

Diving deep in SAS® Macro World

*Adapting and developing SAS Macro tools
(for reporting and exploratory analysis of MedDRA coded
adverse events in clinical studies as MS Excel multi-tab
reports)*

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Background: The context

Modeled after reporting tool known as MAED – MedDRA-based Adverse Event Diagnostics

- *Initially developed and launched in 2009*
- *Based on existing SAS code (shared by the author)*
- *Designed for Regulatory authorities to display MedDRA coded AEs for Safety Signals using coding levels and Standardized MedDRA Queries (SMQs)*

Attempt to create and test SAS macro code for similar reporting output, structure and format that reproduces and expands the capabilities of the available MAED tool by

- **Producing multi-sheet Excel reports with common risk estimators for all treatment comparisons of interest**
- **Showing degree of disproportionality between treatments**

Content

- **Purpose:** Present and discuss examples of three powerful SAS Macro techniques used in this project, namely:
 - Various ways to create, validate and use of *macro lists*
 - Capturing and validating user input with *%WINDOW - %DISPLAY*
 - Examples of use of iterative (*%do-%end*) and conditional (*%if-%then-%else*) macro function logic: within DATA steps and PROC statements / in combination with other (regular) SAS keywords and statements

The Model Product (Reverse Engineering needed?)

re-verse en-gi-neer-ing noun
 the reproduction of another manufacturer's product following detailed examination of its construction or composition.

Table 2: AE MedDRA SMQs summary at narrow search

WARNING: THIS IS ONLY AN EXPLORATORY ANALYSIS!
 * after SMQ name indicates SMQ with narrow term only. Broad search will yield the same results.
 Number in parenthesis before SMQ name represents SMQ level.
 P-values should be used for ranking purposes only, not for determining statistical significance.

SMQ (Narrow Search)	STUDY DRUG (N = 166)			PLACEBO (N = 166)			RD (per hundred)	RD C.I. (lower bound)	RD C.I. (upper bound)	RR	STUDY DRUG vs. PLACEBO			P-value		
	Events	Number of subjects	Proportion (%)	Events	Number of subjects	Proportion (%)					(lower bound)	(upper bound)	OR		(lower bound)	(upper bound)
(1) Gastrointestinal nonspecific inflammation and dysfunction	120	57	34.34	75	41	24.7	9.64	-0.12	19.4	139	0.991	1.951	1.594	0.964	2.646	0.071
(2) Gastrointestinal nonspecific symptoms and therapeutic procedures	116	54	32.53	73	41	24.7	7.83	-1.86	17.52	1317	0.933	1.858	1.47	0.886	2.447	0.145
(1) Glaucoma	5	5	3.01	1	1	0.6	2.41	-0.44	5.26	5	0.59	42.337	5.124	0.562	243.801	0.214
(1) Dyslipidaemia *	12	12	7.23	6	6	3.61	3.61	-1.24	8.47	2	0.769	5.203	2.078	0.699	6.908	0.225
(1) Peripheral neuropathy	5	4	2.41	1	1	0.6	1.81	-0.81	4.42	4	0.452	35.411	4.074	0.396	201.829	0.371
(1) Haemodynamic oedema, effusions and fluid overload *	8	7	4.22	12	11	6.63	-2.41	-7.27	2.46	0.636	0.253	1.601	0.62	0.199	1.808	0.468
(1) Accidents and injuries	42	31	18.67	56	37	22.29	-3.61	-12.29	5.06	0.838	0.547	1.283	0.801	0.451	1.414	0.497
(1) Ischaemic heart disease	1	1	0.6	6	3	1.81	-1.2	-3.55	1.14	0.333	0.035	3.172	0.329	0.006	4.162	0.623
(1) Inflammation	4	4	2.41	2	2	1.2	1.2	-1.66	4.07	2	0.371	10.771	2.025	0.285	22.627	0.685
(2) Gastrointestinal nonspecific dysfunction	4	4	2.41	2	2	1.2	1.2	-1.66	4.07	2	0.371	10.771	2.025	0.285	22.627	0.685
(1) Malignancies *	5	5	3.01	3	3	1.81	1.2	-2.09	4.5	1.867	0.405	6.861	1.687	0.322	110.27	0.723
(1) Malignant or unspecified tumours *	5	5	3.01	3	3	1.81	1.2	-2.09	4.5	1.867	0.405	6.861	1.687	0.322	110.27	0.723
(1) Depression and suicide/self-injury	11	11	6.63	12	9	5.42	1.2	-3.91	6.32	1.222	0.52	2.872	1.238	0.452	3.48	0.818
(1) Cerebrovascular disorders	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(2) Central nervous system haemorrhages and cerebrovascular accidents	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(1) Ischaemic cerebrovascular conditions *	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(1) Acute central respiratory depression	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(1) Noninfectious meningitis	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(1) Ischaemic colitis	1	1	0.6	0	0	0	0.6	-0.57	1.78	3	0.123	73.114	3.018	0.122	74.624	1
(1) Hyperglycaemia/new onset diabetes mellitus	2	2	1.2	2	2	1.2	0	-2.35	2.35	1	0.143	7.015	1	0.072	13.948	1
(1) Angioedema	11	5	3.01	6	6	3.61	-0.6	-4.45	3.25	0.333	0.259	2.677	0.828	0.196	3.332	1
(1) Asthma/bronchospasm	2	2	1.2	5	3	1.81	-0.6	-3.22	2.02	0.667	0.113	3.938	0.683	0.055	5.87	1
(2) Suicide/self-injury *	0	0	0	0	0	0	-0.6	-1.78	0.57	0.333	0.014	8.124	0.331	0.013	8.192	1
(1) Extrapyrmidal syndrome	0	0	0	0	0	0	-0.6	-1.78	0.57	0.333	0.014	8.124	0.331	0.013	8.192	1
(2) Parkinson-like events	0	0	0	1	1	0.6	-0.6	-1.78	0.57	0.333	0.014	8.124	0.331	0.013	8.192	1
(1) Biliary disorders *	0	0	0	1	1	0.6	-0.6	-1.78	0.57	0.333	0.014	8.124	0.331	0.013	8.192	1
(2) Functional, inflammatory and gallstone related biliary disorders *	0	0	0	1	1	0.6	-0.6	-1.78	0.57	0.333	0.014	8.124	0.331	0.013	8.192	1

Sorted by P-value

Showing Narrow SMQ

ct_121_28aug12_1529.xls - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View JMP Acrobat

Clipboard Font Alignment Number Styles Cells Editing

WARNING: THIS IS ONLY AN EXPLORATORY ANALYSIS!
 Secondary preferred terms excluded.
 P-values should be used for ranking purposes only, not for determining statistical significance.

SOC	STUDY DRUG XR 400 MG QD (N = 295)			COMPARATOR DRUG 200 MG BID (N = 148)			RD (per hundred)	RD C.I. (lower bound)	RD C.I. (upper bound)	RR	STUDY DRUG vs. COMP	
	Events	Number of subjects	Proportion (%)	Events	Number of subjects	Proportion (%)					(lower bound)	(upper bound)
Gastrointestinal disorders	98	70	23.73	11	11	7.43	16.3	9.86	22.73	3.193	1.745	5
Injury, poisoning and procedural complications	34	31	10.51	5	5	3.38	7.13	2.58	11.68	3.111	1.235	7
General disorders and administration site conditions	41	35	11.86	9	9	6.08	5.78	0.45	11.12	1.951	0.964	3
Nervous system disorders	40	33	11.19	10	9	6.08	5.11	-0.16	10.37	1.84	0.904	3
Psychiatric disorders	34	31	10.51	8	8	5.41	5.1	0.05	10.15	1.944	0.917	4
Skin and subcutaneous tissue disorders	41	26	8.81	7	7	4.73	4.08	-0.62	8.79	1.863	0.828	4
Infections and infestations	162	108	36.61	76	49	33.11	3.5	-5.86	12.87	1.106	0.841	1

Sorted by Risk Difference (in this example)

Output from the available SAS MAED macros)

By SOC AE reports

Study X
All MedDRA Levels By Descending Incidence Rates
(MedDRA vXX-0)
SOC = General disorders and administration site conditions

System/Organ/Class High Level Group Term High Level Term Preferred Term	Treatment Group				p-Value*
	Tx 1	Tx 2	Tx 3	Total	
	(N=xx)	(N=xx)	(N=xx)	(N=xx)	
General disorders and administration site conditions (SOC)	72 (20.2%)	62 (14.9%)	62 (15.0%)	168 (14.7%)	0.5982
General system disorders NEC (HLGT)	60 (13.5%)	46 (11.1%)	46 (11.1%)	152 (12.2%)	0.2334
Pain and discomfort NEC (HLT)	38 (6.2%)	28 (6.7%)	30 (7.3%)	96 (7.7%)	0.3880
Chest pain (PT)	23 (5.2%)	16 (3.8%)	15 (3.6%)	54 (4.3%)	0.3353
Non-cardiac chest pain (PT)	16 (3.9%)	12 (2.2%)	14 (3.7%)	42 (3.9%)	0.7408
Chest discomfort (PT)	3 (0.7%)	3 (0.7%)	13 (1.7%)	9 (0.7%)	1.0000
Axillary pain (PT)	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0.3283

By p-value AE reports

Study X
Preferred Terms by p-Value

p-Value*	Preferred Term (MedDRA vXX-0)	Treatment Group		
		Tx 1 (N=xx)	Tx 2 (N=xx)	Tx 3 (N=xx)
0.0196	PARAESTHESIA	7 (2.7%)	3 (0.8%)	2 (0.5%)
0.0290	VASCULAR STENT RESTENOSIS	1 (0.4%)	0 (0.0%)	7 (1.1%)
0.0435	HEADACHE	9 (2.0%)	16 (3.8%)	5 (1.2%)

p-Value*	Standardized MedDRA Query (MedDRA Version YY.0)	Treatment Group		
		Tx 1 (N=xx)	Tx 2 (N=xx)	Tx 3 (N=xx)
0.0176	Shock (SMQ)	8 (2.9%)	0 (0.0%)	4 (1.5%)
0.0451	Haemorrhage terms (excl laboratory terms) (SMQ)	33 (8.0%)	35 (8.0%)	52 (15.6%)
0.0497	Respiratory failure (SMQ)	3 (0.7%)	0 (0.0%)	0 (0.0%)

Prerequisites, Features and Requirements

Original MAED programs create two types of AE reports:

- PDF/RTF reports *grouped by MedDRA term / SMQ and sorted by a single test statistic (Chi-squared test p-value, "By p-value" report)*
- *MedDRA AE terms hierarchically grouped within their SOC ("all in one" report)*
- Generates the pre-processing SAS code from HTML user interface

Both original and updated MAED tools have assumptions and requirements pertaining to

- *Location for input and output sets (report)*
- *Uniform locations (subfolders) and naming conventions for MedDRA versions*
- *Global macro variables allow input for some flexibility*
- *Every AE or SMQ is processed as 2 x 2 table (comparison) – proc FREQ / TABLES with several statistical test options is used*
- *Standard formats and names of the core time and Tx variables (ADaM data)*
- *Analysis data sets from the study (main inputs):*

*ADAE data set (Analysis Data Set for Adverse Events) and
ADSL data set (Analysis Data Set for Subject Level)*

Idea and Strategy: Steps to solve the multi-sheet reporting task

- **STEP 1: Prepare the data:** Declare global macro variables, subset the ADSL as 2 x 2 comparison sets of interest for the study, clean up blanks, missing data, subset on SAE or other conditions - if needed, define the order of *Active vs Comparator* arm
- **STEP 2: Receive and manage user input:** Type of AE report to be created (format, full report versus a single or a subset of all Tx comparisons of interest, define custom rules, etc.)
- **STEP 3: Run iteratively the original MAED macros** for each of the selected 2 x 2 Tx subsets
- **STEP 4: Rename / Index all columns** of the output sets with statistics so they can be merged by **MedDRA (AE) level term** or by **SMQ** (Narrow and Broad scope)
- **STEP 5: Check for and clean up duplicate columns** for event and subject count data in the combined sets
- **STEP 6: Produce the whole multi-tab report** (proc REPORT and ODS EXCEL join forces here)

STEP 1: Get your data ready for input

Subset in series of data steps like these – depending on needs and interest

```
/* Define the input AE data, as well as the desired TX subsets of interest. */  
/* Those should represent 2-arm sets - they will have to be processed as 2 x 2 tables by MAED macros; */
```

```
data ae;  
  set aedata.adae;  
  where SAFFL='Y' and TRTEMFL='Y';  
data dm_nsf;  
  
  set dmdata.adsl;  
  if left(put(&trt,8.)) in('.',') then  
    do;  
      put 'NOTE: Missing treatment code-- deleting: ' &usubjid= &trt= ;  
      delete;  
    end;  
  if (&trt ne 'SCRNFAIL') then do;  
    output dm_nsf;  
  if (&trt eq 'Tx_1') or (&trt eq 'Tx_2') then do;  
    &trt = 'Tx_1_2';  
    output dm_nsf;  
  end;  
end;  
where SAFFL='Y';  
run;  


---

  
%let poplist=;  
%let poplist=dm_Tx1_p dm_Tx2_p dm_Tx2_Tx1 dm_active_p;  


---

  
data &poplist;  
  holdtrt = &trt;  
  if holdtrt in ('Tx_1', 'PLACEBO') then  
    do;  
      ** Append "A_" for Test or "P_", "B_", etc. for Ref based on TRT value;  
      if (holdtrt eq 'Tx_1') then &trt = "A_"||holdtrt;  
      else if (holdtrt eq 'PLACEBO') then &trt = "P_"||holdtrt;  
      output dm_Tx1_p;  
    end; /* ... and so on! */  


---

  
data dm_active_p;  
  set dm_active_p;  
  if &trtdesc in ("Tx dosage 1", "Tx dosage 2") then &trtdesc="Tx dos1+dos2";  
run;
```


STEP 1: Get your data ready for input (next)

Declare global macro variables and paths, set MedDRA /SMQ versions, load (compile) the macros

```
*----- Set the path for the output files -----*;
%let outputpath=H:\My Documents\MedDRA\data_studyx\output;
*----- Specify the MedDRA version in X.X format -----*;
%let meddraver=19.0;
%let smqversion=22.0;
*----- Specify the main variable names -----*;
%let usubjid=USUBJID; * the patient ID variable name;
%let trt=ACTARMCD; * the coded treatment group variable name;
%let trtdesc=ACTARM; * the de-coded treatment group variable name (contains the descriptive name);
%let aeterm=AEDECOD; * the preferred term variable name;
%let repterm=AETERM; * the reported adverse event term;
%let bodsys=AEBODSYS; * the bodysystem or system/organ/class variable name;

options notes nofmterr nodate mprint mlogic symbolgen;
ods escapechar= '^' ;
%global meddraroot;
%let meddraroot=H:\My Documents\MedDRA\;
%let mac_root=H:\My Documents\MedDRA\programs\;
```

... Followed by *%include* and *libname* statements for input and output sets

STEP 2: Manage User Input, as

- Use of *%window* and *%display* features (works in SAS for Windows only)
- Specify the desired number of Tx comparison sets
- Validates the input – checks for misspelled / invalid Tx filenames
- Lists *&badnames* (if any) and gives warning if needed

STEP 2: Manage the User Input

- **%WINDOW** can offer special formatting based on selection rule(s) for rows or cells

```
%window Highlight
#5 @5 'Highlight AEs/SMQs with low Fisher right-sided p-values'
#7 @10 '( <0.050, blue on light pink, large font) or RR>=2.5 (blue on light yellow, large font)
#9 @15 'This output is effective with PDF and MS Excel Workbook formats only'
#11 @20 'Please enter Yes to accept; No, blank, or any string to reject/move on:'
#13 @25 input 7 attr=underline;
%display Highlight;
```

Later in the sequence this can trigger a **COMPUTE / CALL DEFINE** block in **proc REPORT** with **%if-%then-%do-%end** macro function logic ...

```
%if &input=%sysfunc(trim(Yes)) or &input=%upcase(Yes) %then %do;

compute %sysfunc(trim(&cols&y_.p_e));
  if . ne %sysfunc(trim(&cols&y_.p_e)) < 0.050 then
    call define(_col_, "style/replace", "style=[backgroundcolor=mistyrose color=blue fontstyle=italic fontsize=6]");
endcomp;
compute %sysfunc(trim(&cols&y_.p_rr));
  if %sysfunc(trim(&cols&y_.p_rr)) ge 2.50 then
    call define(_col_, "style/replace", "style=[backgroundcolor=lightyellow color=blue fontstyle=italic fontsize=6]");
endcomp;

%end;
```

STEP 3: Run iteratively the `%aefreq` and some other macros

- `%AEFREQ` creates Tx comparison sets with aggregated subject and event counts, plus exploratory statistics (*Fisher's exact test p-value, RD and RR with 95 % confidence bounds*) by MedDRA level term (PT, HLT, HLGTT and SOC) and by SMQ (Narrow and Broad scope)

```
data _null_;
  %do j=1 %to %eval(&items);
  %let popset&j=%scan(&goodlist, &j); %put &&popset&j;

  %AEFREQ(aeset=ae, popset=&popset&j, aeterm=&aeterm, trt=&trt, trtdesc=&trtdesc, usubjid=&usubjid, outset=pt&j, stratvar=&stratvar,
  pflag=1, stat=&stat, pname_e=&pname_e, pname_rd=&pname_rd, pname1=&pname1, pname2=&pname2, pname_rr=&pname_rr, pname3=&pname3, pname4=&pname4);
  /* .... More code here ..... */
  %end;
run;
```

STEP 4: Rename and index all sets and columns

4.1 Reads the sets produced by %aefreq macro → Renames all variables (appends the set name to each variable name) except for the AE level term name (variable)

```
%let popset&j=%scan(&goodlist, &j);
%let dsid=%sysfunc(open(&&set&j, i));
%let varlist=;
data copy&&set&j;
  length sheetlabel $30.;
  set &&set&j;
  sheetlabel=trim(uppercase("&lib"||" "||"Name"));
  if find(sheetlabel, '1', 'i') ge 1 then sheetlabel='SMQ - Broad Scope';
  else if find(sheetlabel, '2', 'i') ge 1 then sheetlabel='SMQ - Narrow Scope';

  %do i=1 %to %sysfunc(attrn(&dsid, nvars));
    %let varlist=&varlist %sysfunc(varname(&dsid, &i));
    %let varname&i=%sysfunc(varname(&dsid, &i));
    %if &&varname&i=variable %then %do;
      rename &&varname&i = &&varname&i; %end;
    %else %do;
      rename &&varname&i = &&set&j&&varname&i;
    %end;
    %put &&varname&i;
  %end;
  %put varlist=&varlist;
run;
```

Builds macro lists of the column names iteratively (log check)

STEP 4: ... Then merge (Continued)

4.2 **Creates and assigns** event and subject count sum labels for each Tx arm in the “copy” sets →

```
%do _i=1 %to %eval(&n_labs);  
  %global events&_i&lib&j;  
  proc sql;  
    select sum(&set&j..e&_i) into :events&_i&lib&j  
    from copy&set&j;  
    alter table copy&set&j modify &set&j..e&_i  
    label="&tx&j._c&_i, |Event |Counts |=%left(&events&_i&lib&j)";  
  ;
```

Number of unique Tx labels in the subset

→ 4.3 **Builds a macro list** of the renamed (“copy”) sets to be passed to a MERGE statement in subsequent DATA step

```
/* ... preceeded by other code here ... */  
  %let name&j=copy&set&j;  
  %let mergelist=&mergelist %trim(&name&j);  
  %let dsid=%sysfunc(close(&items));  
  %put &mergelist;  
%end;
```

```
data big&lib;  
  merge &mergelist;  
  by sheetlabel variable;  
run;
```

To become a sheet for each MedDRA level term or SMQ

STEP 4: Rename and index all sets and columns, then merge (Last)

→ 4.4 Replace missing values of subject and event counts in the combined dataset (MedDRA level term / SMQ) with zeros:

```
data big&lib;
  set big&lib;
  by sheetlabel variable;
  %do y=1 %to %eval(&items);
    array events_&y{*} %sysfunc(trim(&lib&y.el))-%sysfunc(trim(&lib&y.e&n_arm)) _n
    array counts_&y{*} %sysfunc(trim(&lib&y.nl))-%sysfunc(trim(&lib&y.n&n_arm)) _n
    /* ... some other code here ... */
    do i=1 to &n_arm;
      if events_&y[i] =. then events_&y[i]=0;
      if counts_&y[i] =. then counts_&y[i]=0;
      /* ... other statements here ... */
    end;
  drop i;
%end;
run;
```

STEP 5: Check for and remove duplicate count columns from the combined sets

- After merging the Tx comparison sets there will almost always be *duplication of some subject and event count columns in the combined (MedDRA level term / SMQ sets)*
- Duplicates should be removed

5.1 Collect info about all columns in the combined datasets



```
proc contents data=big&lib out=varinfo; run;
```

→ 5.2 Extract subject / event count variables section (where duplicates may appear)

```
proc sql; ** all_counts lists variables and labels of the count columns (Active and Comparator);  
create table all_counts as  
select distinct name, label  
from varinfo  
where (name like '%c1' or name like '%e1'  
or name like '%c2' or name like '%e2');
```

→ Holds unique column label information from the combined count data

→ 1 indicates *Active* (left), 2 - *Comparator* (right) for subject (c) and event (e) counts respectively

STEP 5: Check for and remove duplicate count columns in the merged sets (Next)

5.3 Creates Tx identifiers in a data step (not shown) and removes duplicates

```
proc sort data=all_counts out=nodupcnts nodupkey; by label; run;
proc sort data=nodupcnts; by type id tx_id; run;
```



nodupcnts will list the unique subject and event counts for each Tx in the final, cleaned set (Excel sheet).

	Treatment 1			Treatment 2		
Preferred Term (MedDRA vXX-0)	Tx 1, Subjects w/Event (N=xx)	Tx 1 Proportion, Subj. w/Event(%)	Tx 1, Event Counts =YY	Tx 2, Subjects w/Event (N=xx)	Tx 2, Proportion, Subj. w/Event(%)	Tx 2, Event Counts =YY
PULPITIS DENTAL	0	0.00	0	1	0.24	1
PUNCTURE SITE PAIN	0	0.00	0	0	0.00	0
PYREXIA	5	1.20	5	1	0.24	1
PYURIA	0	0.00	0	0	0.00	0
RADICULOPATHY	0	0.00	0	1	0.24	1
RASH	2	0.48	3	6	1.44	6
RASH GENERALISED	0	0.00	0	1	0.24	1
RASH MACULO-PAPULAR	0	0.00	0	1	0.24	1
RASH PRURITIC	1	0.24	1	0	0.00	0
RECTAL HAEMORRHAGE	0	0.00	0	0	0.00	0
RECTAL POLYP	0	0.00	0	0	0.00	0
RED BLOOD CELLS URINE POSITIVE	1	0.24	1	0	0.00	0

STEP 5: Reconstruct the combined sets (ready for Excel report sheets)

5.4 Using ordered lists of the remaining, non-duplicate *Active* and *Comparator* count columns

```
proc sql;  
  select name  
  into :tx_cols separated by ' '  
  from nodupcnts  
  ;  
  select name  
  into :stat_cols separated by ', '  
  from all_stats  
  ;  
  select name  
  into :tx_cols_sql separated by ', '  
  from nodupcnts  
  ;  
  create table dist counts as  
  select sheetlabel, variable, &tx_cols_sql  
  from big&lib  
  ;  
quit;
```

*Passed to the next proc SQL /
SELECT query*

*Final, ordered, non-duplicate count section of the report sheet – to be
re-merged with the test statistics block*

STEP 5: Re-identify the remaining, non-duplicate count columns

5.5 ... Last!: The non-duplicate count columns need to be re-indexed / re-identified again ...

WHY?: To force proc REPORT to map and output exactly this arrangement of the count/proportion section

HOW?: Use *proc DATASETS with MODIFY / RENAME statements + %do-%end macro loop processing inside*

```
proc datasets library=work nolist;
  modify dist_counts;
  rename
    %do i=1 %to %eval(&arm_cnt);
      %let var&i=%scan(&tx_cols, &i);
      %let vartype&i=%substr(&&var&i, %length(&&var&i));
      %let arm_type&i=%substr(&&var&i, %length(&&var&i)-1);

      %if &&vartype&i=1 %then
        %do;
          &&var&i = &lib._act_&unquote(&&tx_id_num&i)_&&arm_type&i
          %put &&var&i;
        %end;
      %else %if &&vartype&i=2 %then
        %do;
          &&var&i = &lib._comp_&unquote(&&tx_id_num&i)_&&arm_type&i
          %put &&var&i;
        %end;
    %end;
;
quit;
```

Active Tx count columns

Comparator Tx count columns

STEP 6: Produce the multi-tab Excel report

Ordered, non-duplicate count, combined sets (MedDRA term level / SMQ) will be passed to proc REPORT

```
/* Merge again the COUNT and STAT sets to get the
whole AE/SMQ term data ready for reporting */
data reportset_&lib.;
  merge dist_counts test_stats;
  by sheetlabel variable;
run;

%mend nodup_counts;
```

The reporting macro (`%excel_report3`) is called iteratively – through a list of MedDRA term level / SMQ combined sets

```
%global libnames filecount items libcount;
%let libnames=pt hlt hlgt soc smql smq2;
```

```
%let items=%sysfunc(countw(&goodlist)); %put &items;
%let libcount=%sysfunc(countw(&libnames)); %put &libcount;
%let meddraver=%sysfunc(tranwrd(&meddraver,.,-));
%let smqversion=%sysfunc(tranwrd(&smqversion,.,-));
%let meddratext=(MedDRA v&meddraver)
```

```
%do l=1 %to %eval(&libcount);
```

```
  %let libref&l=%scan(&libnames, &l, ' ');
  %let dataset&l=reportset_&libref&l;
```

```
/* ... other macro assignments and statements (SQL queries) in the inner loop
creating tab headers, titles and some labels ... */
```

```
%send;
```

```
;
```

```
%excel_report3(dataset=&dataset&l, cols=&col_id&l, title=&title&l,
collhead=&collhead&l, smqversion=&smqversion);
```

```
%send;
```

```
ods excel close;
ods listing;
```

```
proc datasets lib=work memtype=data;
```

```
  delete big: copy: __: pt: hlt: hlgt: soc: smq: smql: smq2: ; run; quit;
```

```
%mend XLS_report3;
```

STEP 6: The multi-tab Excel report

ODS EXCEL with options controls for the overall structure of the workbook, *i.e.* tabs (by groups / MedDRA level term sheets), embedded titles, auto filter (dropdown menus), frozen headers, etc.

```
ods listing close;
ods excel file="&outfile" options(sheet_interval="bygroup"
suppress_bylines="yes" sheet_name="#byvall" frozen_headers='yes' embedded_titles="yes"
embed_titles_once="yes" embedded_footnotes='yes' tab_color='yellow' autofilter='all' zoom='75');
ods escapechar='^';
```

Proc REPORT does the rest

													SECTION 3: TEST STATISTICS FOR ALL PAIRS						
SECTION 2: ACTIVE (colored) and COMPARATOR (Grey) SUBJECT and EVENT COUNTS, RATES													Treatment Comparison: 1						
SECTION 1: MedDRA Item	Tx 1			Tx 2			Tx 1+2			Tx 3			Tx 1 vs Tx 3						
System/Organ/Class (MedDRA vXX-0)	Tx 1, Subjects w/Event (N=xx)	Tx 1 Proporti on, Subj. w/Event(%)	Tx 1, Event Counts =yy	Tx 2, Subjects w/Event (N=xx)	Tx 2, Proporti on, Subj. w/Event(%)	Tx 2, Event Counts =yy	Tx 1+2, Subjects w/Event (N=xx)	Tx 1+2, Proporti on, Subj. w/Event(%)	Tx 1+2, Event Counts =yy	Tx 3, Subjects w/Event (N=xx)	Tx 3, Proporti on, Subj. w/Event(%)	Tx 3, Event Counts =yy	Fisher's right- sided p-value *	Risk Differen ce, %	Lower CI Bound, RD, % *	Upper CI Bound, RD, % *	Relative Risk	Lower CI Bound, RR *	Upper CI Bound, RR *
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.00	0	1	0.24	1	1	0.12	1	1	0.24	1	1.000	-0.242	-0.716	0.232	0.000	.	.
EAR AND LABYRINTH DISORDERS	2	0.48	2	7	1.68	7	9	1.08	9	6	1.21	6	0.939	-0.729	-1.976	0.519	0.398	0.078	2.040
ENDOCRINE DISORDERS	1	0.24	1	1	0.24	1	2	0.24	2	5	0.97	5	0.970	-0.728	-1.783	0.328	0.249	0.028	2.217
EYE DISORDERS	3	0.72	3	6	1.44	10	10	1.08	13	5	0.97	6	0.776	-0.246	-1.493	1.002	0.746	0.168	3.314
GASTROINTESTINAL DISORDERS	42	10.12	61	45	10.10	67	84	10.11	128	46	11.14	68	0.722	-1.018	-5.216	3.181	0.909	0.612	1.349
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	90	20.24	122	62	14.90	92	146	17.57	214	62	15.01	92	0.030	5.229	0.051	10.407	1.348	1.000	1.817
HEPATOBIILIARY DISORDERS	6	1.45	7	0	0.00	0	6	0.72	7	6	1.21	6	0.503	0.235	-1.324	1.794	1.194	0.367	3.882
IMMUNE SYSTEM DISORDERS	2	0.48	2	2	0.48	2	4	0.48	4	0	0.00	0	0.251	0.482	-0.184	1.148	1	.	.
INFECTIONS AND INFESTATIONS	47	11.33	61	39	9.38	49	86	10.35	110	38	9.20	42	0.186	2.124	-2.007	6.256	1.231	0.821	1.846
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	20	4.34	25	18	4.09	30	35	4.21	55	24	5.81	27	0.870	-1.474	-4.462	1.515	0.746	0.411	1.354

STEP 6: Inside PROC REPORT: Managing Grouping and Common (MedDRA term) columns

Define the common *part* once (MedDRA term / SMQ)

```
%if &smq by^= %then %do;
  column sheetlabel variable pt_cnt pt_name;
  define variable / group "&collhead" flow style(column)={width=2in font_weight=bold font_style=italic} left;
  define pt_cnt / order style(column)={width=0.6in font_weight=bold font_style=italic} center;
    %end;
  %else %do;
  column sheetlabel variable;
  define variable /display "&collhead" flow width=30 left;
    %end;
  by sheetlabel;
  define sheetlabel / group noprint;
```

STEP 6: Inside PROC REPORT: Setting Count and Proportion columns

Displaying the non-duplicate *Count and Proportion* columns. Switches between styles / formats and iterates through colors depending on the type of Tx arm (*Active vs Comparator*)

```
%do _j_ = 1 %to %eval(&act_pairs);
* Shows all Active TX (subject and AE counts) columns: Block #2;
column ("&&tx_label&j_" %sysfunc(trim(&cols._act_&j_.c1)) %sysfunc(trim(&cols._act_&j_.e1)));
%let color&j_=%scan(&color_list, &j_, ' ');
%let style1=style(column)=[width=0.8in color=black backgroundcolor=&color&j_ font_weight=bold
                          borderrightcolor=red borderrightwidth=4]
                          style(header)=[width=1.4in height=1.2in color=red backgroundcolor=aliceblue font_weight=bold];
define %sysfunc(trim(&cols._act_&j_.c1)) / display &style1 center;

%if &smq_by^= %then %do;
  define %sysfunc(trim(&cols._act_&j_.e1)) / analysis sum &style1 center;
  %end;
  %else %do;
    define %sysfunc(trim(&cols._act_&j_.e1)) / display &style1 center;
  %end;
%end;

%do k=%eval(&start_comp_pairs) %to %eval(&all_pairs);
* Shows Comparator/Placebo subject and AE count columns: Block #2;
column ("&&tx_label&k" %sysfunc(trim(&cols._comp_&k_.c2)) %sysfunc(trim(&cols._comp_&k_.e2)));
define %sysfunc(trim(&cols._comp_&k_.c2)) / display &style2 center;

%if &smq_by^= %then %do;
  define %sysfunc(trim(&cols._comp_&k_.e2)) / analysis sum &style2 center;
  %end;
  %else %do;
    define %sysfunc(trim(&cols._comp_&k_.e2)) / display &style2 center;
  %end;
%end;
```


STEP 6: Inside PROC REPORT: Test Statistics Section

Block with test statistics for all *selected pairs (Tx comparison sets)*

```
%do _y_=1 %to %eval(&items);
    column ("&trtlabel.: &_y_" ("&&tx&_y_._cl vs &&tx&_y_._c&n_arm"
        %sysfunc(trim(&cols&_y_.p_e)) %sysfunc(trim(&cols&_y_.p_rd))
        %sysfunc(trim(&cols&_y_.p_l)) %sysfunc(trim(&cols&_y_.p_2))
        %sysfunc(trim(&cols&_y_.p_rr)) %sysfunc(trim(&cols&_y_.p_3))
        %sysfunc(trim(&cols&_y_.p_4)))));
;
    define %sysfunc(trim(&cols&_y_.p_e)) /display order=internal f=5.2
        "Fisher's |right-sided |p-value *" style(header)=[color=red
        backgroundcolor=yellow] style(column)=[width=0.8in font_weight=bold
        borderrightcolor=green borderrightwidth=3] format=5.3 center;

    /* ... MORE DEFINE statements here ... */
;
    compute %sysfunc(trim(&cols&_y_.p_rd));
        %sysfunc(trim(&cols&_y_.p_rd)) = %sysfunc(trim(&cols&_y_.p_rd))*100;
    endcomp;

    /* ... TWO MORE COMPUTE blocks here ... */

    %if &input=%sysfunc(trim(Yes)) or &input=%upcase(Yes) %then %do;

        /* COMPUTE blocks with conditional formatting (CALL DEFINE) from macro
        user input - as seen earlier ... */

;
    %end;
%end;
```


Use of UNNAMED PIPE: FILENAME + PIPE + CALL SYMPUT in a DATA step

Other ways to list and store file names as macro variables?

```
filename pipedir pipe "dir ""%unquote(&dir)"" /b" lrecl=32767;
data _null_;
  infile pipedir trunccover; input popname $char1000.;
  popname=scan(popname, 1); count = left(put(_n_,6.));
  call symput('popset' || count, popname);
  call symput('filecount', count);
  put popname=;
run;
filename pipedir clear;
```

Number of files found – stored as global macro variable

Global, indexed macro variables holding the names of the files in the directory

Location (path) of the sets

Use of DICTONNARIES / PROC SQL

```
proc sql noprint;
  select distinct memname, count (distinct memname)
  into :set1-:set999, :setnum
  from dictionary.columns
  where libname=upcase("&lib");
quit;
```

Final Notes

Thank You + Questions?

- **What this IS NOT about?:**
 - Presenting and discussing the original SAS macro code
 - Claiming a genuinely new reporting tool was created
- **Then, what this IS about?:**
 - Sharing my SAS learning and programming experience with using common but powerful macro tools and functions in the context of this project
 - Hoping to demonstrate that “*Learning-by-Doing*” really works

Resources and Paper References

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- ***A General-Purpose Macro to Obtain a List of Files: Plus Macro Programming Techniques*** Mel Widawski, UCLA, Los Angeles, California