

PPG, a metadata driven solution for patient profile generation

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ABSTRACT

To facilitate the medical review, data management programmer need to provide the patient profile (PP) to medical reviewer. In most cases, delivering a set of PP for one study takes at least 5 days as data manager need to prepare its specification and then the programmer need to develop the SAS code accordingly. But with PP Generator (PPG), specification preparation and routine programming are not needed any more. It will create PP based on RAVE study design specification (SDS) and source data extracted from clinical database directly, minimize the mistake you might make and greatly reduce repetitive programming, so as to improve the programming efficiency and accuracy and save development time (taking no more than 3 hours). PPG also has the flexibility by providing the interface for PP population, context, styles and format customization to meet data manager's individual demands while reviewing.

INTRODUCTION

PP is individualized patient data for medical review, it includes a big amount of tables and variables in a study, while each table could contain some aspects of information. Most of cases, it need Data Manager provide a very detail specification and send to SAS programmer, then SAS programmer manually program the PP table by table per this specification. For Data Manager, it's really a grueling work as it need to write a very detail specification for a proposal layout. For SAS programmer, a lengthy SAS programming effort will be involved. Both the specification and the program for one study are usually not reusable for another study. It would be time consuming and error prone for both Data Manager and SAS programmer. For RAVE-EDC system studies, with PPG, PP could automatically created. No additional specification and programming needed. As long as the SDS and source data are ready, PPG could create a specification in EXCEL format all by itself. Then Data Managers go to fill the parameters in the PP specification to customize the PP as what they want. By simply using one command button, PP can be automatically created.

WHAT IS PPG

SDS is downloaded from RAVE-EDC system. It contains e-CRF structure data such as Forms, items, label, order and sequence information. PPG is a generic SAS macro package used to create PP based on SDS and source data extracted from clinical database.

WHAT IS PPS

PPS is the patient profile specification created by PPG based on SDS, and also the centralized configure file for PP output customization, it will determine:

- What data will be displayed in PP
- How clinical data structured and render in the PP
- The style and format of the PP
- The population of the PP
- Some other aspects of the PP

THE INTERFACE OF PPS

PPS is composed with the following six sheets: INSTRUCTION, PARAMETER, POP, DOMAIN, FORM and FIELD. PARAMETER and POP are used to control the parameter and population at study level. DOMAIN, FORM and FIELD are used to customize PP output context and style for study specific requirement.

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Instruction sheet

INSTRUCTION is the precaution that contains the rules and constraints of configuring the PPS.

Parameter sheet

PARAMETER contains the parameters at study level. It will apply to all patients. For example, if the table is empty and not expected in the PP output, “N” could be filled in “Value” column under “SHOW EMPTY TABLE” parameter, then only the tables which have records would be displayed in the output.

ID	Name	Description	Valid value	Default value	Value
1	START DATE	Records created or modified since this date will be highlighted in red	Any valid date value in format of ddmmyyyy		
2	END DATE	Records created or modified before this date will be highlighted in red	Any valid date value in format of ddmmyyyy		
3	MULTIPLE FILTER MODE	Specify the relationship between filters if multiple filters ticked in POP sheet; And=Patient meet all of the active filters will be included in POP; Or=Patient meet any one of the active filters will be included in POP	AND; OR	OR	
4	DEST_FMT	The format of the output	RTF; PDF; BOTH	PDF	
5	SHOW EMPTY TABLE	Whether show the table if it is empty	Y; N	Y	
6	REFRESH PPS	Whether refresh pps in case of eCRF amendment	Y; N	N	
7	BY FORM	Determine if organize the output by form, if yes, then by form; otherwise, by domain, then by form	Y; N	N	

Display 1. Matrix Interface of Parameter

Pop sheet

POP contains all the predefined population list at study level, Data Manager could choose one or more population at the same time, the relationship among the populations could be defined via “MULTIPLE FILTER MODE” on PARAMETER sheet. If none of the populations meet Data Manager’s needs, SAS programmer could derive a program to generate a population and fill the “Customized POP” parameter on POP sheet.

ID	Filter	Description	Valid value	Value	Active
1	All	All of the subjects/patients	NA	NA	N
2	Subject list	List of patients	List of subject number without quotation marks separated by space	040100100001	Y
3	Site list	List of site ID	List of site number without quotation marks separated by space		
4	Country list	List of country ID	List of country number without quotation marks separated by space		
5	AE grade	Subjects/patients with Grade X AE	Toxic grade value like 1; 2; 3; 4 without quotation marks		
6	AE relationship	Subjects/patients with Related AE/SAE	NA	NA	
7	AE immediate	Subjects/patients with at least one immediate AE	NA	NA	
8	SAE	Subjects/patients with at least one SAE	NA	NA	
9	AESI	Subjects/patients with at least one AESI	NA	NA	
10	PT_TERM list	Subjects/patients having at least one AE that corresponds to a list of selected Preferred Terms	list of selected Preferred Terms without quotation marks separated by @		
11	AE termination	Subjects/patients with at least one AE leading to termination	NA	NA	
12	SAE Death	Subjects/patients with SAE = Death	NA	NA	
13	Early termination	Subjects/patients early terminated	NA	NA	
14	Pregnancy	Subjects/patients with Pregnancy = Yes	NA	NA	
15	Overdose	Subjects/patients with Overdose = Yes	NA	NA	
16	Start date	Subjects/patients with records created or modified since this date	Any valid date value in format of ddmmyyyy without quotation marks		
17	End date	Subjects/patients with records created or modified before this date	Any valid date value in format of ddmmyyyy without quotation marks		
18	Customized POP	Specific population defined at study level	Any valid SAS dataset name: sds.pop; rdc.population; work.screened; or screened. Or any existed SAS program name: pop.sas; my_pop.sas or just my_pop. If the dataset name, then the dataset should be ready before submit PPG program. If the program name, then program should create a population table with exactly the same name as program in temp library WORK, and the program should be stored in PGM folder under the same triplet.		

Display 2. Matrix Interface of Pop

Domain sheet

DOMAIN sheet contains all the domains the study involved. The relative position of each table in PP output could be controlled by “Order” column. The domain label which appear into the bookmark of output could be defined by “Label” column. Meanwhile, the appearance of domain level table(s) could be controlled by “Display” column. For example, very frequently, Data Manager also request a sub-PP for dedicated review, via “Display” column, Data Manager could choose the tables only they want.

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Domain	Library	Memname	Display	Label	Order	Derived	Location	PGM name
SUB	RDC	CBX_TSTGLP02_SUB	N		1	N		
IVRS	RDC	CBX_TSTGLP02_IVRS	N		2	N		
SV	RDC	CBX_TSTGLP02_SV	N		3	N		
DM	RDC	CBX_TSTGLP02_DM	N		4	N		
DS	RDC	CBX_TSTGLP02_DS	N		5	N		
MH	RDC	CBX_TSTGLP02_MH	Y		6	N		
SU	RDC	CBX_TSTGLP02_SU	N		7	N		
CM	RDC	CBX_TSTGLP02_CM	Y		8	N		
VS	RDC	CBX_TSTGLP02_VS	N		9	N		
EG	RDC	CBX_TSTGLP02_EG	N		10	N		
LB	RDC	CBX_TSTGLP02_LB	N		11	N		
PE	RDC	CBX_TSTGLP02_PE	N		12	N		
EX	RDC	CBX_TSTGLP02_EX	N		13	N		
DA	RDC	CBX_TSTGLP02_DA	N		14	N		
ML	RDC	CBX_TSTGLP02_ML	N		15	N		

Display 3. Matrix Interface of Domain

Form sheet

FORM sheet contains all the forms the study involved. The relative position of forms within one domain, the form title, footnote, the displaying of the forms could be controlled by “Order”, “Title”, “Footnote”, “Display” columns. Meanwhile, the “sort” column could indicate the sorting variable(s) for the form. If Data Manager want to filter the records within one form, it could be customized by “Restriction” column. For example, if only serious AE would be considered, it could be filled as “AESER= ‘Y’”. If the form need transpose, it could be customized by “Transpose” as “Y”.

Domain	Form	Display	Title	Footnote	Order	Sort	Restriction	Transpose	BY	ID	IDLABEL	IDOrder	VAR	Width
SUB	SUB_ID	Y	Subject Identifier		1	SYSDAT		N						
IVRS	IVRS_ALL	Y	IVRS Library		1	VISDAT DSRUDAT DSSTDAT DSSTTIM RDALDAT RDALTIM RDALGDAT RDALGTIM RDBKDAT EXPRTDT		N						
SV	SV_01	Y	Visit Date		1	VISDAT		N						
DM	DM_DAT	Y	Demographics Date Of Birth		1	BRTHDAT		N						
DS	DS_IC_DAT	Y	Informed Consent Date		1	DSSTDAT		N						
DS	DS_C_SCR	Y	Completion of Screening and Run-In		2	DSSTDAT		N						
DS	DS_TS_ALL	Y	Treatment Status Library		3	DSSTDAT		N						
DS	DS_CB_ALL	Y	Code Breaking Library		4	DSSTDAT DSSTTIM		N						
DS	DS_C_ED3	Y	Completion of End of Study/Follow-		5	DSSTDAT		N						

Display 4. Matrix Interface of Form

Field sheet

FIELD sheet contains all the variables for each form. The relative position of all variables within one form, the label of each variable, the width of each variable in PP output, the displaying of each variables could be customized by “Order”, “Label”, “Width”, “Display” columns. For “Define” and “Compute”, they follow the same syntax as report procedure. For example, add format of variables could be fulfilled by “Define”, highlight rows, columns which meet some conditions could be defined via “Compute”.

Domain	Form	Field	Display	Label	Width	Order	Define	Compute
AE	AE	AESIIN	Y	Is the event an AESI?		6		
AE	AE	AESTDAT_RAW	Y	Start Date/ Date of Worsening/Date Event Became Serious		7		
AE	AE	AESTTIM	Y	Time		8		
AE	AE	AESEV	Y	Intensity		9		
AE	AE	AECONTRT	Y	Corrective Treatment/Therapy		10		
AE	AE	AEACNC	Y	Action Taken with \Study Treatment 1\		11		
AE	AE	AEACNC2	Y	Action Taken with \Study Treatment 2\		12		

Display 5. Matrix Interface of Field

FEATURES AND FUNCTIONALITY

PPG has the following features.

- Meta data driven, based on the SDS from RAVE.
- PPG with its customization function is robust and applicable for all studies on RAVE.
- Programming and specification are not required if no study specific requirement.

PPG has multiple useful functions.

- The customization function can help users with controlling the output for his/her purpose.
- The highlight function can highlight the data that created or modified between the START_DATE and END_DATE that users specified in the PPS.
- PPG can use multiple population.

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- PPG has two kinds of output: PDF and Word.
- PPG can retrieve the previous settings for the amendment of CRF.

TECHNICAL SOLUTION

To automate the PP, PPG, a SAS macro package is created. User could generate the PP via simply submitting the ppg.sas program if no study specific requirement. For complicated requirement from Data Manager, the macros also provide the interfaces for customization.

PPG SAS MACRO PACKAGE COMPONENT

The PPG tool is composed by 11 macros. Every macro has its special usage, every macro is also a important part of the whole chain.

%npp_create_pps

This macro is used to create PPS based on SDS.

%npp_read_pps

This macro is used to read PPS matrix information.

%npp_fresh_pps

This macro is used to fresh PPS based on previous PPS, amended SDS and database. Also the difference between SDS and database would be indenified in the new PPS.

%npp_get_pop

This macro is used to get the population predefined and also check the logic with "PARAMETER" sheet.

%npp_prepare_data_from_pps

This macro is used to prepare active data for reporting.

%npp_report_byform

This macro is used to generate PP by form order.

%npp_report

This macro is used to generate PP by domain, then by form order.

%npp_pdf_style

This macro defined the PP output style.

%npp_doc_restructure

This macro is used for generating PDF output bookmark.

%npp_transpose

This macro is used to transpose tables defined in PPS matrix.

%npp_ppg

Include all the macros above to generate PP based on the condition.

PPG SAS MACRO LOGIC PROCESS

After you run ppg.sas, PPG will detect if the PPS exists in the dedicated folder, if it does exist, PPG will generate a new PPS automatically according to the content of SDS. If it exists, PPG will identify the value of "REFRESH PPS", if it is "Y", then PPG will refresh the PPS base on SDS, if it is "N", PPG will re-organizes and renders the patient data, then generate PP output automatically. The workflow of PPG can be shematically represented as below.

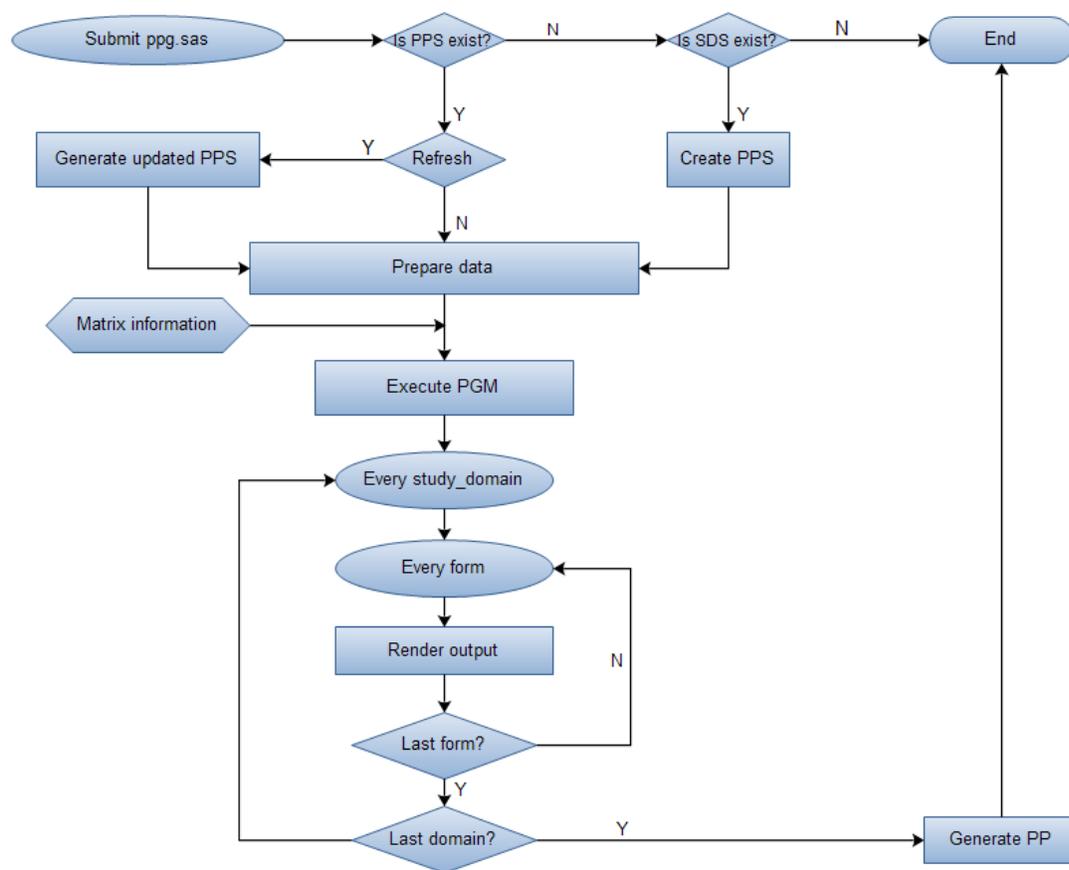


Figure 1. Basic Algorithm of PPG

CONCLUSION

This paper introduced PPG, a effective and reusable tool to generate patient profile as long as SDS is ready, without requiring additional programming and patient profile specification if no study specific requirement. Highly customized reports also could be created by configure PPS. We hope this methodology could help you saving time and resources for developing patient profile on all Rave studies.

REFERENCES

SAS® 9.4 Macro LanguageReference Fourth Edition

<http://support.sas.com/documentation/cdl/en/mcrolref/67912/PDF/default/mcrolref.pdf>

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