Software Tools for ClinicalTrials.Gov Basic Results Reporting

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Entering Results into ClinicalTrials.gov

- **Participant Flow**: Progress of research participants through trial stages.
  - Single *Period* or multiple *Periods*
  - Each *Period* must include two *Milestones*:
    - Number ***STARTED***
    - Number ***COMPLETED***
  - Reasons for non-completion are optional, but should be included as a best practice.
- **Baseline Characteristics**: Demographic & baseline data for all study participants and by *Arm*.
  - *Age* and *Gender* are required.
  - All other baseline measures are optional, but should be reported as a best practice.

Entering Results into ClinicalTrials.gov

- **Outcome Measures**: Summary statistic values for *Outcome Measure* by *Arm.*
  - *Primary Outcome Measure* is required.
  - *Secondary Outcome Measure(s)* is(are) optional.
  - Statistical analysis results reporting is optional.
- **Adverse Events**: Number and frequency of all *Serious Adverse Events (SAEs)* and *AEs* grouped by *Organ System* by *Arm*. If all *AEs* are not collected, describe AE collection protocol.

Simple Forms from ClinicalTrials.gov

Participant Flow Summary Form — *ClinicalTrials.gov*

Recruitment Details	
Pre-assignment Details	

Period ① Title: Overall Study

Arm/Group Title *		*	*	*
Arm/Group Description ②				
		Number of Participants *	Number of Participants *	Number of Participants *
STARTED *		*	*	*
Milestone Title③	[*]	[*]	[*]	[*]
Milestone Title③	[*]	[*]	[*]	[*]
Milestone Title③	[*]	[*]	[*]	[*]
COMPLETED *		*	*	*
Reason Not Completed				
Adverse Event		[*]	[*]	[*]
Death		[*]	[*]	[*]
Lack of Efficacy		[*]	[*]	[*]
Lost to Follow-up		[*]	[*]	[*]
Physician Decision		[*]	[*]	[*]
Pregnancy		[*]	[*]	[*]
Protocol Violation		[*]	[*]	[*]
Withdrawal by Subject		[*]	[*]	[*]
Other Reason③	[*]	[*]	[*]	[*]
Other Reason③	[*]	[*]	[*]	[*]
Other Reason③	[*]	[*]	[*]	[*]

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

① Complete a Period table for each Period you wish to report. Provide a descriptive Title for each reported Period.

② Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

③ [Optional] Add as many Milestone Title or Other Reason Not Completed rows as needed. A descriptive title for each row is required.

Simple Forms from ClinicalTrials.gov

Baseline Characteristics Summary Form Age * — ClinicalTrials.gov

Arm/Group Title *		*		*		*
Arm/Group Description ①						
Overall Number of Baseline Participants *		*		*		*
Age, Categorical ②		Number of Participants		Number of Participants		Number of Participants
Unit of Measure	Participants					
<=18 years		[*]		[*]		[*]
Between 18 and 65 years		[*]		[*]		[*]
>=65 years		[*]		[*]		[*]
Age, Continuous ②		Measure Type [*]	Dispersion/ Precision Type [*]	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
		(Circle One) Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) Standard Deviation Inter-quartile Range Full Range				
Unit of Measure	[*]	[*]	③[*]	[*]	③[*]	[*]	③[*]
Age, Customized ②		Measure Type [*]	Dispersion/ Precision Type [*]	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
		(Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) Not Applicable④ Standard Deviation Inter-quartile Range Full Range				
Unit of Measure	[*]						
Category Title⑤	[*]	[*]	③[*]	[*]	③[*]	[*]	③[*]
Category Title⑤	[*]	[*]	③[*]	[*]	③[*]	[*]	③[*]

* Required by ClinicalTrials.gov
[*] Conditionally required by ClinicalTrials.gov
① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.
② At least one Age Baseline Measure (Categorical, Continuous, or Customized) is required by ClinicalTrials.gov
③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.
④ "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number".
⑤ [Optional] Add as many Categories as needed. When more than one Category is entered, Category Title and Baseline Measure Data are required for each row.

Simple Forms from ClinicalTrials.gov

Baseline Characteristics Summary Form Gender * — *ClinicalTrials.gov*

Arm/Group Title *		*	*	*
Arm/Group Description ①				
Overall Number of Baseline Participants*		*	*	*
Gender, female, male② Unit of Measure: Participants		Number of Participants	Number of Participants	Number of Participants
Female		[*]	[*]	[*]
Male		[*]	[*]	[*]
Gender, Customized ② Unit of Measure: Participants		Number of Participants	Number of Participants	Number of Participants
Category Title③	[*]	[*]	[*]	[*]
Category Title③	[*]	[*]	[*]	[*]
Category Title③	[*]	[*]	[*]	[*]

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② At least one Gender Baseline Measure (female, male or Customized) is required by ClinicalTrials.gov

③ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Baseline Measure Data are required for each row.

Simple Forms from ClinicalTrials.gov

Baseline Characteristics Summary Form *Race, Ethnicity, Region* — *ClinicalTrials.gov*

Arm/Group Title *	*	*	*
Arm/Group Description ①			
Overall Number of Baseline Participants*	*	*	*
Race (NIH/OMB) ② Unit of Measure: Participants	Number of Participants	Number of Participants	Number of Participants
American Indian or Alaska Native	[*]	[*]	[*]
Asian	[*]	[*]	[*]
Native Hawaiian or Pacific Islander	[*]	[*]	[*]
Black or African American	[*]	[*]	[*]
White	[*]	[*]	[*]
More then one race	[*]	[*]	[*]
Unknown or Not Reported	[*]	[*]	[*]
Ethnicity (NIH/OMB) ② Unit of Measure: Participants	Number of Participants	Number of Participants	Number of Participants
Hispanic or Latino	[*]	[*]	[*]
Not Hispanic or Latino	[*]	[*]	[*]
Unknown or Not Reported	[*]	[*]	[*]
Region of Enrollment Unit of Measure: Participants	Number of Participants	Number of Participants	Number of Participants
United States	[*]	[*]	[*]
Region/Country Name ③ [*]	[*]	[*]	[*]
Region/Country Name ③ [*]	[*]	[*]	[*]
Region/Country Name ③ [*]	[*]	[*]	[*]

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② If not using the NIH/OMB standard categories, you may create customized categories by using "Race, Customized" and/or "Ethnicity, Customized".

③ [Optional] Region of Enrollment Baseline Measure is optional. At least one Region/Country is required when reporting Region of Enrollment. Also, add as many Regions/Countries as needed. Region/Country Name and Baseline Measure Data are required for each reported Region of Enrollment row.

Simple Forms from ClinicalTrials.gov

Outcome Measure Summary Form — *ClinicalTrials.gov*

Outcome Measure Type*	*(Circle One)*	Primary	Secondary	Other Pre-specified	Post-Hoc	**Safety Issue?**	*(Circle One)*	Yes / No
Outcome Measure Title*								*
Outcome Measure Description								
Outcome Measure Time Frame*								*

Arm/Group Title*		*	*	*
Arm/Group Description ①				
Number of Participants Analyzed*		*	*	*
Analysis Population Description				

		Measure Type*	**Dispersion/Precision Type ***	**Measure Type**	**Dispersion/ Precision Type**	**Measure Type**	**Dispersion/ Precision Type**
		(Circle One) Number, Mean, Median, Least Squares Mean, Geometric Mean, Log Mean	*(Circle One)* ② Not Applicable, Standard Deviation, Inter-Quartile Range, Full Range, Standard Error, 95% Confidence Interval, 90% Confidence Interval, Geometric Coefficient of Variation				
Unit of Measure *	*						
Category Title ④	[*]	*	③*	*	③*	*	③*
Category Title ④	[*]	[*]	③ [*]	[*]	③ [*]	[*]	③ [*]

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".

③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.

④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.

Simple Forms from ClinicalTrials.gov

Serious Adverse Event Summary Form — *ClinicalTrials.gov*

Time Frame for Adverse Event Reporting	
Adverse Event Reporting Additional Description	
Source Vocabulary Name for Table Default ①	
Assessment Type for Table Default ①	(Circle One) Systematic Non-Systematic

Arm/Group Title *	*	*	*
Arm/Group Description ②			

Serious Adverse Events *

		Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events
Total Number for Serious Adverse Events *		*	*		*	*		*	*	
Adverse Event Term *	Organ System *									
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	

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[*] Conditionally required by ClinicalTrials.gov

① The table defaults provide a short-cut for entering the Source Vocabulary Name or Assessment Type for all Adverse Events in a study. If entered, the table default values respectively apply to any Adverse Event with a blank Source Vocabulary Name or Assessment Type. The table default values may be changed for any single Adverse Event , if necessary.

② Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

③ Organ System must be selected from a pick-list of high-level categories. See the "Basic Results" Data Element Definitions for details.

④ Number of Participants at Risk for a single Adverse Event in an Arm/Group is only required when the value differs from the Total Number of Participants at Risk for Serious Adverse Event in the Arm/Group.

Simple Forms from ClinicalTrials.gov

Other (Not Including Serious) Adverse Event Summary Form *ClinicalTrials.gov*

Time Frame for Adverse Event Reporting			
Adverse Event Reporting Additional Description			
Source Vocabulary Name for Table Default ①			
Assessment Type for Table Default ①	(Circle One) Systematic Non-Systematic		
Arm/Group Title *	*	*	*
Arm/Group Description ②			

Other (Not Including Serious) Adverse Events *

		Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events
Total Number for Other (Not Including Serious) Adverse Events *		*	*		*	*		*	*	
Adverse Event Term *	Organ System *									
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	
*	③*	*	④[*]		*	④[*]		*	④[*]	

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① The table defaults provide a short-cut for entering the Source Vocabulary Name or Assessment Type for all Adverse Events in a study. If entered, the table default values respectively apply to any Adverse Event with a blank Source Vocabulary Name or Assessment Type. The table default values may be changed for any single Adverse Event , if necessary.

② Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

③ Organ System must be selected from a pick-list of high-level categories. See the "Basic Results" Data Element Definitions for details.

④ Number of Participants at Risk for a single Adverse Event in an Arm/Group is only required when the value differs from the Total Number of Participants at Risk for Other (Not Including Serious) Adverse Event in the Arm/Group.

Basic Results SAS Macros Overview

- **%PopFlowForm**

  Create Participant Flow Summary Form
- **%BaselineMForm**

  Create Baseline Characteristic Summary Form (combined)
- **%OMForm**

  Create Outcome Measure Summary Form
- **%SAEForm**

  Create Serious Adverse Event Summary Form
- **%FreqAEForm**

  Create Other (Not Including Serious) Adverse Event Summary Form

Basic Results SAS Macros Overview

- **Requirements:**

  Base SAS and SAS/STAT software are required to run these macros which have been tested in SAS version 9.3.

- **Usage:**

  Save SAS macro programs to your system. In a SAS program, add a `%inc` statement to specify the physical folder name where the macros are stored to enable their use:

  ```
  %inc "<location of macro %PopFlowForm>";
  ```

  Example: `%inc 'c:\mysas\PopFlowForm.sas';`

  Then call the macro `%PopFlowForm` as follows :

Macro %PopFlowForm

Create Participant Flow Summary Form

Parameters:

REQUIRED

`inds` = input SAS dataset with data on participant level

`arm` = numeric variable (values: 1, 2,..., *n*) to specify study randomization group or *Arm*; 1 for 1st *Arm*, 2 for 2nd *Arm*, ... n for *n*-th *Arm*

`armTitle` = text strings to specify titles for each *Arm*;

- separated by *****
- for each title, use **/** to split into multiple lines, if needed,
- e.g., **`Trt A /Only * Trt A /+B`**

`varCompleted` = dummy or indicator variable to indicate if a participant completed the *Period*, **1**=completed or **0**=not completed

`outFile` = text string to specify RTF file name to save the *Participant Flow* table

OPTIONAL

`periodTitle`=text string to specify a title for the study period, default=Overall Study

Macro %PopFlowForm (continued)

Parameters:

OPTIONAL (continued)

milestone = dummy or indicator variable for each additional *milestone*, separated by space(s) and each indicator variable has value **1**=completed or **0**=not completed

milestoneTitle = text strings to specify titles for each of the above additional *milestones*, separated by *****

reasonNC= numeric variable to represent the reason why each participant did not complete the *Period*. If a participant completed the *Period*, set this variable as missing (.)

reasonFmt= specifies the format for **reasonNC**, the reason not completed, defined using **proc format**,

e.g., **proc format**;

```
value rncf  1='Adverse Event'
            2='Lost to Follow-Up‘
            3='Pregnancy'
            4='Withdrawal by Subject'
            5=‘Other’; run;
```

Macro %PopFlowForm (continued)

Mocked-up Data Structure (1 row per participant)

SAS - [VIEWTABLE: Work.Popflow]

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	participantID	arm	armTitle	completedPeriod	reasonNotCompleted	reasonType	inMilestone1yr	inMilestone2yr
1	10001	1	Trt A Only	0	2	Lost to Follow-Up	0	0
2	10005	2	Trt A + B	0	2	Lost to Follow-Up	1	0
3	10007	1	Trt A Only	1	.		1	1
4	10009	2	Trt A + B	1	.		1	1
5	10011	1	Trt A Only	1	.		1	1
6	10012	2	Trt A + B	1	.		1	1
7	10013	2	Trt A + B	1	.		1	1
8	10019	1	Trt A Only	0	2	Lost to Follow-Up	1	1
9	10021	1	Trt A Only	0	2	Lost to Follow-Up	1	0
10	10023	2	Trt A + B	0	4	Withdrawal by Subject	1	0
11	10025	2	Trt A + B	1	.		1	1
12	10026	1	Trt A Only	0	2	Lost to Follow-Up	0	0

Macro %PopFlowForm (continued)

Examples

1. **With only required parameters**

```
%let armTitle=%str(Trt A /Only * Trt A /+ B);
%popFlowForm(inds=popFlow, arm=arm,
             armTitle=&armTitle,
             varCompleted=completedPeriod,
             outFile='Participant Flow1.rtf');
```

2. **With required parameters and optional parameters – milestone, milestoneTitle, reasonNC and reasonFmt**

```
%popFlowForm(inds=popFlow, arm=arm,
             armTitle=%str(Trt A Only * Trt A + B),
             varCompleted=completedPeriod,
             milestone=inMilestone1yr inMilestone2yr,
      milestoneTitle=%str(1yr follow-up*2yr follow-up),
             reasonNC=reasonNotCompleted,
             reasonFmt=rncf,
             outFile='Participant Flow2.rtf');
```

Macro %BaselineMForm

Create Baseline Characteristic Summary Form (combined)

Parameters:

REQUIRED

`inds` = input SAS dataset with data on participant level

`arm` = numeric variable (values: 1, 2, ..., *n*) to specify study *Arm*,
1 for 1st *Arm*, 2 for 2nd *Arm*, ... *n* for *n*-th *Arm*

`armTitle` = text strings to specify titles for each *arm*, separated by *****;
within each title, use **/** to split into multiple lines, if needed;

e.g., **`Trt A /Only * Trt A /+ B`**

`var` = specifies baseline measure variables, separated by space(s);

e.g., **`Age Gender Ethnicity`**

`dataType` = specifies data type as either **categorical** or **continuous** for each variable in the above **`var`** list, separated by space(s);

e.g., **`continuous categorical categorical`**

Macro %BaselineMForm (continued)

Parameters: REQUIRED (continued)

`varTitle` = specifies variable titles for first column of the table for the **`var`**, separated by *;

e.g., **`Age*Gender*Ethnicity (NIH/OMB)`**

`dataFmt` = specifies the data format for each **categorical `dataType`** variable , separated by space(s); set it **none** for **continuous** variables;

e.g., **`none sexf ethf`**

Data formats for categorical variables can be defined with `proc format`. If you report Gender with variable title 'Gender', Age with variable title 'Age, Categorical', Ethnicity and Race using NIH/OMB standard, recode these variables to values illustrated next with the corresponding formats. If you report these variables in customized categories, then add 'Customized' in the variables' titles; i.e. 'Age, Customized', 'Gender, Customized', 'Ethnicity, Customized', and 'Race, Customized'; define customized formats with `proc format`.

Macro %BaselineMForm (continued)

```
proc format;
  value sexf 1='Female‘
             2='Male';

  value ethf 1='Hispanic or Latino'
             2='Not Hispanic or Latino'
             98='Unknown or Not Reported';

  value racef 1='American Indian or Alaska Native'
              2='Asian‘
              3='Native Hawaiian or Other Pacific Islander'
              4='Black or African American'
              5='White'
              6='More than one race'
              98='Unknown or Not Reported';

  value agecatf 1='<=18 years'
                2='Between 18 and 65 years'
                3='>=65 years';
run;
```

Macro %BaselineMForm (continued)

Parameters: REQUIRED (continued)

`measureUnit`=specifies unit of measure for variables in the **`var`** list, separated by *****;

e.g., **`years*participants*participants`**

`measureType`=specifies measure type for each variable in the **`var`** list, separated by *****, which can be chosen from

- **`Number`** (e.g., frequency count or number of participants)
- Measure of Central Tendency, if a continuous measure is reported

  `Mean`

  `Median`

e.g., **`Mean*Number*Number`**

Macro %BaselineMForm (continued)

Parameters:

REQUIRED (continued)

dispersionType=specifies measure of dispersion for each variable in the **var** list. The values are selected from

- o **Not Applicable**
- o **Standard Deviation**
- o **Inter-Quartile Range**
- o **Full Range**

Select **Not Applicable** if the **measureType** = **Number**.

Do NOT select **Not Applicable** for other measure types.

e.g., **Standard Deviation*Not Applicable*Not Applicable**

outFile= specify RTF file name to save the *Baseline Characteristic* table

Macro %BaselineMForm (continued)

Mocked-up Data Structure (1 row per participant)

SAS - [VIEWTABLE: Work.Baselinemeasures]

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	participantID	arm	armTitle	age	sex	ethnicity	race	region
1	10001	1	Trt A Only	8	1	1	5	1
2	10005	2	Trt A + B	8	1	1	5	1
3	10007	1	Trt A Only	8	2	1	5	1
4	10009	2	Trt A + B	7	2	1	5	1
5	10011	1	Trt A Only	9	2	1	5	1
6	10012	2	Trt A + B	6	1	1	5	1
7	10013	2	Trt A + B	8	1	1	5	1
8	10019	1	Trt A Only	6	1	1	5	1
9	10021	1	Trt A Only	8	2	1	5	1
10	10023	2	Trt A + B	9	2	2	4	1
11	10025	2	Trt A + B	6	2	98	7	1
12	10026	1	Trt A Only	7	1	1	5	1

Macro %BaselineMForm (continued)

Example

```
%BaselineMForm(inds=baselineMeasures, arm=arm,
               armTitle=%str(Trt A Only * Trt A + B),
               var=age sex ethnicity race region,
               dataType=continuous categorical
                        categorical categorical categorical,
               varTitle=%str(Age * Gender*Ethnicity
                           (NIH/OMB)* Race (NIH/OMB)*
                            Region of Enrollment),
               dataFmt=none sexf ethf racef regnf,
               measureUnit=months*participants*
                      participants*participants*participants,
               measureType=Mean*Number*Number*Number*Number,
               dispersionType=Standard Deviation*
                              not applicable*not applicable*
                              not applicable*not applicable,
              outFile='baseline Measures.rtf');
```

Macro %OMForm

Create Outcome Measure Summary Form

Parameters: REQUIRED

`inds` = input SAS dataset with data on participant level

`arm` = numeric variable (values: 1, 2,..., *n*) to specify study *Arm*, 1 for 1st *Arm*, 2 for 2nd *Arm*, ... n for *n*-th *Arm*

`armTitle` = text strings to specify titles for each *Arm*, separated by *****; within each title, use **/** to split into multiple lines, if needed,

e.g., **`Trt A /Only * Trt A /+ B`**

`var` = specifies *Outcome Measure* variable, which must be numeric; a dichotomous/binary *Outcome Measure* should have values **0** or **1**.

`dataType` = specifies data type as either **`categorical`** or **`continuous`** for the *Outcome Measure* variable; if the *Outcome Measure* variable is dichotomous/binary, **1** should represent the event of interest; e.g., **1**=disease, **0**=no disease.

Macro %OMForm (continued)

Parameters: REQUIRED (continued)

`varTitle` = specifies *Outcome Measure* variable title for display in the first column of the table

`dataFmt` = specifies data format for *Outcome Measure* variable. Set it **none** for each **continuous** or **binary** variable; format for **categorical** variables with 3 or more categories can be defined using `proc format`, e.g., **`proc format;`**

```
value tstatusf 1="decayed/filled/missing"
               2="sound"
               3="sealant";
run;
```

`measureUnit` = specifies unit of measure for *Outcome Measure* variable

`measureType` = specifies measure type for *Outcome Measure* variable, from the following list :

- **`Number`** (e.g., frequency count or number of participants)
- Measure of Central Tendency, if a continuous measure is reported

  `Mean`

  `Median`

Macro %OMForm (continued)

Parameters:

REQUIRED (continued)

dispersionType = specifies measure of dispersion for the *Outcome Measure* variable, and choose from the following list:

- **Not Applicable** (only if **measureType**=**Number**)
- **Standard Deviation**
- **Inter-Quartile Range**
- **Full Range**
- **Standard Error**
- **95% Confidence Interval**
- **90% Confidence Interval**

outFile = specifies RTF file name to save the *Outcome Measure* table

OPTIONAL

displayTotal = whether to display total number of participants affected / at-risk by *Arm*; value = **Yes** or **No**; default=**No**

Macro %OMForm (continued)

Mocked-up Data Structure (1 row per participant)

SAS - [VIEWTABLE: Work.Outcomemeasures]

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	participantID	arm	armTitle	dfs	decay
1	10007	1	Trt A Only	5	1
2	10009	2	Trt A + B	0	0
3	10011	1	Trt A Only	0	0
4	10012	2	Trt A + B	0	0
5	10013	2	Trt A + B	2	1
6	10014	1	Trt A Only	0	0
7	10017	1	Trt A Only	2	1
8	10025	2	Trt A + B	1	1
9	10029	1	Trt A Only	0	0
10	10031	2	Trt A + B	0	0
11	10032	1	Trt A Only	0	0
12	10037	2	Trt A + B	2	1

Macro %OMForm (continued)

Examples

1. **for continuous outcome**

```
%let armTitle=%str(Trt A Only*Trt A + B);
%OMForm(inds=outcomeMeasures, arm=arm, armTitle=&armTitle,
        var=dfs,  dataType=continuous,
        varTitle=%str(Caries Increment), dataFmt=none,
        measureUnit=tooth surfaces, measureType=Mean,
        dispersionType=Standard Error, displayTotal=Yes,
        outFile='Outcome Measure1.rtf');
```

2. **for dichotomous / binary (2-category) categorical outcome**

```
%OMForm(inds=outcomeMeasures, arm=arm, armTitle=&armTitle,
        var=decay, dataType=categorical,
        varTitle=%str(Any Caries Incidence), dataFmt=none,
        measureUnit=participants, measureType=Number,
        dispersionType=Not Applicable,
        outFile='Outcome Measure2.rtf');
```

Macro %OMForm (continued)

Examples

3. for 3 or more category categorical outcome

```
%OMForm(inds=outcomeMeasures, arm=arm,
        armTitle=&armTitle,
        var=status, dataType= categorical,
        varTitle=%str(Tooth Status),
        dataFmt=tstatusf,
        measureUnit=participants,
        measureType=Number,
        dispersionType=Not Applicable,
        displayTotal=Yes,
        outFile='Outcome Measure3.rtf');
```

Macro %SAEForm

Create Serious Adverse Event Summary Form

Parameters:

REQUIRED

inds = input SAS dataset with serious adverse events on participant level

arm = numeric variable (values: 1, 2, ..., *n*) to specify study *Arm*, 1 for 1st *Arm*, 2 for 2nd *Arm*, ... *n* for *n*-th arm

armTitle = text strings to specify titles for each arm, separated by *****; within each title, use **/** to split into multiple lines, if needed,

e.g., **`Trt A /Only*Trt A /+ B`**

saeVar = specifies numeric organ system *Serious Adverse Event* variables, separated by space(s);

e.g., **`saeVar=sae_bloodDisorders sae_cardiDisorders`**.

If at least 1 participant had at least 1 *SAE* in an organ system, then its *SAE* variable should be included in this list. If a participant did not have a *SAE* in an organ system, then set the corresponding *SAE* organ system variable to **0** (e.g., **`sae_bloodDisorders=0`**)

Macro %SAEForm (continued)

Parameters: REQUIRED (continued)

saeVarTitle = specifies titles (high-level categories of organ systems) for *SAE* variables included in **saeVar** for the table's 1st column.

saeFmt= specifies formats for each of the high-level organ system *SAE* variables, which can be defined with `proc format`; e.g.,

```
proc format;
  value bloodDf 1="Anaemia"
                2="Leukopenia"
                3="Lymphadenitis"     …  ;
  value cardiDf  1="Cardiac Failure"
                 2="Atrial Fibrillation"
                 3="Cardiogenic Shock"…  ;
run;
```

outFile = specifies RTF file name to save the *SAE* table

Macro %SAEForm (continued)

Parameters:

OPTIONAL

`displayTotalPct` = indicates whether to display percent for total number of participants affected / at risk by *Arm*; value=**`yes`** or **`no`**; default=**`yes.`**

Macro %SAEForm (continued)

Mocked-up Data Structure (1 row per participant)

SAS - [VIEWTABLE: Work.Sae]

File Edit View Tools Data Solutions Window Help

	participantID	arm	armTitle	SeriousAdverseEvent	sae_bloodDisorders	sae_cardiDisorders
1	1001	1	Trt A Only		0	0
2	1002	2	Trt A + B		0	0
3	1003	2	Trt A + B	Anaemia, Leukopenia	1, 2	0
4	1004	1	Trt A Only	Cardiogenic Shock	0	3
5	1005	2	Trt A + B		0	0
6	1006	1	Trt A Only	Atrial Fibrillation	0	2
7	1007	1	Trt A Only		0	0
8	1008	2	Trt A + B	Cardiac Failure	0	1
9	1009	2	Trt A + B	Anaemia	1	0
10	1010	1	Trt A Only		0	0
11	1011	2	Trt A + B		0	0
12	1012	1	Trt A Only	Lymphadenitis	3	0
13	1013	1	Trt A Only		0	0
14	1014	2	Trt A + B		0	0

Macro %SAEForm (continued)

Call Example

```
%SAEForm(inds=sae, arm=arm,
         armTitle=%str(Trt A Only*Trt A + B ),
         saeVar=sae_bloodDisorders
                sae_cardiDisorders,
         saeVarTitle=%str(Blood and lymphatic
                          system disorders*
                          Cardiac disorders),
         saeFmt=bloodDf  cardiDf,
         outFile='Severe Adverse Events.rtf');
```

Macro %FreqAEForm

Create Other (Non-Serious) Adverse Event Summary Form

Parameters: REQUIRED

inds = input SAS dataset with *Other (Non-Serious) Adverse Events* on participant level

FreqThreshold = The percentages, between 0 and 5, of *Other (Non-Serious) Adverse Event* variables that, when exceeded within an *Arm*, are reported for all *Arms*.; any number from 0 to 5 such as 0, 2.5, and 5 without symbols (e.g., %).

arm = numeric variable (values: 1, 2, ..., *n*) to specify *Arm*,

1 for 1st *Arm*, 2 for 2nd *Arm*, ... *n* for the *n*-th *Arm*

armTitle = text strings to specify titles for each *Arm*, separated by *****; within each title, use **/** to split into multiple lines, if needed;

e.g., **`Trt A /Only*Trt A /+ B`**

Macro %FreqAEForm (continued)

Parameters: REQUIRED (continued)

oaeVar = specify numeric *Other (not including Serious) Adverse Event* variables grouped by organ system; e.g., **oae_nervDisorders oae_respDisorders**, separated by space(s). If there was at least 1 participant affected by an *Other(Non-Serious) Adverse Event*, its corresponding AE variable should be included in the **oaeVar** parameter. If a participant was not affected by any *Other Adverse Event* in a high-level category (organ system), then the adverse event variable is 0 (e.g., **oae_nervDisorders=0**) for this participant.

oaeVarTitle= specifies titles (high-level category organ systems) for *Other Adverse Event* variables in **oaeVar** for the first column of the table, such as Nervous system disorders, and Respiratory, thoracic and mediastinal disorders.

Macro %FreqAEForm (continued)

Parameters: REQUIRED (continued)

oaeFmt = specifies the formats for each of the Other Adverse Events variables, which can be defined using proc format, e.g.,

```
proc format;
    value genDf   1='Asthenia'
                  2='Injection site pain‘ …;
    value nervDf  1="Headache"  …;
    value respDf  1="Dyspnoea"
                  2="Epistaxis"
                  3="Cough"    …;
run;
```

outFile = specifies RTF file name to save the *AE* table

OPTIONAL

displayTotalPct = whether to display percent for total number of participants affected / at-risk by *Arm*; value= **yes** or **no**; default=**yes**

Macro %FreqAEForm (continued)

Mocked-up Data Structure (1 row per participant)

SAS - [VIEWTABLE: Work.Ae]

File Edit View Tools Data Solutions Window Help

	participantID	arm	armTitle	OtherAdverseEvent	oae_genDisorders	oae_nervDisorder	oae_respDisorders
1	1001	1	Trt A Only	Asthenia	1	0	0
2	1002	2	Trt A + B	Headache, Cough	0	1	3
3	1003	2	Trt A + B		0	0	0
4	1004	1	Trt A Only	Dyspnoea	0	0	1
5	1005	2	Trt A + B	Injection site pain	2	0	0
6	1006	1	Trt A Only		0	0	0
7	1007	1	Trt A Only		0	0	0
8	1008	2	Trt A + B	Dyspnoea, Cough	0	0	1, 3
9	1009	2	Trt A + B		0	0	0
10	1010	1	Trt A Only		0	0	0
11	1011	2	Trt A + B		0	0	0
12	1012	1	Trt A Only	Epistaxis	0	0	2
13	1013	1	Trt A Only	Headache	0	1	0
14	1014	2	Trt A + B		0	0	0

Macro %FreqAEForm (continued)

Examples

1. **Any other adverse events (0% frequency threshold)**

```
%FreqAEForm(inds=ae,  FreqThreshold=0,  arm=arm,
            armTitle=%str(Trt A Only*Trt A + B),
             oaeVar=oae_genDisorders  oae_nervDisorders
                    oae_respDisorders,
            oaeVarTitle=%str(General disorders
                             *Nervous system disorders
        *Respiratory, thoracic and mediastinal disorders),
             oaeFmt=genDf nervDf  respDf,
            outFile='Other Adverse Events.rtf');
```

2. **2.5% frequency threshold**

```
%FreqAEForm(inds=ae,  FreqThreshold=2.5,  arm=arm,
            armTitle=%str(Trt A Only*Trt A + B),
             oaeVar=oae_genDisorders oae_nervDisorders
                    oae_respDisorders,
            oaeVarTitle=%str(General disorders
                             *Nervous system disorders
        *Respiratory, thoracic and mediastinal disorders),
          oaeFmt=genDf nervDf respDf, displayTotalPct=no,
             outFile='Other Adverse Events.rtf');
```

Notes

- Basic Results SAS Macros can be used to populate basic result forms to help comply with federal requirements to report basic results in ClinicalTrials.gov
- They don’t calculate complicated results, such as geometric means, least squares means, or statistical analyses, which must be calculated separately but they can report those externally calculated statistics in these tables.

QUESTIONS?