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 length 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;
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;
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: XXXXXXX
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

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
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
  – ODSLIST
PROC ODSTEXT - Text Slide

ODS ESCAPECHAR='~';
ODS POWERPOINT FILE="TITLE_SLIDE.pptx" NOGTITLE NOGFOOTNOTE;
PROC ODSTEXT;
   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

ODS ESCAPECHAR='~';
ODS POWERPOINT FILE="TITLE_SLIDE.pptx" NOGTITLE NOGFOOTNOTE;
PROC ODSTEXT;
   P " " / STYLE={FONTSIZE=30};
P "Title of the DSMB Presentation" / STYLE={FONTSIZE=20 JUST=C FONTWEIGHT=BOLD};
P " " / STYLE={FONTSIZE=30};
P "Protocol Number: XXXXXXX ~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 ODSTEXT - Text Slide Macro

ODS ESCAPECHAR='~';
%MACRO TITLESLIDE
(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 TITLESLIDE;
PROC ODSTEXT - Text Slide Macro Call and Result

%TITLESLED (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
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 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 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;
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 aged 18-55 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

- Creating lists of varying lengths

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
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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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  - Arm 2: Sublingual Immunotherapy + Subcutaneous Placebo
  - Arm 3: Double Placebo
- Enrollment goal: 300 randomized in a 1:1:1 fashion
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Text Slide Hints

- Creating lists of varying lengths

Study Design

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- 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
%MACRO STUDYDESIGN(DO NOT USE THE NAME \%

**Text Slide Hints**

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

... PROC ODSLIST;
    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(DESIGN= ..., ARM1= , ARM2= , ARM3= ,ARM4=..., PRIMARY1=, PRIMARY2=, PRIMARY3=);

... PROC ODSLIST;
  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

<table>
<thead>
<tr>
<th>Deviation</th>
<th>Since Last Report: N = 20</th>
<th>To Date: N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>4 (20%)</td>
<td>8 (15%)</td>
</tr>
<tr>
<td>Missed Safety, Efficacy or Endpoint Assessments</td>
<td>7 (35%)</td>
<td>12 (24%)</td>
</tr>
<tr>
<td>Reporting of SAEs</td>
<td>1 (5%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Study treatment administration</td>
<td>5 (25%)</td>
<td>14 (28%)</td>
</tr>
<tr>
<td>Use of Prohibited Medications</td>
<td>1 (5%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Other: Violation of visit window</td>
<td>2 (10%)</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>

### Protocol Deviations by Site

<table>
<thead>
<tr>
<th>Site</th>
<th>Since Last Report: N = 20</th>
<th>To Date: N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlanta</td>
<td>0 (0%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Boston</td>
<td>1 (5%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Dallas</td>
<td>12 (60%)</td>
<td>21 (42%)</td>
</tr>
<tr>
<td>Denver</td>
<td>4 (20%)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>New York</td>
<td>1 (5%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Washington, DC</td>
<td>2 (10%)</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>

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

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=CENT
  FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
  BACKGROUND=BIGB];
DEFINE COL3 / DISPLAY LEFT FLOW "To Date:~N = &TOTN" STYLE=[JUST=CE
  CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENT
  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
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  STYLE(HEADER)=[BACKGROUND=BIGB FONTWEIGHT=BOLD FOREGROUND=WHITE];
COLUMN LINE COL1 ("Deviations: n (%)" COL2 COL3);
DEFINE LINE / ORDER NOPRINT;
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  STYLE(COLUMN)=[ASIS=ON] STYLE(HEADER) = [JUST=LEFT
  FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
  BACKGROUND=BIGB];
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  CENTER CELLWIDTH=2IN] COLOR=WHITE STYLE(HEADER)=[JUST=CENTER
  FONTWEIGHT=BOLD FONTSIZE=5.8 FOREGROUND=WHITE
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  FONTWEIGHT=BOLD FONTSIZE=5.8
  BACKGROUND=BIGB],
FOREGROUND=WHITE
RUN;
ODS POWERPOINT CLOSE;
Table/Listings Slide Hints

- Standardized datasets across studies
  - Allows for fewer macro variables or default macro variable definitions
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>
  , DEVVVAR=<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>,
          DEVVVAR=<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

<table>
<thead>
<tr>
<th>Deviation</th>
<th>Deviations: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Since Last Report: N = 20</td>
</tr>
<tr>
<td></td>
<td>To Date: N = 50</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>4 (20%)</td>
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<td></td>
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<tr>
<td></td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Other: Violation of visit window</td>
<td>2 (10%)</td>
</tr>
<tr>
<td></td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>
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
  – Need to report all CRF options, but don’t want to inadvertently omit ‘Other, specify’ entries

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### Table/Listing Slide Hints

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**Protocol Deviations**

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</tbody>
</table>
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);

<table>
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</table>
Table/Listing Slide Hints

• “Other, specify” lists

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

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

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

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

<table>
<thead>
<tr>
<th>Deviation</th>
<th>Deviations: n (%)</th>
<th>Since Last Report: N = 20</th>
<th>To Date: N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td></td>
<td>4 (20%)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>Missed Safety, Efficacy or Endpoint Assessments</td>
<td></td>
<td>7 (35%)</td>
<td>12 (24%)</td>
</tr>
<tr>
<td>Reporting of SAEs</td>
<td></td>
<td>1 (5%)</td>
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<td></td>
<td>1 (5%)</td>
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</tr>
<tr>
<td>Other: Violation of visit window</td>
<td></td>
<td>2 (10%)</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Deviation</th>
<th>Deviations: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Since Last Report: N = 20</td>
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<tr>
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<td>Other: Violation of visit window</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site</th>
<th>Deviations: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Since Last Report: N = 20</td>
</tr>
<tr>
<td>Atlanta</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Boston</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Dallas</td>
<td>12 (60%)</td>
</tr>
<tr>
<td>Denver</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>New York</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Washington, DC</td>
<td>2 (10%)</td>
</tr>
</tbody>
</table>
“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;
%DEVSLIDE();

Protocol Deviations

<table>
<thead>
<tr>
<th>Deviation</th>
<th>To Date: n (%)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Deviation Slide Options – 1 Program

%DEVSLIDE();
Protocol Deviations

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<td>7 (14%)</td>
</tr>
</tbody>
</table>

%DEVSLIDE(CUTOFF= 07JUN2017);
Protocol Deviations

<table>
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<th>To Date: N = 50</th>
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</tbody>
</table>
**Deviation Slide Options – 1 Program**

**%DEVSLIDE(); Protocol Deviations**

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

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</tr>
</tbody>
</table>

**%DEVSLIDE(CUTOFF= 07JUN2017, SITE=SITEID); Protocol Deviations by Site**

<table>
<thead>
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<td>2 (10%)</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>

**Site**

- 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%)
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 SG PLOT
  – PROC REPORT
  – ODS LAYOUT
- Information needed to generate enrollment figure
  - Subject Level Dataset
    - Randomization Flag
    - Randomization Date
  - Protocol Information
    - Total Goal
    - Rate per 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
Figure Slides – Two Studies

Enrollment By Study Month

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

N= 100 at Month 11

Expected
Actual

Study Month
Number Randomized

Enrollment By Study Month

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

N= 300 at Month 35

Expected
Actual

Study Month
Number Randomized
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

```plaintext
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 ESCAPECHAR='~';
TITLE "Outline";
ODS LAYOUT GRIDDED COLUMNS=2;
ODS REGION WIDTH=5IN;
PROC ODSLIST;
  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;
ODS LAYOUT

Example: Outline Slide

ODS ESCAPECHAR='~';
TITLE "Outline";
ODS LAYOUT GRIDDED COLUMNS=2;
ODS REGION WIDTH=5IN;
PROC ODSLIST;
  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;
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
1st DSMB, 1 site, Food Allergy, Actively Enrolling

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
Contact Information

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Brett Jepson
Email: Brett_Jepson@rhoworld.com