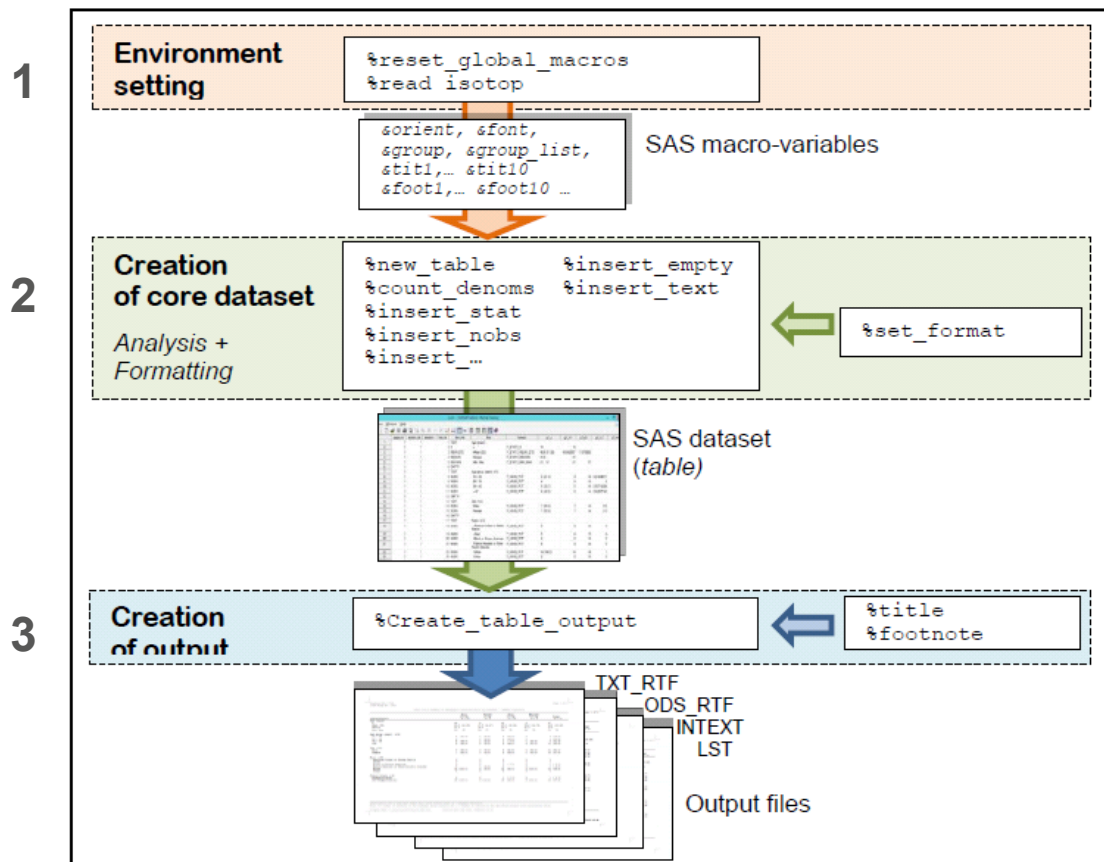


# Background

## ICON's DIAMOND:

- Statistical **Tables and Listings** generation
- Set of modular **SAS® macro-functions** created and used by ICON statistical programmers since 2009
- DIAMOND macro-functions work like building blocks, and when **logically grouped together**, supports each step of output development:
  - Environment setting
  - Creation of a core dataset with the statistical analysis
  - Creation of output

# Process



Note: A list of all current DIAMOND macros and their functionalities is given in the Appendix of the paper.

# Brief Example as Introduction

1

```
*** Environment setting ***;
```

```
%reset_global_macros;
```

```
%let rep = T_example;
```

```
%read_isotop;
```

```
%let group = TRTA;
```

```
%let group_list = A@B;
```

```
&denom_1.
```

```
&denom_2.
```

```
...
```

```
&denom_t.
```

2

```
*** Creation of core dataset (table) ***;
```

```
%new_table
```

```
%count_denoms(DS=dataset, WHR= SAFFL eq 'Y');
```

```
%insert_nobs(DS=dataset, TX='Safety Set', WHR=SAFFL eq 'Y', pct=0);
```

```
%insert_empty;
```

```
%insert_nobs(DS=dataset, TX='Lead-in Safety Set', WHR=SAF01FL eq 'Y');
```

3

```
*** Creation of output ***;
```

```
%create_table_output(
```

```
    line_width          = 60
```

```
    ,group_width        = 16
```

```
    ,line_header_txt    = 'Population'
```

```
    ,group_denom_in_header = 1
```

```
);
```

SAS - [VIEWTABLE: Work.Table]

|   | line_nb | line_info | line               | format       | g1_c      | g1_n1 | g1_n2 |
|---|---------|-----------|--------------------|--------------|-----------|-------|-------|
| 1 | 1       | NOBS      | Safety Set         | F_NOBS_NOPCT | 31        | 31    | 31    |
| 2 | 2       | EMPTY     |                    |              |           |       |       |
| 3 | 3       | NOBS      | Lead-in Safety Set | F_NOBS_PCT   | 28 (90.3) | 28    | 31    |

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Table 9 - Baseline Demographics

| Population         | A<br>(N = 31) | B<br>(N = 7) |
|--------------------|---------------|--------------|
| Safety Set         | 31            | 7            |
| Lead-in Safety Set | 28 (90.3)     | 4 (57.1)     |



- Study level
- Report level
- Titles/Footnotes

# Environment setting (1/3)

## Study level

Macro-variables are:

1. **Initialized** to default value  
at start of a session
2. Called at each start of report  
program to **re-set to default  
value**

```
%reset_global_macros(  
  def_group      = TRTA,      /*report-level*/  
  def_group_list = A@B,  
  def_totals     = 0,  
  def_subjno     = USUBJID,  
  
  def_page_format= A4,        /*pagination*/  
  def_orient     = LS,  
  def_font       = 0,  
  def_fontsize   = 8,  
  def_LS_ls      = 151,  
  def_LS_ps      = 52,  
  def_LS_marginT = 2 cm,  
  def_LS_marginB = 2 cm,  
  def_LS_marginL = 2 cm,  
  def_LS_marginR = 2 cm,  
  
  def_tit_ver     =ICON,      /*layout*/  
  def_foot_ver    =ICON,  
  def_layout_center=nocenter,  
  
  def_folder_structure = ICON,      /*folder, file*/  
  def_output_path      = &path\dev\programs,  
  def_automatic_log     = 0,  
  def_automatic_log_check = 0  
);
```

## Environment setting (2/3)

### Report level

**Macro-variables** are given with:

|                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <code>%let rep=name_of_output;</code>                                            | To specify the name of the output file                                                                                                                                                                                                                                                                                                                                                                         |
| <code>%let group=variable;</code><br><code>%let group_list=value1@value2;</code> | To specify the variable and associated modalities which will define the treatment columns.<br>Each value of <i>&amp;group_list</i> , separated with @, will create a condition (i.e. variable="value1") which will create a column in the output.<br>The column will be created with respective order of <i>&amp;group_list</i> .<br>Default values can also be given with <code>%reset global macros</code> . |
| <code>%let total=0;</code>                                                       | To specify if a total column must be printed in the final output, with the combination/sum of all other columns.<br>This column is always calculated but not necessarily printed.<br>Default values can also be given with <code>%reset global macros</code> .                                                                                                                                                 |
| <code>%let output_mode=ODS_RTF;</code>                                           | To specify the type of output to be produced (see later, paragraph output file – type of outputs)                                                                                                                                                                                                                                                                                                              |
| <code>%let output_dataset=1;</code>                                              | To specify if the core dataset <i>table</i> needs to be kept in a specific folder at the end of the analysis.                                                                                                                                                                                                                                                                                                  |

# Environment setting (3/3)

## Titles/Footnotes

- Assigned with **macro-variables** :

```
%let tit1=Table 14.1 - Summary of Demographic Characteristics;
```

```
%let tit2=Safety Population;
```

```
...
```

```
%let foot1=...
```

```
%let foot2=...
```

```
...
```

- Or retrieved from an ISOTOP.xml file with `%read_isotop()`

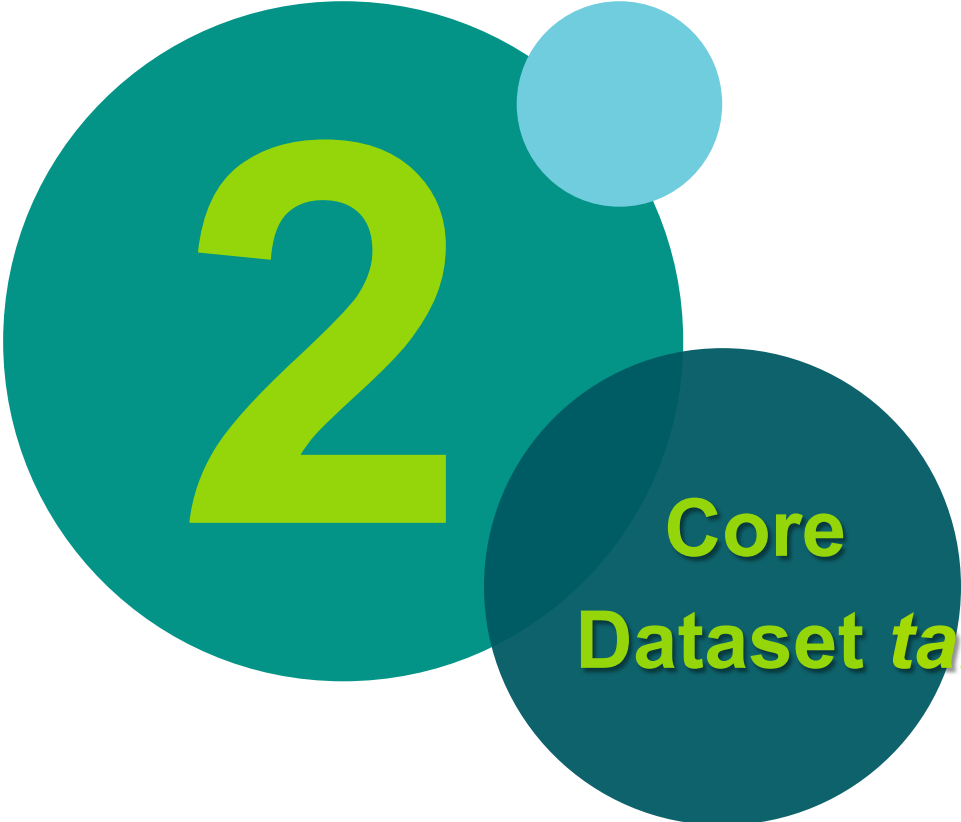
- and **combined with study-level information** with `%title()/%footnote()`

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Table 14.1 - Summary of Demographic Characteristics  
Safety Population

| Treatment | Placebo | Treatment | Placebo | Total |
|-----------|---------|-----------|---------|-------|
| 150 mg    | 150 mg  | 300 mg    | 300 mg  |       |



# 2

## Core Dataset *table*

- Default variables
- Additional variables
- Format
- DIAMOND macro-functions:
  - List of all
  - Frequently used

# Core Dataset *table* (1/3)

## Default variables:

```
%let group=treat;  
%let group_list=A@B;
```

g1\_c ⇔ treat='A';  
g2\_c ⇔ treat='B';

SAS - [VIEWTABLE: Work.**Table**]

File Edit View Window Help

Icons: New, Open, Save, Print, Find, Copy, Paste, Undo, Redo, Sort, Filter, etc.

|   | page_nb | line_nb | line_info | line               | format       | g1_c      | g1_n1 | g1_n2 | g1_n3   | g1_n4 | g1_n5 | g1_n6 | g2_c      | g2_n1 | g2_n2 |
|---|---------|---------|-----------|--------------------|--------------|-----------|-------|-------|---------|-------|-------|-------|-----------|-------|-------|
| 1 | 1       | 1       | NOBS      | Safety Set         | F_NOBS_NOPCT | 12        | 12    | 12    | 1       |       |       |       | 4         | 4     | 4     |
| 2 | 1       | 2       | EMPTY     |                    |              |           |       |       |         |       |       |       |           |       |       |
| 3 | 1       | 3       | NOBS      | Lead-in Safety Set | F_NOBS_PCT   | 11 (91.7) | 11    | 12    | 0.91667 |       |       |       | 4 (100.0) | 4     | 4     |

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Table 14.X.X Disposition - Safety Population

|                    | A<br>N = 12<br>n (%) | B<br>N = 4<br>n (%) |
|--------------------|----------------------|---------------------|
| Safety Set         | 12                   | 4                   |
| Lead-in Safety Set | 11 (91.7)            | 4 (100.0)           |

## Core Dataset *table* (2/3)

### Additional variables:

```
%let group=treat;
%let group=C1@C2@C3@C4@C5;
```

|    | page_nb | section_nb | section                       | line_nb | line_info | line                     | line2     | format               | g1_c          | g1_n1   | g1_n2 | g1_n3 | g1 |
|----|---------|------------|-------------------------------|---------|-----------|--------------------------|-----------|----------------------|---------------|---------|-------|-------|----|
| 30 | 2       | 9          | RR Interval, Aggregate (msec) | 30      | N         | Day 4 (4 Hours Postdose) | n         | F_STATS01EG_N        | 16            | 16      | .     | .     | .  |
| 31 | 2       | 9          | RR Interval, Aggregate (msec) | 31      | MEAN STD  |                          | Mean (SD) | F_STATS01EG_MEAN_STD | 949.5 (112.7) | 949.5   | 112.7 | .     | .  |
| 32 | 2       | 9          | RR Interval, Aggregate (msec) | 32      | STDERR    |                          | SE        | F_STATS01EG_STDERR   | 28.2          | 28.1836 | .     | .     | .  |
| 33 | 2       | 9          | RR Interval, Aggregate (msec) | 33      | MEDIAN    |                          | Median    | F_STATS01EG_MEDIAN   | 943.0         | 943     | .     | .     | .  |
| 34 | 2       | 9          | RR Interval, Aggregate (msec) | 34      | MIN MAX   |                          | Min, Max  | F_STATS01EG_MIN_MAX  | 734, 1232     | 734     | 1232  | .     | .  |
| 35 | 2       | 9          | RR Interval, Aggregate (msec) | 35      | EMPTY     |                          |           |                      |               | .       | .     | .     | .  |
| 36 | 3       | 9          | RR Interval, Aggregate (msec) | 36      | N         | Day 4 (8 Hours Postdose) | n         | F_STATS01EG_N        | 16            | 16      | .     | .     | .  |
| 37 | 3       | 9          | RR Interval, Aggregate (msec) | 37      | MEAN STD  |                          | Mean (SD) | F_STATS01EG_MEAN_STD | -42.8 (110.8) | -42.75  | 110.8 | .     | .  |
| 38 | 3       | 9          | RR Interval, Aggregate (msec) | 38      | STDERR    |                          | SE        | F_STATS01EG_STDERR   | 27.7          | 27.7097 | .     | .     | .  |
| 39 | 3       | 9          | RR Interval, Aggregate (msec) | 39      | MEDIAN    |                          | Median    | F_STATS01EG_MEDIAN   | -35.0         | -35     | .     | .     | .  |
| 40 | 3       | 9          | RR Interval, Aggregate (msec) | 40      | MIN MAX   |                          | Min, Max  | F_STATS01EG_MIN_MAX  | -220, 140     | -220    | 140   | .     | .  |

(... right end of the dataset *table*)

|    | g4_n5 | g4_n6 | g5_c          | g5_n1     | g5_n2    | g5_n3 | g5_n4 | g5_n5 | g5_n6 | gt_c          | gt_n1     | gt_n2   | gt_n3 | gt_n4 | gt_n5 | gt_n6 |
|----|-------|-------|---------------|-----------|----------|-------|-------|-------|-------|---------------|-----------|---------|-------|-------|-------|-------|
| 30 | .     | .     | 16            | 16        | .        | .     | .     | .     | .     | 48            | 48        | .       | .     | .     | .     | .     |
| 31 | .     | .     | 970.8 (134.6) | 970.75    | 134.6281 | .     | .     | .     | .     | 963.7 (125.4) | 963.66667 | 125.41  | .     | .     | .     | .     |
| 32 | .     | .     | 33.7          | 33.657032 | .        | .     | .     | .     | .     | 18.1          | 18.101304 | .       | .     | .     | .     | .     |
| 33 | .     | .     | 944.0         | 944       | .        | .     | .     | .     | .     | 944.0         | 944       | .       | .     | .     | .     | .     |
| 34 | .     | .     | 830, 1326     | 830       | 1326     | .     | .     | .     | .     | 734, 1326     | 734       | 1326    | .     | .     | .     | .     |
| 35 | .     | .     | .             | .         | .        | .     | .     | .     | .     | .             | .         | .       | .     | .     | .     | .     |
| 36 | .     | .     | 16            | 16        | .        | .     | .     | .     | .     | 48            | 48        | .       | .     | .     | .     | .     |
| 37 | .     | .     | -44.1 (152.9) | -44.125   | 152.9313 | .     | .     | .     | .     | -43.7 (137.3) | -43.66667 | 137.294 | .     | .     | .     | .     |
| 38 | .     | .     | 38.2          | 38.232826 | .        | .     | .     | .     | .     | 19.8          | 19.816743 | .       | .     | .     | .     | .     |
| 39 | .     | .     | -39.0         | -39       | .        | .     | .     | .     | .     | -39.0         | -39       | .       | .     | .     | .     | .     |
| 40 | .     | .     | 282, 288      | -282      | 288      | .     | .     | .     | .     | 282, 288      | -282      | 288     | .     | .     | .     | .     |

# Core Dataset *table* (3/3)

## Format:

- Combination of the numeric columns g\*\_n1, g\*\_n2,... to create g\*\_c
- %set\_format creates all the formats in background
- List of standard format given

```
* %insert_NOBS() and %insert_FREQ() by default;
%_set_format(name=f_nobs_pct      ,value='put (n1#,4.)!!" "!!put (n3#,pct.)' )
%_set_format(name=f_nobs_nopct    ,value='put (n1#,4.)' )

* %insert_STAT() by default;
%_set_format(name=f_stats_N      ,value='put (n1#,4.)' );
%_set_format(name=f_stats_MEAN   ,value='put (n1#,%eval (6+&decimal) .%eval (1+&decimal))' );
%_set_format(name=f_stats_STD    ,value='put (n1#,%eval (7+&decimal) .%eval (2+&decimal))' );
%_set_format(name=f_stats_STDERR ,from_format=f_stats_STD );
...
```

- If needed, study specific format can be created

```
* New format;
%_set_format(name=f_stats2_N      ,value='put (n1#,4.)' )
%_set_format(name=f_stats2_MEAN   ,value='put (n1#,6.1)' )
%_set_format(name=f_stats2_STD    ,value='put (n1#,6.1)' )
```

# DIAMOND Macro-functions (1/2)

## List of current DIAMOND Macro-Functions

| Standard macros                                           |                                                                                                                                                                                                                                                                     |                                                                               |                                                                                     |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Environment settings                                      | Creation of core dataset                                                                                                                                                                                                                                            | Functions used by other macro-functions                                       | Creation of output                                                                  |
| %reset_global_macros<br>%read_isotop<br><br>%count_denoms | %new_table<br><br>%insert_nobs<br>%insert_freq<br>%insert_stats<br>%insert_stats_finish<br>%insert_dimensions<br>%insert_mcibin01<br>%insert_mcidbsi1<br><br>%insert_text<br>%insert_empty<br><br>%stat_mcibin01<br>%stat_mcidbsi1<br><br>%end_page<br>%end_section | %fmt_apply<br>%fmt_repeat<br><br>%next_line<br>%break_line<br>%indent_ods_rtf | %create_table_output<br><br>%output_file_start<br>%output_file_end<br><br>%make_rtf |

| Study specific macros – updated per study request |                          |                                         |                              |
|---------------------------------------------------|--------------------------|-----------------------------------------|------------------------------|
| Environment settings                              | Creation of core dataset | Functions used by other macro-functions | Creation of output           |
| %titles<br>%footnotes                             | %define_right_group      | %set_formats                            | %ods_rtfstyle<br>%fix_labels |

# DIAMOND Macro-functions (2/2)

## Frequently used statistical DIAMOND Macro-functions

```
%insert_nobs(DS=dataset, WHR=condition, TX='text to display', PCT=1);
```

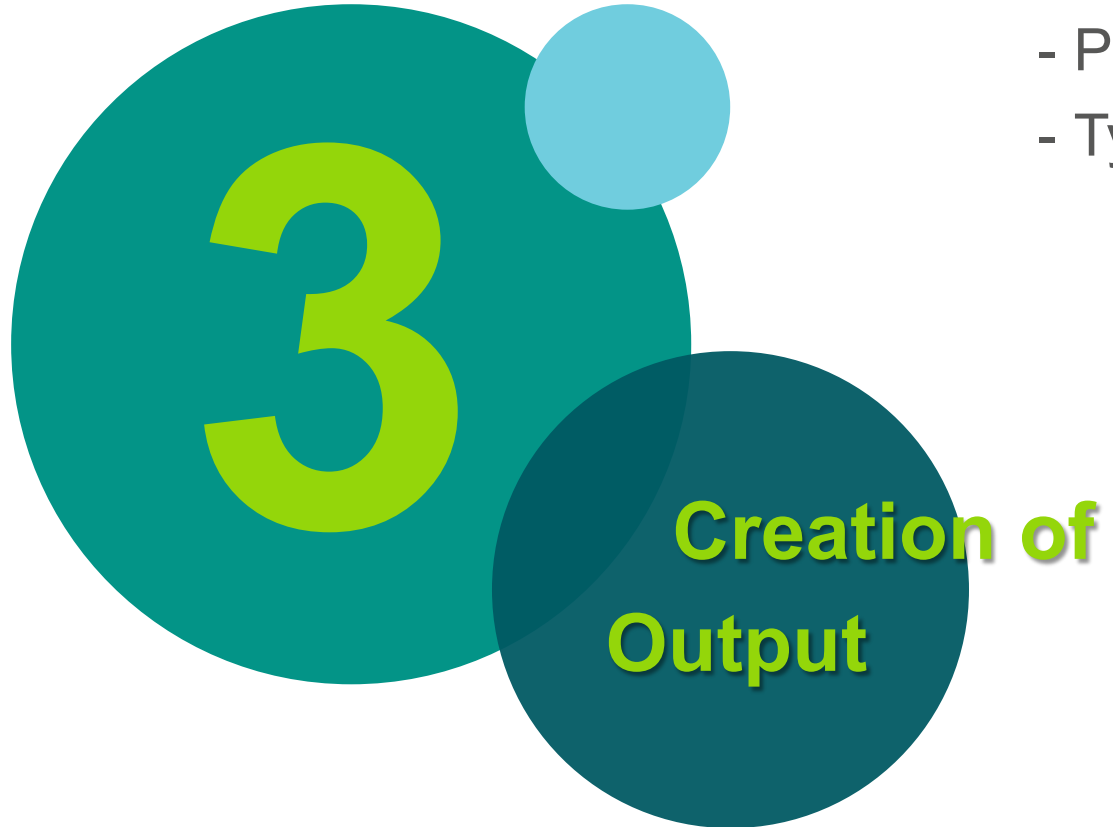
| line_nb | line_info | line            | format     | g1_c     | g1_n1 | g1_n2 | g1_n3    | g1_n4 | g1_n5 | g1_n6 | g2_c     | g2_n1 | g2_n2 | g2_n3 |
|---------|-----------|-----------------|------------|----------|-------|-------|----------|-------|-------|-------|----------|-------|-------|-------|
| 1       | NOBS      | text to display | F_NOBS_PCT | 4 (28.6) | 4     | 14    | 0.285714 |       |       |       | 4 (80.0) | 4     | 5     | 0.8   |

```
%insert_freq(DS=dataset, WHR=condition,  
VAR=variable,  
VALUES='18-25'='>18 - <=25'  
@'26-35'='>26 - <=35'  
@'36-45'='>36 - <=45',  
@'45more'='>45');
```

| line_nb | line_info | line       | format     | g1_c     | g1_n1 | g1_n2 | g1_n3     | g1_n4 | g1_n5 | g1_n6 | g2_c     | g2_n1 | g2_n2 |
|---------|-----------|------------|------------|----------|-------|-------|-----------|-------|-------|-------|----------|-------|-------|
| 1       | NOBS      | >18 - <=25 | F_NOBS_PCT | 3 (21.4) | 3     | 14    | 0.2142857 |       |       |       | 1 (20.0) | 1     | 5     |
| 2       | NOBS      | >26 - <=35 | F_NOBS_PCT | 0        | 0     | 14    | 0         |       |       |       | 1 (20.0) | 1     | 5     |
| 3       | NOBS      | >36 - <=45 | F_NOBS_PCT | 5 (35.7) | 5     | 14    | 0.3571429 |       |       |       | 1 (20.0) | 1     | 5     |
| 4       | NOBS      | >45        | F_NOBS_PCT | 6 (42.9) | 6     | 14    | 0.4285714 |       |       |       | 2 (40.0) | 2     | 5     |

```
%insert_stats(DS=dataset, WHR=condition,  
VAR=variable,  
STATS=N=n'  
@MEAN STD='Mean (SD)'  
@MEDIAN='Median'  
@MIN MAX='Min, Max');
```

| line_nb | line_info | line      | format           | g1_c         | g1_n1    | g1_n2   | g1_n3 | g1_n4 | g1_n5 | g1_n6 | g2_c         | g2_n1 | g2_n2     |
|---------|-----------|-----------|------------------|--------------|----------|---------|-------|-------|-------|-------|--------------|-------|-----------|
| 1       | N         | n         | F_STATS_N        | 14           | 14       |         |       |       |       |       | 5            | 5     |           |
| 2       | MEAN STD  | Mean (SD) | F_STATS_MEAN_STD | 40.6 (11.68) | 40.64286 | 11.6791 |       |       |       |       | 37.8 (14.27) | 37.8  | 14.272351 |
| 3       | MEDIAN    | Median    | F_STATS_MEDIAN   | 41.0         | 41       |         |       |       |       |       | 36.0         | 36    |           |
| 4       | MIN MAX   | Min, Max  | F_STATS_MIN_MAX  | 21, 57       | 21       | 57      |       |       |       |       | 23, 57       | 23    | 57        |



- Principle
- Type of outputs

# Creation of Output (1/2)

## Principle:

```
%create_table_output(  
  ,line_width           = 60  
  ,group_width          = 20  
  ,line_header_txt      = 'Baseline~Characteristic'  
  ,group_header2_txt    = 'n (%)'  
  ,group_denom_in_header = 1  
);
```

Which is equivalent (but not only) to:

```
%output_file_start;  
proc report data = table nowd headline headskip split = "~" missing spacing = 1;  
  column line_nb line g1_c g2_c g3_c gt_c;  
  
  define line_nb / order order=internal noprint;  
  define line    / display left flow width = 60 "Baseline~Characteristic";  
  define g1_c    / display left flow width = 20 "Study Group A~[N=&denom_1.]~n (%)";  
  define g2_c    / display left flow width = 20 "Study Group B~[N=&denom_2.]~n (%)";  
  define g3_c    / display left flow width = 20 "Study Group C~[N=&denom_3.]~n (%)";  
  define gt_c    / display left flow width = 20 "Total~[N=&denom_t.]~n (%)";  
  
  %titles;  
  %footnotes;  
run;  
%output_file_end;
```

# Creation of Output (2/2)

## Type of outputs:

- **Standard table/listing**: an .rtf file produced with a .txt file [output.txt + output.rtf]

```
%let output_mode=TEXT_RTF;
```

- **LST file**: file produced with SAS® output window [output.lst]

```
%let output_mode=LST;
```

- **ODS RTF file**: file produced with SAS® ODS RTF [output.rtf]

```
%let output_mode=ODS_RTF;
```

- **In-text table**: file produced with SAS® ODS RTF with minimal features (no pagination, no page breaks, no empty lines,...) which able to copy/paste the output with one click in another document [output.rtf, prefixed with 'it']

```
%let output_mode=INTEXT;
```



# 4

**Some  
Capabilities**

- Example 1: AE Table
- Example 2: Severity Table
- Example 3: Efficacy Table

# Example 1: AE Table with SOC and PT (1/2)

## Full code:

```
%reset_global_macros;

%let rep = T_ae_socpt;
%read_isotop;

%let group = ARMCD;
%let group_list =150MG_TRT@150MG_PBO@300MG_TRT@300MG_PBO;
%let totals = 1;

*** Select data;
proc sort data = libanal.adae out = rep (keep = USUBJID &group. SAFFL AETEAFL AEDECOD AEBODSYS);
  by USUBJID;
  where SAFFL='Y' and AETEAFL='Y';
run;

*** Create core dataset;
%new_table
%count_denoms(DS = libanal.adsl, whr = SAFFL eq 'Y', unique_subjno = 1)

%Insert_Dimensions(
  DS=rep,
  level1=AEBODSYS, level1_sort=EVENTS, /*ALPHA, SUBJECTS, EVENTS*/
  level2=AEDECOD, level2_sort=ALPHA,
  line_width=70,
  report_lines=
    L0_0='Subjects with Any TEAE'
    @L1_0=skip#level1
    @L2_0=indent2#level2 );

*** Create output;
%fix_labels;
%create_table_output(line_header_txt      = 'System Organ Class~ Preferred Term'
                    ,group_header2_txt   = '          n(%)'
                    ,group_denom_in_header = 1
                    ,group_denom_brackets = "[N = xx]"
                    ,line_width           = 70
                    ,group_width          = 16
                    );
```

# Example 1: AE Table with SOC and PT (2/2)

## Output:

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Table 14.X.X Treatment Emergent Adverse Events (TEAE) by System Organ Class and Preferred Term - Safety Population

| System Organ Class<br>Preferred Term                 | Treatment<br>150 mg<br>[N = 14]<br>n(%) | Placebo<br>150 mg<br>[N = 5]<br>n(%) | Treatment<br>300 mg<br>[N = 13]<br>n(%) | Placebo<br>300 mg<br>[N = 5]<br>n(%) | Total<br>[N = 37]<br>n(%) |
|------------------------------------------------------|-----------------------------------------|--------------------------------------|-----------------------------------------|--------------------------------------|---------------------------|
| Subjects with Any TEAE                               | 10 (71.4)                               | 4 (80.0)                             | 12 (92.3)                               | 4 (80.0)                             | 30 (81.1)                 |
| Infections and infestations                          | 6 (42.9)                                | 1 (20.0)                             | 7 (53.8)                                | 3 (60.0)                             | 17 (45.9)                 |
| Bronchitis                                           | 1 (7.1)                                 | 0                                    | 1 (7.7)                                 | 0                                    | 2 (5.4)                   |
| Cellulitis                                           | 0                                       | 1 (20.0)                             | 1 (7.7)                                 | 0                                    | 2 (5.4)                   |
| Gastroenteritis                                      | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Influenza                                            | 0                                       | 0                                    | 0                                       | 1 (20.0)                             | 1 (2.7)                   |
| Nasopharyngitis                                      | 4 (28.6)                                | 0                                    | 5 (38.5)                                | 2 (40.0)                             | 11 (29.7)                 |
| Skin infection                                       | 0                                       | 1 (20.0)                             | 0                                       | 0                                    | 1 (2.7)                   |
| Tooth infection                                      | 1 (7.1)                                 | 0                                    | 0                                       | 0                                    | 1 (2.7)                   |
| Musculoskeletal and connective tissue disorders      | 2 (14.3)                                | 1 (20.0)                             | 1 (7.7)                                 | 2 (40.0)                             | 6 (16.2)                  |
| Arthralgia                                           | 0                                       | 0                                    | 0                                       | 1 (20.0)                             | 1 (2.7)                   |
| Back pain                                            | 0                                       | 1 (20.0)                             | 1 (7.7)                                 | 0                                    | 2 (5.4)                   |
| Bursitis                                             | 1 (7.1)                                 | 0                                    | 0                                       | 0                                    | 1 (2.7)                   |
| Muscle spasms                                        | 0                                       | 0                                    | 0                                       | 1 (20.0)                             | 1 (2.7)                   |
| Neck pain                                            | 1 (7.1)                                 | 0                                    | 0                                       | 0                                    | 1 (2.7)                   |
| Tenosynovitis                                        | 0                                       | 1 (20.0)                             | 0                                       | 0                                    | 1 (2.7)                   |
| General disorders and administration site conditions | 1 (7.1)                                 | 0                                    | 3 (23.1)                                | 0                                    | 4 (10.8)                  |
| Injection site erythema                              | 1 (7.1)                                 | 0                                    | 0                                       | 0                                    | 1 (2.7)                   |
| Injection site mass                                  | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Injection site pruritus                              | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Injection site swelling                              | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Pyrexia                                              | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Vessel puncture site haematoma                       | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Gastrointestinal disorders                           | 1 (7.1)                                 | 0                                    | 1 (7.7)                                 | 0                                    | 2 (5.4)                   |
| Diarrhoea                                            | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Nausea                                               | 1 (7.1)                                 | 0                                    | 1 (7.7)                                 | 0                                    | 2 (5.4)                   |
| Skin and subcutaneous tissue disorders               | 1 (7.1)                                 | 0                                    | 1 (7.7)                                 | 2 (40.0)                             | 4 (10.8)                  |
| Alopecia                                             | 1 (7.1)                                 | 0                                    | 0                                       | 0                                    | 1 (2.7)                   |
| Haemorrhage subcutaneous                             | 0                                       | 0                                    | 1 (7.7)                                 | 0                                    | 1 (2.7)                   |
| Pruritus                                             | 0                                       | 0                                    | 0                                       | 2 (40.0)                             | 2 (5.4)                   |

Note: Classifications of adverse events are based on the MedDRA (version xx.x).

Source Listing: 16.X.X  
Program ID: T\_ae\_socpt2.SAS Source Data: ADAE File ID: xxxxxx.HTM

Transfer Date: 01AUG2015 Runtime ID: 22SEP2016 15:35

## Example 2: Severity Table (1/2)

### -Display in column:

```
%Insert_Dimensions(  
  DS=rep,  
  level1=AEBODSYS, level1_sort=EVENTS,  
  level2=AEDECOD, level2_sort=ALPHA,  
                                     /*ALPHA, SUBJECTS, EVENTS*/  
  dim2=GRADE,  
  dim2_order='1'@'2'@'3'@'4'@'5',  
  dim2_type=MAX,  
  dim2_in_columns=1,  
  denom_subjects=POPUL,  
  
  line_width=30,  
  report_lines=  
    L1_0=skip#level1  
    @L2_0=indent2#level2,  
  format_prefix=f_dimSEV5N  
);
```

### -Display in line

```
%Insert_Dimensions(  
  DS=rep,  
  level1=AEBODSYS, level1_sort=EVENTS,  
  level2=AEDECOD, level2_sort=ALPHA,  
                                     /*ALPHA, SUBJECTS, EVENTS*/  
  dim2=GRADE,  
  dim2_order='1'@'2'@'3'@'4'@'5',  
  dim2_type=MAX,  
  dim2_in_columns=0,  
  denom_subjects=POPUL,  
  
  line_width=30,  
  report_lines=  
    L1_0=skip#level1  
    @L2_0=skip#indent2#level2  
    @L2_1=indent4#Dim2  
);
```

## Example 2: Severity Table (2/2)

| System Organ Class<br>Preferred Term                       | Treatment<br>150 mg<br>[N = 14] |                  |                   |                  |                 | Placebo<br>150 mg<br>[N = 5] |                  |                   |                  |                 |
|------------------------------------------------------------|---------------------------------|------------------|-------------------|------------------|-----------------|------------------------------|------------------|-------------------|------------------|-----------------|
|                                                            | Grade I<br>n(%)                 | Grade II<br>n(%) | Grade III<br>n(%) | Grade IV<br>n(%) | Grade V<br>n(%) | Grade I<br>n(%)              | Grade II<br>n(%) | Grade III<br>n(%) | Grade IV<br>n(%) | Grade V<br>n(%) |
| Infections and infestations                                | 6 (42.9)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Bronchitis                                                 | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Nasopharyngitis                                            | 4 (28.6)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Tooth infection                                            | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Musculoskeletal and<br>connective tissue disorders         | 2 (14.3)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Arthralgia                                                 | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Back pain                                                  | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Bursitis                                                   | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Muscle spasms                                              | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Neck pain                                                  | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Tenosynovitis                                              | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| General disorders and<br>administration site<br>conditions | 0                               | 1 ( 7.1)         | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Injection site erythema                                    | 0                               | 1 ( 7.1)         | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Injection site mass                                        | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Injection site pruritus                                    | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Injection site swelling                                    | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Pyrexia                                                    | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Vessel puncture site<br>haematoma                          | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Gastrointestinal disorders                                 | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Diarrhoea                                                  | 0                               | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Nausea                                                     | 1 ( 7.1)                        | 0                | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Skin and subcutaneous tissue<br>disorders                  | 0                               | 1 ( 7.1)         | 0                 | 0                | 0               |                              |                  |                   |                  |                 |
| Alopecia                                                   | 0                               | 1 ( 7.1)         | 0                 | 0                | 0               |                              |                  |                   |                  |                 |

| System Organ Class<br>Preferred Term               | Treatment<br>150 mg<br>[N = 14]<br>n(%) | Placebo<br>150 mg<br>[N = 5]<br>n(%) | REGN668<br>300 mg<br>[N = 13]<br>n(%) |
|----------------------------------------------------|-----------------------------------------|--------------------------------------|---------------------------------------|
| Infections and infestations                        | 6 (42.9)                                | 0                                    | 6 (46.2)                              |
| Bronchitis                                         | 1 ( 7.1)                                | 0                                    | 1 ( 7.7)                              |
| 1                                                  | 1 ( 7.1)                                | 0                                    | 1 ( 7.7)                              |
| 2                                                  | 0                                       | 0                                    | 0                                     |
| 3                                                  | 0                                       | 0                                    | 0                                     |
| 4                                                  | 0                                       | 0                                    | 0                                     |
| 5                                                  | 0                                       | 0                                    | 0                                     |
| Nasopharyngitis                                    | 4 (28.6)                                | 0                                    | 5 (38.5)                              |
| 1                                                  | 4 (28.6)                                | 0                                    | 5 (38.5)                              |
| 2                                                  | 0                                       | 0                                    | 0                                     |
| 3                                                  | 0                                       | 0                                    | 0                                     |
| 4                                                  | 0                                       | 0                                    | 0                                     |
| 5                                                  | 0                                       | 0                                    | 0                                     |
| Tooth infection                                    | 1 ( 7.1)                                | 0                                    | 0                                     |
| 1                                                  | 1 ( 7.1)                                | 0                                    | 0                                     |
| 2                                                  | 0                                       | 0                                    | 0                                     |
| 3                                                  | 0                                       | 0                                    | 0                                     |
| 4                                                  | 0                                       | 0                                    | 0                                     |
| 5                                                  | 0                                       | 0                                    | 0                                     |
| Musculoskeletal and<br>connective tissue disorders | 2 (14.3)                                | 1 (20.0)                             | 1 ( 7.7)                              |
| Arthralgia                                         | 0                                       | 0                                    | 0                                     |
| 1                                                  | 0                                       | 0                                    | 0                                     |
| 2                                                  | 0                                       | 0                                    | 0                                     |
| 3                                                  | 0                                       | 0                                    | 0                                     |
| 4                                                  | 0                                       | 0                                    | 0                                     |
| 5                                                  | 0                                       | 0                                    | 0                                     |

## Example 3: Efficacy Table (1/2)

| Table 14.2.1.1.1                                  |                  |                            |               |
|---------------------------------------------------|------------------|----------------------------|---------------|
| Summary of global health score at Visit 8 (ANOVA) |                  |                            |               |
| ITT population                                    |                  |                            |               |
|                                                   | TREAT<br>[N=149] | Control formula<br>[N=151] |               |
| Global health score at baseline                   |                  |                            |               |
| N                                                 | 105              | 105                        |               |
| Mean                                              | 66.43            | 60.80                      |               |
| SD                                                | 20.908           | 23.397                     |               |
| Median                                            | 66.70            | 66.70                      |               |
| Minimum                                           | 16.7             | 0.0                        |               |
| Maximum                                           | 100.0            | 100.0                      |               |
| Global health score at Visit 8                    |                  |                            |               |
| N                                                 | 73               | 63                         |               |
| Mean                                              | 57.88            | 56.22                      |               |
| SD                                                | 17.395           | 20.189                     |               |
| Median                                            | 58.30            | 58.30                      |               |
| Minimum                                           | 16.7             | 8.3                        |               |
| Maximum                                           | 91.7             | 100.0                      |               |
| Change from baseline at Visit 8                   |                  |                            |               |
| N                                                 | 61               | 52                         |               |
| Mean                                              | -11.06           | -6.73                      |               |
| SD                                                | 24.039           | 28.344                     |               |
| Median                                            | -8.40            | 0.00                       |               |
| Minimum                                           | -58.4            | -83.3                      |               |
| Maximum                                           | 41.6             | 75.0                       |               |
| LS-Means                                          | 57.88            |                            | 56.22         |
| 95% CI for LS-Means                               | 53.54 ; 62.22    |                            | 51.55 ; 60.89 |
| P-value                                           | <0.001           |                            | <0.001        |
| Difference of LS-Means                            | 1.66             |                            |               |
| 95% CI for LS-Means                               | -4.71 ; 8.04     |                            |               |
| P-value                                           | 0.607            |                            |               |

## Example 3: Efficacy Table (2/2)

```
PROC MIXED DATA=model;
  CLASS armcd;
  MODEL score = armcd base covar;
  lsmeans armcd / diff cl;
  ESTIMATE "treatment" armcd 1 -1 / cl;
  ods output lsmeans=lsmeanc;
  ods output estimates=ancova;
run;

data lsmeanc;
  set lsmeanc;
  keep_group=1;
run;

data ancova;
  set ancova;
  &group=scan("&group_list",1,"@");
  keep_group=1;
run;

%insert_stats_finish(DS=lsmeanc,STATS=Estimate      ='LS-Means',          format_prefix=F_STATS3);
%insert_stats_finish(DS=lsmeanc,STATS=Lower Upper  ='95% CI for LS-Means', format_prefix=F_STATS3);
%insert_stats_finish(DS=lsmeanc,STATS=Probt        ='P-value',          format_prefix=F_GM);
%insert_empty;

%insert_stats_finish(DS=ancova,STATS=Estimate      ='Difference of LS-Means', format_prefix=F_STATS3);
%insert_stats_finish(DS=ancova,STATS=Lower Upper  ='95% CI for LS-Means', format_prefix=F_STATS3);
%insert_stats_finish(DS=ancova,STATS=Probt        ='P-value',          format_prefix=F_GM);
```

# Conclusion



## **Flexible**

Can be logically grouped together in order to produce a variety of reports and meet study reporting requirements



## **Reusable**

Standardization is applied at each step and level



## **Efficient**

Reduce programming effort with minimal set up



## **User-friendly**



Any questions ?...

**Thanks  
for your  
attention !**

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