

Excel-VBA Tool to Auto-Create Validation Log and Review Form using List of TLF's

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ABSTRACT

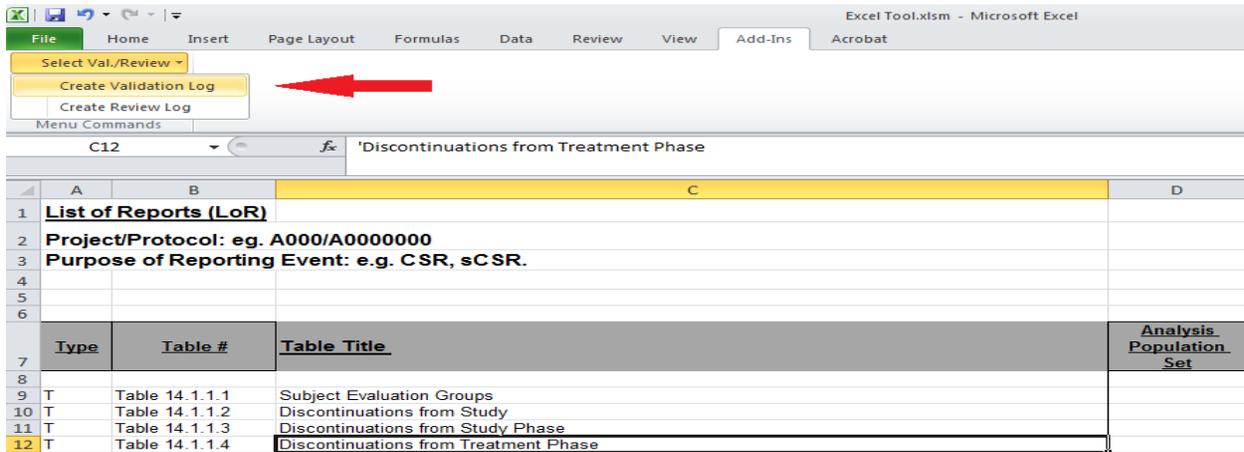
When a clinical study gets started we start with the List of Reports (Tables, Listings, Figures and Appendices) to be created for interim analysis (like BDR's, DMC, SRT deliveries) and Final CSR delivery. Creating and maintaining the Validation Log and Review Form documents are vital and needed for the submission process. We created a tool to auto create the Validation Log and Client Review Form. Validation Log File is created with pre-defined columns for the corresponding TLF's - where programmers/statisticians need to enter their work status, comments, validation comments, initials and dates during work progress. In Review Form, client fills their comments, issues/solutions discussed during review meeting with initials and dates. This tool helps to create these documents in time efficient way and avoid manual error. This tool is developed using Excel-VBA technology.

INTRODUCTION

The Objective of this tool is to create the Validation Log and Review Form which are used for BDR/CSR delivery for the given List of Reports (LOR). LOR file is used as the source for creating this review document. The whole tool is developed using Excel VBA macros. It has Add-in buttons and Excel VBA USERFORMS for creating Validation Log or Review Form. Screenshots are displayed under each steps.

PROCESS

Step 1: When you open the macro enabled excel file, go to ADD-Ins Tab in the main menu, Click "Create Validation Log" or "Create Review Log" from the list.



Step 2: USERFORM is opened in front of the sheet, where you will be seeing different options to select for creating required file.

Use Current LOR File

Use LOR Sheet

Select Sheet Name

Use LOR Column

Select Sheet Name

Folder Path

Enter File Name

Create Validation Log

Create Client Review File

Use Another LOR File

Choose File:

Browse

Use LOR Sheet Name

Select Sheet Name

Import Excel Sheet

Clear

Cancel

Step 3: There are two ways of creating it.

- i. Create using LOR Sheet.
- ii. Create using Selected Column.

Step 4: To Create Validation Log/Review Form using LOR sheet as the source, in which all Tables, Listings, Figures and Appendices information are filled with their respective Table No# and Table Title. Select the **“Use LOR Sheet”** option; select the corresponding LOR Sheet name that needs to be used.

Use Current LOR File

Use LOR Sheet

Select Sheet Name

Use LOR Column

Folder Path

Enter File Name

Create Validation Log

Create Client Review File

| |
|--------------------------------|
| Version |
| LOR |
| BDR Issue ID & Resolution Temp |
| LOR_ADJ |
| Others |

Step 5: After selecting required LOR sheet name, click on the “**Folder Path**” to choose the “Output Directory” and enter the “**File Name**” that needs to be created. Then click “**Create Validation Log / Review File option**” button to create the new file in the given name. All the reports in the LOR Sheet carried to output file.

(In the above example: Validation_Log_A00 name is given, Validation_Log_A00.xls will be created in the specified directory, current date format will be automatically added to given file name.)

Step 6: Suppose if you have LOR Sheet and only certain set of reports needed for BDR1, BDR2, DMC, SRT, CSR delivery, then we need to select the corresponding Column that needed for Validation/Review file. Please check the below screen shot example, where LOR Sheet has BDR1, BDR2, etc., columns.

Project/Protocol: eg. A00
Purpose of Reporting Event: eg. NDA, CSR, IA, DMC, etc.
*NOTE: Tables are examples only based on PDS naming convention. Table numbers and/or titles may need to be modified.
 Italicized table numbers/titles are sections to be defined based on what is collected for each study.*

| Type | Table # | Table Title | .tot file if using CDARS | Standard Used | BDR1 | BDR2 |
|------|----------------|---------------------------------------|--------------------------|---------------|------|------|
| T | Table 14.1.1.1 | Subject Evaluation Groups | sa_sum.tot | PDS1_0 | X | |
| T | Table 14.1.1.2 | Discontinuations from Study | dc531s.tot | PDS1_0 | | X |
| T | Table 14.1.1.3 | Discontinuations from Study Phase | dc531ss.tot | PDS1_0 | X | |
| T | Table 14.1.1.4 | Discontinuations from Treatment Phase | dc531st.tot | PDS1_0 | X | X |
| T | Table 14.1.2.1 | Demographic Characteristics | de_sum.tot | PDS1_0 | | |
| T | Table 14.1.2.2 | Primary Diagnosis and Durations | pd_sum.tot | PDS1_0 | X | X |

Step 7: If you need to create (Example: BDR1 delivery) Validation Form, you need to select “**Use LOR Column**” option, select required sheet name and “**BDR1**” column from the list. Fill the “**Folder path**” and “**Output File Name**” information and click “**Create Validation Log**” button, it creates the output file for the reports which are marked “**X**” in the selected column (similar to step 5, output name added with current date, Output File is created in specified directory.)

Use Current LOR File

Use LOR Sheet

 Use LOR Column

Select Sheet Name

C:\Users\bayyapp\Documents

Enter File Name

Validation_Log_A00

Create Validation Log Create Client Review File

Select Sheet Name dropdown menu:

- Type
- Table #
- Table Title
- .tot file if using CDARS
- Standard Used
- BDR1**
- BDR2
- Clinical Programmer Name

Step 8: Suppose if you want to import particular sheet from another file (external file) that need to be used for creating Validation Log, then below method is used. Click “**Browse**” button to select the required file, click on “**Use LOR Sheet Name**” and select the required sheet name that need to be imported, then click the “**Import Excel Sheet**” button, it import the selected sheet to current file which can be used to create Validation Log.

Use Another LOR File

Choose File: I:\temp\other_LOR.xls Browse

Use LOR Sheet Name

Select Sheet Name

Clear Cancel

Select Sheet Name dropdown menu:

- Version
- Summary**
- Listing
- Graph
- Sheet1

Use Another LOR File

Choose File: I:\temp\other_LOR.xls Browse

Use LOR Sheet Name

Select Sheet Name

Summary

Import Excel Sheet

Clear Cancel

Step 9: “Clear” Button is used to clears all the filled USERFORM information, “Cancel” Button close the USERFORM in the screen.

VBA CODE

```

Sub Crt_BDR_Using_ShtNm()
'Method 1
Dim ROW_CNT, last_L, last_S, last_T, last_F, req_note, req_text,
lstrqdrow As Long
Dim Rqrd_Shtnm As String
Rqrd_Shtnm = UserForm1.ShtNm_Combobox1.Text
ROW_CNT = Sheets(Rqrd_Shtnm).Range("A65536").End(xlUp).Row
For i = 1 To ROW_CNT
    If Sheets(Rqrd_Shtnm).Cells(i, 1) = "L" Then
        last_L = i
    End If
Next i
lstrqdrow = WorksheetFunction.Max(last_L, last_S, last_T, last_F)
If req_note > 0 And lstrqdrow > 0 And req_note <> lstrqdrow + 1
Then
MsgBox "Blank records between LOR Note and Last Report in LOR"
End If
Sheets(Rqrd_Shtnm).Range("B" & req_text + 1 & ":C" & lstrqdrow).Copy
Destination:=Sheets(UserForm1.TxtBox_NwBDR_Shtnm.Text).Range("A10")
Sheets(Rqrd_Shtnm).Range("B" & req_text + 1 & ":C" & lstrqdrow).Copy

Sheets(UserForm1.TxtBox_NwBDR_Shtnm.Text).Activate
Range("A10").Select
ActiveSheet.Paste
Application.CutCopyMode = False
    
```

OUTPUT

Below Validation Form or Review Log is created automatically in specified Directory.

Validation Log:

| Table | Table Title | Table Shell Type | Prod Progr. | Validtn. Progr. | Timepoint | Flag | Comment by: | Date Added | Delivery Type | Comment / Finding | Resolution | OP | OP.Date |
|----------|--------------------------------------|------------------|-------------|-----------------|---------------------|------|-------------|------------|---------------|-------------------|------------|----|---------|
| 14.1.1.1 | Subject Evaluation Groups | | | | Original Release | | | | CSR1 | | | | |
| 14.1.1.1 | Subject Evaluation Groups | | | | Original Validation | | | | CSR1 | | | | |
| 14.1.1.1 | Subject Evaluation Groups | | | | Initial Stats QC | | | | CSR1 | | | | |
| 14.1.1.1 | Subject Evaluation Groups | | | | Senior Stats QC | | | | CSR1 | | | | |
| 14.1.1.2 | Discontinuation From Treatment Phase | | | | Original Release | | | | CSR1 | | | | |
| 14.1.1.2 | Discontinuation From Treatment Phase | | | | Original Validation | | | | CSR1 | | | | |
| 14.1.1.2 | Discontinuation From Treatment Phase | | | | Initial Stats QC | | | | CSR1 | | | | |
| 14.1.1.2 | Discontinuation From Treatment Phase | | | | Senior Stats QC | | | | CSR1 | | | | |

Review Log:

| Protocol: | | | | | | | | | |
|--|---------------------------------------|-------|----------------------------|------|-------------------|--------------------|--------------------|-------------------|---------------------------|
| Purpose of Reporting Event: BDR1 | | | | | | | | | |
| Reporting Event Date | | | | | | | | | |
| Document Issues from BDRs (add additional rows to table and/or attach additional documentation as necessary) | | | | | | | | | |
| Issue | | | | | Resolution | | | | |
| Data Presentation # | Data Presentation Name | Issue | Person who Found the Issue | Date | Resolution People | Cause of the Issue | Planned Resolution | Actual Resolution | Initial and Date Resolved |
| Table 14.1.1.1 | Subject Evaluation Groups | | | | | | | | |
| Table 14.1.1.2 | Discontinuations from Study | | | | | | | | |
| Table 14.1.1.3 | Discontinuations from Study Phase | | | | | | | | |
| Table 14.1.1.4 | Discontinuations from Treatment Phase | | | | | | | | |
| Table 14.1.2.1 | Demographic Characteristics | | | | | | | | |

CONCLUSION

First two columns (Table No#, Table Title) are automatically filled using this tool, other column headers are predefined. This tool helps to create these documents in time efficient way and avoid manual error.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. You can contact us at:

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