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Making Customized ICH Listings with ODS RTF

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ABSTRACT

ICH (International Consortium on Harmonization) data listings are common reports prepared by pharmaceutical companies in regulatory submission. Such listings are often submitted in RTF format. This paper presents a technique that can be used to efficiently produce a customized ICH Abnormal Lab Listing based on a company's uniform RTF output standards. This technique includes five components: data preparation; and four SAS® syntaxes (SYSTEM OPTIONS, ODS TAGSETS.RTF, PROC TEMPLATE style, and PROC REPORT) can be utilized to define the layout and to render a data listing table. This paper will first describe the problem that we are trying to solve and then give details on the ODS TAGSETS.RTF options that we have chosen to solve this problem with mock data.

KEYWORDS

ODS TAGSETS.RTF, PROC TEMPLATE, PROC REPORT, ICH LISTING

INTRODUCTION

Data listing at first glance is just a simple listing that can be fulfilled using PROC PRINT procedure or simple PROC REPORT procedure. However, there are certain data formats and display guidelines that need to be followed, when it is used for submission to a regulatory agency, for example, ICH listing. The International Consortium on Harmonization provides a guiding document, ICH Guideline E3, specifically on the content of a CSR.

Below is a snapshot of the ICH E3 guideline on abnormal lab data listing.

12.4 Clinical Laboratory Evaluation

12.4.1 **Listing of individual laboratory measurements by patient (16.2.8) and each abnormal laboratory value (14.3.4)**

When required by regulatory authorities, the results of all safety-related laboratory tests should be available in tabular listings, using a display similar to the following, where each row represents a patient visit at which a laboratory study was done, with patients grouped by investigator (if more than one) and treatment group, and columns include critical demographic data, drug dose data, and the results of the laboratory tests. As not all tests can be displayed in a single table, they should be grouped logically (haematological tests, liver chemistries, electrolytes, urinalysis, etc.). Abnormal values should be identified, e.g. by underlining, bracketing etc. These listings should be submitted as part of the registration/ marketing application, when this is required, or may be available on request.

According to the ICH E3 guideline, pharmaceutical companies design the outlook for each ICH data listing, and make sure that the listing fulfills the requirements for data formats and display principles. For example, data are grouped by investigator or not. Decide how and where to present the treatment arm and subject information, on top of the table or present it as individual columns inside the table body. For abnormal lab finding listing, the data should be displayed by laboratory category alphabetically or be based on the order of importance of the tests.

In order to create a listing based on the ICH E3 guideline while also satisfying a company's uniform RTF output standards, We have developed a technique that integrates the following five components to produce the desired output: thoughtful data preparation based on the desired table contents, and use SAS options/procedures (SYSTEM OPTIONS, ODS TAGSETS.RTF, PROC TEMPLATE style, and PROC REPORT) to tweak table layout and appearance. Novel conglomeration of these components creates Table 1 as the RTF output.

16.2.8.1 Listing of Laboratory Values

Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States

Subject ID	Category	Test	Epoch	Visit	Date/Time	Relative Day†	Result	Normal Range Low	Normal Range High	Abnormal‡
ISG										
Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB										
000001	Hematology	RBC	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
			Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
			Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	
			Period 1	Week 12	29SEP15	85	4.2 10^12/L	4.4	5.8	L
			Period 1	Week 24	22DEC15	169	4.2 10^12/L	4.4	5.8	L
			Period 1	Week 28	19JAN16	197	4.3 10^12/L	4.4	5.8	L
			Period 1	Week 36	17MAR16	255	5.5 10^12/L	4.4	5.8	
			Period 1	Week 48	29JUN16	359	4.3 10^12/L	4.4	5.8	L
		Hemoglobin	Screening	Screening	22JUN15	-15	10.7 g/dL	13.8	17.2	L
			Screening	Day 1	07JUL15	1	9.9 g/dL	13.8	17.2	L
			Period 1	Week 4	06AUG15	31	12.3 g/dL	13.8	17.2	L
			Period 1	Week 12	29SEP15	85	10.9 g/dL	13.8	17.2	L
			Period 1	Week 24	22DEC15	169	10.6 g/dL	13.8	17.2	L
			Period 1	Week 28	19JAN16	197	10.9 g/dL	13.8	17.2	L
			Period 1	Week 36	17MAR16	255	13.5 g/dL	13.8	17.2	L
			Period 1	Week 48	29JUN16	359	10.7 g/dL	13.8	17.2	L
		Hematocrit	Screening	Screening	22JUN15	-15	35.1 %	41	50	L
			Screening	Day 1	07JUL15	1	32.1 %	41	50	L
			Period 1	Week 4	06AUG15	31	41.4 %	41	50	
			Period 1	Week 12	29SEP15	85	36.8 %	41	50	L

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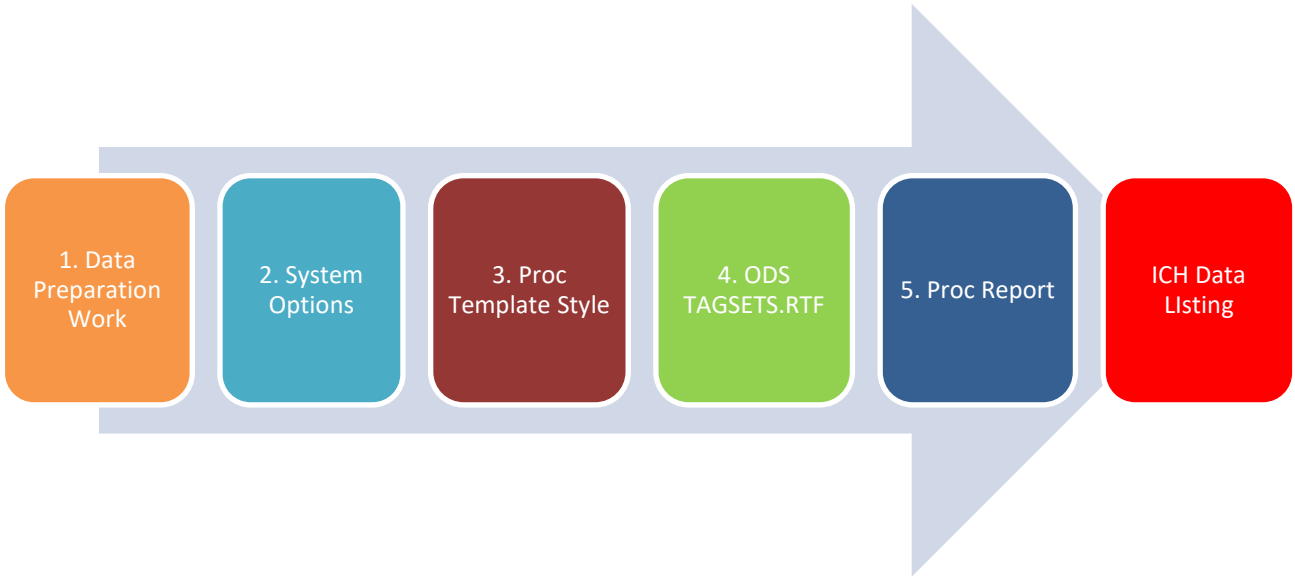
Output 1: ICH Abnormal Lab Listing using mock up data

KEY TECHNIQUE



1. DATA PREPARATION WORK

The required data is assembled by integrating information from three different domains: LB provides the actual abnormal lab readings and its associated lab information; DM provides details on the subject who originated the abnormal lab readings; VS provides vital sign information such as weight of the subject who originated the abnormal lab readings.

Display 1 is the mock up data for Output 1 in original data form.

Obs	SUBJID	LBCAT	LBTEST	EPOCH	VISIT	LBDTC_ CHAR	LBDY_ CHAR	RESULT_ WITH_UNIT	LBORNRLO	LBORNRHI	ABN_COL
1	000001	Hematology	RBC	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
2	000001	Hematology	RBC	Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
3	000001	Hematology	RBC	Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	
4	000001	Hematology	RBC	Period 1	Week 12	29SEP15	85	4.2 10^12/L	4.4	5.8	L
5	000001	Hematology	RBC	Period 1	Week 24	22DEC15	169	4.2 10^12/L	4.4	5.8	L
6	000001	Hematology	RBC	Period 1	Week 28	19JAN16	197	4.3 10^12/L	4.4	5.8	L
7	000001	Hematology	RBC	Period 1	Week 36	17MAR16	255	5.5 10^12/L	4.4	5.8	
8	000001	Hematology	RBC	Period 1	Week 48	29JUN16	359	4.3 10^12/L	4.4	5.8	L
9	000001	Hematology	Hemoglobin	Screening	Screening	22JUN15	-15	10.7 g/dL	13.8	17.2	L
10	000001	Hematology	Hemoglobin	Screening	Day 1	07JUL15	1	9.9 g/dL	13.8	17.2	L
11	000001	Hematology	Hemoglobin	Period 1	Week 4	06AUG15	31	12.3 g/dL	13.8	17.2	L
12	000001	Hematology	Hemoglobin	Period 1	Week 12	29SEP15	85	10.9 g/dL	13.8	17.2	L

Display 1: mock up data for Output 1 (original data)

Group the data by the investigator and place the investigator site information as a 'site' title row at each page. Two headlines are inserted and present the treatment arm and subject information. To carry out these tasks, three variables are added to the dataset. See the **orange box columns** in Display 2.

- A site title row (variable name: **Study_Site_Line**)
  - Variable value example: "Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States"
- A line row with treatment arm text name (variable name: **Decode_1**)
  - Variable value example: "ISG"
- A line row with demographic data for each subject row (variable name: **Subj_Detail _Line**)
  - Variable value example: "Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB"

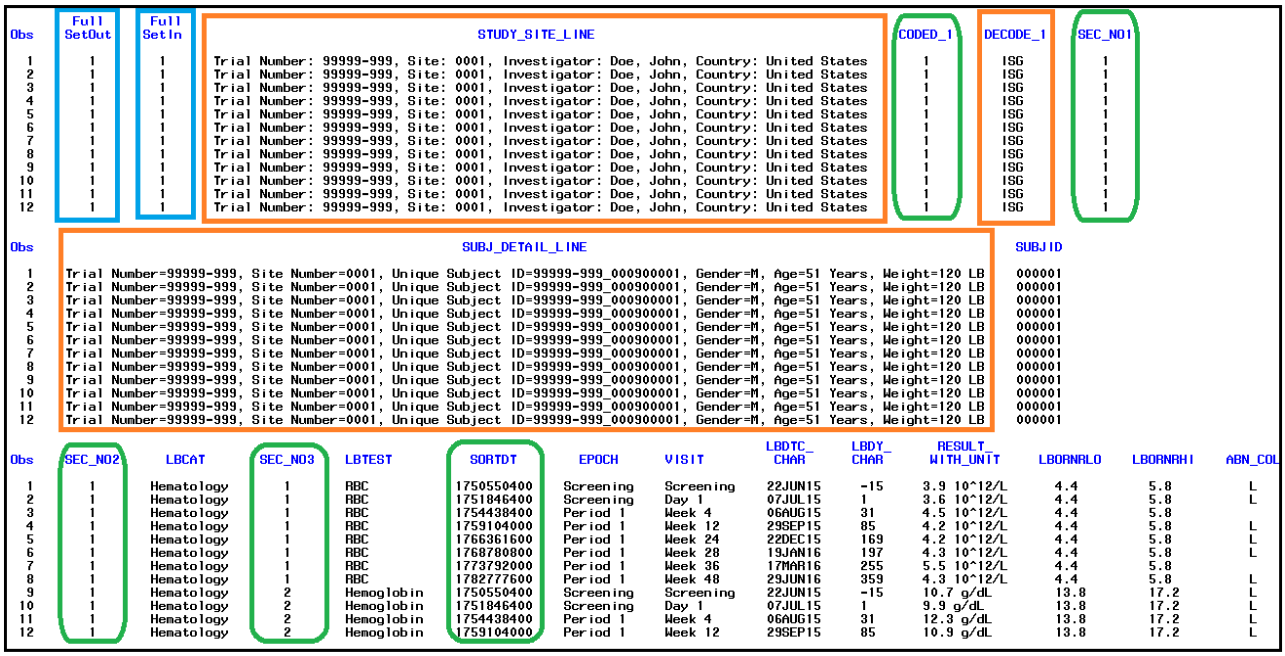
Instead of displaying the listing alphabetically, sometimes it is necessary to add numeric display ordering variables in the COLUMN statement using PROCE REPORT to indicate the right listing order. In this paper, five variables are added. See the **green box columns** in Display 2.

- A treatment arm order variable with 1 to 1 match to variable Decode_1 (variable name: **Coded_1**)
  - Missing out this numeric variable, the data listing will be sorted alphabetically by the treatment arm text name.
- An order variable with 1 to 1 match to variable Subj_Detail_Line (variable name: **Sec_No1**)
- An order variable with 1 to 1 match to variable LBCAT (variable name: **Sec_No2**)
- An order variable with 1 to 1 match to variable LBTEST (variable name: **Sec_No3**)
- An order variable to sort the data by collection date (variable name: **Sortdt**)
  - Missing out this numeric variable, the data listing will be sorted alphabetically by the Epoch name, instead of the right collection date.

Two dummy variables are added for placing the footnotes at bottom of the table. See the **blue box columns** in Display 2.

- Dummy variable 1 (variable name: **FullSetIn**)
- Dummy variable 2 (variable name: **FullSetOut**)

Display 2 is the complete data feeding into Proc Report procedure to create Output 1.



Obs	Full SetOut	Full SetIn	STUDY_SITE_LINE	CODED_I	DECODE_I	SEC_NO1
1	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
2	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
3	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
4	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
5	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
6	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
7	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
8	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
9	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
10	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
11	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1
12	1	1	Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States	1	ISG	1

Obs	SUBJ_DETAIL_LINE	SUBJID
1	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
2	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
3	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
4	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
5	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
6	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
7	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
8	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
9	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
10	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
11	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001
12	Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB	000001

Obs	SEC_NO2	LBCAT	SEC_NO3	LBTEST	SORTDT	EPOCH	VISIT	LBDTC_ CHAR	LBDY_ CHAR	RESULT_ WITH_UNIT	LBORNRLO	LBORNRHI	ABN_COL
1	1	Hematology	1	RBC	1750550400	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
2	1	Hematology	1	RBC	1751846400	Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
3	1	Hematology	1	RBC	1754438400	Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	
4	1	Hematology	1	RBC	1759104000	Period 1	Week 12	29SEP15	85	4.2 10^12/L	4.4	5.8	L
5	1	Hematology	1	RBC	1766361600	Period 1	Week 24	22DEC15	169	4.2 10^12/L	4.4	5.8	L
6	1	Hematology	1	RBC	1768780800	Period 1	Week 28	19JAN16	197	4.3 10^12/L	4.4	5.8	L
7	1	Hematology	1	RBC	1773792000	Period 1	Week 36	17MAR16	255	5.5 10^12/L	4.4	5.8	
8	1	Hematology	1	RBC	1782777600	Period 1	Week 48	29JUN16	359	4.3 10^12/L	4.4	5.8	L
9	1	Hematology	2	Hemoglobin	1750550400	Screening	Screening	22JUN15	-15	10.7 g/dL	13.8	17.2	L
10	1	Hematology	2	Hemoglobin	1751846400	Screening	Day 1	07JUL15	1	9.9 g/dL	13.8	17.2	L
11	1	Hematology	2	Hemoglobin	1754438400	Period 1	Week 4	06AUG15	31	12.3 g/dL	13.8	17.2	L
12	1	Hematology	2	Hemoglobin	1759104000	Period 1	Week 12	29SEP15	85	10.9 g/dL	13.8	17.2	L

Display 2: mock up data for Output 1 (complete data for Proc Report procedure)

2. SYSTEM OPTIONS TO SETUP THE PAGE LAYOUT AND THE WORKING ENVIRONMENT

```
OPTIONS cbufsize=65535 ORIENTATION=landscape nodate nobyline number
        topmargin=1.25in bottommargin = 1in leftmargin=0.5in
        rightmargin=0.5in;
```

- **nodate**: suppress date information in the display
- **nobyline**: suppress the automatic printing of BY lines above each BY group
- **Cbufsize**: increase the buffer size to handle large data

When dealing with huge data, the following error message may appear.

"ERROR: The SAS System stopped processing this step because of insufficient memory."

This issue can easily be resolved.by increasing the buffer size using "cbufsize=65535" in OPTIONS statement

3. PROC TEMPLATE STYLE TO DEFINE APPEARANCE FOR TABLE COMPONENTS AND CONTENTS

When using PROC TEMPLATE procedure to define the style, there is no need to define every single element from scratch. Rather, we can take an existing style template, such as STYLES.RTF, as the parent style and only modify a few styles according to the preferred table format, for example, fonts, colors, table margins, page number, etc.

```
proc template;
     define style mytemplate;
     parent = styles.rtf;

     < style element syntax>

run;
```

Style Element Syntax	Notes
replace fonts / 'TitleFont2' = ("Times New Roman",8pt) 'TitleFont' = ("Times New Roman",12pt) 'StrongFont' = ("Times New Roman",8pt) 'EmphasisFont' = ("Times New Roman",8pt) 'FixedEmphasisFont' = ("Times New Roman,Courier",8pt) 'FixedStrongFont' = ("Times New Roman,Courier",8pt) 'FixedHeadingFont' = ("Times New Roman,Courier",8pt) 'BatchFixedFont' = ("Times New Roman, Courier",8pt) 'FixedFont' = ("Times New Roman,Courier",8pt) 'headingEmphasisFont' = ("Times New Roman",8pt) 'headingFont' = ("Times New Roman",8pt) 'docFont' = ("Times New Roman",8pt);	The fonts of the tables are defined within the style element Fonts. In the table, fonts 'Time New Roman' is specified.
replace color_list "Colors used in the default style" / **'bg' = _undef_** 'fg' = black **'bgH' = _undef_** 'link' = blue;	Undefine table background and table header background color. This setting exposes the water marker.
replace table from Output / borderwidth = .5pt borderspacing = 0pt cellpadding = 0.5pt **rules = group** **frame = box;**	RULES=GROUP will place a divider between the Header and the table area of the table. FRAME=BOX option will draw only the outside border lines.
replace Body from Document "Controls the Body file." / marginbottom = 1.25in margintop = 2in marginright = 0.5in marginleft = 0.5in;	Set up the table margins.
replace pageno from pageno / fontsize = 12 pt cellpadding = 0 cellspacing = 0 **pretext="Page "** **posttext=" of (*ESC*){lastpage} ";**	Display page number in header area of rtf table.
class SystemFooter / font = ("Times New Roman",8pt);	Customize the footer by adding the SystemFooter style element.

Note that when using some table row margin control or **parskip** in the template, it is necessary to pay attention to the page break in large output with tagset.rtf. Some combinations of settings may cause the page break abnormally. If this case happens, the cell padding/parskip option needs to be adjusted to adapt the page break.

4. ODS TAGSETS.RTF TO SPECIFY USING RTF SYNTAX WITH PREDEFINED TEMPLATE TO GENERATE LISTING TABLE

This paper utilizes settings in the SAS® Output Deliver System (ODS) destinations RTF tagset.

```
ods noresults escapechar='~';
ods listing close;
      ODS tagsets.rtf
          FILE="C:\ProcReport\output\ichlablisting.rtf"
          style = mytemplate
          uniform
          tablerows=25
          options(continue_tag="no" watermark="xxx")
```

```
            bodytitle;

      < PROC REPORT syntax >

      ODS tagsets.rtf CLOSE;
ODS listing;
```

The ODS TAGSETS.RTF provides the formats that are most frequently used by the pharmaceutical industry. ODS TAGSETS.RTF have several advantages over traditional ODS RTF in that it offers more controls over Table of Contents, and titles/footnotes could be repeated on each page as a body type instead of going to the header/footer area in a Word document.

- **style**: Specify the template to use in the RTF output
- **uniform**: Specify that every page of a table is formatted the same
- **tablerows**: Specify the maximum number of table rows in a page
- **options(continue_tag="no")**: Do not add continue tag when a table break and continue to the next page
- **options(watermark="xxx")**: Add watermark at the table background, such as "CONFIDENTIAL".
- **bodytitle**: Specify the table titles and footnotes are displayed in the RTF body instead of in the header and footnote area.

5. PROC REPORT TO RENDER TABLE CONTAINT WITH MORE FORMATING

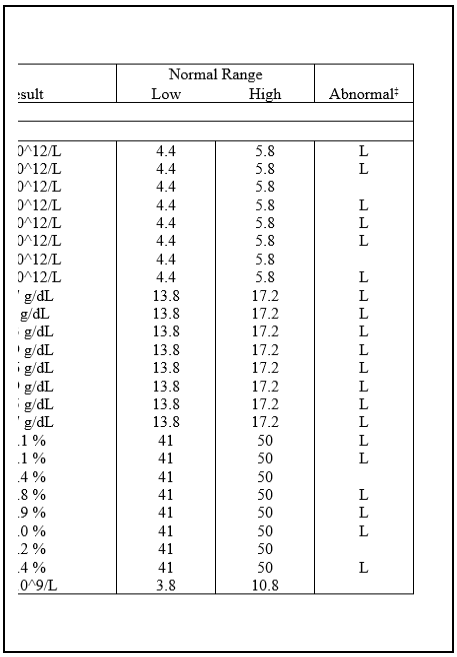
```
PROC REPORT DATA=temp SPACING=1 LS=118 PS=20 SPLIT='|' MISSING NOWD
                      spanrows
   style(report)= . . .
   STYLE(HEADER)= . . .
   BY study_site_line;

   COLUMN FullSetOut FullSetIn study_site_line coded_1 decode_1 sec_no1
          subj_detail_line  . . .

   DEFINE FullSetOut /order noprint "" LEFT ;
   DEFINE FullSetIn /order noprint "" LEFT ;
   DEFINE study_site_line / ORDER ORDER=INTERNAL noprint "" ;
   DEFINE coded_1 / ORDER ORDER=INTERNAL noprint "" ;
   DEFINE decode_1 / ORDER ORDER=INTERNAL noprint "" ;
   DEFINE sec_no1 / ORDER ORDER=INTERNAL noprint "" ;
   DEFINE subj_detail_line / ORDER ORDER=INTERNAL noprint "" ;
    . . .

   < COMPUTE BLOCKS >
RUN;
```

CREATING A TABLE WITH OUTSIDE BORDER LINE, INSIDE VERTICAL BORDER LINE, NO INSIDE HORIZONTAL BORDER LINE

Proc Template style uses **frame = box** option to draw only the outside border lines. The inside vertical border line can be defined in Proc Report syntax using **style (column)** option in the **define** statement of Proc Report syntax.

Proc Template Style	`proc template;`
	`  define style mytemplate;`
	`  parent = styles.rtf;`
	`  replace table from Output /`
	`  borderwidth = 0.5pt`
	`  borderspacing = 1pt`
	`  cellpadding = 2pt`

	rules = group **frame = box;**
Proc Report	PROC REPORT . . . COLUMN . . . **DEFINE** LBORNRLO/ ORDER ORDER=INTERNAL "" LEFT **style(column)**={**borderleftcolor=black borderleftwidth=1** **borderrightcolor=black borderrightwidth=1** ASIS=ON }; **DEFINE** LBORNRHI/ ORDER ORDER=INTERNAL "" LEFT **style(column)**={**borderleftcolor=black borderleftwidth=1** **borderrightcolor=black borderrightwidth=1** ASIS=ON }; Run;



sult	Normal Range Low	High	Abnormal[2]
0^12/L	4.4	5.8	L
0^12/L	4.4	5.8	L
0^12/L	4.4	5.8	
0^12/L	4.4	5.8	L
0^12/L	4.4	5.8	L
0^12/L	4.4	5.8	L
0^12/L	4.4	5.8	
0^12/L	4.4	5.8	L
' g/dL	13.8	17.2	L
g/dL	13.8	17.2	L
g/dL	13.8	17.2	L
' g/dL	13.8	17.2	L
g/dL	13.8	17.2	L
' g/dL	13.8	17.2	L
g/dL	13.8	17.2	L
' g/dL	13.8	17.2	L
.1 %	41	50	L
.1 %	41	50	L
.4 %	41	50	
.8 %	41	50	L
.9 %	41	50	L
.0 %	41	50	L
.2 %	41	50	
.4 %	41	50	L
0^9/L	3.8	10.8	

Output 2: A table with inside vertical border line but no inside horizontal border line

ERASING THE BORDER LINE BETWEEN HEADERS

Notice the column normal range (low, high) has two lines of header. The text 'Normal Range' is on the top header line. The texts, 'Low' and 'High', are on the bottom header line. There are no inside border line between these headers. The in-line formatting code is used here to erase the inside border lines between these three head texts. Choose the escape character tilde (~) symbol. Another commonly used character is hat (^) symbol. Since some laboratory test unit ^ symbol appears in the data, a safer choice, tilde symbol, is used as escape character. The **borderbottomcolor=white** and **borderbottomwidth=.1pt** make the line white color and minimize the line width.

Proc Report	PROC REPORT . . . COLUMN . . . **("~S={borderbottomcolor=white borderbottomwidth=.1pt}Normal Range"** **("~S={bordertopcolor=white bordertopwidth=.1pt** **borderrightcolor=white borderrightwidth=.1pt}Low"** LBORNRLO) **("~S={bordertopcolor=white bordertopwidth=.1pt** **borderleftcolor=white borderleftwidth=.1pt}High"** LBORNRHI)) DEFINE LBORNRLO/ . . . DEFINE LBORNRHI/ . . . Run;

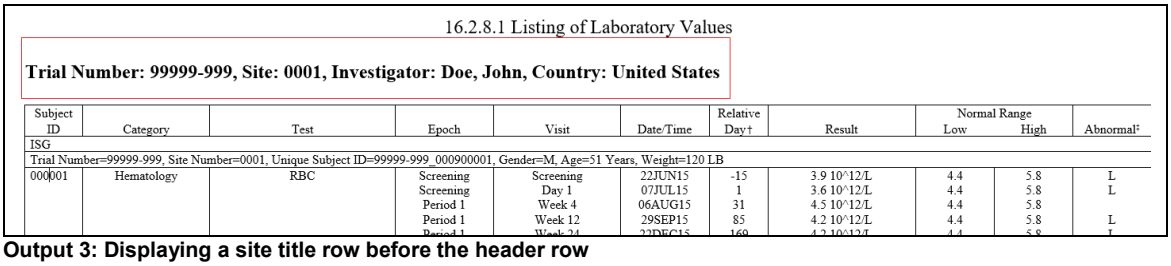
DISPLAYING A SITE TITLE ROW BEFORE THE HEADER ROW

By ICH E3 requirement, data should be sorted and grouped by investigators. Based on this requirement and company's standard, a site title row is used to display the investigator site information at the top of the body section on each page right before the header row.

A site title row variable **study_site_line** is added to the dataset, as mentioned before. Use COMPUTE BLOCK feature in the Proc Report procedure. We can specify to display that variable at the LOCATION of BEFORE the REPORT_ITEM of _PAGE_ to print out the investigator site information at the top of each page.

Data Preparation Work	Add site title row variable **study_site_line** to the dataset.

Proc Report	`PROC REPORT . . .`
	`  BY study_site_line;`
	
	`  COMPUTE BEFORE _PAGE_ / left style={font_size=12pt };`
	`  line "~R'\b '" study_site_line $120.;`
	`  line "";`
	`  ENDCOMP;`
	
	`Run;`



16.2.8.1 Listing of Laboratory Values

Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States

Subject ID	Category	Test	Epoch	Visit	Date/Time	Relative Day†	Result	Normal Range Low	Normal Range High	Abnormal‡
ISG										
Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB										
000001	Hematology	RBC	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
			Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
			Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	
			Period 1	Week 12	29SEP15	85	4.2 10^12/L	4.4	5.8	L
			Period 1	Week 24	22DEC15	169	4.2 10^12/L	4.4	5.8	L

Output 3: Displaying a site title row before the header row

INSERTING LINE ROWS WITH TREATMENT ARM AND DEMOGRAPHIC DATA FOR EACH SUBJECT

Based on ICH requirement and company's standard we also need to have two headlines containing subject demographic data before of the records of each patient. The required demographic data for each subject includes therapy group, protocol number, site number, subject identifier, gender, age, and weight.

Two variables containing the headlines information are added to the dataset.

Again, we can create two COMPUTE BLOCKs to display the headline variables at the LOCATION of BEFORE the corresponding REPORT_ITEMs.

Notice style option is utilized here to draw the horizontal border line for these two headlines.

Data Preparation Work	Two headline variables, **decode_1** and **subj_detail_line,** are created to present the treatment arm and subject information variable to the dataset.

Proc Report	`PROC REPORT . . .`
	
	`  COMPUTE BEFORE decode_1 /`
	`  STYLE={BORDERLEFTWIDTH=1`
	`  BORDERTOPWIDTH=1`
	`  BORDERRIGHTWIDTH=1`
	`  BORDERBOTTOMWIDTH=1};`
	`  line "~R' \ql '" decode_1 $200.;`
	`  ENDCOMP;`

```
  COMPUTE BEFORE subj_detail_line /
                STYLE={BORDERLEFTWIDTH=1
                       BORDERTOPWIDTH=1
                       BORDERRIGHTWIDTH=1
                       BORDERBOTTOMWIDTH=1};
      line "~R' \ql '" subj_detail_line $200.;
  ENDCOMP;

Run;
```

Trial Number: 99999-999, Site: 0001, Investigator: Doe, John, Country: United States

Subject ID	Category	Test	Epoch	Visit	Date/Time	Relative Day†	Result	Normal Range Low	Normal Range High	Abnormal‡
ISG										
Trial Number=99999-999, Site Number=0001, Unique Subject ID=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB										
000001	Hematology	RBC	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
			Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
			Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	

Output 4: Inserting line rows with treatment arm and demographic data for each subject

DISPLAYING PAGE NUMBER IN THE HEADER AREA

Displaying page numbers can be done in multiple methods. SAS option PAGENO is one method. The easiest way is to add RTF code with ODS Escape character, **Page ~{pageof}**, in the title statement. However, SAS option BODYTITLE places the table title on page content, not in the header area. This method makes the page number in the page content as well.

In case the page number need to be displayed in the header area, here we demonstrate another method.

Proc Template Style

```
proc template;
   define style mytemplate;
      parent = styles.rtf;
      replace pageno from pageno /
         fontsize = 12 pt
         cellpadding = 0 cellspacing = 0
         pretext="Page "
         posttext=" of (*ESC*){lastpage} ";
```

System Options

```
OPTIONS NUMBER;
```

The page number in Output 5 is in grey out header area, not on page content.

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16.2.8.1 Listing of Laboratory Values

estigator: Doe, John, Country: United States

	Epoch	Visit	Date/Time	Relative Day†	Result	Normal Range Low	Normal Range High	Abnormal‡
D=99999-999_000900001, Gender=M, Age=51 Years, Weight=120 LB								
	Screening	Screening	22JUN15	-15	3.9 10^12/L	4.4	5.8	L
	Screening	Day 1	07JUL15	1	3.6 10^12/L	4.4	5.8	L
	Period 1	Week 4	06AUG15	31	4.5 10^12/L	4.4	5.8	
	Period 1	Week 12	29SEP15	85	4.2 10^12/L	4.4	5.8	L
	Period 1	Week 24	22DEC15	169	4.2 10^12/L	4.4	5.8	L
	Period 1	Week 28	19JAN16	197	4.3 10^12/L	4.4	5.8	L

Output 5: Displaying page number in the header area

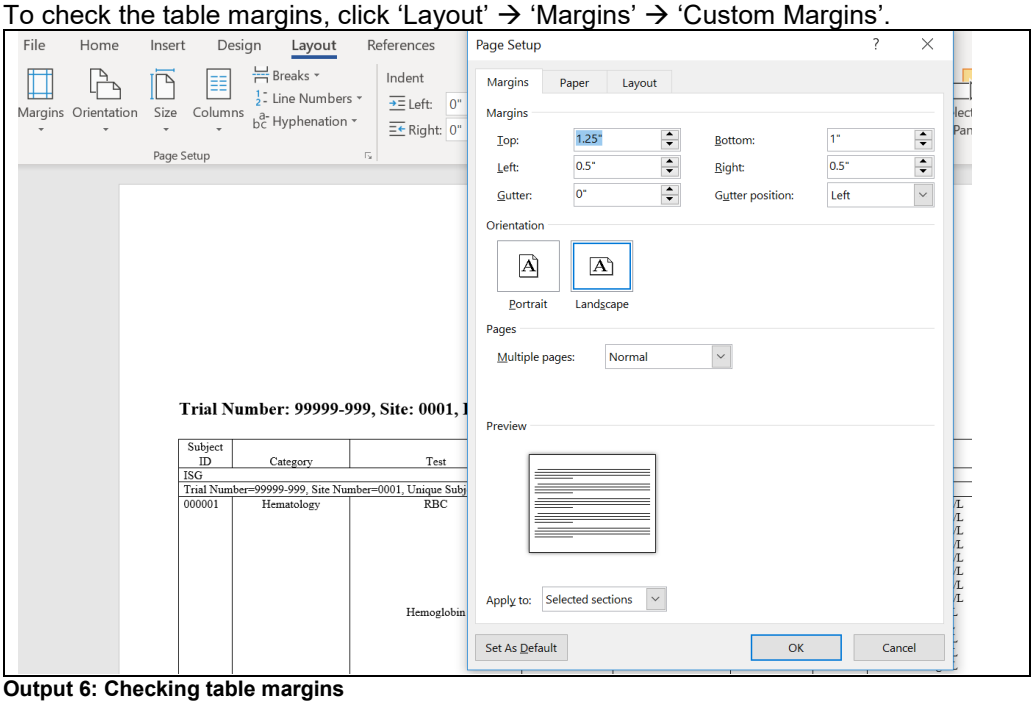
TABLE MARGINS

There are multiple ways to set up the margins of the table. **Proc Template style** uses **margintop, marginbottom, marginleft, and marginright** to set up the margins. System options also can do it.

Proc Template Style	`proc template;`
	`  define style mytemplate;`
	`  parent = styles.rtf;`
	`  replace Body from Document "Controls the Body file." /`
	`  margintop = 1.25in`
	`  marginbottom = 1in`
	`  marginleft = 0.5in`
	`  marginright = 0.5in`
	`  ;`

System Options	`OPTIONS topmargin = 1.25in`
	`  bottommargin = 1in`
	`  leftmargin = 0.5in`
	`  rightmargin = 0.5in ;`

To check the table margins, click 'Layout' → 'Margins' → 'Custom Margins'.



Output 6: Checking table margins

TWO DIFFERENT FOOTNOTES, ONE INSIDE THE TABLE BOX, ONE OUTSIDE TABLE BOX

There is certain standard table design requires two groups of footnotes at the end of the entire listing. One group of footnotes are for study specific information to be displayed inside of the table frame. The other group of footnotes are for data source information, to be displayed outside of the table frame.

Two dummy variables with value of 1, can be added to the dataset to facilitate these kinds of footnote creation.

Once again, we can use COMPUTE BLOCKs to display the footnotes at the LOCATION of AFTER the REPORT_ITEMs of the value of two dummy variables. Since the records of entire dataset have the same value of 1, the footnote will be only displayed after all the records, which is the end of the entire table.

The style options are utilized here to draw the lines at necessary place.

There are two benefits of using the compute block to create footnotes, instead of the commonly used footnote statement. It is much easier to have the footnotes align with table using this method. It also brings the flexibility of style options to draw border lines.

Data Preparation Work	Add FULLSETIN and FULLSETOUT variables to the dataset.
Proc Report	PROC REPORT . . . **COLUMN FullSetOut FullSetIn** study_site_line coded_1 . . . **COMPUTE AFTER FullSetIn /** STYLE={**BORDERLEFTWIDTH=1 BORDERTOPWIDTH=1** **BORDERRIGHTWIDTH=1 BORDERBOTTOMWIDTH=1**}; LINE "~R'\ql' ~{super ~{unicode '2020'x}}Relative Day ..."; LINE "~R'\ql' ~{super ~{unicode '2021'x}}Indicates this …"; LINE "~R'\ql' Baseline Regimen = …"; ... **ENDCOMP;** **COMPUTE AFTER FullSetOut/** STYLE={**BORDERLEFTWIDTH=0 BORDERTOPWIDTH=0** **BORDERRIGHTWIDTH=0 BORDERBOTTOMWIDTH=0**}; LINE "Source: ~R'\ql' [P999MK9999A: adam-adsl] [P999MK9999A: sdtm-lb; supplb; vs; suppvs]"; **ENDCOMP;** Run;

16.2.8.1 Listing of Laboratory Values

Trial Number: 99999-999, Site: 0002, Investigator: Roe, Richard, Country: Spain

Subject ID	Category	Test	Epoch	Visit	Date/Time	Relative Day†	Result	Normal Range Low	Normal Range High	Abnormal²
000004	Virology	HIV-1 Viral Load	Period 1	Week 24	07JUN16	180	<40 DETECTED copies/mL		39.9999	
			Period 2	Week 28	13JUL16	216	<40 TARGET NOT DETECTED copies		39.9999	
			Period 2	Week 36	02SEP16	267	<40 DETECTED copies/mL		39.9999	
			Period 2	Week 48	02DEC16	358	<40 TARGET NOT DETECTED copies		39.9999	
			Extension 1	Week 64	03MAR17	449	<40 DETECTED copies/mL		39.9999	
			Extension 1	Week 80	21JUN17	559	<40 DETECTED copies/mL		39.9999	
			Extension 1	Week 96	09NOV17	700	<40 TARGET NOT DETECTED copies		39.9999	
		HIV-2 Antibody	Screening	Screening	19NOV15	-22	NEGATIVE			

†Relative Day is the day of laboratory sample collection relative to the start of study medication.
²Indicates this value is out of normal range. A=Abnormal, H=High, L=Low
Baseline Regimen = ritonavir or cobicistat-boosted PI, or cobicistat-boosted elvitegravir, or NNRTI, each administered with two NRTIs.
ISG = Immediate Switch Group; DSG = Delayed Switch Group.
Note: The DSG continues their baseline regimen until the time of the switch to DOR/3TC/TDF QD at Study Week 24.
Subjects in ISG take DOR/3TC/TDF QD in Period 1 (Study Weeks 0-48). Subjects in DSG take baseline regimen in Period 1 (Study Weeks 0-24) and DOR/3TC/TDF QD in Period 2 (Study Weeks 24-48).
Source: [P999MK9999A: adam-adsl] [P999MK9999A: sdtm-lb; supplb; vs; suppvs]

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Output 7: Footnotes inside/outside table box

DISPLAYING WATERMARK

In some case the watermark could convey message in a specific way. Here in the template, we undefined the table and header back ground color to ensure the watermark could appear in the back of tables.

Proc Template Style	proc template; define style mytemplate; parent = styles.rtf; replace color_list "Colors used in the default style" / **'bg' = _undef_** 'fg' = black **'bgH' = _undef_**

	'link' = blue; ;
ODS TAGSETS.RTF	**ODS tagsets.rtf** FILE="C:\ProcReport\output\ichlablisting.rtf" **style** = mytemplate uniform tablerows=25 **options**(continue_tag="no" **watermark="xxx"**) bodytitle; *< PROC REPORT syntax >* **ODS tagsets.rtf CLOSE;**

OTHER TECHNIQUES USED IN THIS MACRO DESIGN:

AUTO-ADJUSTING THE COLUMN WIDTH

If we plan to display all the columns in one page, it is better to automatically assign the column widths according to user input. Here we used percent unit to specify column width. Depending on the number of columns, practically use 95-99 percent of the page width (not include the margins) is the best fit. For example, each column width is current_specified_col_width/sum_of_columns*95 pct. In this case, the lines between the columns are considered.

SPECIFYING SPECIAL CHARACTER IN THE TABLE OR FOOTNOTE

In order to display special character, especially to be compatible with long lasting standard system, a new set of special character sets need to be defined for proc report. In this version we applied escape charrcter directly in the macro variable assign statement. So, user could call the macro variable directly. For example, the double daggers superscript (††) is defined as a macro variable as following:

```
%LET dagger2_ = ~{super ~{unicode '2020'x '2020'x}};
```

If we pass this special character to proc report procedure, we need to be cautious what mask function is to be used. Especially when we transfer multiple special characters, such as comma (,), which is a parameter divider, or another unpaired quotation mark, a proper mask function is needed to be called to make sure the full string was masked and transferred to proc report correctly.

CONCLUSION

Although these techniques may appear intimidating and tedious, the benefits of efficiently producing a customized ICH Abnormal Lab Listing with a company's uniform RTF output standards certainly outweigh the effort. A great number of companies in the pharmaceutical industry use PROC REPORT for reporting, highlighting the tool's reliability and current popularity.

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