

Power Data Explorer (PDE) - Data Exploration in an All-In-One Dynamic Report Using SAS & EXCEL

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ABSTRACT

Getting to know your data is the first key step for every data analyst. Usually we write ad-hoc procs or data steps to summarize and compare different data, or we develop sophisticated macros that create multi- page listings or even 'dynamic' html files to summarize all SAS® datasets.

This paper explores a technique to perform an “easy-to-explore” overview of multiple SAS datasets in an all-in-one, dynamic report. This is accomplished via a combination of SAS PROCs to summarize your data in a standardized way and Excel Pivot tables on these summary tables, to help users better understand the data including elements (data, variable, value), structure/hierarchy (cross-table) and relationship across data, and other patterns of the data. This technique also compares differences between versions and can be used in clinical data analysis and can be extended to other uses.

INTRODUCTION

Clinical data analysis requires the programmer to have an in-depth knowledge of the source SDTM data to translate the statistical analysis requirements into ADaM data for analysis and reporting. It is also important to have that same in-depth knowledge of the ADaM data and changes in the data over time. In the past this was always a tedious, repetitive and time-consuming process involving comparing/exploring define.xml or via SAS programming with hundreds of pages of outputs to review. Opening SAS data sets requires scrolling up and down, left and right over and over again. This paper describes how the combination of SAS and Excel Pivot tables can provide an efficient way to review and explore data.

EASY DATA EXPLORATION

Power Data Explorer provides a powerful, easy-to-use means of exploring and reviewing clinical trial data. SAS is used to summarize your data in a standardized, yet flexible, manner. On these standardized summaries, a set of predefined Excel pivot tables are applied with built-in filters to allow users to quickly review data. It can be also used on a single database, to compare different database releases, or even across different trials. And it can be used for both SDTM or ADaM data. The tool is simple to set up with minimal user input, one SAS program and ability to refresh the data directly in the Excel pivot table.

SUMMARIZING THE DATA

A SAS program called PDE.sas calls a series of macros that summarizes the data and produces several datasets as described below:

```

%powerDataExplorer(
    summaryClassXlsFile    = &inputfile
    ,outdir = &rptdrv\PDEV\&username\PDE
    ,_PlanningSheet2Vardef = Y
    ,_debug = Y /*keep output sasdatasets?*/
    ,_nMaxClassVar=10
    ,_nMaxIDVar=2
    ,_nOutMaxMinID=1
    ,_maxLevLimitValuelist= 200 /*default limit if not specified in input file*/
    ,_maxLevLimitCrossTable= 300 /*default limit if not specified in input file*/
    ,_doSubset =Y              /*sample the input data?*/
    ,_compare=Y                /*compare between two data folders? */
);

```

SAS Dataset	Description
 _01_datalist.sas7bdat	Dataset level metadata including studyid, data standard (SDTM or ADaM), datasets, labels, filesize, number of observations, number of variables, number of subjects and CDISC class, e.g. Events, Interventions, Findings, BDS, Occurrence.
 _02_varlist.sas7bdat	Variable level metadata including variable level attributes, number of subjects, observations
 _03_valuelist.sas7bdat	Value level metadata including frequency counts per value
 _04_tablevalues.sas7bdat	Table of relationship values across variables, e.g. LBCAT*LBSCAT*LBTESTCD*LBTEST*LBORRESU*LBORRES

These datasets are converted to an intermediate Excel spreadsheet called *inMeta.xlsx*. The data from *inMeta.xlsx* is used by the dynamic Power Data Explorer spreadsheet template that includes pivot tables and filters that allow for easy point, click and filter to get a comprehensive overview of the data. It can easily be refreshed as you receive new data.

INPUT FILES

To produce the summary datasets as described above, three additional Excel templates are needed to generate the Power Data Explorer dynamic Excel file. These include two similar input templates for either SDTM or ADaM. For example, SummaryClass_SDTM_template.xls allows the user to identify key information such as study or studies and directory paths for comparisons. The input templates allow the user to specify which domains and variables to analyze as well as to restrict how many levels of that data to display. For example, there are variables for which there is no interest to see in the report, like --SEQ and --REFID. These selections are included in the SDTM/ADAM template in a standard, pattern-like manner to exclude from the valuelist summary. In a predefined sheet in the SDTM template the user will define excludedData=_all_ and excludedVar=--SEQ --REFID to exclude --SEQ and --REFID from all domains from the Valuelist summary. Note the use of dashes/hyphens as “wildcards.” This convention is used throughout the template.

Another predefined sheet in the template input file controls which cross-tabulations are to be generated, this is only set up one time upfront. A specification of --cat*--spec*--testcd*--test*--pos*--STRESU*--ORRESU may yield different cross-tabs across different domains of data. In case a domain does not have one or more of the specified variables, the cross-tab of those variables that do exist will be generated instead. For example, in the VS domain, the cross-tab would consist of VSTESTCD*VSTEST*VSPOS*VSSTRESU*VSORRESU will be generated since

VSCAT and VSSPEC do not exit, while in the LB domain there is no LBPOS and so LBCAT*LBSPEC*LBTESTCD*LBTEST*LBSTRESU*LBORRESU will be used.

studyID	dataStandard	inDir	Compare
StudyA	SDTM	&topdrv\studyA\Data_Prod\Metadata	compare
StudyA	SDTM	&topdrv\studyA\Data_Prod	
StudyB	SDTM	&topdrv\studyB\Data_Prod\Metadata	base
StudyB	SDTM	&topdrv\studyB\Data_Prod	

Data	types	var	idvar	where	formatVars	formats
all	visitnum*visitdy*visit*epoch*--tpnum*--tpt					
all	--cat*--scat*--sscat*--SPEC*--testcd*--test*--POS*--ORRESU*--STRESU*--stnrlo*--stnrhi					
all	--cat*--scat*--sscat*--testcd*--test*--STRESU*--STAT	--stresn	usubjid	--seq		
all	--cat*--scat*--sscat*--testcd*--test*--STRESU*visitnum*visitdy*visit*epoch*--STAT	--stresn	usubjid	--seq		
all	--cat*--scat*--sscat*--testcd*--test*--ORRESU*--ORRES				#RES #RESC #RESU	\$num2x. \$parenthesis.
all	RDOMAIN>IDVAR*QNAM*QLABEL*QORIG*QEQVAL					
dm	ARMCD*ARM*ACTARMCD*ACTARM SEX Race	age	usubjid		SEX	\$total.
AE MH CM	--CAT*--scat*--sscat*--OCCUR*--PRES					
EX	visitnum*visitdy*visit*epoch*--tpnum*--tpt --CAT*--SCAT*--SSCAT*--TRT*--DOSU*--DOSE--DOSFRM*--DOSFRQ*--ROUTE*--DOSADJ					
FA	--cat*--scat*--sscat*--testcd*--test*--OBJ*--ORRES*--STRESC				#RES #RESC	\$num2x.
IE	IECAT*IESCAT*IETESTCD*IETEST*IESTRESC					
all	#DTC				#DTC	\$num2x.
CD	CODELST*CODEVAL*RNK*DECOD			CODELST in ('ACN' 'ACT')		

The template files provide user flexibility to adapt to specific needs, however the majority of users choose to start with defaults. The third Excel template (output template) is the PowerDataExplorer_template.xls which includes six worksheets and into which data is imported from the intermediate *inMeta.xlsx* file. This template makes use of pivot tables and includes predefined slicers/filters to ease the exploration.

POWER DATA EXPLORER (PDE)

Once the summary data is imported into the PDE template spreadsheet, the user will rename the file to reflect the study and is now ready to explore all aspects of the data. The tool provides the ability to filter, subset, see differences between studies as well as changes between data cuts. It provides a very helpful tool when planning analysis specifications, pooling to see differences across trials, as well as changes, both expected and unexpected, to data between transfers. The PDE file includes six worksheets of which the primary ones are detailed below.

1_Data

The first tab provides an overview of the **data sets**, which includes the ability to compare multiple studies, a filter to select the CDISC class and a “Refresh Data” button to reload the summary file *inMeta.xlsx* after a new run of the PDE.SAS program that re-generates the summary data. Here, the user can see the differences in both the number of variables and number of subjects in a dataset. The pivot table shows horizontal, histogram-like bars overlaid atop the actual numbers allowing for a quick assessment of differences.

studyID	CLASSNM	Refresh Data
studyA	Events	
studyA-COMPARE ONLY	Findings	
studyA-DIF	Interventions	
studyB	Relationship	
	Special Purpose	
	Trial Design	

CLASSNM	MEMNAME	MEMLABEL	NVAR	NOBS	NSubject	FILESIZE	CRDATE	studyID
Events	TI		(blank)	(blank)	(blank)	(blank)	1/17/1960 23:06	studyA-DIF
	TS		(blank)	2	(blank)	(blank)	1/17/1960 23:06	studyA-DIF
	TV		(blank)	12	(blank)	(blank)	1/17/1960 23:06	studyA-DIF
	VALDEF		(blank)	6	(blank)	(blank)	1/16/1960 21:10	studyA-DIF
	VARDEF		(blank)	39	(blank)	16384	1/16/1960 21:10	studyA-DIF
	VS		(blank)	6414	218	6569984	1/17/1960 23:06	studyA-DIF
	AE	Adverse Events	35	311	74	540672	5/22/2015 10:19	studyB
				736	220	1228800	6/8/2015 9:25	studyA
	CE	Clinical Events	13	7	7	32768	6/8/2015 9:25	studyA
				8	7	32768	5/22/2015 10:19	studyB
	DS	Disposition	15	603	147	638976	5/22/2015 10:19	studyB
				1680	375	1753088	6/8/2015 9:25	studyA
	DV	Protocol Deviations	7	3	3	32768	6/8/2015 9:25	studyA
				7	7	32768	5/22/2015 10:19	studyB
	HO	Hospitalization	11	5	4	32768	5/22/2015 10:19	studyB
				7	6	32768	6/8/2015 9:25	studyA

2_Var

The next tab gives insight into **Variable-level** details including formats, code lists, number of observations, and number of subjects. When multiple cuts of data are summarized and compared, the user can quickly assess similarities and differences. This worksheet also provides the ability to filter by various CDISC classifications which allows for quick review of variable level metadata with click of a filter. The information updates quickly once the summarization has been created.

studyID	CLASSNM	MEMNAME	CORE	DERVCOPY	VARROLE	DATATYPE	UserExcludedFL...	Nlevel
studyA	Events	AE	Exp		Identifier	integer	x	1
studyA-DIF	Relationship	CD	Perm		Record Qualifier	text		2
studyB		CE	Req		Synonym Quali...			3
studyA-BASE ONLY	Findings	CM			Timing	float		4
studyA-COMPARE ONLY	Interventions	CO			Topic			5
	Special Purp...	COMPMETH			Variable Qualifier			6
								7
								15

MEMNAME	NAME	LABEL	TYPE	CODLIST	LENGTH	FORMA	Nlevel	VARNUM	NMiss	Nobs	NSubje	studyID
AE	AEACN	Action Taken with Study Treatment	char	ACN	20	\$20.	2	19	0	736	220	studyA
							4	19	0	311	74	studyB
	AEBDSYCD	Body System or Organ Class Code	num	MedDRA	8	8.	19	15	0	311	74	studyB
							22	15	0	736	220	studyA
	AEBODSYS	Body System or Organ Class	char	MedDRA	100	\$100.	19	14	0	311	74	studyB
							22	14	0	736	220	studyA
	AECONTRT	Concomitant or Additional Trtmt Give	char	NY	1	\$1.	2	28	0	311	74	studyB
										736	220	studyA
	AEDECOD	Dictionary-Derived Term	char	MedDRA	200	\$200.	146	8	0	311	74	studyB
							227	8	0	736	220	studyA

3_Value

The third tab of the spreadsheet provides insight into the **Value level** data, including frequency of values and comparisons between studies. User can select different domains as well as specific variables per domain, or subset based upon **_Nlevel** (number of distinct levels – where negative values are from the comparisons between studies). The PDE.SAS program allows the user to limit the number of variables displayed on this tab to those with an **_Nlevel** at or below a certain number. For example, if there are over 200 distinct values of AETERM or AEDECOD, those variables would not be displayed here. Displaying all those values are what our statistical outputs are for.

studyID	NAME	_Nlevel
studyA	ACTARM ACTAR... AEACN AECON... AEENDY AEENRF AELLT	(bl... -5 -4 -3 -2 -1
studyA - BASE ONLY	AEOUT AEREL AESCO... AESDIS... AESDTH AESER AESHOSP	1 2 3 4 5 6
studyA - COMPARE ONLY	AESLIFE AESMIE AESTDY AETOX... AGE AGEU ARM	7 8 9 10 11 12
studyA - DIF	ARMCD CEACN... CEENDY CESTDY CLASSN... CMCAT CMDOSE	13 14 15 16 17 18
studyB	CMDOS... CMDOS... CMDOSU CMDUR CMENDY CMENRF CMINDC	19 20 21 22 23 24

MEMNAME	NAME	_Nlevel	LEVEL	VALUE	studyID	Sum of _FREQ
AE	AEACN	(blank)	(blank)	DRUG INTERRUPTED	studyA - BASE ONLY	1
				DRUG WITHDRAWN	studyA - BASE ONLY	4
		-2	(blank)	DOSE NOT CHANGED	studyA - DIF	348
				NOT APPLICABLE	studyA - DIF	82
		2		1 DOSE NOT CHANGED	studyA	611
				2 NOT APPLICABLE	studyA	125
		4		1 DOSE NOT CHANGED	studyB	263
				2 DRUG INTERRUPTED	studyB	1
				3 DRUG WITHDRAWN	studyB	4
				4 NOT APPLICABLE	studyB	43
	AECONTPT	(blank)	(blank)	NI	studyA - DIF	314

4a_CrossTable and 4b_crossTableMinMax

The fourth and fifth tabs in the spreadsheet summarize the various **Cross Tables** the user set up in the SummaryClass spreadsheet. Recall above where we defined the cross tab --cat*--spec*--testcd*--test*--pos*--STRESU*--ORRESU. Filtering on the VS domain in the pivot table will show how particular vital signs are collected across all the studies being summarized. This is particularly helpful when it comes time to pool the data.

studyID	_classVarType
studyA	VISITNUM*VISIT*EPOCH*QSTPTNUM*QSTPT
studyA-COMPARE ONLY	VISITNUM*VISIT*EPOCH*RFTPTNUM*RFTPT
studyA-DIF	VISITNUM*VISIT*EPOCH*VSTPTNUM*VSTPT
studyB	VSDTC
studyA-BASE ONLY	VSTESTCD*VTEST*VSORRESU*VSORRES
	VSTESTCD*VTEST*VSPOS*VSORRESU*VSSTRESU
	VSTESTCD*VTEST*VSSTRESU

_classVarType	Sum of_FREQ	MEMNAME
VSTESTCD*VTEST*VSPOS*VSORRESU*VSSTRESU		VS
	classValue1	classValue2
	classValue3	classValue4
	classValue5	classValue6
	classValue7	classValue8
	classValue9	classValue10
	classValue11	classValue12
	classValue13	classValue14
	classValue15	classValue16
	classValue17	classValue18
	classValue19	classValue20
	classValue21	classValue22
	classValue23	classValue24
	classValue25	classValue26
	classValue27	classValue28
	classValue29	classValue30
	classValue31	classValue32
	classValue33	classValue34
	classValue35	classValue36
	classValue37	classValue38
	classValue39	classValue40
	classValue41	classValue42
	classValue43	classValue44
	classValue45	classValue46
	classValue47	classValue48
	classValue49	classValue50
	classValue51	classValue52
	classValue53	classValue54
	classValue55	classValue56
	classValue57	classValue58
	classValue59	classValue60
	classValue61	classValue62
	classValue63	classValue64
	classValue65	classValue66
	classValue67	classValue68
	classValue69	classValue70
	classValue71	classValue72
	classValue73	classValue74
	classValue75	classValue76
	classValue77	classValue78
	classValue79	classValue80
	classValue81	classValue82
	classValue83	classValue84
	classValue85	classValue86
	classValue87	classValue88
	classValue89	classValue90
	classValue91	classValue92
	classValue93	classValue94
	classValue95	classValue96
	classValue97	classValue98
	classValue99	classValue100

The PDE system also offers users some basic descriptive statistics on numeric variables by utilizing the cross-tab classification. For example, shown below is the summarization of LBSTRESN in the LB domain. This will not replace the statistical output we would prepare but it does offer the user a quick look at aggregate results as well as identifying outliers.

studyID	_classVarType	_VAR
studyA	LBCAT*LBSCAT*LBTESTCD*LBTEST*LBSTRESU*LBSTAT	LBSTRESN
studyA-BASE ONLY	ARMCD*ARM*ACTARMCD*ACTARM	AGE
studyA-COMPARE ONLY	DACAT*DATESTCD*DATEST*DASTRESU*DASTAT	DASTRESN
studyA-DIF	DACAT*DATESTCD*DATEST*DASTRESU*VISITNUM*VISIT*EPOCH*DASTAT	DPSTRESN
studyB	DPTESTCD*DPTEST*DPSTRESU	FASTRESN
	DPTESTCD*DPTEST*DPSTRESU*VISITNUM*VISIT*EPOCH	HUSTRESN
	FACAT*FASCAT*FATESTCD*FATEST*FASTRESU*FASTAT	PCSTRESN

classVarType	LBSCAT	LBSCAT*LBTESTCD*LBTEST*LBSTRESU*LBSTAT
classValue1	classValue2	classValue3
classValue4	classValue5	classValue6
classValue7	classValue8	classValue9
classValue10	classValue11	classValue12
classValue13	classValue14	classValue15
classValue16	classValue17	classValue18
classValue19	classValue20	classValue21
classValue22	classValue23	classValue24
classValue25	classValue26	classValue27
classValue28	classValue29	classValue30
classValue31	classValue32	classValue33
classValue34	classValue35	classValue36
classValue37	classValue38	classValue39
classValue40	classValue41	classValue42
classValue43	classValue44	classValue45
classValue46	classValue47	classValue48
classValue49	classValue50	classValue51
classValue52	classValue53	classValue54
classValue55	classValue56	classValue57
classValue58	classValue59	classValue60
classValue61	classValue62	classValue63
classValue64	classValue65	classValue66
classValue67	classValue68	classValue69
classValue70	classValue71	classValue72
classValue73	classValue74	classValue75
classValue76	classValue77	classValue78
classValue79	classValue80	classValue81
classValue82	classValue83	classValue84
classValue85	classValue86	classValue87
classValue88	classValue89	classValue90
classValue91	classValue92	classValue93
classValue94	classValue95	classValue96
classValue97	classValue98	classValue99
classValue100	classValue101	classValue102

Another feature in Cross Table summary in Excel Pivot Table is that we can easily select similar structured cross table for multiple variables and compare them across different domain. E.g. We can type 'visitnum*visit*EPOCH*' or

'DTC' to filter all the visit time points in hierarchy or all the DTC variable to see the values (or formatted values) and counts across all the involved domains.

studyID

studyA

studyA - BASE ONLY

studyA - COMPARE ON...

studyA - DIF

studyB

classVarType

VISITNUM-VISIT-EPOCH-HUTPTNUM-HUTPT

VISITNUM-VISIT-EPOCH-HUTPTNUM-HUTPT

VISITNUM-VISIT-EPOCH-HUTPTNUM-HUTPT

VISITNUM-VISIT-EPOCH-LBTPPTNUM-LBTPPT

VISITNUM-VISIT-EPOCH-LBTPPTNUM-LBTPPT

VISITNUM-VISIT-EPOCH-PCTPTNUM-PCTPT

VISITNUM-VISIT-EPOCH-PCTPTNUM-PCTPT

VISITNUM-VISIT-EPOCH-PETPTNUM-PETPT

VISITNUM-VISIT-EPOCH-PETPTNUM-PETPT

VISITNUM-VISIT-EPOCH-QSTPTNUM-QSTPT

VISITNUM-VISIT-EPOCH-QSTPTNUM-QSTPT

VISITNUM-VISIT-EPOCH-RFTPTNUM-RFTPT

VISITNUM-VISIT-EPOCH-RFTPTNUM-RFTPT

classVarType (Multiple Item)

Sum of_FREQ

classValue1

classValue2

classValue4

classValue5

studyID

MEMNAME

DP

EX

FA

GT

HU

II

LB

PC

PE

QS

MEMNAME

DA

DP

EX

FA

GT

HU

II

LB

PC

PE

QS

RF

VS

AE

CO

CE

CM

CO

DM

studyID

studyA

studyA - BASE ONLY

studyA - COMPARE ONLY

studyA - DIF

studyB

classVarType

RFDTC

RFDTC

RFCIDTC

RFPENDTC

RFPENDTC

RFXSTDT

RFXSTDT

RFXSTDT

RFXSTDT

classVarType (Multiple Items)

Sum of_FREQ

classValue1

studyID

AE

CE

CM

CO

DA

DM

DP

DS

EG

EX

FA

GT

HO

HU

II

LB

MEMNAME

AE

CE

CM

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DA

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DS

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EX

FA

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II

LB

studyA

studyA - BASE ONLY

studyA - DIF

studyB

studyA - COMPARE ONLY

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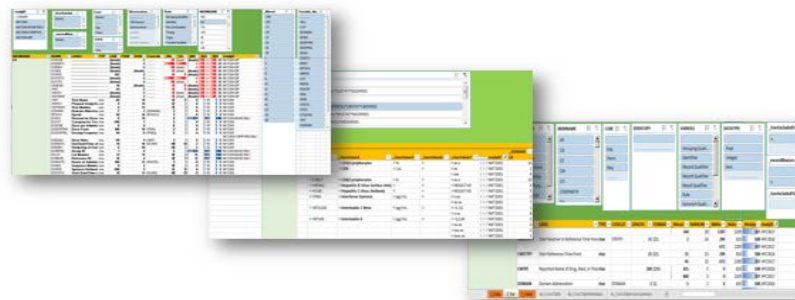
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CONCLUSION

This Power Data Explorer provides an all-in-one dynamic report that allows users to easily explore data providing instant filtering at the dataset, variable, value and relationship level through cross-tabulations. Benefits of the tool include ability to compare data cuts and differences across studies. This is especially helpful for planning integration efforts because it provides the ability to compare multiple studies easily allowing for more efficient planning and integration.



CONTACT INFORMATION

Special thanks to the Janssen Autocode team who contributed to the PowerDataExplorer tool *Ilse Augustyns, Nick Masel, Phyllis Wolf and Sandy Lei*. Your comments and questions are valued and encouraged. Contact the authors at:

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