

CONSORT Diagram: Doing it with SAS

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ABSTRACT:

The CONSORT (Consolidated Standards of Reporting Trials) statement 2010 is used worldwide to improve the reporting of parallel group, randomized trials. It suggests creating a CONSORT diagram that represents the participant flow in the trial. The CONSORT diagram for two arm study can easily be generated using Microsoft Word by manually entering the counts at each phase of the study. However, manual entry may be prone to error, especially when there are more than two arms in a trial. The RTF and macro functionalities of SAS® can be used to develop the CONSORT diagram. SAS macro language reads the RTF template of CONSORT diagram specific to the trial fills in the counts at each phase of the trial and then re-writes the final CONSORT diagram to RTF displaying the counts. This paper will provide an illustration in how RTF and SAS macros can automatically generate a CONSORT flow diagram of choice.

INTRODUCTION:

The CONSORT (CONSolidated Standards of Reporting Trials) 2010 guideline is intended to improve the reporting of parallel-group randomized controlled trials. It enables better understanding of a trial design, conduct, analysis, interpretation and assessment of the validity of its results. The guideline contains a 25-item check list and a CONSORT diagram. The CONSORT diagram is a simple flow diagram showing the enrollment of subjects, their allocation to treatment, disposition status and how they are analysed in the trial. The layout of a CONSORT diagram depends on the study design.

A CONSORT diagram can be generated by either Visual Basic Scripting (VBS), SAS/GRAPH using Annotate macros or manually in Microsoft Word. Each of the methods have their own difficulties. See Table 1.

TABLE 1:

Method	Disadvantage
VBS	Requires scripting knowledge of VBS
SAS/GRAPH®	Requires complex coding
MS Word	Prone to errors, which increases with the complexity of the trial.

This paper explains how to create a CONSORT diagram in RTF. An RTF file consists of unformatted text, control words, control symbols, and groups. RTF control words can have a maximum of 32 characters composed of lower case alphabet characters and delimiters. When read by SAS, an RTF document is encoded as text consisting of the above mentioned components. These properties of RTF and SAS macros are used to generate a CONSORT diagram in SAS.

CONSORT diagram can be generated following the steps below:

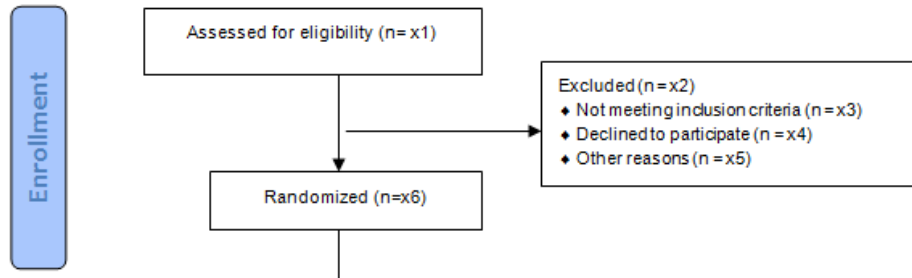
- Preparing CONSORT diagram template in RTF
- Calculating counts for each field and holding them in macro variables
- Reading the RTF template into SAS
- Replacing the unique text codes with counts and outputting the final RTF

PREPARING CONSORT DIAGRAM TEMPLATE IN RTF:

CONSORT diagram described as per the CONSORT statement displays enrollment, allocation, follow-up and analysis phases of the trial. However the fields in each phase can be modified as per the study design to include all the information required and the arms in the study. Initially an RTF is created manually as per the study design to display all the required information. This document is then filled with unique text codes in the fields where counts should be displayed. The unique text codes should be non-RTF control words, which allow us to replace them with the actual counts in the later steps. This template can also include unique text codes to display other information like the protocol number, and date and time of execution in the titles and footnotes.

Figure 1 displays an example of such RTF template for 'Enrollment' phase with unique text codes that cannot be read by RTF.

Figure 1: Enrollment phase of CONSORT Diagram



CALCULATING COUNTS FOR EACH FIELD AND HOLDING THEM IN MACRO VARAIBLES:

The counts for each field can be calculated using whichever SAS procedure you are comfortable with. The basic idea is to hold the counts in macro variables that have the same name as the unique text codes at each field. Having the same name for unique text codes at each field in the template and the macro variables will ease the identification of macro variables that should be used to replace the text code at each field, but this depends on the programmer's decision.

Below is an example of SQL code to derive the counts and hold them in macro variables at each field for Figure 1.

```

%macro popl (i =, whr =);
  proc sql noprint;
    select count (usubjid) into: x&i
    from adsl
    where &whr;
  quit;
%mend popl;

%popl (i = 1, whr = armcd ne ''); /*counts for eligibility*/
%popl (i = 2, whr = upcase (armcd) = 'SCRNFAIL'); /*counts for excluded subjects*/
%popl (i = 6, whr = randdt ne .); /*counts for randomized*/
  
```

Macro variables can also be created at this step to hold any other information to display in the titles or footnotes. Below is a piece of code that creates macro variable to hold the date and time of program execution. Similarly named text codes will of course need to be inserted into the RTF template.

```

data _null_;
  dtstamp = compbl (trim (put (today (), date9.))||trim (put (time(),hhmm5.)));
  call symput ('dt', dtstamp);
run;
  
```

READING THE RTF TEMPLATE INTO SAS:

- The RTF template of CONSORT diagram is now read into SAS using the INFILE and INPUT statements in a DATA step. The option LRECL can be specified in the INFILE statement to avoid truncation.
- As RTF files are composed of unformatted text and control words, SAS reads the RTF file as an RTF code, which is difficult to understand. However, SAS reads the unique text codes exactly the same as defined in the RTF template.
- Simultaneously, an automatic variable `_INFILE_` is created with the use of INFILE statement and this variable holds the contents of RTF file as read by SAS.

Below is a part of the RTF code when the template in Figure 1 is read by SAS. This shows unique text code 'Excluded (n=x2)' is read exactly the same as shown in the CONSORT diagram template.

```

\rtich\fcs1\af1\afs16\ltrch\fcs0\f1\fs16\lang4105\langfe1033\langnp4105
\insrsid10040895Excluded(n=x2)\rtich\fcs1\af1\afs16\ltrch\fcs0
\f1\fs16\lang4105\langfe1033\langnp4105\insrsid10040895\charrsid1184092)
  
```

REPLACING THE UNIQUE TEXT CODES WITH COUNTS AND OUTPUTTING THE FINAL RTF:

The automatic variable `_infile_` can be updated using functions like `TRANWRD`, `TRANSTRN` to find and replace the unique text codes with the counts held by the macro variables. The same process can also be used to display any information which changes after every run like the date and time of execution. The updated `_infile_` variable is output as the final CONSORT diagram in RTF using the `PUT` and `FILE` statements. Below is the RTF code in the updated `_infile_` variable, after the replacement of coded text 'x2' with the counts for 'Excluded' held in the macro variable 'x2'.

```

\rtlch\fcs1\af1\afs16\ltrch\fcs0\fl1\fs16\lang4105\langfe1033\langnp4105
\insrsid10040895Excluded(n=39){\rtlch\fcs1\af1\afs16\ltrch\fcs0
\fl1\fs16\lang4105\langfe1033\langnp4105\insrsid10040895\charrsid1184092)

```

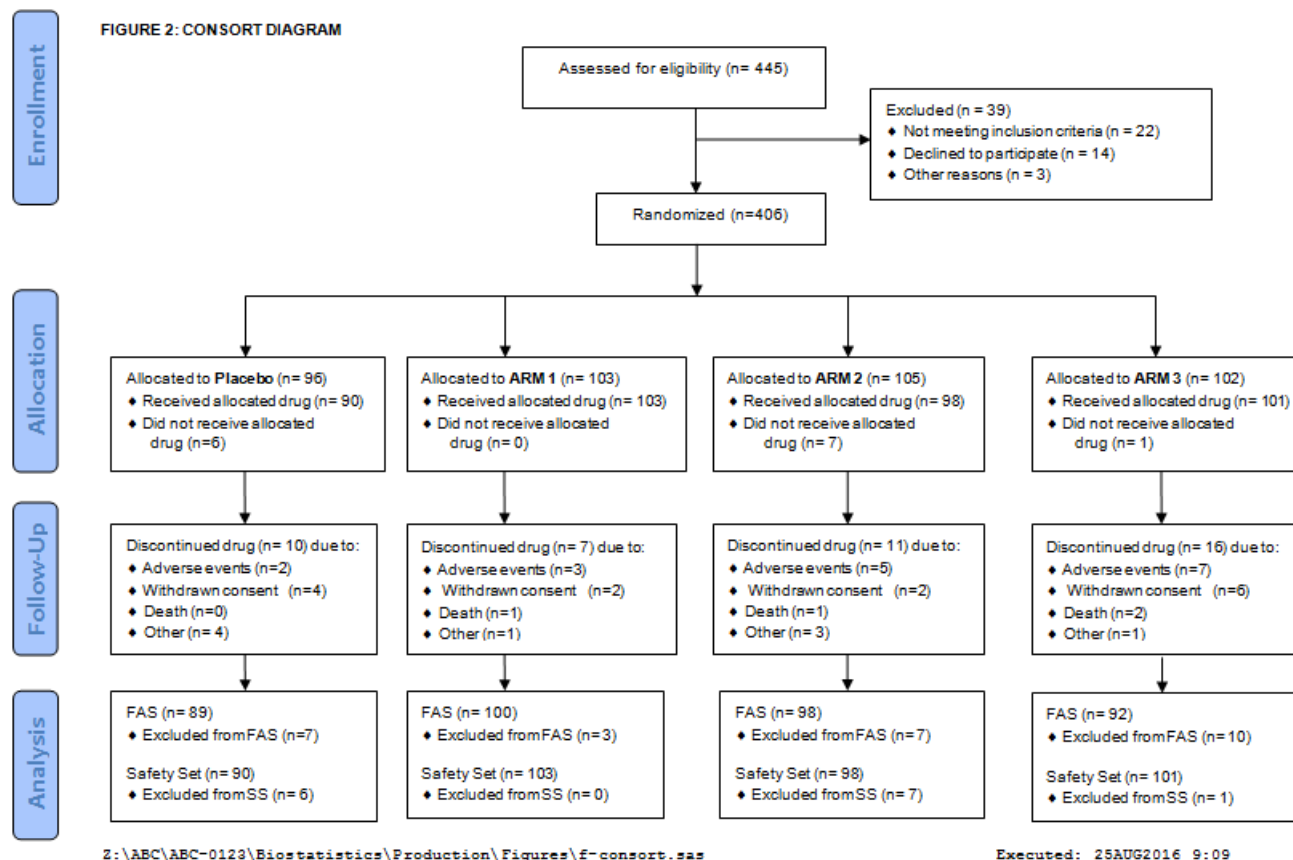
Below is the SAS code that uses the `TRANSTRN` function to replace the unique coded values with the counts held by the macro variables. This also shows the use of the `PUT` statement to output the final CONSORT diagram in the path specified in the `FILE`.

```

filename inrtf "C:\Documents\template.rtf"; /*name and path of CONSORT template*/
filename outrtf "C:\Documents\final.rtf"; /* name and path of final CONSORT diagram*/
data _null_;
  infile inrtf lrecl=2000; /*reading the template using infile*/
  input;
  _infile_ = transtrn (_infile_, 'x2', compress("&x2")); /*replacing coded text with counts*/
  _infile_ = transtrn (_infile_, "edt", "&dt"); /*for execution date time in the footnote*/
  file outrtf lrecl=2000; /*to write the final RTF in the path mentioned*/
  put _infile_;
run;

```

Figure 2 displays the final CONSORT diagram displaying counts at each field.



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The code shown in the above DATA step is partial and _INFILE_ variable can be updated several times in the same DATA step to replace all the unique text codes of the RTF template with their respective counts. Adhoc changes can be made to RTF template of CONSORT diagram to display the new arms with every data extract.

CONCLUSION:

The CONSORT diagram is a becoming a popular way to present the participant flow in a clinical trial. There are many ways to produce this diagram from complicated to simple but each has disadvantages.

The solution we have presented gives a simple method to produce a CONSORT diagram using an RTF template and macro variables derived in SAS. These macro variables are then inserted into the RTF template to create the final CONSORT diagram. The statistics in the resulting CONSORT diagram can now be traced back to the data.

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