



THE
POWER
TO KNOW.

SAS[®] Clinical Data Integration Server 2.1 User's Guide

Preproduction Documentation

THIS DOCUMENT IS A PREPRODUCTION DRAFT AND IS PROVIDED BY SAS INSTITUTE INC. ON AN "AS IS" BASIS WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OR MERCHANTABILITY AND/OR FITNESS FOR A PARTICULAR PURPOSE. The company does not warrant that this documentation is complete, accurate, similar to that which may be released to the general public, or that any such documentation will be released. The company shall not be liable whatsoever for any damages arising out of the use of this documentation, including any direct, indirect, or consequential damages. The company reserves the right to alter or abandon use of this documentation at any time.

The correct bibliographic citation for this manual is as follows: SAS Institute Inc. 2009. *SAS® Clinical Data Integration Server 2.1: User's Guide*. Cary, NC: SAS Institute Inc.

SAS® Clinical Data Integration Server 2.1: User's Guide

Copyright © 2009, SAS Institute Inc., Cary, NC, USA

All rights reserved. Produced in the United States of America.

For a Web download or e-book: Your use of this publication shall be governed by the terms established by the vendor at the time you acquire this publication.

U.S. Government Restricted Rights Notice: Use, duplication, or disclosure of this software and related documentation by the U.S. government is subject to the Agreement with SAS Institute and the restrictions set forth in FAR 52.227-19, Commercial Computer Software-Restricted Rights (June 1987).

SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27513.

1st electronic book, November 2009

SAS® Publishing provides a complete selection of books and electronic products to help customers use SAS software to its fullest potential. For more information about our e-books, e-learning products, CDs, and hard-copy books, visit the SAS Publishing Web site at support.sas.com/publishing or call 1-800-727-3228.

SAS® and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. ® indicates USA registration.

Other brand and product names are registered trademarks or trademarks of their respective companies.

Contents

Chapter 1 • Overview of SAS Clinical Data Integration Server	1
How to Use This Document	1
What is SAS Clinical Data Integration Server?	1
Typical Work Flow in SAS Clinical Data Integration Server	2
Prerequisites	3
Recommended Reading	3
Chapter 2 • Administering Data Standards	5
About Data Standard Administration	5
Importing Data Standard Metadata	6
Customizing Data Standard Properties	8
Customizing Data Standard Domain Templates	9
Managing Controlled Terminology	10
Managing Data Standard Compliance Checks	12
Analyzing Domain Use and Promoting a Custom Domain	19
Chapter 3 • Managing Clinical Components	21
About Clinical Component Management	21
Working with Default Folders in a Clinical Component Type	22
Working with Default Libraries in a Clinical Component Type	24
Defining a Clinical Component	25
Modifying Clinical Component Properties	27
Deleting a Clinical Component	28
Monitoring the Status of Domains	28
Refreshing a Domain	29
Chapter 4 • Working with Domain Data and Metadata	31
About Domain Data and Metadata	32
Creating a Standard Domain	33
Creating a Custom Domain	34
Creating a Custom Domain from an Existing Domain	36
Editing Domain Properties	37
Editing Domain Column Properties	38
Loading Data into Domains	39
Assessing CDISC-SDTM Compliance	39
The CDISC-SDTM to CRT-DDS Transformation	41
Validating a CRT-DDS define.xml File	42
The Subject Sequence Generator Transformation	43
Appendix 1 • Adding Users to the Clinical Administrator Group	45
Adding Users to the Clinical Administrators Group	45
Appendix 2 • Repairing Clinical Objects	47
Repairing Clinical Objects	47
Appendix 3 • SAS Clinical Data Integration Server Icons	49
SAS Clinical Data Integration Server Icons	49

Chapter 1

Overview of SAS Clinical Data Integration Server

How to Use This Document	1
What is SAS Clinical Data Integration Server?	1
Typical Work Flow in SAS Clinical Data Integration Server	2
Overview	2
Workflow Owners	2
Prerequisites	3
Recommended Reading	3

How to Use This Document

For an overview of SAS Clinical Data Integration Server features, see [Chapter 1](#), “[Overview of SAS Clinical Data Integration Server](#),” on page 1.

For tasks that are typically performed by Clinical Administrators, see [Chapter 2](#), “[Administering Data Standards](#),” on page 5.

For tasks that are typically performed by Trial Managers, see [Chapter 3](#), “[Managing Clinical Components](#),” on page 21.

For tasks that are typically performed by Clinical Programmers or Data Managers, see [Chapter 4](#), “[Working with Domain Data and Metadata](#),” on page 31.

For information about giving users Clinical Administration privileges, see [Appendix A1](#), “[Adding Users to the Clinical Administrator Group](#),” on page 45.

For information about troubleshooting and repairing clinical objects, see [Appendix A2](#), “[Repairing Clinical Objects](#),” on page 47.

For information about icons provided by SAS Clinical Data Integration Server, see [Appendix A3](#), “[SAS Clinical Data Integration Server Icons](#),” on page 49.

What is SAS Clinical Data Integration Server?

SAS Clinical Data Integration Server supports pharmaceutical-industry needs for transforming, managing, and verifying the creation of industry-mandated data standards such as Clinical Data Interchange Standards Consortium (CDISC). SAS Clinical Data Integration Server relies upon SAS Data Integration Server to provide centralized metadata

management using the SAS Metadata Server and the tools to visually transform data. SAS Clinical Data Integration Server enhances usability by adding new metadata types, plug-ins, and wizards that assist with clinically oriented tasks such as importing data standards, creating studies and submissions, and adding specialized transformations for transforming clinical data to a standard data model. SAS Clinical Data Integration Server also leverages the SAS Clinical Standards Toolkit to provide validation and conformance checking.

SAS Clinical Data Integration Server enables you to:

- improve the consistency of submissions and studies
- improve long-term management and growth of data standards
- use data standards effectively
- use a centralized metadata server
- use the powerful user-friendly features of SAS Data Integration Studio to manage metadata, generate and execute SAS Clinical Standards Toolkit code, and visualize the results

Typical Work Flow in SAS Clinical Data Integration Server

Overview

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

1. Importing a data standard and controlled terminology.
2. Creating clinical components.
3. Defining domains.
4. Standardizing and validating the data.
5. Monitoring the progress of the clinical domains.
6. Analyzing the data standard use across clinical components.

Workflow Owners

Typically, different people own different parts of the work flow. However, ownership can vary depending on the company and a person might perform tasks in more than one of these definitions. The following user definitions are typical owners of the workflow.

Data standards administrator

Defines and manages data standards; and analyzes how the standards are implemented by programmers. 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 a frequently created custom domain to promote to a standard.

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.

Clinical programmers and data managers

Creates standard and custom domains, writes jobs to extract and transform data into domains, and writes jobs to validate compliance of domains to data standard.

Prerequisites

You must satisfy the following prerequisites in order to use the SAS Clinical Data Integration Server 2.1:

- All prerequisites for SAS Data Integration Studio 4.21 must be satisfied.
- SAS Clinical Data Integration Server 2.1 must be installed.
- SAS Clinical Standards Toolkit 1.2 or later must be installed on the SAS Clinical Data Integration Server work-space server.

Recommended Reading

For the following documentation, see the SAS Support Web site 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*
- *SAS and the Clinical Data Interchange Standards Consortium (CDISC)* at <http://www.sas.com/industry/pharma/cdisc/>.
- *Implementing CDISC data models in the SAS Metadata Server* (white paper)
- *Metadata Promotion in SAS 9.2* (white paper)
- *SAS Intelligence Platform: System Administration Guide*

Chapter 2

Administering Data Standards

About Data Standard Administration	5
Importing Data Standard Metadata	6
Problem	6
Solution	6
Task	6
Customizing Data Standard Properties	8
Problem	8
Solution	8
Task	9
Customizing Data Standard Domain Templates	9
Problem	9
Solution	9
Managing Controlled Terminology	10
Overview	10
Problem	10
Solution	10
Tasks	11
Managing Data Standard Compliance Checks	12
Overview	12
Problem	12
Solution	12
Tasks	13
Analyzing Domain Use and Promoting a Custom Domain	19
Problem	19
Solution	19
Task	19

About Data Standard Administration

SAS Clinical Data Integration Server enables you to centrally define and manage data standards, and analyze how the standards are being used by the clinical programmers. You can detect trends that might suggest adding a new column to a domain because many programmers are adding that column during conversion. You can identify frequently used custom domains and promote these domains to be incorporated into your standard.

Typical user tasks include:

- importing clinical data standards
- customizing clinical data standards
- managing controlled terminology
- managing compliance checks
- analyzing data-standard use

Importing Data Standard Metadata

Problem

You want to define studies using the one of the CDISC standards or using your company data standard.

Solution

Use the Import Model wizard to import data standard metadata from the SAS Clinical Standards Toolkit. Importing the metadata enables you to update your environment with data standard releases from the CDISC organization. The CDISC industry standards are shipped with the SAS Clinical Standards Toolkit. For more information, see the *SAS Clinical Standards Toolkit: User's Guide*.

If your company has its own data standards, you can use SAS Clinical Standards Toolkit to define that standard. Then, you can import your data standard.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To import data standard metadata, complete the following steps:

1. In SAS Data Integration Studio, display the Clinical DI Administration tree. Right-click **Data Standards** and click **Import**. The Import wizard opens and the Select Metadata Source page is displayed.
2. Select the metadata source to use—for example, **Clinical Data Standards Toolkit**. Then click **Next**. The Select Data Standard Type page is displayed.
3. Select the data standard type to use—for example, **CDISC-SDTM**. Then click **Next**. The Select Data Standard Version page is displayed.
4. Select the data standard version to use and click **Next**. The Define General Properties page is displayed.
5. Edit the default values.
 - a. In the **Name** field, enter a name to replace the default generated name.
Note: It is a best practice to not include spaces in the data standard name.
 - b. (Optional) In the **Description** field, edit the description and in the **Formal Name** field, enter a formal name.

- c. In the **Identifier** field, specify a text value that uniquely identifies the standard in metadata. A default value is provided. The value that you enter is verified as unique before you continue in the wizard.
 - d. In the **Type** list, select a type. The values in this list are set up by your system administrator and are most important when using the data standard metadata in the SAS Clinical Standards Toolkit. If the required value is not in the list, it is recommended that you contact your system administrator about the appropriate value to enter, especially if the data standard is using the SAS Clinical Standards Toolkit. For more information about adding types, see [“Customizing Data Standard Properties” on page 8](#). If the data standard does not use the SAS Clinical Standards Toolkit, any value can be entered.
 - e. In the **Version** field, you can accept the default value or enter additional text in the string.
 - f. (Optional) In the **Vendor** field, enter a vendor value.
6. Click **Next**. The Verify Domain Properties page is displayed.
 7. (Optional) Edit the property values.

Note: Domain properties are an advanced feature of SAS Clinical Data Integration Server. If you are uncertain about what values to choose, accept all the default values.
 8. Click **Next** to view the Verify Domain Column Properties page.
 9. (Optional) Edit the property values.
 10. Click **Next**.
 - If the data standard supports validation, the Define Validation Library page is displayed. Go to step [11 on page 7](#).
 - If the data standard does not support validation but does support a data model, the Verify Column Groups page is displayed. Go to step [13 on page 7](#).
 - If the data standard does not support validation or a data model, the Verify Domain Metadata page is displayed. Go to step [14 on page 8](#).

Note: For more information about registering SAS libraries, see *SAS Data Integration Studio: User's Guide*.
 11. On the Validation Library page, select a library or create a new library. For more information about library definitions, see *SAS Data Integration Studio: User's Guide*.

Note:

 - You must have the appropriate create permissions for the selected library. For more information, see *SAS Management Console: Guide to Users and Permissions*.
 - The path for a selected library must exist.
 - The library metadata object is created immediately. If you cancel the wizard, the library remains.
 12. Click **Next**.
 - If the data standard supports a data model, the Verify Column Groups page is displayed.
 - If the data standard does not support a data model, the Verify Domain Metadata page is displayed. Go to step [14 on page 8](#).
 13. On the Verify Column Groups page, review the column groups defined in the standard. The Verify Column Groups page is refreshed with detailed information about the

columns that are defined in the standard. After you review this information, click **Next**. The Verify Domain Metadata page is displayed.

14. On the Verify Domain Metadata page, review the domain templates that are defined in the standard.

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

15. Click **Next**. The Verify Domain Column Metadata page is displayed.

16. Review the columns that are defined in the standard.

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

17. Click **Next**. The Summary page is displayed.

18. Review the summary of your selections. To make changes, click **Back**. To cancel the changes without saving them, click **Cancel**. To save your changes, click **Finish**.

The domain templates, column groups, and validation data sets (if supported by the data standard) are displayed in the data standard folder in the Clinical DI Administration tree. For example, if you selected the CDISC-SDTM data standard type and version 3.1.1, the domain templates (SDTM domains) and column groups (SDTM classes), and validation data sets (compliance checks) are displayed in the CDISC SDTM V3.1.1 folder.

By default, imported data standards are labeled Inactive in selection lists. This enables a data standard administrator to review the data standard template and make any changes before releasing the template for general use. When you are satisfied with a data standard template, you can change its status to Active. Templates in the Active state are available to other users.

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

1. In SAS Data Integration Studio, display the Clinical DI Administration tree. Expand **Data Standards**.
2. Right-click the standard that you want to activate and click **Properties**.
3. Click the **Properties** tab. In the **Active** field, change **False** to **True**.

Customizing Data Standard Properties

Problem

You want to make changes to the default values for properties in a data standard.

Solution

SAS Clinical Data Integration Server provides a common property model. This model defines the set of properties about which metadata can be collected for an object. These properties are derived from CDISC data standards, but are implemented so you can

customize how the properties are used. For example, if a data standard does not use a property, you can turn that property off. You can also adjust or expand a set of allowable values for a property.

Use the Edit Property Model Defaults dialog box to make your changes. You can add constraints around the content such as minimum and maximum values, lengths, and default value. For CDISC data standards, SAS Clinical Data Integration Server loads all of the CDISC information for you based on the SAS interpretation of the data standard. However, interpretations can vary. The Edit Property Model Defaults dialog box provides the flexibility that enables you to apply your own interpretation.

Then, these property values are inherited by newly created instances of the data standard template.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To view and edit a property model, complete the following steps:

1. In the Clinical DI Administration tree, right-click a clinical object that you want to edit (for example, Data Standards, or Study or Submission in the Clinical Components folder.)
2. Click **Edit Property Model**. The Edit Property Model Defaults dialog box is displayed.
3. Select a property in the **Properties** list. The associated values are displayed to the right of the list. If **Use Lookups** is selected, values are also displayed in the **Lookup Value** list.
4. To change the default value, click the **Default Value** list and make a selection.
5. If the property uses lookups, you can customize default values for the property. You must select **Use Lookups** to enable customization.
 - To add a value, enter the value in the **Lookup Value** field and click **Save**.
 - To edit an existing value, select a value in the **Lookup Value** list. That value is displayed in the **Lookup Value** field. Edit the value in this field and click **Save**. The new value is displayed in the **Lookup Value** list.
 - To delete a value, select a value from the **Lookup Value** list and click **Delete**.

Customizing Data Standard Domain Templates

Problem

You want to make changes to the domain templates for the data standard.

Solution

Customize domain clinical properties and domain column clinical properties to meet your needs:

- To change domain template metadata, see [“Editing Domain Properties” on page 37](#).
- To change domain template columns, see [“Editing Domain Column Properties” on page 38](#).

Managing Controlled Terminology

Overview

SAS Clinical Data Integration Server enables you to manage controlled terminology.

A *terminology table* (terminology data set) is a SAS data set that represents controlled terminology data. SAS Clinical Standards Toolkit provides the CDISC terminology tables.

A *terminology package* is a group of terminology tables. The data standards administrator creates terminology packages containing the terminology tables. Then, the data standards administrator manages the group and the granularity at which terminologies are made available to:

- a clinical component
- the transformations that use the controlled terminology

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

Problem

You want to import a SAS Clinical Standards Toolkit controlled terminology package.

Solution

SAS Clinical Standards Toolkit provides the CDISC controlled terminology packages. You can import these packages using the Import wizard available in the Clinical DI Administration tree.

After a terminology table is imported, you can verify that the import succeeded. Also, you can open, delete, or rename the table using the features provided by SAS Data Integration Studio. For more information, see *SAS Data Integration Studio: User's Guide*.

You can use the New Terminology Package wizard to create new packages. If you want to rename the package or change the order that the terminology tables in the package are applied during a transformation, use the Properties dialog box to view the terminology package and make any changes.

SAS Clinical Data Integration Server provides the following ways to manage your controlled terminology packages:

- [“Import Controlled Terminology from SAS Clinical Standards Toolkit” on page 11](#)
- [“Create a New Controlled Terminology Package” on page 11](#)
- [“Edit a Controlled Terminology Package” on page 12](#)

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,” on page 45](#).

Tasks

Import Controlled Terminology from SAS Clinical Standards Toolkit

To import a terminology table that is supplied by the SAS Clinical Standards Toolkit, complete the following steps:

1. In the Clinical DI Administration tree, right-click **Data Standards** and click **Import**. The Import wizard opens and the Select Metadata Source page is displayed.
2. Click **Clinical Data Standards Toolkit** and click **Next**. The Select Data Standard Type page is displayed.
3. Click the data standard terminology to import (for example, “CDISC-Terminology”) and click **Next**. The Select Data Standard Version page is displayed.
4. Click the data standard version to use and click **Next**. The Terminology Library page is displayed.
5. In the **SAS Library** list, select the library to contain the imported clinical terminology table.
Note: The selected library must have the Create Metadata permission enabled.
6. Click **Next**. The Terminology Data Sets Folder page is displayed.
7. In the Folders tree, select the metadata folder to contain the clinical terminology table and click **Next**. The Summary page is displayed.
8. Click **Finish**.

Create a New Controlled Terminology Package

To create a new controlled terminology package, complete the following steps:

1. In the Clinical DI Administration tree, right-click **Controlled Terminology** and click **Import** ⇒ **New Terminology Package**. The New Terminology Package wizard opens and the General Information page is displayed.
2. In the **Name** field, enter the name for the new package. Optionally, enter the version and description for the package. Click **Next**. The Terminology Sets page is displayed.
3. Click **Add** to add the data sets that contain the controlled terminology tables. SAS Data Integration Studio opens the Add Terminology Sets wizard and the Source Library page is displayed. For more information about this wizard, see the *SAS Data Integration Studio: User's Guide*.
4. In the **SAS Library** list, select the library that contains the terminology table that you want to use and click **Next**. The Source Terminology Tables page is displayed.
5. In the **Tables in the library** list, select the terminology table that you want to add. This table can be either imported from the SAS Clinical Standards Toolkit or your own terminology table.
6. Click **Finish** to exit the Add Terminology Sets wizard and return to the New Terminology Package wizard.
7. Click **Finish**. The new controlled terminology package is displayed in the Controlled Terminology folder.

Edit a Controlled Terminology Package

To view, change, or rename the controlled terminology package, complete the following steps:

1. In the Clinical DI Administration tree, expand **Controlled Terminology**.
2. Right-click the controlled terminology package you want to view or edit and click **Properties**. The Properties dialog box is displayed. In this dialog box you can rename the package or change the order of the terminology tables. Changing the order affects the order in which the controlled terminology is applied during transformation.
3. Click **OK** to save your changes and exit.

Managing Data Standard Compliance Checks

Overview

A set of compliance checks can be associated with each data standard. The data standards administrator can add new checks and customize existing checks for the data standard with which they work. You can validate a clinical domain to determine whether it complies with a version of the data standard. The validation is performed by creating a job that contains the SDTM Compliance transformation.

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

Problem

You want to manage the compliance checks for your data standard.

Solution

If you have Administrator permission, SAS Clinical Data Integration Server provides the following ways to manage your compliance checks:

- [“View Compliance Checks” on page 13](#)
- [“Create a Customized Data Standard Compliance Check” on page 13](#)
- [“Edit an Existing Compliance Check” on page 16](#)
- [“Change the Compliance Check Status” on page 19](#)
- [“Delete a Compliance Check” on page 19](#)

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,” on page 45](#).

Tasks

View Compliance Checks

To view compliance checks, complete the following steps:

1. In the Clinical DI Administration tree, expand **Data Standards**. Right-click the data standard that contains the checks that you want to view and click **Manage Compliance Checks**. The Manage Compliance Checks window is displayed.

Note: If a data standard does not support compliance checking or does not have a compliance check installed, a message is displayed.

2. By default, the **Available checks** table displays all details for each compliance check. To view only the Check ID and Description columns, clear the **Show details** check box.

Note: You can sort the compliance check table by clicking any column heading.

Create a Customized Data Standard Compliance Check

The SAS Clinical Standards Toolkit provides a set compliance checks for the data standards that support validation. SAS Clinical Data Integration Server imports these checks when you import your data standards. You can create additional compliance checks and add them to the data standard set. For more information about compliance or validation, see the *SAS Clinical Standards Toolkit: User's Guide*.

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

- Domain and domain column specifications
- Code source
- Terminology lookup and reporting

The toolkit is invoked by the SAS code generated from a compliance transformation using a check. For more information about the toolkit, see *SAS Clinical Standards Toolkit: User's Guide*.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

To create a new, customized compliance check, complete the following steps:

1. In the Manage Compliance Checks window, right-click a compliance check to copy and customize and click **Customize**. The Custom Compliance Check wizard opens and the Check Properties page is displayed. Most fields in the wizard default to the values used in the selected compliance check.
2. On the Check Properties page, edit the applicable fields required for your customization.
 - a. In the **Check ID** field, type an ID that contains at least one non-whitespace character but no more than 8 characters. All characters except single and double quotes are permitted. The ID must be unique among all the check IDs for any compliance check belonging to a data standard.
 - b. In the **Check Type** list, select or type a check type value that contains at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.

- c. In the **Severity** list, select or type a severity value that contains at least one non-whitespace character but no more than 40 characters. All characters except single and double quotes are permitted.
- d. In the **Description** field, type a description that contains at least one non-whitespace character but no more than 500 characters. All characters are permitted, but you cannot use single quotes and double quotes together in the description. You can use only single quotes or double quotes.
- e. In the **Initial Status** list, the selection always defaults to Draft.

Note: After you test this check using the CDISC-SDTM Compliance transformation, you can set the check to Active.

3. Click **Next**. The Domains page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

4. Edit the applicable fields required for your customization.

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

- a. In the **Domains Referenced** table, you can edit a row to adjust the values for the domain.

Note: This table might not be displayed depending on the check you have selected.

- b. In the **Domain Specification** field, edit the full domain scope string that is passed to the Clinical Standards Toolkit.

Note: If the domain specification string is not valid, the **Next** and **Finish** buttons are disabled. A string might not be valid in the following situations:

- Brackets are mismatched
- Characters are present that are not alphanumeric or the following syntax specifiers:
+, -, *, _ALL_, :
- The length cannot be more than 200 characters

5. Click **Next**. The Domain Columns page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

6. Edit the applicable fields required for your customization.

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

- a. In the **Columns Referenced** table, you can edit a row to adjust the values for the column.

Note: This table is displayed only when the column specification includes one or more column IDs or column specifiers.

- b. In the **Column Specification** field, edit the full column scope string that is passed to the Clinical Standards Toolkit.

Note: If the column specification string is not valid, the **Next** and **Finish** buttons are disabled. A string might not be valid in the following situations:

- Brackets are mismatched

- Characters are present that are not alphanumeric or the following syntax specifiers:
+, -, *, _ALL_, :
- The length cannot be more than 200 characters

7. Click **Next**. The Check Code page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

8. Edit the applicable fields required for your customization.

Note: To enable the **Code Source** list and disable the **Code** field, select the **Direct Edit (Advanced)** check box.

- (Required) In the **Code Source** list, you can select a macro provided by the SAS Clinical Standards Toolkit. The setting must contain at least one non-whitespace character but no more than 32 characters. All characters except single and double quotes are permitted.

Note:

- This table is displayed only when the column specification includes one or more column IDs or column specifiers.
 - For more information about the macro selections, see the *SAS Clinical Standards Toolkit: User's Guide*.
- (Optional) In the **Code** field, edit the check code string that is passed to the Clinical Standards Toolkit. SAS Clinical Data Integration Server does not validate the syntax in this string. However, it does validate the following criteria:

- Contains no more than 2000 characters
- All characters are permitted, but single quotes and double quotes cannot be used together in the description. You can use only single quotes or double quotes.

Note: Any code that you enter must be consistent with the selected code source. Also, you must enter valid SAS code.

9. Click **Next**. If the compliance check already includes a terminology lookup, the Controlled Terminology Lookup page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

10. If terminology lookup is included in this compliance check, edit the applicable fields required for your customization.

Note: To enable the **Lookup Type** and **Lookup Source** lists for editing, select the **Direct Edit (Advanced)** check box.

- (Required) In the **Lookup Type** list, you can select or provide the type of terminology lookup. SAS Clinical Data Integration Server does not validate whether the lookup type exists. The value must contain at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.
- (Required) In the **Lookup Source** field, you can select or provide the terminology lookup source. SAS Clinical Data Integration Server does not validate whether the lookup source exists. The value must contain at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.

11. Click **Next**. The Reporting Options page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

12. Edit the applicable fields required for your customization.

Note: To enable the **Error Message** field for editing, select the **Direct Edit (Advanced)** check box.

- a. Select the **Report All Violations** check box to specify that all violations for the compliance check be reported every time the validation is run. If you clear this check box, only the first violation is reported.
- b. In the **Error Message** field, specify the text to write to the data set when an error is detected. You can use substitution variables in this field and the text must contain at least one non-whitespace character but no more than 500 characters. All characters except single and double quotes are permitted.

13. Click **Finish** to save and exit the wizard.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

Edit an Existing Compliance Check

You can edit only checks that are in the Draft state. To set a check to Draft, right-click the check and select **Make Draft**. To edit an existing compliance check, complete the following steps:

1. In the Manage Compliance Checks window, right-click a compliance check and click **Edit**.

The Edit Compliance Check wizard opens and the Check Properties page is displayed. Most fields in the wizard default to the values used in the selected compliance check.

2. On the Check Properties page, edit the applicable fields required for your customization.
 - a. In the **Check Type** list, select or type a check type value that contains at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.
 - b. In the **Severity** list, select or type a severity value that contains at least one non-whitespace character but no more than 40 characters. All characters except single and double quotes are permitted.
 - c. In the **Description** field, type a description that contains at least one non-whitespace character but no more than 500 characters. All characters are permitted, but you cannot use single quotes and double quotes together in the description. You can use only single quotes or double quotes.
 - d. In the **Initial Status** list, the selection always defaults to Draft.
3. Click **Next**. The Domains page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

4. Edit the applicable fields required for your customization.

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

- a. In the **Domains Referenced** table, you can edit a row to adjust the values for the domain.

Note: This table is displayed only if the domain specification for the check that you editing includes one or more domain IDs or domain specifiers.

- b. In the **Domain Specification** field, edit the full domain scope string that is passed to the Clinical Standards Toolkit.

Note: If the domain specification string is not valid, the **Next** and **Finish** buttons are disabled. A string might not be valid in the following situations:

- Brackets are mismatched
- Characters are present that are not alphanumeric or the following syntax specifiers:
+, -, *, _ALL_, :
- The length cannot be more than 200 characters

5. Click **Next**. The Domain Columns page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

6. Edit the applicable fields required for your customization.

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

- a. In the **Columns Referenced** table, you can edit a row to adjust the values for the column.

Note: This table is displayed only if the column specification for the check that you are editing includes one or more column IDs or column specifiers.

- b. In the **Column Specification** field, edit the full column scope string that is passed to the Clinical Standards Toolkit.

Note: If the column specification string is not valid, the **Next** and **Finish** buttons are disabled. A string might not be valid in the following situations:

- Brackets are mismatched
- Characters are present that are not alphanumeric or the following syntax specifiers:
+, -, *, _ALL_, :
- The length cannot be more than 200 characters

7. Click **Next**. The Check Code page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

8. Edit the applicable fields required for your customization.

Note: To enable the **Code Source** list and **Code** field for editing, select the **Direct Edit (Advanced)** check box.

- a. (Required) In the **Code Source** list, you can select a macro provided by the SAS Clinical Standards Toolkit. The setting must contain at least one non-whitespace character but no more than 32 characters. All characters except single and double quotes are permitted.

Note: This table is displayed only when the column specification includes one or more column IDs or column specifiers.

- b. (Optional) In the **Code** field, edit the check code string that is passed to the SAS Clinical Standards Toolkit. SAS Clinical Data Integration Server does not validate the syntax in this string. However, it does validate the following criteria:

- Contains no more than 2000 characters
- All characters are permitted, but single quotes and double quotes cannot be used together in the description. You can use only single quotes or double quotes.

Note: Any code that you enter must be consistent with the selected code source. Also, you must enter valid SAS code.

9. Click **Next**. If the compliance check already includes a terminology lookup, the Controlled Terminology Lookup page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

10. If terminology lookup is included in this compliance check, edit the applicable fields required for your customization.

Note: To enable the **Lookup Type** and **Lookup Source** lists for editing, select the **Direct Edit (Advanced)** check box.

- a. (Required) In the **Lookup Type** list, you can select or provide the type of terminology lookup. SAS Clinical Data Integration Server does not validate whether the lookup type exists. The value must contain at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.
- b. (Required) In the **Lookup Source** field, you can select or provide the terminology lookup source. SAS Clinical Data Integration Server does not validate whether the lookup source exists. The value must contain at least one non-whitespace character but no more than 20 characters. All characters except single and double quotes are permitted.

11. Click **Next**. The Reporting Options page is displayed.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

12. Edit the applicable fields required for your customization.

Note: To enable the **Error Message** field for editing, select the **Direct Edit (Advanced)** check box.

- a. Select the **Report All Violations** check box to specify that all violations for the compliance check be reported every time the validation is run. If you clear this check box, only the first violation is reported.
- b. In the **Error Message** field, specify the text to write to the data set when an error is detected. You can use substitution variables in this field and the text must contain at least one non-whitespace character but no more than 500 characters. All characters except single and double quotes are permitted.

13. Click **Finish** to save your changes and exit the wizard.

Note: If the **Next** and **Finish** buttons are disabled, one or more of the values on this page are not valid. Review the criteria for each value and make the applicable corrections.

Change the Compliance Check Status

To change the compliance check status, complete the following steps:

1. To change the status of a compliance check to Draft, right-click the row and click **Make Draft**.

Note:

- A compliance check must be in the Draft state before you can edit it.
- You can select one or more compliance checks. To select a range of checks, click the first check. Then while pressing the Shift key, click the last check in the range. To select multiple checks individually, click the first check. Then while pressing the Ctrl key, click the rest of the checks.

2. To change the status of a compliance check to Active, right-click the row and click **Make Active**.

Note: You can select one or more compliance checks.

Delete a Compliance Check

To delete a compliance check, right-click the row and click **Delete**. A confirmation message is displayed. Click **Yes** to delete the check from the table and from persistent storage for the data standard.

Note: You can select one or more compliance checks.

Analyzing Domain Use and Promoting a Custom Domain

Problem

You want to know which domains are used most and, if a custom domain is reused significantly, promote that custom domain to be part of the data standard.

Solution

You can view standard and custom domain use in clinical components. Using this information, you can identify custom domains that have enough use to warrant becoming a standard domain. Typically, a custom domain is for single use and is available only to the clinical component in which the custom domain is defined. When a custom domain is made a standard domain (that is, the domain is promoted to the data standard), it can be included in any clinical component.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

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

1. In the Clinical DI Administration tree, expand **Data Models**. Right-click the data model that you want to analyze and click **Analyze Model Usage**. The Analyze Model Usage dialog box is displayed.
2. In the **Clinical Components** list, select one or more clinical components.
3. In the **Show domains of type** list, select whether you want to include custom, standard, or all domains in the selected clinical components.
4. Click **Show Domain Details**. All domains that match the selected criteria are displayed in the **Domain Details** list. If no domains match the criteria, a message is displayed.
5. In the **Domain Details** list, expand the folders to compare the details of the selected domains. Each domain is displayed as a column in the list. The domain name and frequency of use is reported in the column heading.
6. Right-click a custom domain column heading and click **Promote Custom Domain**. A confirmation message is displayed.
7. Click **Yes**. A new standard domain is created from the custom domain.
8. To verify the promotion, complete the following steps:
 - a. In the Clinical DI Administration tree, expand the selected data model.
 - b. Expand the standard domain.
 - c. Expand **Domain Templates**. The new domain is located in this folder.

Chapter 3

Managing Clinical Components

About Clinical Component Management	21
Working with Default Folders in a Clinical Component Type	22
Problem	22
Solution	22
Tasks	23
Working with Default Libraries in a Clinical Component Type	24
Problem	24
Solution	24
Tasks	24
Defining a Clinical Component	25
Problem	25
Solution	26
Task	26
Modifying Clinical Component Properties	27
Problem	27
Solution	27
Task	27
Deleting a Clinical Component	28
Problem	28
Solution	28
Task	28
Monitoring the Status of Domains	28
Problem	28
Solution	28
Task	29
Refreshing a Domain	29
Problem	29
Solution	29
Task	29

About Clinical Component Management

SAS Clinical Data Integration Server clinical components collect metadata about studies and submissions. SAS Clinical Data Integration Server enables you to manage the following types of clinical components:

- Studies, such as study-level metadata and content
- Submissions, such as aggregated metadata and content or collections of studies

These clinical components are the top-level containers for all the content that you create during the course of the study. SAS Clinical Data Integration Server enables a trial manager to centrally define and manage study definitions, setup default content, and monitor the progress of the domain mapping process.

Before you define a clinical component, you optionally can define defaults for the clinical components. You can use default folders to maintain consistent metadata organization in a component when that component is created. You can use default libraries to maintain consistent use of SAS library references (librefs). This requirement is typical when you have standard programs and macros that are dependent on consistent library references.

For each clinical component you can define one or more default data standard. In making this definition, you limit the available data-standard selections in all SAS Clinical Data Integration Server wizards. Only the data standards that you defined as the defaults are displayed. The default setting ensures that you are using the correct version of a standard for a given study or submission. After you complete the Create Clinical Component wizard, the default content is created automatically in the new clinical component.

Because all the activities and relationships are stored in metadata, SAS Clinical Data Integration Server can produce a summary of the status of all the activities for a selected study. If you have multiple programmers working on the same submission or study, you can easily see what domains have been created, whether they are used in a mapping process, and whether a validation transformation is using it. If you are using change management, you can also view whether someone is working on the submission or study.

Typical user tasks include:

- working with default folders and libraries
- defining a clinical domain
- monitoring the status of domains
- refreshing a standard domain

Working with Default Folders in a Clinical Component Type

Problem

You want to create a metadata folder structure to enable consistent content between studies or submissions.

Solution

SAS Clinical Data Integration Server enables you to define default folders to maintain consistent metadata organization in a clinical component when that component is created.

You can customize the default folders that can be applied to all new studies, or submissions, and modify the default folder properties.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Tasks

Add a Default Folder

To add a folder to the default content for a specific clinical component type, complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type to which you want to add a default library. Then, expand **Default Content**.
2. Right-click **Root Folder** and click **New Subfolder**. The new subfolder is created and displayed.

Note: You can create a subfolder in any default folder.

3. (Optional) Type a new subfolder name and press Enter.

Note: A subfolder name must meet the following criteria:

- Contains no more than 60 characters.
- Is not the same as any existing default folder under the same parent folder. The comparison check is not case sensitive.
- Contains no whitespace characters.

View and Modify a Default Folder

To view and modify default folder properties, complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type that includes the default folder.
2. Expand **Default Content** and then **Root Folder**. The available default folders are displayed in this folder. Default folders can have subfolders; you can expand any default folder to view its subfolders.
3. Right-click the default folder that you want to modify and click **Properties**. The Default Folder Properties window is displayed.
4. In the **Name** field, edit the name of the folder.

Note: A folder name must meet the following criteria:

- Contains no more than 60 characters.
- Is not the same as any existing default folder under the same parent folder. The comparison check is not case sensitive.
- Contains no whitespace characters.

5. In the **Description** field, edit the description of the folder.

Note: A description must be no more than 200 characters.

6. Click **OK** to save the changes. Click **Cancel** to exit the window without saving changes.

Delete a Default Folder

To delete a default folder, complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type from which you want to delete a default folder. Then, expand **Default Content** and **Root Folder**.
2. Right-click the default folder that you want to delete and click **Delete**. The folder and any subfolder contained in that folder are deleted and no longer displayed in the tree.

Working with Default Libraries in a Clinical Component Type

Problem

You want to define default libraries for use in the study to maintain consistent use of SAS library references (librefs).

Solution

SAS Clinical Data Integration Server enables you to define libraries for use in new studies or submissions and edit the library properties. This is a typical requirement when you have standard programs and macros that are dependent on predefined library references.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Tasks

Add a Default Library

To add a library to the default content for a specific clinical component type (that is, a study or submission), complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type to which you want to add a default library. Then, expand **Default Content**.
2. Right-click **Libraries** and click **New Default Library**. The New Default Library wizard opens and the Default Library Information page is displayed.
3. In the **Name** field, specify the name of the library to add.

Note: A name must be no more than 60 characters and must not be the same as any existing default library in the clinical component. The comparison check is not case sensitive.

4. In the **Libref** field, specify the libref of the library to add.

Note: A libref must meet the following criteria:

- No more than 8 characters.
- Not the same as any existing default library in the clinical component. The comparison check is not case sensitive.
- The first character must be an alphabetic character or an underscore.
- Each subsequent character must be an alphabetic character, integer, or an underscore.

5. (Optional) In the **Description** field, specify a description of the library to add.

Note: A description must be no more than 200 characters.

6. Click **Finish** to add the specified library. The new default library is displayed as a child of the Libraries folder.

View and Modify a Default Library

To view and modify default library properties, complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type that includes the default library.
2. Expand **Default Content** and then **Libraries**. The available default libraries are displayed in this folder.
3. Right-click the default library that you want to modify and click **Properties**. The Default Library Properties window is displayed.
4. In the **Name** field, edit the name of the library.

Note: A name must be no more than 60 characters and must not be the same as any existing default library in the clinical component. The comparison check is not case sensitive.

5. In the **Libref** field, edit the libref of the library.

Note: A libref must meet the following criteria:

- No more than 8 characters.
- Not the same as any existing default library in the clinical component. The comparison check is not case sensitive.
- The first character must be an alphabetic character or an underscore.
- Each subsequent character must be an alphabetic character, integer, or an underscore.

6. In the **Description** field, edit the description of the library.

Note: A description must be no more than 200 characters.

7. Click **OK** to save the changes. Click **Cancel** to exit the window without saving changes.

Delete a Default Library

To delete a default library, complete the following steps:

1. In the Clinical DI Administration tree, expand the clinical component type from which you want to delete a default library. Then, expand **Default Content** and **Libraries**.
2. Right-click the default library that you want to delete and click **Delete**. The library is deleted and is no longer displayed in the tree.

Note: You can delete more than one library at a time. Click the first library to delete. Then press the Ctrl key and click additional libraries to delete.

Defining a Clinical Component

Problem

You want to create a new study.

Solution

Studies and submissions are created using the New Clinical Component wizard. The wizard collects basic object metadata such as name, description, and content location in the metadata tree. Then, metadata about the clinical component is collected. For example, a study component collects metadata such as protocol title, indication, and phase. Then, the versions of the standards that can be used for the component are defined.

Note: Only administrators can set default content for clinical components using the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To define a clinical component, complete the following steps:

1. In the Folders tree, right-click a folder and click **New** ⇒ **Clinical Component**. The New Clinical Component wizard opens and the General Information page is displayed.
2. Specify a name for the clinical component. Optionally, you can specify a description. The name must be 60 characters or less in length. The description must be no longer than 200 characters. If you reach the character limit, a message is displayed in the message line and you cannot type any more characters.

By default, the **Location** field is set to the folder in which you opened the New Clinical Component wizard. If you want to change the default location of the new clinical component, click **Browse** to select a new location. The selected folder must not be an existing clinical component root folder or a subfolder of a clinical component root folder.

The **Location** field defaults to your home folder (that is, My Folder) if, when the wizard was started, any of the following situations occurs:

- No folder was selected
- More than one folder was selected
- An object was selected that is not a folder

Click **Next**. The Clinical Component Type Selection page is displayed.

3. Select a component type from the list.

Note: The default selection is Study.

Click **Next**. The Data Standards Selection page is displayed.

4. Select the data standards to associate with the clinical component. All active data standards to which you have access are displayed. You can select any number of data standards or none.

Note: Do not use special characters in the properties fields. These characters include single quotes, quotations marks, and hyphens.

Click **Next**. The Clinical Component Properties page is displayed.

5. Set the values for the properties of the component type (Study, Submission) being created. The properties made available, as well as their default values, are determined by the administrator configuration of the data standard’s property model.

Click **Next**. The Library Selection page is displayed.

6. Select one or more SAS libraries to associate with the clinical component.
The list of available libraries is determined by the default content for the type of clinical component being created. You can select one or more libraries or you can create components without a library assignment.
Click **Next**. The Controlled Terminology page is displayed.
7. (Optional) Associate a controlled terminology package with the clinical component. You can associate one package or none with a clinical component. Click **Add**. The Available Terminology Packages window is displayed and lists all the packages that the administrator has made available. Select a package and click **OK**.
Note: If no packages are available, a message is displayed instead of the Available Terminology Packages window.
To remove a selected package, click **Remove**. Then, click **OK** to confirm the removal.
8. Click **Finish** to create the new clinical component.

Modifying Clinical Component Properties

Problem

You want to modify the properties of an existing study or submission.

Solution

You can modify the properties of an existing clinical component from the Clinical DI Administration tree.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To modify the properties of a clinical component, complete the following steps:

1. In the Clinical DI Administration tree, expand **Clinical Components**.
2. Expand either **Study** or **Submissions**, depending on which clinical component that you want to edit.
3. Expand **Instances**.
4. Right-click the study that you want to modify and click **Properties**.
5. Select the tab containing the property you want to edit. For example, if you want to modify the data standards associated with a study, click the **Standards** tab.
6. Make your changes and click **OK** to save the changes and exit the Properties dialog box. Click **Cancel** to exit without making changes.

Deleting a Clinical Component

Problem

You want to delete an existing study or submission.

Solution

You can delete an existing clinical component from the Clinical DI Administration tree.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To delete a clinical component, complete the following steps:

1. In the Clinical DI Administration tree, expand **Clinical Components**.
2. Expand either **Study** or **Submissions**, depending on which clinical component that you want to delete.
3. Expand **Instances**.
4. Right-click the study that you want to delete and click **Delete**.
5. Click **OK** to confirm the deletion.

Note: The Clinical component is deleted, but the associated folder and its contents remain. To delete the contents of the folder, view the Folders tree. Then, right-click the folder that you want to delete and click **Delete**.

Monitoring the Status of Domains

Problem

You want a progress report about the status of the domains for your study.

Solution

You can monitor the status of domains to determine the progress of mapping the source data and whether a domain has been validated for compliance against a data standard.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To monitor the progress of a particular clinical component, in the Clinical DI Administration tree, right-click a clinical component and click **Monitor Domains**. The Domain Status dialog box is displayed. The Domains table reports the following information:

- which domains have mapping jobs defined (that is, jobs where the domain is a target)
- which domains have compliance jobs defined (with the domains selected to be validated)

Refreshing a Domain

Problem

You want to align a modified standard domain instance with the standard domain template from which it was created.

Solution

You can refresh the metadata of the selected domain using the metadata of the domain template from which the selected domain was originally created.

Note: You must have the appropriate privileges to view the Clinical DI Administration tree. For more information, see [Appendix A1, “Adding Users to the Clinical Administrator Group,”](#) on page 45.

Task

To refresh the metadata of a domain, complete the following steps:

1. In the Folders tree, expand the clinical component containing the domain in which you are interested, right-click on the domain and click **Refresh Domain**.
 - If the domain template and selected domain do not differ, a message is displayed. Click **Yes** to view, but not change, the domain properties and columns. Click **No** to continue without viewing the domain and column properties.
 - If the domain template and the selected domain differ, the Refresh Domain window is displayed immediately. Two trees display the domain properties and columns that differ.

If the selected domain was not based on a domain template, a warning message is displayed. Click **OK** to close the window. Because the selected domain was not based on a domain template, it cannot be refreshed.
2. Expand and collapse the tree nodes in either tree to view the differences.
3. In the **Standard Domain** tree, select the check box next to the columns and properties you want refreshed in the selected domain.

Remember the following considerations when selecting check boxes:

- If you select a column, all of its properties are included. A selected check box with a white background indicates that the node and all its child nodes are selected.
 - To include some properties, expand the column node and select the check boxes for each property that you want to include. A selected check box with a gray background indicates that only some child nodes are selected.
 - To update the selected domain metadata to match the domain template metadata, select the root node check box in the **Standard Domain** tree.
4. Click **Apply Changes** to apply all the changes you selected to the domain. If there are no remaining differences, or you chose to update the selected domain to match the domain template, the Refresh Domain window changes to view-only mode. Click **Close** to close the window.

Chapter 4

Working with Domain Data and Metadata

About Domain Data and Metadata	32
Domain Creation	32
Custom Domain Creation	32
Domain Duplication (Copy from an Existing Domain)	33
Creating a Standard Domain	33
Problem	33
Solution	33
Task	33
Creating a Custom Domain	34
Problem	34
Solution	34
Task	34
Creating a Custom Domain from an Existing Domain	36
Problem	36
Solution	36
Task	36
Editing Domain Properties	37
Problem	37
Solution	37
Task	37
Editing Domain Column Properties	38
Problem	38
Solution	38
Task	38
Loading Data into Domains	39
Problem	39
Solution	39
Assessing CDISC-SDTM Compliance	39
Problem	39
Solution	39
Task	39
The CDISC-SDTM to CRT-DDS Transformation	41
Problem	41
Solution	41
Task	41
Validating a CRT-DDS define.xml File	42
Problem	42

Solution	42
Task	43
The Subject Sequence Generator Transformation	43
Overview	43
Problem	43
Solution	43
Task	44

About Domain Data and Metadata

Domain Creation

After the clinical components are created, you can create domains. A domain is based on a data standard. Data standards define templates that are used in creating domains. You can select as many templates as you want. The selected templates are copied into a folder, but there are associations in the metadata that bind the copy to the originating data standard. This association permits you to customize the copy without affecting the data standard. The association also permits you to run validation comparing the copy and the data standard to determine whether any changes in the copy breaks conformance to the data standard.

After selecting the templates, you can assign a library. The *library* is where the physical data is created when the job is run.

Note: In the tree, any domains that you create are denoted by the SAS Clinical Data

Integration icon



. This icon helps you distinguish domains from other non-clinical tables.

Custom Domain Creation

During a study there might not be an appropriate template for the domain. You can create a custom domain to solve this problem.

Instead of using a domain template, you create a custom domain by basing it on the underlying data standard model. For example, SDTM defines a model based on assembling domains from groups of columns, specifically identifiers, interventions, events, or findings, and timing. SAS Clinical Data Integration Server generalizes this concept into *column groups*. These are groups of columns that make up portions of a complete table. If a data standard does not have column groups, then creating a custom domain is not available.

The key criterion for defining a custom domain is whether it is an intervention, event, or finding. In SAS Clinical Data Integration Server, these are called *conditional column groups*. From all column groups in the conditional set, you can select only one. In addition to a conditional column group, you must specify identifiers and timing columns.

Next, you select the individual columns that you want to include in the custom domain from the column groups. Some column names must be prefixed by the identifier. If you select a column that meets this condition, SAS Clinical Data Integration Server automatically creates the correct column name. The Custom Domain wizard permits you to define keys and set column order before the domain is created.

Domain Duplication (Copy from an Existing Domain)

If you already have a domain that *almost* meets your needs, you can create a new domain using the existing domain as a template.

Creating a Standard Domain

Problem

You want to create a domain for a study using one of the data standard domain templates.

Solution

SAS Clinical Data Integration Server provides domain templates that conform to existing data standards. You can create a new domain, using the New Standard Domain wizard. The domain name, identifier, description, and other properties cannot be edited in the wizard. The new domain is an exact copy of a domain template from the selected standard.

Task

To create a new domain using one of the data-standard-domain templates, complete the following steps:

1. In the Folders tree, right-click a clinical component folder where you want to create the domain and click **New** ⇒ **Standard Domain(s)**. The New Standard Domain wizard opens and the Domain Location page is displayed.
2. By default, the **Location** field is set to the folder from you initiated the action. If you want to change the default location of the new domain, click **Browse** to select a new location.

Note: A domain can be created only in a folder that is a clinical component root folder, or in a subfolder of a clinical component root folder. The name of the clinical component that is associated with the domain location is displayed in the **Clinical Component** field. If the domain location is not contained within a clinical component, the **Clinical Component** field is empty. You must select a valid domain location before you can proceed in the wizard.

Click **Next**. The Data Standard Selection page is displayed.

3. Select a standard from the list of standards that are associated with the clinical component in which the domains is to be created.

All domains within a specified folder must be associated with the same data standard. If you want to create the same domain using different versions of a standard, you must create the domains in different folders. If a domain already exists within the target folder, and that domain is associated with a different data standard than what is specified in the wizard page, a warning message is displayed. You must correct the data standard selection before you can proceed in the wizard.

Click **Next**. The Domain Template Selection page is displayed.

4. Select one or more domain templates to use when creating the new domains.

If a domain already exists in the target folder with the same ID or name as a selected domain template, a warning message is displayed. You must correct the name or ID before you can proceed in the wizard.

Click **Next**. The Library Selection page is displayed.

5. Select a library to assign to the domain. The library can be any library in the clinical component that contains the domain. If no libraries exist within the clinical component root folder, a message is displayed.

Note: You can create domains without a library assignment. Then, you can create a library later and associate that library with the domain. However, if you use the domain in a job without an associated library, the job fails. The job generates errors that indicate you must associate a library. Also, if you attempt to open the domain to view the contents and records, the open fails and an error message is displayed.

6. Click **Finish** to create the new domain.

Creating a Custom Domain

Problem

You need to create a domain for this study and there is not a standard-domain template that satisfies your need.

Solution

You can create a new, customized domain inside a clinical component. The new domain uses the data model defined by the data standard to create the appropriate columns and metadata.

Task

To create a custom domain, complete the following steps:

1. In the Folders tree, right-click a folder and click **New** ⇒ **Custom Domain**. The New Custom Domain wizard opens and the Domain Location page is displayed.
2. By default, the **Location** field is set to the folder from which you initiated the action. If you want to change the default location of the new domain, click **Browse** to select a new location.

Note: A custom domain can be created only in a folder that is a clinical component root folder, or in a subfolder of a clinical component root folder. The name of the clinical component that is associated with the domain location is displayed in the **Clinical Component** field. If the domain location is not contained within a clinical component, the **Clinical Component** field is empty. You must select a valid domain location before you can proceed in the wizard.

Click **Next**. The Data Standard Selection page is displayed.

3. Select a standard from the list of standards that are associated with the clinical component in which the domain is to be created.

All domains within a specified folder must be associated with the same data standard. If you want to create the same domain using different versions of a standard, you must

create the domains in different folders. If a domain already exists within the target folder, and that domain is associated with a different data standard than what is specified in the wizard page, a warning message is displayed. You must correct the data standard selection before you can proceed in the wizard.

Click **Next**. The General Information page is displayed.

4. Specify the name and identifier for the new domain.

Note: The domain name and identifier cannot be the same as the name or identifier of a domain template for that data model. When you click **Next**, the wizard validates the name and identifier. A warning message is displayed if either the name or identifier fail the validation.

Click **Next**. The Domain Information page is displayed.

5. Specify the property values for the new domain.

Click **Next**. The Library Selection page is displayed.

6. Select a library to assign to the domain. The library can be any library in the clinical component that contains the domain. If no libraries exist within the clinical component root folder, a message is displayed.

Note: You can create domains without a library assignment. Then, you can create a library later and associate that library with the domain. However, if you use the domain in a job without an associated library, the job fails. The job generates errors that indicate you must associate a library. Also, if you attempt to open the domain to view the contents and records, the open fails and an error message is displayed.

Click **Next**. The Column Group Selection page is displayed.

7. Select a conditional column group to use in the new domain. Column groups are groups of columns that are available to all new domains in a standard. This page also displays the core column groups that are available to all new domains in a standard.

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

Click **Next**. The Column Selection page is displayed.

8. Select one or more columns to include in the new domain template and click **Add**. The **Available Columns** list displays all the core column groups and the selected conditional column group. You can add columns individually or by group. To remove a column from the **Selected Columns** list, select the column or group of columns and click **Remove**.

If you want to customize column properties, click **Next** to view the Column Elaboration page. Otherwise, go to step 10.

9. Edit properties for one or more selected columns. The Selected Columns table displays all the selected columns and their properties. Not all properties can be edited and the editable properties can vary by data model.

You can change the column order. Select a column. Then click **Move Up** or **Move Down** to adjust its order.

If two or more columns are keys, you can change the key order. To change the key order, click Order Keys. The Order Domain Keys window is displayed. Select a key. Then click **Move Up** or **Move Down** to adjust its order. Click **OK** to save the key order.

10. Click **Finish** to create the new domain.

Creating a Custom Domain from an Existing Domain

Problem

You want to create a domain for a study and there is not a standard domain template that satisfies your need, but there is a domain in another study that meets your needs.

Solution

You can create a new customized domain using an existing domain.

CAUTION:

Use this action, instead of the standard SAS Data Integration Studio Copy and Paste actions. The Copy and Paste actions do not copy important domain metadata.

Task

To create a custom domain from an existing domain, complete the following steps:

1. In the Folders tree, right-click a folder and click **New** ⇒ **Custom Domain From Existing**. The New Custom Domain from Existing Domain wizard opens and the Domain Location page is displayed.
2. By default, the **Location** field is set to the folder in which you initiated the action. If you want to change the default location of the new domain, click **Browse** to select a new location.

Note: A domain can be created only in a folder that is a clinical component root folder, or in a subfolder of a clinical component root folder. The name of the clinical component that is associated with the domain location is displayed in the **Clinical Component** field. If the domain location is not contained within a clinical component, the **Clinical Component** field is empty. You must select a valid domain location before you can proceed in the wizard.

Click **Next**. The Data Standard Selection page is displayed.

3. Select a standard from the list of standards that are associated with the clinical component in which the domain is to be created.

All domains within a specified folder must be associated with the same data standard. If you want to create the same domain using different versions of a standard, you must create the domains in different folders. If a domain already exists within the target folder, and that domain is associated with a different data standard than what is specified in the wizard page, a warning message is displayed. You must correct the data standard selection before you can proceed in the wizard.

Click **Next**. The Domain Selection page is displayed.

4. The **Available Domains by Clinical Component** list displays the clinical components and domains for the selected data standard. Expanding a clinical component node displays all the domains within the clinical component. Both standard and custom domains can be selected. You can select only one domain.

Click **Next**. The General Information page is displayed.

5. The default values on this page are provided by the domain you selected. Edit the name and identifier for the new domain.

Note: The domain name and identifier cannot be the same as the name or identifier of a domain template for that data model. When you click **Next**, the wizard validates the name and identifier. A warning message is displayed if either the name or identifier fail the validation.

Click **Next**. The Domain Information page is displayed.

6. The default values on this page are provided by the domain you selected. Edit the property values for the new domain.

Click **Next**. The Library Selection page is displayed.

7. Select a library to assign to the domain. The library can be any library in the clinical component that contains the domain. If no libraries exist within the clinical component root folder, a message is displayed.

Note: You can create domains without a library assignment. Then, you can create a library later and associate that library with the domain. However, if you use the domain in a job without an associated library, the job fails. The job generates errors that indicate you must associate a library. Also, if you attempt to open the domain to view the contents and records, the open fails and an error message is displayed.

Click **Next**. The Column Elaboration page is displayed.

8. Edit properties for one or more selected columns. The Selected Columns table displays all the selected columns and their properties. Not all properties can be edited and the editable properties can vary by data model.

You can change the column order. Select a column. Then click **Move Up** or **Move Down** to adjust its order.

If two or more columns are keys, you can change the key order. To change the key order, click Order Keys. The Order Domain Keys window is displayed. Select a key. Then click **Move Up** or **Move Down** to adjust its order. Click **OK** to save the key order.

9. Click **Finish** to create the new domain.

Editing Domain Properties

Problem

You want to edit the properties of a domain.

Solution

Use the Properties dialog box.

Task

To edit domain properties, complete the following steps:

1. In the Folders tree, right-click a domain and click **Properties**. The Properties dialog box is displayed.
2. Click the **General** tab to change the metadata name and description.
3. Click the **Columns** tab to manage the columns contained in the domain.
4. Click the **Indexes** and **Keys** tabs to define columns used as keys.
5. Click the **Physical Table** tab to change the data set name.
6. Click the **Notes** tab to add general information about your domain.
7. Click the **Extended Attributes** tab to optionally add custom metadata properties for a domain.
8. Click the **Clinical Domain** tab to change clinical properties about your domain. The Property page supports text entry and selection lists depending on the property definition. Select the property and make the applicable changes.
Note: You might not be able to edit some values.
9. Click **OK** to save the changes and exit the Properties dialog box.

Editing Domain Column Properties

Problem

You want to edit the properties of a domain column.

Solution

Use the Column Properties dialog box.

Task

To edit domain column properties, complete the following steps:

1. In the Folders tree, right-click a domain and click **Properties**. The Properties dialog box is displayed.
2. Click the **Columns** tab. The domain columns are listed.
3. Right-click a column and select **Properties**. The Column Properties dialog box is displayed.
4. Click the **Notes** tab to add general information about your domain column.
5. Click the **Extended Attributes** tab to optionally add custom metadata properties for a domain column.
6. Click the **Clinical Domain** tab to change clinical properties about your domain column. The Property page supports text entry and selection lists depending on the property definition. Select the property and make the applicable changes.
Note: You might not be able to edit some values.
7. Click **OK** to save the changes and exit the Column Properties dialog box.
8. Click **OK** to save the changes and exit the Properties dialog box.

Loading Data into Domains

Problem

You want to convert your study data into CDISC SDTM target files (domains).

Solution

Create a SAS Data Integration Studio job to populate each domain. Creating these jobs uses standard SAS Data Integration Studio functionality and does not require any added functionality from SAS Clinical Data Integration Server. For detailed information about creating a job, see the *SAS Data Integration Studio: User's Guide*.

Assessing CDISC-SDTM Compliance

Problem

You want to validate one or more domains for compliance against the CDISC-SDTM data standard.

Solution

Using the CDISC-SDTM Compliance transformation, you can assess structural and content compliance to a standard specification. You can make this assessment against an individual domain or a set of domains. The validation assesses whether the selected domains meet the appropriate specifications and requirements.

Note:

- For detailed information about creating a job, see the *SAS Data Integration Studio: User's Guide*.
- SAS Clinical Data Integration Server supports multiple industry standard models. However, a separate compliance transformation is required for each industry standard.
- The compliance of custom domains cannot be performed unless the custom domain has been promoted to the data standard.

Task

To assess compliance, complete the following steps:

1. In SAS Data Integration Studio, create a new job. An empty job diagram is displayed on the Diagram page.
2. In the Transformations tree, expand **Clinical**, select **CDISC-SDTM Compliance transformation**, and drag it onto the job. The Diagram page displays the compliance transformation and the following outputs: Results and Metrics.

Note: By default, the Results and Metrics data sets are written out to a temporary work location. If you want to store the results permanently, open the Properties for the tables and, on the **Physical Storage** tab, select a SASLibrary.

3. In the diagram, double-click the **CDISC-SDTM Compliance transformation**. The CDISC-SDTM Compliance Properties dialog box is displayed.

Note: By default, the validation_results data set is written to a temporary work location. To change the output location of the data set to point to a permanent location, right-click the **Validation data set** and click **Properties**. For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide*.

4. Click the **Data Standards** tab. All active SDTM data standards are displayed.
5. Select a data standard against which you want to check the compliance. Then, click the **Domains** tab. The clinical components are displayed.
6. Expand your selected clinical component to view its domains. Click one or more domains that you want to validate.

Note: You can select domains from multiple clinical components.

7. Click the **Checks** tab. If no checks are displayed, click **Add**. The Add Compliance Checks dialog box is displayed with a list of all available checks.
8. To view more information, click the **Show details** check box. Detailed information about the check is displayed. Select one or more checks from the list. Click **Add Selected**. A confirmation message is displayed.

Note: You can add more than one check. Select the first check. Then press the Ctrl key and click the rest of the checks that you want.

Note: Some checkIDs are listed more than once. When you click the **Show Details** check box, you can view details that make the individual check unique. For example, consider the checkID SDTM001:

- On the first record, Source=Janus and Severity=Note. If the domain fails this check the results data set reports a NOTE.
- On the second record, Source=WebSDM and Severity=Warning. If the domain fails this check the results data set reports a WARNING.

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

9. Click **OK**. The list of available compliance checks no longer includes the checks that you selected.
10. Click **OK**. The selected compliance checks are displayed on the Checks page.
11. Click **OK** to close the CDISC-SDTM Compliance Properties dialog box. A green check-mark icon indicates that the transformation is completed.

Note: If you do not see the green check-mark icon next to the CDISC-SDTM Compliance transformation, hover over the indicator to view problem information for the incomplete transformation. A typical error is that the selected domains do not have a library associated with them. Correct the indicated problems before running the job.

12. Run the job. SAS Data Integration Studio generates the SAS code for the validation checks for the selected model and submits the code to SAS. Then, the results and metrics data sets are generated.

13. Review the Results data set to see the results of the compliance checks. Also, you might want to connect the Results and Metric data sets as inputs to reporting code to generate formatted reports of the results.

Note: You might encounter errors or warnings in the SAS Log during the execution of the job. These errors or warnings do *not* mean that the compliance process was unsuccessful. Most errors that halt a validation process are reported in the Results data set. As a general rule, the Results data set signal process failures and provide information about the cause of the failure. For more information about debugging a validation process, see the *SAS Clinical Standards Toolkit: User Guide*.

The CDISC-SDTM to CRT-DDS Transformation

Problem

You want to transform domains collected during a study from the CDISC-SDTM standard format into the CRT-DDS standard format.

Solution

Use the CDISC-SDTM to CRT-DDS transformation to transform SDTM domains into a define.xml file meeting the CRT-DDS standard.

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

Task

Before you can create a job to create a CRT-DDS define.xml file, you must register a new document file, which is a reference to the target define.xml file.

Note: This target file is created on the server. If you want to open the target file from the job, then the target file must be located in a shared location (for example, a network drive) that can be accessed from the computer on which you are using SAS Data Integration Studio.

For more information about registering a new document, see the *SAS Data Integration Studio: User's Guide*.

To transform CDISC-SDTM domains into a CRT-DDS define.xml file, complete the following steps:

1. In SAS Data Integration Studio, create a new job. An empty job diagram is displayed on the Diagram page.
2. In the Transformations tree, expand **Clinical**, select **CDISC-SDTM to CRT-DDS**, and drag it onto the job. The Diagram page displays the transformation.
3. Right-click the **CDISC-SDTM to CRT-DDS** transformation and click **Properties**. The CDISC-SDTM to CRT-DDS Properties dialog box is displayed.
4. Click the **Domains** tab.
5. In the **Available Domains by Clinical Component** tree, select one or more domains to include in the define.xml file.

6. (Optional) Click the **Generation** tab.
7. (Optional) In the **Header comment** field, enter the header comment text for the define.xml file.
8. (Optional) In the **Output encoding** list, select the encoding to use.
9. (Optional) In the **Output Stylesheet** group, select the style sheet to use.
Note: By default, no style sheet is used. Alternatively, you can use a default style sheet provided by SAS Clinical Standards Toolkit or select your own style sheet.
10. Click **OK**.
11. From the Folders tree, drag the define.xml file onto the job.
12. Draw a connector from the CDISC-SDTM to CRT-DDS transformation to the define.xml file.
13. By default, the CRT-DDS results data set is written to a temporary work location. To change the output location of the data set to point to a permanent location, right-click **CRT-DDS Results** and click **Properties**. For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide*.
14. Save and run the job. SAS Data Integration Studio generates the SAS code for the transformation and submits the code to SAS. The define.xml file is created. Then, the results are written to the CRT-DDS Results data set. Open and view the Results data sets to check for errors or warnings.

You can view the define.xml file by navigating to the location where you defined the document and opening the 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, the define.xml file is located on a drive to which you do not have access. To resolve the problem, relocate the file.

Validating a CRT-DDS define.xml File

Problem

You want to validate a CRT-DDS define.xml file to ensure that the input data meets the CRT-DDS standard and that the resulting define.xml file meets XML standards.

Solution

Using the Validate CRT-DDS transformation, you can assess the validity of the file according to the XML schema for CRT-DDS 1.0.0, as defined by CDISC.

This assessment is limited to whether the XML:

- is well formed
- meets the XML schema specification

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

Task

Before you can create a job to validate a CRT-DDS define.xml file, you must register a new document file and point to an existing define.xml file in a location that the work-space server can access. For more information about registering a new document file, see the *SAS Data Integration Studio: User's Guide*.

To validate a CRT-DDS define.xml file, complete the following steps:

1. In SAS Data Integration Studio, create a new job. An empty job diagram is displayed on the Diagram page.
2. In the Transformations tree, expand **Clinical**, select **Validate CRT-DDS**, and drag it onto the job. The Diagram page displays the transformation.
3. From the Folders tree, drag the define.xml file that you want to validate onto the job.
4. Draw a connector from the define.xml file to the Validate CRT-DDS transformation.
5. By default, the validation_results data set is written to a temporary work location. To change the output location of the data set to point to a permanent location, right-click the **CRT-DDS Validation data set** and click **Properties**. For detailed information about the Properties dialog box, see the *SAS Data Integration Studio: User's Guide*.
6. Save and run the job. SAS Data Integration Studio generates the SAS code for the validation and submits the code to SAS. The define.xml file is validated. Then, the results are written to the validation_results data set.

If there are errors, the validation_results data set provides a message for each error. Error messages include the line and column number in the define.xml file that generated the error.

The Subject Sequence Generator Transformation

Overview

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

Problem

You want to load study data into the SDTM VS domain. In the study, each subject came in and had a series of vital signs collected during each visit (for example, on day 17, several readings were taken for heart rate and blood pressure). You need to uniquely identify each of these vital signs for each subject. This means that when you convert the study data, not only do you need to populate each domain, you also need to populate the VSSEQ variable.

Solution

Use the Subject Sequence Generator transformation to generate a unique sequence number across subjects in a given domain. After running the Subject Sequence Generator

transformation you have another variable that enables you to uniquely identify each vital sign.

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

Task

To use the Subject Sequence Generator transformation, complete the following steps:

1. In SAS Data Integration Studio, create a new job. An empty job diagram is displayed on the Diagram page.
2. From the Folders tree, drag and drop the source table for the selected domain onto the job.
3. In the Transformations tree, expand **Clinical**, select **Subject Sequence Generator**, and drag it onto the job. The Diagram page displays the transformation.
4. Draw a connector from the source data table to the transformation.
5. In the Transformations tree, expand the **Access** folder, select the **Table Loader** transform and drag it onto the job.
6. Draw a connector from the output table of the Subject Sequence Generator to the Table Loader input.
7. Draw a connector from a table loader to the SDTM domain (the data target).
8. Right-click the **Subject Sequence Generator** transformation and click **Properties**. The Subject Sequence Generator Properties dialog box is displayed.
9. From the Folders tree, drag and drop the CDISC-SDTM domain that you want to populate onto the job.
10. Click the **Options** tab.
11. (Optional) In the **Update Source** list, select the applicable setting:
 - 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 the Proc Sort in the code generation.
12. In the **Business Keys** list, adjust the order of the available keys. This list identifies the keys in the source table, which make a record unique. Use these keys to sort the data.
13. In the **Sequence Key Variable** list, select the name of the Sequence variable in the target domain (—SEQ).
14. In the **Subject Variable** list, select a variable. The subject variable identifies the variable that represents the unique subject identifier (USUBJID).
15. Click **OK**.
16. Save and run the job. SAS Data Integration Studio generates the SAS code for the transformation and submits the code to SAS. The —SEQ variable is populated with a sequence number unique for each record for a given subject.

Appendix 1

Adding Users to the Clinical Administrator Group

Problem

Only users added to the Clinical Administrators group have permission to see the Clinical DI Administration tree in SAS Data Integration Studio. Significant features and functions are available only by way of the Clinical DI Administration tree.

The default security model for SAS Clinical Data Integration Server is described in the following table. Depending on the level of security required in your organization, users can modify the configuration after installation. Contact your system administrator to determine how security is implemented at your site.

Table A1.1 Default User Groups and Roles

Group	Role
SAS Administrators	Default Metadata Server administration group. This group should not be removed from any object in the metadata. It is recommended that very few users be added to this group.
Clinical Administrators	Members of this group can use the Clinical DI Administration tree and are responsible for managing standards, clinical components, and controlled terminology.
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.

Solution

Add the affected user to the Clinical Administrators group.

Task

To add a user to the Clinical Administrators group, complete the following steps:

1. Start SAS Management Console and connect to the metadata server as the unrestricted user. For more information, see *SAS 9.2 Management Console: Guide to Users and Permissions*.
2. On the **Plug-ins** tab, expand **Environment Management** and select **User Manager**. The contents are displayed.

3. Select **Clinical Administrators** and right-click **Properties**.
4. Click the **Groups and Roles** tab.
5. Select one or more users or groups to move to the **Member of** list.
6. Click **OK** to save the changes.

Appendix 2

Repairing Clinical Objects

Problem

You receive a message that any of the following clinical objects must be repaired:

- data standard
- controlled terminology package
- clinical component
- clinical domain or clinical columns

Solution

You can use the Repair wizard to validate and, if necessary, repair clinical objects.

Note: It is not recommended that you export data standards or controlled terminology packages using the SAS Data Integration Studio Export metadata package tool. Instead, create the data standards or controlled terminology package using the SAS Clinical Data Integration Server feature.

Tasks

Repair a Copy of a Data Standard

To repair a copy of a data standard, complete the following steps:

1. In the Folders tree or the Clinical DI Administration tree, navigate to the data standard copy that you want to repair.
2. Right-click the data standard copy and click **Repair Copy**. The Repair Copy wizard opens and the Repair Copy of Metadata page is displayed.
3. In the **New Name** field, accept the default name or enter a new name for the clinical component and click **Next**.
4. Review the summary and click **Finish**. The analysis starts and any repairs are made. The Folders tree is updated with any new information.

Repair a Domain Template

To repair a standard domain template, complete the following steps:

1. In the Clinical DI Administration tree, navigate to the data standard containing the domain template that you want to repair.

2. Right-click the domain template and click **Repair**. A message is displayed when the repair analysis is completed.
3. If no problems are found, click **OK**. If you want to review the analysis report, click **Details**. Click **Yes** to repair the detected problems or click **No** to decline the repair. When you choose to repair, a progress indicator is displayed. A message is displayed when the repair is completed.

Repair a Column Group

To repair a data standard domain template, complete the following steps:

1. In the Clinical DI Administration tree, navigate to the data standard containing the column group that you want to repair.
2. Right-click the column group and click **Repair**. A message is displayed when the repair analysis is completed.
3. If no problems are found, click **OK**. If you want to review the analysis report, click **Details**. Click **Yes** to repair the detected problems or click **No** to decline the repair. When you choose to repair, a progress indicator is displayed. A message is displayed when the repair is completed.

Repair a Controlled Terminology Package

To repair a controlled terminology package, complete the following steps:

1. In the Folders tree or the Clinical DI Administration tree, navigate to the terminology that you want to repair.
2. Right-click the terminology package and click **Repair**. A message is displayed when the repair analysis is completed.

Repair a Copy of a Clinical Component

To repair a copy of a clinical component, complete the following steps:

1. In the Folders tree or the Clinical DI Administration tree, navigate to the clinical component folder that you want to repair.
2. Right-click the folder and click **Repair Copy**. The Repair Copy wizard opens and the Repair Copy of Clinical Component page is displayed.
3. In the **New Name** field, accept the default name or enter a new name for the clinical component and click **Next**.
4. Review the summary and click **Finish**. The analysis starts and any repairs are made. The Folders tree is updated with any new information.

Repair a Domain







To repair a domain or domain column, complete the following steps:

1. In the Folders tree, navigate to the domain you want to repair.
2. Right-click the domain and click **Repair Domain**. A message is displayed when the repair analysis is completed.
3. If no problems are found, click **OK**. If you want to review the analysis report, click **Details**. Click **Yes** to repair the detected problems or click **No** to decline the repair. When you choose to repair, a progress indicator is displayed. A message is displayed when the repair is completed.

Appendix 3

SAS Clinical Data Integration Server Icons

The following icons are displayed in the SAS Data Integration Studio user interface. The icons indicate objects or transformation that are provided by the SAS Clinical Data Integration Server plug-in.

Description	Icon
SAS Clinical Data Integration	 <p><i>Note:</i> This graphic overlays standard graphics used in SAS Data Integration Studio to indicate that the object is a clinical object.</p>
Clinical Component	
Clinical Domain	
CDISC-SDTM to CRT-DDS Transformation	
CDISC-SDTM Compliance	
Validate CRT-DDS	

Your Turn

We welcome your feedback.

- If you have comments about this book, please send them to **`yourturn@sas.com`**. Include the full title and page numbers (if applicable).
- If you have comments about the software, please send them to **`suggest@sas.com`**.

SAS® Publishing Delivers!

Whether you are new to the work force or an experienced professional, you need to distinguish yourself in this rapidly changing and competitive job market. SAS® Publishing provides you with a wide range of resources to help you set yourself apart. Visit us online at support.sas.com/bookstore.

SAS® Press

Need to learn the basics? Struggling with a programming problem? You'll find the expert answers that you need in example-rich books from SAS Press. Written by experienced SAS professionals from around the world, SAS Press books deliver real-world insights on a broad range of topics for all skill levels.

support.sas.com/saspress

SAS® Documentation

To successfully implement applications using SAS software, companies in every industry and on every continent all turn to the one source for accurate, timely, and reliable information: SAS documentation. We currently produce the following types of reference documentation to improve your work experience:

- Online help that is built into the software.
- Tutorials that are integrated into the product.
- Reference documentation delivered in HTML and PDF – **free** on the Web.
- Hard-copy books.

support.sas.com/publishing

SAS® Publishing News

Subscribe to SAS Publishing News to receive up-to-date information about all new SAS titles, author podcasts, and new Web site features via e-mail. Complete instructions on how to subscribe, as well as access to past issues, are available at our Web site.

support.sas.com/spn



**THE
POWER
TO KNOW®**