

ADAM IMPLEMENTATION IN SAS CLINICAL DATA INTEGRATION

**MARK LAMBRECHT, DAVID JORDAN, BILL GIBSON
SAS INSTITUTE**

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SAS Clinical Data Integration is a data transformation solution designed to help companies organize, standardize and manage their clinical research data and metadata. The solution enables companies to

- Integrate data from disparate sources

- Integration with EDC systems, e.g. Medidata Rave

- Standardize their in-process data to industry models

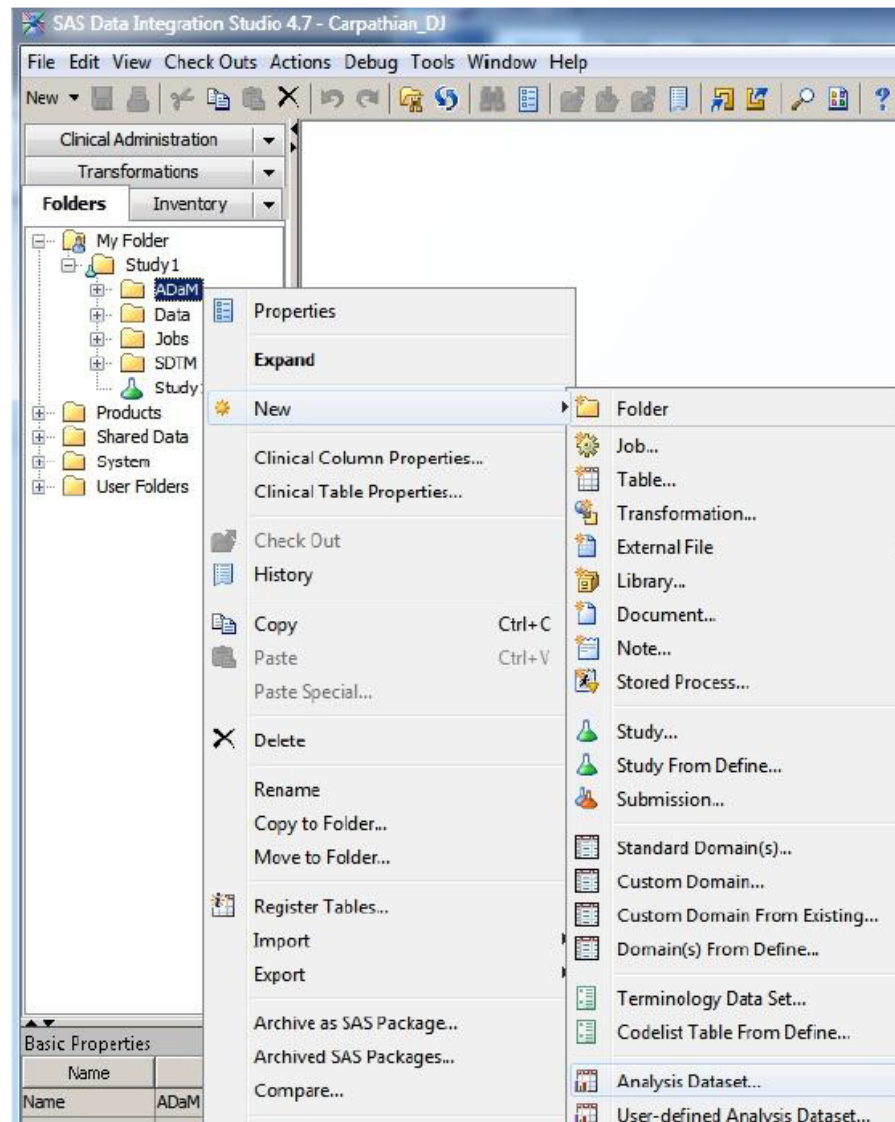
- Migrate legacy data to modern standard models

- Leverage standardized data to efficiently prepare data for analysis and submission to regulatory authorities.

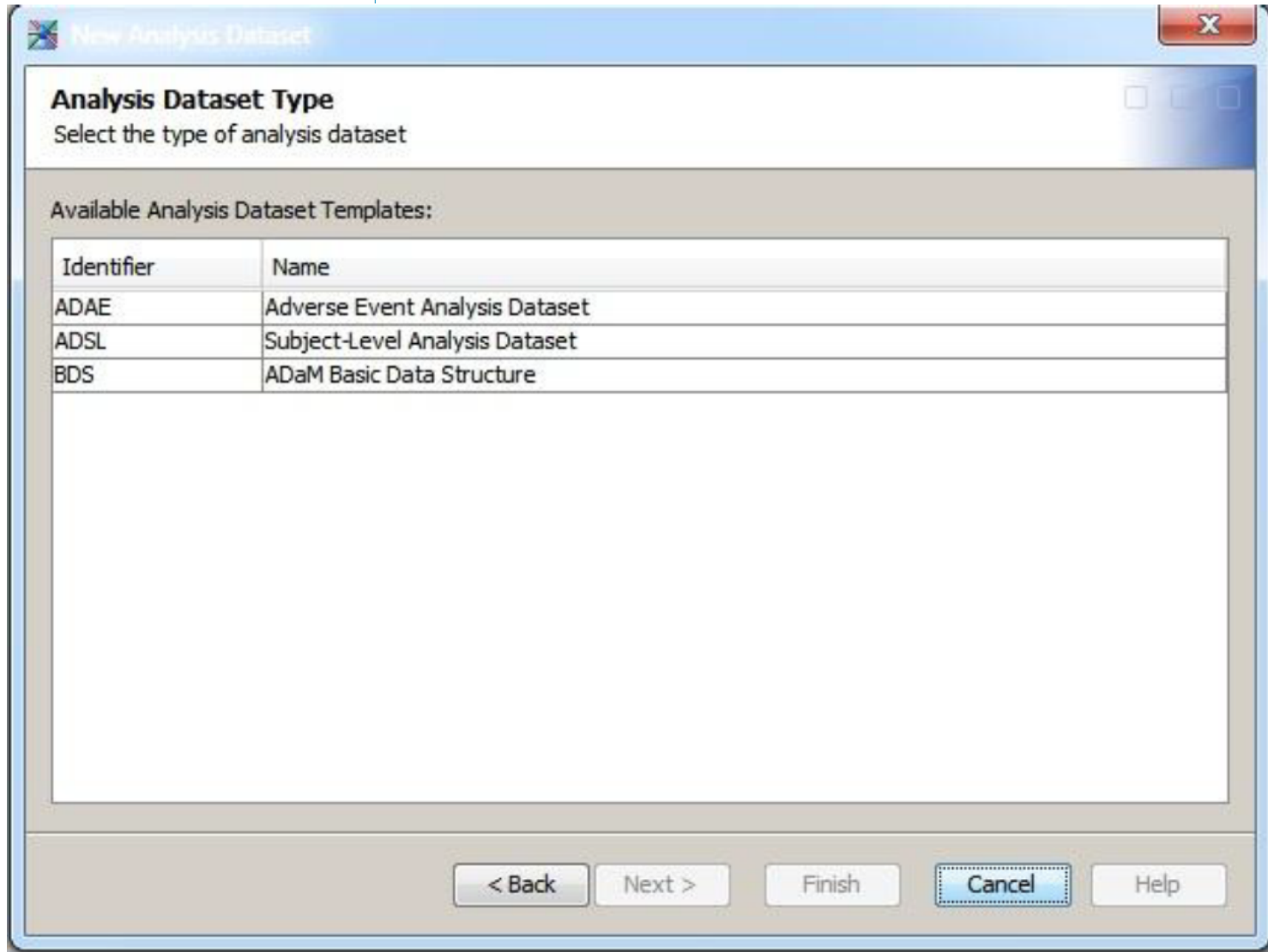
- Is targeted for both SAS programmers and clinical data managers
- SAS Clinical Standards Toolkit “under the hood”
- SAS Clinical Data Integration capabilities now integrated in SAS Drug Development with code that is generated in SAS CDI can be executed straight from SAS Drug Development

- Designing an ADaM dataset can be complex due to a number of factors:
 - ADaM Implementation Guide and data model documentation total over 130 pages!
 - Sheer number of variables to choose from in the specification is daunting
 - Management of values for xx, y, and zz parameters in variable names is cumbersome
 - Use of wildcard characters in variable names
 - Use of variables pulled from other ADAM, SDTM, and SAS tables
- SAS Clinical Data Integration 2.4 – further improved in 2.5
 - Provides an ADAM Dataset Definition Wizard
 - Leverages metadata about the ADaM standard to ease the definition process

CREATE ADAM DATASET



SELECT DATASET



The image shows a SAS dialog box titled "New Analysis Dataset". The main heading is "Analysis Dataset Type" with the instruction "Select the type of analysis dataset". Below this, a section titled "Available Analysis Dataset Templates:" contains a table with three rows. The first row is the header with columns "Identifier" and "Name". The subsequent rows list "ADAE" (Adverse Event Analysis Dataset), "ADSL" (Subject-Level Analysis Dataset), and "BDS" (ADaM Basic Data Structure). At the bottom of the dialog are five buttons: "< Back", "Next >", "Finish", "Cancel" (which is highlighted with a dashed border), and "Help".

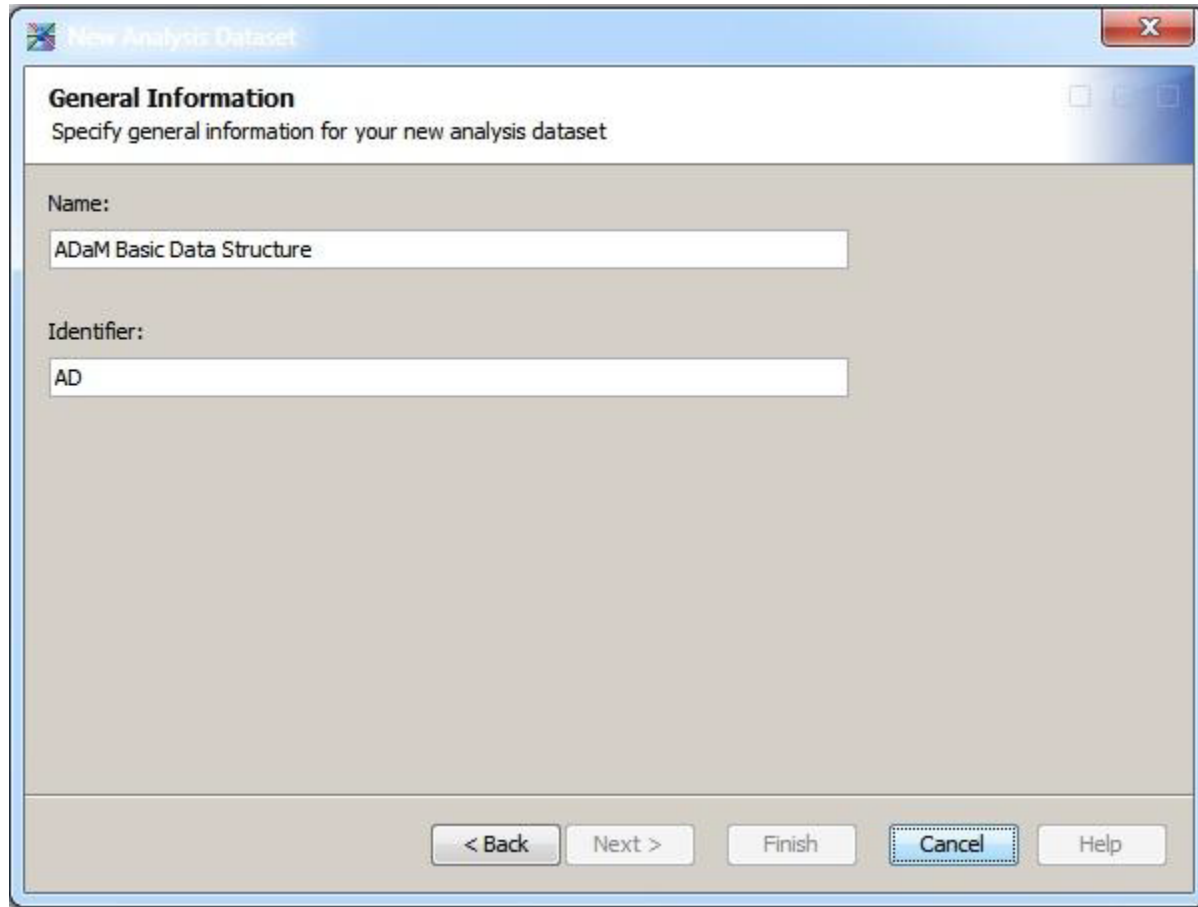
Analysis Dataset Type
Select the type of analysis dataset

Available Analysis Dataset Templates:

Identifier	Name
ADAE	Adverse Event Analysis Dataset
ADSL	Subject-Level Analysis Dataset
BDS	ADaM Basic Data Structure

< Back Next > Finish **Cancel** Help

PROPERTIES OF DATASET



New Analysis Dataset

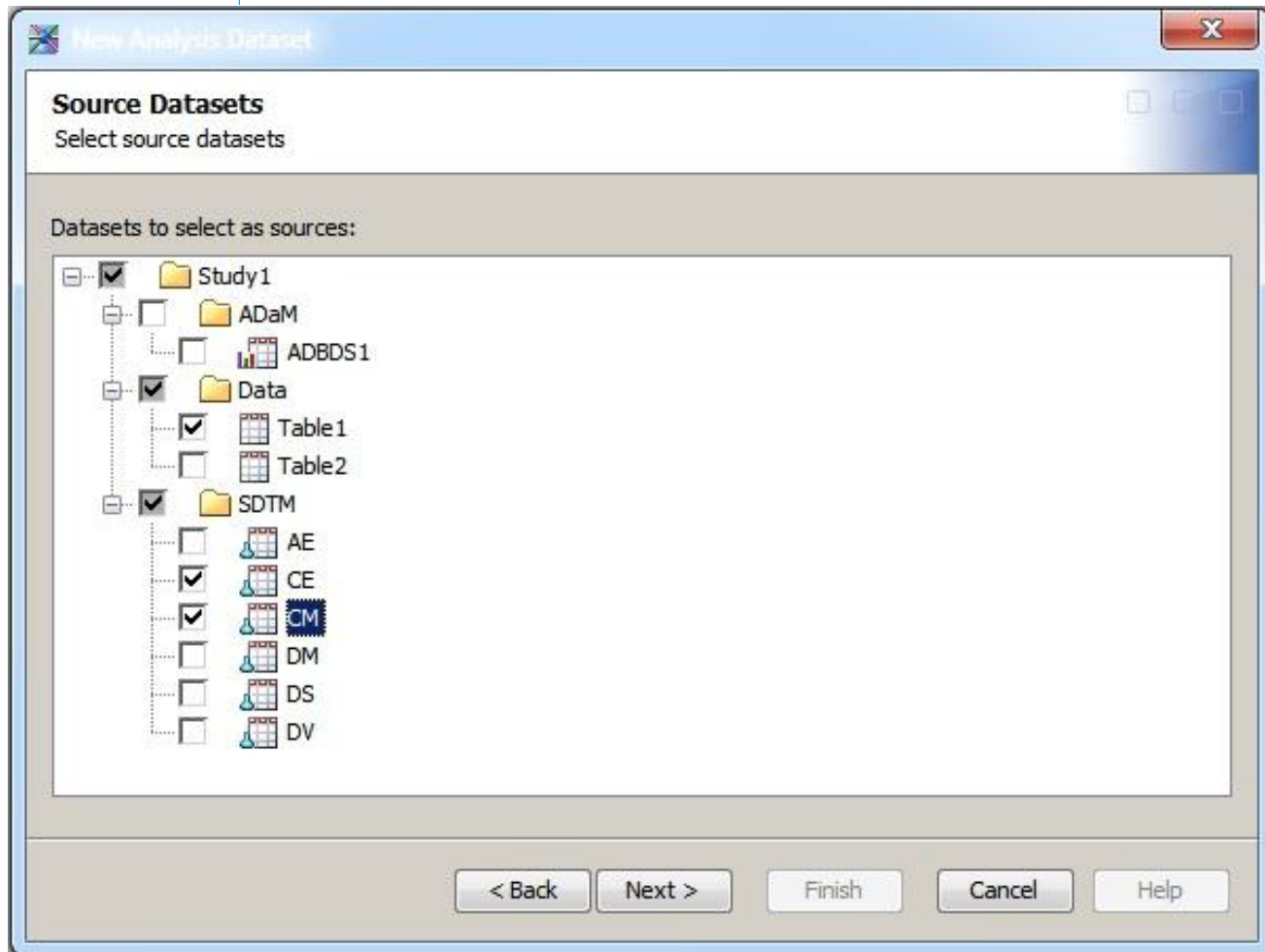
General Information
Specify general information for your new analysis dataset

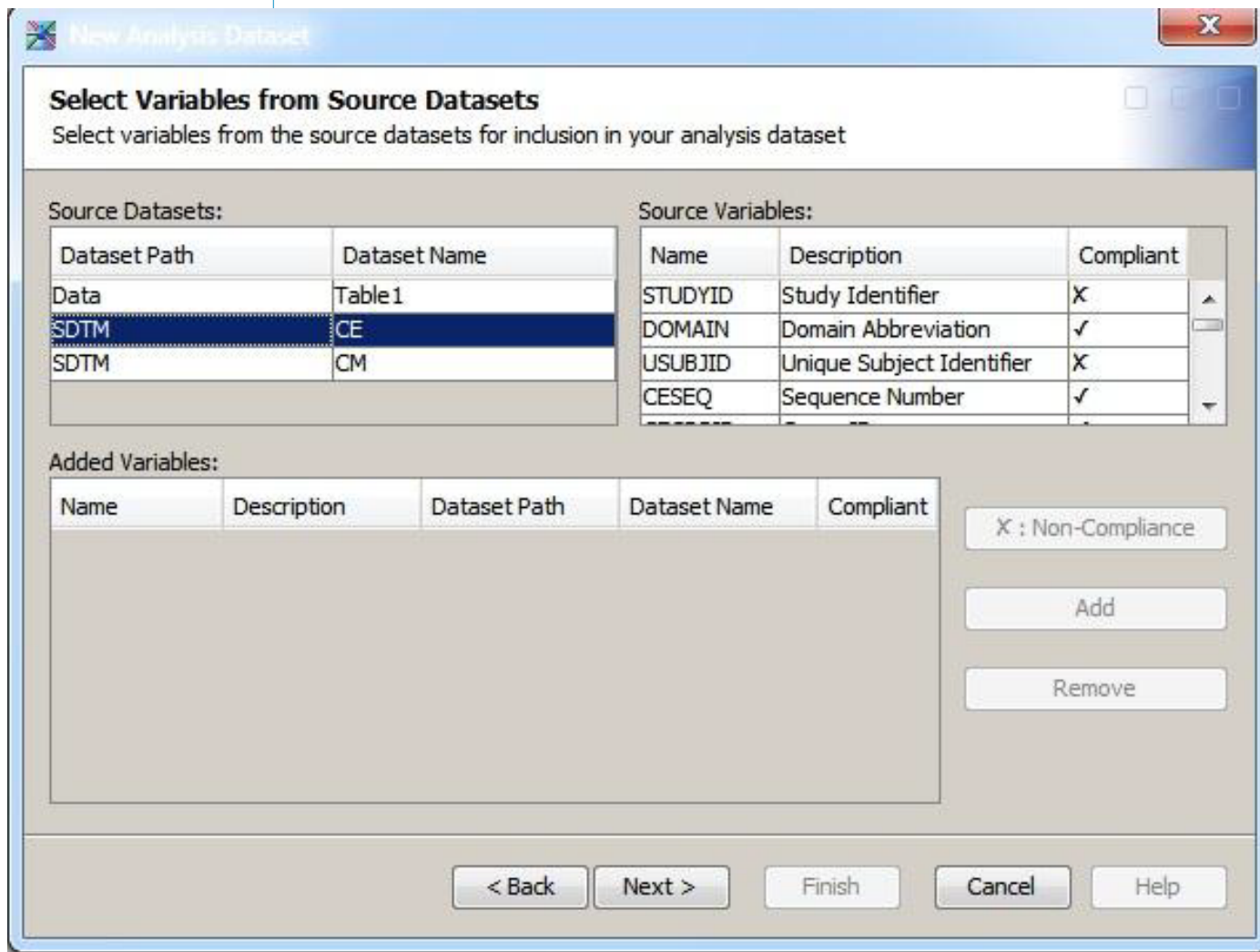
Name:
ADaM Basic Data Structure

Identifier:
AD

< Back Next > Finish Cancel Help

SELECT DATASETS



The image shows a SAS 'New Analysis Dataset' dialog box. The title bar is blue with a close button (X) on the right. The main area has a white background with the title 'Select Variables from Source Datasets' and a subtitle 'Select variables from the source datasets for inclusion in your analysis dataset'. There are three main sections: 'Source Datasets', 'Source Variables', and 'Added Variables'. The 'Source Datasets' table has two columns: 'Dataset Path' and 'Dataset Name'. The 'Source Variables' table has three columns: 'Name', 'Description', and 'Compliant'. The 'Added Variables' table has five columns: 'Name', 'Description', 'Dataset Path', 'Dataset Name', and 'Compliant'. On the right side of the 'Added Variables' table, there are three buttons: 'X : Non-Compliance', 'Add', and 'Remove'. At the bottom of the dialog, there are five buttons: '< Back', 'Next >', 'Finish', 'Cancel', and 'Help'.

Select Variables from Source Datasets

Select variables from the source datasets for inclusion in your analysis dataset

Source Datasets:

Dataset Path	Dataset Name
Data	Table 1
SDTM	CE
SDTM	CM

Source Variables:

Name	Description	Compliant
STUDYID	Study Identifier	X
DOMAIN	Domain Abbreviation	✓
USUBJID	Unique Subject Identifier	X
CESEQ	Sequence Number	✓

Added Variables:

Name	Description	Dataset Path	Dataset Name	Compliant
------	-------------	--------------	--------------	-----------

X : Non-Compliance

Add

Remove

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DESIGNING ADAM DATASETS

BDS HAS MANY DIFFERENT CATEGORIES OF VARIABLES

New Analysis Dataset

Select analysis variables
Select analysis variables to add to the new ADaM dataset

Available Variables:

- + Analysis Descriptor Variables
- + Flag Variables
- + Lab-related Analysis Variables
- + Analysis Parameter Variables
- + Subject Identifier Variables
- + Time To Event Variables
- + Timing Variables
- + Data Point Traceability Variables
- + Treatment Variables
- + Analysis Visit Windowing Parameters

Selected Variables:

- Analysis Descriptor Variables
- Flag Variables
- Lab-related Analysis Variables
- + Analysis Parameter Variables
- + Subject Identifier Variables
- Time To Event Variables
- Timing Variables
- Data Point Traceability Variables
- + Treatment Variables
- Analysis Visit Windowing Parameters

[] = required (cannot be removed)

Check Compliance

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

MANY VARIABLES WITHIN A CATEGORY

New Analysis Dataset

Select analysis variables
Select analysis variables to add to the new ADaM dataset

Available Variables:

- + Analysis Descriptor Variables
- + Flag Variables
- + Lab-related Analysis Variables
- Analysis Parameter Variables
 - PARAMN
 - PARAMTYP
 - PARCATy
 - PARCATyN
 - AVAL
 - AVALC
 - AVALCATy
 - BASE
 - BASFC

Selected Variables:

- Analysis Descriptor Variables
- Flag Variables
- Lab-related Analysis Variables
- + Analysis Parameter Variables
- + Subject Identifier Variables
- Time To Event Variables
- Timing Variables
- Data Point Traceability Variables
- + Treatment Variables
- Analysis Visit Windowing Parameters

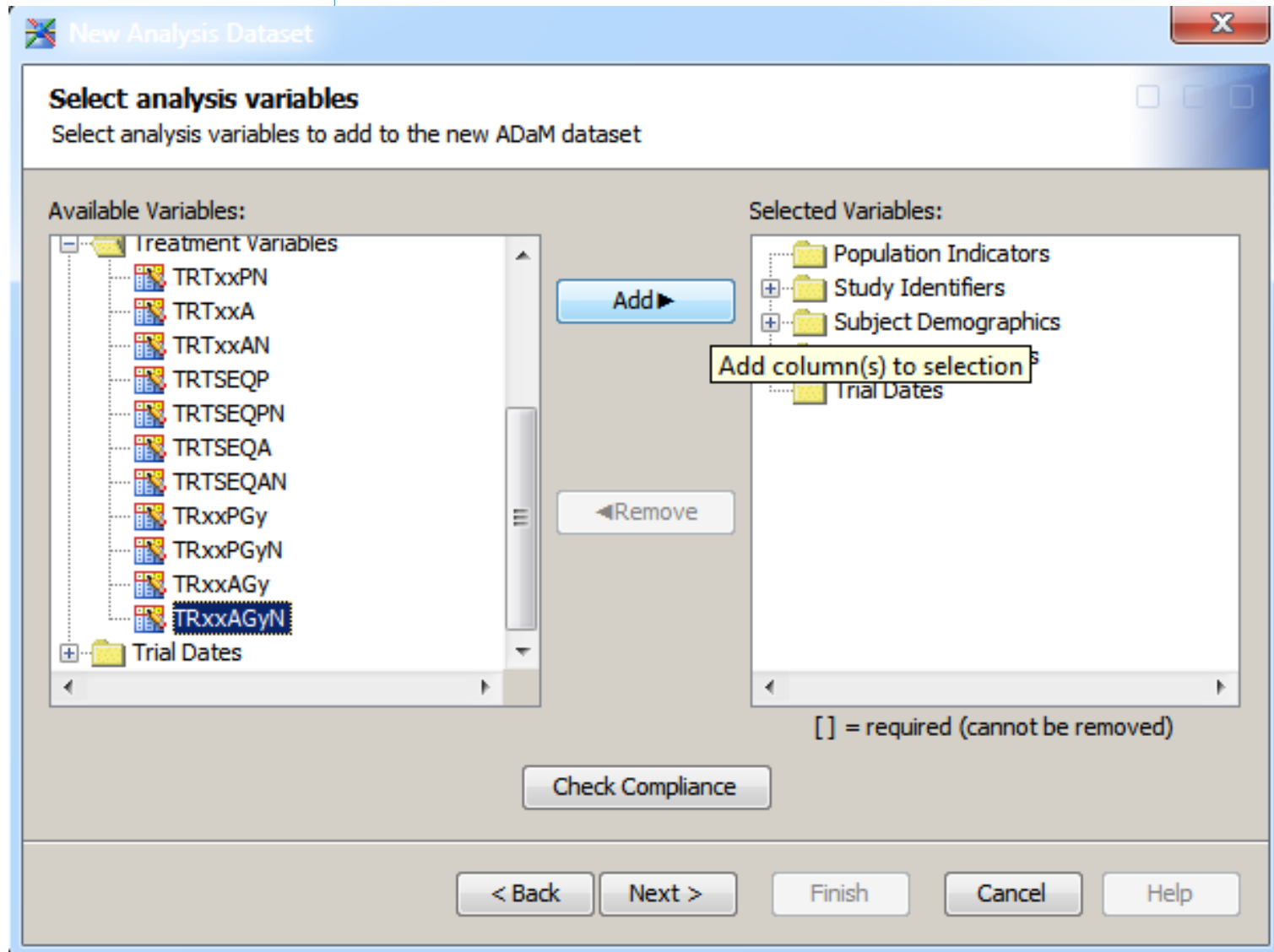
[] = required (cannot be removed)

Check Compliance

< Back Next > Finish Cancel Help

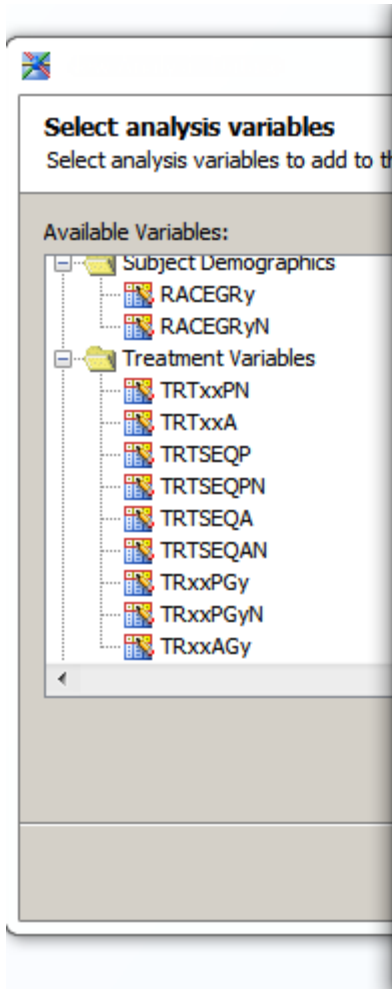
DESIGNING ADAM DATASETS

EASE OF SELECTING VARIABLES



DESIGNING ADAM DATASETS

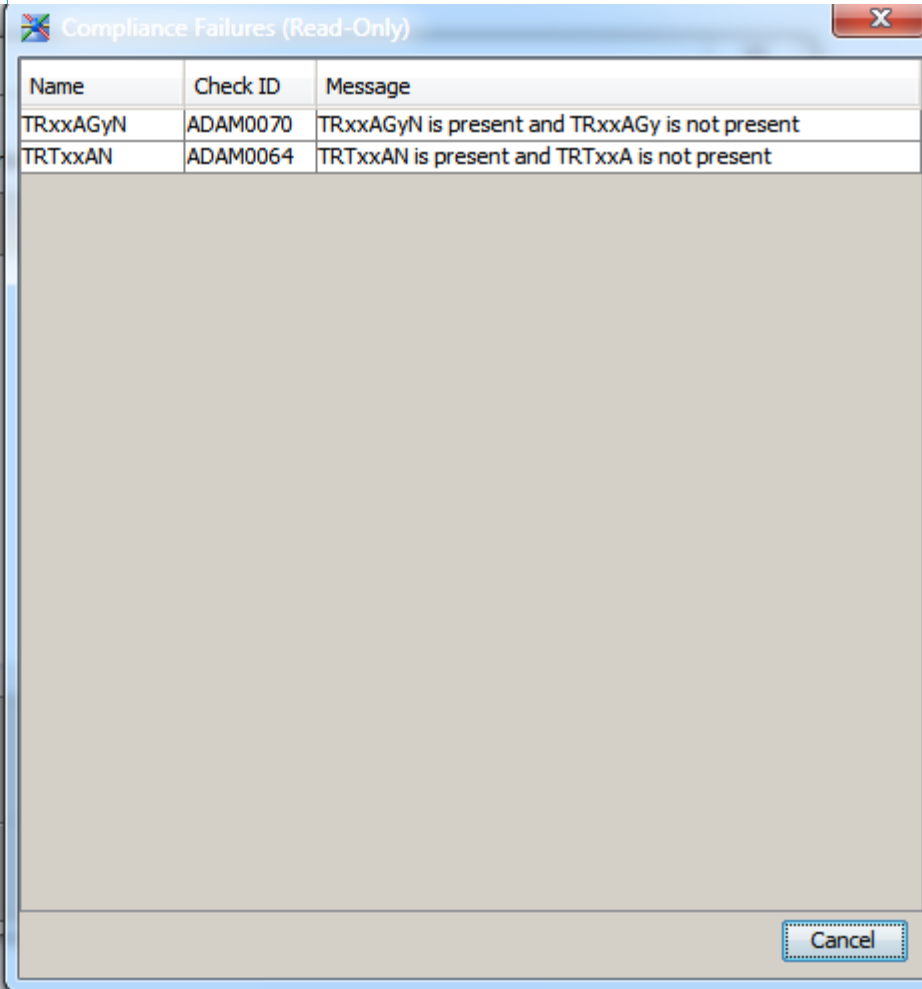
AUTOMATED COMPLIANCE CHECKING



Select analysis variables
Select analysis variables to add to the dataset

Available Variables:

- Subject Demographics
 - RACEGRy
 - RACEGRyN
- Treatment Variables
 - TRTxxPN
 - TRTxxA
 - TRTSEQP
 - TRTSEQPN
 - TRTSEQA
 - TRTSEQAN
 - TRxxPGy
 - TRxxPGyN
 - TRxxAGy



Compliance Failures (Read-Only)

Name	Check ID	Message
TRxxAGyN	ADAM0070	TRxxAGyN is present and TRxxAGy is not present
TRTxxAN	ADAM0064	TRTxxAN is present and TRTxxA is not present

Cancel

DESIGNING ADAM DATASETS

SELECT VALUES TO ASSIGN TO X VARIABLE PARAMETERS

New Analysis Dataset

Specify the Period Variables
Set the period(xx) values for the variables

Period(xx) Variables:

Name	Description	Values
TRTxxP	Planned Treatment for Period xx	
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	
TRTxxAN	Actual Treatment for Period xx (N)	
TRTxxA	Actual Treatment for Period xx	
TRxxAGy	Actual Pooled Treatment y for Period xx	
TRxxPGy	Planned Pooled Treatment y for Period xx	
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	
TRxxSDT	Date of First Exposure in Period xx	
TRxxEDT	Date of Last Exposure in Period xx	

Maximum value:

Values:

- 01
- 02
- 03
- 04
- 05
- 06
- 07
- 08
- 09
- 10
- 11
- 12
- 13
- 14

Assign

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

VALUES ARE ASSIGNED TO X PARAMETERS

New Analysis Dataset

Specify the Period Variables
Set the period(xx) values for the variables

Period(xx) Variables:

Name	Description	Values
TRTxxP	Planned Treatment for Period xx	01, 03, 05
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	01, 03, 05
TRTxxAN	Actual Treatment for Period xx (N)	01, 03, 05
TRTxxA	Actual Treatment for Period xx	01, 03, 05
TRxxAGy	Actual Pooled Treatment y for Period xx	01, 03, 05
TRxxPGy	Planned Pooled Treatment y for Period xx	01, 03, 05
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	01, 03, 05
TRxxSDT	Date of First Exposure in Period xx	01, 03, 05
TRxxEDT	Date of Last Exposure in Period xx	01, 03, 05

Maximum value:

Values:

- 01
- 02
- 03
- 04
- 05
- 06
- 07
- 08
- 09
- 10
- 11
- 12
- 13
- 14

Assign

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

SELECT VALUES TO ASSIGN TO Y VARIABLE PARAMETERS

New Analysis Dataset

Specify the Grouping Variables
Set the grouping(y) values for the variables

Grouping(y) Variables:

Name	Description	Values
SITEGRy	Pooled Site Group y	
RACEGRy	Pooled Race Group y	
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	
TRxxAGy	Actual Pooled Treatment y for Period xx	
TRxxPGy	Planned Pooled Treatment y for Period xx	
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	

Values:

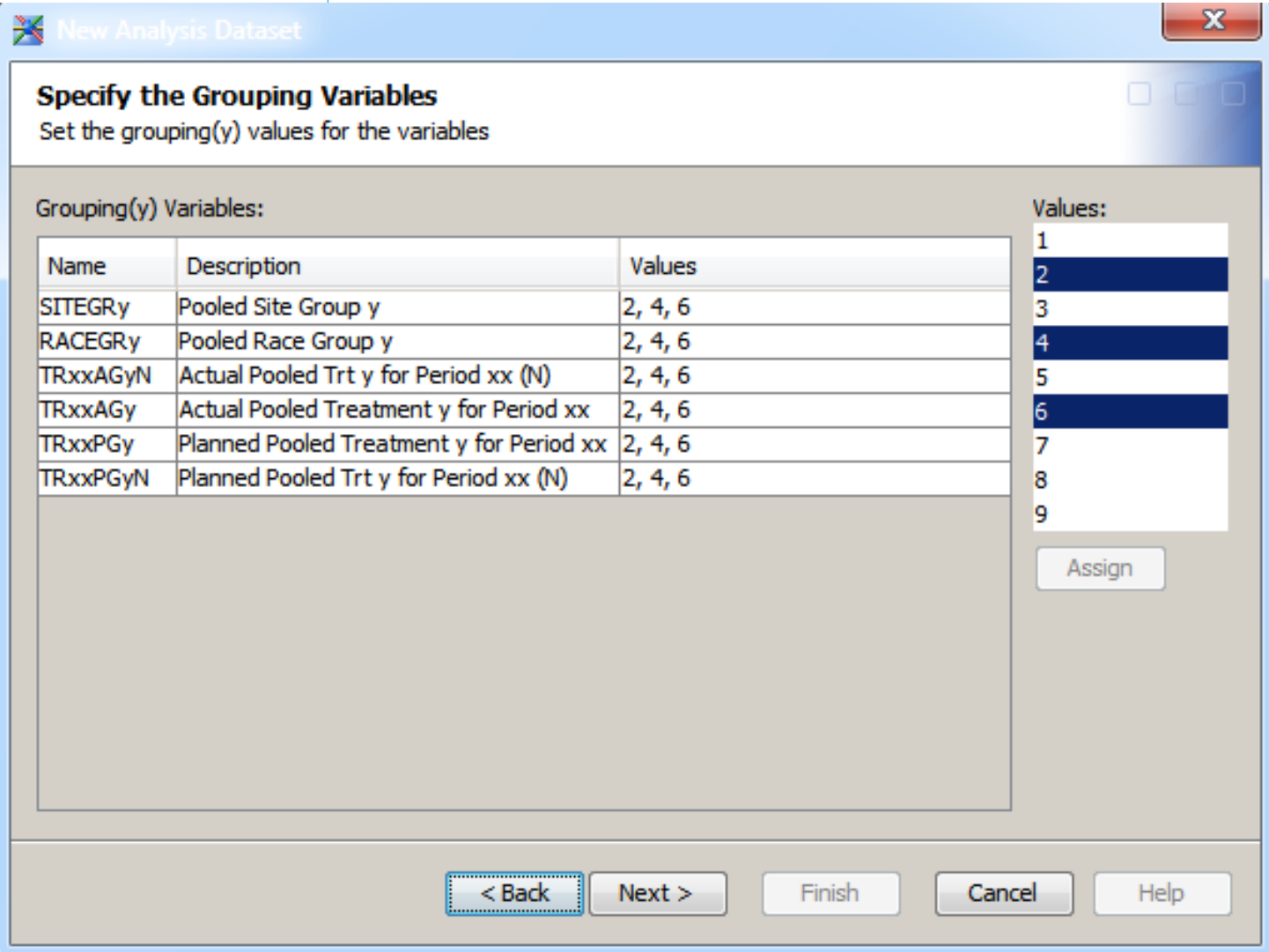
1
2
3
4
5
6
7
8
9

Assign

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

VALUES ARE ASSIGNED TO Y PARAMETERS



The image shows a SAS dialog box titled "New Analysis Dataset". Inside, there is a section titled "Specify the Grouping Variables" with the instruction "Set the grouping(y) values for the variables". Below this is a table with three columns: "Name", "Description", and "Values". The table lists six variables: SITEGRy, RACEGRy, TRxxAGyN, TRxxAGy, TRxxPGy, and TRxxPGyN, all with descriptions related to pooled site, race, and treatment groups, and all with values 2, 4, and 6. To the right of the table is a list of values from 1 to 9, with values 2, 4, and 6 highlighted in dark blue. Below the list is an "Assign" button. At the bottom of the dialog are five buttons: "< Back", "Next >", "Finish", "Cancel", and "Help".

Specify the Grouping Variables
Set the grouping(y) values for the variables

Grouping(y) Variables:

Name	Description	Values
SITEGRy	Pooled Site Group y	2, 4, 6
RACEGRy	Pooled Race Group y	2, 4, 6
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	2, 4, 6
TRxxAGy	Actual Pooled Treatment y for Period xx	2, 4, 6
TRxxPGy	Planned Pooled Treatment y for Period xx	2, 4, 6
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	2, 4, 6

Values:

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9

Assign

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

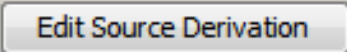
AUTOMATED GENERATION OF VARIABLES WITH X AND Y

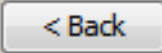
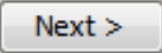
 New Analysis Dataset ✕

Complete Set of Variables □ □ □
View the complete set of variables

Name	Description	Source...	Source D...	Sourc...	Sourc...
AKM	Description of Planned Arm				
TRT01P	Planned Treatment for Period 01				
TRT03P	Planned Treatment for Period 03				
TRT05P	Planned Treatment for Period 05				
TR01AG2N	Actual Pooled Trt 2 for Period 01 (N)				
TR01AG4N	Actual Pooled Trt 4 for Period 01 (N)				
TR01AG6N	Actual Pooled Trt 6 for Period 01 (N)				
TR03AG2N	Actual Pooled Trt 2 for Period 03 (N)				
TR03AG4N	Actual Pooled Trt 4 for Period 03 (N)				
TR03AG6N	Actual Pooled Trt 6 for Period 03 (N)				
TR05AG2N	Actual Pooled Trt 2 for Period 05 (N)				
TR05AG4N	Actual Pooled Trt 4 for Period 05 (N)				
TR05AG6N	Actual Pooled Trt 6 for Period 05 (N)				
TRT01AN	Actual Treatment for Period 01 (N)				



ORDER THE VARIABLES

New Analysis Dataset

Order the variables
Arrange the order of the variables in the dataset

Selected Variables:

Name	Description	Key	Type	Length	Nullable	Values
ANLzzFL	Analysis Record Flag zz	☐	CHARACTER	1	☒	zz(01,02,03)
ANLzzFN	Analyzed Record Flag zz (N)	☐	NUMERIC	8	☒	zz(01,02,03)
CRITyFL	Criterion y Evaluation Result Flag	☐	CHARACTER	1	☒	y(3)
AyLO	Analysis Range y Lower Limit	☐	CHARACTER	40	☒	y(3)
AyHI	Analysis Range y Upper Limit	☐	CHARACTER	40	☒	y(3)
PARAM	Parameter	☐	CHARACTER	200	☒	
PARAMCD	Parameter Code	☒	CHARACTER	8	☐	
STUDYID	Study Identifier	☐	CHARACTER	40	☒	
USUBJID	Unique Subject Identifier	☒	CHARACTER	40	☐	
PROCDT	Date of procedure	☐	NUMERIC	8	☒	
RESULTDT	Date of results	☐	NUMERIC	8	☒	
TRTP	Planned Treatment	☐	CHARACTER	40	☒	

Move Up ▲ Move Down ▼ Order Keys...

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ADD TRACEABILITY INFORMATION

 New Analysis Dataset ✕

Complete Set of Variables □ □ □
View the complete set of variables

Name	Description	Source Folder	Source Dataset	Source Variable	Source Derivation
ANL01FL	Analysis Record Flag 01				
ANL02FL	Analysis Record Flag 02				
ANL03FL	Analysis Record Flag 03				
ANL01FN	Analyzed Record Flag 01 (N)				
ANL02FN	Analyzed Record Flag 02 (N)				
ANL03FN	Analyzed Record Flag 03 (N)				
CRIT3FL	Criterion 3 Evaluation Result Flag				
A3LO	Analysis Range 3 Lower Limit				
A3HI	Analysis Range 3 Upper Limit				
PARAM	Parameter				
PARAMCD	Parameter Code				
STUDYID	Study Identifier				
USUBJID	Unique Subject Identifier				
PROCDT	Date of procedure				
RESULTDT	Date of results				
TRTP	Planned Treatment				
CESEQ	Sequence Number	SDTM	CE	CESEQ	
var1	variable 1	Data	Table1	var1	

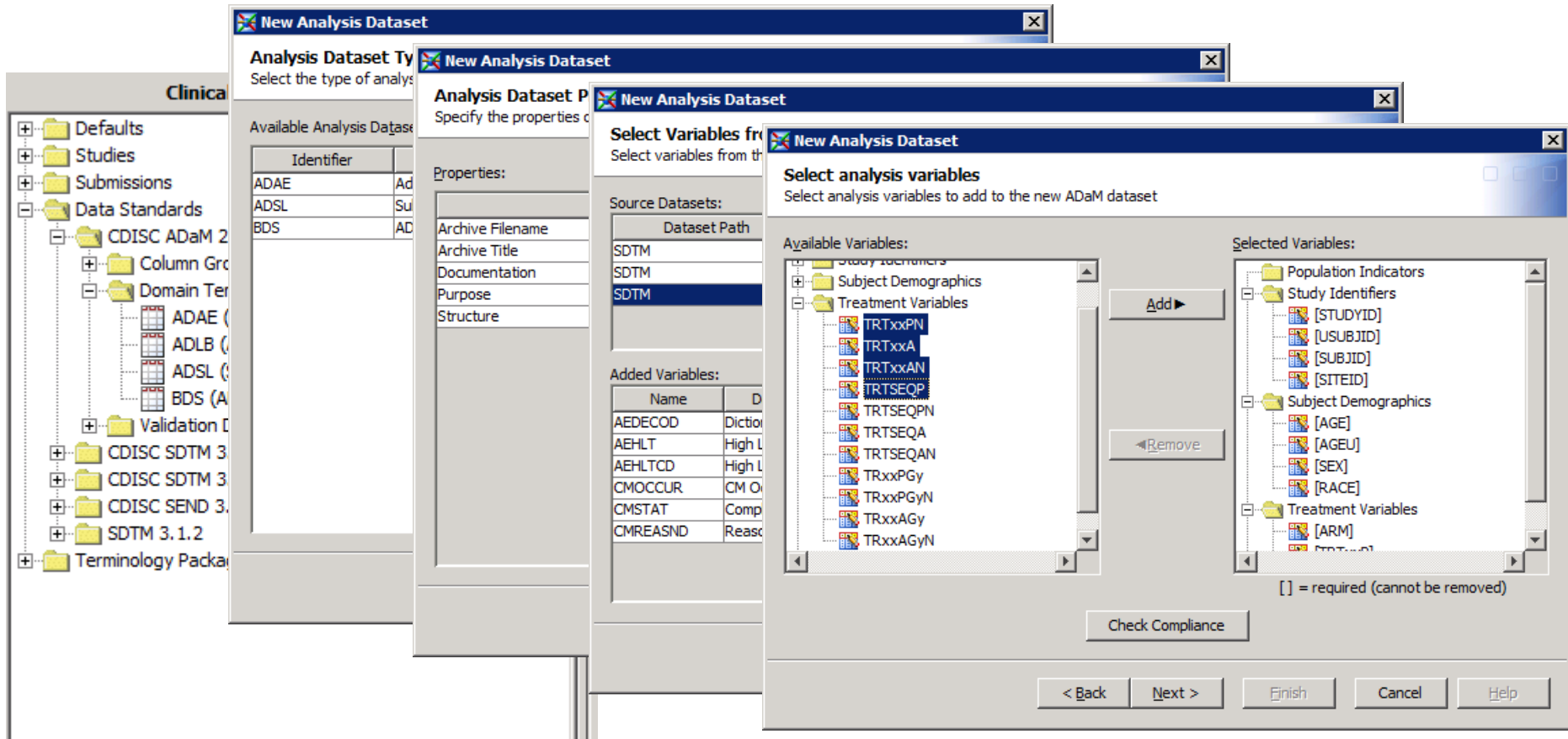
Edit Source Derivation

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- Determine study and location to place the ADaM dataset
- Select the dataset type (ADAE, ADSL, BDS)
- Provide a name, identifier and properties
- Select a library in which to place the dataset
- Optionally select source datasets and variables
- Select analysis variables
- Associate values with xx, y, zz parameters found in variable names
- Assign text within variables with wildcard characters
- Order the variables within the dataset
- Provide traceability information for variables
 - Those variables pulled from source datasets have this automatically populated

ADAM SUPPORT

CDI 2.4



BULK METADATA MANIPULATION

CDI 2.4

Clinical Table Properties

Clinical Table Selection
Select the clinical tables whose properties you wish to modify.

Name	Path	Clinical Standard	Description
ADAE	ADAM/ADAE	CDISC ADaM 2.1	Analysis Dataset - Adverse Even
ADLB	ADAM/ADLB	CDISC ADaM 2.1	Analysis Dataset for Lab results
ADSL	ADAM/ADSL	CDISC ADaM 2.1	ADaM Subject-Level Dataset
AE	SDTM/AE	CDISC SDTM 3....	Adverse Events
DM	SDTM/DM	CDISC SDTM 3....	Demographics
DS	SDTM/DS	CDISC SDTM 3....	Disposition
EX	SDTM/EX	CDISC SDTM 3....	Exposure
TA	SDTM/TA	CDISC SDTM 3....	Trial Arms
TE	SDTM/TE	CDISC SDTM 3....	Trial Elements
TI	SDTM/TI	CDISC SDTM 3....	Trial Inclusion/Exclusion Criteria
TS	SDTM/TS	CDISC SDTM 3....	Trial Summary
TV	SDTM/TV	CDISC SDTM 3....	Trial Visits
VS	SDTM/VS	CDISC SDTM 3....	Vital Signs

Select All Deselect All

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Clinical Column Properties

Property Value Updates
Update property values for selected table columns.

Property:

Role

Contributes to Key

Core

Display Format

Method

Origin

Qualifiers

Role

Term

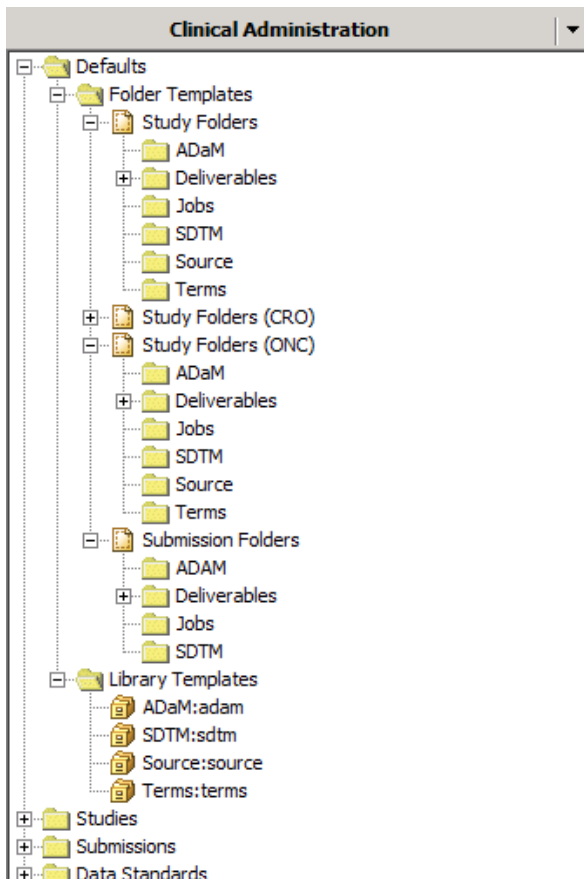
Table	Column	Property Value
AE	AESPID	Identifier
AE	AETERM	Topic
AE	AEMODIFY	SynonymQualifier
AE	AELLT	VariableQualifier
AE	AELLTCD	VariableQualifier
AE	AEDECOD	SynonymQualifier

Update...

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STUDY/SUBMISSION FOLDER TEMPLATES

CDI 2.4



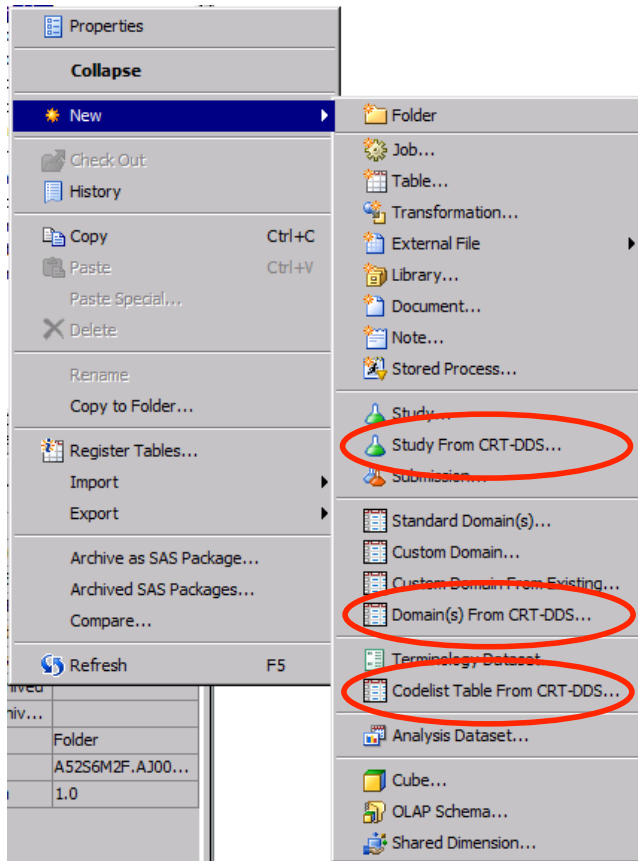
The screenshot shows the 'New Study' dialog box with the 'General Information' tab selected. The dialog has a title bar with a close button. The main area contains the following fields:

- Name:** A text box containing 'new study'.
- Description:** A large text area.
- Folder template:** A dropdown menu with 'Study Folders' selected. Below the dropdown is a list of available templates: 'Study Folders', 'Submission Folders', 'Study Folders (ONC)', and 'Study Folders (CRO)'. 'Study Folders (ONC)' is currently selected.

At the bottom of the dialog are five buttons: '< Back', 'Next >', 'Finish', 'Cancel', and 'Help'.

CLINICAL DATA INTEGRATION

IMPORT DEFINE.XML ATTRIBUTES



- Define.xml closest thing to import/export standard
- Extract study name, phase, and other attributes
- Define SDTM, ADaM or other data structures, including clinical metadata
- Turn controlled terminology into SAS data set

**CLINICAL DATA INTEGRATION 2.5
INCLUDES A WIZARD THAT ALLOWS YOU
TO EASILY DEFINE YOUR ADAM DATASETS**



**THE
POWER
TO KNOW®**