

Automating Frequency Tables with ClinXport SAS Macro Package

Loizos Nicolaou¹, Julien Vanswinsberghe²

¹ClinBAY, Cyprus; ²ClinBAY, Belgium

¹loizos@clinbay.com; ²julien@clinbay.com

1. INTRODUCTION

- Progressive increase in standardisation of clinical data formats.
- Clinical data processing and analysis are becoming increasingly amenable to automation.
- ClinXport is a tool developed by ClinBAY, for streamlining statistical analysis and reporting of clinical trials.
- SAS Macro Package, REP_AEV, enables automation of frequency tables production within ClinXport, without writing a single line of SAS code.
- Similar methodology can be applied outside the ClinXport environment, to automate production of frequency tables and other TFLs.

2. CLINXPORT OVERVIEW

ClinXport consists of an add-in toolbar (Figure 1) in a Microsoft Excel interface and a SAS macro library. All reporting activities are managed within a single Excel workbook, which contains different sheets including DOMAIN (Figure 2), FORMATS (Figure 3) and TEMPLATE (Figure 4) sheets:

➤ ClinXport add-in toolbar

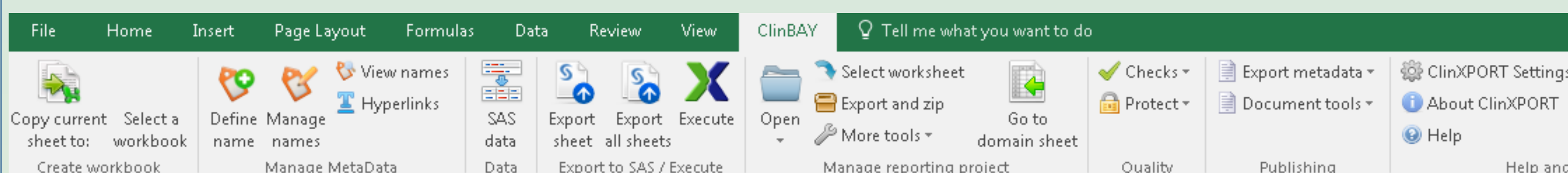


Figure 1: The ClinXport add-in toolbar provides several functionalities, such as defining meta-data, exporting data to SAS and executing SAS for generating outputs.

➤ DOMAIN sheet

Template Name	Output Type (Table, Listing, Figure)	Output number	Table title	Population	Output filename (without extension)	Dataset Name	Program Name (without .sas extension)
AET01	Table	11	Treatment emergent Adverse events, regardless of study treatment relationship	Safety analysis set	t1_01	ADAE	rep_aev
AET01	Table	12	Treatment emergent Adverse events related to study treatment	Safety analysis set	t1_02	ADAE	rep_aev

Figure 2: The DOMAIN sheet contains the list of outputs and associated output information.

➤ FORMATS sheet

	A	B	C	D	E
	Format name	Format type (VALUE, INVALUE, PICTURE)	Value type (num or char)	In Value	Out Value
56	TRTAN	value	char	01	Drug A
57				02	Drug B
58				999	Total
59	SEV	value	num	1	Mild
60				2	Moderate
61				3	Severe

Figure 3: The FORMATS sheet contains formatted values that can be applied to SAS variables.

3. REP_AEV MACRO OPTIONS

REP_AEV is a macro that allows the user to create complex frequency tables without using SAS Code. Macro-specific options stated below allow user to create frequency tables with user-desired specifications.

- ✓ **Cluster*i*:** Used to determine variables with dependent responses, forming part of cluster group *i*.
- ✓ **TotalT/TotalB:** Used to create total category rows/columns on top or bottom respectively for any variable.
- ✓ **Max/Min:** Can be applied to numeric variables and give the possibility of counting a subject with occurrences of an event in different grades in the maximum /minimum grade only.
- ✓ **{1, 2 ... n}:** Used to determine the numerical categories that can be reported in the table, even if no occurrences were observed for some of the numerical categories.

4. OPERATIONAL STEPS OF MACRO

Below is a summary of the operational steps of the macro, that can be applied in a similar manner in the user's reporting environment.

1. Import of SAS data and Excel metadata.
2. Data processing prior to counting frequencies, such as creating total groups.
3. Frequency count calculation using PROC SQL, taking into account max/min options.
4. Creation of report skeleton, adjusting for clustered variables and numerical unobserved categories that should be included in the report.
5. Merging of skeleton dataset (created in step 4) and dataset of frequency results (created in step 3) creates the final dataset, which will be subsequently used for reporting.
6. Production of frequency table using PROC REPORT.

5. GOING FURTHER

- SAS custom programs can be used for more complex tables.
- REP_AEV can be called in a SAS program, to enable performance of complex manipulations before and after execution of the macro.
- Programs are referenced in the Excel sheet and executed automatically.

➤ Template sheet

System organ class#	Severity	Drug A n (%)	Drug B n (%)	Total n (%)
Number of subjects with AEs	Mild Moderate Severe	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)
Cardiac disorders	Mild Moderate Severe	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)
Sinus bradycardia	Mild Moderate Severe	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)	xx (xx.x) xx (xx.x) xx (xx.x)

Figure 4: The Template sheet AET01, referenced in the DOMAIN sheet, that contains output-specific input information.



➤ Final Output

Demo study

Table 1.1 (Page 1 of 5)

Treatment emergent Adverse events, regardless of study treatment relationship
by system organ class, preferred term and maximum severity
Analysis Set : Safety analysis set

System organ class Preferred term	Severity	Drug A 10 mg N=22	Drug B 50 mg N=22	Total N=22
Number of subjects with AEs	Mild	0 (36.4)	6 (27.3)	11 (50.0)
	Moderate	2 (9.1)	1 (4.5)	2 (9.1)
	Severe	0	0	0
Blood And Lymphatic System Disorders	Mild	0	0	0
	Moderate	1 (4.5)	0	1 (4.5)
	Severe	0	0	0
Eosinophilia	Mild	0	0	0
	Moderate	1 (4.5)	0	1 (4.5)
	Severe	0	0	0
Gastrointestinal Disorders	Mild	2 (9.1)	2 (9.1)	3 (13.6)
	Moderate	0	0	0
	Severe	0	0	0
Abdominal Pain	Mild	0	1 (4.5)	1 (4.5)
	Moderate	0	0	0
	Severe	0	0	0
Dry Mouth	Mild	2 (9.1)	0	2 (9.1)
	Moderate	0	0	0
	Severe	0	0	0
Toothache	Mild	0	1 (4.5)	1 (4.5)
	Moderate	0	0	0
	Severe	0	0	0

Program: N:\Software\ClinXPORT\releases\v2\v2.2\SAS\BOM\compiled_x32\rep_aev.sas 02AUG2016:11:14

Figure 5: Adverse Event Frequency Table.

6. CONCLUSIONS

- Simplification of frequency table production.
- Easy to reuse or adapt templates.
- Availability of similar macros for standard TFLs.
- Similar method can be applied outside ClinXport environment.
- Contribution towards reducing time in clinical trial reporting.