



A Metadata Driven System for Creating a Library of Standard Tables, Figures and Listings

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Transforming Clinical Trials

- This session will be a demonstration of the functionality of PRA's EXACT system.
- The EXACT system is an integrated SAS[®] based development environment that can create reusable programs for
 - data extraction
 - data transformation (SDTM and ADaM datasets)
 - **statistical reporting (Tables, Figures and Listings)**
← What we will cover in this demonstration
 - electronic publishing (e.g. define.xml, module 5 of eCTD)

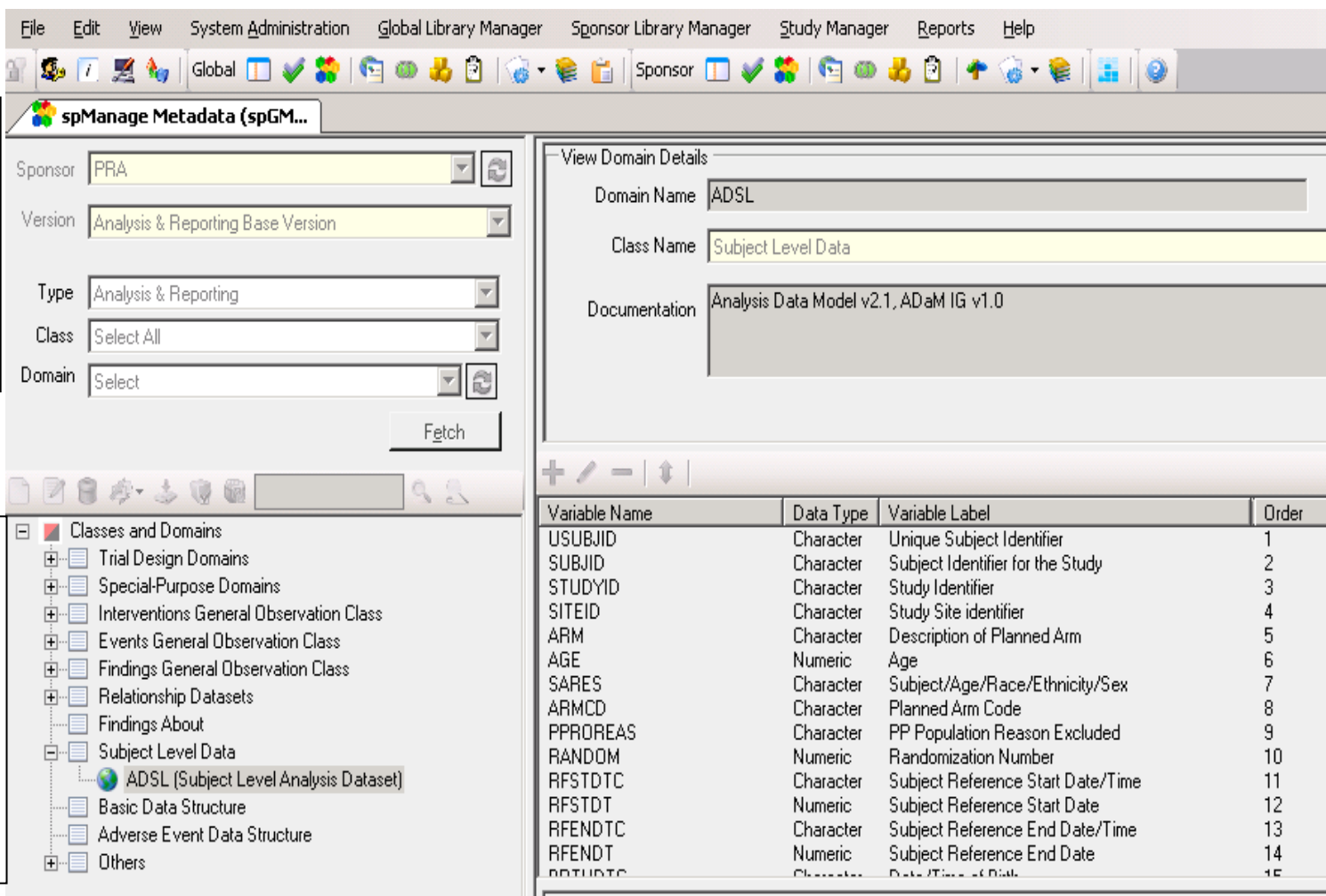
Demonstration Overview

- Creating a library of table configurations
 - Based upon ADaM compliant metadata
 - Configurable with a easy to use GUI that offers a great deal of flexibility for specifying the details needed for most standard displays
- Creating table shells and data displays within a study using a library object
 - Requires very little work by study programmer
 - The same table can be run as a shell pre-study and as a data display after the study data has been collected
 - Tables can be scheduled as a batch for easy deliverable preparation.

Global Metadata Repository

- You must setup the analysis dataset metadata and load this in the Global Metadata Repository (GMDR)
- This should be based upon ADaM guidelines
- Can be organized by sponsor
- Versioning is possible should the ADaM guidelines change
- GMDR can be populated using the graphical user interface, or my batch loading the metadata using an import template

GMDR Screenshot



The screenshot displays the GMDR (Global Metadata Data Repository) interface. The main window is titled "spManage Metadata (spGM...)" and features a menu bar with options: File, Edit, View, System Administration, Global Library Manager, Sponsor Library Manager, Study Manager, Reports, and Help. Below the menu is a toolbar with various icons.

On the left side, there is a sidebar with a tree view titled "Classes and Domains". The tree structure includes:

- Classes and Domains
 - Trial Design Domains
 - Special-Purpose Domains
 - Interventions General Observation Class
 - Events General Observation Class
 - Findings General Observation Class
 - Relationship Datasets
 - Findings About
 - Subject Level Data
 - ADSL (Subject Level Analysis Dataset)
 - Basic Data Structure
 - Adverse Event Data Structure
 - Others

On the right side, there is a "View Domain Details" panel. It contains the following information:

- Domain Name: ADSL
- Class Name: Subject Level Data
- Documentation: Analysis Data Model v2.1, ADaM IG v1.0

Below the domain details, there is a table listing variables. The table has four columns: Variable Name, Data Type, Variable Label, and Order.

Variable Name	Data Type	Variable Label	Order
USUBJID	Character	Unique Subject Identifier	1
SUBJID	Character	Subject Identifier for the Study	2
STUDYID	Character	Study Identifier	3
SITEID	Character	Study Site identifier	4
ARM	Character	Description of Planned Arm	5
AGE	Numeric	Age	6
SARES	Character	Subject/Age/Race/Ethnicity/Sex	7
ARMCD	Character	Planned Arm Code	8
PPROEAS	Character	PP Population Reason Excluded	9
RANDOM	Numeric	Randomization Number	10
RFSTDTC	Character	Subject Reference Start Date/Time	11
RFSTD	Numeric	Subject Reference Start Date	12
RFENDTC	Character	Subject Reference End Date/Time	13
RFEND	Numeric	Subject Reference End Date	14
RFENDTC	Character	Subject Reference End Date/Time	15

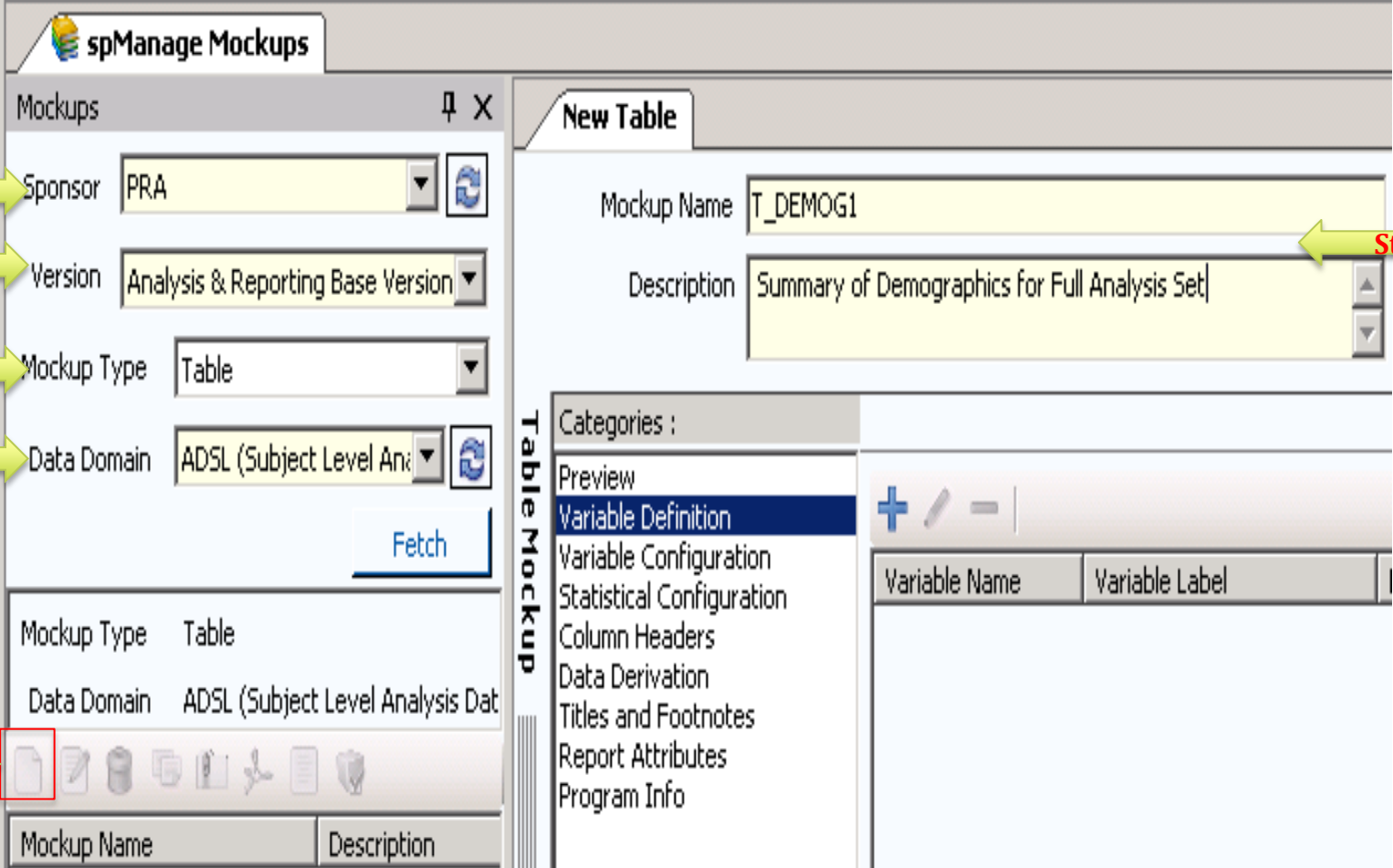
Annotations on the screenshot:

- Sponsor and Version identifier:** Points to the "Sponsor" (PRA) and "Version" (Analysis & Reporting Base Version) fields in the top left.
- Dataset Level Metadata:** Points to the "View Domain Details" panel on the right.
- Datasets organized by Class:** Points to the "Classes and Domains" tree view on the left.
- Dataset Level Metadata:** Points to the variable table at the bottom right.

CONFIGURING A TABLE IN THE LIBRARY

- Go to Manage Mockups Screen
 1. Select your sponsor and metadata version
 2. Choose mockup type =Table
 3. Select Data Domain as the input dataset for the table you are about to configure (e.g. ADSL for a demographics table)
 4. Click “New” to begin the creation of a new table configuration
 5. Provide a name and description of your table

Manage Mockup Screen Shot



spManage Mockups

Mockups

Step 1 Sponsor: PRA

Step 1 Version: Analysis & Reporting Base Version

Step 2 Mockup Type: Table

Step 3 Data Domain: ADSL (Subject Level Analysis Data)

Step 4 [New Mockup Icon]

Fetch

Mockup Type: Table

Data Domain: ADSL (Subject Level Analysis Data)

New Table

Mockup Name: T_DEMOG1

Description: Summary of Demographics for Full Analysis Set

Step 5

Table Mockup

Categories :

- Preview
- Variable Definition**
- Variable Configuration
- Statistical Configuration
- Column Headers
- Data Derivation
- Titles and Footnotes
- Report Attributes
- Program Info

Variable Name	Variable Label

Variable Definition

Go to the Variable Definition Category within Manage Mockup screen

1. Select the variables from the GMDR that will be needed for your table
2. Specify for each variable whether they are:
 - A. analysis variables – you will be summarize them in some way on the table
 - B. report display variable – if they will appear on the table in any way
3. Add SAS® formats as necessary for decoding value on table
4. Provide mockup values for all character variables to be used in generation of dummy data for shell creation

Variable Definition Screenshot

**Add
Variable -
Step 1**

Variable Name	Variable Label	Data Type	Variable Type
USUBJID	Unique Subject Identifier	Character	Categorical
TRT01P	Planned Treatment for Pe...	Character	Categorical
FASFL	Full Analysis Set Populati...	Character	Categorical
SEX	Sex	Character	Categorical
RACE	Race	Character	Categorical
AGEGR1N	Pooled Age Group 1 (N)	Numeric	Categorical
AGE	Age	Numeric	Continuous

**Attach a SAS
format to a
variable for
better decoding
on the table**

Variable Details | Analysis Variable Details | Missing Data Information | Comparator

GMDR Domain: ADSL (Subject Level Analysis Dataset)

Variable Name: AGEGR1N

Variable Label: Pooled Age Group 1 (N)

Data Type: Numeric

Variable Type: Categorical

Report Display Label: Age Group [n(%)]

Case: Select ☐ Desired Case

☒ Report Display Variable ☒ Analysis Variable

Step 3

Step 4

Step 2



Variable Configuration

Go to the Variable Configuration category on the Manage Mockups screen

1. Select your “Subject Identifier Variable”
2. Specify your “Analysis Population” and Where Condition for table sub-setting (e.g. FASFL=“Y”)
3. Specify whether you want SAS Procedure output in addition to your table output
4. Add a Mockup value for the summary statistics in a shell (i.e. place an x where the numbers would appear)

Variable Configuration (continued)

5. Select the variable to be used on a Column Header Variable and provide its mockup values.
6. Determine whether you want to add a total column and want to include missing values for your column header variable in the total column
7. Specify if you want a Header N added to each column to indicate the number of unique subjects within that column.

Variable Configuration Screen Shot

T_DEMOG

Mockup Name T_DEMOG

Description Summary of Demographics Full Analysis Set

Table Mockup

Categories :
 Preview
 Variable Definition
Variable Configuration
 Statistical Configuration
 Column Headers
 Data Derivation
 Titles and Footnotes
 Report Attributes
 Program Info

Column Header Variable Configuration

Other Variable(s) Configuration

Section Label for Analysis Variables

Step 1 → Subject Identification Variable USUBJID

Step 2 → Analysis Population FASFL

Step 2 → Where Condition Y|

SAS Procedure Output No **Step 3** ←

Statistical Type None

Summary Statistics Mockup Value x **Step 4** ←

+
✎
-

		Total Calculation		Header N			
Column Header Variable	Mockup Value	Need Total	Include Missing	Need Header N	Position	Sort Type	Sort Treatment Column
TRT01P	A B C	With Total	No	(N=xx)	Bottom	Ascending	

Step 5 →

Step 6 →

Step 7 →

Statistical Configuration Overview

- Each “Analysis Variable” needs to have a statistical configuration attached.
- Separate libraries of statistical configuration can be created for categorical analysis variables and continuous analysis variables
- From the Statistical Configuration screen you simply select a configuration from the library. In the demo we will show you what you look for on the statistical configuration to determine if it is what you are wanting to use.
- If the configuration you desire does not exist in the library you create a new configuration and add it to the library.

Categorical Count Statistical Configurations

The Categorical Statistical Configuration is organized into Count configurations and Percent Configurations.

For the Count Configurations you must:

1. Pick the layout of the count and percent (i.e. parentheses around percent)
2. Set the number of spaces to indent the categories in the row just below the variable label on the table layout
3. Select whether you want an actual or Unique Subject count
4. Determine the print order for the categories on the table
5. Specify if you want a total category added; if so how and where
6. Do you want a MISSING value category added
7. Determine if you also want confidence limits added in addition to the actual count

Categorical Count Statistical Configurations Screenshot

Step 1 → Summary Statistics Type

Step 2 → Indentation ☒ Include All Categories (Formats)

Step 3 → Count Configuration

Count Type ☒ Actual Count ☐ Unique Subject

Print Order ☒ Alphabetic ☐ Frequency

Step 4 → ☐ Total ☒ n (%) ☐ n Position

Step 5 → ☐ Need Superscript for N

Total Label

Step 6 → ☒ Include Missing ☒ Display Missing

Missing Label

Step 7 → Confidence Limits ☒ None ☐ 90 % ☐ 95 %

Display Formats

Categorical Percent Configurations

For Percent Configurations how must:

1. Specify which total will be used as the denominator
2. Specify the number of decimals to present for percentages
3. Give some logic for special formatting conditions (e.g. if count=0 do not show the percentage, or if count is not 0 and percentage would round to 0 show as “<0.1”)

Categorical Percent Configurations Screenshot

Percentage Configuration

Percentage Type

☐ Row
 ☒ Column
 ☐ Total

☐ Alternate Denominator

Step 1 →

Number of Decimals ▼

Step 2 →

Percentage Representation

	Type	Condition	Value	Label
▶	Count ▼	=	0	0.00
*	▼			

Step 3 →

Continuous Statistical Configurations

The Continuous Statistical Configuration includes the following:

1. Selecting the set of summary statistics you want to present on your table from the list of available statistics
2. Determining the label to display on the table for each statistic
3. Determining the decimal precision for each statistic
4. Checking a box if you want to present the mean and variance component on the same line and choosing the layout of this combination from a drop down list.
5. Checking a box if you want to present the median and quartiles on the same line and choosing the layout of this combination from a drop down list.
6. Checking a box if you want to present the minimum and maximum on the same line and choose the layout of this combination from a drop down list.

Continuous Statistical Configurations Screenshots

Available Summary Statistics		Selected Summary Statistics			
n (%)	↑	Order	Statistics	Display Label	Decimal Precision
Missing	↓	1	n	n	0
Missing (%)		2	Mean	Mean	1
Mode		3	Median	Median	1
Standard Error		4	Standard Deviation	std	2
Co-efficient of Variation (%)		5	Minimum	Min	0
Geometric Mean		6	Maximum	Max	0
90% Confidence Limit		7	First Quartile (Q1)	Q1	1
95% Confidence Limit		8	Third Quartile(Q3)	Q3	1

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Display Labels

☐ None

☒ Mean $\pm$ SE/SD

Mean (SD)

☐ Median (Q1, Q3)

Select

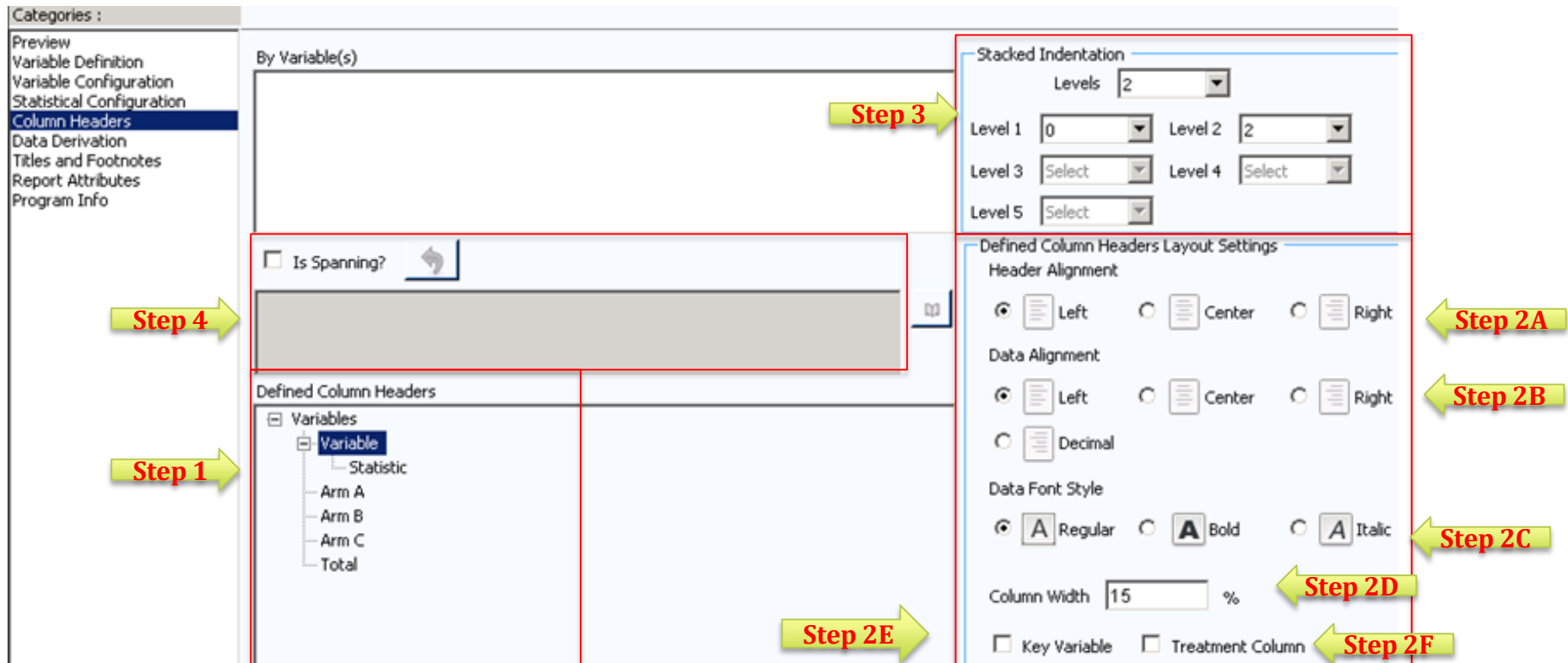
☒ Range

Min, Max

Column Headers

1. The column headers category is where you define the header labels for the columns of the report.
2. For each Column header you can specify
 - A. Header alignment
 - B. Data Alignment
 - C. Font style
 - D. Column width as a % of the page
 - E. Whether a column represents a key variable to repeat on each page should the columns be too wide to fit on a single page
 - F. Whether a column represents a treatment column which will need to be replaced with study treatments at the study level
3. You can stack up to 5 labels in the same column
4. If you need a header to span multiple columns, you will need to provide the spanning condition SAS syntax that will be applied to the column statement in a PROC REPORT call.

Column Headers Screenshot



The screenshot shows the 'Column Headers' configuration window. The left sidebar contains a list of categories: Preview, Variable Definition, Variable Configuration, Statistical Configuration, **Column Headers**, Data Derivation, Titles and Footnotes, Report Attributes, and Program Info. The main area is divided into sections for 'By Variable(s)', 'Is Spanning?', and 'Defined Column Headers'. The 'Defined Column Headers' section shows a tree view with 'Variables' expanded, containing 'Variable', 'Statistic', 'Arm A', 'Arm B', 'Arm C', and 'Total'. The 'Variable' node is selected. The right panel contains settings for 'Stacked Indentation' and 'Defined Column Headers Layout Settings'. The 'Stacked Indentation' section has a 'Levels' dropdown set to 2, and five level-specific dropdowns (Level 1 to Level 5). The 'Defined Column Headers Layout Settings' section includes options for 'Header Alignment' (Left, Center, Right), 'Data Alignment' (Left, Center, Right, Decimal), 'Data Font Style' (Regular, Bold, Italic), 'Column Width' (15%), and checkboxes for 'Key Variable' and 'Treatment Column'. Yellow arrows with red text labels point to specific elements: 'Step 1' points to the 'Variable' node in the tree; 'Step 2A' points to the 'Header Alignment' section; 'Step 2B' points to the 'Data Alignment' section; 'Step 2C' points to the 'Data Font Style' section; 'Step 2D' points to the 'Column Width' field; 'Step 2E' points to the 'Defined Column Headers' section; 'Step 2F' points to the 'Key Variable' and 'Treatment Column' checkboxes; 'Step 3' points to the 'Stacked Indentation' section; and 'Step 4' points to the 'Is Spanning?' checkbox.

Categories :

- Preview
- Variable Definition
- Variable Configuration
- Statistical Configuration
- Column Headers**
- Data Derivation
- Titles and Footnotes
- Report Attributes
- Program Info

By Variable(s)

☐ Is Spanning?

Defined Column Headers

- Variables
 - Variable**
 - Statistic
 - Arm A
 - Arm B
 - Arm C
 - Total

Stacked Indentation

Levels: 2

Level 1: 0, Level 2: 2, Level 3: Select, Level 4: Select, Level 5: Select

Defined Column Headers Layout Settings

Header Alignment

☒ Left, ☐ Center, ☐ Right

Data Alignment

☒ Left, ☐ Center, ☐ Right, ☐ Decimal

Data Font Style

☒ Regular, ☐ Bold, ☐ Italic

Column Width: 15 %

☐ Key Variable, ☐ Treatment Column

Report Attributes

Items that can be configured in the report attributes category include:

1. Column header font style and size
2. The body of the table font style and size
3. Settings to control how page breaks are created
4. The report width and alignment on the page
5. A Message to print if a table is executed against a null record dataset (e.g. a Serious Adverse Event table created in a study with no SAEs)

Report Attributes Screenshot

Reporting Settings

Step 1 → Column Header Font Style: Regular Column Header Font Size: 8

Step 2 → Body Font Style: Regular Body Font Size: 8

☐ Border

Step 3 → Display Settings

☒ Total Number of Rows: 15

☐ Page Break

☐ Automatic Page Break

Step 4 → Report Width: 100 Report Alignment: Center

No Data Available Message: No Data

Step 5 →

Additional Categories

The remaining categories are Data Derivation, Titles and Footnotes and Program Info.

- The Data Derivation screen is where you can write SAS code to serve as a pre-processing of the data prior to the table configuration macro calls.
- The Title and Footnotes screen is where you define titles and footnotes for the table.
 - These will be loaded into the study titles and footnote database when the table configuration is pulled into a study.
 - They will then be editable at the study level if necessary.
- The Program Info screen you can add detailed programming notes that will be available to serve as a communication tool to study team programmers who will be using this table configuration.

Categories :
Preview
Variable Definition
Variable Configuration
Statistical Configuration
Column Headers
Data Derivation
Titles and Footnotes
Report Attributes
Program Info

Creating Tables at Study Level

- These steps would now be completed by a study team programmer or biostatistician
- Before you can create tables you must first create an 'Analysis'
- Analysis is way to organize your analysis dataset and TFL for differing purposes within a study
- Within the ADaM and TFL screens you will always start by selecting the Analysis you want to work within



Setting up an Analysis

- Open the Analysis Screen
- Click New to create a New Analysis
- Select your Analysis Group from the drop down list (e.g. finalanalysis)
- GO through workflow defined by the various categories on the Analysis screen.

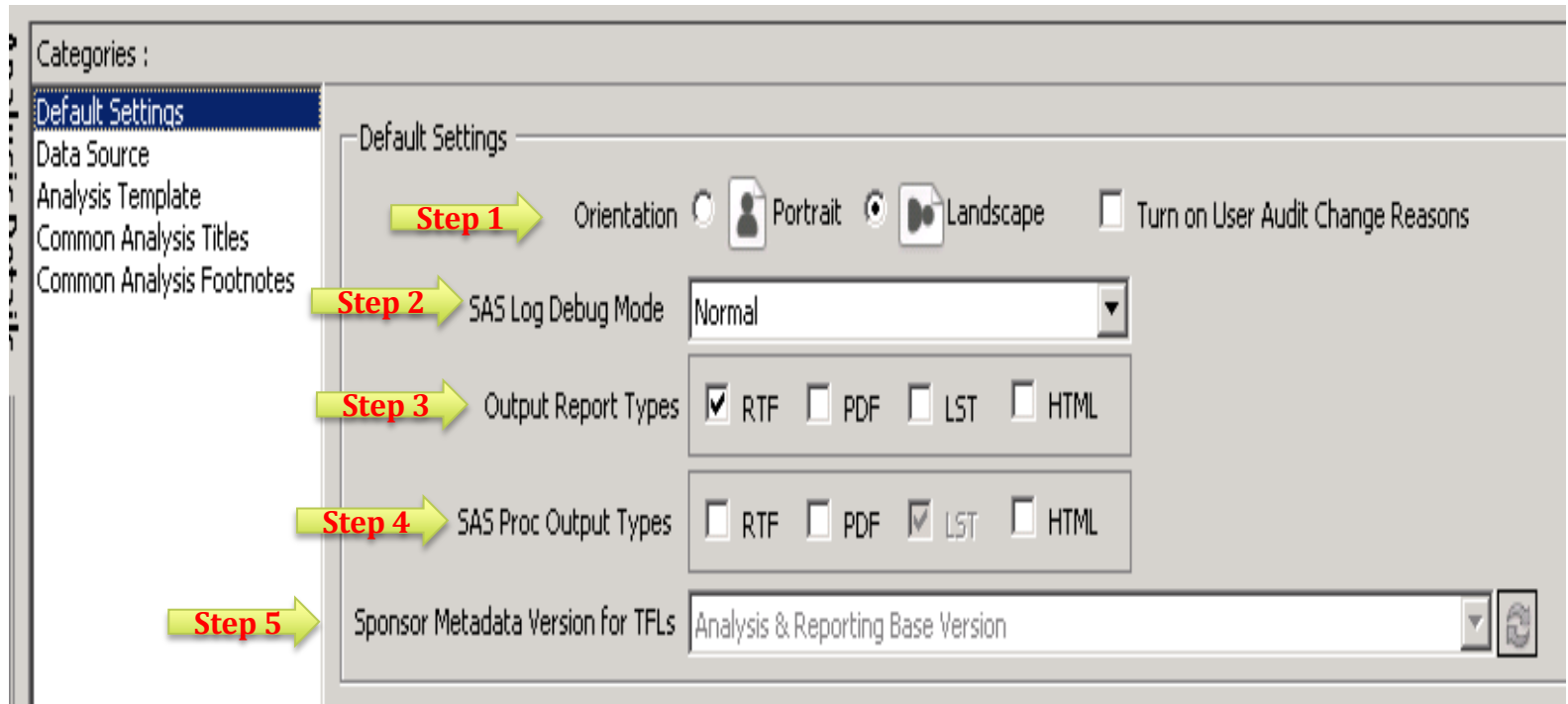


Default Analysis Settings

This screen allows you to select the default setting for the following

1. Orientation (landscape or portrait),
2. SAS log debug mode
3. Output File types for TFL as RTF, PDF, LST and HTML
4. Output file type for SAS STAT procedure output
5. Select the Sponsor metadata version for TFL metadata (this determines which library version of table mockups you can use)

Default Analysis Settings Screenshot





Common Analysis Titles

Allow you to set two common titles to serve as the header for all TFL shells and data displays.

1. Set the header font style and size
2. Using drop down list chose fields to place in the left justified panel, center panel and right justified panel
3. IF you have selected a date field or a page numbering field you must also specify the date format and page number format.

These steps must be repeated for Title 2

Common Analysis Titles Screenshot

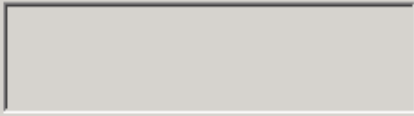
Categories :

- Default Settings
- Data Source
- Analysis Template
- Common Analysis Titles**
- Common Analysis Footnotes

Step 1 → Common Header Font Style **Bold** Common Header Font Size **8**

Common Title 1

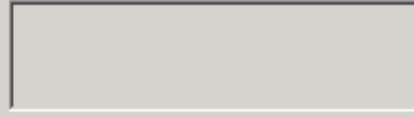
Left **Sponsor Name** Center **None** Right **Date**

Sponsor Logo 

Date Format **DDMONYY** Page Format **Select** **Step 3** →

Common Title 2

Left **Study Name** Center **None** Right **None**

Sponsor Logo 

Date Format **Select** Page Format **Select** **Step 3** →

Step 2 →

Common Analysis Footnotes

Configuring the common footnotes is similar but there is more flexibility to add multiple fields to a panel and you can add free text as part of the standards footnotes not just fields.

1. Select footers field from the “Available Footers” list
2. Use Arrows to move items in the various panels for footnote 1 or footnote 2.
3. To add free text move the Free Text fields in the panel and add the text to the label column.
4. Formatting for date fields and Page number use the drop down list at the bottom of the screen.

Common Analysis Footnotes

Categories :

- Default Settings
- Data Source
- Analysis Template
- Common Analysis Titles
- Common Analysis Footnotes**

Common Footer Font Style: Regular Common Footer Font Size: 8 ☐ Print Footnote in Footer Section

Common Footer 1

Left		Center		Right	
Footers	Label	Footers	Label	Footers	Label
		Free Text			

Common Footer 2

Left		Center		Right	
Footers	Label	Footers	Label	Footers	Label
				Page No	

Available Footers:

- Program Source
- Data Files
- Data Cut-off
- Page No/Date
- Programmer Name
- Confidential
- TPL Version
- Free Text

Date Format: DDMONYY Page Format: Page x of y

Data Cut-off Format:

Date: 2013-08-26 SAS Date Format: DATE

SAS Date Format Width: 7



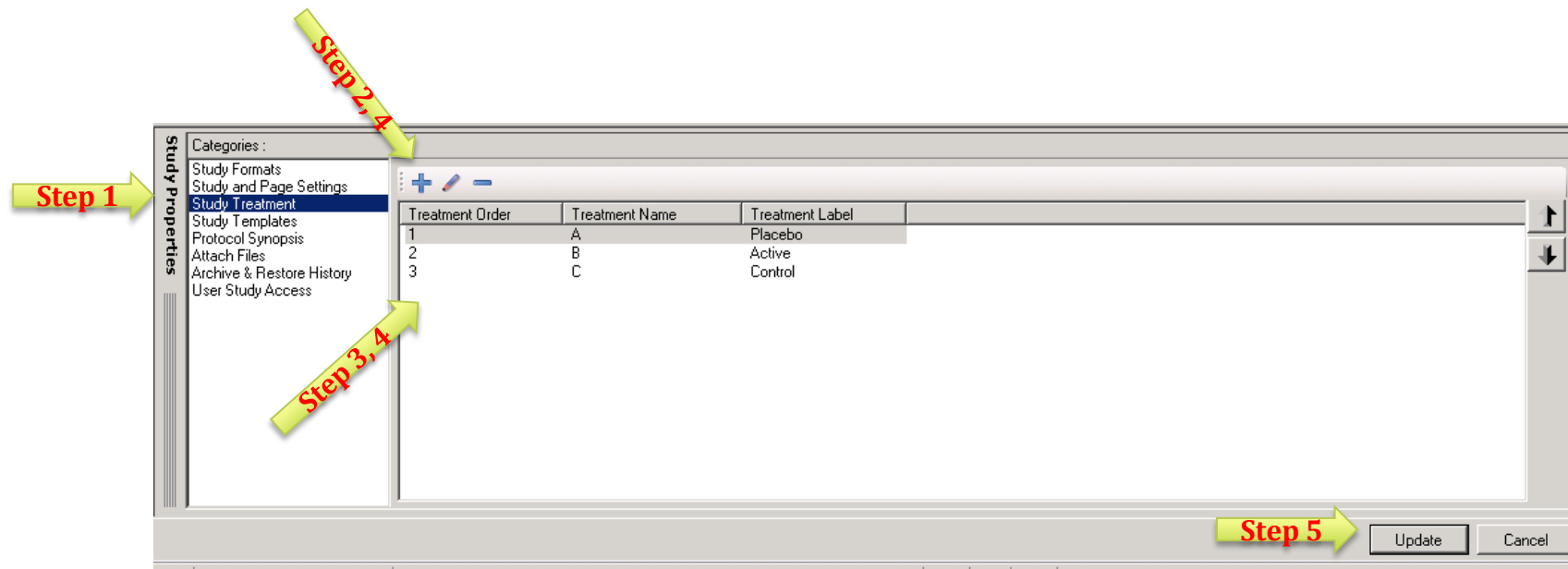
Study Treatment

Since the library of tables will not have the study specific treatments in the column headers these need to be updated within the study.

These can be added a single time in the Study setup screen and be applied to all tables where the treatment columns were set of “treatment columns”

1. Go to Study Setup screen and then select Study Treatment and click the edit icon
2. Click the blue plus sign to add a treatment
3. Complete the Treatment Name and Treatment Label fields.
4. Repeat steps 2 and 3 until all treatments have been added
5. Click the Update Button to Save the changes

Study Treatment Screen



The screenshot shows the 'Study Properties' dialog box with the 'Study Treatment' category selected. The 'Treatment Order' table is visible, showing three treatments: A (Placebo), B (Active), and C (Control). The 'Update' and 'Cancel' buttons are at the bottom right.

Step 1 points to the 'Study Treatment' category in the left sidebar.

Step 2, 4 points to the '+' icon in the toolbar above the table.

Step 3, 4 points to the table header row.

Step 5 points to the 'Update' button.

Treatment Order	Treatment Name	Treatment Label
1	A	Placebo
2	B	Active
3	C	Control

Creating Tables

You are now ready to create table programs in your study from the the Analysis and Reporting (TFLs) screen.

1. Select Table from the Mockup Type drop down list
2. Select your analysis
3. Select the Data Domain you will be using as the input for the table (e.g. ADSL for the Demographics tables)
4. Click New
5. Select the mockup from the library by selecting it from the drop down list.

This will load the configuration for the mockup you selected from the library.

Creating Tables (Continued)

The study mockup name and description will be populated from the library. There are only two fields that need to be provided at the study level.

1. The first is the output file name on the Repeat/Titles and Footnotes screen
2. The second is Source Data and Output report types on the Program Info tab

Creating Tables Screenshots

Categories :

- Preview
- Variable Definition
- Variable Configuration
- Statistical Configuration
- Column Headers
- Data Derivation
- Report Attributes
- Repeat/Titles and Footnotes**
- Program Info

☐ Repeat Configurations

Output File Name

Step 1

Categories :

- Preview
- Variable Definition
- Variable Configuration
- Statistical Configuration
- Column Headers
- Data Derivation
- Report Attributes
- Repeat/Titles and Footnotes**
- Program Info

Source Dataset: ADSL

Output Report Types: ☒ RTF ☐ PDF ☐ LST ☐ HTML

SAS PROC Output Types: ☐ RTF ☐ PDF ☐ LST ☐ HTML

Step 2



Custom Tables

- There are also ways you can also create non-standard tables without selecting a mockup from the library.
1. Click the custom table check box and then write your own SAS program to create a table
 2. Go through the Categories screens and configure a table at the study level just as you would to when creating tables in the library.

Custom Tables Screenshots

New Table

Study Mockup Name
Sponsor Mockup
Select
Custom Table

Description

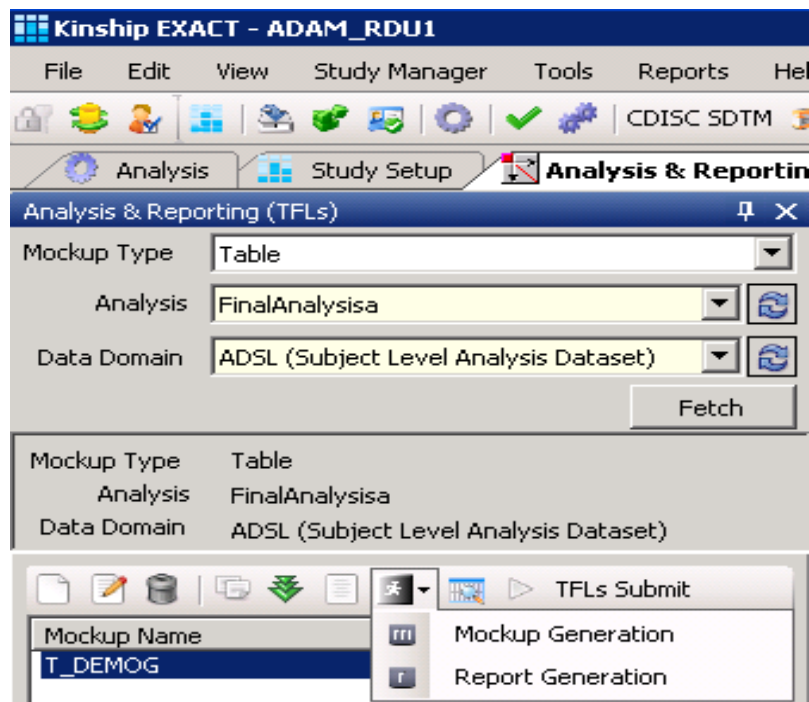
Study Table Mockup
Categories :
Preview
Variable Definition
Variable Configuration
Statistical Configuration
Column Headers
Data Derivation
Report Attributes
Repeat/Titles and Footnotes
Program Info

Preview not available.

To create a table shell you will

1. Select the Mockup Name that you want to execute as a shell from the list
2. Click the Running Man icon and select Mockup Generation from the pop-up window. The job will begin executing on the SAS server
3. When the job completes another pop-up will notify you that ***output filename*** was generated successfully.

Executing the Configuration to Create a Shell Screen Shot

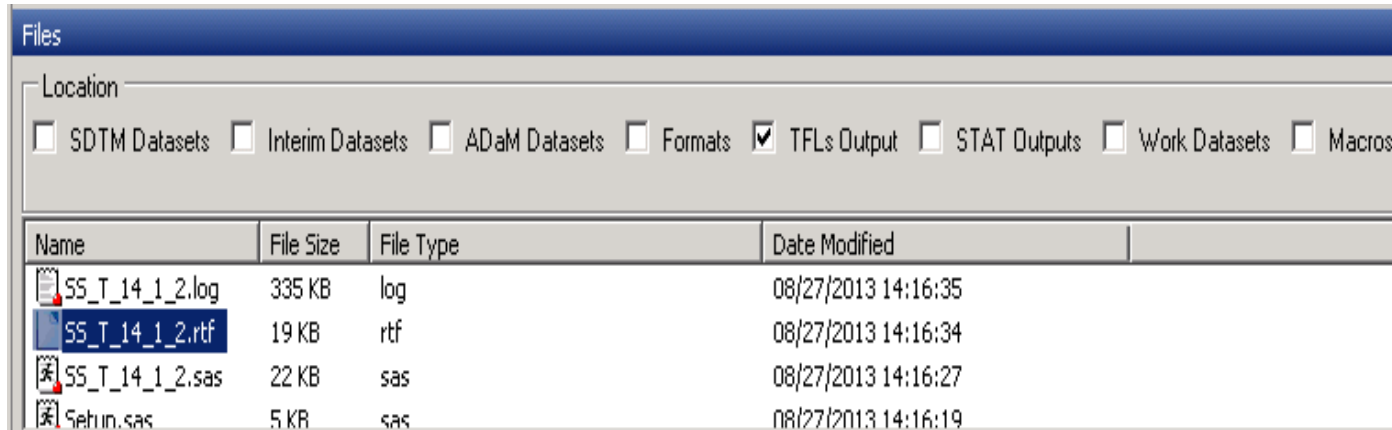


Viewing the Output from Your SAS Job

- To view the outputs from your job, click the View TFL Outputs Icon  which brings up a files window
- You can browse files as you might in Windows Explorer and it will filter by file Type
- This allows you to keep all of the output files organized in various folders but easily browsed from a single screen



Viewing the Output from Your SAS Job Screenshot



The screenshot shows a window titled "Files" with a "Location" section containing several checkboxes. The "TFLs Output" checkbox is checked. Below this is a table with four columns: "Name", "File Size", "File Type", and "Date Modified". The table lists four files: "SS_T_14_1_2.log", "SS_T_14_1_2.rtf", "SS_T_14_1_2.sas", and "Sehin.sas". The "SS_T_14_1_2.rtf" file is highlighted with a blue selection bar.

Name	File Size	File Type	Date Modified
SS_T_14_1_2.log	335 KB	log	08/27/2013 14:16:35
SS_T_14_1_2.rtf	19 KB	rtf	08/27/2013 14:16:34
SS_T_14_1_2.sas	22 KB	sas	08/27/2013 14:16:27
Sehin.sas	5 KB	sas	08/27/2013 14:16:19



Mockup Screenshot

PRA International
ADAM_POOL

14.1.2 Demographics

Variable	Placebo [N = XX]	Active [N = XX]	Control [N = XX]	Total [N = XX]
Sex: [n (2)]				
Female	XXX XXX.XX	XXX XXX.XX	XXX XXX.XX	XXX XXX.XX
Male	XXX XXX.XX	XXX XXX.XX	XXX XXX.XX	XXX XXX.XX
Race: [n (2)]				
American Indian or Alaska Native	XX XXX.XX	XX XXX.XX	XX XXX.XX	XXX XXX.XX
Asian	XX XXX.XX	XX XXX.XX	XX XXX.XX	XXX XXX.XX
Black or African American	XX XXX.XX	XX XXX.XX	XX XXX.XX	XXX XXX.XX
Other	XX XXX.XX	XX XXX.XX	XX XXX.XX	XXX XXX.XX
White	XX XXX.XX	XX XXX.XX	XX XXX.XX	XXX XXX.XX
Age: [summary]				
n	XXX	XXX	XXX	XXX
Mean (std)	XX.XX [XX.XXX]	XX.XX [XX.XXX]	XX.XX [XX.XXX]	XX.XX [XX.XXX]
Median	XX.XX	XX.XX	XX.XX	XX.XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

Page 1 of 2
Program: Copy of T_03RDG.xax, Dataset: AD5L.xax1dat



Mapping Study Metadata Repository (SDMR) to Global Metadata Repository (GMDR)

As the study progresses you will re-run the configuration to create a data display.

You will need to map the study analysis metadata to the GMDR structure you define in the TFL library.

If you have set up both metadata sources to be compliant with your company ADaM standards this will be an auto-mapping

1. Go to Study Metadata (SMDR) Screen
2. Select Analysis
3. Add SMDR Dataset
4. Add GMDR Dataset
5. Right click on SMDR dataset panel
6. Select auto-map with select the corresponding GMDR dataset
7. Click Save Mapping

Study Metadata (SMDR) Screenshot

Study Metadata Repository SMDR Mapping

Analysis: FinalAnalysisa Save Mapping Add SMDR Dataset Add spGMDR Domain

SMDR : ADSL

Analysis - Subject Level Data

SMDRVars

1. STUDYID (C)
2. USUBJID (C)
3. SUBJID (C)
4. SITEID (C)
5. BRTHDTC (C)
6. BRTHDT (N)
7. BRTHDTF (C)
8. AGEDE (N)
9. AGEU (C)
10. SEX (C)
11. SEXN (N)
12. RACE (C)
13. RACE0TH (C)
14. ARM (C)
15. TRT01P (C)
16. SAFFL (C)
17. SAFFN (N)
18. BASEDT (N)
19. TRTSDT (N)
20. TRTEDT (N)
21. BASEBMI (N)

spGMDR : ADSL

spGMDRVars

1. USUBJID (C)
2. SUBJID (C)
3. STUDYID (C)
4. SITEID (C)
5. ARM (C)
6. AGE (N)
7. SARES (C)
8. ARMCD (C)
9. PPROEAS (C)
10. RANDOM (N)

Auto-Map With

Remove SMDR

Remove Mapping

View Report

18/21 Variables get mapped

spGMDR : ADSL

11. SEXN (N)
12. RACE (C)
13. RACE0TH (C)
14. ARM (C)
15. TRT01P (C)
16. SAFFL (C)
17. SAFFN (N)
18. BASEDT (N)
19. TRTSDT (N)
20. TRTEDT (N)
21. BASEBMI (N)
22. LASTDDT (N)
23. TRTSDT (N)
24. TRTEDT (N)

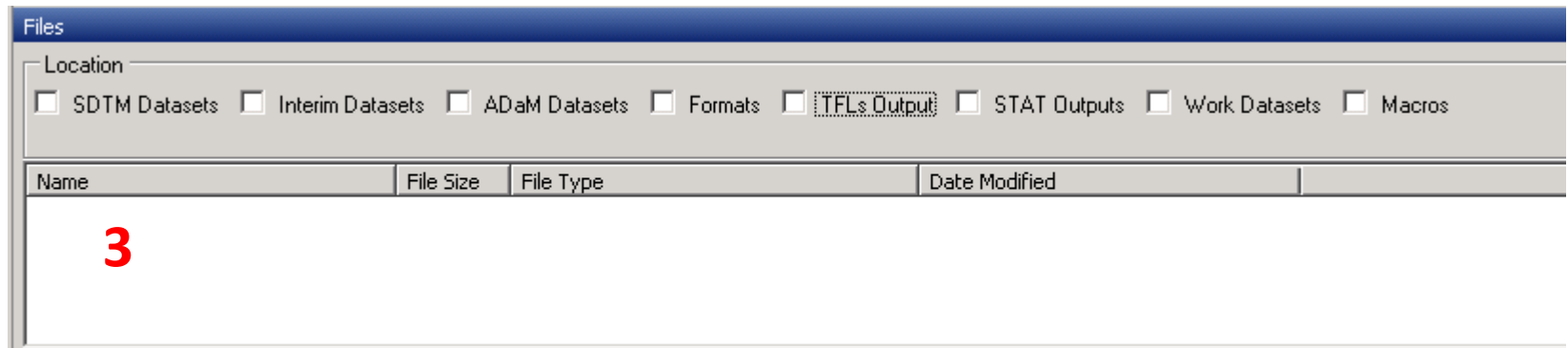
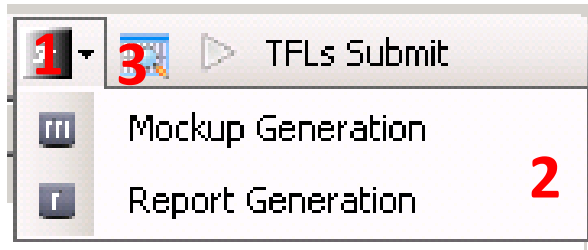


Create a Data Display

From the Analysis and Reporting (TFLs) screen you can now create a data display for your table configuration.

1. Click Generate Table
2. Select Report Generation
3. View the output, logs and programs by clicking View TFL Outputs and browse the Files area.

Create a Data Display Screenshot





Scheduling a Batch of Table to Run Together

You can scheduler a batch of TFL together in a single group to create shells or data displays from the Scheduler screen

1. Click Report Program Group
2. Select your analysis
3. Click New
4. Give your group a Name (e.g. All Tables – shells)
5. Select whether you want shells or data displays
6. Select which of the available TFL you want to include in your group using the arrow buttons
7. Click Save



Report Program Group Screenshot

Step 1 ↓

Step 2 ↓

Step 3 ↓

Step 4 ←

Step 5 ↓

Step 6 →

Step 7 →

Report Program Group

Analysis: ShellTFL1a

Report Program Group Name: Listing Test

Report Program Group Name: []

Report Generation ☒ Mockup Generation ☐

Show By: Group

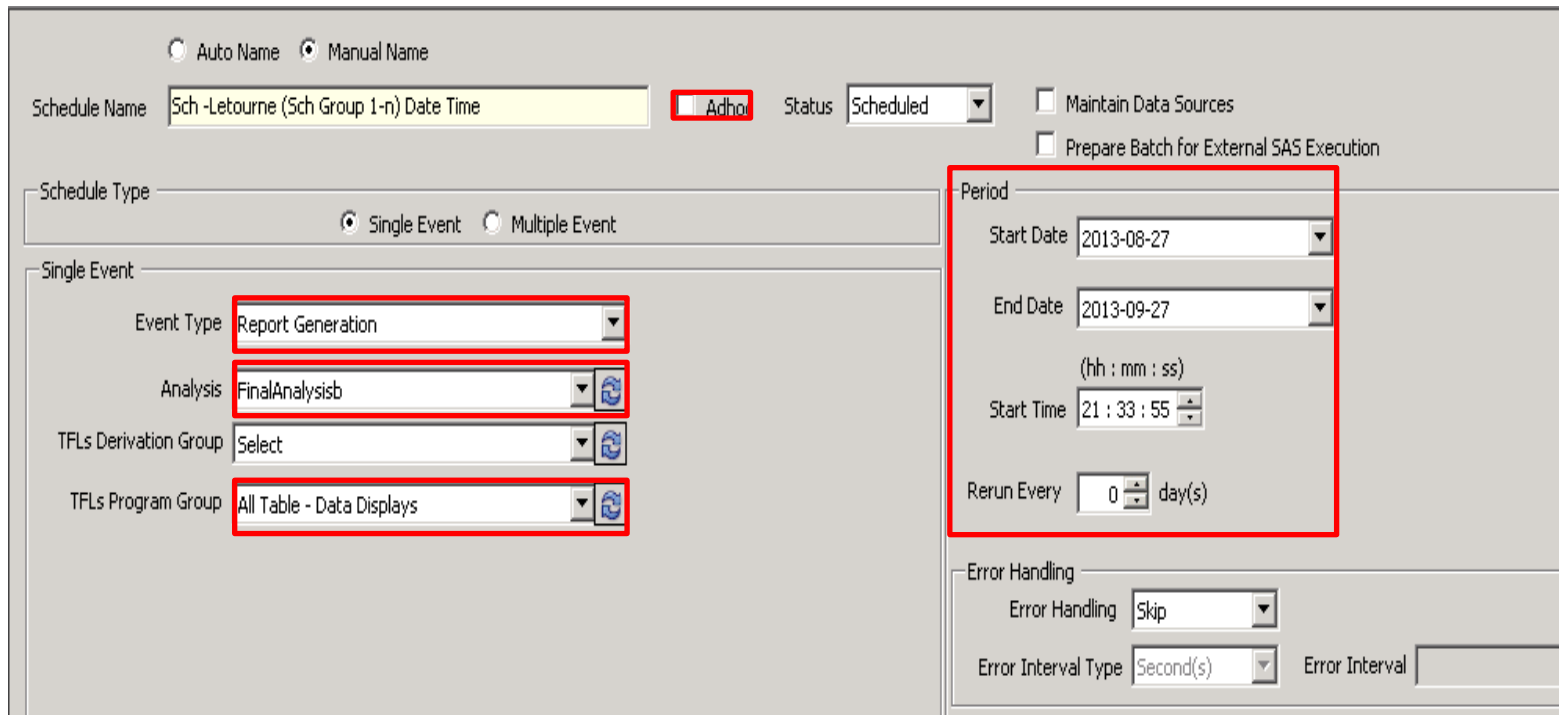
Available Study Mockup Name	Domain
Listings	
L_DM_001	Subje...
L_VS_001	Vital S...
Tables	
KMLSS_T_14.3.2_001	Adver...
QC_ADAE	Subje...
Test_T_AE_001	Adver...
Test_T_AE_001_a1	Adver...
Test_T_DM_001	Subje...
Test_T_VS_001	Vital S...
T_AE_001	Adver...
T_AE_002	Adver...
T_DM_001	Subje...
T_VS_001	Vital S...
Update ADaM Programs	Subje...

Selected Study Mockup Name: [] Domain: []

Save

Scheduling Your Group

From the scheduler screen you can schedule a group to run on the SAS server.



The screenshot shows the SAS scheduler configuration window. Several fields are highlighted with red boxes:

- Adhoc** checkbox: Located next to the Schedule Name field.
- Event Type**: Set to "Report Generation".
- Analysis**: Set to "FinalAnalysisb".
- TFLs Derivation Group**: Set to "Select".
- TFLs Program Group**: Set to "All Table - Data Displays".
- Period** section: Contains date and time fields.
 - Start Date: 2013-08-27
 - End Date: 2013-09-27
 - Start Time: 21 : 33 : 55
 - Rerun Every: 0 day(s)

Other visible fields include:

- Schedule Name**: Sch -Letourne (Sch Group 1-n) Date Time
- Status**: Scheduled
- Schedule Type**: Single Event (selected)
- Error Handling**: Skip
- Error Interval Type**: Second(s)

- CDISC standards for tabulation (SDTM) and analysis (ADaM) datasets, provide the possibility of creating a library of standard TFL that could be used across multiple sponsors.
- PRA has created the EXACT system as a comprehensive enterprise class system used for the creation of SDTM, and ADaM datasets, Define.xml files, validation and compliance reports in addition to creating TFL.
- In this paper we have demonstrated
 - EXACT can be used to create a library of tables
 - After this library has been created study teams can create tables, at the study level by selecting objects from the library and with very little inputs have them ready to run to create both shells and data displays.
 - These TFL programs can then be batched to run as a group via the EXACT scheduler interface.

- **ACKNOWLEDGMENTS**
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A Clear Difference