



# **DESIGNING ADAM DATASETS: KISS THE COMPLEXITY GOODBYE**

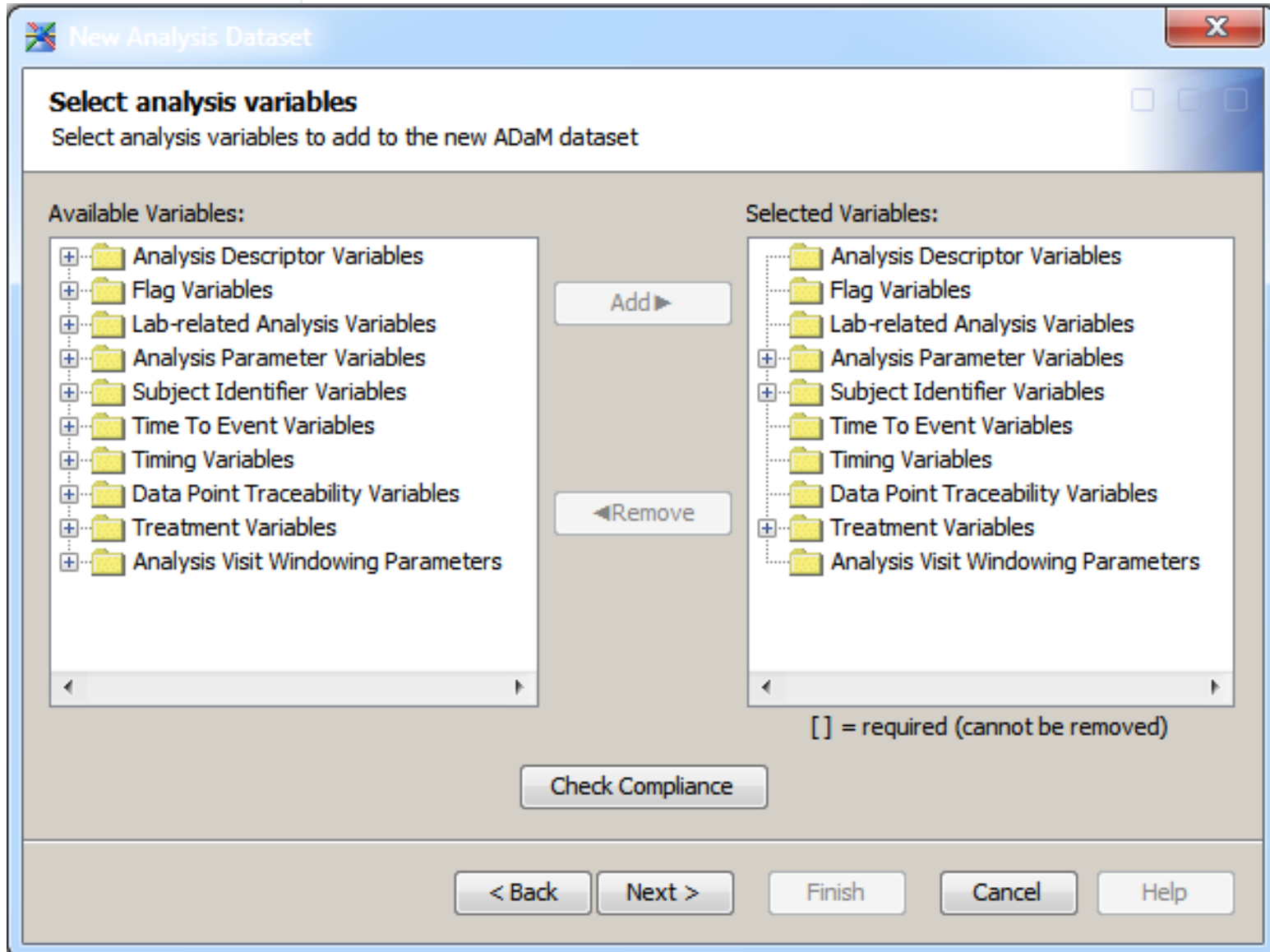
**BILL GIBSON AND DAVID JORDAN, SAS INSTITUTE**



- 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
  - Provides an ADAM Dataset Definition Wizard
  - Leverages metadata about the ADaM standard to ease the definition process

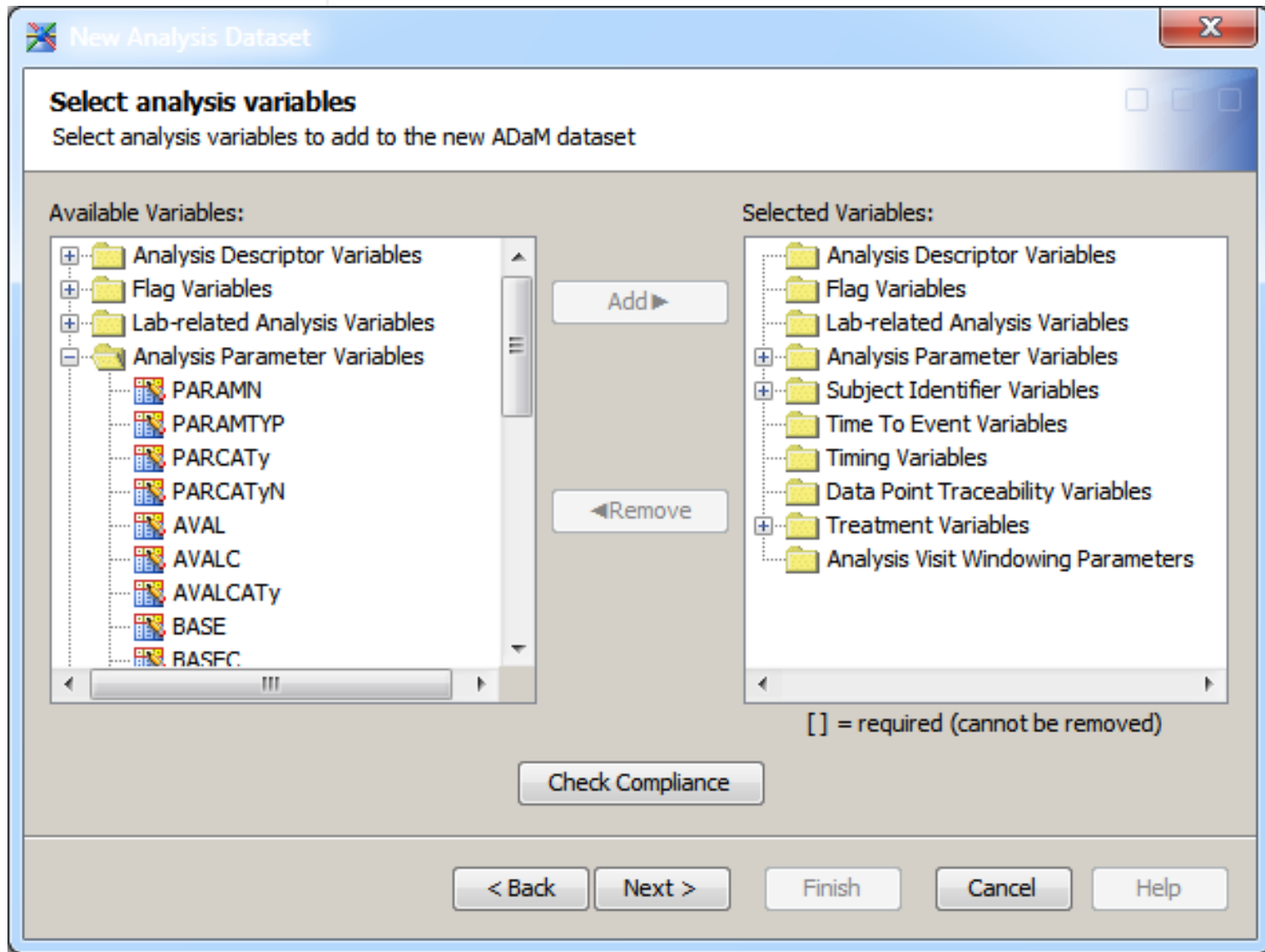
# DESIGNING ADAM DATASETS

## BDS HAS MANY DIFFERENT CATEGORIES OF VARIABLES



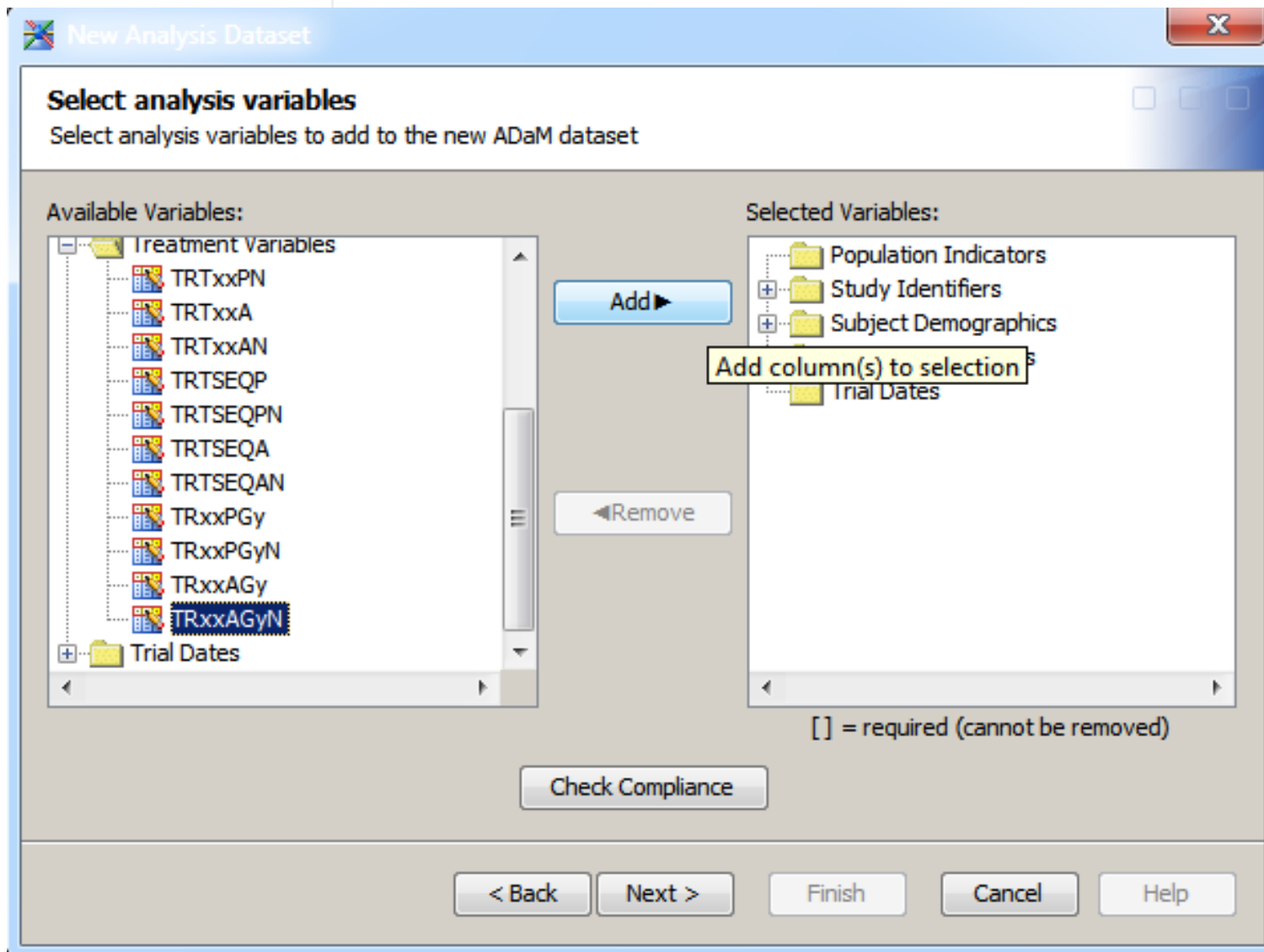
# DESIGNING ADAM DATASETS

## MANY VARIABLES WITHIN A CATEGORY



# DESIGNING ADAM DATASETS

## EASE OF SELECTING VARIABLES



# DESIGNING ADAM DATASETS

## AUTOMATED COMPLIANCE CHECKING

The image shows two overlapping windows from a SAS application. The background window is titled 'Select analysis variables' and contains a tree view of 'Available Variables'. The foreground window is titled 'Compliance Failures (Read-Only)' and displays a table of compliance checks.

**Select analysis variables**  
Select analysis variables to add to the

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

**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

**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

**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

**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				
<b>TR01AG2N</b>	<b>Actual Pooled Trt 2 for Period 01 (N)</b>				
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)				

**Edit Source Derivation**

< Back   Next >   Finish   Cancel   Help

- 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

**CLINICAL DATA INTEGRATION 2.4  
INCLUDES A WIZARD THAT ALLOWS YOU  
TO EASILY DEFINE YOUR ADAM DATASETS**



**THE  
POWER  
TO KNOW.**