



Michigan SAS[®] Users Group
June 7th | Detroit, MI

Auto Populating PowerPoint Presentations So You Don't Have To

Kaitie Lawson

- Senior biostatistician at Rho, Inc. in Chapel Hill, NC
 - since 2011
 - Works on federally funded food allergy (mostly peanut) and hay fever clinical trials
- From Tennessee
- Uses SAS[®] daily at work
- SAS user for 9 years

Brett Jepson

- Senior biostatistician at Rho, Inc. in Chapel Hill, NC
 - since 2009
 - Works on federally funded atopic dermatitis, asthma and vaccine clinical trials
- From Utah
- Uses SAS[®] daily at work
- SAS user for 11 years

SECTION 1: BACKGROUND

Baseline Assumptions

- Basic knowledge of macro coding
- Familiarity with the PROC REPORT and PROC SGPLOT

Our Problem

- Budget restrictions
 - Fewer resources to put the same (if not more) amount of time and effort into preparing presentations
- Standardized DSMB presentation
 - Move away from lengthy physical/electronic binders to succinct presentations
 - Multiple studies reporting to the same DSMB
 - Study-to-study customizations required

Our Solution

- ODS POWERPOINT combined with macro coding
 - Allows for few study-to-study customizations
 - Ensures standardized formatting is preserved
 - Minimal effort for each presentation setup
 - Eliminates need to copy/paste or hand enter data into presentations

SECTION 2: REPORTS

Brief Introduction

Structure

- Create a macro for each slide
- Each study has its own program with multiple macro calls
- Example of presentation program

```
ODS POWERPOINT;
```

```
<Macro calls for each slide>
```

```
ODS POWERPOINT CLOSE;
```

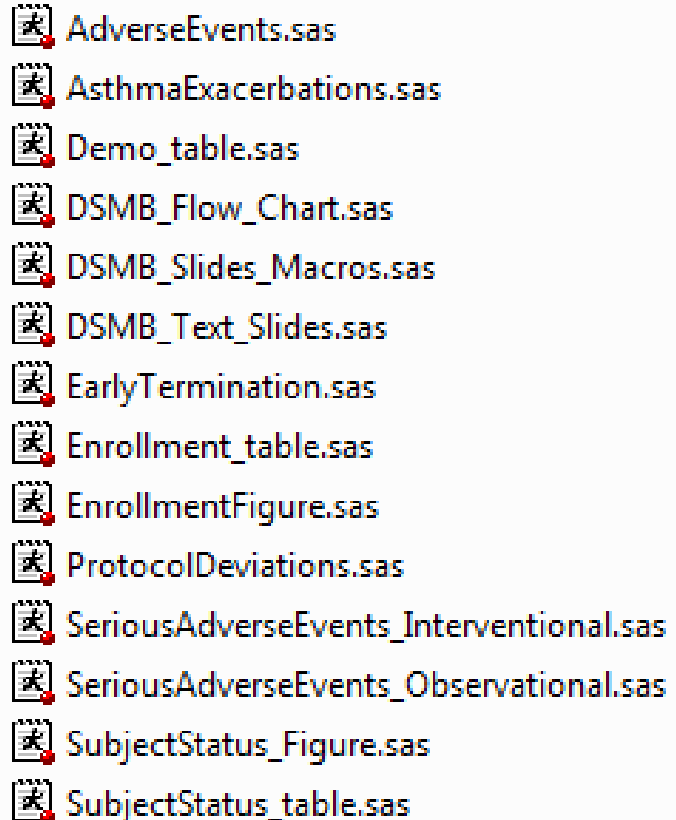

Structure

- Create a macro for each slide
- Each study has its own program with multiple macro calls
- Example of presentation program

ODS POWERPOINT;

<Macro calls for each slide>

ODS POWERPOINT CLOSE;



- AdverseEvents.sas
- AsthmaExacerbations.sas
- Demo_table.sas
- DSMB_Flow_Chart.sas
- DSMB_Slides_Macros.sas
- DSMB_Text_Slides.sas
- EarlyTermination.sas
- Enrollment_table.sas
- EnrollmentFigure.sas
- ProtocolDeviations.sas
- SeriousAdverseEvents_Interventional.sas
- SeriousAdverseEvents_Observational.sas
- SubjectStatus_Figure.sas
- SubjectStatus_table.sas

Structure

- Create a macro for each slide
- Each study has its own program with multiple macro calls
- Example of presentation program
ODS POWERPOINT;
 <Macro calls for each slide>
ODS POWERPOINT CLOSE;

```
%include "S:\...\Macros\DSMB\DSMB_Slides_Macros.sas";
options nodate;
ods powerpoint file="Output Directory\DSMB_Report.pptx" nogtitle nogfootnote ;
%titleslide(protocol_title = New Study
            , protocol_number = Study 01
            , pi_names = %str(John Doe, MD)
            , cutoff_date = %str(January 16, 1960)
            , dsmb_date = %str(January 16, 1960)
            );

%studydesign_interventional(design = %str(Phase 3, 3 site, randomized trial in Peanut Allergy)
                           , arm1 = Peanut Oral Immunotherapy
                           , arm2 = Peanut Patch
                           , arm3 = Placebo
                           , enrollgoal = 600 randomized participants
                           , primary = Proportion of subjects who pass a 5g peanut oral food challenge
                           );
...
%DevSlide(DevDS = ADDV
          , SubDS = ADSL
          , IDVAR = USUBJID
          , Cat = DEVCA
          , Site = SITEID
          );
...
%AESlide( AEDS = ADAE
          , SubDS = ADSL
          , IDVar = USUBJID
          , SAEFL = %str(AESER = 'Yes')
          , SEVN = AESEV
          , AETRT = AERELC
          , AEPRC = AERELP
          );
...
ods powerpoint close;
```

Types of Slides

- Text slides
 - Title slides
 - List Slides
 - Text Slides
- Table/Listing slides
- Figure slides
- Combination slides

SECTION 3: TEXT SLIDES

Example of Text Slides

Title of the DSMB Presentation

Protocol Number: XXXXXXXX

Sponsor: XXXXXX

Report Prepared by:
My CRO, Inc. (My City, USA)

Data Cutoff Date: Month Day, Year
DSMB Meeting Date: Month Day, Year
Open Meeting Presentation

Title Slide

Study Design

- Phase 3, 1-site, 3-arm, double-blind, double-dummy, placebo-controlled, randomized trial in adults aged 18-55 with Seasonal Allergic Rhinitis
 - Arm 1: Subcutaneous Immunotherapy + Sublingual Placebo
 - Arm 2: Sublingual Immunotherapy + Subcutaneous Placebo
 - Arm 3: Double Placebo
- Enrollment goal: 300 randomized in a 1:1:1 fashion
- Primary Endpoints:
 - Total Nasal Symptom Score Area Under the Curve in response to Nasal Allergen Challenge measured at 3 Years
 - Peak Nasal Inspiratory Flow Area Under the Curve in response to Nasal Allergen Challenge measured at 3 Years

Study Design Slide

Text Slides

- Why?
 - Necessary for creating one presentation program
 - No need to copy/paste or hand enter data after running program
 - Ensures standardized text
 - Avoids typographical errors
 - Can pull data directly from SAS programs/datasets
- SAS Procedures
 - ODSTEXT
 - ODSLIS

PROC ODSSTEXT - Text Slide

```
ODS ESCAPECHAR='~';
ODS POWERPOINT FILE="TITLE_SLIDE.pptx" NOGTITLE NOGFOOTNOTE;
PROC ODSSTEXT;
    P " " / STYLE={FONTSIZE=30};
    P "Title of the DSMB Presentation" / STYLE={FONTSIZE=20 JUST=C FONTWEIGHT=BOLD};
    P " " / STYLE={FONTSIZE=30};
    P "Protocol Number: XXXXXX ~n Sponsor: XXXXXXXXX" / STYLE={FONTSIZE=12 JUST=C};
    P "Report Prepared by:~n My CRO, Inc. (My City, USA)" / STYLE ={FONTSIZE=8 JUST=C};
    P "Data Cutoff Date: Month Day, Year ~n DSMB Meeting Date: Month, Day Year ~n
        Open Meeting Presentation" / STYLE ={FONTSIZE=8 JUST=C};
RUN;
ODS POWERPOINT CLOSE;
```

PROC ODSSTEXT - Text Slide

```
ODS ESCAPECHAR='~';
ODS POWERPOINT FILE="TITLE_SLIDE.pptx" NOGTITLE NOGFOOTNOTE;
PROC ODSSTEXT;
  P " " / STYLE={FONTSIZE=30};
  P "Title of the DSMB Presentation" / STYLE={FONTSIZE=20 JUST=C FONTWEIGHT=BOLD};
  P " " / STYLE={FONTSIZE=30};
  P "Protocol Number: XXXXXX ~n Sponsor: XXXXXXXX" / STYLE={FONTSIZE=12 JUST=C};
  P "Report Prepared by:~n My CRO, Inc. (My City, USA)" / STYLE ={FONTSIZE=8 JUST=C};
  P "Data Cutoff Date: Month Day, Year ~n DSMB Meeting Date: Month, Day Year ~n
    Open Meeting Presentation" / STYLE ={FONTSIZE=8 JUST=C};
RUN;
ODS POWERPOINT CLOSE;
```


PROC ODSTEXT - Text Slide Macro

```
ODS ESCAPECHAR='~';
%MACRO TITLESIDE
(PRESENTATION_TITLE=,PROTOCOL_NUMBER=,SPONSOR=,CUTOFF_DATE=,DSMB_DATE=);
ODS POWERPOINT FILE="TITLE_SLIDE.pptx" NOGTITLE NOGFOOTNOTE;
PROC ODSTEXT;
  P " " / STYLE={FONTSIZE=30};
  P "&PRESENTATION_TITLE. " / STYLE={FONTSIZE=20 JUST=C FONTWEIGHT=BOLD};
  P " " / STYLE={FONTSIZE=30};
  P "Protocol Number: &PROTOCOL_NUMBER.~n Sponsor: &SPONSOR." / STYLE={FONTSIZE=12
                                                                    JUST=C};
  P "Report Prepared by:~n My CRO, Inc. (My City, USA)" / STYLE ={FONTSIZE=8 JUST=C};
  P "Data Cutoff Date: &CUTOFF_DATE.~n DSMB Meeting Date: &DSMB_DATE.~n Open Meeting
    Presentation" / STYLE ={FONTSIZE=8 JUST=C};
RUN;
ODS POWERPOINT CLOSE;
%MEND TITLESIDE;
```

PROC ODSTEXT - Text Slide Macro Call

```
%TITLESIDE (PRESENTATION_TITLE= Title of the DSMB Presentation,  
            PROTOCOL_NUMBER= Study-01,  
            SPONSOR= Pharma Company,  
            CUTOFF_DATE= %STR(March 30, 2017) ,  
            DSMB_DATE= %STR(May 15, 2017)) ;
```

PROC ODSTEXT - Text Slide Macro Call and Result

```
%TITLESIDE (PRESENTATION_TITLE= Title of the DSMB Presentation,  
            PROTOCOL_NUMBER= Study-01,  
            SPONSOR= Pharma Company,  
            CUTOFF_DATE= %STR(March 30, 2017) ,  
            DSMB_DATE= %STR(May 15, 2017)) ;
```

Title of the DSMB Presentation

Protocol Number: Study-01
Sponsor: Pharma Company

Report Prepared by:
My CRO, Inc. (My City, USA)

Data Cutoff Date: March 30, 2017
DSMB Meeting Date: May 15, 2017
Open Meeting Presentation

PROC ODSLIT – Study Design Slide

Study Design

- Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-55 with Lupus Nephritis
 - Arm 1: A
 - Arm 2: B
- Enrollment goal: 100 Randomized
- Primary Endpoint: Proportion of subjects who achieve a complete response at 24 weeks

PROC ODSLIS – Study Design Slide

```
ODS POWERPOINT FILE = "DESIGN_SLIDE.PPTX";
PROC ODSLIS;
  ITEM;
  P "Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-
    55 with Lupus Nephritis" || " " /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
  LIST / STYLE={FONTSIZE=10.5 LISTSTYLETYPE="circle"};
    ITEM "Arm 1: A";
    ITEM "Arm 2: B";
  END;
END;
ITEM "Enrollment goal: 100 randomized" || " " /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
ITEM "Primary Endpoint: Proportion of subjects who achieve a complete response at 24 weeks"
  /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
RUN;
ODS POWERPOINT CLOSE;
```

PROC ODSLIST – Study Design Slide

```
ODS POWERPOINT FILE = "DESIGN_SLIDE.PPTX";
PROC ODSLIST;
  ITEM;
  P "Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-55 with Lupus Nephritis" || " " /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
  LIST / STYLE={FONTSIZE=10.5 LISTSTYLETYPE="circle"};
    ITEM "Arm 1: A";
    ITEM "Arm 2: B";
  END;
END;
ITEM "Enrollment goal: 100 randomized" || " " /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
ITEM "Primary Endpoint: Proportion of subjects who achieve a complete response at 24 weeks"
  /STYLE={FONTSIZE=12 LISTSTYLETYPE="disc"};
RUN;
ODS POWERPOINT CLOSE;
```

PROC ODSLIT – Study Design Slide

Study 1

Study Design

- Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-55 with Lupus Nephritis
 - Arm 1: A
 - Arm 2: B
- Enrollment goal: 100 Randomized
- Primary Endpoint: Proportion of subjects who achieve a complete response at 24 weeks

```
%STUDYDESIGN(  
DESIGN= %STR(Phase 2, 3 site, 2 arm,  
double-blind, placebo controlled, randomized trial  
in adults aged18-55 years with Lupus Nephritis),  
ARM1= A,  
ARM2= B,  
ENROLLGOAL= 100 Randomized,  
PRIMARY= Proportion of subjects who  
achieve a complete response at  
24 weeks );
```

Text Slide Hints

- Creating lists of varying lengths

Text Slide Hints

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Study Design

- Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-55 with Lupus Nephritis
 - Arm 1: A
 - Arm 2: B
- Enrollment goal: 100 Randomized
- Primary Endpoint: Proportion of subjects who achieve a complete response at 24 weeks

Study Design

- Phase 3, 1-site, 3-arm, double-blind, double-dummy, placebo-controlled, randomized trial in adults aged 18-55 with Seasonal Allergic Rhinitis
 - Arm 1: Subcutaneous Immunotherapy + Sublingual Placebo
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Text Slide Hints

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- Phase 2, 3-site, 2-arm, double-blind, placebo-controlled, randomized trial in adults aged 18-55 with Lupus Nephritis
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Study Design

- Phase 3, 1-site, 3-arm, double-blind, double-dummy, placebo-controlled, randomized trial in adults aged 18-55 with Seasonal Allergic Rhinitis
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- Primary Endpoints:
 - Total Nasal Symptom Score Area Under the Curve in response to Nasal Allergen Challenge measured at 3 Years
 - Peak Nasal Inspiratory Flow Area Under the Curve in response to Nasal Allergen Challenge measured at 3 Years

Text Slide Hints

```
%MACRO STUDYDESIGN(DSIGN= ..., ARM1= , ARM2= , ARM3= ,ARM4=...,  
                    PRIMARY1=, PRIMARY2=, PRIMARY3=);
```

...

```
PROC ODSLST;
```

```
  ITEM;
```

```
  LIST / STYLE={FONTSIZE=16 LISTSTYLETYPE="DISC"};
```

```
  %IF &ARM1. ^= %THEN %DO I = 1 %TO 4;
```

```
    %IF &&ARM&I. ^= %THEN %DO;
```

```
      ITEM "&&ARM&I.~ ";
```

```
    %END;
```

```
  %END;
```

```
END;
```

```
END;
```

```
RUN;
```

...

```
%MEND STUDYDESIGN;
```

```
% STUDYDESIGN(ARM1 = A, ARM2 = B);
```

Text Slide Hints

```
%MACRO STUDYDESIGN(DSIGN= ..., ARM1= , ARM2= , ARM3= ,ARM4=...,  
                    PRIMARY1=, PRIMARY2=, PRIMARY3=);
```

```
...
```

```
PROC ODSLST;
```

```
  ITEM;
```

```
  LIST / STYLE={FONTSIZE=16 LISTSTYLETYPE="DISC"};
```

```
    %IF &ARM1. ^= %THEN %DO I = 1 %TO 4;
```

```
      %IF &&ARM&I. ^= %THEN %DO;
```

```
        ITEM "&&ARM&I.~ ";
```

```
      %END;
```

```
    %END;
```

```
  END;
```

```
END;
```

```
RUN;
```

```
...
```

```
%MEND STUDYDESIGN;
```

```
% STUDYDESIGN(ARM1 = A, ARM2 = B);
```

SECTION 4: TABLE/LISTING SLIDES

Example of Table Slides

Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

Summarized over all sites, a study that as been previously presented to the DSMB



Protocol Deviations by Site

Site	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Atlanta	0 (0%)	2 (4%)
Boston	1 (5%)	5 (10%)
Dallas	12 (60%)	21 (42%)
Denver	4 (20%)	11 (22%)
New York	1 (5%)	4 (8%)
Washington, DC	2 (10%)	7 (14%)

Summarized by site opposed to by Deviation Type

Table/Listing Slides

- Why?

- Ensures standardized formatting
- Avoids typographical errors 
- Eliminates copying/pasting 
- Can pull data directly from SAS programs/datasets

- SAS Procedures

- Code to create summary dataset (PROC FREQ, PROC SQL, etc.)
- PROC REPORT
- Any other table/listing format (not covered here)

PROC REPORT – Protocol Deviation Slide

```
ODS POWERPOINT FILE = "DEVIATION SLIDE.PPTX";
TITLE "Protocol Deviations";
PROC REPORT DATA=SUMMARY_DATA NOWD SPLIT = "~" HEADSKIP CENTER
  STYLE(REPORT) = [HEIGHT=6IN WIDTH=9.25IN]
  STYLE(HEADER)=[BACKGROUND=BIGB FONTWEIGHT=BOLD FOREGROUND=WHITE];
  COLUMN LINE COL1 ("Deviations: n (%)" COL2 COL3);
  DEFINE LINE / ORDER NOPRINT;
  DEFINE COL1 / DISPLAY LEFT FLOW "~Deviation" STYLE=[JUST=LEFT CELLWIDTH=7IN]
    STYLE(COLUMN)=[ASIS=ON] STYLE(HEADER) =[JUST=LEFT
      FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
      BACKGROUND=BIGB];
  DEFINE COL2 / DISPLAY LEFT FLOW "Since Last Report:~N = &NEWN" STYLE=[JUST=
    CENTER CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
    BACKGROUND=BIGB];
  DEFINE COL3 / DISPLAY LEFT FLOW "To Date:~N = &TOTN" STYLE=[JUST=CENTER
    CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8
    FOREGROUND=WHITE
    BACKGROUND=BIGB];
RUN;
ODS POWERPOINT CLOSE;
```


PROC REPORT – Protocol Deviation Slide

```
ODS POWERPOINT FILE = "DEVIATION SLIDE.PPTX";
TITLE "Protocol Deviations";
PROC REPORT DATA=SUMMARY_DATA NOWD SPLIT = "~" HEADSKIP CENTER
  STYLE(REPORT) = [HEIGHT=6IN WIDTH=9.25IN]
  STYLE(HEADER)=[BACKGROUND=BIGB FONTWEIGHT=BOLD FOREGROUND=WHITE];
  COLUMN LINE COL1 ("Deviations: n (%)" COL2 COL3);
  DEFINE LINE / ORDER NOPRINT;
  DEFINE COL1 / DISPLAY LEFT FLOW "~Deviation" STYLE=[JUST=LEFT CELLWIDTH=7IN]
    STYLE(COLUMN)=[ASIS=ON] STYLE(HEADER) =[JUST=LEFT
      FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
      BACKGROUND=BIGB];
  DEFINE COL2 / DISPLAY LEFT FLOW "Since Last Report:~N = &NEWN" STYLE=[JUST=
    CENTER CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
    BACKGROUND=BIGB];
  DEFINE COL3 / DISPLAY LEFT FLOW "To Date:~N = &TOTN" STYLE=[JUST=CENTER
    CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8
    FOREGROUND=WHITE
    BACKGROUND=BIGB];
RUN;
ODS POWERPOINT CLOSE;
```

PROC REPORT – Protocol Deviation Slide

```
ODS POWERPOINT FILE = "DEVIATION SLIDE.PPTX";
TITLE "Protocol Deviations";
PROC REPORT DATA=SUMMARY_DATA NOWD SPLIT = "~" HEADSKIP CENTER
  STYLE(REPORT) = [HEIGHT=6IN WIDTH=9.25IN]
  STYLE(HEADER)=[BACKGROUND=BIGB FONTWEIGHT=BOLD FOREGROUND=WHITE];
  COLUMN LINE COL1 ("Deviations: n (%)" COL2 COL3);
  DEFINE LINE / ORDER NOPRINT;
  DEFINE COL1 / DISPLAY LEFT FLOW "~Deviation" STYLE=[JUST=LEFT CELLWIDTH=7IN]
    STYLE(COLUMN)=[ASIS=ON] STYLE(HEADER) =[JUST=LEFT
      FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
      BACKGROUND=BIGB];
  DEFINE COL2 / DISPLAY LEFT FLOW "Since Last Report:~N = &NEWN" STYLE=[JUST=
    CENTER CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
    BACKGROUND=BIGB];
  DEFINE COL3 / DISPLAY LEFT FLOW "To Date:~N = &TOTN" STYLE=[JUST=CENTER
    CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
    FONTWEIGHT=BOLD FONTSIZE=5.8
    FOREGROUND=WHITE
    BACKGROUND=BIGB];
RUN;
ODS POWERPOINT CLOSE;
```

Table/Listing Slide Hints

- Standardized datasets across studies
 - Allows for fewer macro variables or default macro variable definitions

Table/Listing Slide Hints

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 - Allows for fewer macro variables or default macro variable definitions

```
%DEVSLIDE(DEVDS=<Protocol Deviation Dataset>  
          , SUBDS=<Subject Level Dataset>  
          , IDVAR=<ID Variable>  
          , DEVVAR=<Deviation Type Variable>  
          , CUTOFF=<Cutoff Date>);
```

Table/Listing Slide Hints

- Standardized datasets across studies
 - Allows for fewer macro variables or default macro variable definitions

```
%DEVSLIDE(DEVDS=<Protocol Deviation Dataset>  
          , SUBDS=<Subject Level Dataset>  
          , IDVAR=<ID Variable>  
          , DEVVAR=<Deviation Type Variable>  
          , CUTOFF=<Cutoff Date>);
```

Table/Listing Slide Hints

- Standardized datasets across studies
 - Allows for fewer macro variables or default macro variable definitions

%DEVSLIDE(CUTOFF=07JUN2017);

Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

Table/Listing Slide Hints

- “Other, specify” lists
 - Example: CRF protocol deviation types
 - Need to report all CRF options, but don’t want to inadvertently omit ‘Other, specify’ entries

Table/Listing Slide Hints

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- Example: CRF protocol deviation types
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	Since Last Report: N = 20	To Date: N = 50
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Table/Listing Slide Hints

- “Other, specify” lists
 - Example: CRF protocol deviation types
 - Need to report all CRF options, but don’t want to inadvertently omit ‘Other, specify’ entries

Protocol Deviations

Deviation	Deviations: n (%)	
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Informed Consent	4 (20%)	8 (16%)
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Study treatment administration	5 (25%)	14 (28%)
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Other: Violation of visit window	2 (10%)	7 (14%)

Table/Listing Slide Hints

- “Other, specify” lists

```
%MACRO DEVSLIDE(DEVDS=, SUBDS=,  
IDVAR=, DEVVAR, CUTOFF=, TYPELIST=);
```

```
%DEVSLIDE(..., TYPELIST=%STR(Informed Consent | Missed Safety, Efficacy or Endpoint  
Assessments | Reporting of SAEs | Study treatment administration | Use of Prohibited  
Medications);
```

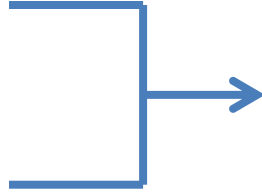
Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
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Table/Listing Slide Hints

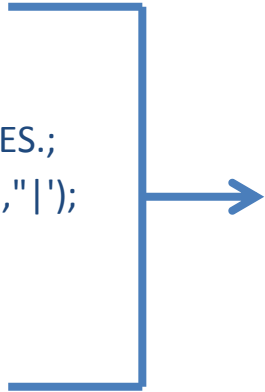
- “Other, specify” lists

```
DATA _NULL_;  
  TYPES = "&TYPESLIST."  
  NUMTYPES = COUNT(TYPES, '|') + 1;  
  CALL SYMPUTX("NUMTYPES", NUMTYPES);  
RUN;
```



Creates a macro variable of the number of items in the list.

```
DATA SHELL;  
  FORMAT COL1_ $132.;  
  TYPES = "&TYPESLIST."  
  %DO I = 1 %TO &NUMTYPES.;  
    COL1_ = SCAN(TYPES, &I., '|');  
    SORT = &I.;  
    OUTPUT;  
  %END;  
RUN;
```

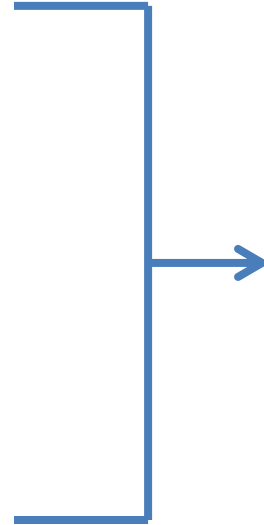


Creates a shell of all items in the list.

Table/Listing Slide Hints

- “Other, specify” lists

```
DATA DEVIATIONS;  
  LENGTH COL1 $132;  
  MERGE DEVIATION_DATASET SHELL (IN=A);  
  BY COL1_;  
  IF A THEN COL1 = COL1_;  
  ELSE DO;  
    COL1 = "Other: " || COL1_;  
    SORT = 99;  
  END;  
RUN;
```



Merges the deviation dataset with the shell, adds 'Other: ' to the beginning of each item in your list and sets a SORT variable so the 'Other' items will appear last.

Table/Listing Slide Hints - Continued

- “Since Last Report” option
 - Not needed for the first DSMB report

Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

Table/Listing Slide Hints - Continued

- “Since Last Report” option

```
%MACRO DEVSLIDE(DEVDS=, SUBDS=, IDVAR=, DEVVAR, CUTOFF=, TYPELIST=, SITE=);  
...  
PROC REPORT DATA=SUMMARY_DATA <OPTIONS>;  
  COLUMN LINE COL1 ("Deviations: n (%)" COL2 %IF &CUTOFF. ^= %THEN COL3);  
  DEFINE LINE / ORDER NOPRINT;  
  DEFINE COL1 / DISPLAY LEFT FLOW "~Deviation" <OPTIONS>;  
  %IF &CUTOFF. ^= %THEN %DO;  
    DEFINE COL2 / DISPLAY LEFT FLOW "Since Last Report:~N = &NEWN" <OPTIONS>;  
    DEFINE COL3 / DISPLAY LEFT FLOW "To Date:~N = &TOTN" <OPTIONS>;  
  %END;  
  %ELSE %DO;  
    DEFINE COL2 / DISPLAY LEFT FLOW "N = &TOTN" <OPTIONS>;  
  %END;  
RUN;  
%MEND DEVSLIDE;
```

Table/Listing Slide Hints - Continued

- “By Site” option
 - Creates an optional ‘by site’ table that borrows much of the same coding to create the non-‘by site’ table

Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

Protocol Deviations by Site

Site	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Atlanta	0 (0%)	2 (4%)
Boston	1 (5%)	5 (10%)
Dallas	12 (60%)	21 (42%)
Denver	4 (20%)	11 (22%)
New York	1 (5%)	4 (8%)
Washington, DC	2 (10%)	7 (14%)

Table/Listing Slide Hints - Continued

- “By Site” option
 - Creates an optional ‘by site’ table that borrows much of the same coding to create the non-‘by site’ table

```
%MACRO DEVSLIDE(DEVDS=, SUBDS=, IDVAR=, DEVVAR=, CUTOFF=, TYPELIST=, SITE=);  
  TITLE "Protocol Deviations";  
  <CODE TO CREATE A PROTOCOL DEVIATIONS TABLE>  
  %IF &SITE. ^= %THEN %DO;  
    TITLE "Protocol Deviations by Site";  
    <CODE TO CREATE A PROTOCOL DEVIATIONS BY SITE TABLE>  
  %END;  
%MEND DEVSLIDE;
```


Deviation Slide Options – 1 Program

%DEVSLIDE();

Protocol Deviations

	Deviations: n (%)
Deviation	To Date: N = 50
Informed Consent	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	12 (24%)
Reporting of SAEs	4 (8%)
Study treatment administration	14 (28%)
Use of Prohibited Medications	5 (10%)
Other: Violation of visit window	7 (14%)

Deviation Slide Options – 1 Program

%DEVSLIDE(); Protocol Deviations

	Deviations: n (%)
Deviation	To Date: N = 50
Informed Consent	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	12 (24%)
Reporting of SAEs	4 (8%)
Study treatment administration	14 (28%)
Use of Prohibited Medications	5 (10%)
Other: Violation of visit window	7 (14%)

%DEVSLIDE(**CUTOFF= 07JUN2017**); Protocol Deviations

	Deviations: n (%)	
Deviation	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

Deviation Slide Options – 1 Program

%DEVSLIDE();
Protocol Deviations

Deviation	Deviations: n (%)	
	To Date: N = 50	
Informed Consent	8 (16%)	
Missed Safety, Efficacy or Endpoint Assessments	12 (24%)	
Reporting of SAEs	4 (8%)	
Study treatment administration	14 (28%)	
Use of Prohibited Medications	5 (10%)	
Other: Violation of visit window	7 (14%)	

%DEVSLIDE(CUTOFF= 07JUN2017);
Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
Use of Prohibited Medications	1 (5%)	5 (10%)
Other: Violation of visit window	2 (10%)	7 (14%)

**%DEVSLIDE(CUTOFF= 07JUN2017,
SITE=SITEID);**

Protocol Deviations

Deviation	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Informed Consent	4 (20%)	8 (16%)
Missed Safety, Efficacy or Endpoint Assessments	7 (35%)	12 (24%)
Reporting of SAEs	1 (5%)	4 (8%)
Study treatment administration	5 (25%)	14 (28%)
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Other: Violation of visit window	2 (10%)	7 (14%)

Protocol Deviations by Site

Site	Deviations: n (%)	
	Since Last Report: N = 20	To Date: N = 50
Atlanta	0 (0%)	2 (4%)
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Dallas	12 (60%)	21 (42%)
Denver	4 (20%)	11 (22%)
New York	1 (5%)	4 (8%)
Washington, DC	2 (10%)	7 (14%)

SECTION 5: FIGURE SLIDES

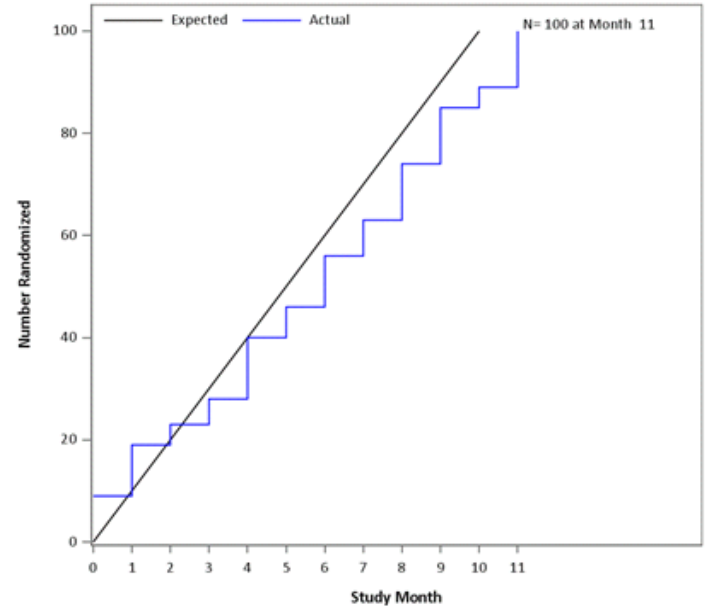
Example of Figure Slides

Study Design



Study Design Figure taken from the Protocol

Enrollment By Study Month



Enrollment during the trial

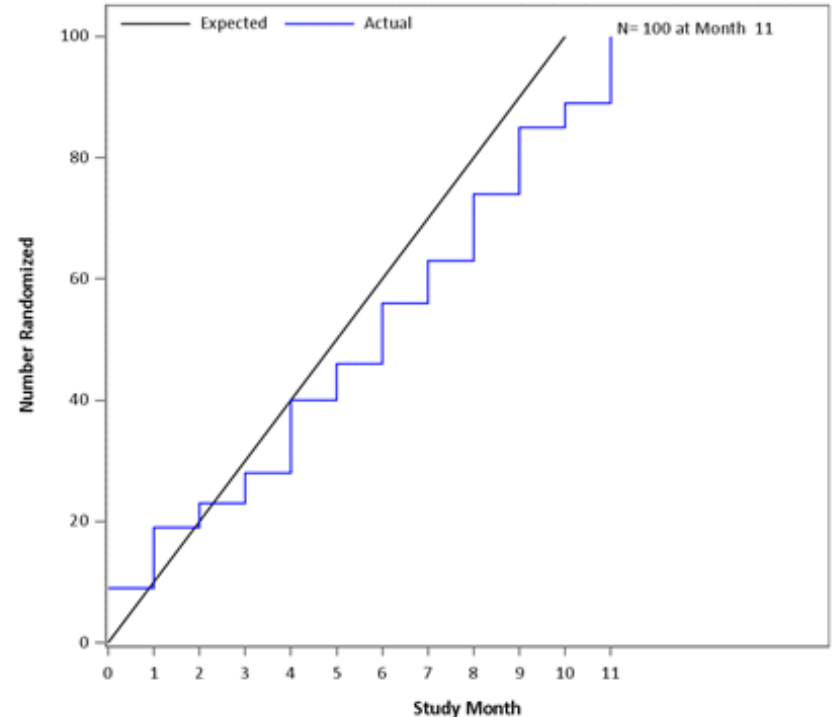
Figure Slides

- Why?
 - Necessary for creating one presentation program
 - No need to copy/paste or hand enter data after running program
 - Ensures standardized text
 - Can pull data directly from SAS programs/datasets
- SAS Procedures
 - PROC SGPLOT
 - PROC REPORT
 - ODS LAYOUT

PROC SGPLOT - Figure Slide

- Information needed to generate enrollment figure
 - Subject Level Dataset
 - Randomization Flag
 - Randomization Date
 - Protocol Information
 - Total Goal
 - Rate per month

Enrollment By Study Month



PROC SGPLOT - Figure Slide

- Information needed to generate enrollment figure
 - Subject Level Dataset
 - Randomization Flag
 - Randomization Date
 - Protocol Information
 - Total Goal
 - Rate per month

Enrollment By Study Month

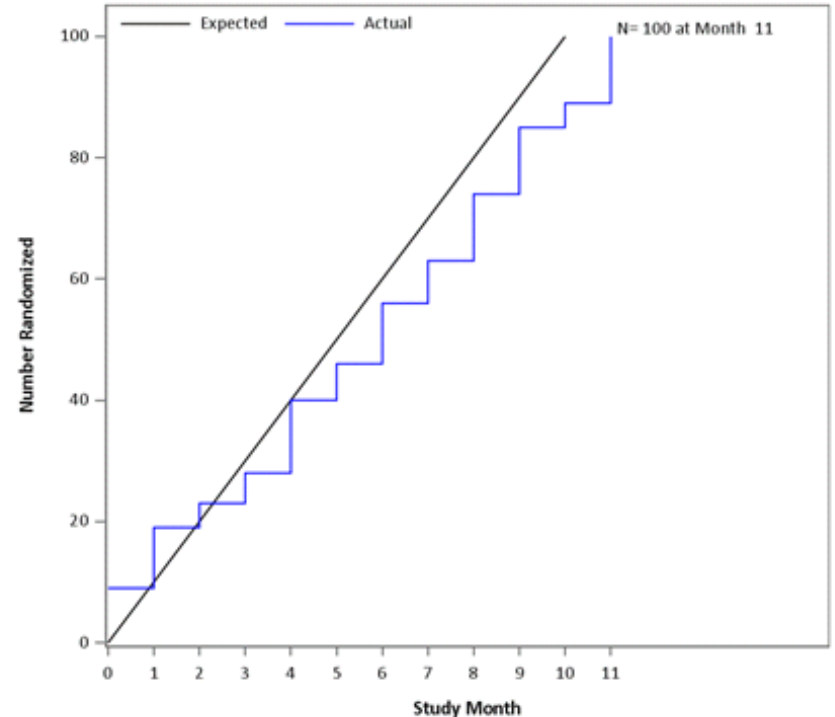
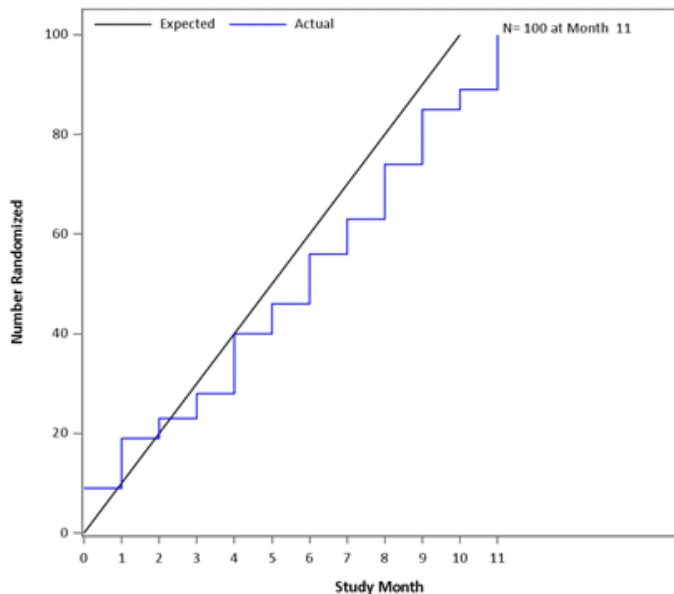


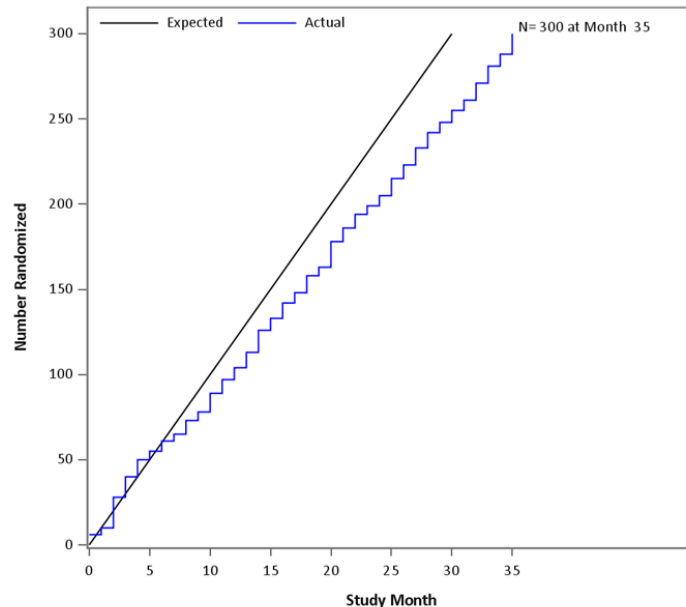
Figure Slides – Two Studies

Enrollment By Study Month



```
%ENROLLMENTFIGURE(GOAL=100,  
RATEPM=10);
```

Enrollment By Study Month



```
%ENROLLMENTFIGURE(GOAL=300,  
RATEPM=10);
```

Figure Slide Hints

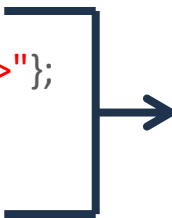
- Including a figure that is not created in SAS or already created in another program

```
DATA DUMMY;  
  LABEL = "";  
RUN;
```



Creates a dummy dataset.

```
PROC REPORT DATA=DUMMY NOHEADER NOFS  
  STYLE(REPORT)={PREIMAGE="<FIGURE PATH>"};  
  COLUMN LABEL;  
  DEFINE LABEL / NOPRINT ;  
RUN;
```



Uses PREIMAGE option to add figure in the presentation.

Figure Slide Hints

- Including a figure that is not created in SAS or already created in another program
 - Any non-PDF figure format
 - Drawbacks
 - Need to resize file prior to running the program
 - Make sure preloaded images are up to date

ODS LAYOUT

- Allows to include multiple types of data on a slide

```
ODS LAYOUT GRIDDED COLUMNS=2;
```

```
ODS REGION WIDTH=5IN;
```

```
<CODE TO CREATE LEFT COLUMN>
```

```
ODS REGION WIDTH=3IN;
```

```
<CODE TO CREATE RIGHT COLUMN>
```

```
ODS LAYOUT END;
```

ODS LAYOUT

- Example: Outline Slide

```
ODS ESCAPECHAR='~';
TITLE "Outline";
ODS LAYOUT GRIDDED COLUMNS=2;
ODS REGION WIDTH=5IN;
PROC ODSLST;
  ITEM "Study Design"/ STYLE= {LISTSTYLETYPE=DISC};
  ITEM "Study Status"/ STYLE={LISTSTYLETYPE=DISC};
  ...
RUN;
ODS REGION WIDTH=3IN;
PROC ODSTEXT;
  P "3~n" || "5~n" || "6~n" || ... / STYLE={JUST=LEFT};
RUN;
ODS LAYOUT END;
```

Outline

• Study Design	3
• Study Status	5
• Enrollment	6
• Demographics	7
• Subject Status	8
• Reasons for Early Termination	10
• Study Stopping Rules	11
• Serious Adverse Events	12
• Non-serious Adverse Events	13
• Asthma Exacerbations	14
• Protocol Deviations	15
• Interim Analysis	16
• Appendix Content	20

ODS LAYOUT

- Example: Outline Slide

```
ODS ESCAPECHAR='~';  
TITLE "Outline";  
ODS LAYOUT GRIDDED COLUMNS=2;  
ODS REGION WIDTH=5IN;  
PROC ODSLST;  
  ITEM "Study Design" / STYLE= {LISTSTYLETYPE=DISC};  
  ITEM "Study Status" / STYLE={LISTSTYLETYPE=DISC};  
  ...  
RUN;  
ODS REGION WIDTH=3IN;  
PROC ODSTEXT;  
  P "3~n" || "5~n" || "6~n" || ... / STYLE={JUST=LEFT};  
RUN;  
ODS LAYOUT END;
```

Outline

- | | |
|---------------------------------|----|
| • Study Design | 3 |
| • Study Status | 5 |
| • Enrollment | 6 |
| • Demographics | 7 |
| • Subject Status | 8 |
| • Reasons for Early Termination | 10 |
| • Study Stopping Rules | 11 |
| • Serious Adverse Events | 12 |
| • Non-serious Adverse Events | 13 |
| • Asthma Exacerbations | 14 |
| • Protocol Deviations | 15 |
| • Interim Analysis | 16 |
| • Appendix Content | 20 |

List of Template Slides

- Introduction
- Outline
- Study Design Text
- Study Design Figure
- DSMB Recommendations
- Study Status
- Enrollment Table
- Enrollment Table by Site – optional
- Enrollment Figure
- Demographics Table
- Subject Status Flow Chart
- Subject Status Table by Site – optional
- Subject Status Visits Chart – optional
- Reasons for Termination Table
- Reasons for Termination by Site - optional
- Study Stopping Rules
- Study Stopping Rules Met
- Serious Adverse Events (SAE) Summary Table
- New SAE
- New SAE Narratives – optional
- Non-Serious AE Summary Table
- Treatment and Procedure Related AEs Table
- WAO Graded Reactions Table – optional
- Epinephrine Use Table – optional
- Protocol Deviation Table
- Protocol Deviation Table by Site – optional
- Appendices

Compare Studies

- Study Design Text
- Study Design Figure
- Study Status
- Enrollment Table
- Enrollment Figure
- Demographics Table
- Subject Status Flow Chart
- Reasons for Termination Table
- Stopping Rules
- Stopping Rules Met
- SAE Table
- Non-Serious AE Table
- Treatment and Procedure Related AEs
- Epinephrine Use
- Protocol Deviation Table

1st DSMB, 1 site, Food Allergy,
Actively Enrolling

- DSMB Recommendations
- Study Status
- Demographics Table
- Subject Status Flow Chart
- Subject Status Table by Site
- Reasons for Termination Table
- Reasons for Termination by Site
- Study Stopping Rules
- Study Stopping Rules Met
- SAE Table
- New SAE Narratives
- Non-Serious AE Table
- Non-Serious AE Table by Site
- Treatment and Procedure Related AEs
- Protocol Deviation Table
- Protocol Deviation Table by Site

4th DSMB, 6 sites, Atopic Dermatitis, No
Longer Enrolling

Compare Studies

- **Study Design Text**
- **Study Design Figure**
- ~~Study Status~~
- **Enrollment Table**
- **Enrollment Figure**
- ~~Demographics Table~~
- ~~Subject Status Flow Chart~~
- ~~Reasons for Termination Table~~
- ~~Stopping Rules~~
- ~~Stopping Rules Met~~
- ~~SAE Table~~
- ~~Non-Serious AE Table~~
- ~~Treatment and Procedure Related AEs~~
- **Epinephrine Use**
- ~~Protocol Deviation Table~~

1st DSMB, 1 site, Food Allergy,
Actively Enrolling

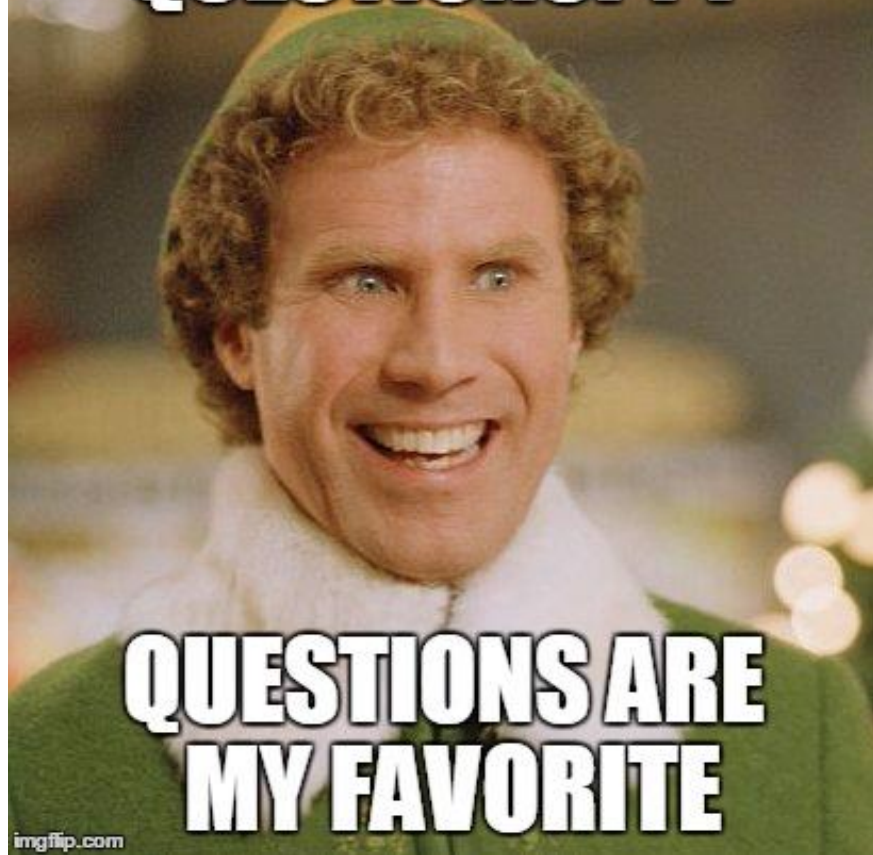
- **DSMB Recommendations**
- ~~Study Status~~
- ~~Demographics Table~~
- ~~Subject Status Flow Chart~~
- **Subject Status Table by Site**
- ~~Reasons for Termination Table~~
- **Reasons for Termination by Site**
- ~~Study Stopping Rules~~
- ~~Study Stopping Rules Met~~
- ~~SAE Table~~
- **New SAE Narratives**
- ~~Non-Serious AE Table~~
- **Non-Serious AE Table by Site**
- ~~Treatment and Procedure Related AEs~~
- ~~Protocol Deviation Table~~
- **Protocol Deviation Table by Site**

4th DSMB, 6 sites, Atopic Dermatitis, No
Longer Enrolling

Summary

- Using ODS POWERPOINT eliminates opportunities for errors due to hand-entering values or copying and pasting tables and figures into slides
- It is possible to create efficiencies that will save time and ensure DSMB presentations have the same formatting for every presentation
- We explored several methods and tips that we used to create DSMB presentation macros and will give you a start on creating your own.

QUESTIONS???



**QUESTIONS ARE
MY FAVORITE**

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