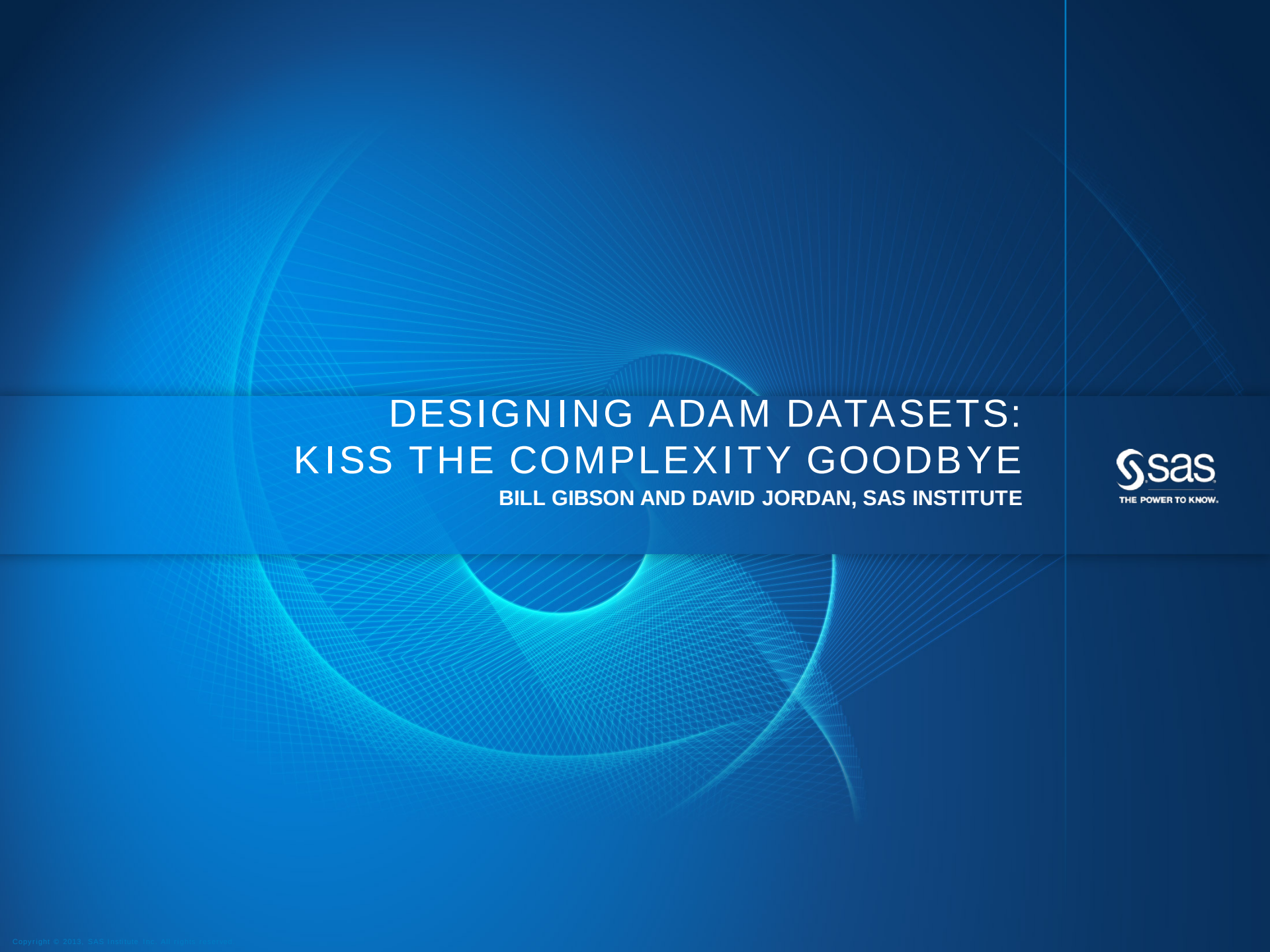




DESIGNING ADAM DATASETS: KISS THE COMPLEXITY GOODBYE

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- 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

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

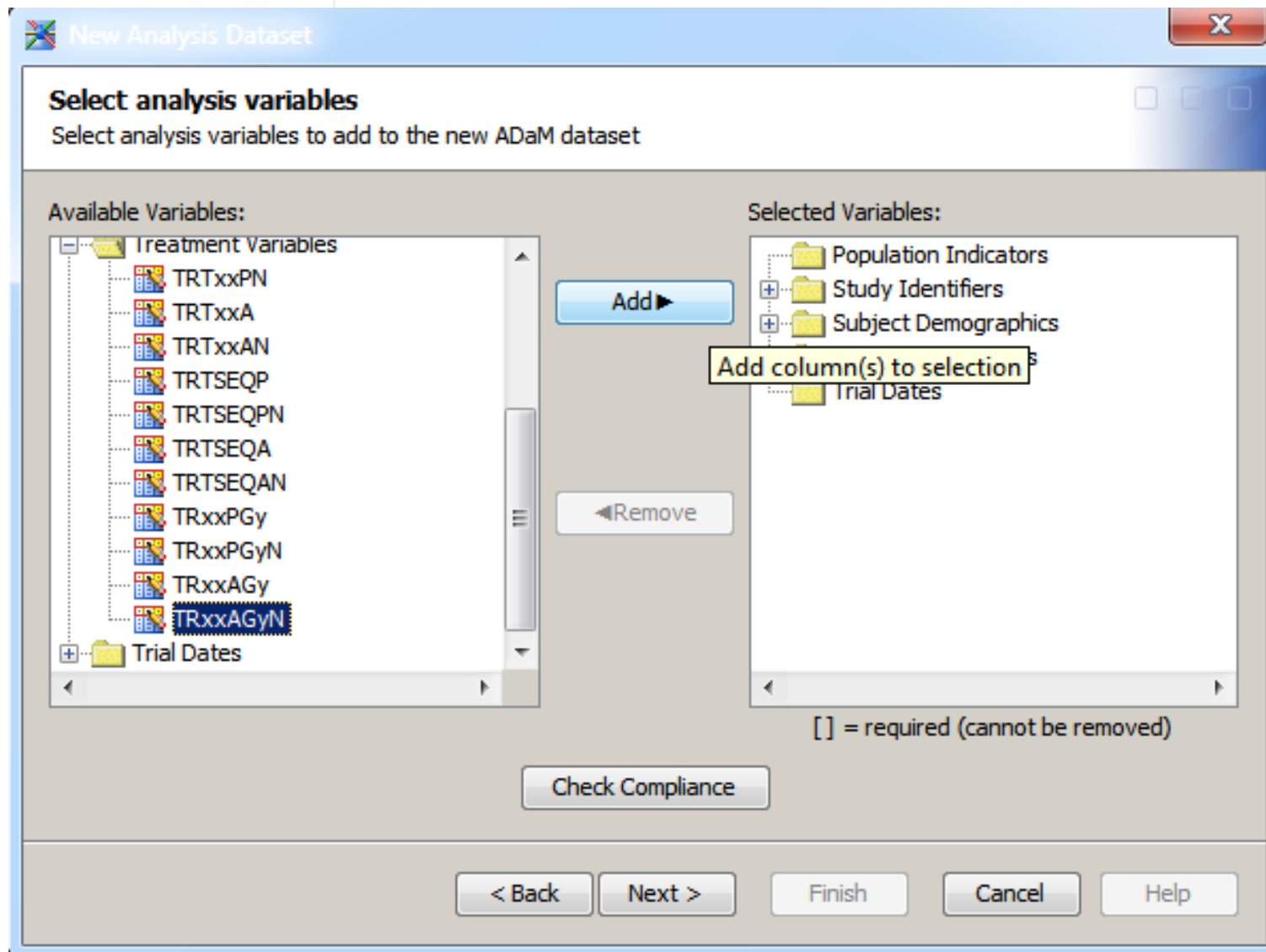
[] = required (cannot be removed)

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

 New Analysis Dataset X

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

DESIGNING ADAM DATASETS

VALUES ARE ASSIGNED TO X PARAMETERS

 New Analysis Dataset X

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:

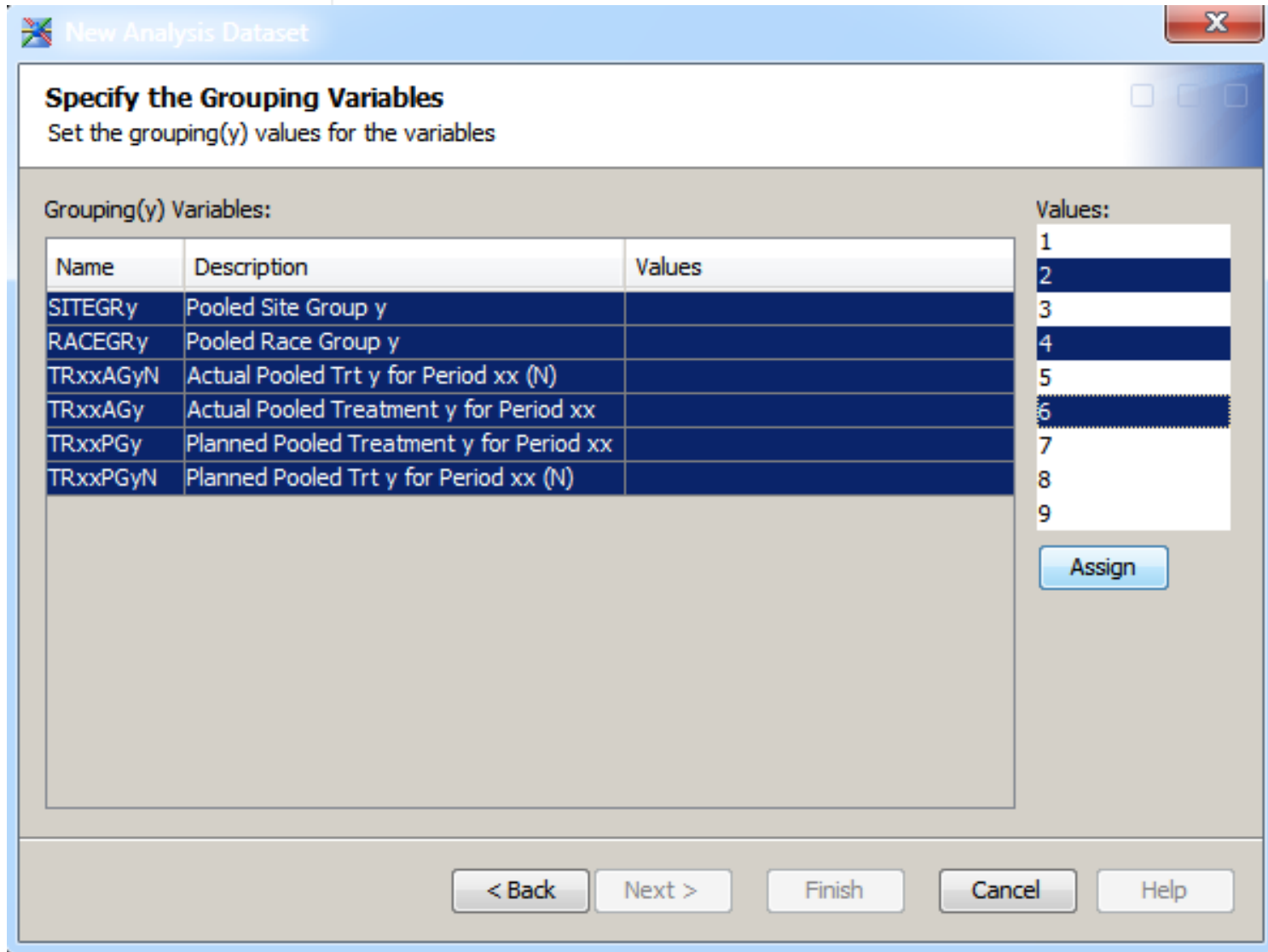
- 01
- 02
- 03
- 04
- 05
- 06
- 07
- 08
- 09
- 10
- 11
- 12
- 13
- 14

Assign

< Back Next > Finish Cancel Help

DESIGNING ADAM DATASETS

SELECT VALUES TO ASSIGN TO Y VARIABLE PARAMETERS



The image shows a SAS software window 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. To the right of the table is a list of values from 1 to 9. Value 6 is currently selected. An "Assign" button is located below the values list. At the bottom of the dialog are navigation 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	
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

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	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

 New Analysis Dataset X

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)				

[Edit Source Derivation](#)

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[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[®]