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# SAS®
# Clinical Data Integration 2.5

User's Guide

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# What's New

## What's New in SAS Clinical Data Integration 2.5

## Overview

SAS Clinical Data Integration 2.5 contains these enhancements:

- SDTM 3.2 support

- Define-XML 2.0 support

- SAS Version 5 transport file handling

- Creation of metadata from a define.xml file

- Incremental update of data standard metadata from the SAS Clinical Standards Toolkit

- Comment metadata support

- Controlled terminology handling

- Data standard management

## SDTM 3.2 Support

There is full support for the CDISC SDTM 3.2 data standard.

## Define-XML 2.0 Support

You can create and validate CDISC Define-XML 2.0 files using SAS Clinical Data Integration transformations.

## SAS Version 5 Transport File Handling

You can use SAS Clinical Data Integration transformations to read and write SAS Version 5 transport files.

## Creation of Metadata from a Define.xml File

You can import study and table definitions from a define.xml file, including definitions for SDTM and ADaM.

# Incremental Update of Data Standard Metadata from the SAS Clinical Standards Toolkit

You can update SAS Clinical Data Integration data standard metadata incrementally at any time with the current definitions from the SAS Clinical Standards Toolkit. You can select any subset of domain templates and column groups to update. You can update validation checks with those currently registered to the SAS Clinical Standards Toolkit.

# Comment Metadata Support

SAS Clinical Data Integration reads and stores the SAS Clinical Standard Toolkit's default comment definitions for tables and columns defined in a data standard. These comments are written to the output file during define.xml file creation.

# Controlled Terminology Handling

SAS Clinical Data Integration supports additional controlled terminology information in imported terminology tables. SAS Clinical Data Integration transformation support for controlled terminologies defined outside of the SAS Clinical Standards Toolkit has been enhanced.

# Data Standard Management

Data standard administrators have additional flexibility in managing custom data standard definitions for their organizations. SDTM domains, SEND domains, and ADaM

data sets in a study can be reassociated with different SAS Clinical Data Integration data standard definitions. Custom domains and data sets can be promoted from a study to replace existing definitions within a data standard.

# Part 1

# Introduction

1

# Overview: SAS Clinical Data Integration

## What Is SAS Clinical Data Integration?

SAS Clinical Data Integration supports the pharmaceutical-industry needs for transforming, managing, and verifying the creation of industry-mandated data standards such as those created by Clinical Data Interchange Standards Consortium (CDISC). SAS Clinical Data Integration relies on SAS Data Integration Studio to provide centralized metadata management using the SAS Metadata Server and the tools that it provides to visually transform data. SAS Clinical Data Integration enhances its usability by adding new metadata types, plug-ins, and wizards. These enhancements help you perform clinically oriented tasks such as importing data standards, creating studies and submissions, and adding specialized transformations for mapping clinical data into a standard data model. SAS Clinical Data Integration leverages the SAS Clinical Standards Toolkit to provide validation and conformance checking.

SAS Clinical Data Integration enables you to accomplish these goals:

■ improve the consistency of submissions and studies

■ improve the long-term management and growth of data

■ use data standards effectively

■ use a centralized SAS Metadata Server

■ use the powerful and user-friendly features of SAS Data Integration Studio to manage metadata, generate and execute SAS Clinical Standards Toolkit code, and visualize the results

# Typical Workflow in SAS Clinical Data Integration

## Overview: Typical Workflow

The features and functionality provided by SAS Clinical Data Integration enables the following workflow:

1 Import a data standard and controlled terminology. (For more information, see "Importing Data Standards Metadata" on page 11 and "Importing Terminology Data Sets" on page 24.

2 Create studies and submissions. (For more information, see "Creating a Study or Submission" on page 64.)

3 Create domains. (For more information, see "Creating a Domain" on page 88.)

4 Standardize and validate data. (For more information, see "Assess CDISC SDTM Compliance" on page 108 and "Assess ADaM Compliance" on page 132.)

5 Analyze data standard use across studies and submissions. (For more information, see "Analyzing Domain Use and Promoting a Domain to Be a Template" on page 42.)

## Workflow Owners

Typically, different people own different tasks in the workflow. However, ownership can vary depending on the company, and a person might perform tasks in more than one role. The following user definitions explain the typical owners and their tasks in the workflow.

Clinical administrator
> defines and manages data standards. Analyzes how data standards are implemented by programmers. Data standards administrators can view trends about how a domain is used by programmers. These trends might identify a new column to add to a domain, or point to a custom domain that you should promote into the standards.

> For tasks that are typically performed by clinical administrators, see Chapter 2, "Data Standards Administration," on page 9.

Trial manager
> defines studies and submissions, defines authorization, and sets the defaults that programmers use when defining content. Setting defaults ensures that programmers use the correct version of the data standards.

> For tasks that are typically performed by trial managers, see Chapter 4, "Studies and Submissions Management," on page 53.

Clinical programmer and data manager
> creates standard and custom domains, writes jobs to extract and transform data into domains, and writes jobs to validate compliance of domains to a data standard.

> For tasks that are typically performed by clinical programmers or data managers, see Chapter 5, "SDTM Domains," on page 85.

# Recommended Reading

For the following documentation, see the SAS Customer Support website at `http://support.sas.com`.

- *SAS Data Integration Studio: User's Guide* at `http://support.sas.com/documentation/onlinedoc/etls/`

- *SAS Clinical Standards Toolkit: User's Guide* at `http://support.sas.com/documentation/onlinedoc/clinical/`

- *SAS and the Clinical Data Interchange Standards Consortium (CDISC)* at `http://www.sas.com/industry/life-sciences/cdisc/`

- *SAS Intelligence Platform: System Administration Guide* at `http://support.sas.com/documentation/onlinedoc/intellplatform/`

# Part 2

Information for Clinical Administrators

# 2

# Data Standards Administration

# Overview: Data Standards Administration

SAS Clinical Data Integration enables you to centrally define and manage data standards. You can also analyze how data standards are implemented by programmers. For example, you can view trends about how a domain is used by programmers. These trends might identify a new column to add to a standard domain because programmers are often adding the column during conversion. These trends might point to frequently created custom domains that should be promoted into the standards.

Typical user tasks include:

- "Importing Data Standards Metadata" on page 11

- "Customizing Data Standard Properties" on page 18

- "Managing Controlled Terminology" on page 23

- "Managing Data Standard Compliance Checks" on page 31

- "Analyzing Domain Use and Promoting a Domain to Be a Template" on page 42

# Importing Data Standards Metadata

## Overview: Importing Data Standards Metadata

You define a study relative to a particular data standard, such as CDISC-SDTM or a data standard from your company, by importing the data standard from the SAS Clinical Standards Toolkit.

If you want to use a CDISC standard, import data standard metadata from the SAS Clinical Standards Toolkit. Importing the metadata enables you to update your environment with new releases of data standards from CDISC. CDISC data standards are provided with the SAS Clinical Standards Toolkit. For more information, see the *SAS Clinical Standards Toolkit: User's Guide*.

After importing a data standard that supports domain templates, column groups, and validation data sets, these items are displayed in the **Data Standards** folder in the **Clinical Administration** tree. For example, if you select the CDISC-SDTM data standard type and version 3.1.2, the domain templates (SDTM domains), column groups (SDTM classes), and validation data sets (compliance checks) are displayed in a folder that you specify in the Import wizard.

By default, an imported data standard has a status of Inactive. This status enables you or a data standards administrator to review the template and make changes before releasing it for general use. When you or the data standards administrator is satisfied with the template, you can change its status to Active, which makes the template available for general use. For more information, see "Make a Data Standard Available for General Use" on page 14.

**Note:** You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

## Import Data Standards Metadata

To import data standards metadata, perform the following steps:

1   In the **Clinical Administration** tree, select **Data Standards**, right-click, and then select **Import**.

The Import Wizard appears.
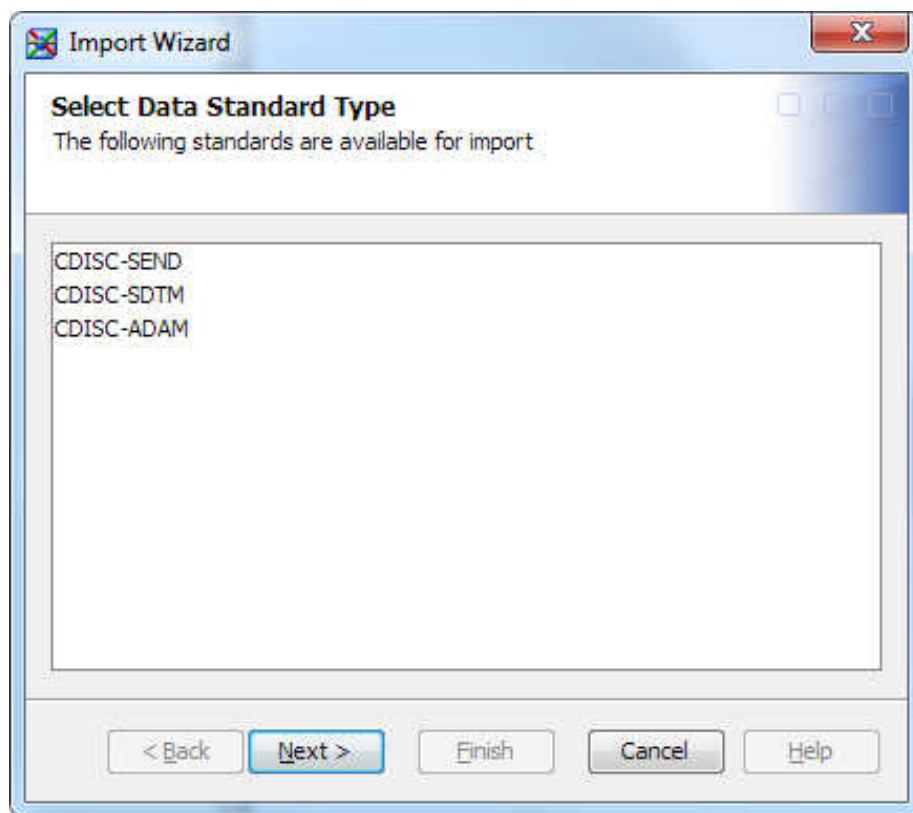


2   If the Default Application Server page appears, select one of the application servers that are listed.

The Default Application Server page appears only when a SAS Foundation application server is accessed for the first time in a SAS Clinical Data Integration session. If you are unsure about which application server to select, contact the SAS installation representative.

3   On the Select Data Standard Type page, select the data standard type, and then click **Next**.

    The Select Data Standard Version page appears.

4   Select the data standard version to use, and then click **Next**.

5   On the Define General Properties page, edit the default values.

    a   Enter a name and an optional description.

        **Note:** It is a best practice not to include spaces in the data standard name.

    b   (Optional) In the **Formal Name** field, enter a more descriptive name for the data standard.

    c   In the **Identifier** field, enter a text value to uniquely identify the data standard in metadata.

        A default value is provided, but it might not be unique. The value that you enter is verified as unique before you continue.

    d   (Optional) Enter the version and vendor.

6   Click **Next**.

    Several Verify Properties pages appear.

    **Note:** The names of the pages depend on the data standard that you selected.

7   (Optional) Edit the property values.

    **Note:** Properties are an advanced feature in SAS Clinical Data Integration. If you are uncertain about what property values to select, accept all of the default values.

8   Click **Next**.

9   (Optional) If the data standard supports validation, on the Validation Library page, perform the following steps:

    a   Select a library or create a library.

For more information about SAS libraries, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

**Note:**

- You must have appropriate permissions for the selected library. For more information about permissions, see *SAS Management Console: Guide to Users and Permissions*.

- The path for the selected library must exist.

- The library metadata object is created immediately. Even if you close the Import Model wizard, the library remains.

**b** Click **Next**.

Several verification pages appear. The names of the pages depend on the data standard that you selected.

**Note:** This information is provided only as a reference. It enables you to review the metadata before storing it. You cannot make changes to this information. If you see problems in the metadata, contact whomever is responsible for registering the data standard in the SAS Clinical Standards Toolkit.

**10** Click **Next**.

**11** Review the summary, and then click **Finish**.

**12** (Optional) Make the data standard available for general use.

For more information, see .
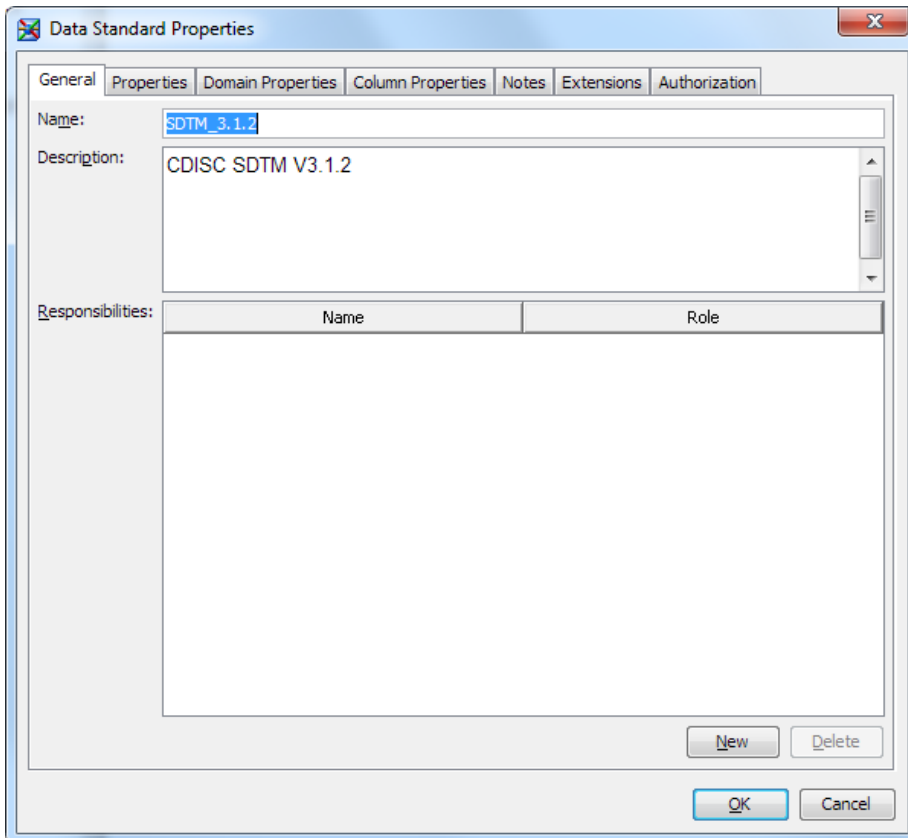
## Make a Data Standard Available for General Use

To make a data standard available for general use, perform the following steps:

**1** In the **Clinical Administration** tree, expand **Data Standards**.
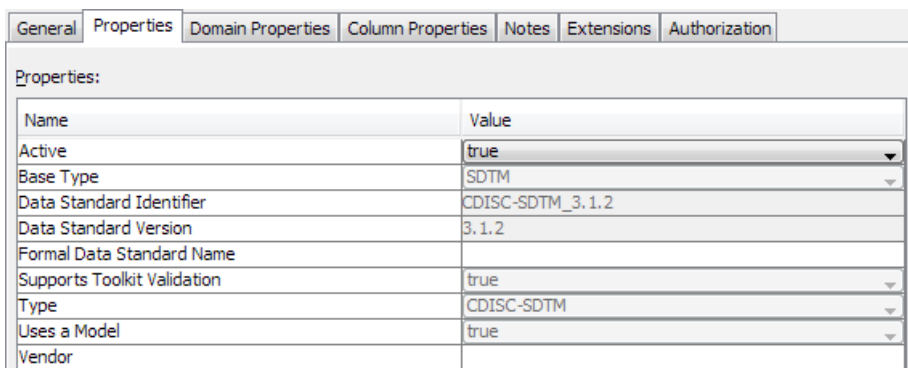
**2** Select the data standard, right-click, and then select **Properties**.

The Data Standard Properties dialog box appears.



**3** Click the **Properties** tab.



**4** In the **Active** row, change **false** to **true**.

5   Click **OK**.

# Refreshing Data Standard Metadata

## Overview: Refreshing Data Standard Metadata

You can refresh the metadata in a data standard. Refreshing the metadata accomplishes the following:

■   rereads the data standard metadata of the data standard that is currently registered in the SAS Clinical Standards Toolkit

■   enables you to update a subset of the data standard in SAS Clinical Data Integration without the need to reimport the full data standard from the SAS Clinical Standards Toolkit

■   minimizes the impact of revisions on users

Here is the metadata that can be refreshed in a data standard:

■   domain templates

    Refresh one or more domain templates of a SAS Clinical Data Integration data standard with domain template definitions from the same data standard that is currently registered in the SAS Clinical Standards Toolkit.

■   column groups

    Refresh the column groups in SAS Clinical Data Integration from the data standard that is currently registered in the SAS Clinical Standards Toolkit.

■   validation checks

    Refresh the validation checks to restore them to the version of the data standard that is currently registered in the SAS Clinical Standards Toolkit.

# Refresh Data Standard Metadata

To refresh data standard metadata, perform the following steps:

1 In the **Clinical Administration** tree, expand **Data Standards**.

2 Select the data standard, right-click, and then select **Refresh Metadata for Standard**.

   The Refresh Metadata for Standard wizard appears.
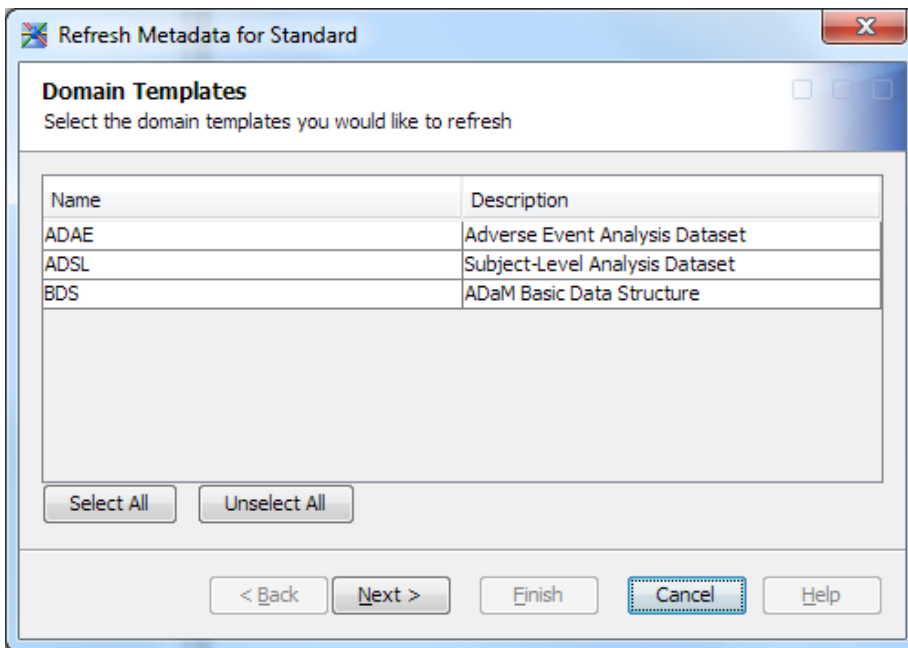


3 (Optional) Select one or more domain templates, and then click **Next**.

   The Column Groups page appears.

4 (Optional) Select one or more column groups, and then click **Next**.

   The Refresh Validation Data page appears.

5 (Optional) Select the **Refresh Validation Data** check box, and then click **Next**.

6 Click **Finish**.

The selected metadata is refreshed.

# Customizing Data Standard Properties

## Overview: Customizing Data Standard Properties

SAS Clinical Data Integration provides a common property model. This model defines the properties for which metadata can be collected. These properties are derived from CDISC data standards, but they are implemented so that you can customize how they are used.

For example, if a data standard does not use a property, then you can disable that property. You can adjust or expand the allowable values for a property. You can add constraints around the content, such as the minimum and maximum values, the length, and the default value.

For CDISC data standards, SAS Clinical Data Integration loads all of the CDISC information for you based on the SAS interpretation of the data standard. However, interpretations can vary, and you have the flexibility to apply your own interpretation.

Property values are inherited by newly created instances of the data standard template.

**Note:** You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

## View and Edit the Property Model of Studies and Submissions

To view and edit the property model of studies and submissions, perform the following steps:

1   In the **Clinical Administration** tree, select **Study** or **Submission**, right-click, and then select **Edit Property Model**.

The Edit Property Model Defaults dialog box appears.



2   Select a property from the **Properties** list.

The associated values are displayed to the right of the list. If **Use Lookups** is selected, values are displayed in the **Lookup Value** list.

3   Specify the label and the minimum and maximum length.

4   (Optional) Enter or select the default value.

5   To specify the values for a property that uses lookup values, select the **Use Lookups** check box. Then, perform any of the following steps:

   ▪   To enable users to enter a value that is not in the list, select the **Lookups are Customizable** check box.

4   (Optional) Select one or more tables, and then click **Next**.

   **Note:**  All tables are selected by default.

   The Property Value Updates page appears.

5   Select a property.

6   Select one or more columns.

7   Click **Update**.

   The Property Value Update dialog box appears.

8   Enter or select a value, and then click **OK**.

9   Click **Finish**.

## Edit Multiple Table Properties in a Data Standard

To edit multiple table properties in a data standard, perform the following steps:

1   In the **Clinical Administration** tree, expand **Data Standards**, and then expand a data standard.

2   Select **Domain Templates**.

3   Right-click, and select **Clinical Table Properties**.
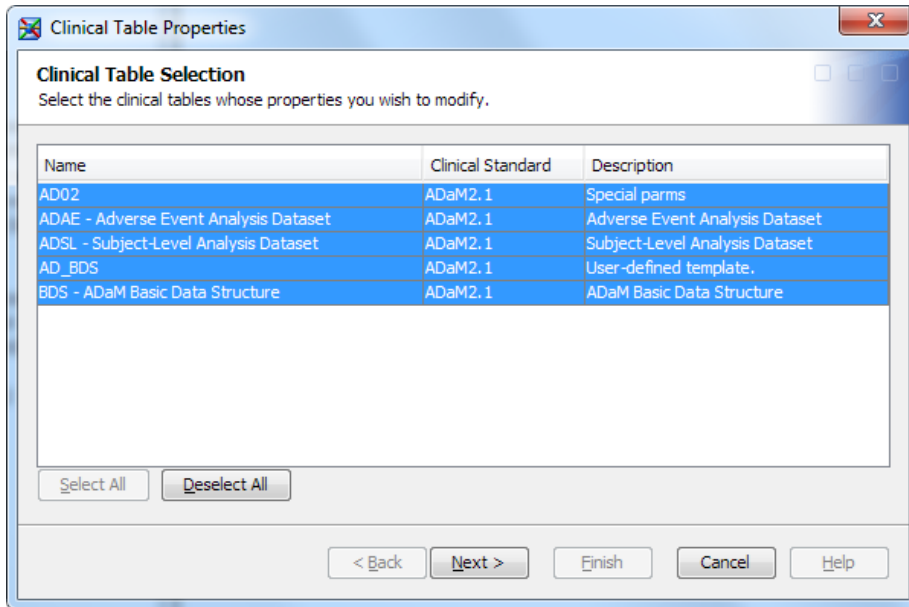
   The Clinical Table Properties wizard appears.

4  (Optional) Select one or more tables, and then click **Next**.

   **Note:**  All tables are selected by default.

   The Property Value Updates page appears.

5  Select a property.

6  Select one or more tables.

7  Click **Update**.

   The Property Value Update dialog box appears.

8  Enter or select a value, and then click **OK**.

9  Click **Finish**.

# Customizing Data Standard Domain Templates

## Overview: Customizing Data Standard Domain Templates

You can make changes to the domain templates for the data standard by customizing domain clinical properties and domain column clinical properties.

To customize domain template metadata, see "Edit Domain Properties" on page 97.

To customize domain template column metadata, see "Edit Domain Column Properties" on page 98.

# Managing Controlled Terminology

## Overview: Managing Controlled Terminology

SAS Clinical Data Integration enables you to manage controlled terminology. *Controlled terminology* is a set of possible values for something. For example, controlled terminology for the valid values of yes and no could be expressed as (1-Yes, 2-No).

A *terminology table* is a SAS data set that contains controlled terminology data. SAS Clinical Standards Toolkit provides CDISC terminology tables.

A *terminology package* is a group of terminology tables. The data standards administrator creates terminology packages. The data standards administrator manages the granularity of the terminology and the groups to which the terminologies are available. For example, the following is the granularity of the terminology and the group to which it is available:

- a study or submission

- the transformations that use the controlled terminology

When a new study or submission is created, the trial manager selects the terminology package to use for the study or submission. This information is used by the CDISC-SDTM Compliance transformation and the CDISC-Define Creation transformation.

If multiple terminology data sets are specified for a study or submission, changing the order of the terminology data sets affects the order in which the terminology tables are applied during a transformation. If a controlled term is defined several times, the first value found is the value used.

## Importing Terminology Data Sets

To manage controlled terminology, you import CDISC terminology data sets from SAS Clinical Standards Toolkit. A wizard imports the controlled terminology and creates the associated terminology data set.

After a terminology data set is imported, you can verify that the import was successful. You can open, delete, or rename the terminology data sets using SAS Data Integration Studio. For more information, see *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

You can create, rename, or change the order in which the terminology tables in the data set are applied during a transformation.

### See Also

## Import a Terminology Data Set

**Note:** You must have the appropriate permissions to import a terminology data set.

To import a terminology data set, perform the following steps:

1   In the **Clinical Administration** tree, select **New ▶ Terminology Data Set**.

    The New Terminology Dataset wizard appears.
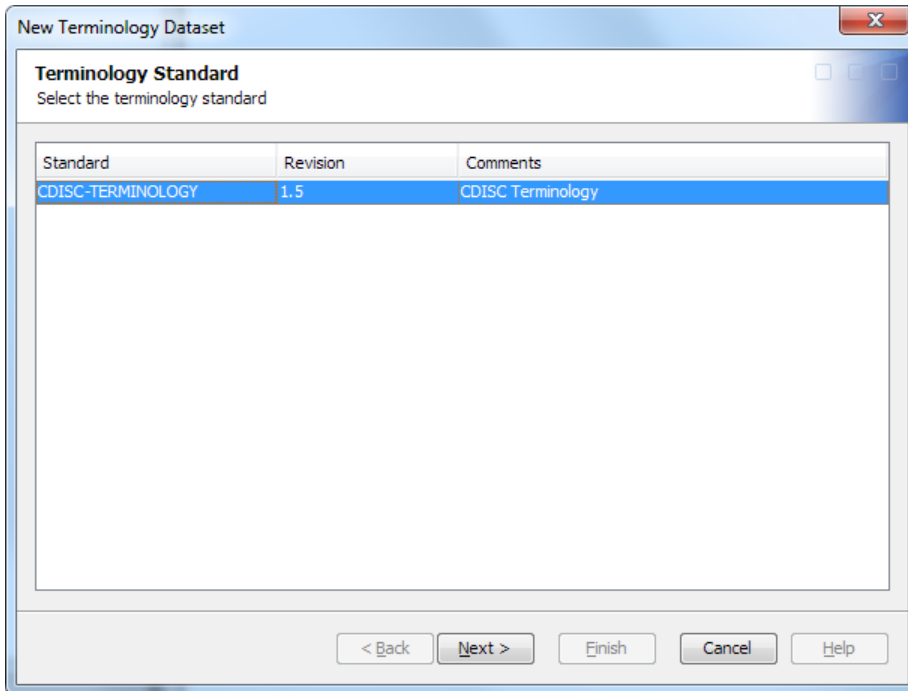
2  Select the terminology standard data set to import, and then click **Next**.

The Terminology Version page appears.

3  Select the terminology version to use, and then click **Next**.

The Terminology Data Set Name page appears.

4  (Optional) Enter a name and description, and then click **Next**.

The Terminology Data Sets Folder page appears.

5  Select the folder in which to create the terminology data set, and then click **Next**.

The Terminology Library page appears.

6  From the **SAS Library** drop-down list, select the library that contains the imported terminology table or create a library.

For information about using the New Library Wizard to create a library, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

**Note:** The selected library must have Create permission for the user who is currently logged on.

7   Click **Next**

The Summary page appears.

8   Click **Finish**.

### See Also

## Create a Terminology Package

**Note:** You must have the appropriate permissions to create a terminology data set. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

To create a terminology package, perform the following steps:

1   In the **Clinical Administration** tree, select **Terminology Packages**, right-click, and then select **New Terminology Package**.

The New Terminology Package wizard appears.

2  Enter a name, an optional version number, and an optional description.

3  Click **Next**.

The Terminology Sets page appears.

4  To add a terminology set, perform the following steps:

a  Click **Add**.

The Add Terminology Sets wizard appears.
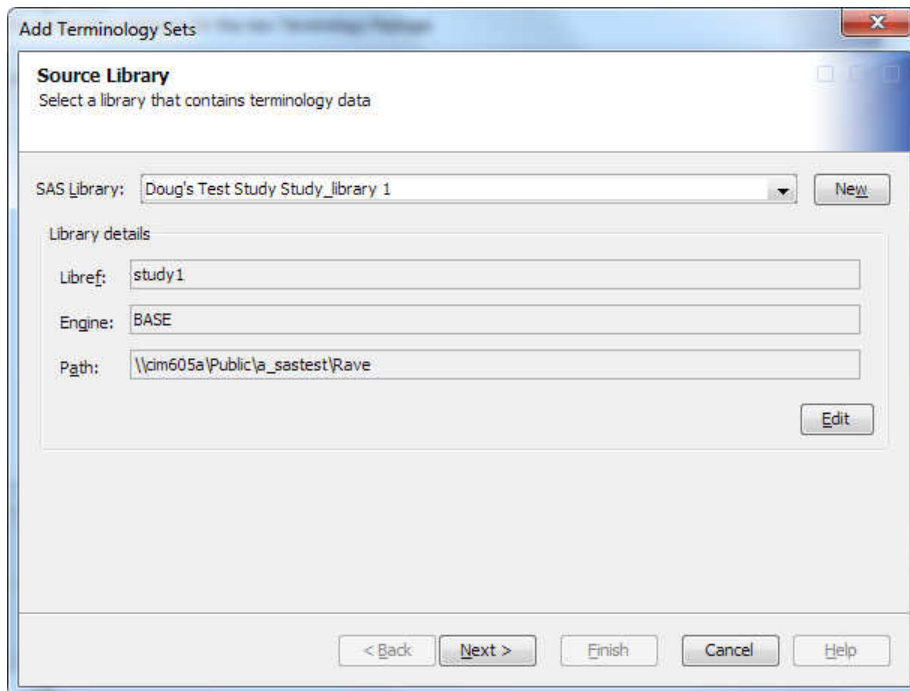
b   Select a SAS library or create a library, and then click **Next**.

For information about creating a new library or editing a library, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

The Source Terminology Tables page appears.

c   Select one or more tables in the library, and then click **Finish**.

5   To order the data sets, select a data set on the Terminology Sets page, and then click **Move Up** or **Move Down**.

6   Click **Finish**.

## Edit a Terminology Package

To edit a terminology package, perform the following steps:

1   In the **Clinical Administration** tree, expand **Terminology Packages**.

**2**  Select a terminology package, right-click, and then select **Properties**.

The Controlled Terminology Properties dialog box appears.
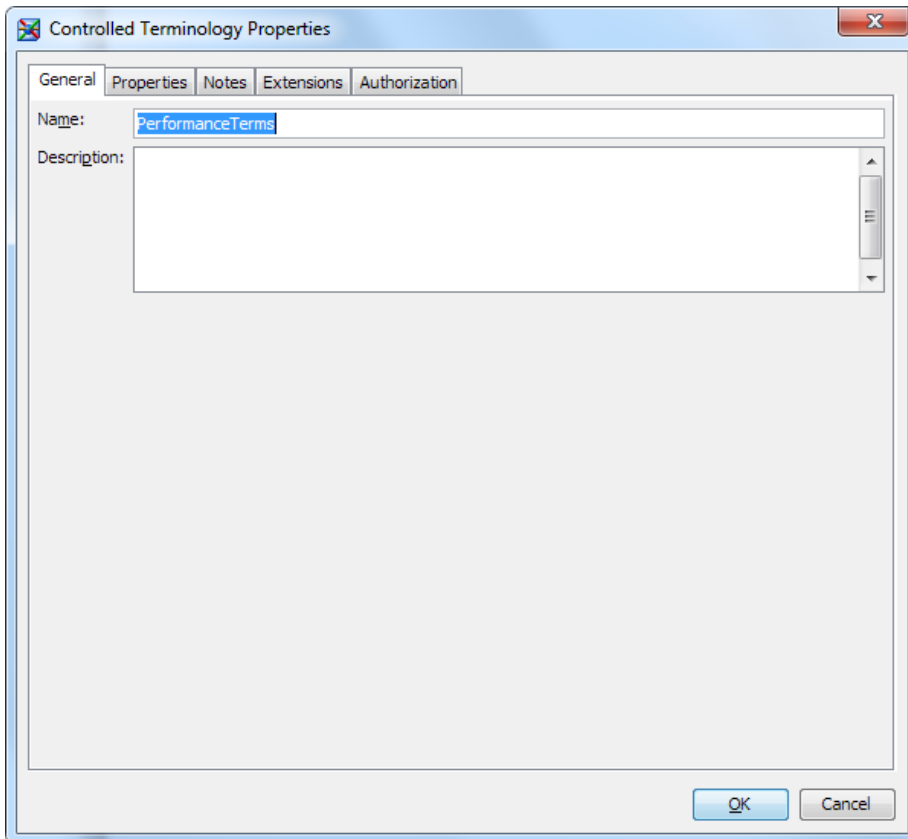


**3**  Edit the properties.

**4**  To add a terminology set, perform the following steps:

**a**  Click the **Properties** tab, and then click **Add**.

The Add Terminology Sets wizard appears.
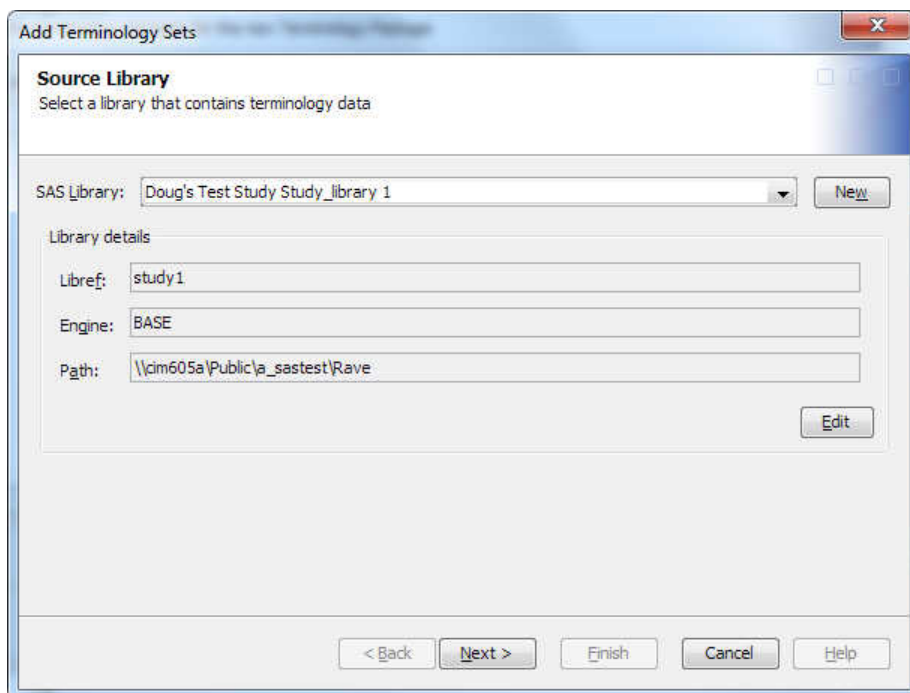
b   Select a SAS library or create a library, and then click **Next**.

For information about creating a new library or editing a library, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

The Source Terminology Tables page appears.

c   Select one or more tables in the library, and then click **Finish**.

5   To order the terminology data sets, select a data set on the **Properties** tab, and then click **Move Up** or **Move Down**.

6   Click **OK**.

# Managing Data Standard Compliance Checks

## Overview: Managing Data Standard Compliance Checks

A set of compliance checks can be associated with each data standard. The data standards administrator can add new compliance checks and customize existing compliance checks for a data standard. Using these checks, you validate a clinical domain to determine whether it complies with the data standard. You perform validation by running a job that contains the CDISC-SDTM Compliance transformation or the CDISC-ADaM Compliance transformation.

The data standards administrator can customize validation for a data standard in the Manage Compliance Checks wizard. A compliance check can have an Active or Draft status. In the CDISC-SDTM Compliance transformation, where compliance checks are applied to clinical domains, non-administrator users can select and use only compliance checks that have an Active status. Only administrators can use compliance checks that have a Draft status. The Draft status enables administrators to set up and run compliance transformations to verify custom compliance checks. When an administrator is satisfied with the compliance check, the administrator changes the status to Active, and then the check is available to all clinical programmers.

**Note:**  You must have the appropriate permissions to manage data standard compliance checks. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

### See Also

- "View Compliance Checks" on page 34

- "Create or Edit a Compliance Check" on page 35

- "Change the Compliance Check Status" on page 41

- "Delete a Compliance Check" on page 41

# Creating a Compliance Check

## Overview: Creating a Compliance Check

**Note:** To create a compliance check, you must be an advanced user who understands how validation works using the SAS Clinical Standards Toolkit. SAS Clinical Standards Toolkit is invoked by the SAS code that is generated from a compliance transformation that uses validation. For more information about the SAS Clinical Standards Toolkit, see *SAS Clinical Standards Toolkit: User's Guide*.

The SAS Clinical Standards Toolkit provides a set of compliance checks for the data standards that support validation. SAS Clinical Data Integration imports these compliance checks when you import your data standards. You can create additional compliance checks and add them to the set.

The syntax for the following settings is determined by SAS Clinical Standards Toolkit:

- Domain and domain column specifications

- Code source

- Terminology lookup and reporting

For task information, see "Create or Edit a Compliance Check" on page 35.

## Domain Specification String and Column Specification String Values Requirements

A value for the domain specification string and column specification string must meet the following requirements:

- Brackets must be matched.

- Valid characters are letters (A-Z and a-z), digits (0 to 9), or the underscore (_).

- The `_ALL_` syntax specifier cannot be used.

- The maximum length is 200 characters.

## Check ID Value Requirements

A value for a check ID must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length is eight characters.

- The value must be unique among all check IDs for any compliance check belonging to that data standard.

## Check Type Value Requirements

A value for the check type must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length is 20 characters.

## Severity Value Requirements

A value for the severity must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length is 40 characters.

## Error Message Value Requirements

A value for the error message must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length is 500 characters.

## Description Value Requirements

A value for the description must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters are valid. However, single and double quotation marks cannot be used together in the description. Use only single quotation marks or only double quotation marks.

- The maximum length is 500 characters.

## Code Source Value Requirements

A value for the code source must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length is 32 characters.

## Code Value Requirements

A value for the code must meet the following requirements:

- All characters are valid. However, single and double quotation marks cannot be used together in the description. Use only single quotation marks or only double quotation marks.

- The maximum length is 2000 characters.

## Lookup Type and Lookup Source Value Requirements

A value for the lookup type and lookup source must meet the following requirements:

- The value must contain at least one non-whitespace character.

- All characters, except single and double quotation marks, are valid.

- The maximum length for a lookup type is 20 characters.

- The maximum length for a lookup source is 32 characters.

# View Compliance Checks

To view compliance checks, perform the following steps:

**1** In the **Clinical Administration** tree, expand **Data Standards**.

2   Select a data standard, right-click, and then select **Manage Compliance Checks**.

The Manage Compliance Checks wizard appears.
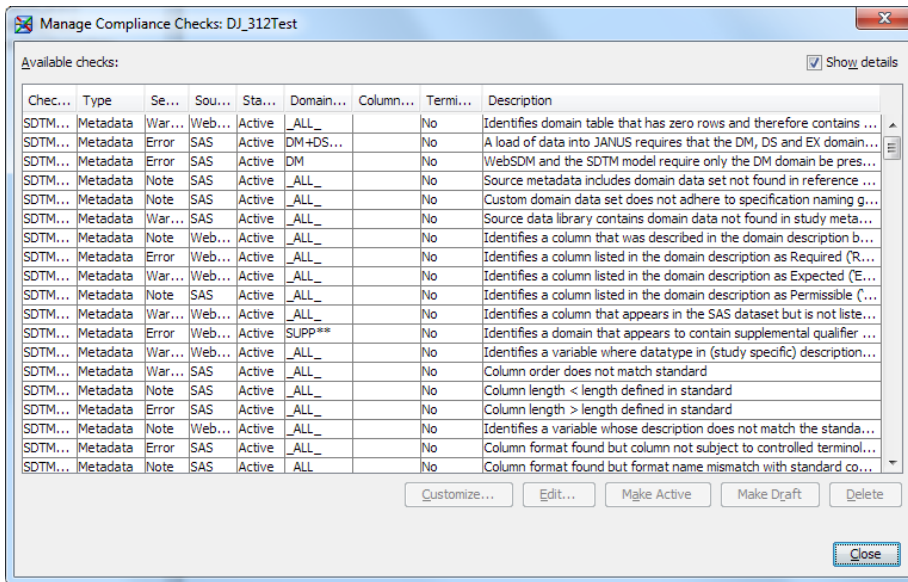


**Note:** If the data standard does not support compliance checking, or it does not have a compliance check installed, then a message appears.

3   To view only the **Check ID** and **Description** columns, clear the **Show details** check box.

By default, the **Available checks** table displays details for each compliance check.

**Note:** You can sort the table by clicking on any column heading.

4   Click **Close**.

# Create or Edit a Compliance Check

## Start the Wizard

For conceptual information, see .

**Note:** If the **Next** and **Finish** buttons are dimmed on a page in the wizard, one or more of the values on the page are not valid, or a required value is missing. Review the requirements for each value, and make corrections as needed.

To start to create or edit a compliance check, perform the following steps:

1 View the compliance checks.

   For more information, see "View Compliance Checks" on page 34.

2 To create a compliance check, right-click a compliance check, and then select **Customize**.

   The Customize Compliance Check wizard appears.



3 To edit a compliance check, perform the following steps:

   a Right-click a compliance check, and then select **Make Draft**.

To edit a compliance check, it must have a status of Draft.

b   Right-click the compliance check, and then select **Edit**.

The Edit Compliance Check wizard appears.



## Specify the Check Properties Values

To specify the check properties values, perform the following steps:

1   On the Check Properties page, edit the values by performing the following steps:

a   If you are creating a compliance check, enter a check ID.

The value must meet the requirements; see "Check ID Value Requirements" on page 32.

b   Select or enter a check type.

The value must meet the requirements; see "Check Type Value Requirements" on page 33.

c Select or enter a severity.

The value must meet the requirements; see "Severity Value Requirements" on page 33.

d Enter a description.

The value must meet the requirements; see "Description Value Requirements" on page 33.

e In the **Initial Status** list, the default is always **Draft**.

**Note:** After you test this check using the compliance transformation, you can set the status to **Active**.

2 Click **Next**.

The Domains page appears.

## Specify the Domains

(Optional) To specify the domains, perform the following steps:

1 To enable the **Domain Specification** field for editing, and disable the **Domains Referenced** table, select the **Direct Edit (Advanced)** check box.

2 (Optional) In the **Domains Referenced** table, edit a row to adjust the values for the domain.

**Note:**

▪ When creating a compliance check, the **Domains Referenced** table might not be displayed. The table's appearance depends on the type of compliance check that you have selected.

▪ When editing a compliance check, the **Domains Referenced** table appears only when the domain specification for the compliance check includes one or more domain IDs or domain specifiers.

3   In the **Domain Specification** field, enter the full domain specification string that is passed to SAS Clinical Standards Toolkit.

The value must meet the requirements; see "Domain Specification String and Column Specification String Values Requirements" on page 32.

4   Click **Next**.

The Domain Columns page appears.

## Specify the Domain Columns

(Optional) To specify the domain columns, perform the following steps:

1   To enable the **Column Specification** field for editing, and to disable the **Columns Referenced** table, select the **Direct Edit (Advanced)** check box.

2   (Optional) In the **Columns Referenced** table, edit a row to adjust the values for the column.

**Note:** The **Columns Referenced** table appears only when the column specification includes one or more column IDs or column specifiers.

3   In the **Column Specification** field, enter the full column specification string that is passed to the SAS Clinical Standards Toolkit.

The value must meet the requirements; see "Domain Specification String and Column Specification String Values Requirements" on page 32.

4   Click **Next**.

The Check Code page appears.

## Specify the Check Code Values

(Optional) To specify the check code values, perform the following steps:

1   To enable the **Code Source** drop-down list and the **Code** field for editing, select the **Direct Edit (Advanced)** check box.

2   (Required) In the **Code Source** list, select or enter a macro provided by the SAS Clinical Standards Toolkit.

**Note:**

■ The **Code Source** list appears only when the column specification includes one or more column IDs or column specifiers.

■ For more information about the macros, see the *SAS Clinical Standards Toolkit: User's Guide*.

3   In the **Code** field, enter the code to pass to the SAS Clinical Standards Toolkit.

SAS Clinical Data Integration does not validate the syntax in the code. However, it does validate that the value requirements are met. For more information, see "Code Value Requirements" on page 34.

**Note:**  All code must be consistent with the selected code source. And, the code must be valid SAS code.

4   Click **Next**.

If a terminology lookup is included in the compliance check, the Controlled Terminology Lookup page appears. Otherwise, the Reporting Options page appears.

## Specify the Controlled Terminology Lookup Values

(Optional) If a terminology lookup is included in the compliance check, specify the values by performing the following steps:

1   To enable the **Lookup Type** and **Lookup Source** drop-down lists for editing, select the **Direct Edit (Advanced)** check box.

2   (Required) In the **Lookup Type** list, select or enter the type of terminology lookup.

**Note:**  SAS Clinical Data Integration does not validate whether the type exists.

3   (Required) In the **Lookup Source** list, you can select or enter the source of the terminology lookup.

**Note:**  SAS Clinical Data Integration does not validate whether the source exists.

4   Click **Next**.

The Reporting Options page appears.

## Specify the Reporting Options Values

(Optional) To specify the reporting options, perform the following steps:

1   To enable the **Error Message** field, select the **Direct Edit (Advanced)** check box.

2   To specify that all violations for the compliance check are reported every time the validation is run, select the **Report All Violations** check box.

    If you clear this check box, only the first violation is reported.

3   In the **Error Message** field, enter the text to write to the data set when a violation is detected.

    You can use substitution variables in this field.

4   Click **Finish**.

## Change the Compliance Check Status

To change the status of a compliance check, select one or more compliance checks, right-click, and then select either **Make Draft** or **Make Active**.

## Delete a Compliance Check

To delete a compliance check, select one or more compliance checks, right-click the compliance check, and then select **Delete**.

The compliance check is deleted from the table and from persistent storage for the data standard.

# Analyzing Domain Use and Promoting a Domain to Be a Template

## Overview: Analyzing Domain Use and Promoting a Domain to Be a Template

You can analyze how standard domains and custom domains are used in studies and submissions. With this usage information, you can perform these tasks:

■ identify custom domains that are used enough to become domain templates

Typically, a custom domain is used within a single study or submission. The custom domain is available only to the study or submission in which it is defined. However, when a custom domain is promoted to be a domain template, the custom domain can be included in any study or submission.

■ replace a current domain template with a revised version

Replacing a current domain template enables you to incrementally evolve a data standard rather than creating a new one.

Here are the requirements to promote a domain:

■ The domain template name and identifier are required.

■ The domain template name and identifier must be unique within a data standard.

■ The domain template identifier must be a valid SAS data set name.

### See Also
"Promoting an ADaM Data Set to Be a User-Defined Template" on page 128

## Analyze Domain Use and Promote a Domain

To analyze domain use and promote a domain, perform the following steps:

1  In the **Clinical Administration** tree, expand **Data Standards**.

**Note:** You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

2   Right-click a data standard, and then select **Analyze Model Usage**.
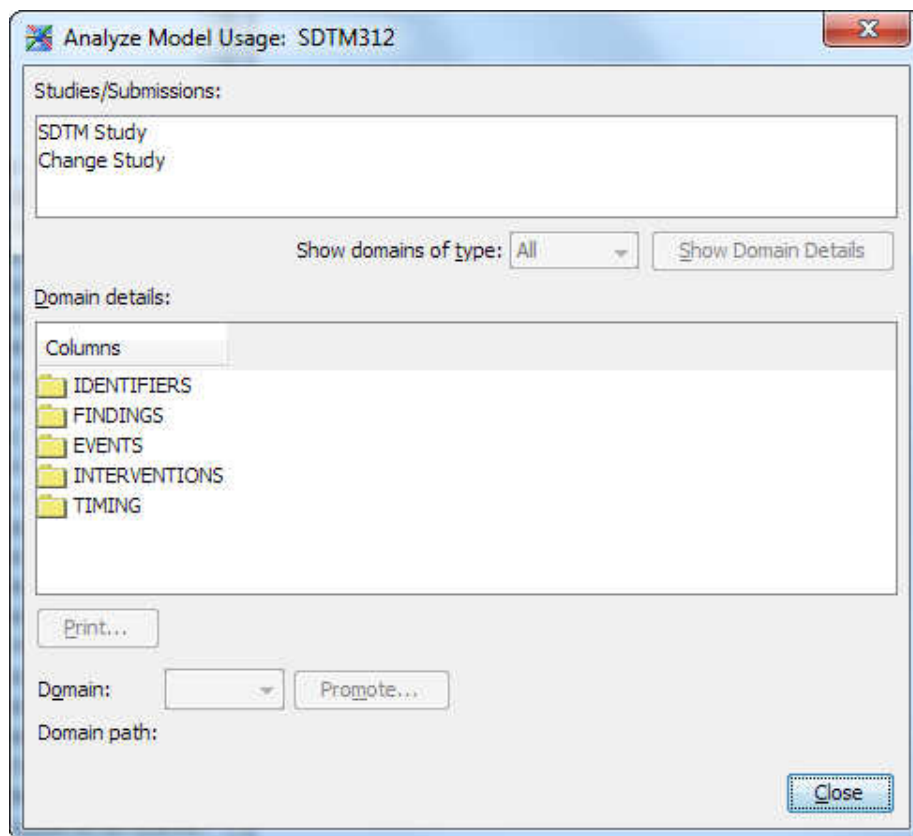
The Analyze Model Usage dialog box appears.



The **Studies/Submissions** list displays all of the studies and submissions that currently use the selected data standard.

3   From the **Studies/Submissions** list, select one or more items.

4   To limit the domains to display, select a type from the **Show domains of type** drop-down list.

5   Click **Show Domain Details**.

In the **Domain details** list, a summary of the domains and domain columns appears. Each domain that is included in the selected study or submission appears as a column in the list.

6 To see the details of a domain, double-click the folder to expand the rows.

Blue boxes specify the columns that are in each domain.



7 To view which study, folder within a study, or submission a domain is associated with, select a domain from the **Domain** drop-down list.

The full metadata path appears adjacent to **Domain path**.

8 To promote a domain, perform the following steps:

a Select a domain from the **Domain** drop-down list, and then click **Promote**.

The Domain Template Name and Identifier dialog box appears.

b Enter a name and identifier for the domain template.

c Click **OK**.

9 Click **Close** in the Analyze Model Usage dialog box.

10 To verify that a domain template was created from the custom domain, perform the following steps:

a In the **Clinical Administration** tree, expand the selected data standard.

b Expand **Domain Templates**.

The new domain template appears in this folder.

# 3

# Reports

## Overview: Reports

You use the reports feature in SAS Data Integration Studio to generate SAS Clinical Data Integration reports. Clinical administrators can generate reports to show the following information:

- basic study information that is defined in the metadata

- basic submission information that is defined in the metadata

- standards that are defined in the metadata

- controlled terminology packages

**Note:** For detailed information about running reports and selecting options, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

# Run and Save a Report

To run and save a SAS Clinical Data Integration report, perform the following steps:

1   Select **Tools** ▶ **Reports**.

The Reports dialog box appears.
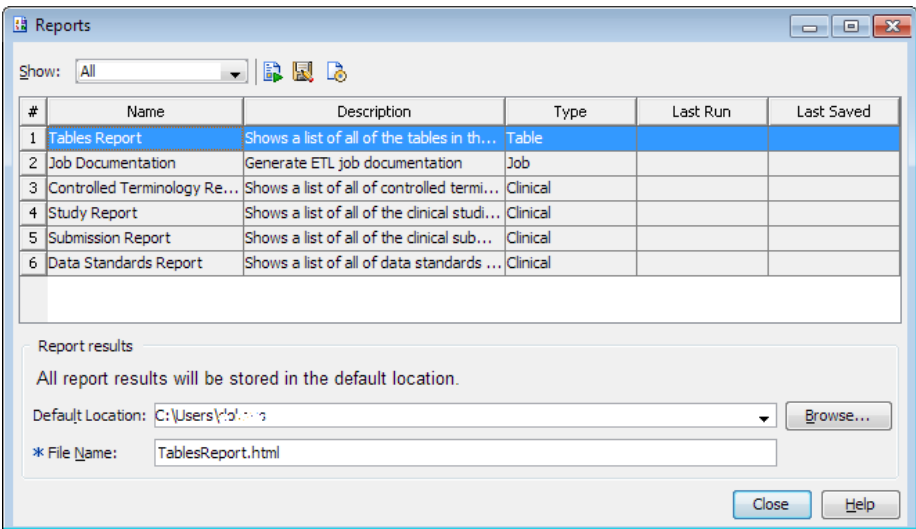


2   In the **Show** field, select **Clinical**.

3   Select a SAS Clinical Data Integration report.

4   (Optional) Specify the path to the location in which to save the report by entering a location or by clicking **Browse** to navigate to a location.

Note:  It is a good idea to browse to examine the file folder hierarchy and to check the path. The folder must be on the server and must not be a local folder.

5   Enter the name.

6   Click the **Run and view a report** icon ( ).

The report is run and saved.

The Report View dialog box appears.

**7**  Choose whether to view the report.

For more information about viewing a report, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

**Note:**  A report opens only if the **Default Location** field contains a valid path.

# Part 3

# Information for Trial Managers

# 4

# Studies and Submissions Management

# Overview: Studies and Submissions Management

SAS Clinical Data Integration studies and submissions are the top-level containers for all of the content and metadata created during the course of an entire study. A study contains study-level metadata and content. A submission contains aggregated metadata and content, or a collection of studies.

In SAS Clinical Data Integration, a trial manager can centrally define and manage study definitions, set up default content, and monitor the progress of the domain mapping process.

Before you create a study or submission, you can define the defaults for the study or submission. You can use folder templates to maintain consistent metadata organization

in a study and submission when it is created. You can use library templates to maintain consistent use of SAS librefs. This consistency is necessary when you have standard programs and macros that are dependent on consistent SAS librefs.

For each study and submission, you can define one or more default data standards. When defining a data standard, remember that you are affecting the available data standard selections in all SAS Clinical Data Integration wizards within that study or submission. Only the data standards that you define as the defaults are displayed. These default settings ensure that you are always using the correct version of a data standard for a study or submission. After you create a study or submission, default content is created automatically.

Because all activities and relationships are stored in metadata, SAS Clinical Data Integration can produce a summary of the statuses of all activities for a selected study or submission. If you have multiple programmers working on the same study or submission, you can easily see what domains have been created, what domains are used in a mapping process, and whether a validation transformation is using a certain domain. If you are using change management, you can view who is working on the study or submission. For more information about change management, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

# Working with Folder Templates

## Overview: Working with Folder Templates

You can enforce a uniform folder structure across submissions and studies by creating a folder template. You can select a folder template when you create a study or submission.

You can create any number of folder templates. You can create any number of folders within a folder template, and you can create any depth of hierarchy.

A folder template appears in the **Clinical Administration** tree when you expand **Defaults** ▶ **Folder Templates**.

**Note:**  You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

**See Also**

- "Create a Study or Submission" on page 66

- "Create a Folder Template" on page 57

- "View and Modify the Properties of a Folder Template or a Folder within a Folder Template" on page 59

- "Duplicate a Folder Template" on page 58

- "Create a Folder within a Folder Template" on page 58

## Access Permissions for Folder Templates

To more easily manage study structure at the department level, you can control which users can access a folder template. This eliminates the need to create a global list of templates, which might result in the selection of an inappropriate template during the creation of a study.

**Note:**  The access permissions that you specify for a folder template are not propagated to the objects that are created from the folder template.

For more information about access permissions on the **Authorization** tab, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Folder Name Requirements

A folder name must meet the following requirements:

- The maximum length is 60 characters.

- The name must not be the same as any existing folder name in the same parent folder. The comparison check is not case sensitive.

- The name cannot include whitespace characters.

## Folder Descriptions Requirements
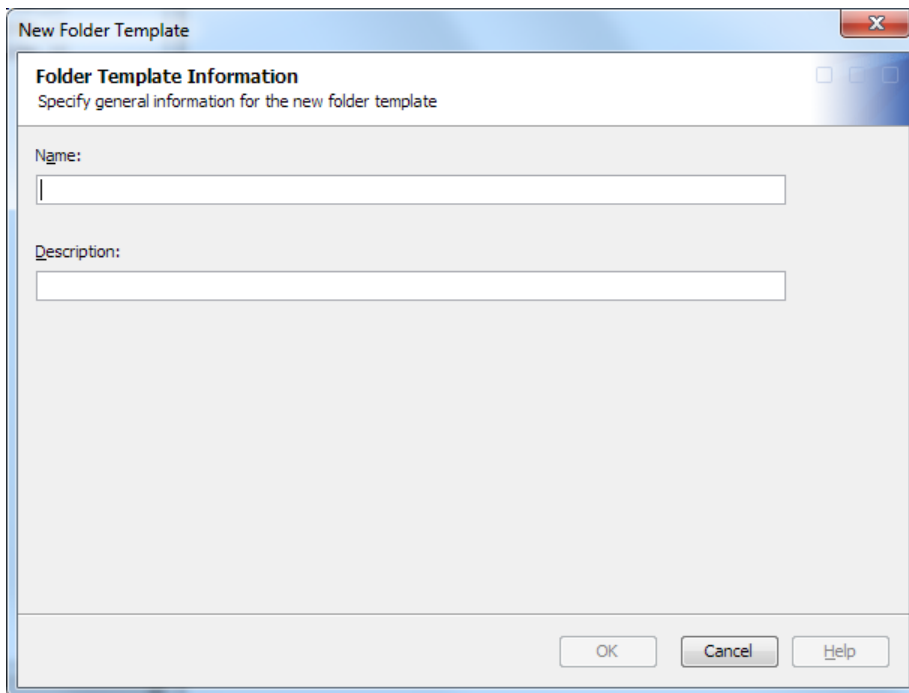
The maximum length of a description for a folder is 200 characters.

## Create a Folder Template

To create a folder template, perform the following steps:

1   In the **Clinical Administration** tree, expand **Defaults**.

2   Right-click **Folder Templates** and select **New Folder Template**.

The New Folder Template dialog box appears.



3   Enter a name and an optional description.

The name and the description must meet the requirements; see "Folder Name Requirements" on page 56 and "Folder Descriptions Requirements" on page 57.

4   Click **OK**.

5  (Optional) Create folders within the folder template hierarchy.

For more information, see "Create a Folder within a Folder Template" on page 58.

**See Also**
"Working with Folder Templates" on page 55

## Create a Folder within a Folder Template

To create a folder within a folder template, perform the following steps:

1  In the **Clinical Administration** tree, expand **Defaults** ▶ **Folder Templates**.

2  Select a folder template or a folder within a folder template, right-click, and then select **New Folder**.

A new node appears under the selected item. The name is selected, ready to edit.

3  Enter the name, and press Enter.

The name must meet certain requirements. (See "Folder Name Requirements" on page 56.)

**See Also**

■  "Working with Folder Templates" on page 55

■  "View and Modify the Properties of a Folder Template or a Folder within a Folder Template" on page 59

## Duplicate a Folder Template

To duplicate a folder template, perform the following steps:

1  In the **Clinical Administration** tree, expand **Defaults** ▶ **Folder Templates**.

2  Right-click a folder template, and select **Duplicate**.

The Duplicate Folder Template dialog box appears.
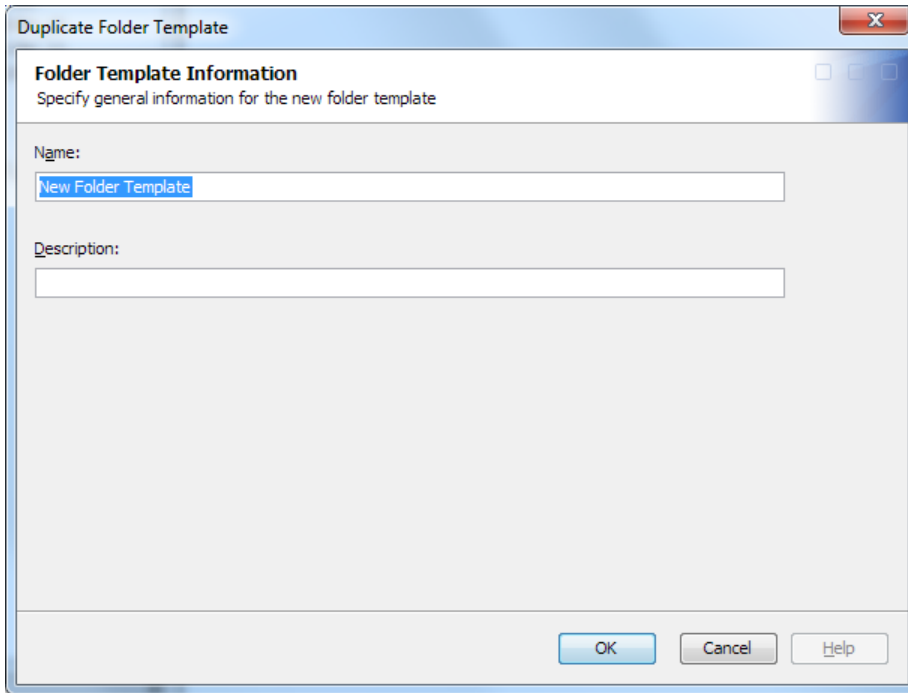
3   Enter a name and an optional description.

4   Click **OK**.

## View and Modify the Properties of a Folder Template or a Folder within a Folder Template

To view and modify the properties of a folder template or a folder within a folder template, perform the following steps:

1   In the **Clinical Administration** tree, expand **Defaults ▶ Folder Templates**.

2   Right-click a folder template or a folder within a folder template and select **Properties**.

    The Folder Template Properties dialog box appears.

3   Enter a name and an optional description.

The name and the description must meet the requirements; see and .

**4**   Click **OK**.

### See Also

# Working with Library Templates

## Overview: Working with Library Templates

You can share a default library reference across studies and submissions by creating a library template. You can select a library template when you create a study or submission.

The library templates that are available appear in the **Clinical Administration** tree when you expand **Defaults ▶ Library Templates**.

**Note:**  You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see .

### See Also

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## Access Permissions for Library Templates

To more easily manage study structure at the department level, you can control which users can access a library template.

**Note:** The access permissions that you specify for a library template are not propagated to the objects that are created from the library template.

For more information about access permissions on the **Authorization** tab, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Library Templates Descriptions Requirements

The maximum length of a description for a library template is 200 characters.

## Library Templates Name Requirements

A library template name must meet the following requirements:

- The maximum length is 60 characters.

- The name must not be the same as any existing library template name in the study or submission. The comparison check is not case sensitive.

## libref Name Requirements

A libref name must meet the following criteria:
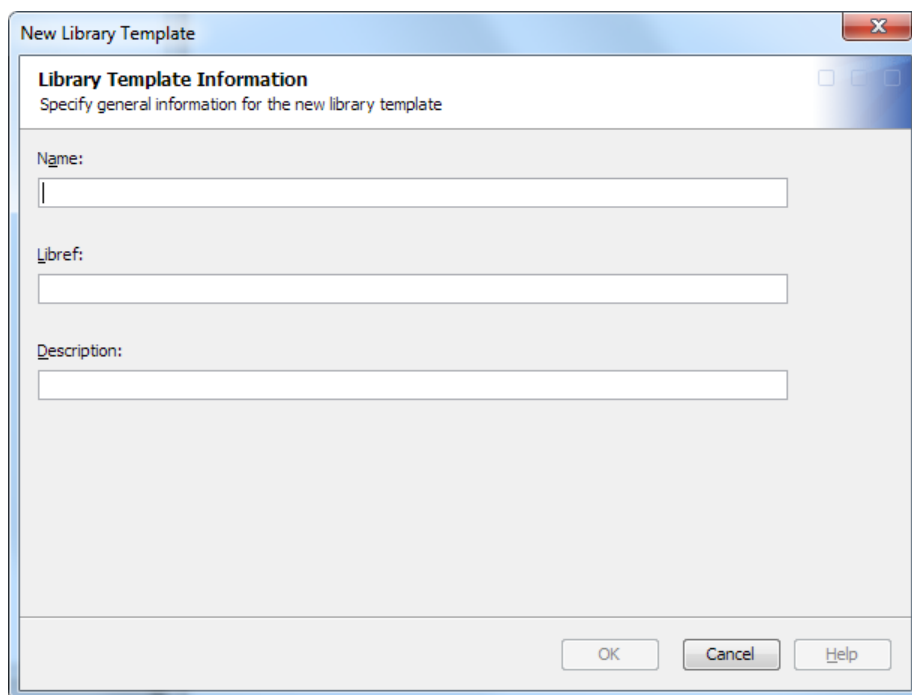
- The first character must be an alphabetic character or an underscore.

- Each subsequent character must be an alphabetic character, integer, or an underscore.

- The maximum length is eight characters.

- The name must not be the same as any existing library template name in the study or submission. The comparison check is not case sensitive.

## Create a Library Template

To create a library template, perform the following steps:

**1** In the **Clinical Administration** tree, expand **Defaults**.

**2** Right-click **Library Templates** and select **New Library Template**.

The New Library Template dialog box appears.



**3** Enter a name for the library and a name for the libref.

The names must meet the requirements; see "Library Templates Name Requirements" on page 61 and "libref Name Requirements" on page 61.

**4** (Optional) Enter a description.

The description must meet certain requirements. (See "Library Templates Descriptions Requirements" on page 61.)

**5** Click **Finish**.

# View and Modify Library Template Properties

To view and modify library template properties, perform the following steps:

1   In the **Clinical Administration** tree, expand **Defaults ▶ Library Templates**.

2   Select a library template, right-click, and then select **Properties**.

The Library Template Properties dialog box appears.



3   Enter a name for the library and a name for the libref.

The names must meet the requirements; see "Library Templates Name Requirements" on page 61 and "libref Name Requirements" on page 61.

4   (Optional) Enter a description.

The description must meet certain requirements. (See .)

5 Click **OK**.

## Delete a Library Template

To delete a library template, perform the following steps:

1 In the **Clinical Administration** tree, expand **Defaults ▶ Library Templates**.

2 Select one or more library templates, right-click, and then select **Delete**.

# Creating a Study or Submission

## Overview: Creating a Study or Submission

You create a study or submission by providing basic object metadata such as name, description, and content location in the metadata tree. Then, SAS Clinical Data Integration collects metadata about the item. For example, a study collects metadata such as protocol title, indication, and phase. After metadata is collected, the versions of the data standards that can be used for the study or submission are defined.

**Note:** Only an administrator can set the default content for a study or submission. For more information, see .

You can create a study from a study definition in a define.xml file. If the define.xml file contains multiple study definitions, only the first study definition is imported.

### See Also

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■    "Creating a Domain" on page 88

# Folder Organization of Studies and Submissions

A study or submission can be located at the root of the hierarchy in the **Folders** tree (Study 1 and Submission 1 in the following figure) or within a general folder (Study 2 and Submission 2).

*Figure 4.1*    *Illustration of Basic Folder Hierarchy*
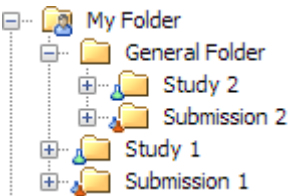


You can create more complex hierarchies based on the containment rules shown in the following table:

*Table 4.1*    *Folder Containment Rules*

|  |  | Content | |
| --- | --- | --- | --- |
|  |  | Study | Submission |
| Container | Study | not allowed | not allowed |
|  | Submission | allowed | not allowed |

Using the containment rules, here is an example of a more complex folder hierarchy:

*Figure 4.2* Illustration of Complex Folder Hierarchy
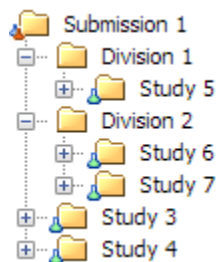


## Name Requirements

A study or submission name has a maximum length of 60 characters.

## Description Requirements

A study or submission description has a maximum length of 200 characters.

## Create a Study or Submission

To create a study or submission, perform the following steps:

1 In the **Folders** tree, right-click a folder, and then select **New** ▶ **Study** or **Submission**.

   The New Study or New Submission wizard appears.

2   Enter a name and an optional description.

The name must meet certain requirements. (See "Name Requirements" on page 66. )The description must meet certain requirements. (See "Description Requirements" on page 66.)

3   Select a folder template.

For more information, see "Working with Folder Templates" on page 55.

4   To change the location of the study or submission, click **Browse**, and then select a new location.

For information about the location of a study or submission, see "Folder Organization of Studies and Submissions" on page 65.

5   Click **Next**.

The Data Standards Selection page appears.

6   (Optional) Select one or more data standards.

All active data standards to which you have access are displayed.

**Note:** You cannot select multiple items for the same data standard.

7   Click **Next**.

The Properties page appears.

8   (Optional) Specify the property values.

The properties that appear on this page and their default values are predetermined by the administrator's configuration of the data standard's property model.

**Note:** Do not use single quotation marks, double quotations marks, or hyphens in the property value fields.

9   Click **Next**.

The Library Selection page appears.

10  (Optional) Select one or more libraries to associate with the study or submission.

The libraries that are available on this page are predetermined by the default content for a study or submission. For more information, see "Working with Library Templates" on page 60.

11  Click **Next**.

The Controlled Terminology page appears.

12  (Optional) To select a controlled terminology package to associate with the study or submission, perform the following steps:

a   Click **Add**.

The Available Terminology Packages dialog box appears. The controlled terminology packages that are available, as predetermined by the administrator, are listed.

b   Select a package, and then click **OK**.

13  To remove a selected controlled terminology package, click **Remove**.

**14** If you are creating a study, click **Finish**.

**15** If you are creating a submission, click **Next**.

The Contributing Studies page appears.

**16** (Optional) Select one or more studies to associate with the submission, and then click **Finish**.

All studies to which you have access are displayed.

### See Also

- ■ "Creating a Study or Submission" on page 64
- ■ "Edit the Properties of a Study or Submission" on page 72
- ■ "Creating a Domain" on page 88

## Create a Study from a Define.xml File

To create a study from a study definition in a define.xml file, perform the following steps:

**1** In the **Folders** tree, right-click a folder, and then select **New** ▶ **Study From Define**.

The New Study From Define wizard appears.
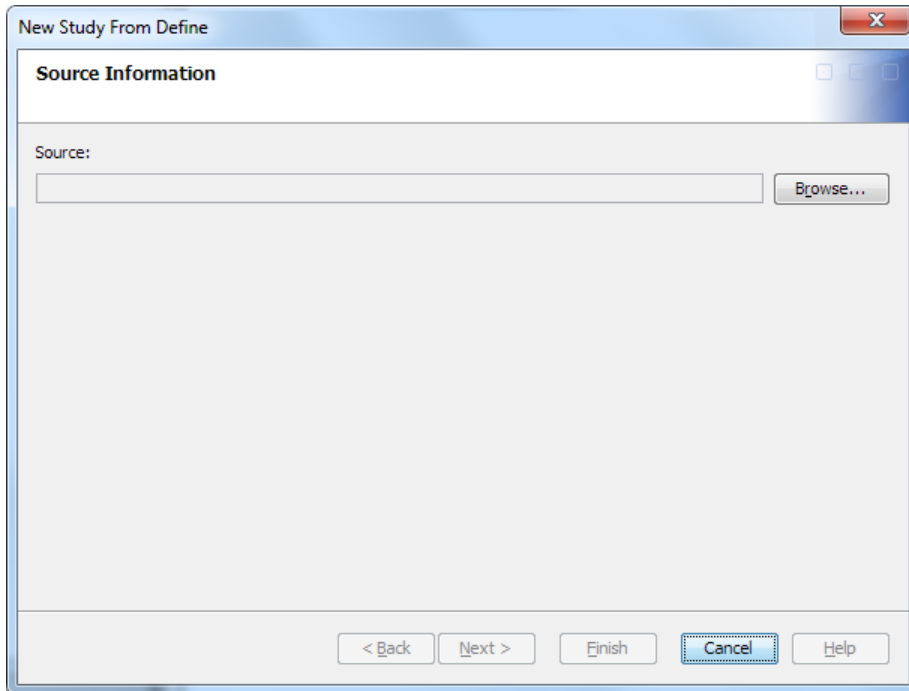
2   Click **Browse**, select a define.xml file on your local computer, and click **Open**.

3   Click **Next**.

The General Information page appears.

4   (Optional) Enter a name and a description.

**Note:**  The name and description are automatically derived from the define.xml file. However, you can change the values.

The name must meet certain requirements. (See "Name Requirements" on page 66. )The description is not required. If you provide a description, it must meet certain requirements. (See "Description Requirements" on page 66.)

5   Select a folder template.

For more information, see "Working with Folder Templates" on page 55.

6   To change the location of the study, click **Browse**, and then select a new location.

For information about the location of a study, see "Folder Organization of Studies and Submissions" on page 65.

7   Click **Next**.

The Data Standards Selection page appears.

8   (Optional) Select one or more data standards to associate with the study.

All active data standards to which you have access are displayed.

9   Click **Next**.

The Properties page appears.

10  (Optional) Specify the property values.

The properties that appear on this page and their default values are predetermined by the administrator's configuration of the data standard's property model.

The attribute values that are specified in the define.xml file and that map to SAS Clinical Data Integration properties are imported.

**Note:**   Do not use single quotation marks, double quotations marks, or hyphens in the property value fields.

11  Click **Next**.

The Library Selection page appears.

12  (Optional) Select one or more libraries to associate with the study.

The libraries that appear on this page are predetermined by the default content of a study. For more information, see "Working with Library Templates" on page 60.

13  Click **Next**.

The Controlled Terminology page appears.

14  (Optional) To select a controlled terminology package to associate with the study, perform the following steps:

a   Click **Add**.

The Available Terminology Packages dialog box appears. The controlled terminology packages that appear are predetermined by the administrator.

b   Select a controlled terminology package, and then click **OK**.

15 To remove a selected controlled terminology package, click **Remove**.

16 Click **Finish**.

### See Also

- "Creating a Study or Submission" on page 64
- "Edit the Properties of a Study or Submission" on page 72

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# Managing Studies and Submissions

## Edit the Properties of a Study or Submission

To edit the properties of a study or submission, perform the following steps:

1   In the **Clinical Administration** tree, expand **Studies** or **Submissions**.

2   Select the study or submission, right-click, and then select **Properties**.

The Study Properties or the Submission Properties dialog box appears.
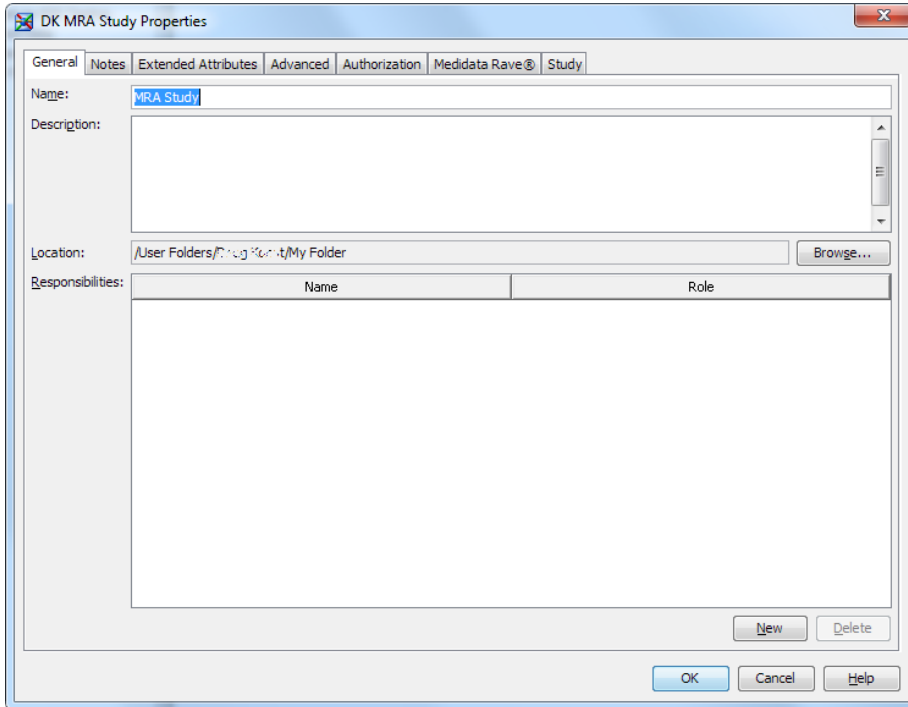
3  Select the tab that contains the information that you want to edit, edit the information, and then click **OK**.

For more information about any tab except the **Study** tab, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help. The **Study** tab displays Read-Only information.

### See Also

## Edit Multiple Column Properties in a Study or Submission

To edit multiple column properties in a study or submission, perform the following steps:

1  In the **Folders** tree, select a folder that contains one or more domains, right-click, and then select **Clinical Column Properties**.

The Clinical Column Properties wizard appears.
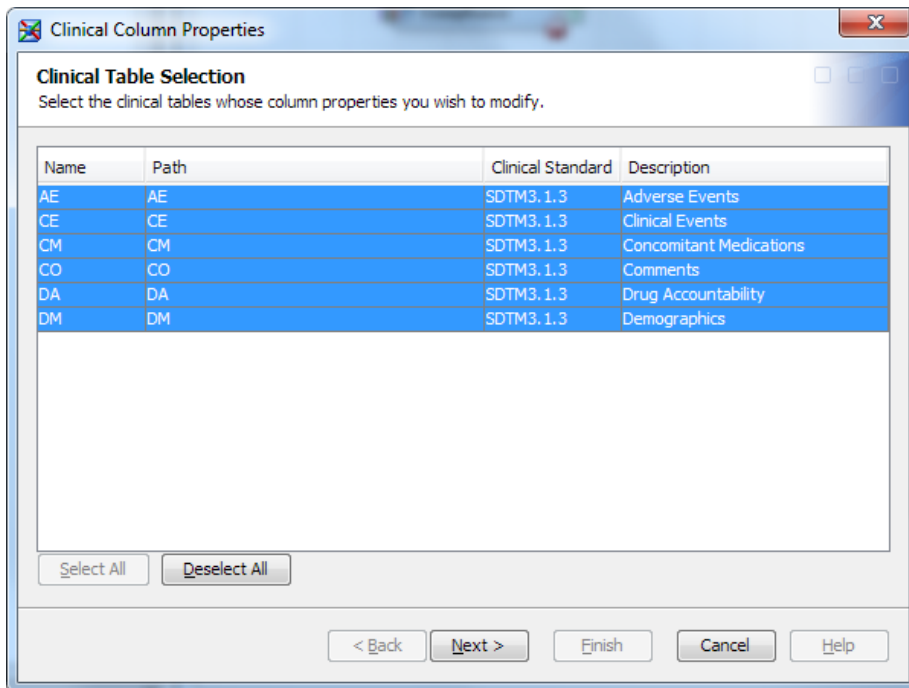
2   (Optional) Select one or more tables, and then click **Next**.

    **Note:**  All tables are selected by default.

    The Property Value Updates page appears.

3   Select a property.

4   Select one or more columns.

5   Click **Update**.

    The Property Value Update dialog box appears.

6   Enter or select a value, and then click **OK**.

7   Click **Finish**.

# Edit Multiple Table Properties in a Study or Submission

To edit multiple table properties in a study or submission, perform the following steps:

1  In the **Folders** tree, select a folder that contains one or more domains, right-click, and then select **Clinical Table Properties**.
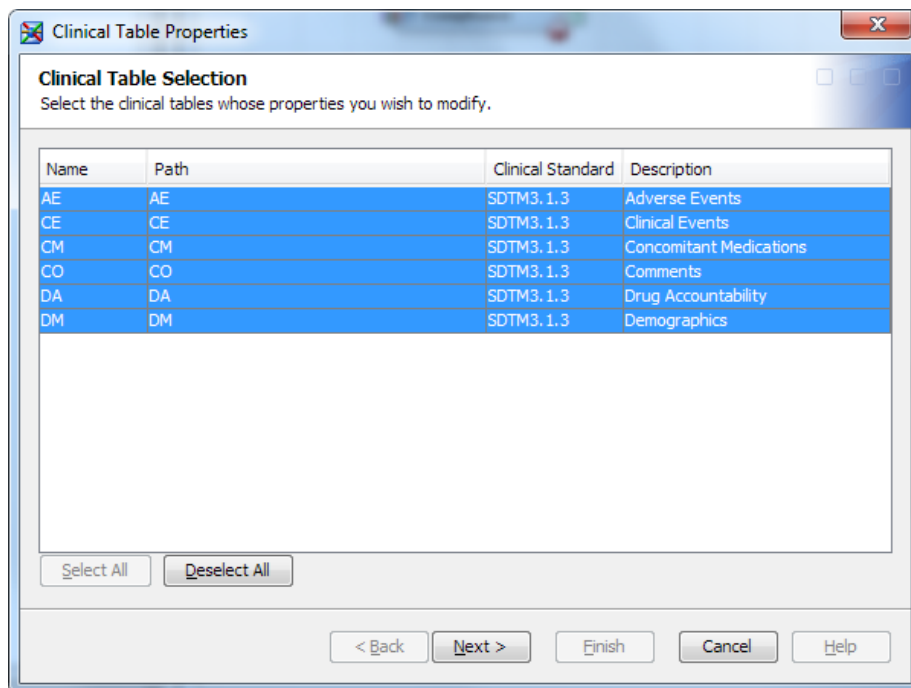
   The Clinical Table Properties wizard appears.



2  (Optional) Select one or more tables, and then click **Next**.

   **Note:**  All tables are selected by default.

   The Property Value Updates page appears.

3  Select a property.

4  Select one or more tables.

5   Click **Update**.

The Property Value Update dialog box appears.

6   Enter or select a value, and then click **OK**.

7   Click **Finish**.

## Delete a Study or Submission

To delete a study or submission, perform the following steps:

1   In the **Clinical Administration** tree, expand **Studies** or **Submissions**.

2   Right-click the study or submission, and then select **Delete**.

3   Click **OK** to confirm the deletion.

The study or submission is deleted, but the associated folder and its contents are not.

4   To delete the contents of the associated folder, in the **Folders** tree, right-click the folder, and then select **Delete**.

**Note:**  If you do not have the correct permissions, you cannot delete a folder. You cannot delete the root folder of a study or submission in the **Folders** tree unless you have first deleted the item from the **Clinical Administration** tree.

### See Also

# Import a Codelist Table into a Study or Submission from a Define.xml File

To import a codelist table into a study or submission from a define.xml file, perform the following steps:

1   In the **Folders** tree, right-click a study or submission, and then select **New ▶ Codelist Table From Define**.

The New Codelist Table From Define wizard appears.



2   Click **Browse** adjacent to the **Source** field, and then select a define.xml file.

3   Click **Next**.

The Codelist Selection page appears.

4   Select one or more codelist tables, and click **Next**.

The Table and Library Specification page appears.

5   Enter a name and optional description.

6   Select a library, and click **Next**.

The Summary page appears.

7   Review the information, and then click **Finish**.

# Monitoring the Statuses of Domains

## Overview: Monitoring the Statuses of Domains

You can monitor the statuses of domains to determine the progress of mapping the source data. In addition, you can determine whether a domain has been validated for compliance with a data standard.

**Note:**  You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

## Monitor the Progress of a Study or Submission

To monitor the progress of a study or submission, perform the following steps:

1   In the **Clinical Administration** tree, expand **Studies** or **Submissions**.

2   Select a study or submission, right-click, and then select **Monitor Domain Status**.

The Domain Status dialog box appears.
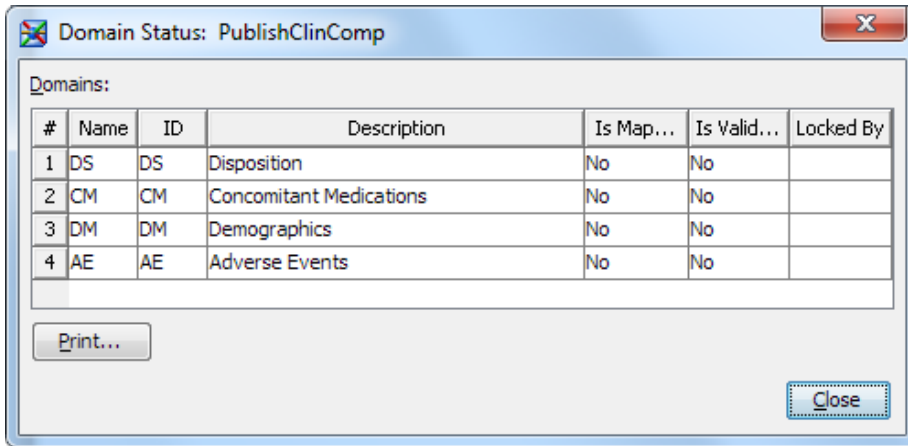


The **Domains** table reports the following information:

▪ the name of the domain

▪ the ID of the domain

▪ the description of the domain

▪ whether the domain contains defined mapping jobs (that is, the domain contains a job where the domain is a target)

▪ whether the domain contains defined compliance jobs (that is, the domain is selected to be validated)

▪ whether the domain is locked and by whom

# Comparing the Metadata of a Standard Domain to Its Template

## Overview: Comparing the Metadata of a Standard Domain to Its Template

You can compare the metadata of a standard domain to its template and you can refresh the metadata. When you compare the metadata, the standard domain is compared with the standard domain template from which it was created. Then, you can choose to refresh the metadata of the standard domain with the standard domain template metadata.

Refreshing the metadata of a standard domain replaces the metadata of the standard domain (in whole or in part) with the metadata of the standard domain template. Refreshing the metadata of a standard domain is useful when the properties of the domain have been changed in a way that is no longer applicable.

**Note:** You can refresh the metadata of a standard domain only if the domain was based on a standard domain template.

Consider the following points when selecting an item to refresh:

■ If you refresh a column, all of its properties are refreshed.

■ To refresh some properties of a column, expand the **Columns** node, and then select the check boxes for each property that you want to refresh.

■ To update the standard domain metadata to match the standard domain template metadata, select the root node check box.

**Note:** You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

# Refresh the Metadata of a Standard Domain

To refresh the metadata of a selected standard domain, perform the following steps:

1  In the **Folders** tree, expand a folder, expand a study or submission, and then expand any subfolders to locate a standard domain.

2  Select a standard domain, right-click, and then select **Refresh Domain**.

3  If a message appears that indicates that the standard domain template from which the domain was created and the standard domain are identical, choose whether to continue or not.

4  In the Refresh Domain dialog box, expand the nodes in either tree to view the differences.
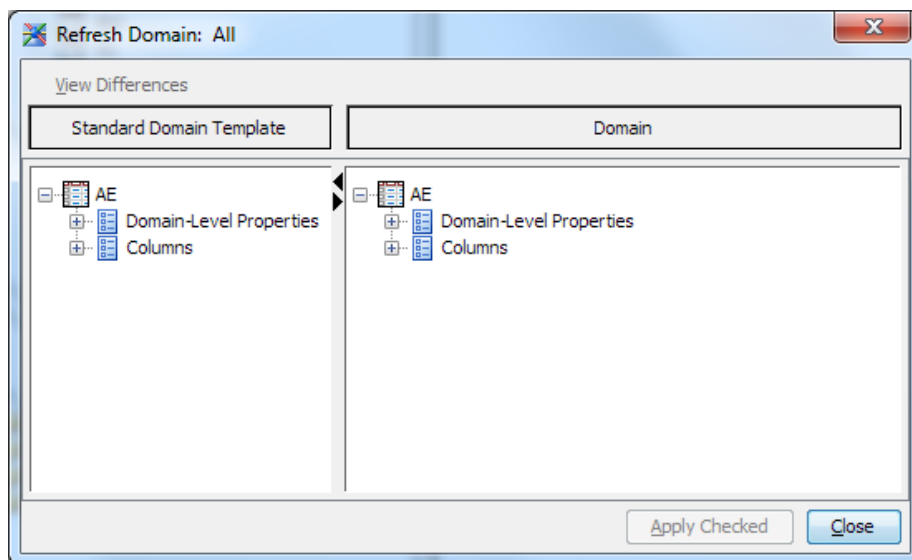


5  (Optional) Click **View Differences**.

Only the properties that are different from the domain template appear.

6  (Optional) In the **Standard Domain Template** tree, select the check box adjacent to one or more items to refresh.

**7**   Click **Apply Checked**.

If there are no remaining differences to apply, or if you chose to update the standard domain metadata to match the standard domain template metadata, then the Refresh Domain dialog box changes to view-only mode.

**8**   Click **Close**.

# Part 4

Information for Clinical Programmers or Data Managers

# 5

# SDTM Domains

# Types of Domains

## Standard Domain

A standard domain is created from a data standard that defines the domain template. When you create a standard domain, the new domain is a copy of the domain template. You can use as many domain templates as you need. The domain templates that you use to create domains are copied into a folder. Associations in the domain template metadata associate the domain template copy in this folder to the data standard from which it originated. These associations enable you to customize the domain template copy without affecting the data standard. In addition, these associations enable you to validate the copy to determine whether any customizations in the copy do not conform to the data standard.

All standard domains within a folder must be associated with the same data standard. If you want to create a copy of the standard domain using a different version of the data standard, you must create the copy in a different folder. SAS Clinical Data Integration provides domain templates that conform to existing data standards.

After selecting the standard domain templates that you want to use, you can assign a library. The library is where the physical data is created when the job is run.

## Custom Domain

During a study, there might not be an appropriate domain template for the domain that you want to create. In this case, you can create a custom domain. The custom domain uses the data model defined by the data standard to create the appropriate columns and metadata.

For example, SDTM defines a data model that is based on creating domains from groups of columns, specifically identifiers, interventions, events, findings, and timings. SAS Clinical Data Integration generalizes the concept of grouping columns with the term *column group*. A column group makes up a portion of a complete table.

**Note:** To create a custom domain, the data standard must have column groups.

The key criterion for creating a custom domain is whether it is meant to hold data for interventions, events, or findings. In SAS Clinical Data Integration, interventions, events, or findings are considered *conditional column groups*. You can select only one conditional column group per custom domain.

In addition to selecting a conditional column group, you must specify identifiers and timing. You must also select the individual columns that you want to include in the custom domain. Some column names must be prefixed with the identifier. If you select a column that has this requirement, SAS Clinical Data Integration automatically creates the correct column name with the prefix. You can define keys and set the column order before the domain is created.

You can also create a custom domain based on an existing domain. Select an existing domain that most closely satisfies your needs, duplicate it, and then modify it as needed.

### See Also

# Creating a Domain

## Overview: Creating a Domain

After you create a study or submission, you create domains within that study or submission. You can create a domain only in a folder that is the root folder of a study or submission, or in a subfolder within the root folder of a study or submission. The domain can be a standard domain or a custom domain.

**Note:** In a study folder, a domain that you create is marked with the SAS Clinical Data Integration icon . This icon helps you distinguish domains from other non-clinical tables.

**Note:** If you are working in a SAS Data Integration Studio project repository, domains that you create are created in that project repository. The project repository can be versioned. However, complex clinical objects such as data standards, studies, and submissions, cannot be versioned.

**See Also**
"Create a Study or Submission" on page 66

## Create a Standard Domain

To create a domain using a standard domain template, perform the following steps:

1  In the **Folders** tree, select a study or submission folder, right-click, and then select **New ▶ Standard Domain(s)**.

The New Standard Domain(s) wizard appears.
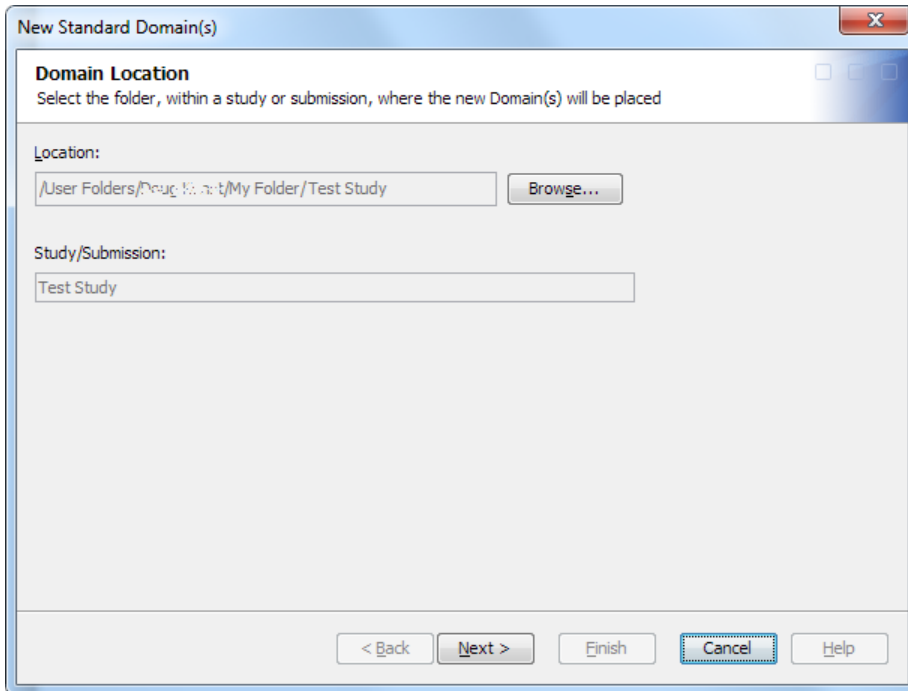
2  To change the default location of the domain, click **Browse**, and then select a new location.

   By default, the location is set to the folder that you selected in step 1.

3  Click **Next**.

   The Data Standard Selection page appears.

4  Select a data standard.

   The data standards in the list are associated with the study or submission in which the domain is to be created.

5  Click **Next**.

   The Domain Template Selection page appears.

6  Select one or more domain templates to use to create the domain.

If a domain already exists in the target folder with the same ID or with the same name as a selected domain template, then a warning message appears. You must specify a valid name or ID before you can proceed.

7   Click **Next**.

The Library Selection page appears.

8   (Optional) Select a library to assign to the domain.

The library can be any library in the study or submission. If no libraries exist within the study or submission root folder or within a subfolder of the study or submission root folder, a message appears.

**Note:**  You can create a domain without assigning a library. Later, you can create a library and assign it to the domain. However, if you use the domain in a job without first assigning a library, the job fails. The job generates errors that indicate you must assign a library. If you attempt to open the domain to view the contents and records, the open fails, and an error message appears.

9   Click **Finish**.

## Create a Custom Domain

To create a custom domain, perform the following steps:

1   In the **Folders** tree, select a study or submission folder, right-click, and then select **New ▶ Custom Domain**.

The New Custom Domain wizard appears.
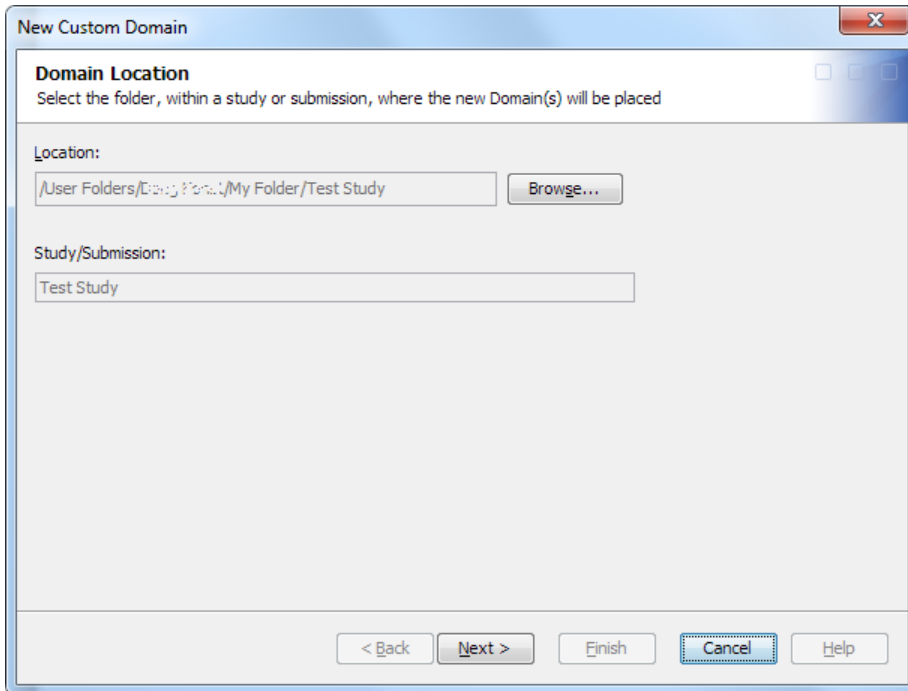
2 To change the default location of the domain, click **Browse**, and then select a new location.

By default, the location is set to the folder that you selected in step 1.

3 Click **Next**.

The Data Standard Selection page appears.

4 Select a data standard.

The data standards in this list are associated with the study or submission in which the domain is to be created.

5 Click **Next**.

The General Information page appears.

6 Enter a name and an identifier, and then click **Next**.

**Note:** The name and identifier cannot be the same as the name or identifier of a domain template in the data model.

The Domain Information page appears.

7  (Optional) Specify the property values for the new domain.

8  Click **Next**.

The Library Selection page appears.

9  (Optional) Select a library to assign to the domain.

The library can be any library in the study or submission. If no libraries exist within the study or submission root folder or within a subfolder of the study or submission root folder, a message appears.

**Note:**  You can create a domain without assigning a library. Later, you can create a library and assign it to the domain. However, if you use the domain in a job without first assigning a library, the job fails. The job generates errors that indicate you must assign a library. If you attempt to open the domain to view the contents and records, the open fails, and an error message appears.

10 Click **Next**.

The Column Group Selection page appears.

11 Select one or more conditional column groups to use in the new domain.

Column groups are groups of columns that are available to all new domains in a data standard. This page displays the core column groups that are available to all new domains in the data standard.

**Note:**  Column groups can differ depending on the selected data model.

12 Click **Next**.

The Column Selection page appears.

13 Using **Add** and **Remove**, move columns between the list **Available Columns** and the **Selected Columns** list.

You can add columns individually or as a group.

14 (Optional) To customize column properties, perform the following steps:

a Click **Next**.

The Column Elaboration page appears.

b Edit the properties for selected columns.

The **Selected Columns** table displays all of the selected columns and their properties. Not all properties can be edited. The properties vary by data model.

c (Optional) To change the column order, select a column, and then click **Move Up** or **Move Down**.

d (Optional) If two or more columns are keys, change the key order by clicking **Order Keys**.

The Order Domain Keys dialog box appears. Select a key, and then click **Move Up** or **Move Down** to adjust its order. Click **OK** to save the key order.

15 Click **Finish**.

## Create a Custom Domain from an Existing Domain

**CAUTION! Use this process to create a custom domain instead of using the standard SAS Data Integration Studio copy-and-paste method.** The copy-and-paste method does not copy important domain metadata.

To create a custom domain using an existing domain, perform the following steps:

1 In the **Folders** tree, select a study or submission folder, right-click, and then select **New ▶ Custom Domain From Existing**.

The New Custom Domain From Existing Domain wizard appears.
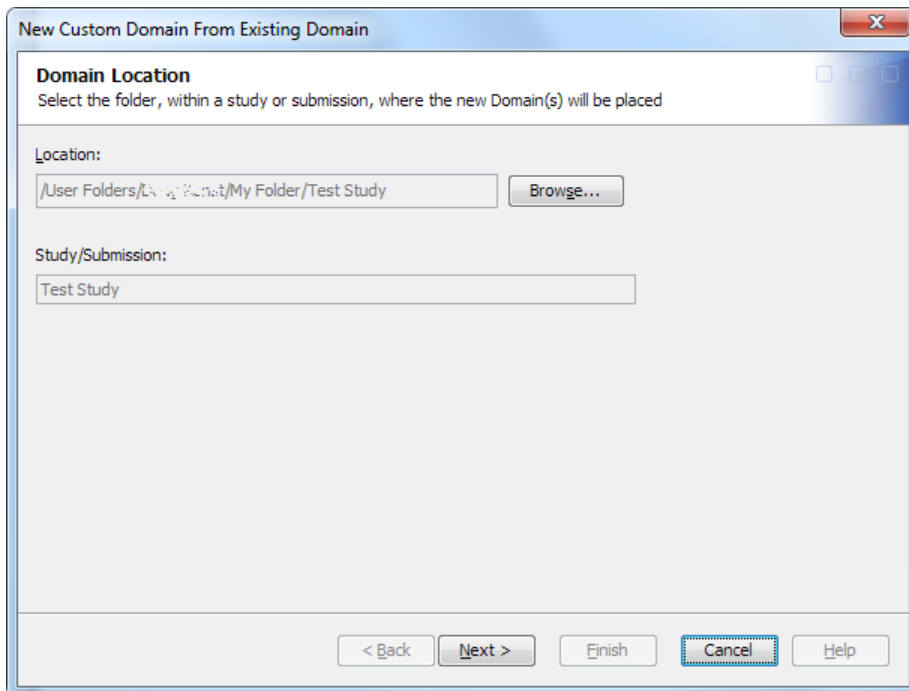
2   To change the default location of the domain, click **Browse**, and then select a new location.

    By default, the location is set to the folder that you selected in step 1.

3   Click **Next**.

    The Data Standard Selection page appears.

4   Select a data standard.

    The data standards in this list are associated with the study or submission in which the domain is to be created.

5   Click **Next**.

    The Domain Selection page appears.

6   Select a domain.

    The **Available Domains by Study/Submission** list displays the studies and submissions and their domains for the selected data standard. Expanding a study or

submission node displays all of the domains in the study or submission. Both standard and custom domains can be selected.

7 Click **Next**.

The General Information page appears.

8 Enter the name and identifier for the new domain, and then click **Next**.

The Domain Information page appears.

**Note:** The name and identifier cannot be the same as the name or identifier of a domain template in the data model.

9 Specify the property values for the new domain, and then click **Next**.

The Library Selection page appears.

10 (Optional) Select a library to assign to the domain.

The library can be any library in the study or submission. If no libraries exist within the study or submission root folder or within a subfolder of the study or submission root folder, a message appears.

**Note:** You can create a domain without assigning a library. Later, you can create a library and assign it to the domain. However, if you use the domain in a job without first assigning a library, the job fails. The job generates errors that indicate you must assign a library. If you attempt to open the domain to view the contents and records, the open fails, and an error message appears.

11 Click **Next**.

The Column Elaboration page appears.

12 Specify the properties for selected columns.

The **Selected Columns** table displays all of the selected columns and their properties. Not all properties can be edited. The properties vary by data model.

13 (Optional) To change the column order, select a column, and then click **Move Up** or **Move Down**.

**14** (Optional) If two or more columns are keys, change the key order by clicking **Order Keys**.

The Order Domain Keys dialog box appears. Select a key, and then click **Move Up** or **Move Down** to adjust its order. Click **OK** to save the key order.

**15** Click **Finish**.

## Add Domain Columns

To add domain columns, perform the following steps:

**1** In the **Folders** tree, select a domain, right-click, and then select **Properties**.

The Properties dialog box appears.
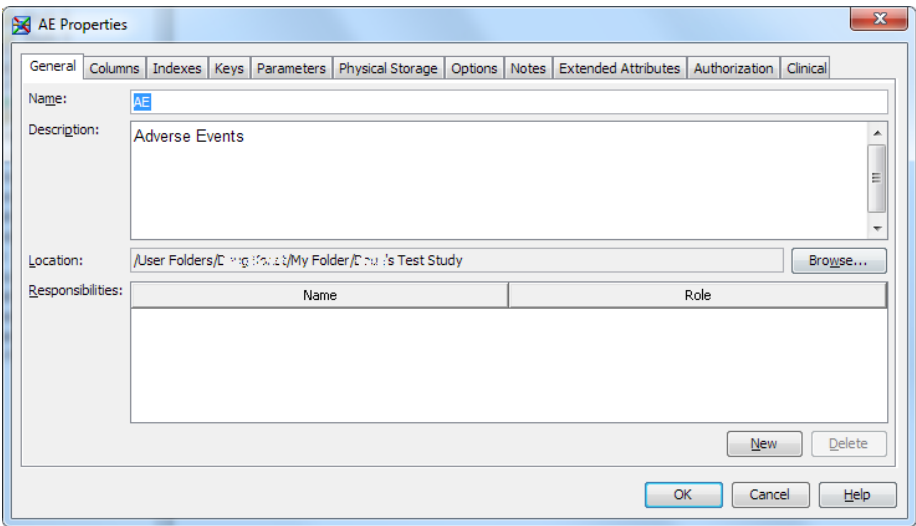


**2** Click the **Columns** tab.

The domain columns are listed.

**3** Click the **New Column** button 🏢.

A new entry appears as the last row of the table.

**4**   Enter a name and description for the column.

**5**   Edit the default column characteristics, if necessary.

**6**   Click **OK**, or edit the column's properties.

**7**   Repair the domain column.

For more information, see "Repair a Domain or Domain Column" on page 199.

# Domain Properties

## Edit Domain Properties

To edit domain properties, perform the following steps:

**1**   In the **Folders** tree, select a domain, right-click, and then select **Properties**.

The Properties dialog box appears.
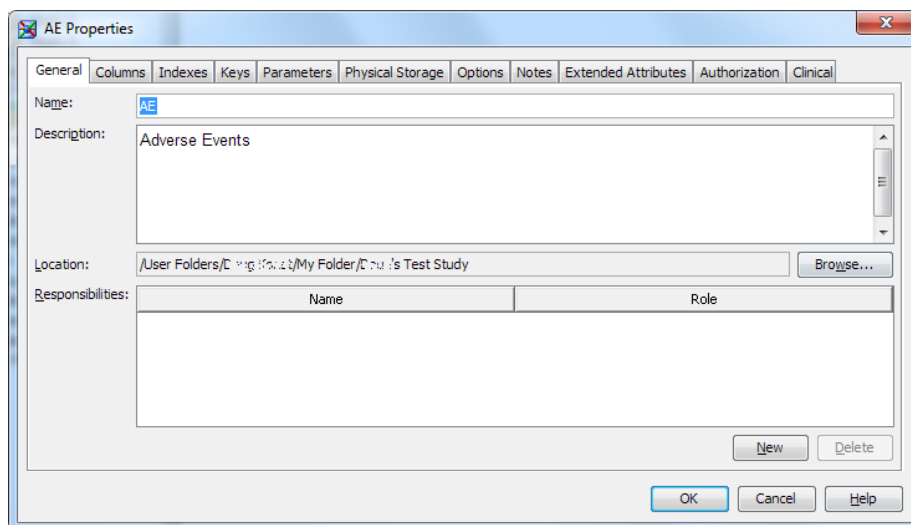


**2**   Select the tab that contains the information that you want to edit, and then edit the information.

**Note:** Property values cannot contain double quotation marks.

For more information about any tab except the **Clinical** tab, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

3 (Optional) To change properties for the domain, click the **Clinical** tab.

The **Properties** table enables you to enter values and select values from lists, depending on the property definition.

**Note:**

- ■ You might not be able to edit some property values.

- ■ Some properties of a domain, such as Archive Title, appear in CRT-DDS files that are generated by SAS Clinical Data Integration. The CRT-DDS files can contain metadata about the domain. If you plan to generate CRT-DDS files that include metadata about a domain, ensure that the metadata is complete by supplying values for the corresponding properties of the domain. For more information about updating properties, see "Edit Domain Properties" on page 97.

4 Click **OK**.

## Edit Domain Column Properties

To edit domain column properties, perform the following steps:

1 In the **Folders** tree, select a domain, right-click, and then select **Properties**.

The Properties dialog box appears.
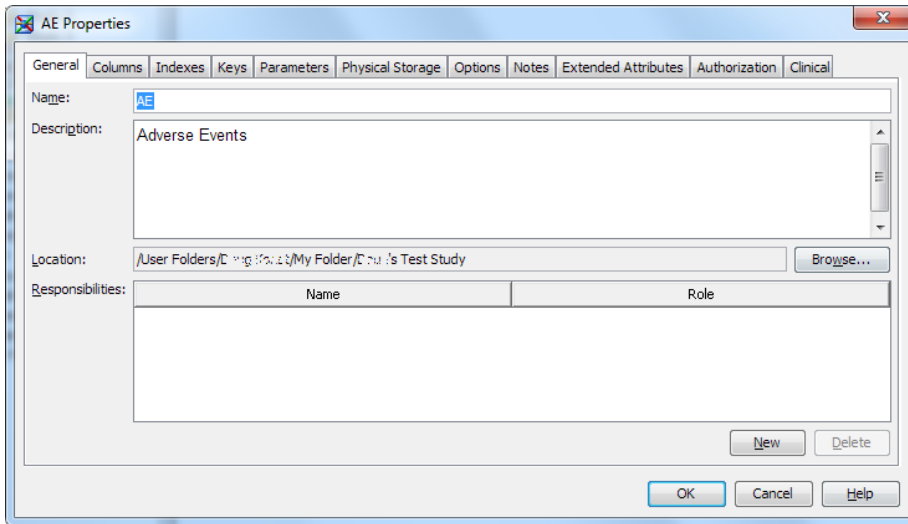
2   Click the **Columns** tab.

The domain columns are listed.

3   Right-click a column, and then select **Properties**.

The Column Properties dialog box appears.
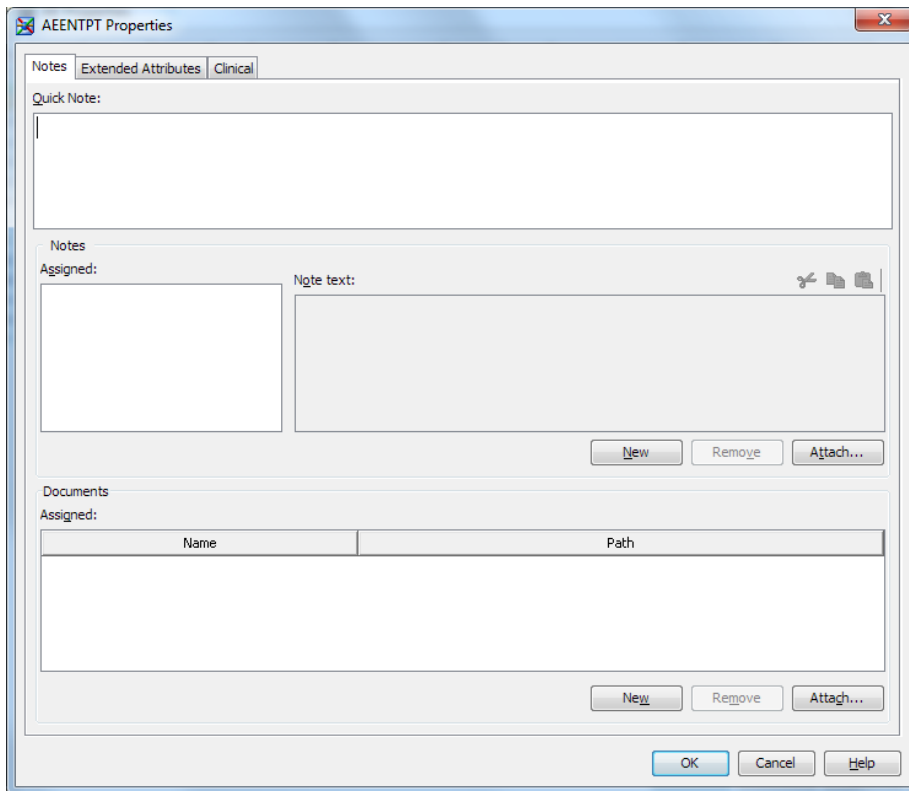
4   Select the tab that contains the information that you want to edit, and then edit the information.

> **Note:** Property values cannot contain double quotation marks.

> For more information about any tab except the **Clinical** tab, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

5   To change properties for the domain column, click the **Clinical** tab.

> The **Properties** tables enables you to enter text and select values from lists depending on the property definition.

> **Note:** You might not be able to edit some property values.

6   (Optional) To specify that the column is automatically designated a key when a custom domain is created, select the value **true** for the **Contributes to Key** property.

**7**   Click **OK** twice.

# Converting a Domain from One Data Standard to Another Data Standard

## Overview: Converting a Domain from One Data Standard to Another Data Standard

You can convert a domain in a study or submission to be associated with a data standard other than the current data standard. Converting a domain might be needed in these situations:

- You want to upgrade to a newer version of the same data standard.

- You want to change to a different data standard that is compatible with the current data standard.

- You want to merge a SEND domain with a custom SDTM+ data standard.

By converting a domain, you can reorganize domains relative to your data standards without modifying jobs that reference the domain.

**CAUTION! The property model for the new data standard might differ from the current data standard.** Validate the properties of the converted domain against the expected properties of the new data standard. For more information, see "Refresh the Metadata of a Standard Domain" on page 81.

**Note:**  Before you convert a domain to another data standard, ensure that the study (or the folder in the study) contains domains from only one data standard. Although SAS Clinical Data Integration prevents mixing domains from different data standards, there are ways in SAS Data Integration Studio to mix domains from different data standards.

# Convert a Domain from One Data Standard to Another Data Standard

To convert a domain from one data standard to another data standard, perform the following steps:

1    In the **Folders** tree, select a study or a folder in a study, right-click, and then select **Properties**.
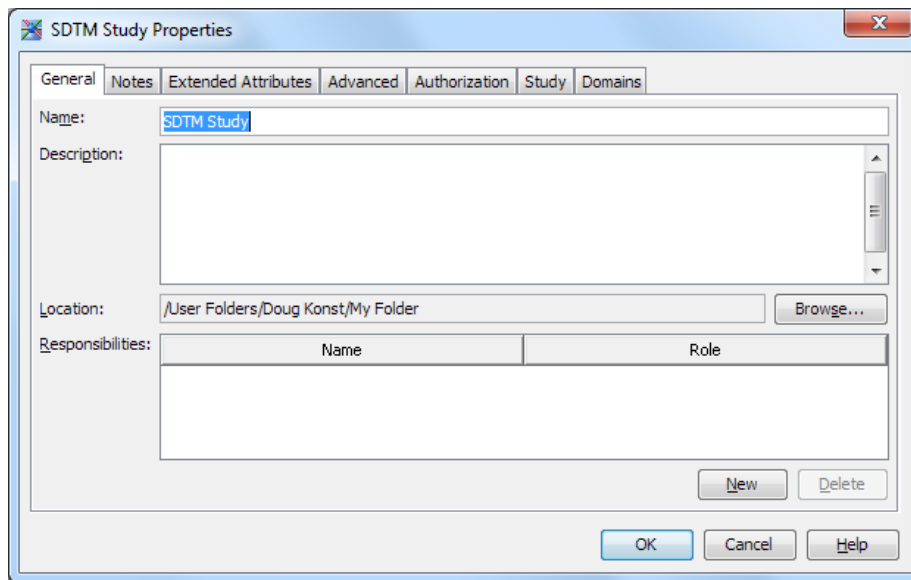
     The Properties dialog box appears.



2    Click the **Domains** tab.

     **Note:** If the **Domains** tab does not appear, the study or folder does not contain a domain. Create a domain in the study or folder, and then return to this step. For more information, see "Overview: Creating a Domain" on page 88.

3    Click **Change** adjacent to the **Data Standard** field.

     The Change Standard Association of Domains dialog box appears.

4    Select a compatible data standard, and then click **OK**.

5    In the Properties dialog box, click **OK**.

6    Validate the properties of the converted domain against the expected properties of the new data standard. For more information, see "Refresh the Metadata of a Standard Domain" on page 81.

# Importing Domain Tables from a Define.xml File

## Overview: Importing Domain Tables a Define.xml File

You can create a domain by importing the domain definition from a define.xml file. This enables you to rapidly define the metadata necessary to add the domain to the repository.
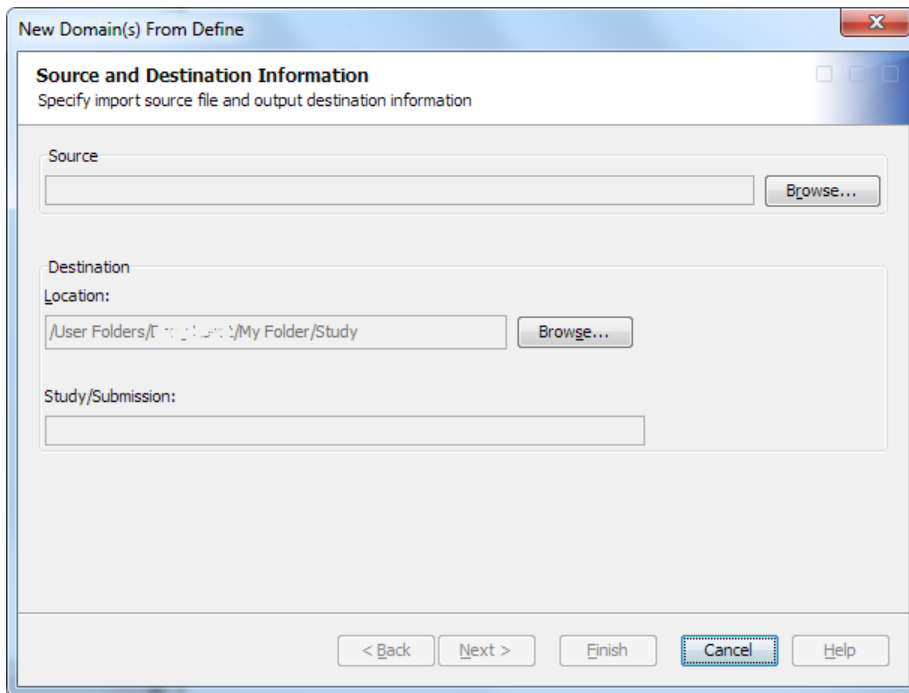
The domain is created as a custom domain.

## Create a Domain from a Define.xml File

To create a domain from a define.xml file, perform the following steps:

1    In the **Folders** tree, right-click a study, submission, or a folder within a study or submission.

2    Select **New ▶ Domain(s) From Define**.

The New Domain(s) From Define wizard appears.

3  Click **Browse** adjacent to the **Source** field, and then select a define.xml file.

4  (Optional) Click **Browse** adjacent to the **Location** field, and then select a location in which to create the domain.

5  Click **Next**.

The Data Standard Selection page appears.

6  Select a data standard to associate with the domain, and then click **Next**.

The Domain Selection page appears.

7  Select one or more domains to import, and then click **Next**.

The Library Selection page appears.

8  (Optional) Select a library to associate with the imported domain, and then click **Next**.

The Summary page appears.

**9**   Review the summary information, and then click **Finish**.

---

# Loading Data into Domains

## Overview: Loading Data into Domains

You load study data into a domain (convert the study data into CDISC SDTM target files) by creating a SAS Data Integration Studio job. The job that you create to load the data uses standard SAS Data Integration Studio functionality. The job does not require any functionality from SAS Clinical Data Integration.

For more information about creating a job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Generating Unique Sequence Numbers as an Identifier Variable

### Overview: Generating Unique Sequence Numbers as an Identifier Variable

Some of the domains in the CDISC SDTM data standard model require a sequence number as an identifier variable (–SEQ). This sequence number ensures the uniqueness of records for each subject within a data set.

For example, a study might contain a series of vital signs collected during each visit. On some days, several readings were taken for heart rate and blood pressure. Before you can load study data into the SDTM VS domain, you need to uniquely identify each of these vital signs for each subject. This means that when you convert the study data, you need to populate each domain and populate the VSSEQ variable.

Use the Subject Sequence Generator transformation to generate a unique sequence number across subjects in a domain. After running the Subject Sequence Generator transformation, another variable is generated. This variable enables you to uniquely identify each vital sign.

**Note:** For detailed information about creating a job with a transformation, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Generate Unique Sequence Numbers

To generate unique sequence numbers with the Subject Sequence Generator transformation, perform the following steps:

1 Create an empty job.

   For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2 From the **Folders** tree, drag and drop and drop the source table for the domain onto the diagram.

3 In the **Transformations** tree, expand **Clinical**, and then drag and drop **Subject Sequence Generator** onto the diagram.

4 Drag the cursor from the source table to the input port of the transformation.

   This action connects the source to the Subject Sequence Generator transformation.

5 In the **Transformations** tree, expand the **Access** folder, and then drag and drop **Table Loader** onto the diagram.

6 Drag the cursor from the output table to the input port of the Table Loader.

   This action connects the Subject Sequence Generator_OUTPUT table to the Table Loader.

7 From the **Folders** tree, drag and drop the SDTM VS domain that you want to populate onto the diagram.

8 Drag the cursor from the output port of the Table Loader to the input port of the SDTM VS domain.

   This action connects the Table Loader to the SDTM VS domain (the data target).

9 In the diagram, double-click **Subject Sequence Generator**.

   The Subject Sequence Generator Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

10 Click the **Options** tab.

11 (Optional) From the **Update Source** drop-down list, select a value.

   ■ **NO** indicates that the source table is not modified (that is, PROC SORT output is sent to a work table).

   ■ **YES** indicates that the source table is modified directly by PROC SORT in the code generation.

12 From the **Sequence Key Variable** drop-down list, select the name of the sequence variable in the target domain (–SEQ).

13 In the **Business Keys** list, adjust the order of the available keys.

   This list identifies the keys in the source table. Use these keys to sort the data.

14 From the **Subject Variable** drop-down list, select a variable.

   The subject variable represents the unique subject identifier (USUBJID).

15 Click **OK**.

16 Save and run the job.

   SAS Data Integration Studio generates the SAS code for transforming, and then submits the code to SAS. The –SEQ variable is populated with a sequence number that is unique for each record for each subject.

# Assessing CDISC SDTM Compliance

## Overview: Assessing CDISC SDTM Compliance

You assess the structural and content compliance of a domain with a data standard (such as CDISC SDTM) by using the CDISC-SDTM Compliance transformation. You can assess an individual domain or a set of domains. The process assesses whether the selected domains comply with the data standard.

**Note:** For detailed information about creating a job with a transformation, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Assess CDISC SDTM Compliance

To assess CDISC SDTM compliance, perform the following steps:

1 Create an empty job.

   For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2 In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-SDTM Compliance** onto the diagram.

   The Diagram tab displays the **CDISC-SDTM Compliance** transformation and the Results and Metrics work tables.
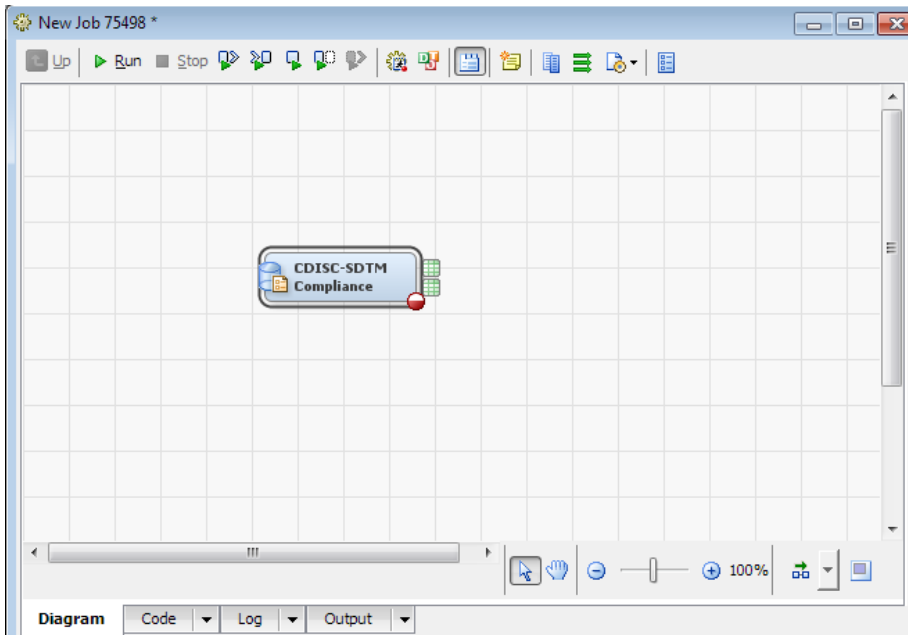
3  (Optional) To store the Results and Metrics work tables in a permanent location, perform the following steps:

   **Note:** By default, the work tables are written to a temporary work location.

   a  Right-click each Work Table icon ( ), and then select **Properties**.

      The Properties dialog box appears.

      For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

   b  Click the **Physical Storage** tab, select a SAS library for the **Location** field, and then click **OK**.

4  In the diagram, double-click **CDISC-SDTM Compliance**.

   The CDISC-SDTM Compliance Properties dialog box appears.

5  Click the **Data Standard** tab.

   All active SDTM data standards are displayed.

6  Select a data standard, and then click the **Tables** tab.

The studies and submissions are displayed.

7   Expand a study or submission to view its domains.

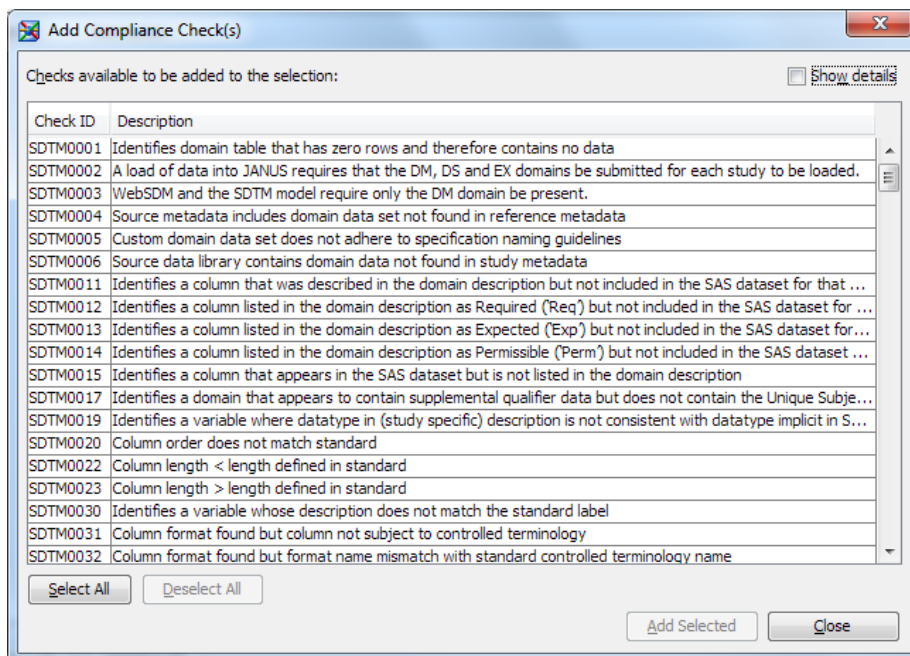8   Select the domains to validate, or select the study or submission to select all of its domains.

   **Note:** You can select domains from multiple studies and submissions.

9   Click the **Checks** tab.

10  If no compliance checks are displayed, perform the following steps:

   a   Click **Add**.

      The Add Compliance Check(s) dialog box appears with a list of all available compliance checks.



   b   Click **Show details**.

      Detailed information about each compliance check appears.

**Note:** If you imported the CDISC SDTM 3.1.2 data standard, then compliance checks for this data standard also appear in the **Standard** column in the **Checks** tab. A check that has the value **CDISC-SDTM** applies to both the CDISC SDTM 3.1.1 and CDISC SDTM 3.1.2 standards. A check that has the value `CDISC-SDTM 3.1.2` applies to the CDISC SDTM 3.1.2 standard only.

  **c**  Select one or more checks, click **Add Selected**, and then click **Close**.

**Note:** Some check IDs are listed more than once. When you select **Show details**, you can view information that makes the individual compliance check unique. For example, consider the check ID SDTM0001:

- In the first record, **Source** is **Janus** and **Severity** is **Note**. If the domain fails this compliance check, then the Results work table reports a note.

- In the second record, **Source** is **WebSDM** and **Severity** is **Warning**. If the domain fails this compliance check, then the Results work table reports a warning.

To be efficient, choose only a subset of the compliance checks. It is inefficient to run the same compliance checks multiple times if the only differences between the checks are severity and source.

**11** (Optional) Click the **Reports** tab, and perform the following steps:

  **a**  Perform one of the following steps:

- Select **Report by Domain** and the **Generate Domain Report** check box

- Select **Report by Check** and the **Generate Check Report** check box

  **b**  Perform one of the following steps:

- Click **Browse** adjacent to **Browse to Folder**, and then navigate to a server folder.

- In the **Server Folder** field, enter the name of a server folder.

The folder must be on the server and must not be a local folder.

    c  Enter a name for the report in the **Report File Name** field, and then specify the report output format.

    d  To limit the number of records to include in the report, enter a number in the **Limit # of records to** field.

      If you leave this field blank, all records are included in the report.

    e  Select the panels to include in the report and whether informational messages are included.

**12** Click **OK** to close the CDISC-SDTM Compliance Properties dialog box.

A green check mark adjacent to the CDISC-SDTM Compliance transformation indicates that the transformation is complete.

**Note:**  If you see 🔴 in the lower right corner of the transformation, click 🔴 and review the error information that appears. A typical error is that selected domains do not contain an assigned library. Correct any errors before running the job.

**13** Click **Run**.

SAS Data Integration Studio generates the SAS code for validating the selected data standard model, and then submits the code to SAS. The Results and Metrics work tables are generated.

**14** Review the Results work table to see the results of the compliance checks.

You might want to connect the Results and Metrics work tables as input to the code that is used to generate formatted reports of the results.

**Note:**  You might encounter errors or warnings in the SAS log during job execution. These errors or warnings do not mean that validation was unsuccessful. Most errors that halt a validation are reported in the Results work table. As a general rule, the Results work table reports failures and provides information about the cause of the failures. For more information about validation, see the *SAS Clinical Standards Toolkit: User Guide*.

# 6

# ADaM Data Sets

# Types of ADaM Data Sets

## Overview: Types of ADaM Data Sets

The ADaM data set can be one of these types:

- ADAE (Analysis Dataset for Adverse Events)
- ADSL (Analysis Dataset for Subject Level)
- BDS (Basic Data Structure analysis data set)

## ADAE Data Set

An ADAE data set relies on one or more of the treatment variables (for example, TRTP, TRTA, TRTxxP, and TRTxxA) in an ADSL data set. Therefore, you must create an ADSL data set before an ADAE data set. When you create an ADAE data set, you must include the ADSL data set as a source data set.

## ADSL Data Set

Only one ADSL data set can be associated with a study or submission.

## BDS Data Set

The BDS data set contains two variables that are required and are key fields: USUBJID and PARAMCD. They are automatically selected to be included in the data set.

The variable AVISIT is also a key field, but it is conditional. You must explicitly select it if your BDS data set includes visit-specific data.

---

# Special Variables

## Variables with xx, y, and zz Parameters

### Overview: Variables with xx, y, and zz Parameters

Some ADaM variables contain embedded parameters that require values. These parameters can be a single digit (denoted by **y** in the name of the variable) or two digits (denoted by **xx** or **zz** in the name of the variable). Example names of such variables are CRITy, TRTxxP, and ANLzzFL. Some variables contain multiple parameters, such as TRxxPGy.

If you include a variable with a parameter in an ADaM data set, you must select the value (or values) to use for the parameter. The values of the parameters become part of the variable's name.

For example, if the variable TRxxPGy is used, and you select values 01 and 02 for xx, and 3 and 4 for y, these variables are created: TR01PG3, TR01PG4, TR02PG3, and TR02PG4.

**Note:** An ADaM data set might contain only a subset of the values that are associated with the xx, y, and zz parameters.

### xx Parameter

The xx parameter represents a two-digit period. Single digits are padded with a leading zero. Valid values are 01–99.

When planning to create an ADaM data set, consider the periods to include in the analysis. Then, assign a unique two-digit number to each period.

### y Parameter

The y parameter represents a single-digit grouping or category, an analysis criterion, or an analysis range. Valid values are 1–9.

When planning to create an ADaM data set, consider the groups or categories, analysis criteria, and ranges to include in the analysis. Then, assign a unique single-digit number to each.

These tables indicate how the y parameter is used in various variables.

*Table 6.1*   *ADSL Grouping Variables*

| Variable | Description of y |
| --- | --- |
| SITEGRy, SITEGRyN | The index of a site-grouping algorithm |
| RACEGRy, RACEGRyN | Denotes the index for a particular pooling or grouping of race |
| TRxxPGy, TRxxPGyN | The index for a particular planned pooled treatment |
| TRxxAGy, TRxxAGyN | The index for a particular actual pooled treatment |

*Table 6.2*   *BDS Grouping Variables*

| Variable | Description of y |
| --- | --- |
| TRTPGy, TRTPGyN | The planned pooled treatment scheme |
| TRTAGy, TRTAGyN | The actual pooled treatment scheme |
| PARCATy, PARCATyN | A parameter category |
| AVALCATy | An analysis category |
| BASECATy, CHGCATy, PCHGCATy | A baseline category |
| R2AyLO, R2AyHI, AyLO, AyHI | An analysis range |
| SHIFTY, SHIFTyN | A group |
| CRITy, CRITyFL, CRITyFN | An analysis criterion |

## zz Parameter

The zz parameter represents a two-digit index for the zzth record selection algorithm. Single digits are padded with a leading zero. Valid values are 01–99.

When planning to create an ADaM data set, consider the record-selection algorithms to use. Then, assign a two-digit number to each algorithm.

## Wildcard Variables

Some ADaM variables contain a wildcard character that requires a value. A wildcard is denoted by an underscore (_) in the name of the variable. Example names of such variables are _DTF, _STM, and _SDTM.

If you include a variable with a wildcard in an ADaM data set, you must select the value to substitute for the wildcard and a value to substitute for the ellipsis (**…**) in the variable description.

**Note:**  The variable name is limited to no more than eight characters.

**Note:**  Part of the variable description is automatically generated. You cannot change this text.

For example, here is the wildcard variable _STM:



In this example, the value for **Name prefix** replaces the underscore in the name _STM. And, the value for **Description suffix** replaces the ellipsis. The generated variable name becomes **prefSTM**. The generated description becomes **Start Time of descSuffix**.

# Creating an ADaM Data Set

## Overview: Creating an ADaM Data Set

You create an ADaM data set in a study or submission. At least one ADaM data standard must be associated with the study or submission. If more than one ADaM data standard is associated with the study or submission, you must choose the data standard to use.

The name of an ADaM data set must start with *AD*, and must be between three and eight characters in length.

**Note:** SAS Clinical Data Integration automatically provides *AD* in the name.

**See Also**

## Data Set Properties

You can view and assign values to the properties that are associated with a data set and its variables.

## Data Sources

The data source for an ADaM data set can be an SDTM domain, another ADaM data set, or any SAS data sets that are associated with the study or submission.

## Variables to Include in the Data Set

You can select which variables to include in an ADaM data set. The variables are listed by category. The variables that are available to you are based on the type of ADaM data set that you choose to create.

**Note:** Certain variables are required and cannot be removed. The names of these variables are contained in [ ].

After you have selected the variables, you can specify this information about the variables:

■ the order of the variables

■ whether a variable is nullable (can have a null value)

■ the variables that are part of the key

■ the order of the key variables

## Compliance Checks

There are dependencies between some variables and rules that govern the inclusion or exclusion of some variables. You can check that these dependencies and rules are satisfied before you create an ADaM data set.

Here are some examples of dependencies and rules:

■ If the TRTxxAN variable is included in a data set, the TRTxxA variable must be included.

■ An ADSL data set must contain at least one TRTxxP variable.

■ An ADAE data set must contain one or more of the ADSL variables TRTP, TRTA, TRTxxP, and TRTxxA.

## Data Set Keys and Nullable Variables

You can choose to make a variable in an ADaM data set a key and to enable the variable to have a null value (nullable).

Here are the rules for data set keys:

■ There must be at least one key variable.

■ At least one key variable cannot be nullable.

## Complete Set of Variables

Before you create an ADaM data set, you review the complete set of variables that you have chosen to include in the data set. For traceability, the source folder, source data set, source variable, and source derivation are shown for each variable.

If a variable is associated with a variable in a source data set, the values are supplied automatically. Otherwise, provide the values.

For each variable, a source derivation field is provided so that you can enter a description or SAS code that describes how the data is mapped from the source data into the variable.

> **TIP** Best practices for traceability require that you provide information about the origin of the data in a data set.

## Create an ADaM Data Set

### Specify Data Set Location and Type

To create an ADaM data set, perform the following steps:

1 In the **Folder** tree, select an ADaM-specific study or submission, and then select **New ▸ Analysis Dataset**.

 The New Analysis Dataset wizard appears.
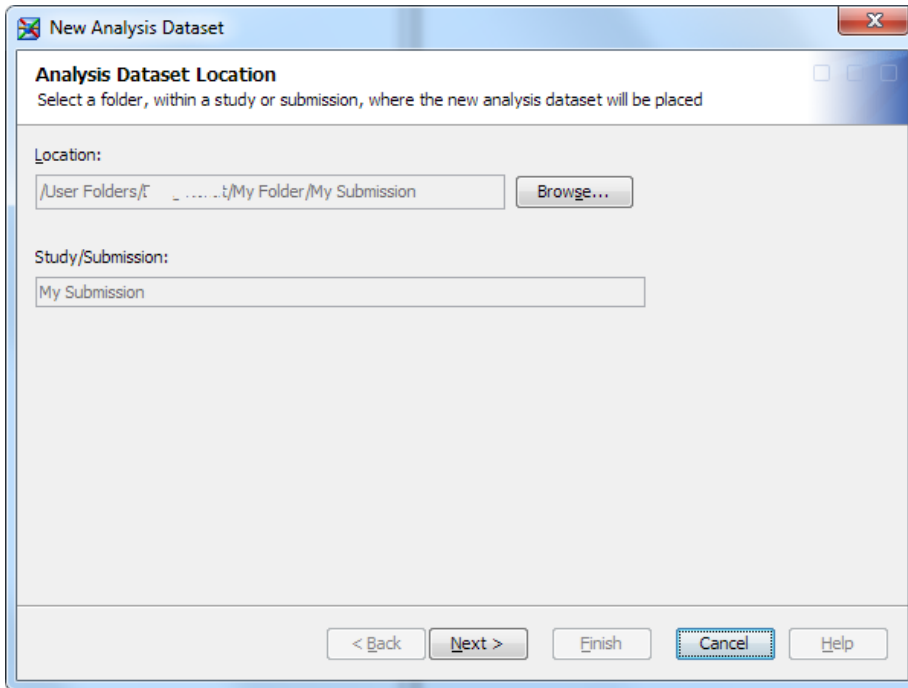
2  (Optional) Click **Browse**, and navigate to the location of an ADaM-specific study or submission.

3  Click **Next**.

   If the study or submission contains multiple ADaM standards, the Analysis Standard Selection page appears. Otherwise, the Analysis Dataset Type page appears.

4  If the Analysis Standard Selection page appears, select a standard, and click **Next**.

   The Analysis Dataset Type page appears.

5  Select an analysis data set type, and click **Next**.

   For more information, see "Overview: Types of ADaM Data Sets" on page 114.

   The General Information page appears.

## Specify General Information and Data Set Properties

1  Enter a name and an identifier.

**Note:** There can be only one ADSL analysis data set in a study or submission. It must be named ADSL.

2   Click **Next**.

The Analysis Dataset Properties page appears.

3   (Optional) Specify the properties.

For more information, see "Data Set Properties" on page 118.

4   Click **Next**.

The Library Selection page appears.

## Specify Library

1   (Optional) Select a library.

2   Click **Next**.

The Source Datasets page appears.

## Specify Data Sources

1   (Optional) Select one or more source data sets.

For more information, see "Data Sources" on page 118.

2   Click **Next**.

If you selected one or more source data sets, the Select Variables from Source Datasets page appears. Otherwise, the Select analysis variables page appears.

## Specify Variables and Check Compliance

1   On the Select Variables from Source Datasets page, perform the following steps:

   a   Select a source data set and one or more source variables.

   b   Click **Add**.

   The variable appears in the **Added Variables** table.

c (Optional) To review variables that do not conform, select one or more variables from the **Source Variables** table or the **Added Variable** table, and click **Non-Compliance**.

The Compliance Check Failures dialog box appears. Each non-compliant variable is listed with the reason why it does not comply.

d To remove an added variable, select a variable in the **Added Variable** table, and click **Remove**.

2 On the Select analysis variables page, use the arrows to move variables between the **Available Variables** list and the **Selected Variables** list.

**Note:** Certain variables are required and cannot be removed. The names of these variables are contained in [ ].

**TIP** You can select a category to move all of the variables in the category at one time.

For more information, see "Variables to Include in the Data Set" on page 118.

3 (Optional) To determine whether the selected variables comply with the rules concerning the dependencies between variables, perform the following steps:

a Click **Check Compliance**.

The Compliance Failures dialog box appears.

For more information, see "Compliance Checks" on page 119.

b Review the error messages, and click **Cancel**.

4 Click **Next**.

If you selected a variable with a parameter, one or more pages appear so that you can specify values for the parameters.

For more information, see "Variables with xx, y, and zz Parameters" on page 115 and "Wildcard Variables" on page 117.

## Specify Variable Parameters

**Note:** You must provide at least one value for each variable parameter. Without a value for each variable parameter, the variables cannot be generated.

1   If the Specify the Grouping Variables page appears, perform the following steps:

   a   From the **Grouping(y) Variables** table, select one or more variables.

   b   From the **Values** list, select one or more values, and click **Assign**.

   c   Click **Next**.

2   If the Specify the Period Variables page appears, perform the following steps:

   a   From the **Period(xx) Variables** table, select one or more variables.

   b   From the **Values** list, select one or more values, and click **Assign**.

   > **TIP**  To limit the number of values, enter a value in the **Maximum value** field, and press Enter.

   c   Click **Next**.

3   If the Specify the Record Selection Algorithm Variables page appears, perform the following steps:

   a   From the **Record Selection(zz) Variables** table, select one or more variables.

   b   From the **Values** list, select one or more values, and click **Assign**.

   > **TIP**  To limit the number of values, enter a value in the **Maximum value** field, and press Enter.

   c   Click **Next**.

4   If the Wildcard Variables page appears, perform the following steps:

   a   From the **Wildcard Variable Templates** table, select one or more variables.

b   Enter a value in the **Name prefix** field and the **Description suffix** field.

c   Click **Add**.

The variable is added to the **Generated Variables** table.

**Note:** You can add the same variable multiple times as long as the name differs.

d   To remove a variable from the **Generated Variables** table, select the variable, and click **Remove**.

e   Click **Next**.

## Order Variables

1   (Optional) On the Order the variables page, select one or more variables, and click **Move Up** and **Move Down** below the table to order the variables.

2   (Optional) To order the data set keys, perform the following steps:

a   Click **Order Keys**.

The Order Domain Keys dialog box appears.

b   Use **Move Up** and **Move Down** to order the keys.

3   Click **Next**.

The Complete Set of Variables page appears.

## Review and Finish

1   Review the set of variables.

> **TIP** Best practices for traceability require that you provide information about the origin of the data in a data set.

2   To edit a value in the **Source Folder**, **Source Dataset**, or **Source Variable** columns, double-click a cell and enter a value.

**Note:** If a variable is associated with a variable in a source data set, the values are supplied automatically.

3   To edit the source derivation of a variable, perform the following steps:

    a   Select a variable, and click **Edit Source Derivation**.

       The **Edit Multiline Property Value for Source Derivation** dialog box appears.

    b   Enter the property value, and click **OK**.

4   Click **Next**.

   The Summary page appears.

5   Review the summary, and click **Finish**.

## Create an ADaM Data Set from a Define.xml File

To create an ADaM data set from a define.xml file, perform the following steps:

1   In the **Folders** tree, select a study or submission specific to ADaM, and then select **New** ▶ **Analysis Dataset(s) From Define**.

   The New Analysis Dataset(s) From Define wizard appears.
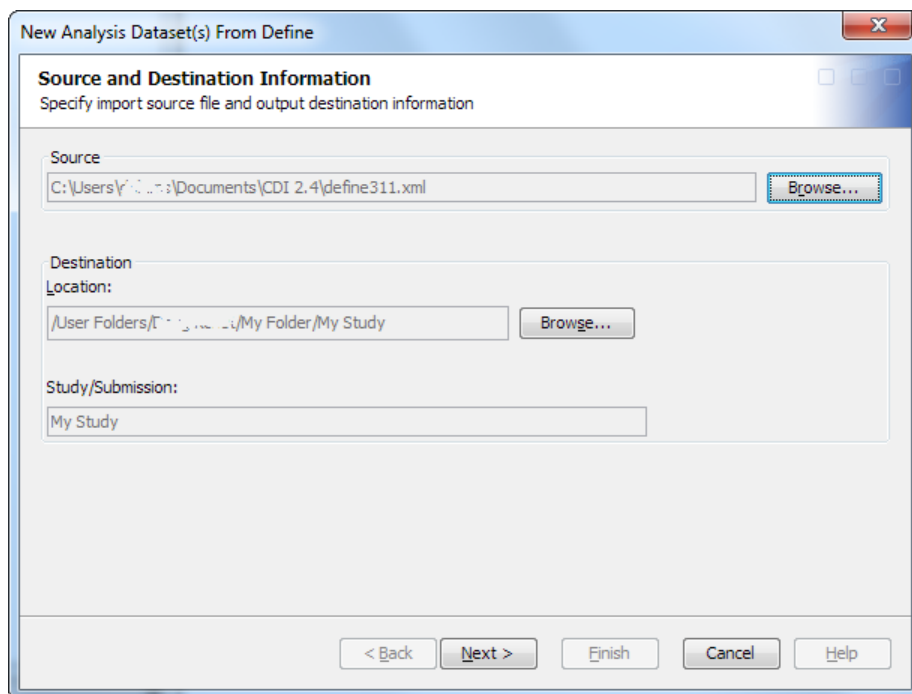
2   Click **Browse** adjacent to **Source**, and navigate to the location of a define.xml file.

3   (Optional) Click **Browse** adjacent to **Location**, and then select a location in which to create the ADaM data set.

4   Click **Next**.

   The Data Standard Selection page appears.

5   Select a data standard to associate with the analysis table, and then click **Next**.

   The Analysis Table Selection page appears.

6   Select one or more analysis tables to import, and then click **Next**.

   The Library Selection page appears.

7   (Optional) Select a library to associate with the analysis table, and then click **Next**.

   The Summary page appears.

8   Review the summary, and then click **Finish**.

# Promoting an ADaM Data Set to Be a User-Defined Template

## Overview: Promoting an ADaM Data Set to Be a User-Defined Template

Typically, an ADaM data set is used within a single study or submission. The ADaM data set is available only to the study or submission in which it is defined. However, when an ADaM data set is promoted to be a user-defined template, the data set can be included in any study or submission.

> **TIP** You can replace a current user-defined template with a revised version. Replacing a current user-defined template enables you to incrementally evolve a data standard rather than creating a new one.

Here are the requirements to promote an ADaM data set:

- The user-defined template name and identifier are required.

- The user-defined template name and identifier must be unique within a data standard.

- The user-defined template identifier must be a valid SAS data set name.

### See Also

## Promote an ADaM Data Set to Be a User-Defined Template

To promote an ADaM data set to be a user-defined template, perform the following steps:

1   In the **Clinical Administration** tree, expand **Data Standards**.

**Note:** You must have appropriate permissions to view the **Clinical Administration** tree. For more information, see Appendix 1, "Addition of Users to the Clinical Administrator Group," on page 193.

2   Right-click an ADaM data set, and then select **Analyze Model Usage**.
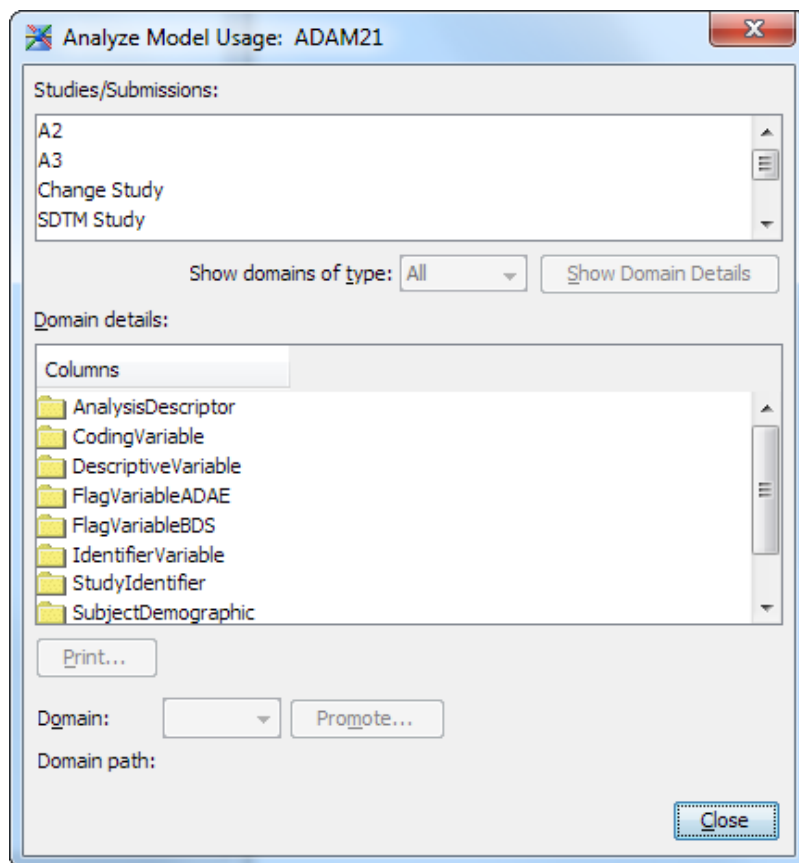
The Analyze Model Usage dialog box appears.



The **Studies/Submissions** list displays all of the studies and submissions that currently use the selected ADaM data set.

3   From the **Studies/Submissions** list, select one or more items.

4   To limit the ADaM data sets to display, select a type from the **Show domains of type** drop-down list.

5   Click **Show Domain Details**.

In the **Domain details** list, a summary of the ADaM data sets and data set columns appears. Each ADaM data set that is included in the selected study or submission appears as a column in the list.

6   To promote an ADaM data set, perform the following steps:

    a   Select a data set from the **Domain** drop-down list, and then click **Promote**.

       The ADaM Template Name and Identifier dialog box appears.

    b   Enter a name and identifier for the user-defined template.

    c   Click **OK**.

7   Click **Close** in the Analyze Model Usage dialog box.

8   To verify that a template was created from the ADaM data set, perform the following steps:

    a   In the **Clinical Administration** tree, expand the selected data standard.

    b   Expand **Domain Templates**.

       The new ADaM data set template appears in this folder.

# Create an ADaM Data Set from a User-Defined Analysis Data Set

To create an ADaM data set from a user-defined analysis data set, perform the following steps:

1   In the **Folders** tree, select an ADaM-specific study, submission, or folder, and then select **New ▶ User-defined Analysis Dataset**.

    The New Analysis Dataset From User Template wizard appears.
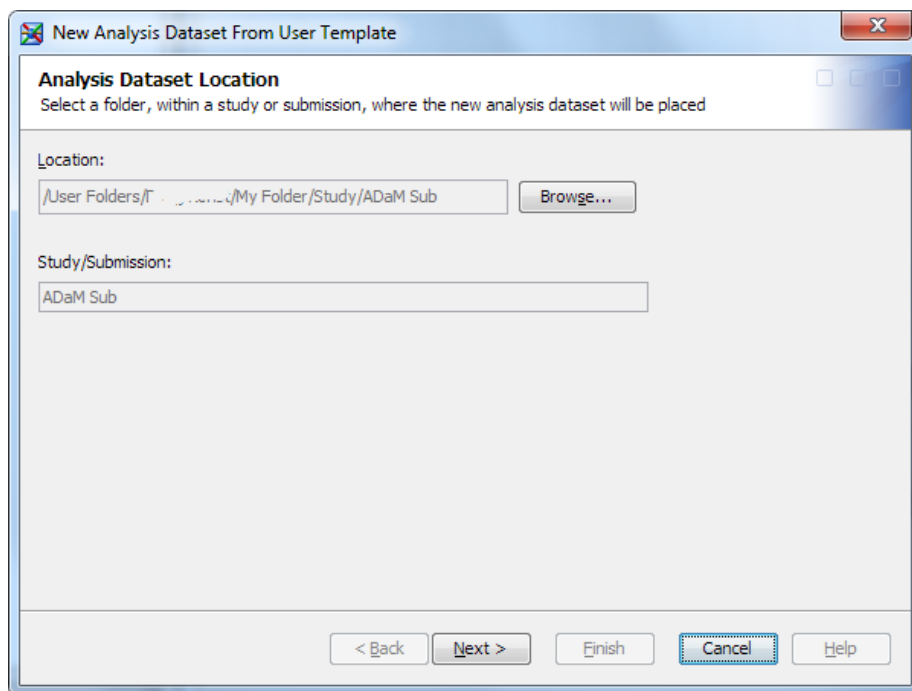
2  (Optional) Click **Browse**, and navigate to the location of an ADaM-specific study or submission.

3  Click **Next**.

The Analysis Dataset Type page appears.

4  Select an analysis data set type, and then click **Next**.

The list contains the data sets that have been promoted to be user-defined templates.

The General Information page appears.

5  Enter a name and an optional description, and then click **Next**.

The Analysis Dataset Properties page appears.

6  (Optional) Specify the properties.

For more information, see "Data Set Properties" on page 118.

7  Click **Next**.

The Library Selection page appears.

8   (Optional) Select a library, and then click **Next**.

The Summary page appears.

9   Review the summary, and then click **Finish**.

## See Also

# Assessing ADaM Compliance

## Overview: Assessing ADaM Compliance

You assess the structural and content compliance of a data set with the ADaM data standard by using the ADaM Compliance transformation. You can assess an individual data set or a set of data sets. The process assesses whether the selected data set complies with the data standard.

**Note:**  For detailed information about creating a job with a transformation, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Assess ADaM Compliance

To assess ADaM compliance, perform the following steps:

1   Create an empty job.

For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2   In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-ADaM Compliance** onto the diagram.

The Diagram tab displays the **CDISC-ADaM Compliance** transformation and the Results and Metrics work tables.
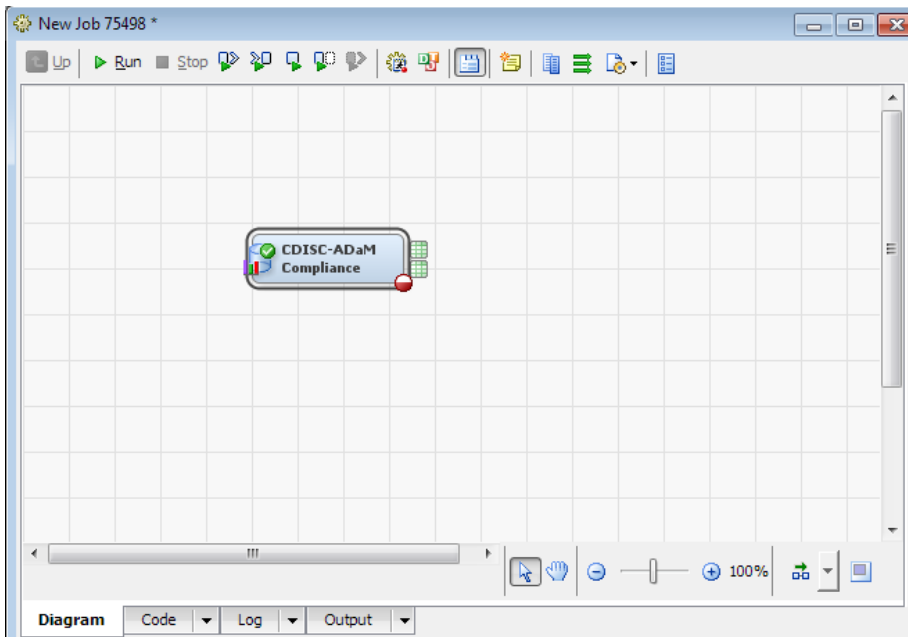


3  (Optional) To store the Results and Metrics work tables in a permanent location, perform the following steps:

**Note:** By default, the work tables are written to a temporary work location.

a  Right-click each Work Table icon ( ), and then select **Properties**.

The Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

b  Click the **Physical Storage** tab, select a SAS library for the **Location** field, and then click **OK**.

4  In the diagram, double-click **CDISC-ADaM Compliance**.

The CDISC-ADaM Compliance Properties dialog box appears.

5  Click the **Data Standard** tab.

All active ADaM data standards are displayed.

6   Select a data standard, and then click the **Tables** tab.

The studies and submissions are displayed.

7   Select an ADaM model and a source model.

8   In the **ADaM Tables to Check** and the **Source Tables to Check** lists, expand a study or submission to view its data sets.

9   Select the data sets to validate, or select the study or submission to select all of its data sets.

**Note:**  You can select data sets from multiple studies and submissions.

10  Click the **Checks** tab.

11  If no compliance checks are displayed, perform the following steps:

a   Click **Add**.

The Add Compliance Check(s) dialog box appears with a list of all available compliance checks.
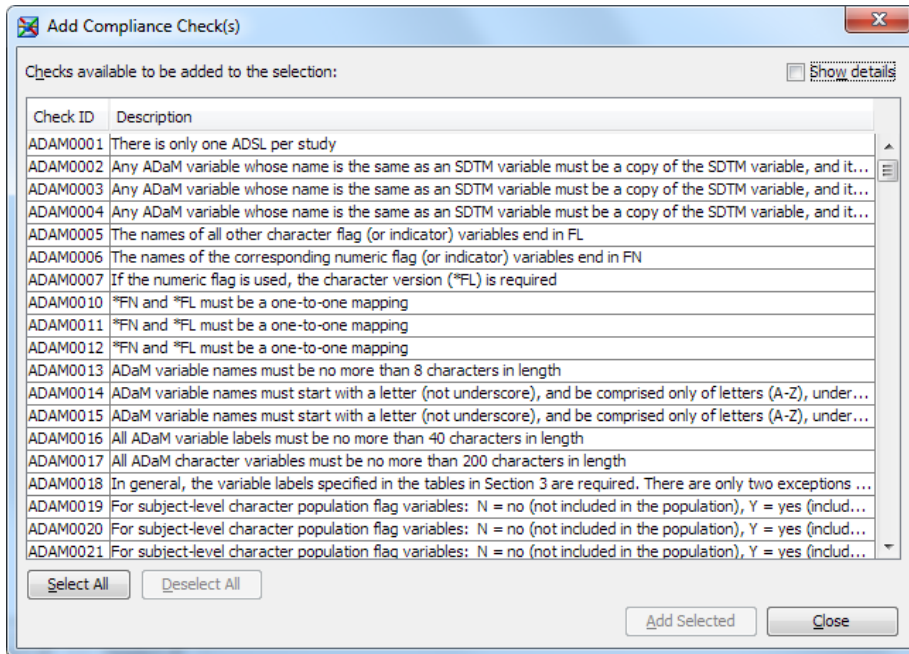
b Click **Show details**.

Detailed information about each compliance check appears.

c Select one or more checks, click **Add Selected**, and then click **Close**.

12 (Optional) Click the **Reports** tab, and perform the following steps:

a Perform one of the following steps:

- Select **Report by Domain** and the **Generate Domain Report** check box

- Select **Report by Check** and the **Generate Check Report** check box

b Perform one of the following steps:

- Click **Browse** adjacent to **Browse to Folder**, and then navigate to a server folder.

- In the **Server Folder** field, enter the name of a server folder.

The folder must be on the server and must not be a local folder.

c Enter a name for the report in the **Report File Name** field, and then specify the report output format.

d To limit the number of records to include in the report, enter a number in the **Limit # of records to** field.

If you leave this field blank, all records are included in the report.

e Select the panels to include in the report and whether informational messages are included.

13 Click **OK** to close the CDISC-ADaM Compliance Properties dialog box.

A green check mark adjacent to the CDISC-ADaM Compliance transformation indicates that the transformation is complete.

**Note:** If you see 🔴 in the lower right corner of the transformation, click 🔴 and review the error information that appears. A typical error is that selected domains do not contain an assigned library. Correct any errors before running the job.

14 Click **Run**.

SAS Data Integration Studio generates the SAS code for validating the selected data standard model, and then submits the code to SAS. The Results and Metrics work tables are generated.

15 Review the Results work table to see the results of the compliance checks.

You might want to connect the Results and Metrics work tables as input to the code that will be used to generate formatted reports of the results.

**Note:** You might encounter errors or warnings in the SAS log during job execution. These errors or warnings do not mean that validation was unsuccessful. Most errors that halt a validation are reported in the Results work table. As a general rule, the Results work table reports failures and provides information about the cause of the failures. For more information about validation, see the *SAS Clinical Standards Toolkit: User Guide*.

# 7

# Creating a Define.xml File

# Transforming SDTM Domains or ADaM Data Sets into a Define.xml File

## Overview: Transforming SDTM Domains or ADaM Data Sets into a Define.xml File

The CDISC-Define Creation transformation transforms SDTM domains or ADaM data sets into a define.xml file. The define.xml file complies with the CRT-DDS standard.

**Note:** For detailed information about creating a job with a transformation, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Register a New Document File

Before you can create a job that uses a define.xml file, you must register a new document file. The document file references the target define.xml file.

**Note:** The target define.xml file is created on the server. If you want to open the target define.xml file from the job, then the target file must be in a shared location that can be accessed from the computer on which you are using SAS Data Integration Studio. An example of a shared location is a network drive.

To register a new document file, perform the following steps:

1 In the **Folders** tree, right-click a folder, and then select **New ▶ Document**.

   The New Document dialog box appears.

2 Enter a name and an optional description.

3 (Optional) Click **Browse** adjacent to the **Location** field, and then navigate to the location in which to store the document.

4 Click **Browse** adjacent to the **File** field, and then navigate to the location of the define.xml file.

5   Click **OK**.

# Transform SDTM Domains or ADaM Data Sets into a Define.xml File

To transform SDTM domains or ADaM data sets into a define.xml file that complies with the CRT-DDS standard, perform the following steps:

1   Create an empty job.

  For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2   In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-Define Creation** onto the diagram.
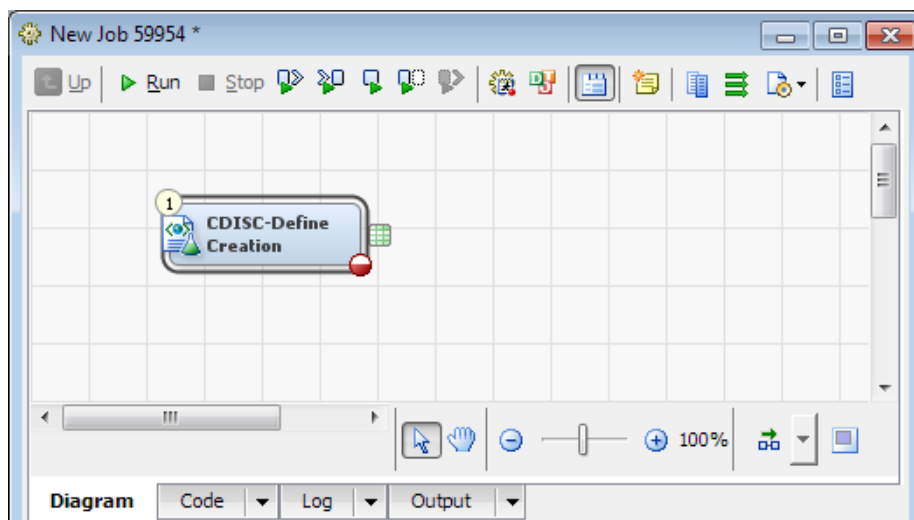


3   In the diagram, double-click **CDISC-Define Creation**.

  The CDISC-Define Creation Properties dialog box appears.

  For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

4   Click the **Tables** tab.

5 From the **Data Model Type** drop-down list, select the type of table or domain to include in the define.xml file.

6 From the **Study/Submission** drop-down list, select a study or submission.

   The **Available Tables by Study/Submission** table displays all data tables that are associated with the study or submission.

7 Select one or more data tables.

8 If you selected multiple data tables and want to change the order of the data tables in the define.xml file, perform the following steps:

   a Click **Order Tables**.

      The Order Tables dialog box appears.

   b Select a data table, and click **Move Up** and **Move Down** to change the order.

   c Click **OK**.

9 (Optional) Click the **Generation** tab, and perform the following steps:

   a Enter the header comment text for the define.xml file.

   b Select a define version, output encoding, and log level.

   c Choose whether to create a define.pdf file and whether to create internal hyperlinks.

   d Select an output style sheet to use.

      **Note:** By default, no output style sheet is used. You can use a default style sheet provided by SAS Clinical Standards Toolkit, or you can select your own style sheet.

   e Choose whether to save the work tables to a permanent location, and browse to the location.

> **TIP**  Saving the work table to a permanent location enables you to further customize the define.xml file. For more information, see "Adding Information to the Define.xml File" on page 142.

10 (Optional) Click the **Reports** tab, and perform the following steps:

   a   Select the **Generate Report** check box.

   b   Perform one of the following steps:

       ■   Click **Browse** adjacent to **Browse to Folder**, and then navigate to a server folder.

       ■   In the **Server Folder** field, enter the name of a server folder.

       The folder must be on the server and must not be a local folder.

   c   Enter a name for the report in the **Report File Name** field, and then specify the report output format.

   d   To limit the number of records to include in the report, enter a number in the **Limit # of records to** field.

       If you leave this field blank, all records are included in the report.

   e   Select the panels to include in the report and whether informational messages are included.

11 Click **OK**.

12 From the **Folders** tree, drag and drop the define.xml file onto the diagram.

13 To connect the CDISC-Define Creation transformation to the define.xml file, drag and drop the cursor from the output port of the transformation to the define.xml file.

14 To store the Results work table in a permanent location, perform the following steps:

   **Note:**  By default, the Results work table is written to a temporary work location.

   a   Right-click the Work Table icon (⊞), and then select **Properties**.

The Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

**b** Click the **Physical Storage** tab, select a SAS library for the **Location** field, and then click **OK**.

**15** Save and run the job.

SAS Data Integration Studio generates the SAS code for transforming, and then submits the code to SAS. The define.xml file is created. If a define.xml already exists in that location, then it is overwritten (if the permissions on the file allow it to be overwritten). The results are written to the CDISC-Define Creation Results table.

**16** Review the Results table, and check for errors or warnings.

You can view the define.xml file by navigating to the location where you created the document file, and then opening the define.xml file with a Web browser. If the Web browser fails to open the define.xml file, and displays an error message about an invalid path, then the define.xml file is located on a drive to which you do not have access. To resolve the problem, move the define.xml file.

# Adding Information to the Define.xml File

## Overview: Adding Information to the Define.xml File

You can save the data from the CDISC-Define Creation transformation so that you can edit the tables to add information to the define.xml file that is not represented in the SAS Clinical Data Integration metadata. The process involves the following tasks:

- save the data from a CDISC-Define Creation transformation

For information, see "Save the Work Tables from a CDISC-Define Creation Transformation" on page 143.

- ▪ include computational algorithm and codelist metadata in the define.xml file

- ▪ add annotated CRF and value-level metadata to the define.xml file

  For information, see "Adding Annotated CRF and Value-Level Metadata to the Define.xml File" on page 145.

## Save the Work Tables from a CDISC-Define Creation Transformation

To save the work tables from a CDISC-Define Creation transformation, perform the following steps:

1 Create an empty job.

  For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2 In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-Define Creation** onto the diagram.

For information about adding a CDISC-Define Creation transformation, see "Transforming SDTM Domains or ADaM Data Sets into a Define.xml File" on page 138.

3   In the diagram, double-click **CDISC-Define Creation**.

The CDISC-Define Creation Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

4   Click the **Generation** tab.

5   Select the **Save work tables to permanent location** check box, and then click **Browse** adjacent to the **Location** field.

The Select Path dialog box appears.

**Note:** The file type is **Folder**. You can select entries that are folders.

6   Select a folder, and then click **OK** twice.

**Note:** The folder must be accessible by the SAS Workspace Server where the code executes. This means that the folder that appears is not on your local computer, but is on the SAS Workspace Server. You must have Write access permission to this folder. If there are tables from a previous CDISC-Define Creation transformation in this folder, they will be overwritten without any prompting.

When creating a define.xml file, select a location into which tables that are created by the CDISC-Define Creation transformation can be copied.

7   Save and run the job.

SAS Data Integration Studio generates the SAS code for creating the define.xml file, and then submits the code to SAS. The define.xml file is created. Several tables are created in the folder that you selected. Depending on the metadata found for the domain and study, many of these tables will be empty. For more information about the tables that are created, see the *SAS Clinical Standards Toolkit: User's Guide*.

# Adding Annotated CRF and Value-Level Metadata to the Define.xml File

## Overview: Adding Annotated CRF and Value-Level Metadata to the Define.xml File

You can include the annotated Case Report Form (CRF) metadata and value-level metadata about the domains that you collected during a study. To do this, you edit the SAS data sets that were generated by the CDISC-Define Creation transformation to include the metadata. Then, you run the %CRTDDS_WRITE macro to generate the define.xml file.

Here is example code that includes annotated CRF metadata:

```
*Lookup OID for the SDTM 3.1.2 standard in MetaDataVersion;
proc sql noprint;
select OID into :mdv from _svWork.MetaDataVersion
where name="CDISC-SDTM 3.1.2";
quit;
*Add records for Annotated CRF;
proc sql;
insert into _svWork.AnnotatedCRFs
set DocumentRef = "BlankCRF",
leafID= "AnnotatedCRF",
FK_MetaDataVersion = "&mdv";
insert into _svWork.MDVLeaf
set ID= "AnnotatedCRF",
href = "./blankcrf.pdf",
FK_MetaDataVersion = "&mdv";
insert into _svWork.MDVLeafTitles
set title= "Blank Annotated CRF",
FK_MDVLeaf = "AnnotatedCRF";
quit;
*reassign srcdata to location of _svWork data sets;
data _null_; path=pathname('_svwork'); rc=libname('srcdata');
rc=libname('srcdata',path);
run;
*create new define.xml file using updated SAS CRT-DDS data sets;
%crtdds_write(_cstCreateDisplayStyleSheet=1);
```

Here is example code that includes the value-level metadata in the SC domain. The code includes two values: **height without shoes** and **weight without shoes**.

```
*Lookup OID for the SDTM 3.1.2 standard in MetaDataVersion;
proc sql noprint;
select OID into :mdv from _svWork.MetaDataVersion
where name="CDISC-SDTM 3.1.2";
quit;
*Lookup OID for the SCTEST column in ItemDefs;
proc sql noprint;
select OID into :srccol from _svWork.ItemDefs
where name='SCTEST';
quit;
*add record for a new valuelist SCTESTVALS;
proc sql ;
insert into _svWork.ValueLists
set OID= "SCTESTVALS",
FK_MetaDataVersion = "&mdv";
*add record associating the value list SCTESTVALS to the OID for SCTEST ItemDefs record;
insert into _svWork.ItemValueListRefs
set ValueListOID= "SCTESTVALS",
FK_ItemDefs = "&srccol";
*add records to the ItemDefs data set for each value in the SCTESTVAL value list;
insert into _svWork.ItemDefs
set OID= "VAL001",
Name = "SCTEST",
DataType = "text",
Length = 3,
SASFieldName = "SCTEST",
comment = "Height taken barefoot",
label="Height in inches",
FK_MetaDataVersion = "&mdv"
set OID= "VAL002",
Name = "SCTEST",
DataType = "text",
Length = 4,
SASFieldName = "SCTEST",
comment = "Weight without shoes",
label="Weight in pounds",
FK_MetaDataVersion = "&mdv";
*add records associating the value list SCTESTVALS to rows in the ItemDefs data set;
insert into _svWork.ValueListItemRefs
set ItemOID= "VAL001",
OrderNumber=1,
Mandatory="Yes",
KeySequence=1,
FK_ValueLists = "SCTESTVALS"
set ItemOID= "VAL002",
OrderNumber=2,
Mandatory="Yes",
```

```
KeySequence=2,
FK_ValueLists = "SCTESTVALS";
quit;
*reassign srcdata to location of _svWork data sets;
data _null_; path=pathname('_svwork'); rc=libname('srcdata');
rc=libname('srcdata',path);
run;
*create new define.xml file using updated SAS CRT-DDS data sets;
%crtdds_write(_cstCreateDisplayStyleSheet=1);
```

For the example code, the define.xml file created contains the value-level metadata for
**Height** and **Weight** for the SCTEST column in the SC domain.

**Note:** If you are viewing an electronic version of this document, you can cut and paste
the example code.

## Add Annotated CRF Metadata or Value-Level Metadata to the Define.xml File

To add annotated CRF metadata or value-level metadata to the define.xml file, perform
the following steps:

1 Create an empty job.

   For detailed information about creating an empty job, see the *SAS Data Integration
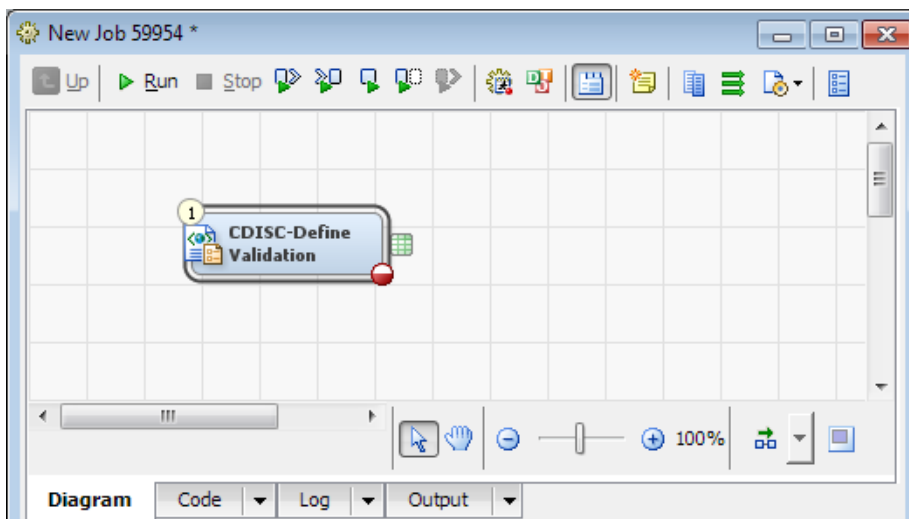   Studio: User's Guide* or the SAS Data Integration Studio online Help.

2 In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-
   Define Creation** onto the diagram.

For detailed information about adding a CDISC-Define Creation transformation, see "Transforming SDTM Domains or ADaM Data Sets into a Define.xml File" on page 138.

3  In the diagram, double-click **CDISC-Define Creation**.

The CDISC-Define Creation Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

4  Click the **Generation** tab.

5  Select the **Save work tables to permanent location** check box, click **Browse** adjacent to the **Location** field, and then select a location.

For more information about saving tables, see "Save the Work Tables from a CDISC-Define Creation Transformation" on page 143.

6  Click **OK** twice.

7  Click **Run**.

The define.xml file is generated, and the SAS data sets used to generate the file are included.

8  To add records to the annotatedcrfs, mdvleaf, and mdvleaftitles data sets (for CRF metadata), or valuelists, itemvaluelistrefs, valuelistitemrefs, and itemdefs data sets (for value-level metadata), perform the following steps:

   a  In the **Transformations** tree, expand **Data**, and then drag and drop **User Written Code** onto the diagram.

   b  In the diagram, double-click **User Written**.

      The User Written Properties dialog box appears.

      For more information about the properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

   c  (Optional) Click the **General** tab, and then rename the transformation.

   d  Click the **Code** tab.

   e  From the **Code generation mode** drop-down list, select **All user written**.

   f  In the code editor, enter the code to include annotated CRF metadata or the value-level metadata.

      For example code, see "Overview: Adding Annotated CRF and Value-Level Metadata to the Define.xml File" on page 145.

   g  Click **OK**.

9  Click **Run**, and then review the define.xml file to ensure that the annotated CRF metadata or the value-level metadata is included.

# Creating the Define.xml file from Customized Data

## Overview: Creating the Define.xml file from Customized Data

The CDISC-Define Creation transformation operates on saved data so that SAS programmers who are familiar with the table model representation for CRT-DDS can add customizations to a define.xml file. This is a two-step process:

1 Insert custom study metadata into the saved CRT-DDS tables.

2 Generate a customized define.xml file from these updated tables.

Here is example code that creates a define.xml file from saved data. Edit this example code to point to the location of the customized tables.

```
%let SASCrtddsTables = %nrquote(\\myCDIServer\mydatatables);

%let DefPath = %nrquote(\\myCDIServer\myDefineLocation);

%let DefFile = %nrquote(define.xml);

%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);

%cst_setStandardProperties(_cstStandard=CDISC-CRTDDS,_cstSubType=initialize);

%let workPath=%sysfunc(pathname(work));

%let _cstSASRefs=work.sasreferences;

%let _cstSASRefsLoc=&workpath;

%let _cstSASRefsName=sasreferences;

%let _cstResultsds=crtdds_results;

%cst_createdsfromtemplate(_cstStandard=CST-FRAMEWORK, _cstType=control,_cstSubType=reference, _cstOutputDS=work.sasreferences);

%LET _CSTSTANDARD=CDISC-CRTDDS;

%LET _CSTSTANDARDVERSION=1.0;

proc sql;

insert into work.sasreferences

values ("CST-FRAMEWORK" "1.2" "messages" "" "messages" "libref" "input" "dataset"
            "N" "" "" 1 "" "")

values ("&_cstStandard" "&_cstStandardVersion" "messages" "" "crtmsg" "libref" "input" "dataset"
            "N" "" "" 2 "" "")

values ("&_cstStandard" "&_cstStandardVersion" "autocall" "" "auto1" "fileref" "input" "folder" "
            N" "" "" 1 "" "")

values ("&_cstStandard" "&_cstStandardVersion" "control" "reference" "control" "libref" "both" "dataset"
            "Y" "" "&workpath" . "sasreferences" "")
```

```
values ("&_cstStandard" "&_cstStandardVersion" "sourcedata" "" "srcdata" "libref" "input" "folder"
          "N" "" "&SASCrtddsTables" . "" "")
values ("&_cstStandard" "&_cstStandardVersion" "externalxml" "xml" "extxml" "fileref" "output" "file"
          "Y" "" "&defpath" . "&deffile" "")
values ("&_cstStandard" "&_cstStandardVersion" "referencexml" "stylesheet" "xslt01" "fileref" "output" "file "
          Y" "" "" . "" "")
;
quit;
%let _cstReallocateSasrefs=1;
%cstutil_allocatesasreferences;
%crtdds_write(_cstCreateDisplayStyleSheet=1,_cstResultsOverrideDS=&_cstResultsDS);
```

In the example code, edit SASCrtddsTables to specify the location where the saved data sets exist, and edit DefPath to specify the location to write the resulting define.xml file.

**Note:** If you are viewing an electronic version of this document, you can cut and paste the example code.

# Create a Define.xml File Using Customized Data

To create a define.xml file using customized data, perform the following steps:

1  Create an empty job.

   For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2  In the **Transformations** tree, expand **Data**, and then drag and drop **User Written Code** onto the diagram.

3  In the diagram, double-click **User Written**.

   The User Written Properties dialog box appears.

4  Click the **Code** tab.

5  From the **Code generation mode** drop-down list, select **All user written**.

6  In the code editor, enter the code to create the define.xml file.

For example code, see "Overview: Creating the Define.xml file from Customized Data" on page 150.

7    Click **OK** and then click **Run**.

8    From the Windows **Start** menu, select **Run**, and then enter the location where the data sets are located (for example, `\\myCDIServer\mydata\crtdds_tables`).

9    Open the define.xml file to view the customizations that you created.

# Validating a Define.xml File

## Overview: Validating a Define.xml File

The CDISC-Define Validation transformation assesses the validity of the define.xml file. Validity is based on the XML standards as defined by CDISC.

Validity is based on the following criteria:

■   The XML is well formed.

■   The XML meets the XML schema specification for the CDISC standard.

**Note:** For detailed information about creating a job with a transformation, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

## Register a New Document File

Before you can create a job to validate a define.xml file, you must register a new document file. The new document file must point to an existing define.xml file in a location that the SAS Workspace Server can access.

For more information about registering a new document file, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

# Validate a Define.xml File

To validate a define.xml file, perform the following steps:

1   Create an empty job.

    For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2   In the **Transformations** tree, expand **Clinical**, and then drag and drop **CDISC-Define Validation** onto the diagram.



3   From the **Folders** tree, drag and drop the define.xml file onto the diagram.

4   Drag the cursor from the define.xml file to the input port of the transformation.

    This action connects the define.xml file to the transformation.

5   To store the Results work table permanently, perform the following steps:

    **Note:**  By default, the Results work table is written to a temporary work location.

    a   Right-click the Work Table icon ▦, and then select **Properties**.

        The Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

   **b**  Click the **Physical Storage** tab, select a SAS library for the **Location** field.

**6**  (Optional) In the diagram, double-click **CDISC-Define Validation**.

The CDISC-Define Validation Properties dialog box appears.

   **a**  Click the **Validation** tab, and select a define version to use for the validation.

   **b**  Click the **Reports** tab, and perform the following steps:

      **a**  Select the **Generate Report** check box.

      **b**  Perform one of the following steps:

         ■  Click **Browse** adjacent to **Browse to Folder**, and then navigate to a server folder.

         ■  In the **Server Folder** field, enter the name of a server folder.

      The folder must be on the server and must not be a local folder.

      **c**  Enter a name for the report in the **Report File Name** field, and then specify the report output format.

      **d**  To limit the number of records to include in the report, enter a number in the **Limit # of records to** field.

      If you leave this field blank, all records are included in the report.

      **e**  Select the panels to include in the report and whether informational messages are included.

   **c**  Click **OK** to close the CDISC-Define Validation Properties dialog box.

**7**  Click **Run**.

SAS Data Integration Studio generates the SAS code for validating, and then submits the code to SAS. The define.xml file is validated, and then the results are written to the Validation Results work table.

If there are errors in the define.xml file, the Validation Results work table provides a message for each error. An error message includes the line and column number in the define.xml file that generated the error.

# 8

# SAS Transport Files

## Overview of SAS Transport Files

When this document was published, the Food and Drug Administration expects clinical and non-clinical data to be delivered in the SAS Version 5 transport format.

SAS Clinical Data Integration provides two transformations to support this goal. One transformation imports a SAS Version 5 transport file, and one transformation exports a SAS Version 5 transport file.

## Import a SAS Version 5 Transport File

To import a SAS Version 5 transport file, perform the following steps:

1 Create an empty job.

   For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

2   In the **Transformations** tree, expand **Clinical**, and then drag and drop **SAS Version 5 Transport File Import** onto the diagram.
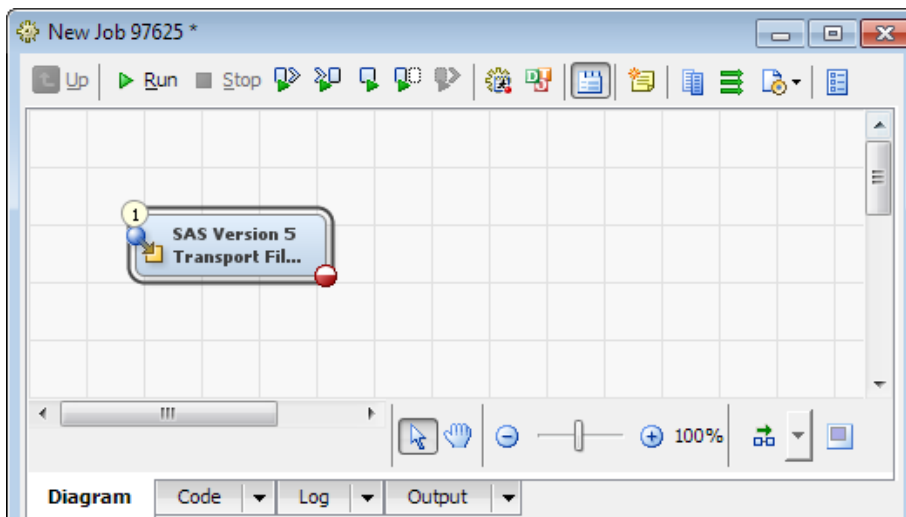


3   In the diagram, double-click **SAS Version 5 Transport File Import**.

The SAS Version 5 Transport File Import Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

4   Click the **Options** tab, and then select **General** from the list on the left.

5   Click **Browse** adjacent to the **SAS Version 5 Transport File** field, and then select a location that is accessible by the remote SAS server.

**Note:** The Select a File dialog box displays only files with the extension .xpt.

6   Click **Browse** adjacent to the **Imported Data Library** field, and then select a location in which to write the data sets.

7   Click **OK** to close the SAS Version 5 Transport File Import Properties dialog box.

A green check mark adjacent to the SAS Version 5 Transport File Import transformation indicates that the transformation is complete.

**Note:** If you see ⬤ in the lower right corner of the transformation, click ⬤ and review the error information that appears.

**8**  Click **Run**.

**9**  Verify that there are no errors.

**10** Register the tables in the library that was created.

For more information about registering tables, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

# Export a SAS Version 5 Transport File

To export a SAS Version 5 transport file, perform the following steps:

**1**  Create an empty job.

For detailed information about creating an empty job, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

**2**  In the **Transformations** tree, expand **Clinical**, and then drag and drop **SAS Version 5 Transport File Export** onto the diagram.
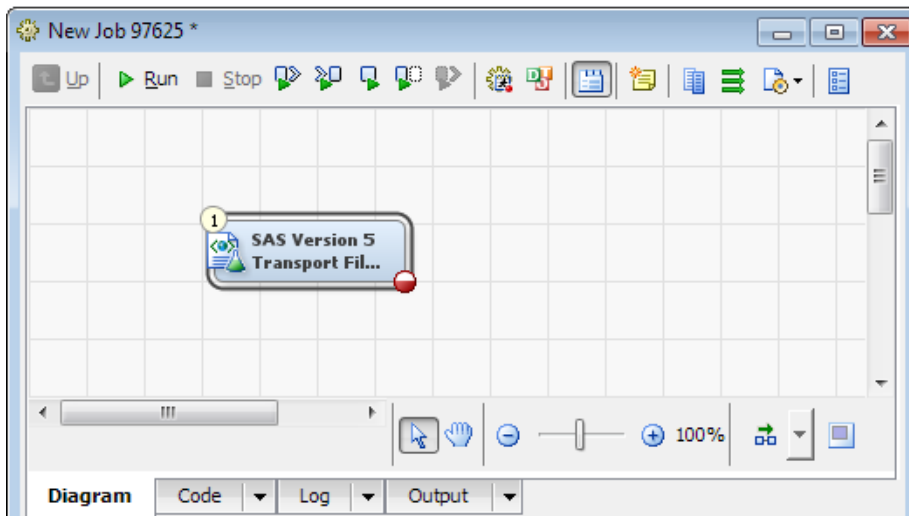


**3**  In the diagram, double-click **SAS Version 5 Transport File Export**.

The SAS Version 5 Transport File Export Properties dialog box appears.

For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

4 Click the **Export Options** tab, click **Browse** adjacent to the **Libref** field, and then select a SAS library.

The list of registered tables in the SAS library appears.

5 Select one or more tables.

6 Click **Browse** adjacent to the **Destination Folder** field, and then select a location in which to write the transport file.

7 To disable overwriting an existing transport file, clear **Allow overwrite of existing transport files**.

8 Click **OK** to close the SAS Version 5 Transport File Export Properties dialog box.

A green check mark adjacent to the SAS Version 5 Transport File Export transformation indicates that the transformation is complete.

**Note:** If you see 🔴 in the lower right corner of the transformation, click 🔴 and review the error information that appears.

9 Click **Run**.

10 Verify that there are no errors.

# Part 5

# SAS Integration Adapter for Medidata Rave

# 9

# General Administration

## Define a Medidata Rave Server

To define a Medidata Rave server, perform the following steps:

1  Log in to SAS Management Console.

2  Define a new server with the following properties:

■ For the server type, select **Resource Templates ▶ Servers ▶ Content Servers ▶ HTTP Server**.

■ For the base path, define a new base path that is set to the Medidata Rave Web Services, such as /RWS.

■ For the application server type, select **Medidata Rave**.

■ For the authentication domain, specify a new or existing authentication domain. Specify the application protocol as HTTPS, and enter the host name.

For more information about defining a server, see the SAS Management Console online Help.

# Enable a SAS Clinical Data Integration User to Log In to Medidata Rave

To enable a SAS Clinical Data Integration user to log in to Medidata Rave, perform the following steps:

1  Log in to SAS Management Console as a user with permission to add server instances and manage users and groups.

2  Add or modify a SAS Clinical Data Integration user account with the following properties:

   ▪ For the login information, create new login information using the user ID and password to access the Medidata Rave server.

   ▪ For the authentication domain, specify the same authentication domain that is specified for the Medidata Rave server that you are using.

For more information about adding or modifying a user account, see the SAS Management Console online Help.

# Verify That the Medidata Rave Server Has Been Registered Properly

To verify that the Medidata Rave server has been registered properly, perform the following steps:

1  Log in to SAS Clinical Data Integration.

2  Select **Tools** ▶ **Medidata Rave** ▶ **Servers**.

The Registered Rave Servers dialog box appears.
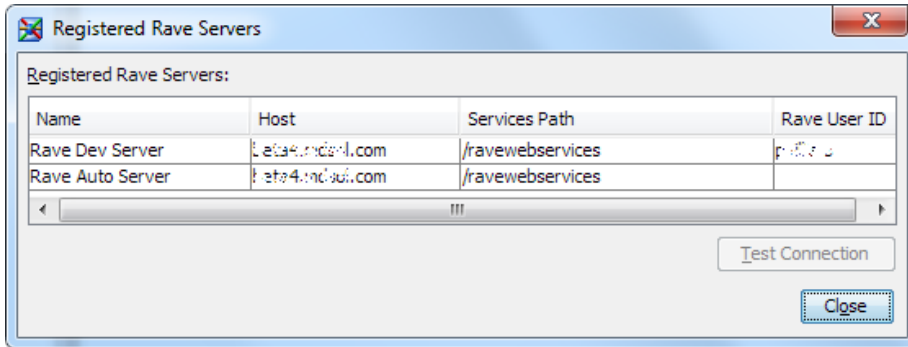


3   Verify that the **Host**, **Services Path**, and **Rave User ID** (the Medidata Rave user ID for the current SAS Clinical Data Integration user) are correct.

4   Select the row for the Medidata Rave server that you just defined, and then click **Test Connection**.

5   Click **Close**.

# 10

# Study Administration

# Manage the Connection between a SAS Clinical Data Integration Study and a Medidata Rave Study

## Create a Connection between Studies

**Note:** You must have Administrator access permissions to the SAS Clinical Data Integration study.

To create a connection between studies, perform the following steps:

1   In the **Folders** tree, right-click a SAS Clinical Data Integration study root folder, and then select **Connect to Medidata Rave**.

The Connect to a Rave Study wizard appears.
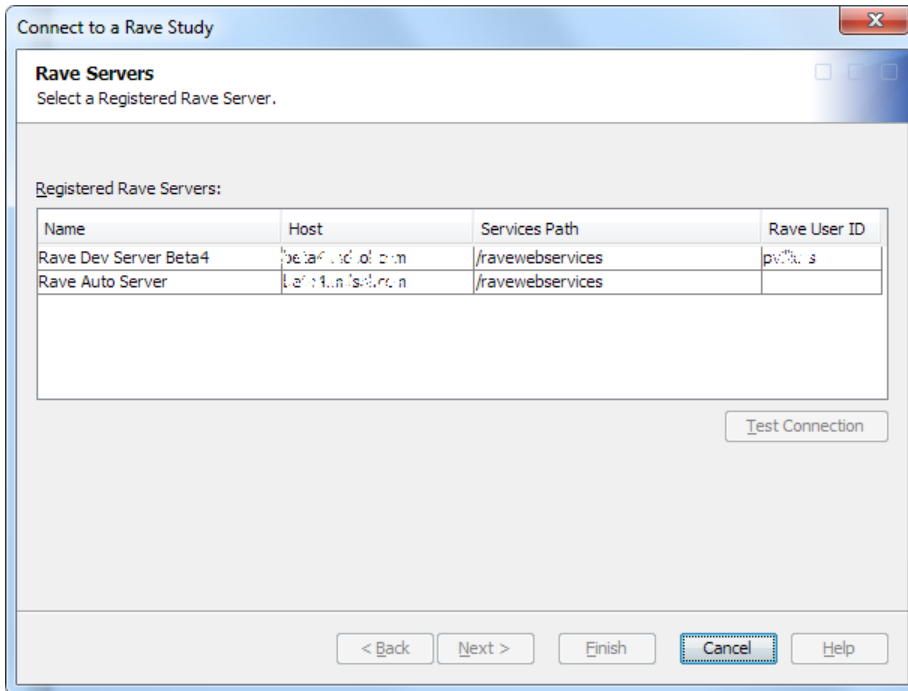
2   Select a server from the **Registered Rave Servers** table.

3   (Optional) Test the connection to the server.

4   Click **Next**.

The Rave Studies page appears.
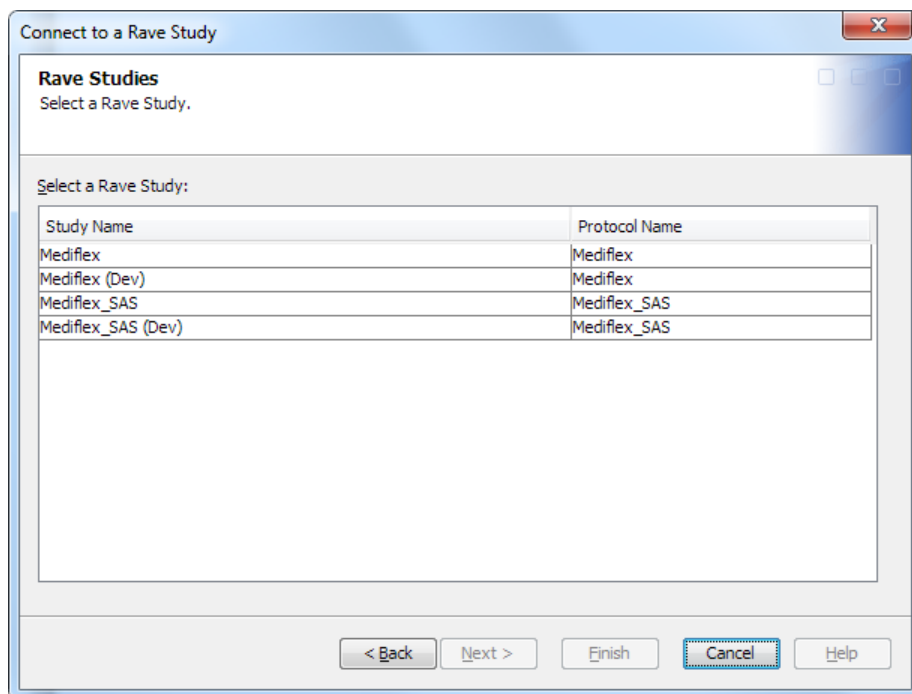
5   Select a study from the **Select a Rave Study** table, and then click **Finish**.

6   (Optional) Verify the connection by performing the following steps:

   a   In the **Folders** tree, right-click the study root folder, and then select **Properties**.

       The Properties dialog box appears.

   b   Click the **Medidata Rave** tab.

       The **Medidata Rave** tab contains a table with entries that specify the properties
       of the Medidata Rave study associated with the SAS Clinical Data Integration
       study. This information includes the Medidata Rave server information (name,
       host, base path, and user name) and the Medidata Rave study information (OID,
       study name, and protocol name).

   c   Click **OK**.

# View the Mappings between Studies

To view the mappings between studies, perform the following steps:

1 Select **Tools** ▶ **Medidata Rave** ▶ **Study Mappings**.

The CDI-Rave Study Mappings dialog box appears.
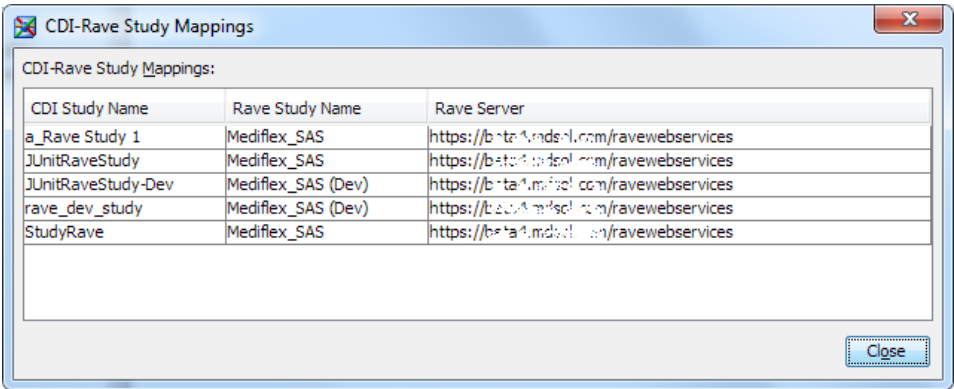


Each row of the table shows a mapping between a SAS Clinical Data Integration study and a Medidata Rave study on a specific Medidata Rave server.

2 Review the mappings, and then click **Close**.

# Disconnect a SAS Clinical Data Integration Study from a Medidata Rave Study

To disconnect a SAS Clinical Data Integration study from a Medidata Rave study, in the **Folders** tree, right-click a mapped SAS Clinical Data Integration study root folder, and then select **Disconnect from Medidata Rave**.

**Note:** When you disconnect the studies, the data and objects are not deleted. However, all metadata properties specific to the Medidata Rave connection are deleted from the objects.

# Create a SAS Clinical Data Integration Data Table Definition from Medidata Rave Metadata

**Note:** You must have Administrator access permissions to the SAS Clinical Data Integration study.

Before you can populate a SAS Clinical Data Integration study with data extracted from a Medidata Rave study, you must create at least one data table definition.

To create a SAS Clinical Data Integration data table definition from Medidata Rave metadata, perform the following steps:

1   In the **Folders** tree, navigate to the SAS Clinical Data Integration study root folder that is mapped to a Medidata Rave study.

2   Right-click a SAS Clinical Data Integration study folder, and then select **Import Medidata Rave Table Definitions**.

A progress indicator appears, and then the Import Medidata Rave Table Definitions wizard appears.

All Medidata Rave table definitions for the study and the study version are listed.
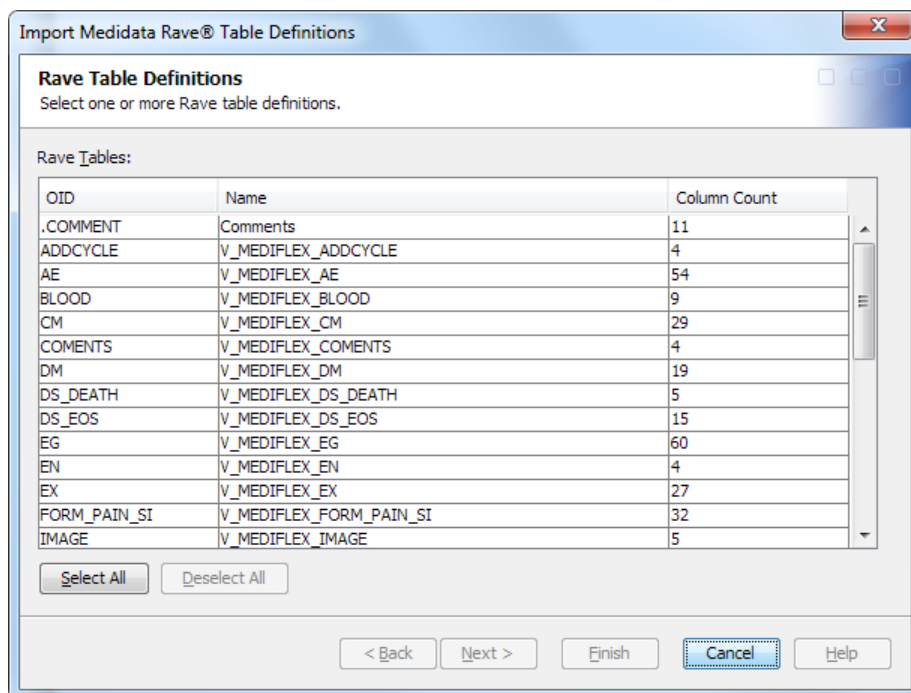
**Note:** The list does not contain table definitions that have no columns.

3   Select one or more tables to import.

4   Click **Next**.

If you select a Medidata Rave table that has been previously imported into the target folder, a warning appears. You must select a different table. Or, you can exit the wizard, and delete the table from the target folder.

The SAS Library page appears.
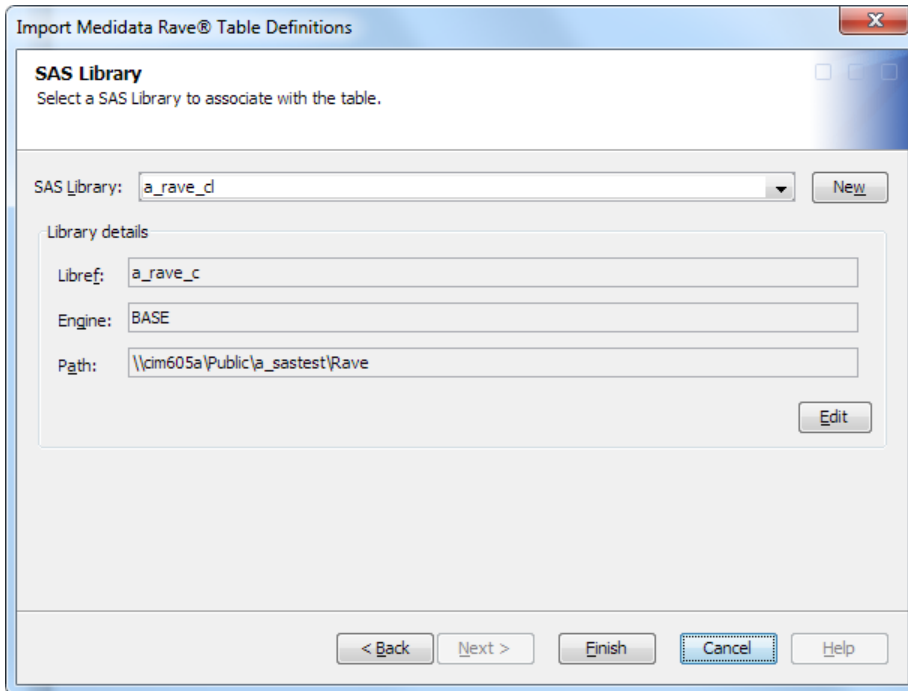
5   Using the standard SAS Data Integration Studio library controls, select a library, or create a library definition.

**Note:** You must have Create access permission to the library that you select.

For help with using these controls, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

6   Click **Finish**.

The tables are imported.

A SAS Data Integration Studio physical table appears in the folder for each imported Medidata Rave table.

**Note:** The data table definition has been created, but the data table has no data at this point.

The name of the SAS Data Integration Studio table is the same as the Medidata Rave table name, except that any characters in the Medidata Rave table name that are not valid for a SAS table name are removed.

## See Also

- ■ "Review the Medidata Rave Properties of a SAS Clinical Data Integration Data Table Definition" on page 184

- ■ "Retrieving Medidata Rave Study Data" on page 185

# Manage the Medidata Rave Properties of a SAS Clinical Data Integration Study

## Display the Medidata Rave Properties

To display the Medidata Rave properties, perform the following steps:

1   In the **Folders** tree, navigate to the SAS Clinical Data Integration study root folder that is mapped to a Medidata Rave study.

  For information, see "Create a Connection between Studies" on page 168.

2   Right-click the SAS Clinical Data Integration study root folder, and then select **Properties**.

  The Properties dialog box appears.

**3** Click the **Medidata Rave** tab.

4   Modify the properties, and then click **OK**.

# Create a Transformation Log Table for a SAS Clinical Data Integration Study

**Note:**  The primary purpose of the Medidata Rave transformation log table is to debug and provide technical support. Do not alter this table in any way.
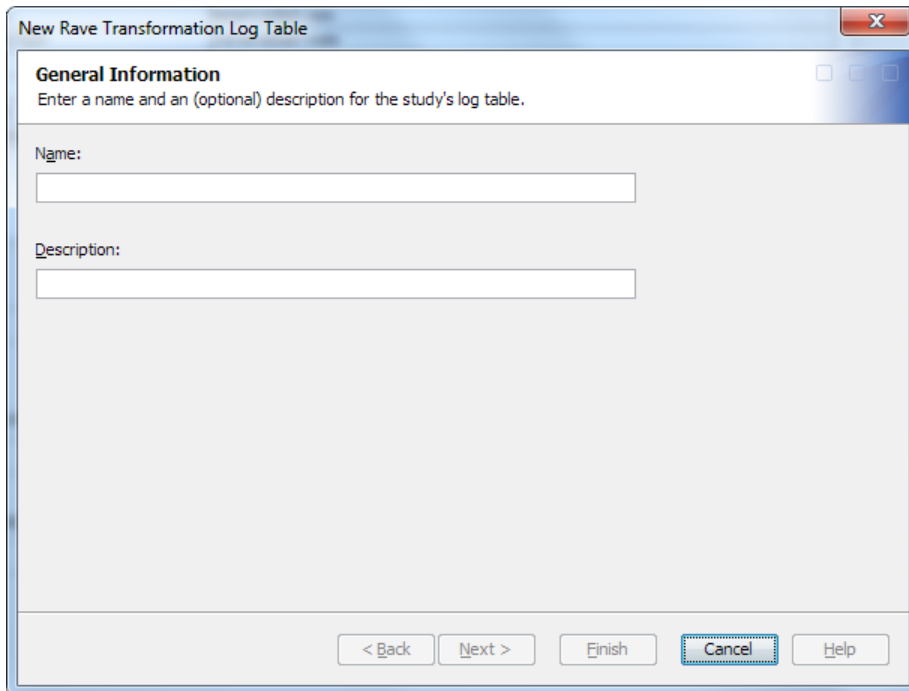
To create a Medidata Rave transformation log table for a SAS Clinical Data Integration study, perform the following steps:

1   Display the Medidata Rave properties.

For information, see "Display the Medidata Rave Properties" on page 175.

2   Click **New** adjacent to the **Transformation Log Table** field.

The New Rave Transformation Log Table wizard appears.



3   Enter a name and optional description, and then click **Next**.

**Note:** The name must be a valid SAS table name.

The SAS Library page appears.



4   Using the standard SAS Data Integration Studio library controls, select a library, or create a library definition.

   **Note:** You must have Create access permission to the library that you select.

   For help with using these controls, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

5   Click **Finish**.

   The log table is created directly beneath the study root folder.

## Disassociate a Log Table from a SAS Clinical Data Integration Study

To disassociate a log table from a SAS Clinical Data Integration study, perform the following steps:

1   Display the Medidata Rave properties.

    For information, see "Display the Medidata Rave Properties" on page 175.

2   Click **Remove** adjacent to the **Transformation Log Table** field.

## Specify the ODM Archive Location for a SAS Clinical Data Integration Study

To specify the Operational Data Model (ODM) archive location for a SAS Clinical Data Integration study, perform the following steps:

1   Display the Medidata Rave properties.

    For information, see "Display the Medidata Rave Properties" on page 175.

2   Click **Browse** adjacent to the **ODM Document Archive Folder** field.

3   If you are prompted to log in to the SAS Foundation server, log on so that you can access the SAS Foundation server's file system.

4   In the ODM Archive Folder dialog box, select a folder to which you have Read and Write access permissions, and then click **OK**.

# Managing the Codelist Table in a SAS Clinical Data Integration Study

## Overview: Managing the Codelist Table in a SAS Clinical Data Integration Study

When you import a codelist table, SAS Clinical Data Integration imports the codelist table only for the study versions that currently have or that could have (in the future) enrolled subjects. These study versions are considered *non-retired* versions.

A non-retired version is the desired version set for a specific study environment. This version set contains all study versions which, for that study environment, contain at least one enrolled subject. The most recent version for an environment or site is included in the set for any environment or site in that study. As a result, the most recent version is always available for the forward migration of subject data, even if no subjects are currently enrolled in the most recent version.

Limiting the codelist table in this way ensures that the codelist table does not include data for versions that will never be referenced.

The structure of a SAS data set required to store Medidata Rave codelist table information is the same across all versions. Therefore, the data in a SAS data set for a codelist table can be reimported without data mismatch or metadata mismatch.

## Create the Codelist Table for a SAS Clinical Data Integration Study
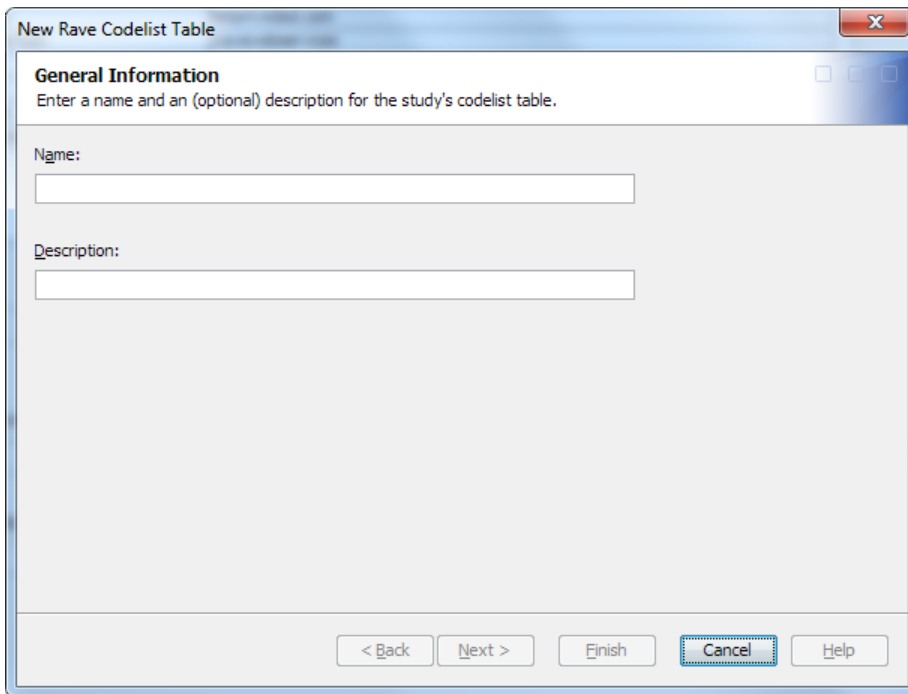
To create the codelist table for a SAS Clinical Data Integration study, perform the following steps:

1   Display the Medidata Rave properties.

    For information, see "Display the Medidata Rave Properties" on page 175.

2   Click **New** adjacent to the **Codelist Table** field.

The New Rave Codelist Table wizard appears.



**3** Enter a name and optional description, and then click **Next**.

**Note:** The name must be a valid SAS table name.

The SAS Library page appears.

4  Using the standard SAS Data Integration Studio library controls, select a library, or create a library definition.

   **Note:** You must have Create access permission to the library that you select.

   For help with using these controls, see the *SAS Data Integration Studio: User's Guide* or the SAS Data Integration Studio online Help.

5  Click **Next**.

   The Codelists page appears.
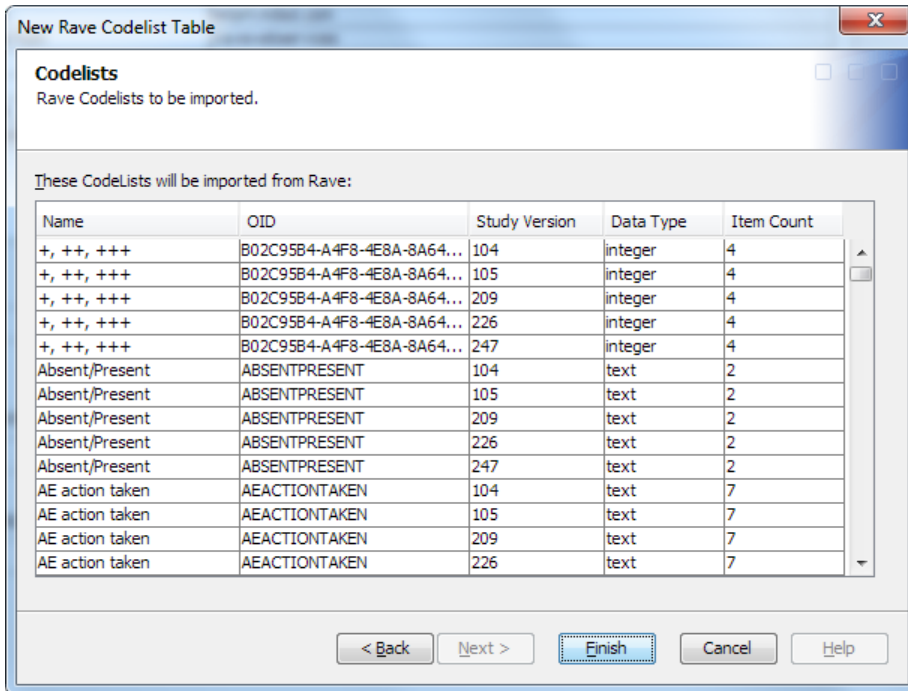
The table lists the codelist tables that are registered to active Medidata Rave studies to which the SAS Clinical Data Integration study is mapped.

Each row in the table represents one declared codelist table to import. The same codelist table can appear multiple times, once for each study version.

6   (Optional) Click a column heading to reorder the table.

**Note:** The information in this table is read-only. You cannot select a row.

7   Click **Finish**.

A codelist table with the specified name and description is created directly beneath the study root folder. The codelist table contains the necessary columns and is associated with the SAS library that you selected.

## Reimport a Codelist Table into a SAS Clinical Data Integration Study

To reimport a codelist table into a study, perform the following step:

In the **Folders** tree, right-click on a codelist table, and then select **Import Codelists from Medidata Rave**.

## Remove the Codelist Table from a SAS Clinical Data Integration Study

To remove the codelist table from a study, perform the following steps:

1   Display the Medidata Rave properties.

For information, see "Display the Medidata Rave Properties" on page 175.

The **Codelist Table** field displays the name of the codelist table associated with the study.

2   Click **Remove** adjacent to the **Codelist Table** field.

Although the codelist table is no longer associated with the study, the codelist table still exists in its original location and retains its data.

## Review the Medidata Rave Properties of a SAS Clinical Data Integration Data Table Definition

To review the Medidata Rave properties of a SAS Clinical Data Integration data table definition, perform the following steps:

1   In the **Folders** tree, right-click a SAS Clinical Data Integration data table definition that was imported from Medidata Rave, and then select **Properties**.

The Properties dialog box appears.

2   Click the **Medidata Rave** tab, and then review the properties of the Medidata Rave data table definition.

3   Click the **Columns** tab, right-click on a column, and then select **Properties**.

The Properties dialog box appears.

4   Click the **Medidata Rave** tab, and then review the properties of the Medidata Rave table column.

5   Click **OK**.

## See Also

# Retrieving Medidata Rave Study Data

## Overview: Retrieving Medidata Rave Study Data

After you have created the SAS Clinical Data Integration data table definitions from Medidata Rave metadata, you can populate the SAS Clinical Data Integration study with data extracted from a Medidata Rave study. There are two transformations to retrieve study data from Medidata Rave.

The Extract Medidata Rave Data transformation deletes all Medidata Rave data from the specified data tables in the associated SAS Clinical Data Integration study. Then, the transformation inserts the Medidata Rave study data into the specified data tables. You specify the data tables when you set up the job.

The Update from Medidata Data Rave transformation updates the Medidata Rave study data in the specified data tables with data that has changed since the study data was last retrieved. You specify the data tables when you set up the job.

If you run the Update from Medidata Data Rave transformation on a SAS Clinical Data Integration data table that has not been populated using either of these two transformations, the Update from Medidata Data Rave transformation populates the study just as the Extract Medidata Rave Data transformation does.

### See Also

## Notification of Potential Changes

When you retrieve study data from Medidata Rave, it is possible that the Medidata Rave table metadata has changed since the data table definition was initially imported. You can choose how to handle a potential change. You can attempt to retrieve the changed data, or you can skip the retrieval of study data for any data table with Medidata Rave table metadata that might have changed. And, you can choose to notify one or more users via e-mail if the transformation detects potential table metadata changes.

The value that you specify for the e-mail address can be a single address, a mailing list, or any other value that is valid for your default e-mail client. The transformation passes the value to the e-mail client without any validation.

**Note:** Notification does not apply to the Medidata Rave Comments table. The structure of the Comments table cannot change across study versions. Therefore, omitting notification prevents unnecessary notifications.

## Set Up the Job to Retrieve Medidata Rave Data

To set up the job to retrieve Medidata Rave data, perform the following steps:

1  In the **Folders** tree, navigate to a SAS Clinical Data Integration study that is mapped to Medidata Rave, and create a job.

2  In the **Transformations** tree, expand **Clinical**.

3  Drag the **Extract Medidata Rave Data** transformation or the **Update from Medidata Rave Data** transformation onto the job, and then double-click the transformation.

   The Properties dialog box appears.

4  To select a Medidata Rave data table definition, perform the following steps:

a   Click the **Tables** tab, select a clinical study, and then select one or more Medidata Rave data table definitions.
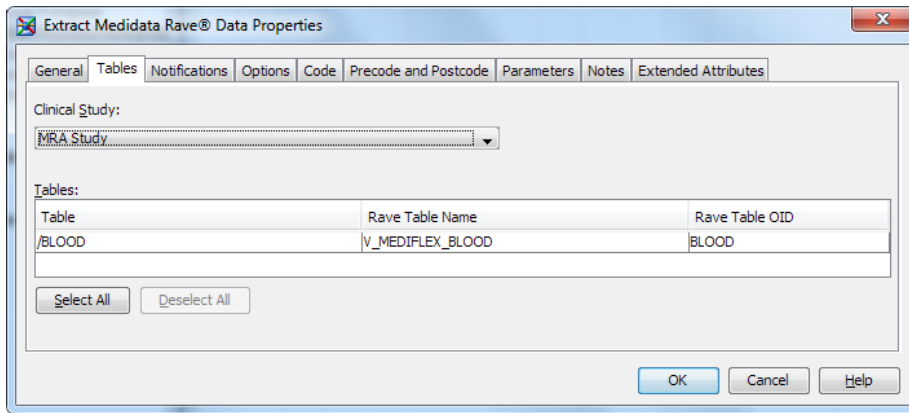


Note the selected data table definitions.

**Note:**  You can select a Medidata Rave data table definition that contains no data.

b   Click **OK**.

5   To notify users of potential changes to the Medidata Rave table metadata, perform the following steps:

a   Click the **Notifications** tab.
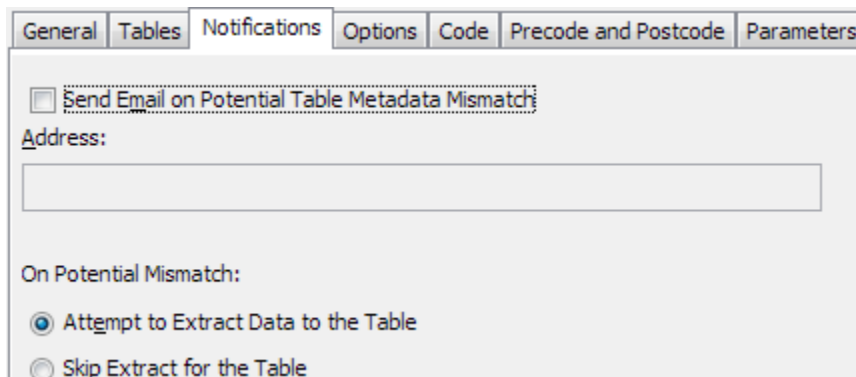


b   Select the **Send Email on Potential Table Metadata Mismatch** check box.

c   In the **Address** field, enter a valid e-mail address or e-mail group.

    d   Specify what action to take when a potential mismatch is detected, and then click **OK**.

6   Confirm that there is a green check mark in the lower right corner of the transformation.

    If the green check mark is not there, click on the transformation to display a message that indicates any problems.

## Run the Job, and Then Check the Results

To update data table data from Medidata Rave, perform the following steps:

1   Run the job

    After the job runs, there should be no errors or warnings in the log. If there are, debug them, and run the job again.

2   Save and close the job.

3   Select the transformation log table, and open it.

    There is a record per selected table.

4   Close the transformation log table.

5   For each data table that was selected for processing, perform the following steps:

    a   In the **Folders** tree, right-click a table, and then select **Open**.

       The View Data page appears.

    b   Confirm that the data is correct.

    c   Compare the values in the regular data columns to the **_RAW** data columns to ensure that no raw data was lost.

       For more information, see

If the Medidata Rave data tables contain data, the tables selected for processing contain data. If the Medidata Rave data tables do not contain data, the tables selected for processing do not contain data.

**Note:** It is possible that a table will not have data in it if there are no records in the data entry system.

## Ensuring No Raw Data Is Lost during Transformation

When the Medidata Rave Web Services transforms raw data into regular data, some data might fail validation or transformation. Failure during validation or transformation is the result of flawed raw data in Medidata Rave. To ensure that this flawed raw data is not lost during transformation, you can examine in SAS Clinical Data Integration the raw data that was used during the transformation. The ability to examine the raw data helps you prevent submitting null data to a regulatory body when flawed data was entered in Medidata Rave.

The raw data is included in the SAS Clinical Data Integration data set so that you can examine the data and correct it.

For every _RAW data column definition in a Medidata Rave data table definition, there is a corresponding regular data column with the same name, minus the _RAW designation. For example, the IT_SEVERE_RAW data column has a corresponding regular data column named IT_SEVERE.

If the raw data was validated or transformed without error, the values in both the regular data column and the _RAW data column will be identical.

If the raw data was not validated or transformed without error, the value in the regular data column will be empty, and the _RAW data column will contain the raw, invalid value that was in Medidata Rave.

# Schedule a Job to Update Study Data from Medidata Rave

## Deploy a Job

To deploy a job to update study data from Medidata Rave, perform the following steps:

1   Select the job that will retrieve data from Medidata Rave.

2   In the **Folders** tree, right-click the job, and then select **Scheduling** ▶ **Deploy**.

The Deploy a job for scheduling dialog box appears.
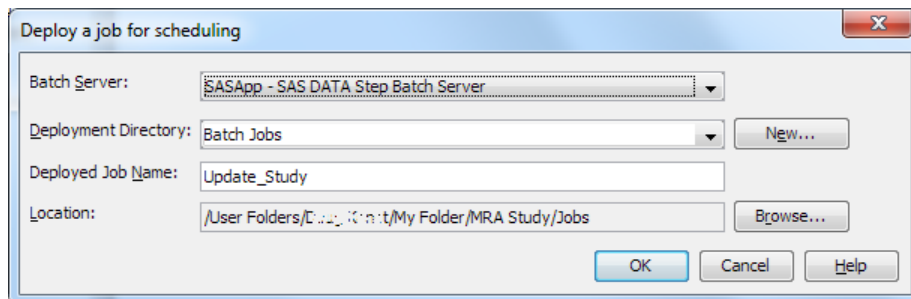


3   Specify the information for deployment, and then click **OK**.

## Create and Schedule a Job Flow

To create and schedule a job flow, log in to SAS Management Console. Create a flow, and select **Platform Process Manager** as the scheduling server.

**Note:** You must log in to SAS Management Console as the same user who created and deployed the job in SAS Clinical Data Integration.

For more information about creating and scheduling a job flow, see the SAS Management Console online Help.

# Part 6

## Appendixes

# Appendix 1

## Addition of Users to the Clinical Administrator Group

### Overview: Adding Users to the Clinical Administrators Group

Only users in the Clinical Administrators group have permission to see the **Clinical Administration** tree in SAS Data Integration Studio. Significant features and functions are available through the **Clinical Administration** tree.

The default security model for SAS Clinical Data Integration is described in the following table. Depending on the level of security required in your organization, users can modify security after installation. Contact your system administrator to determine how security is implemented in your organization.

*Table A1.1   Default Users, Groups, Roles, and Descriptions*

| User, Group, or Role | Description |
|---|---|
| SAS Administrators | Default SAS Metadata Server administration group. This group should not be removed from any object in the metadata. Very few users should be added to this group. |
| Clinical Administrators | Members of this group can use the **Clinical Administration** tree and are responsible for managing data standards, studies or submissions, and controlled terminology. |

| User, Group, or Role | Description |
|---|---|
| SASUSERS | All authenticated users belong to this group. These users are responsible for defining content such as creating domains, jobs, and output. Users are assigned to this group by default. |

# Add a User to the Clinical Administrators User Group

To add a user to the Clinical Administrators user group, perform the following steps:

1 Start SAS Management Console, and then connect to the SAS Metadata Server as an unrestricted user.

For more information, see *SAS Management Console: Guide to Users and Permissions*.

2 On the **Plug-ins** tab, expand **Environment Management**, and then select **User Manager**.

3 In the right pane, right-click **Clinical Administrators**, and then select **Properties**.

The Clinical Administrators Properties dialog box appears.
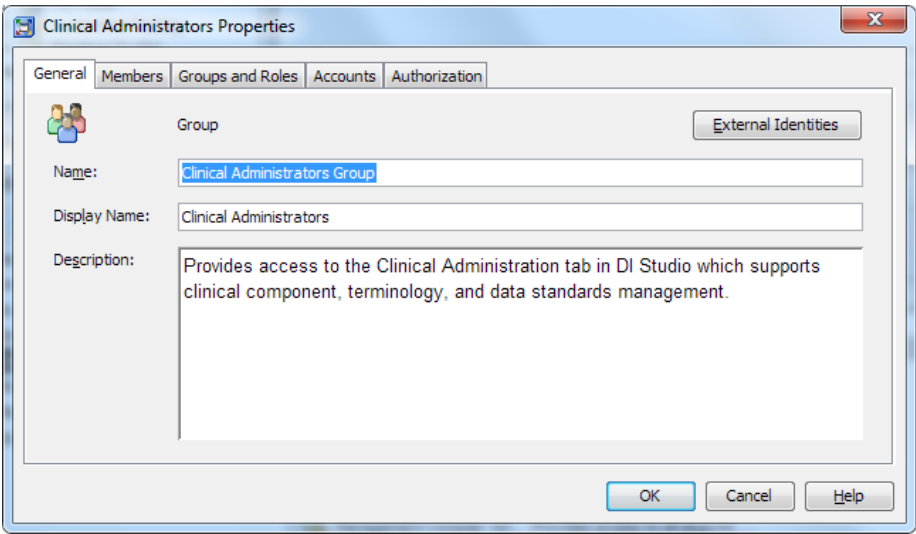
**4** Click the **Groups and Roles** tab.

**5** Use the arrows to move one or more users or user groups between the **Available Groups and Roles** list and the **Member of** list.

**6** Click **OK**.

# Appendix 2

## Repair of Clinical Objects

### Overview: Repairing Clinical Objects

When a clinical object is damaged and must be repaired, you receive a message. These are the objects that you might need to repair:

- data standard

- domain template

- column group

- controlled terminology package

- study or submission

- domain or domain column

**Note:**  A clinical object can be damaged when you export data standards or controlled terminology packages using **Export** ▶ **SAS Package** or **Export** ▶ **Metadata** in SAS Data Integration Studio. These methods are not recommended. Instead, create the data standard or controlled terminology package using SAS Clinical Data Integration.

# Repair a Domain Template, Column Group, or Controlled Terminology Package

To repair a domain template, column group, or controlled terminology package, perform the following steps:

1   In the **Folders** tree or in the **Clinical Administration** tree, navigate to a domain template, column group, or controlled terminology package.

2   Right-click the item, and then select **Repair**.

    A message appears when the repair is completed.

3   If no problems are found, click **OK**.

4   To review the analysis report for a domain template or column group, click **Details**.

    If you choose to repair the problems, a progress indicator appears. A message appears when the repair is completed.

# Repair a Copy of a Data Standard, Study, or Submission

To repair a copy of a data standard, study, or submission, perform the following steps:

1   In the **Folders** tree, navigate to a data standard, study, or submission.

2   Right-click the item, and then select **Repair Copy**.

    The Repair Copy wizard appears.

3   In the **New Name** field, accept the default name, or enter a new name.

4   Click **Next**.

5   Review the summary, and then click **Finish**.

Repairs are made. The **Folders** tree or the **Clinical Administration** tree is updated with new information.

## Repair a Domain or Domain Column

To repair a domain or domain column, perform the following steps:

1  In the **Folders** tree or in the **Clinical Administration** tree, navigate to a domain or a domain column.

2  Right-click the domain or domain column, and then select **Repair**.

3  If no problems are found, click **OK**.

4  To review the analysis report, click **Details**.

   If you choose to repair the problems, a progress indicator appears. A message appears when the repair is completed.

# Appendix 3

## SAS Clinical Data Integration Icons

### The Folders Tree

The following icons represent objects in the **Folders** tree that are provided by SAS Clinical Data Integration. All other icons are standard SAS Data Integration icons.

| Icon | Description |
|------|-------------|
| | Root folder of a submission |
| | Root folder of a study |
| | SAS Clinical Data Integration study that is connected to a Medidata Rave study |
| | Clinical domain |
| | Submission |
| | Study |
| | Medidata Rave table |
| | Medidata Rave codelist |
| | Medidata Rave log |
| | Analysis data set |

## The Clinical Administration Tree

The following icons represent objects in the **Clinical Administration** tree that are provided by SAS Clinical Data Integration. All other icons are standard SAS Data Integration icons.

| Icon | Description |
|------|-------------|
|  | Study |
|  | Submission |

# Index