

A SAS-based Tool Introduction for TLF Programs Management

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Contents

- **Background**
- **SAS based tool**
 - **What**
 - **How-PostScript Language**
- **Examples**
- **Summary**

Background

- **Manage programs during the lifecycle of TLF programs development**
 - **Tracking, reference and usage**
 - **Easily archived**
 - **Protected from unauthorized change**
- **One effective and efficient way**
 - **Create a bookmarked PDF document using SAS**
- **Creation of a PDF file manually from multiple ASCII files is a time-consuming task.**

SAS Based Tool

- **SAS macros which incorporate PostScript language**
 - **Read the programs into datasets**
 - **Use the PostScript language format**
- **Two Marcos can do**
 - **Combine the programs into PDF(Portable Document Format)**
 - **Retrieve the PDF into original format**
- **Can be use with any ASCII files**
- **Make the PDF file easily read and used**

Source files

What

PDF file

Name	Date modified	Type
rmcntpct	12/10/2012 10:02 ...	SAS File
rmcolprep	10/6/2011 10:00 PM	SAS File
rmdefaults	2/24/2012 4:11 AM	SAS File
rmddpstyle	12/3/2011 12:31 A...	SAS File
rmexist	2/23/2012 3:59 AM	SAS File
rmfmtstat	2/23/2012 12:51 A...	SAS File
rmouttitle	1/20/2012 9:14 PM	SAS File
rmpchisq	6/16/2011 10:39 PM	SAS File
rmpcmh	6/16/2011 10:40 PM	SAS File
rmpcmhrms	6/16/2011 10:40 PM	SAS File
rmplexact	6/16/2011 10:41 PM	SAS File
rmpkwallis	6/16/2011 10:41 PM	SAS File
rmprval	6/16/2011 3:46 AM	SAS File
rmprvwancova	12/13/2011 5:13 A...	SAS File
rmprvwanova	6/16/2011 11:05 PM	SAS File
rmprwmwrnk	6/16/2011 11:05 PM	SAS File
rmrtftemplate	2/24/2012 1:08 AM	SAS File
rmstats	2/8/2012 2:29 AM	SAS File
rmssyspgmname	12/3/2011 12:14 A...	SAS File
rmrtfreq	12/12/2012 10:18 ...	SAS File
rmrtgenlist	2/23/2012 4:21 AM	SAS File
rmrtgentbl	2/29/2012 2:47 AM	SAS File
rmrtsetup	12/11/2012 2:37 PM	SAS File
rmrtunivar	2/7/2012 9:49 PM	SAS File
rmqcmadata	10/14/2012 10:43 ...	SAS File
rmssinter	12/13/2012 2:54 PM	SAS File
rmtdmattrib	12/12/2012 10:52 ...	SAS File
rmtdmcd	4/25/2012 11:22 A...	SAS File

Bookmarks

- adae
- adcm
- adds
- adeg
- adex
- adlb
- admh
- adml
- adsl
- adsl_bx
- advs
- calcu_egchange
- check_data_in_process
- check_raw
- code
- envre
- fintdt
- fucase
- fwords06
- getDREFDT
- getaedy
- getaenone
- getaetrtem
- getage

```

*****
Program Name      : ADASL.sas
SAS Version       : 9.4
Short Description  : Creation of analysis dataset ADASL
Author            : Billy Liu
Date              : NOV 2012

Input             : ADASL dataset from P.101 file
Output            : ADASL dataset in P.101 file
Format            : None

Macro Parameters  : ?
Macro Sample Call : not applicable.
Modification History :

New #   Modified By   Reporting Effort   Date       Description
-----
***** LOGICAL STEP : Add subject variable;
*****
%let ADASL=(index = d_in_nm,
              dmtm = ad,
              outdm = adaslt);

***** LOGICAL STEP : Derive subject level information;
*****
***** add dummy information;
%let ADASL=(index = adaslt, dmtm = adaslt, outdm = adaslt);
%let ADASL=(index = adaslt, outdm = adaslt);
***** reference start & end dates;
%let ADASL=(index = adaslt, outdm = adaslt);

***** population flags;
%let ADASL=(index = adaslt, outdm = adaslt);

***** arm, arm & port;
%let ADASL=(index = adaslt, outdm = adaslt);

***** LOGICAL STEP : create dataset variables;
*****
%let ADASL=(index = adaslt,
              outdm = adaslt);
***** LOGICAL STEP : allocate ADASL to their treatment period;
*****
***** create dataset datasets;
%let ADASL=(index = adaslt, outdm = adaslt);
%let ADASL=(index = adaslt, outdm = adaslt);

data adaslt;
  set adaslt;
  where adaslt_nm = 1 and adaslt_nm = "ADASL OF STUDY";
run;

***** allocate ADASL that have start date and time;
data adaslt_nm;
  set adaslt;
  if adaslt_nm = 1 then output;
run;
%let ADASL=(index = adaslt_nm,
              outdm = adaslt_nm,
              outdm = adaslt_nm,
              outdm = adaslt_nm);
***** allocate ADASL that have no complete start date & time;
data adaslt_nm;
  set adaslt;
  if adaslt_nm = 1 then output;
run;
%let ADASL=(index = adaslt_nm,
              outdm = adaslt_nm,
              outdm = adaslt_nm,
              outdm = adaslt_nm);
***** define treatment emergent ADASL;
%let ADASL=(index = adaslt_nm, outdm = adaslt_nm);
*****
Page 1/2
  
```

How-Post Script Language

■ The created PDF is actually a text file

```
%PDF-1.5
%懺嫌
1 0 obj
<<
/Author (Chen Gang)
/CreationDate (D:20141117144332)
/Creator (combsasprog.SAS)
/Producer (Prd)
/Title (sascode26Nov2011.pdf)
/Subject (Convert SAS programs to PDF files)
>>
endobj
10 0 obj
<<
/Type /Font
/Subtype /Type1
/Name /F1
/Encoding 14 0 R
/BaseFont /Courier
>>
endobj
```

```
11 0 obj
<<
/Type /Font
/Subtype /Type1
/Name /F2
/Encoding 14 0 R
/BaseFont /Courier-Oblique
>>
endobj
12 0 obj
<<
/Type /Font
/Subtype /Type1
/Name /F3
/Encoding 14 0 R
/BaseFont /Courier-Bold
>>
endobj
13 0 obj
<<
/Type /Font
/Subtype /Type1
/Name /F4
/Encoding 14 0 R
/BaseFont /Courier-BoldOblique
>>
Endobj
.....
```



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How-Post Script Language

- **Structure**
- **Logic of file structure**
- **Elements of Objects**

Post Script Language

- PDF file and its structure

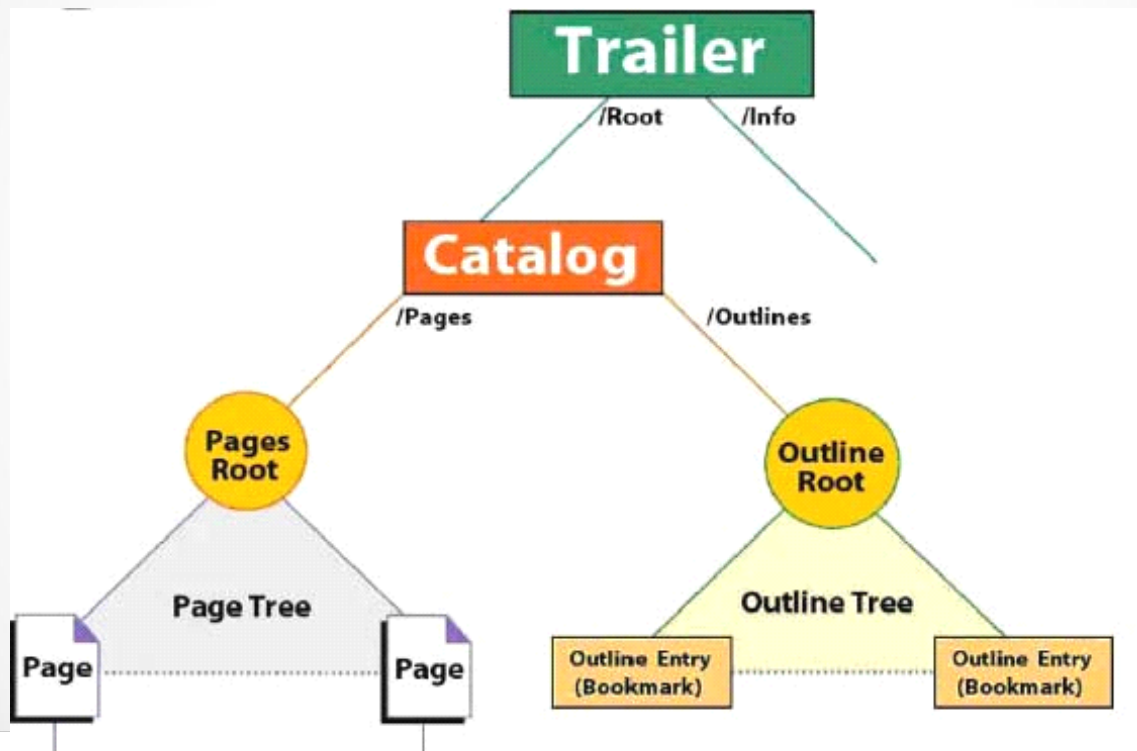


Post Script Language

- **Component of A PDF file**
- **Header—first 2 rows**
 - **%PDF-1.5---Version 1.5**
 - **%226 227 207 211→ E2 E3 CF D3 (16 bit)→忤嫌(GBK code): tolerate unsatisfied**
- **Body**
 - **A series of PDF objects, e.g font,page,image etc;**
- **Xref tables (Cross-reference Table)**
 - **Index table for randomly use the objects**
- **Trailer**
 - **Announce the address of the Xref table**
 - **Identify the Catalog object**
 - **Preserve the security information**

Post Script Language

- Logic of file structure



Post Script Language

■ Elements of Objects

- Information

- Catalog

- Page

- Font

- Encoding

- Stream

e.g

30 0 OBJ

<<

.....

.....

.....

>>

ENDOBJ

Elements of Objects

■ Information Object

1 0 obj

<<

/Author (Chen Gang)

/CreationDate (D:20141103112917)

/Creator (combsasprog.SAS)

/Producer (Prd)

/Title (lst_pdf99.pdf)

/Subject (Convert SAS programs to PDF files)

>>

endobj

Elements of Objects

■ Catalog

```
2 0 obj
<<
/Type /Catalog
/Outlines 3 0 R
/Pages 9 0 R
/PageMode /UseOutlines
/PageLayout /OneColumn
>>
endobj
```

```
3 0 obj
<<
/Type /Outlines
/First 4 0 R
/Last 8 0 R
/Count 5
>>
endobj
4 0 obj
<<
/Title (Dsub02)
/Parent 3 0 R
/Next 5 0 R
/Dest [ 16 0 R/FitH 622 ]
>>
endobj
```

Elements of Objects

■ Page

9 0 obj

<<

/Type /Pages

/Count 15

/MediaBox [0 0 612 792]

/Kids [

16 0 R

.....

58 0 R

]

>>

endobj

Elements of Objects

■ Font

```
10 0 obj
<<
/Type /Font
/Subtype /Type1
/Name /F1
/Encoding 14 0 R
/BaseFont /Courier
>>
endobj
```

Elements of Objects

■ Stream

17 0 obj

stream

T*(.....)Tj

.....

.....

endstream

endobj

Macro %combSASprog

/******

* Create page objective of a PDF file

page:

array spages { %eval(&oi+&pages-1)} \$80 _temporary_ (

"&la"

'/Type /Pages'

"/Count &pages"

"/MediaBox &lb 0 0 &lsz &psize &rb"

"/Kids &lb"

%do i = %eval(&oi+&count+2) %to %eval(&oi+&count+3*&pages-1) %by 3;

"&i 0 R"

%end;

'endobj'

);

string=compress(put(obj+1,8.))!!' 0 obj';

addobj=1;

link output;

do i=1 to %eval(&oi+&pages-1);

string=spages{i};

link output;

end;

return;

Macro %combSASprog

- %CombSASprog
(inDir=, /*Filename associated with a directory where SAS programs located in*/
Selmember=, /*Files names of SAS programs names or _all_ */
Memtype=, /*File extension of SAS programs*/
OutPDFDir=, /*File name associated with a directory where a PDF file resides in*/
PDFFilename=, /*File name of a PDF file that contains SAS programs*/
Font=Courier, /*Font chosen for a PDF file. The default font is Courier.*/
FntStyle=R, /*Font style chosen for a PDF file. The default style is R (Regular)*/
FntSize=, /*Font size chosen for a PDF file. The default font size is 10*/
PgHeader=, /*Option of printing programs names at the top of each page*/
PgFooter=, /*Option of printing page numbers at the bottom of each page*/
WMargin=, /*Left and right sides margins of pages of a PDF file*/
HMargin=, /*Top and bottom margins of pages of a PDF file*/
Wmark=, /*Watermark of a PDF file*/
WmMargin=, /*Margins of watermark of a PDF file*/
PortLand=L, /*Page orientation of a PDF file. */
Usernam=); /*user name of the PDF file*/

Macro %RetrievePDF

%RetrievePDF

(Dir =, /*Filename associated with a directory where a PDF */
PDFFile=, /*File name of a PDF file used by macro combsasprog*/
PDFType=PDF, /*File extension of a PDF file*/
FileDir=, /*Filename associated with a directory where to-be-retrieved */
Files=, /*File names of SAS programs*/
FileType=, /*File extension of to-be-retrieved SAS programs*/
PgHeader=N, /*Whether a PDF file has file names on the top of pages*/
PgFooter=N, /*Whether a PDF file has page numbers on the bottom*/
WMark=N); /*Whether a PDF file has watermark on pages*/



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Example

- Exp 1—manage SAS Code

```
%CombSASprog(indir=soupgmfn,  
  memtype      =sas,  
  selmember    =_all_,  
  outpdfdir     =pdfpgmfn,  
  pdffilename   =sascode26Nov2011,  
  font          =Courier,  
  fntstyle      =R,  
  fntsize       =6,  
  pgheader      =N,  
  pgfooter      =Y,  
  wmargin       =1,  
  hmargin       =1,  
  wmark         =archive26Nov,  
  wmmargin      =1.5,  
  PortLand      =P,  
  usernam      =Chen);
```

Filename soupgmfn
"location of the programs";

- **Exp 1—mange SAS Code**

```
1 / 15
75%
Bookmarks
Dsub02
Dsub03
Lsub01
Lsub03
Lsub04

*****
SAS Version: 6.1
Trial: CXXXXX dial052
Program ID: 1\user\cm\randeforces\A11\00M\PMO\COMPOND\NXXXXX\dial052\pgenel1\desk01.sas
Author: Deng Shun
Created: Dec 2011
Description: Create T4G for Subject and Disease Characteristics
Source from:
Source author:

Index:
Modification:
Date: Purpose: Reason:
---
Var SIG: 1.For weight, height and BMI, keep to one decimal place for both mean and SD
2.Change the reporting order should be AGE, SEX, RACE, ETHNICITY, WEIGHT, HEIGHT and BMI
Based on Day's email on 10Aug2011.
*****
Input: -----
Input --- 0. General Initialization -----
Input -----
***** LOGICAL STEP: Initialize system and assign trial directories;
*****
*****
*****
***** LOGICAL STEP: Execute trial dependent statements;
*****
*****
*****
***** LOGICAL STEP: Clear Interventions and visits;
*****
*****
*****
***** LOGICAL STEP: Create trial dependent formats;
*****
*****
*****
***** LOGICAL STEP: Run;
*****
*****
*****
***** LOGICAL STEP: Display;
*****
*****
*****
***** LOGICAL STEP: Data adjustment (redesign labels);
*****
*****
***** LOGICAL STEP: Add cGPP;
*****
*****
*****
***** LOGICAL STEP: Create table cGPP01 as
*****
*****
*****
***** LOGICAL STEP: Quit;
*****
*****
*****
***** LOGICAL STEP: Print out data=ad01; by usebjid; run;
*****
Page 1/3
```

Example

■ Exp 2—Mange outputs(.txt, .lst, ASCII file)

```
%CombSASprog(indir=soupgmfn,  
  memtype      =lst,  
  selmember    =_all_,  
  outpdfdir    =pdfpgmfn,  
  pdffilename  =lstout26Nov2011,  
  font         =Courier,  
  fntstyle     =R,  
  fntsize      =6,  
  pgheader     =N,  
  pgfooter     =Y,  
  wmargin      =1,  
  hmargin      =1,  
  wmark        =archive26Nov,  
  wmmargin     =1,  
  PortLand     =L,  
  usernam      =Chen);
```

Example

Bookmarks

- Output DSUB02: Demographic and Baseline Characteristics
- Output DSUB03: Study Completion/Early Withdrawal Information
- Output LSUB01: Demographic and Baseline Characteristics
- Output LSUB03: Medical History Abnormalities
- Output LSUB04: Study Completion/Early Withdrawal Information

Page 1 of 2

23APR2012 03:55
System Used: dsu02

STUDY: XXXX01A6.2

Output: DSUB02: Demographic and Baseline Characteristics

Analysis Set: Safety

	Sequence AB (N=32)	Sequence BA (N=32)	Total (N=64)
Age (years)			
N	32	32	64
Mean (SD)	38.2 (8.6)	37.4 (7.6)	37.8 (8.1)
Median	39.5	38.0	38.0
Range	(22,55)	(21,55)	(21,55)
Sex, n (%)			
N	32	32	64
Female	10 (31)	18 (56)	28 (44)
Male	22 (69)	14 (44)	36 (56)
Race, n (%)			
N	32	32	64
Asian	0	1 (3)	1 (2)
Black or African American	0	1 (3)	1 (2)
White	32 (100)	30 (94)	62 (97)
Ethnicity, n (%)			
N	32	32	64
Hispanic or Latino	23 (72)	20 (61)	43 (67)
Not Hispanic or Latino	9 (28)	12 (37)	21 (33)
Weight (kg)			
N	32	32	64
Mean (SD)	71.8 (11.0)	73.3 (11.5)	72.6 (11.2)
Median	69.1	69.5	69.1
Range	(52,94)	(52,97)	(52,97)

Sequence AB: TrtA: XXXX 300-mg and XXXX 1700-mg; TrtB: XXXX/XXXX FDC 300-mg/1700-mg
Sequence BA: TrtB: XXXX/XXXX FDC 300-mg/1700-mg; TrtA: XXXX 300-mg and XXXX 1700-mg

Page 1/2

Example

■ Exp 3—Retrieve pdf

The screenshot displays a web application interface. On the left, a sidebar contains a 'Bookmarks' section with a list of files: Dsub02, Dsub03, Lsub01, Lsub03, and Lsub04. The main area shows a PDF document with text that is mostly illegible due to a large diagonal watermark reading 'CONFIDENTIAL'. On the right, a file explorer window is open, showing a list of files in a table format.

Name	Date modified	Type
Dsub02	11/17/2014 9:28 A...	SAS File
Dsub03	11/17/2014 9:28 A...	SAS File
Lsub01	11/17/2014 9:28 A...	SAS File
Lsub03	11/17/2014 9:27 A...	SAS File
Lsub04	11/17/2014 9:27 A...	SAS File

Below the table, there is a 'Favorites' section with icons for Desktop, Downloads, Recent Places, Libraries, Documents, Music, Pictures, Videos, Computer, Local Disk (C:), Software Media, and jnjcnmpdfsroot. A text prompt 'Select a file to preview' is visible on the right side of the interface.

Summary

- **Used to manage SAS programs(any ASCII files)**
- **Using PDF PostScript language to produce PDF files, which is a text file**
- **Can be used in any SAS version and dose not rely on the third software**
- **Retrieved from the PDF are also applicable**

Acknowledge

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 - **Jay Ren**
- **And all of my colleagues**

Reference

- **Guidance for Industry: Providing Regulatory Submissions in Electronic Format – NDAs. US Food and Drug Administration Center for Drug Evaluation and Research (CDER) www.fda.gov/cder/guidance/2353fnl.pdf**
- **Adobe pdfmark Reference Manual, Technical Note #5150:Website:<http://partners.adobe.com/asn/developer/acrosdk/DOCS/pdfmark.pdf>**
- **L. Jansen, “Creating PDF™ Document including Links,Bookmarks and a Table of Contents with SAS® Software”. Proceedings of the PharmaSUG 2010 Conference.**

Thank you!



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