 1.));
%sh_texts(text=%STR(^n Interpretation: There was a Statistically Significant
Difference Observed/No Statistically significant difference observed between Active
Drug and Placebo for number of severe Asthma Exacerbations.
^n^n b&right. Time to severe Asthma Exacerbations
^n^n ^{style[font_style=italic textdecoration=underline]Table for Time to Severe
Asthma Exacerbations}
^n^n Interpretation: There was a Statistically Significant Difference Observed/No
Statistically significant difference observed between Active Drug and Placebo for
number of severe Asthma Exacerbations.));

*6 SAFETY.
%sh_title(title=6  SAFETY);
%sh_texts(text=%STR(^n A total of XX patients experienced at least one adverse
event. There was a total of XX patients in Placebo arm experiencing at least one
adverse event and a total XX patients in Active Drug arm experiencing at least one
adverse event.
^n A total of XX patient died in the study. A total of XX patients had serious
adverse events.));
%sh_title(title=6.1.1.1 Table: Overall Summary of Adverse Events (AEs) Claim
Population);
*Need to insert report;
%sh_ftnote(ftnote=%STR(Abbreviations: AE= Adverse event&semicolon. m = Number of
Events.
&nl. Note: Events were coded using MedDRA Dictionary (Version 18.1). For each
category, other than total AE count, subjects are included only once, even if they
experienced multiple AEs in that category with in "n" column. Percentage is
calculated based on number of subjects in Claim population. Related includes
Suspected and Not assessable.));
%sh_title(title= 6.1.1.2  Table: Analysis of Time to First Asthma Exacerbation
(Severe and Moderate) - Claim Population);
*Need to insert report;
%sh_ftnote(ftnote=%STR(Note: CI = confidence interval.
&nl. For Censor Patients: If no exacerbation is observed during the study, data on
time to first asthma exacerbation will be censored at the last asthma exacerbation
assessment of the concerned patient.
&nl. Time to First Asthma Exacerbation Duration = Date of first documented Asthma
Exacerbation - date of first treatment intake + 1.
&nl. [a] Percentages are based on the number of subjects per treatment group in the
FAS population.
&nl. [b] Estimates are from a Kaplan-Meier analysis. Minimum and Maximum include
censored time to event.
&nl. [c] The hazard ratio and associated 95&percent. Confidence Interval comes from
proportional hazards modelling.));
%sh_title(title=6.1.1.3  Figure: Comparison of observed Cmax of Pediatric with
expected Cmax with Adults. ^n);
%sh_image(image=%SYSFUNC(PATHNAME(inout))\PK_profile1.png);
%sh_ftnote(ftnote=%STR(Note: PK = Pharmacokinetics Concentration));
```

```
*6 EFFICACY;
%sh_title(title=7  EFFICACY);
%sh_texts(text=%STR(^n A total of XX patients experienced at least one adverse
event. There were a total of XX patients in Placebo arm experiencing at least one
adverse event and a total XX patients in Active Drug arm experiencing at least one
adverse event. ^n^n A total of XX patient died in the study. A total of XX patients
had serious adverse events.));
%sh_title(title=7.1.1.1  Figure: Correlation between Weight vs Height of the
Students);
TITLE;
PROC SGPLOT DATA=sashelp.class NOAUTOLEGEND;
      PBSPLINE Y=weight X=height;
      FOOTNOTE;
RUN;
%sh_ftnote(ftnote=%STR(Note: SG Procedure Examples));

*7  CONCLUSION;
%sh_title(title=8  CONCLUSION);
%sh_texts(text=%STR(^n There was a Statistically Significant difference observed
between Active Drug and Placebo.));

*Stop the process;
%sh_stop;


  ************************************************************************;
  ***                                                                  ***;
  ***                      End of Program                              ***;
  ***                                                                  ***;
  ************************************************************************;
```